Medtronic

Aurora EV-ICD™ MRI SureScan™ DVEA3E4

Digital single chamber extravascular implantable cardioverter defibrillator (VVE-VVI) with Antitachycardia Pacing (ATP), Pause Prevention, and Post-Shock Pacing
MR Conditional with PhysioCurve™ Design

Device Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Contents

1 System overview

1.1 Introduction

This manual describes the Medtronic Aurora EV-ICD MRI SureScan Model DVEA3E4 single chamber, extravascular implantable cardioverter defibrillator (ICD). It contains feature information, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, and parameter tables.

The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine. When programmed to On, MRI SureScan operation disables pacing, arrhythmia detection and all user-defined diagnostics. Before performing an MRI scan, refer to the MRI technical manual.

The following manuals and documents also contain information about the device:

MRI technical manual – This manual provides MRI-specific procedures and warnings and precautions.

Reference manual – This manual contains information about device features and describes how to use a programmer to conduct a session.

Programming guide – This manual explains how to use the programmer software to conduct a patient session.

Explanation of symbols – This document defines the symbols that may appear on the device package. Refer to the package label to see which symbols apply specifically to this device.

Medical Procedure and EMI Warnings, Precautions, and Guidance Manual for Health Care Professionals – This manual provides warnings, precautions, and guidance for health care professionals who perform medical therapies and diagnostic procedures on cardiac device patients. This manual also includes information about hazards from sources of electromagnetic interference (EMI) in the patient's home, recreational environments, and occupational environments.

Radio regulatory compliance information – This document provides compliance information related to the radio components of the device.

1.2 System description

The Medtronic Aurora EV-ICD MRI SureScan Model DVEA3E4 single chamber, implantable cardioverter defibrillator (ICD) is a multiprogrammable cardiac device that monitors and regulates the patient's heart rate. It provides ventricular tachyarrhythmia detection and therapy, post-shock pacing, and prolonged pause detection and therapy (Pause Prevention pacing).

The device also provides diagnostic and monitoring features to assist with system evaluation and patient care.

1.2.1 Usage environments

The device is intended to be used in the following environments and conditions:

- The device must be implanted in a properly equipped, staffed, and sterile surgical environment.
- The device must be implanted under standard surgical protocols and in the patient population for which the device is indicated.
- Post-surgical patient and device follow-up care must be conducted in a properly equipped and staffed cardiology clinic or office.
- MRI procedures for patients with this device must be conducted in a properly equipped and staffed MR facility, and in consideration of the conditions and requirements described in *Section 1.6*.
- After the device and lead are implanted, patients can resume their lives at home, at work, and in other environments with consideration of the advice and restrictions documented in the Medical Procedures and EMI Warnings, Precautions, and Guidance Manual for Health Care Professionals and in the patient literature.

1.2.2 System components and accessories

Contents of sterile package – The package contains 1 implantable cardioverter defibrillator and 1 torque wrench.

Connector – The device has a Medtronic EV4 quadripolar inline connector. This connector facilitates the connection of a Medtronic EV4-LLHH extravascular quadripolar lead. EV4-LLHH is a Medtronic proprietary design where the lead connector contacts are defined as low voltage (L) and high voltage (H). The mechanical specifications for the EV4-LLHH connector are defined by the Medtronic EV4 connector specification.

Lead – The device is intended for implant with a Medtronic EV4-LLHH extravascular quadripolar lead. The Medtronic Model DVEA3E4 device can be used with EV4 labeled leads only. See *Section 4.2, Implanting the lead, page 17* for more information.

Implantable device system – The implantable device system includes the Medtronic Aurora EV-ICD MRI SureScan Model DVEA3E4 device connected to a Medtronic EV4-LLHH extravascular quadripolar lead.

Programmers and software – The Medtronic programmer and software are used to program this device. Refer to the reference manual for information about using the programmer.

Programmers from other manufacturers are not compatible with Medtronic devices, but they do not damage Medtronic devices.

Medtronic pacing system analyzer – A pacing system analyzer can be used to measure some electrical characteristics of the implanted lead prior to its attachment to the device.

Medtronic patient monitor – The Medtronic CareLink Network, if available, provides remote monitoring of patients. Patients use the Medtronic patient monitor to gather information from their implanted devices and communicate the information to their physicians through the Medtronic CareLink Network. For information on using the patient monitor, refer to the patient monitor literature.

1.3 Indications

The Aurora EV-ICD MRI SureScan Model DVEA3E4 device is indicated for the automated treatment of patients who have experienced or are at significant risk of developing life-threatening ventricular tachyarrhythmias through the delivery of antitachycardia pacing, cardioversion, and defibrillation therapies. Medical conditions that may indicate a patient for an EV-ICD for primary or secondary prevention of sudden cardiac death due to life-threatening ventricular tachyarrhythmias include:

- Previous ventricular tachyarrhythmias
- Coronary disease with left ventricular dysfunction
- Cardiomyopathy
- Inherited primary arrhythmia syndromes
- Congenital heart disease

Note: For patient-specific recommendations regarding indications for primary and secondary prevention of sudden cardiac death, refer to current clinical guidelines from the European Society of Cardiology (ESC), American Heart Association (AHA), American College of Cardiology (ACC), and Heart Rhythm Society (HRS).

1.4 Contraindications

The Aurora EV-ICD MRI SureScan Model DVEA3E4 device is contraindicated for use in the following situations:

- If implanted with a unipolar pacemaker
- If implanted with a device delivering dual-chamber or triple-chamber pacing
- If implanted with a device delivering antitachyarrhythmia therapies
- If incessant VT or VF exists

- If the patient's primary disorder is chronic atrial tachyarrhythmia with no concomitant VT or VF
- If symptomatic bradycardia exists
- If tachyarrhythmias with transient or reversible causes exist

1.5 Pre-implant consideration

Patient evaluation for the implant of Aurora EV-ICD MRI SureScan Model DVEA3E4 should include the following consideration about a concomitant implant with a neurostimulator:

Concomitant neurostimulator and cardiac device implants – Some patients have medical conditions that require the implant of both a neurostimulator and a cardiac device (for example, a pacemaker, a defibrillator, or a monitor). In this case, physicians (for example, a neurologist, a neurosurgeon, a cardiologist, and a cardiac surgeon) involved with either device should contact Medtronic Technical Services or their Medtronic representative before implanting the patient with the second device. Based on the particular devices that the physicians have prescribed, Medtronic can provide the necessary precautions and warnings related to the implant procedure. For information about how to contact Medtronic, see the telephone numbers and addresses provided on the back cover of this manual.

1.6 MR conditions for use

A complete SureScan defibrillation system is required for use in the MR environment. Before performing an MR scan, refer to the MRI technical manual for MRI-specific warnings and precautions.

A complete SureScan system only includes components that have been certified by Medtronic as being MR conditional.

A complete SureScan defibrillation system includes the following components:

- The Model DVEA3E4 device
- A SureScan extravascular defibrillation lead

To verify that components are part of a SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan.

Warning: Do not scan a patient without first programming the MRI SureScan feature to On. Scanning the patient without programming the MRI SureScan feature to On may result in patient harm or damage to the SureScan defibrillation system.

Note: The MRI SureScan feature cannot be programmed to On if the device is recommended for replacement.

Patients and their implanted systems must be screened to meet the following requirements:

Cardiology requirements

- The patient has no implanted lead extenders, lead adaptors, or abandoned leads.
- The patient has no broken leads or leads with intermittent electrical contact as confirmed by lead impedance history.
- The SureScan device is operating within the projected service life.
- The device does not provide pacing therapy when SureScan mode is programmed to On. Do not scan pacemaker-dependent patients.

Notes:

- For radiology requirements, refer to the MRI technical manual.
- **Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions.**

Patient monitoring and rescue requirements

Continuous patient monitoring is required while MRI SureScan is programmed to On.

In the event that patient rescue is required, an external defibrillator must be immediately available.

Training requirements

- A health professional who has completed cardiology SureScan training must be present during the programming of the MRI SureScan feature.
- A health professional who has completed radiology SureScan training must be present during the MRI scan.

1.7 Feature summary

The following features are available in this device. For a list of the features that are enabled at shipping, see the "Shipped" column of the tables in *Chapter 7*.

1.7.1 Programmer software features

For more information about these features, see the reference manual.

Conexus wireless telemetry – This feature enables wireless transmission of data between an implanted device and the programmer in the hospital or clinic and between an implanted device and a home monitor in the patient's home.

Emergency therapies – During a patient session, defibrillation and cardioversion can be initiated manually to treat ventricular tachyarrhythmia episodes quickly.

Live Rhythm Monitor – This window on the programmer displays ECG, LECG, Marker Channel (with marker annotations), and telemetered EGM waveform traces. It also displays the patient heart rate and interval in the upper left-hand corner of the window.

Patient Information – This feature allows clinicians to store patient-related information on the programmer that they can view and print during a patient session.

1.7.2 Diagnostic data features

When MRI SureScan is programmed to On, diagnostic data is not collected. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions.

For more information about these features, see the reference manual.

Arrhythmia episode data – The system compiles an arrhythmia episode log that the clinician can use to view summary and detailed diagnostic data quickly, including stored EGM, for the selected arrhythmia episode. Also available on the programmer are episode and therapy counters, stored data showing the number of times that arrhythmias and therapies have occurred.

Cardiac Compass Trends – This feature presents an overview of the patient's condition over the past 14 months with graphs that display long-term clinical trends in heart rhythm and device status, such as frequency of arrhythmias, heart rates, and device therapies.

Flashback Memory – This diagnostic feature records the intervals that immediately preceded tachyarrhythmia episodes or that preceded the last interrogation of the device and plots the interval data over time.

Medtronic CareAlert events – If the device identifies any CareAlert programmed or automatic alert conditions, this feature sounds a Patient Alert tone to notify the patient to seek medical attention.

Quick Look II – This screen on the programmer presents overview data about device operation and patient rhythms collected since the last patient session. It includes links to more detailed status and diagnostic information stored in the device, such as arrhythmia episodes and therapies provided.

Rate Histograms – This diagnostic feature shows range distributions for the patient's heart rate.

1.7.3 Tachyarrhythmia detection features

When MRI SureScan is programmed to On, tachyarrhythmia detection and therapies are suspended. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions.

For more information about these features, see the reference manual.

Feature Match – This feature prevents ventricular tachyarrhythmia detection for rapidly conducted SVTs whose morphology features are similar to a template collected during sinus rhythm.

High Rate Timeout – This feature allows the device to deliver therapy for any ventricular tachyarrhythmia that continues beyond the programmed length of time.

Morphology Noise – This feature withholds detection of ventricular tachyarrhythmias when the morphology on the EGM2 channel shows noise.

Onset – This feature helps prevent the detection of sinus tachycardia as VT by evaluating the acceleration of the ventricular rate.

Rapid AF – This feature withholds detection for rapid atrial fibrillation conducted into the ventricles with periodic slow intervals that have consistent morphology and amplitudes.

Sensed EMI – This feature withholds ventricular tachyarrhythmia detection when noise is sensed during the blanking periods.

Smart Sense – This feature withholds ventricular tachyarrhythmia detection in the presence of P-wave oversensing or when the device senses noise, but the EGM2 signal is free of noise.

Stability – This feature helps to prevent detection of atrial fibrillation as ventricular tachyarrhythmia by evaluating the stability of the ventricular rate. If the device determines that the ventricular rate is not stable, it withholds VT detection.

TWave Discrimination – This feature withholds VT/VF detection when a fast ventricular rate is detected because of oversensed T-waves, avoiding the delivery of an inappropriate therapy.

VF Count reset – This feature monitors events that accumulate counts toward detection to identify if events are VF. The counts toward detection will be reset if sensed events are determined to be other than VF.

VT/VF detection – This feature uses programmable detection zones to classify ventricular events. If the number of tachyarrhythmia events in a zone exceeds a programmed threshold, the device detects a ventricular tachyarrhythmia episode. Depending on programming, the device delivers a scheduled therapy, re-evaluates the patient's heart rhythm, and terminates or redetects the episode.

Wavelet – This feature is designed to prevent the detection of rapidly conducted SVTs as ventricular tachyarrhythmias by comparing the shape of each QRS complex during a fast ventricular rate to a template. The feature offers the option to collect and maintain the stored template automatically.

1.7.4 Tachyarrhythmia therapy features

When MRI SureScan is programmed to On, tachyarrhythmia detection and therapies are suspended. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions.

For more information about these features, see the reference manual.

Progressive Episodes Therapies – This feature causes the device to skip therapies or modify high-voltage energy levels to ensure that each therapy delivered during an episode is at least as aggressive as the previous therapy.

Smart Mode – This feature disables an ATP therapy that has been unsuccessful in 4 consecutive episodes so the device can treat subsequent episodes more quickly with therapies that have been effective.

Ventricular antitachycardia pacing (ATP) therapies – ATP therapies respond to a VT episode or an FVT episode with rapid sequences of pacing pulses to terminate detected ventricular tachyarrhythmias. Therapy options include Burst and Ramp, each with a programmable number of sequences.

Ventricular cardioversion (CV) – This therapy delivers a high-voltage shock to treat a VT or FVT episode. Therapy is synchronized to a sensed ventricular event.

Ventricular defibrillation (VF Therapies) – Programmable defibrillation therapy is available to treat VF episodes. The first defibrillation therapy requires VF confirmation before delivery. If synchronization fails following delivery of the first defibrillation therapy, subsequent therapies are delivered asynchronously.

1.7.5 Pacing features

When MRI SureScan is programmed to On, pacing features are suspended. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions.

For more information about these features, see the reference manual.

Pause Prevention pacing – This feature monitors for prolonged pauses of programmed duration between intrinsic ventricular events in OVO mode. If a pause is detected, the device switches to VVI pacing. After 30 s of VVI pacing, the device switches back to OVO mode and resumes monitoring for prolonged pauses between intrinsic ventricular events.

Post Shock pacing – This feature provides VVI pacing for 30 s following a defibrillation or cardioversion therapy.

1.7.6 Testing features

For more information about these features, see the reference manual.

Charge/Dump test – This feature tests the charge time of the capacitors and dumps any charge remaining on the capacitors.

EP Study tests – This set of protocols allows clinicians to induce arrhythmias and deliver on-demand tachyarrhythmia therapies during electrophysiology studies. The available protocols are T-Shock, Burst Induction, Programmed Electrical Stimulation (PES), Defibrillation, Cardioversion, and Burst ATP.

Lead Impedance Test – This feature tests the integrity of the implanted lead system by measuring the impedance of the pacing and high-voltage electrodes. The test uses low-voltage, subthreshold pulses to make these measurements.

Pacing Threshold test – This feature allows the clinician to determine the patient's pacing stimulation thresholds. This information can be used to determine appropriate amplitude and pulse width settings that ensure capture and minimize output.

Sensing test – This feature measures R-wave amplitudes to help the clinician assess lead integrity and sensing performance.

Wavelet Test – This feature evaluates the accuracy of the current wavelet template and allows the clinician to collect a new template, if necessary.

1.7.7 Additional operations

MRI SureScan – This feature allows patients to be scanned safely by an MRI machine when used according to the specified MR conditions for use. Refer to the MRI technical manual for additional information.

1.8 Data security

Medtronic has designed safeguards to protect patient information and device data for the Aurora EV-ICD MRI SureScan Model DVEA3E4 device. A primary safeguard is the required use of the inductive telemetry communication, which requires a proximity of 17 cm or less to the patient, to initiate any communication session with the implant.

Inductive telemetry communication system – The Medtronic inductive telemetry communication system is used for the communication to initiate a session between the device and a Medtronic programming head, which communicates back to a Medtronic instrument to interrogate and program the device. This communication occurs in cleartext. All information is protected in transit by security controls, including following proximity and physical security best practices.

Long range wireless telemetry communication system – The Medtronic long range wireless telemetry communication system is used with the clinician programmer to interrogate and program the device. This system uses cleartext RF telemetry for wireless communications between the device and the programmer. During a wireless telemetry session, all other programmers are locked out from communications with the patient's implanted device to protect patient information and the device data and integrity.

If you or the patient experience a cybersecurity event, contact customer support. If you are a security researcher and believe that you have identified a potential security vulnerability involving a Medtronic ICD, consult the Medtronic Coordinated Disclosure Process website at www.medtronic.com/security to report your concerns.

2 Warnings, precautions, and potential adverse events

2.1 General warnings and precautions

Refer to the Medical Procedure and EMI Warnings, Precautions, and Guidance Manual for Health Care Professionals for information about hazards related to medical therapies and diagnostic procedures on patients with cardiac devices. This manual also includes information about sources of EMI in the patient's environment.

Medical procedure warnings and precautions that pertain to the Medtronic implanted system are provided in the manual that is packaged with the device or on the Medtronic Manual Library website (www.medtronic.com/manuals).

Avoiding shock during handling – Disable tachyarrhythmia detection during implant, explant, or postmortem procedures. The device can deliver a high-voltage shock if the defibrillation terminals are touched.

Electrical isolation during implant – Do not allow the patient to have contact with grounded electrical equipment that might produce electrical current leakage during implant. Electrical current leakage may induce tachyarrhythmias that may result in the patient's death.

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during post-implant testing.

Lead compatibility – This device has not been tested for use with non-Medtronic leads. The known potential adverse consequences of using such a combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection.

Connector compatibility – Use the lead only with a Medtronic EV4 implantable cardioverter defibrillator system. The known potential adverse consequences of using any other combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection.

Medtronic EV4 devices – The EV4 connector is a Medtronic proprietary design, not an industry standard. No claims of safety and efficacy can be made with regard to devices that are not labeled as EV4 by Medtronic.

Prior sternotomy – Use of the Aurora EV-ICD MRI SureScan Model DVEA3E4 device has not been evaluated in patients who have undergone a prior sternotomy.

Pediatric use – The device has not been tested specifically for pediatric use.

2.2 Explant and disposal

Consider the following information related to device explant and disposal:

- To prevent the device from delivering unwanted shocks, interrogate the device, then disable tachyarrhythmia detection and Pause Prevention detection and therapy before explanting, cleaning, or shipping the device.

- Explant the implanted device postmortem. In some countries, explanting battery-operated implanted devices is mandatory because of environmental concerns; check the local regulations. In addition, the device can explode if subjected to incineration or cremation temperatures.
- Medtronic implantable devices are intended for single use only. Do not resterilize and reimplant explanted devices.
- Contact Medtronic for return mailer kits to return explanted devices for analysis and disposal. See the back cover for addresses.

Note: Observe all local laws and regulations regarding the disposal of explanted devices or leads.

2.3 Handling and storage instructions

Carefully observe these guidelines when handling or storing the device.

2.3.1 Device handling

Checking and opening the package – Before opening the sterile package tray, visually check for any signs of damage that might invalidate the sterility of the package contents.

If the package is damaged – The device packaging consists of an outer tray and an inner tray. Do not use the device or accessories if the outer packaging tray is wet, punctured, opened, or damaged. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment.

Dropped device – Do not implant the device if it is dropped on a hard surface from a height of 30 cm (12 in) or more after it is removed from its packaging.

Fluid immersion – Do not immerse the device in fluid or flush the connector ports at the time of implant. Doing so could adversely affect the performance of the device and lead system.

"Use-by" date – Do not implant the device after the "Use-by" date because the battery longevity could be reduced.

Single use – This product is intended for single use only. Do not resterilize and re-implant the explanted product. Reuse may compromise the structural integrity of the product or create a risk of contamination of the product that could result in patient injury, illness, or death.

2.3.2 Device storage

Avoid magnets – To avoid damaging the device, store the device in a clean area away from magnets, kits containing magnets, and any sources of electromagnetic interference.

Storage temperature – No special temperature considerations are required for storage.

Transit temperature – Transport the package between –18 °C and +55 °C (0 °F and 131 °F). Electrical reset can occur at temperatures below –18 °C (0 °F). Device longevity can decrease and performance may be affected at temperatures above +55 °C (131 °F).

2.4 Lead connection

Refer to the lead technical manuals for specific instructions and precautions about lead handling.

Torque wrench – Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew. Other torque wrenches (for example, a blue-handled or right-angled torque wrench) have torque capabilities greater than the lead connector can tolerate.

Lead connection – Consider the following information when connecting the lead and the device:

- Cap abandoned leads to avoid transmitting electrical signals.
- Verify lead connections. Loose lead connections may result in inappropriate sensing and failure to deliver arrhythmia therapy.
- Prior to taking electrical or defibrillation efficacy measurements, move objects made from conductive materials, such as guide wires, away from all electrodes. Metal objects, such as guide wires, can short a lead and an active implantable device, causing electrical current to bypass the heart and possibly damage the implantable device and lead.

2.5 Device operation

Battery depletion – Carefully monitor device longevity by checking battery voltage and replacement indicators. Battery depletion eventually causes the device to stop functioning.

Charge Circuit Timeout or Charge Circuit Inactive message – Contact a Medtronic representative and replace the device immediately if the programmer displays a Charge Circuit Timeout or Charge Circuit Inactive message. For Charge Circuit Timeout, high voltage and ATP therapies may not be available for the patient. For Charge Circuit Inactive, high voltage and ATP therapies are not available for the patient.

Concomitant devices – If a single-chamber bipolar pacemaker is used concomitantly with the Model DVEA3E4 device, verify that the concomitant device accurately senses and paces the patient's heart:

- Verify that the concomitant device correctly senses all intrinsic ventricular rhythms, including normal sinus rhythm and all ventricular tachyarrhythmias.
- Verify that the concomitant device maintains pacing capture.

If the concomitant device does not correctly sense and pace the patient's heart, it can interfere with the normal operation of the Model DVEA3E4 device. This interference can lead to inappropriate tachyarrhythmia detection and therapy, or it can lead to undersensing of VF.

Note: The concomitant devices for which the Model DVEA3E4 device is contraindicated can be found in *Section 1.4*.

Device status indicators – If any of the device status indicators (for example, Electrical Reset) are displayed on the programmer after interrogating the device, inform a Medtronic representative immediately. If these device status indicators are displayed, therapies may not be available to the patient.

Electrical reset – Electrical reset can be caused by exposure to temperatures below –18 °C (0 °F) or strong electromagnetic fields. Advise patients to avoid strong electromagnetic fields. Observe temperature storage limits to avoid exposure of the device to cold temperatures. If a full reset occurs, the device operates in OVO mode. Electrical reset is indicated by a programmer warning message that is displayed immediately upon interrogation. To restore the device to its previous operation, it must be reprogrammed. Inform a Medtronic representative if your patient's device has reset.

Emergency VVI button disabled – The red, mechanical Emergency VVI button on the Medtronic Model 2090 and Model Encore programmers is disabled during programmer sessions with the Aurora EV-ICD MRI SureScan Model DVEA3E4 device. If emergency therapy is needed during a programmer session, tap **Emergency** at the bottom of the programmer screen. That screen button opens the **Emergency** window from where you can deliver either defibrillation or cardioversion therapy to the patient.

End of Service (EOS) indicator – Replace the device immediately if the programmer displays an EOS indicator. The device may soon lose the ability to pace, sense, and deliver therapy adequately.

SureScan System – A complete SureScan system is required for use in the MR environment. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions. A complete SureScan system only includes components that have been certified by Medtronicas being MRI conditional.

Defibrillation threshold testing (DFT) – Changes in the patient's condition, drug regimen, and other factors may change the defibrillation threshold, preventing the device from terminating the patient's tachyarrhythmias

postoperatively. Successful termination of ventricular fibrillation or ventricular tachycardia during the implant procedure is no assurance that tachyarrhythmias can be terminated postoperatively.

Pacing and sensing safety margins – Lead maturation (at least one month after implant) may cause sensing amplitudes to decrease and pacing thresholds to increase, which can cause undersensing or a loss of capture. Provide an adequate safety margin when selecting values for pacing amplitude, pacing pulse width, and sensitivity parameters.

Patient safety during a wireless telemetry session – Make sure that you have selected the appropriate patient before proceeding with a wireless patient session. Maintain visual contact with the patient for the duration of the session. If you select the wrong patient and continue with the session, you may inadvertently program the patient's device to the wrong settings.

Shipping values – Do not use shipping values or nominal values for pacing amplitude and sensing settings without verifying that the values provide adequate safety margins for the patient.

Short Circuit Protection (SCP) – SCP is a safety feature that can only occur during high-voltage (HV) therapy. SCP is designed to truncate energy delivery to protect the device when an unintended current pathway (a short circuit) is detected during a shock. An SCP event can occur when an unintended current pathway develops in either the lead or in the device. Contact a Medtronic representative for additional guidance if you believe an SCP event occurred.

High-voltage pathway programming – REV (Can to Coils) pathway is not recommended for this device. Devices programmed in the REV pathway may experience sub-therapeutic energy (reduced or no energy) delivery during high-voltage therapy in the presence of an unintended current pathway (a short circuit).

2.6 Potential adverse events

The following are known potential adverse events associated with the use of this product.

Note: Implant and usage of this product may result in adverse events, which may lead to injury, death, or other serious adverse reactions.

- Acute tissue trauma
- Allergic reaction
- Bradyarrhythmia
- Cardiac arrest
- Death
- Device migration
- Discomfort
- Dizziness
- Dyspnea
- Erosion
- Extracardiac stimulation
- Fever
- Hematoma
- Hemorrhage
- Hiccups
- Hospitalization
- Inappropriate shock
- Infection
- Lethargy
- Mental anguish

- Palpitations
- Return of cardiac symptoms
- Seroma
- Syncope
- Tachyarrhythmia
- Toxic reaction
- Wound dehiscence

3 Clinical data

3.1 Adverse events and clinical trial data

Information regarding clinical studies and adverse events related to this device is available at www.medtronic.com/manuals.

The following clinical study is related to this device:

ExtraVascular Implantable Cardioverter Defibrillator (EV ICD) Pivotal Study – This clinical study, which evaluated safety and efficacy of the system, provides support for the system.

Note: Patients with the following medical interventions or clinical conditions were excluded from participate in the EV ICD Pivotal Study:

- Any prior medical condition or procedure that resulted in adhesions in the anterior mediastinal space
- Prior abdominal surgery in the epigastric region
- Prior chest radiotherapy
- Hiatal hernia that distorts mediastinal anatomy
- Marked sternal abnormality
- Decompensated heart failure
- Chronic obstructive pulmonary disease (COPD) with oxygen dependence
- Gross hepatosplenomegaly
- Previous pericarditis that was either chronic or recurrent, resulted in pericardial effusion, or resulted in pericardial thickening or calcification

4 Implant procedure

4.1 Preparing for an implant

To retain the ability to scan the SureScan system safely during MRI scans, the MRI conditions for use in *Section 1.6* must be followed. Refer to the MRI technical manual for additional information.

The following implant procedures are provided for reference only. Proper surgical procedures and sterile techniques are the responsibility of the physician. Each physician must apply the information in these procedures according to professional medical training and experience.

Ensure that you have all of the necessary instruments, system components, and sterile accessories to perform the implant.

4.1.1 Instruments, components, and accessories required for an implant

The following components are used to support the device implant:

- Medtronic programmer.
- Programming head sleeve (if a programming head is used).

  Note: If a sterilized programming head is used during an implant, a sterile programming head sleeve is not necessary.

- SW041 programmer software application for the Aurora EV-ICD MRI SureScan Model DVEA3E4 device.
- Medtronic pacing system analyzer and analyzer cables.
- External defibrillator.

4.1.2 Setting up the programmer and starting the application

See the reference manual for the Medtronic programmer for instructions about how to set up the programmer. The Model SW041 software must be installed on the programmer. Establish telemetry with the device and start a patient session.

Positioning a magnet over the device suspends tachyarrhythmia detection. If you place a programming head over the device during a wireless telemetry session, the magnet in the programming head always suspends tachyarrhythmia detection. If you place a programming head over the device and establish a nonwireless telemetry session, tachyarrhythmia detection is not suspended.

4.1.3 Considerations for preparing for an implant

Review the following information before implanting the lead or device:

Warning: A Medtronic EV4-LLHH extravascular quadripolar lead must be used with the Medtronic Model DVEA3E4 device. If a lead other than a Medtronic EV4-LLHH extravascular quadripolar lead is used, the Aurora EV-ICD MRI SureScan system will present serious risks for adverse events to the patient.

Warning: Do not allow the patient to have contact with grounded electrical equipment that might produce electrical current leakage during implant. Electrical current leakage may induce tachyarrhythmias that may result in the patient's death.

Warning: It is important to have and review a safety or emergency protocol prior to the implant procedure. Keep external defibrillation equipment nearby for immediate use. Potentially harmful spontaneous or induced tachyarrhythmias may occur during device testing, implant procedures, and post-implant testing.

Caution: The device is intended for implant in the left midaxillary region with a Medtronic EV4-LLHH extravascular quadripolar lead. No claims of safety and efficacy can be made about other acutely or chronically implanted device and lead systems that are not manufactured by Medtronic.

Caution: Any device or lead coils or electrodes that are in contact with conductive materials during a high-voltage therapy can cause electrical current to bypass the heart. This current can damage the device and lead. Move objects made of conductive materials away from all coils and electrodes while the device is connected to the leads.

Caution: Do not implant the device after the "Use-by" date on the package label. Device longevity may be reduced.

Caution: Do not immerse the device in fluid or flush the connector ports at the time of implant. Doing so could adversely affect the performance of the device and lead system.

Determine ICD pocket location in the left mid-axillary region; it is recommended to use fluoroscopy (AP and lateral views) as guidance. It is recommended to confirm defibrillation vector based on lead placement and cardiac silhouette for final Medtronic Model DVEA3E4 device implant location.

4.1.4 How to prepare the device for implant

Device temperature – Allow the device to reach room temperature before it is programmed or implanted. Device temperature above or below room temperature may affect initial device function.

Before opening the sterile package, perform the following steps to prepare the device for implant:

1. Interrogate the device and print an Initial Interrogation Report.

   Caution: If the programmer reports that an electrical reset occurred, do not implant the device. Contact a Medtronic representative.

2. To confirm that the device is acceptable for implant, check the status of the Remaining Longevity estimate on the Quick Look II screen. The Remaining Longevity estimate graphic is gray if the battery status is not acceptable for implant and it is green if the battery status is acceptable for implant.

   If the device has been exposed to low temperatures, the battery voltage can be temporarily lower and the charge time can increase. If the battery status is unacceptable, store the device at room temperature for 48 hours and check the battery status again to determine if the device is acceptable for implant. If an acceptable battery status cannot be obtained after 48 hours, contact a Medtronic representative.

   Note: If the Remaining Longevity estimate graphic on the Quick Look II screen is gray, indicating that the battery status is unacceptable, do not charge the capacitors.
3. Tap **Params > Data Collection Setup > Device Date/Time…** to set the device clock.
4. Program the device parameters to values that are appropriate for the patient. Make sure that VF detection, FVT detection, and VT detection are programmed to OFF.

   Note: Additional parameters such as patient information typically is entered at the time of initial implant, but can be revised at any time.

4.2 Implanting the lead

A complete Medtronic Aurora EV-ICD MRI SureScan defibrillation system includes a Medtronic Aurora EV-ICD MRI SureScan Model DVEA3E4 device connected to a Medtronic EV4-LLHH extravascular quadripolar lead.

Consult the Medtronic extravascular lead technical manual for detailed implant instructions.

4.2.1 Lead and connector compatibility

Note: Do not use a lead adaptor with a Medtronic EV4-LLHH extravascular quadripolar lead. Only use the Medtronic EV4-LLHH extravascular quadripolar lead with the Medtronic Model DVEA3E4 device.

Table 1. Lead and connector

Connector port (electrodes)	Lead
V (Connector Pin, Ring 1, Ring 2, Ring 3)	EV4-LLHH quadripolar[a]

[a] EV4-LLHH is a Medtronic proprietary design, where the lead connector contacts are defined as low voltage (L) or high voltage (H). The mechanical specifications for the EV4-LLHH connector are defined by the Medtronic EV4 connector specification.

4.2.2 Implanting the lead

Implant the Medtronic EV4-LLHH extravascular quadripolar lead according to the instructions in the extravascular lead technical manual, supplied with the lead.

Warning: Pinching the lead can damage the lead conductor or insulation, which may cause unwanted high-voltage therapies or result in the loss of sensing or pacing therapy.

4.3 Testing the lead system

After the lead is implanted, test the lead system to verify that the sensing is acceptable.

Acceptable lead measurements must meet either of the following criteria in the Ring 1 to Ring 2 vector:

- R-wave ≥1 mV and P-wave <0.2 mV through a respiratory cycle measured by the analyzer or device.
- If P-waves are measured ≥0.2 mV but less than 0.3 mV, the R-Wave amplitude must be greater than 10 times the P-Wave amplitude through a respiratory cycle measured by the device.

Caution: If unable to meet the criteria above, attempt repositioning or re-tunneling the lead. If still unable to meet the criteria above, there is a potential for undersensing R-waves or oversensing P-waves and the implant of an alternative ICD system should be considered.

Note: See the Medtronic extravascular lead technical manual for supporting information to test the lead.

Note: The EGM telemetered from the device cannot be used to assess sensing directly.

4.3.1 Testing the lead system sensing with a pacing system analyzer

To test the lead system sensing with a pacing system analyzer, perform the following procedure:

1. From the device session, launch a new analyzer session by tapping the analyzer icon on the task bar.

2. Measure the R Wave amplitude with the analyzer:
3. To confirm the measurement values, remeasure the R Wave amplitude if you choose.
4. Manually record the R Wave amplitude measurement to enter into the patient's record.
5. Tap the device icon on the task bar.
6. Tap **Patient > Patient Information > Implant…** field to display the **Implant** pop-up window.
7. Manually enter the measurements you recorded in *Step 4* in the Lead Data from Analyzer fields.
8. To save the measurement values into device memory, tap **OK > Program**.

4.4 Connecting the lead to the device

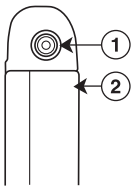
The following procedure describes how to connect the lead to the device, how to confirm that the lead connector is fully inserted in the connector block, and how to verify that the lead connection is secure.

Warning: After connecting the lead, verify that the lead connection is secure by gently tugging on the lead. A loose lead connection may result in inappropriate sensing, which can cause inappropriate arrhythmia therapy or a failure to deliver arrhythmia therapy.

Caution: Use only the torque wrench supplied with the device. The torque wrench is designed to prevent damage to the device from overtightening a setscrew.

See *Figure 1* for information about the lead connector port on the device.

Figure 1. Lead connector port

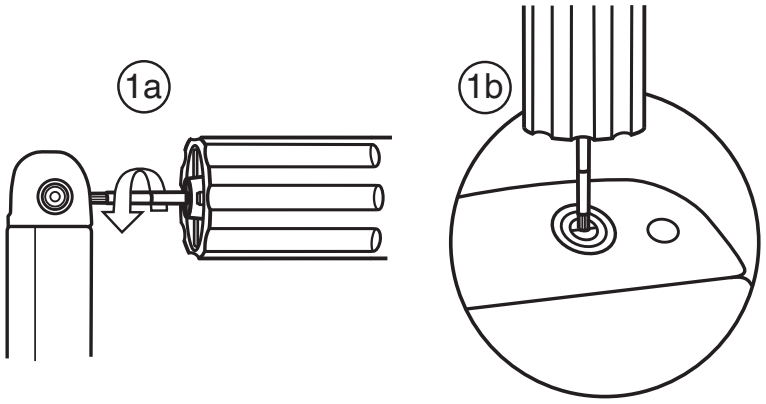


1 EV4-LLHH connector port
2 Device Active Can electrode

4.4.1 How to connect the lead to the device

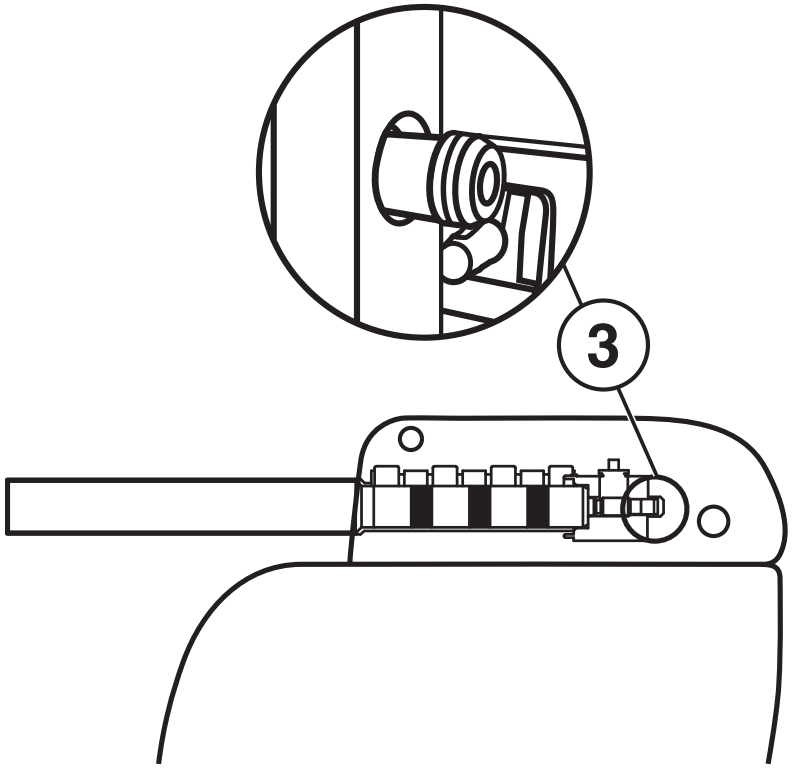
1. Insert the torque wrench into the appropriate setscrew.
    a. If the setscrew obstructs the port, retract the setscrew by turning it counterclockwise until the port is clear. Take care not to disengage the setscrew from the connector block (see *Figure 2*).
    b. To allow a pathway to vent trapped air when the lead connector is inserted into the connector port, leave the torque wrench in the setscrew until the lead connection is secure (see *Figure 2*).

Figure 2. Inserting the torque wrench into the setscrew



2. Insert the lead connector into the connector port, keeping twisting to a minimum. Insert the lead connector until the lead connector pin is visible in the pin viewing area. No sealant is required. If necessary, sterile water may be used as a lubricant.
3. Confirm that the lead is fully inserted into the connector pin cavity by viewing the device connector block from the side. The tip of the lead connector pin is visible in the pin viewing area when the pin is fully inserted (see *Figure 3*).

   Figure 3. Confirming the EV4-LLHH lead connection



4. Tighten the setscrew by turning it clockwise until the torque wrench clicks. Remove the torque wrench.
5. Gently tug on the lead to confirm a secure fit. Do not pull on the lead until the setscrew has been tightened.

4.5 Positioning and securing the device

Caution: Program tachyarrhythmia detection to OFF to avoid inappropriate detection or therapy delivery while closing the surgical pocket.

Note: Implant the device under the patient's adipose tissue, against the muscle tissue. Face the side of the device engraved with the Medtronic logo toward the skin so the patient can better hear any alert tones. This orientation is also most compatible with the device PhysioCurve Design.

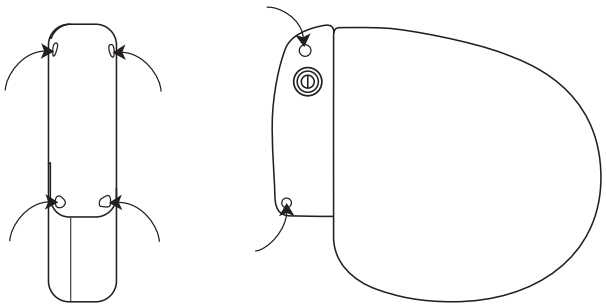
4.5.1 How to position and secure the device

1. Verify that the lead connector pin is fully inserted into the connector port and that the setscrew is tight.
2. To prevent twisting of the lead body, rotate the device to loosely wrap the excess lead length (see *Figure 4*). Do not kink the lead body.

   Figure 4. Rotating the device to wrap the lead

3. Place the device and the lead into the surgical pocket located in the left midaxillary region.
4. Use nonabsorbable sutures to secure the device within the pocket and minimize post-implant rotation and migration. Use a surgical needle to penetrate the suture holes on the device (see *Figure 5*).

   Figure 5. Locating the suture holes



5. Suture the pocket incision closed.

4.6 Performing an Impedance Test

Consider the following information about lead impedance when evaluating the lead system:

- Ring 1 to Ring 2 and Ring 1 to Coil 2 must be between 100 Ω and 1500 Ω.
- High voltage (HV) must be between 30 Ω and 250 Ω.

To get all impedance values, the device should be in the pocket.

To perform an impedance test, complete the following steps:

1. Tap **Tests > Lead Impedance** .
2. Tap **START Measurement**.

a. The message **Measurement in progress...** and a test progress indicator is displayed on the programmer.
b. If necessary, tap **STOP** to terminate the test. Lead impedance measurements are not updated from a test that is stopped.

3. When the test is complete the new measured impedance values of the tested polarities are displayed.

If the lead impedance is out of range, perform one or more of the following tasks:

- Check the lead connections and the lead electrode placement.
- Ensure the set screws are tightened.
- Check the device pocket for air. Remove any air by flushing and massaging the ICD in the pocket.

4.7 Performing a Sensing Test

The sensing test enables you to measure R-wave amplitude on any programmed Sense Polarity.

Considerations for performing a sensing test:

- If no intrinsic events occur, the sensing test ends after a few seconds.
- Tachyarrhythmia detection is suspended during the sensing test.

4.7.1 Selecting a sense polarity to test

Use the following steps to select a Sense Polarity that you wish to test:

1. Tap **Params > Sensing… > Sense Polarity**
2. In the **Sense Polarity** pop-up window, click on the electrodes shown, or select from the list at the bottom of the window.
3. To program the selected polarity, tap **Close > OK > PROGRAM**

4.7.2 Performing a sensing test on the programmed polarity

Use the following steps to perform a sensing test on the programmed polarity:

1. Tap **Tests > Sensing**.
2. Tap **START Measurement**.
3. Observe the Live Rhythm Monitor for an intrinsic rhythm and amplitude measurements.

   Notes:
   - To abort the test, tap **STOP and Restore**.
   - The device measures amplitudes only on intrinsic events. The maximum amplitude value that the sensing test can measure is 10 mV. If the amplitude is over 10 mV, the results are displayed as >10 mV.

The sensing test ends when it has measured 5 intrinsic events. When the test is complete, the R-Wave Amplitude value is updated on the test screen. This value represents the median measured R-wave amplitude.

4.8 Performing a pacing threshold test

The pacing threshold test is used to determine the minimum pacing output that consistently captures the heart. The results of this test also determine which **S1 Pathway** to use in the T-Shock defibrillation test in *Section 4.9*.

4.8.1 How to measure pacing thresholds

1. Tap **Tests > Pacing Threshold**.
2. Select the Pace Polarity for the test, beginning with Ring 1 to Coil 2.
3. Select a Test Value for Lower Rate, Amplitude, and Pulse Width.

4. To change the value for V. Pace Blanking tap **Additional Settings…** to access the V. Pace Blanking | Test Value field. Tap the field and select a Temp. V. Pace Blanking value, then tap **OK**.
5. Select the **Enable** check box.

   Note: When you are testing the Coil 2 to Coil 1 polarity, the **Energy Check - In Progress** pop-up appears briefly to determine the stored capacitor energy. If the energy on the capacitors is higher than the energy level you selected for the test, the programmer displays a warning. To clear this warning, tap either **Dump** to dump the capacitors, or **Cancel** to cancel the Pacing Threshold test.
6. Press and hold **TEST Press and Hold**.
7. Observe the Live Rhythm Monitor for capture or loss of capture.
8. If capture is lost, perform the following procedure. (If capture is not lost, go to *Step 9*.)
   a. Release **TEST Press and Hold**. The device resumes OVO mode operation and displays the **Pacing Threshold Test - Results** window.
   b. Tap **Close** to return to the **Tests - Pacing Threshold** screen.
   c. Repeat *Step 3* through *Step 7* using incrementally higher values until capture is not lost. These values comprise the pacing threshold for the Ring 1 to Coil 2 pace polarity.
9. If capture is not lost, perform the following procedure.
   a. Release **TEST Press and Hold**. The device resumes OVO mode operation and displays the **Pacing Threshold Test - Results** window.
   b. Tap **Close** to return to the **Tests - Pacing Threshold** screen.
   c. Repeat *Step 3* through *Step 7* using incrementally lower values until capture is lost. The lowest tested values at which capture is not lost comprise the pacing threshold for the Ring 1 to Coil 2 pace polarity.
10. To identify the pacing thresholds for the Ring 1 to Ring 2 and Coil 2 to Coil 1 pace polarities, repeat *Step 3* through *Step 9*.

    Note: The pacing amplitude range for the Ring 1 to Ring 2 and Ring 1 to Coil 2 pace polarities is 1.00 V to 8.00 V. If you are unable to capture the heart at a pacing amplitude of ≤8.00 V at any pulse width, you must pace from the Coil 2 to Coil 1 pace polarity. The pacing amplitude range for the Coil 2 to Coil 1 pace polarity is 10.00 V to 30.00 V for Post Shock pacing, 10.00 V to 30.00 V for ATP, and 10.00 V or 13.00 V for Pause Prevention pacing.
11. To print a Pacing Threshold test report at any time, tap **Print…** from the **Pacing Threshold Test - Results** window.

4.9 Performing ventricular defibrillation threshold tests

Test the operation and effectiveness of ventricular defibrillation by inducing VF with the T-Shock test or the Burst Induction test, and then allow the device to detect and treat the VF with programmed therapies. Establish an adequate sensing safety margin and an adequate defibrillation safety margin using your preferred method.

Carefully consider for each patient the decision to induce VF for testing ventricular defibrillation operation and effectiveness. Use discretion in your decision to test or how to test for an adequate safety margin.

4.9.1 High-voltage implant values

See *Table 2* for information about the measured high-voltage therapy values that are recommended at implant.

Table 2. High-voltage (HV) therapy values recommended at implant

Measurement	Values
HV delivery pathway impedance	30–250 Ω
Demonstrated defibrillation success	30 J

4.9.2 How to prepare for defibrillation threshold testing

Warning: Keep external defibrillation equipment nearby for immediate use. Potentially harmful spontaneous or induced tachyarrhythmias may occur during device testing, implant procedures, and post-implant testing.

1. Establish telemetry between the device and programmer, and start a patient session. If you are using wireless telemetry, verify that at least 3 of the green lights on the wireless telemetry icon are illuminated. Interrogate the device if it has not been interrogated.
2. To verify that the device is sensing properly, observe the Marker Channel annotations. Tap **Params > Sensing…** to adjust the sensing parameters, if necessary.
3. Perform a manual Lead Impedance Test to verify defibrillation lead connections. For information about acceptable impedance values, refer to the Medtronic extravascular lead technical manual. Perform this test with the device in the surgical pocket. Keep the surgical pocket moist. If the lead impedance is out of range, perform one or more of the following tasks:
    - Recheck the lead connections and lead electrode placement.
    - Inspect the EGM for abnormalities.
    - Repeat the manual Lead Impedance Test.
4. If desired, enable post shock pacing before performing defibrillation threshold testing. To turn on post shock pacing, perform the following steps:
    - Tap **Params > Pacing… > Post Shock | Setting**. The **Post Shock Pacing Enable** pop-up displays.
    - Tap **Off**. The field will toggle to On.
5. Change the Amplitude, Pulse Width and Pace Polarity values, as desired.
6. Tap **OK > PROGRAM** to program your parameter changes into device memory.

4.9.3 How to perform defibrillation threshold testing using T-Shock

Note: During a wireless telemetry session, you cannot deliver a T-Shock induction when there is a magnet or programming head over the device.

1. Tap **Tests > EP Study > T-Shock**.
2. Tap **Adjust Permanent…** and make the following selections in the **Adjust Permanent** window:
    a. Set the **Energy** parameter for **Rx1** to 30 J (or 10 J less than your desired final programmed value).
    b. Set the **Energy** parameter for **Rx2**, **Rx3**, **Rx4**, **Rx5**, and **Rx6** to 40 J (or 10 J greater than the value you selected in *Step 2a*).
    c. Tap the **Sensitivity** parameter and select a value for a safety margin for detecting VF that is at least 3 times greater than the final programmed sensitivity.

    Note: For a final programmed sensitivity of 0.15 mV, an adequate safety margin typically is attained if you set the value to 0.45 mV during testing.
    d. Set **VF Enable** to On.
    e. Tap **PROGRAM**.
    f. Tap **Close** to close the **Adjust Permanent** window.
3. Select the **S1 Pathway** based on the results of the pacing threshold test (see *Section 4.8, Performing a pacing threshold test, page 21*) as follows:
    - If the pacing threshold is below 8 V, 8 ms, select **Ring 1 to Coil 2**.
    - If the pacing threshold is above 8 V, 8 ms, select **Coil 2 to Coil 1**.
4. Set the desired T-Shock parameters.
5. Check the **Enable** check box. (The **Energy Check - In Progress** pop-up appears briefly to determine the stored capacitor energy.)

Note: If the energy on the capacitors is higher than the energy level you selected for the test, the programmer displays a warning. To clear this warning, tap either **Dump** to dump the capacitors, or **Cancel**.

6. Tap **DELIVER T-Shock**. If necessary, tap **ABORT** to abort the induction.
7. Observe the Live Rhythm Monitor for proper detection, therapy, and post-shock sensing.
8. Tap **Retrieve Data…** to review the stored data for the induced episode. To view more details, tap **Print…** to print an EP Study T-Shock Induction Report, or tap **Data > Clinical Diagnostics > Arrhythmia Episodes** to view the induced episode data on the programmer.
9. Tap **Adjust Permanent…** to program new Therapy Energy levels or to change the Pathway, if desired.

   Note: If sensing parameters other than Sensitivity need to be adjusted, tap **Params > Sensing…** to reprogram those parameters. The Last Induction (mm:ss) timer will continue to count while you do this.
10. Wait until the Last Induction (mm:ss) timer reaches at least 05:00, then repeat *Step 1* through *Step 10*, as needed.

4.9.4 How to perform defibrillation threshold testing using Burst Induction

Note: During a wireless telemetry session, you cannot deliver a T-Shock induction when there is a magnet or programming head over the device.

1. Tap **Tests > EP Study > Burst Induction**.
2. Tap **Adjust Permanent…** and make the following selections in the **Adjust Permanent** window:
   a. Set the **Energy** parameter for **Rx1** to 30 J (or 10 J less than your desired final programmed value).
   b. Set the **Energy** parameter for **Rx2**, **Rx3**, **Rx4**, **Rx5**, and **Rx6** to 40 J (or 10 J greater than the value you selected for **Rx1** in *Step 2a*).
   c. Tap the **Sensitivity** parameter and select a value for a safety margin for detecting VF that is at least 3 times greater than the final programmed sensitivity.

      Note: For a final programmed sensitivity of 0.15 mV, an adequate safety margin is typically attained by setting the value to 0.45 mV during testing.
   d. Set **VF Enable** to On.
   e. Tap **PROGRAM**.
   f. Tap **Close** to close the **Adjust Permanent** window.
3. Select the **Enable** check box. (The **Energy Check - In Progress** window appears briefly to determine the stored capacitor energy.)

   Note: If the energy reserved on the capacitors is greater than the energy that is required to perform the Burst Induction test, the programmer displays a warning. To clear this warning, tap either **Dump** to dump the capacitors, or **Cancel**.
4. Press and hold the touch pen on the **BURST Press and Hold** button. The test aborts if you lift the touch pen. If you do not lift the touch pen, the test times out after 10 s.
5. Observe the Live Rhythm Monitor for proper detection, therapy, and post-shock sensing.
6. Tap **Retrieve Data…** to review the stored data for the induced episode. To view more details, tap **Print…** to print an EP Study Burst Induction Report.
7. Tap **Adjust Permanent…** to program a new **Rx1** energy level or to change the **Pathway**, if desired.

   Note: If sensing parameters other than Sensitivity need to be adjusted, tap **Params > Sensing…** to reprogram those parameters. The Last Induction (mm:ss) timer will continue to count while you do this.
8. Wait until the Last Induction (mm:ss) timer reaches at least 05:00, then repeat *Step 1* through *Step 8*, as needed.

4.10 Completing the implant procedure

4.10.1 How to complete programming the device

1. Enable tachyarrhythmia detection and the desired tachyarrhythmia therapies.
2. Verify that the sensing, pacing, detection, and therapy parameters are programmed to values that are appropriate for the patient.
3. Perform a final VF induction, and allow the implanted system to detect and treat the tachyarrhythmia.
4. Enter the patient's information.

   Note: Enter complete information about the implanted lead in the **Patient Information** screen.

   Note: Enter complete information about other hardware implanted in the patient in the **MRI SureScan System/Other Hardware** screen. Include concomitant or abandoned devices or leads, and lead extenders or adaptors. This information is used if the patient needs to be evaluated for an MRI scan. For more information, see the reference manual.
5. Configure the Medtronic CareAlert feature.
6. Program the **Data Collection Setup** parameters.

4.10.2 How to assess the performance of the device and the lead

After implanting the device, x-ray the patient as soon as possible to verify device and lead placement. Before the patient is discharged from the hospital, assess the performance of the implanted device and lead.

1. Monitor the patient's electrocardiogram until the patient is discharged. If the lead migrates or dislodges, it usually occurs during the immediate postoperative period.
2. If any tachyarrhythmia therapies are enabled while the patient is in the hospital, interrogate the device after any spontaneous episodes to evaluate the detection and therapy parameter settings.
3. Check the pacing and sensing values, and adjust the values if necessary. Verify the safety margin for the pacing threshold, and verify the sensing safety margin for detecting VF.
4. Demonstrate the alert tones.
5. To document the postoperative programmed device status, interrogate the device and print a final report.

5 Replacement procedure

5.1 Replacing a device

To retain the ability to scan the SureScan system safely during future MRI scans, refer to the MRI technical manual for additional information.

Warning: Keep external defibrillation and pacing equipment nearby for immediate use. The patient does not receive defibrillation or pacing therapy from the device when the lead is disconnected.

Warning: A Medtronic EV4-LLHH extravascular quadripolar lead must be used with the Medtronic Model DVEA3E4 device. If a lead other than a Medtronic EV4-LLHH extravascular quadripolar lead is used, the Aurora EV-ICD MRI SureScan system will present serious risks for adverse events to the patient.

Caution: Disable tachyarrhythmia detection to avoid inappropriate therapy delivery while explanting the device.

5.1.1 How to explant and replace a device

1. Disable tachyarrhythmia detection, Post Shock pacing and Pause Prevention detection to avoid potential inappropriate shocks to the patient or clinician while explanting the device.
2. Dissect the lead and the device free from the surgical pocket. Do not nick or breach the lead insulation.
3. Use a torque wrench to loosen the setscrew in the connector block.
4. Gently pull the lead out of the connector port.

5. Evaluate the condition of the lead (see *Section 4.9*). Replace the lead if the electrical integrity is not acceptable or if the lead connector pin is pitted or corroded. If you explant the lead, return it to Medtronic for analysis and disposal.
6. Connect the lead to the replacement device (see *Section 4.4, Connecting the lead to the device, page 18*).
7. Perform a sensing test on the replacement device. See *Section 4.7, Performing a Sensing Test, page 21*.
8. Perform a pacing threshold test on the replacement device. See *Section 4.8, Performing a pacing threshold test, page 21*.
9. Perform ventricular defibrillation threshold tests to evaluate the defibrillation effectiveness of the replacement device. See *Section 4.9*.
10. Position and secure the device in the surgical pocket, and suture the pocket incision closed (see *Section 4.5*).
11. Contact Medtronic for return mailer kits to return explanted devices for analysis and disposal. See the back cover for addresses.

    Note: Observe all local laws and regulations regarding the disposal of explanted devices or leads.

6 Product specifications

6.1 Physical characteristics

Table 3. Physical characteristics

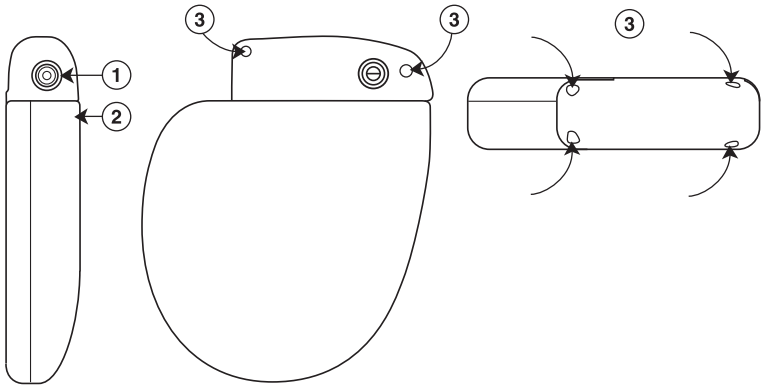
Volume[a]	33 cm^3 (2 in^3)
Mass	77 g
H x W x D	64 mm x 51 mm x 13 mm (2.5 in x 2 in x 0.5 in)
Surface area of device can	57 cm^2 (8.8 in^2)
Connector	
Type	EV4-LLHH
Length	30 mm (1.2 in)
Functional diameter	3.2 mm (0.1 in)
Radiopaque ID[b]	REX
Materials in contact with human tissue[c]	Titanium, polyurethane, silicone rubber adhesive, silicone rubber, liquid silicone rubber
Battery chemistry	Hybrid CFx lithium/silver vanadium oxide

[a] Volume with connector ports unplugged.

[b] The radiopaque ID and Medtronic radiopaque identifier can be viewed in a fluoroscopic image of the device.

[c] These materials have been successfully tested for the ability to avoid biological incompatibility. The device does not produce an injurious temperature in the surrounding tissue during normal operation.

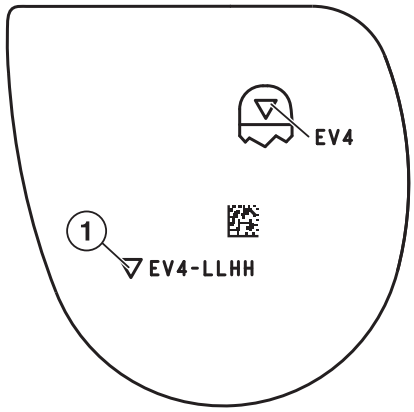
Figure 6. Connector ports and suture holes



1 EV4-LLHH connector port
2 Device Active Can electrode
3 Suture holes

The Aurora EV-ICD MRI SureScan Model DVEA3E4 shield graphics are shown in *Figure 7*.

Figure 7. Shield graphics: Aurora EV-ICD MRI SureScan Model DVEA3E4



1 EV4-LLHH marking

6.2 Replacement indicators

The Remaining Longevity estimate, replacement status, and battery voltage appear on the programmer display and on printed reports. The Recommended Replacement Time (RRT) and the End of Service (EOS) conditions are listed in *Table 4*.

Table 4. Replacement indicators

Recommended Replacement Time (RRT)	<2.73 V on 3 consecutive daily automatic measurements
End of Service (EOS)	3 months after RRT

Remaining Longevity – The Remaining Longevity estimate displays the estimated time remaining until device RRT.

RRT (Recommended Replacement Time) – The programmer displays the RRT battery status to indicate that replacement of the device is recommended.

RRT date – The programmer displays the date when the battery reached RRT on the Quick Look II and Battery and Lead Measurements screens.

EOS (End of Service) – The programmer displays the EOS battery status to indicate that the device should be replaced immediately and may not operate per specifications.

Replace at EOS – If the programmer indicates that the device is at EOS, replace the device immediately.

Prolonged Service Period – The Prolonged Service Period (PSP) is the time between the RRT and EOS. The PSP is defined as 3 months assuming the following conditions: 0% pacing; 6 full-energy charges delivered, at the connector block, into a 50 Ω load. The EOS may be indicated before the end of 3 months if the device exceeds these conditions.

6.3 Projected service life

The service life projection for the device is 11.7 years. This projection is an estimate of the average expected service life based on the following assumptions:

- Pacing at 0%.
- 2 high-voltage therapies per year.
- Pre-arrhythmia EGM storage programmed to On for 6-months, over life of device.
- Wireless telemetry:
  - 3 hours of telemetry enabled at implant.
  - 30 min of telemetry enabled for quarterly scheduled CareLink Monitor remote sessions (if available).
  - 1 hour of in-office wireless telemetry enabled annually.
- Shelf storage life of 5 months, before implant.

6.3.1 Projected service life considerations

Additional full-energy charges – Each additional full-energy charge due to therapy shock or device testing reduces projected service life by approximately 46 days.

Pre-arrhythmia EGM storage – Full-time use of Pre-arrhythmia EGM storage reduces projected service life by approximately 3.7 additional months per year, or 31%.

Medtronic patient monitor remote transmissions – Additional Medtronic patient monitor remote transmissions reduce projected service life. Projected service life reductions for more frequent remote transmission rates are as follows:

- Monthly transmissions over the life of the device reduce projected service life by 99 days, or 2%.
- Weekly transmissions over the life of the device reduce projected service life by 468 days, or 9%.
- Daily transmissions over the life of the device reduce projected service life by 2031 days, or 41%
- A single additional transmission reduces projected service life by approximately 0.8 days, or 0.02%.

Wireless telemetry – Each hour of wireless telemetry use (in-office or at implant) reduces the projected service life by approximately 11.7 days, or 0.27%.

Shelf storage time – Maximum shelf storage time of 18 months reduces projected service life by approximately 4.6%.

6.4 Energy levels and typical charge times

Energy levels – Stored energy is always greater than the delivered energy. Stored energy is derived from the peak capacitor charge.

Typical charge times – The most recent capacitor charge time appears on the programmer display and on printed reports. You can evaluate charge time using the Charge/Dump Test.

Table 5. Maximum energy levels and typical full energy charge times

Maximum programmed energy	40 J
Energy delivered at maximum programmed energy[a]	40 J
Typical charge time at Beginning of Service (BOS)[b]	9.4 s
Typical charge time at Recommended Replacement Time (RRT)[b]	14.8 s

[a] Tolerance for delivered energy delivered into a 75 Ω load is 40 J±15%.

[b] Charge time during a nonwireless telemetry session may be slightly higher.

6.5 Magnet application

When a magnet is placed near the device, tachyarrhythmia detection is suspended and no tachyarrhythmia therapies are delivered. Alert tones sound if programmed. The device ignores the magnet in the programmer head when telemetry communication is established through the programmer head. Before implant and for the first 6 hours after implant, the device does not sound audible tones when a magnet is placed over the device.

6.6 Wireless specifications

Table 6. Wireless specifications

Inductive Telemetry	MedRadio
Operating Band: 175 kHz	Operating Band: 402–405 MHz
Maximum Output Power: –34.9 dBμV/m, measured at 300 m	Maximum Output Power: 0.069 μW EIRP
Operating Range: 10–17 cm	Operating Range: 2–5 m

7 Device parameters

7.1 Emergency settings

Table 7. Emergency settings

Parameter	Selectable values
Defibrillation	
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 J
Pathway	STD
Cardioversion	
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40 J
Pathway	STD

7.2 Tachyarrhythmia detection parameters

Table 8. Ventricular tachyarrhythmia detection parameters

Parameter	Programmable values	Shipped	Reset
VF Detection[a]	On◈; OFF	OFF	On
VF Initial Beats to Detect	12/16; 18/24; 24/32; 30/40◈; 45/60; 60/80; 75/100; 90/120; 105/140; 120/160	30/40	30/40
VF Beats to Redetect	6/8; 9/12; 12/16◈; 18/24; 21/28; 24/32; 27/36; 30/40	12/16	12/16

Table 8. Ventricular tachyarrhythmia detection parameters (continued)

Parameter	Programmable values	Shipped	Reset
VF: Ventricular Interval (Rate)[b]	240; 250 … 320◈ … 400 ms	320 ms	320 ms
FVT Detection	OFF◈; via VF	OFF	OFF
FVT: Ventricular Interval (Rate)[b]	200; 210 … 240◈ … 600 ms	—	—
VT Detection	On; OFF◈	OFF	OFF
VT Interval (Rate)[b]	280; 290 … 360◈ … 650 ms	360 ms	400 ms
VT Initial Beats to Detect	12; 16◈ … 52; 76; 100	16	16
VT Beats to Redetect	8; 12◈ … 52	12	12
Monitor	Monitor◈; Off	Off	Off
Monitored VT Beats to Detect	16; 20; 24; 28; 32◈ … 56; 80; 110; 130	32	32
Monitor: Ventricular Interval (Rate)[b]	280; 290 … 450◈ … 650 ms	450 ms	450 ms
Wavelet …			
Wavelet	On◈; Off; Monitor	On	Off
Template	[date]	None	None
Match Threshold	40; 43; 46 …61◈ … 97%	61%	61%
Auto Collection	On◈; Off	ON	OFF
Rapid AF	On◈; Off	ON	OFF
Feature Match	On◈; Off	ON	OFF
SVT V. Limit[b]	210; 220; … 260◈ … 650 ms	260 ms	260 ms
Other Enhancements			
Stability[b]	Off◈; 30; 40 …100 ms	Off	Off
Onset	Off◈; On; Monitor	Off	Off
Percent	72; 75; 78; 81◈; 84; 88; 91; 94; 97%	81%	81%
High Rate Timeout			
VF Zone Only (min)	Off; 0.25; 0.5; 0.75◈; 1; 1.25; 1.5; 1.75; 2; 2.5; 3; 3.5; 4; 4.5; 5 min	0.75 min	0.75 min
All Zones (min)	Off◈; 0.5; 1; 1.5 … 5; 6; 7 … 20; 22; 24; 26; 28; 30 min	—	—
TWave	On◈; Off	On	Off
Noise			
Smart Sense	On◈; Off	On	Off
Morphology Noise	On◈; Off	On	Off
Sensed EMI	On◈; Off	On	Off
Shared Noise Timeout[c]	Off; 0.25; 0.50; 0.75 … 2.00; 2.50; 3.0◈ … 4.00 min	3 min	—

[a] Reset does not happen in the box. Table shows Reset value when implanted.

[b] The measured intervals are truncated to a 10 ms multiple (for example, 457 ms becomes 450 ms). The device uses this truncated interval value when applying the programmed criteria and calculating interval averages.

[c] Therapy can be withheld by noise oversensing enhancements for up to the total timeout period.

7.3 Ventricular tachyarrhythmia therapy parameters

Table 9. Ventricular tachyarrhythmia therapy parameters

Parameter	Programmable values	Shipped	Reset
VF Therapies			
VF Therapy Status	On◈; Off	On	On
Energy	Rx1–Rx2: 0.4; 0.6; 0.8 J 1; 1.2 J 1.4; 1.6; 1.8; 2; 3; 4 J 5; 6 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J 40◈ J Rx3–Rx6: 10; 11 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J 40◈ J	40 J	40 J
Pathway[a]	STD◈; REV	STD	STD
VT/FVT Therapies			
VT/FVT Therapy Status	Rx1–Rx6: On; Off◈	Off	Off
Therapy Type	Rx1: CV; Burst◈; Ramp Rx2–Rx6: CV◈; Burst; Ramp	—	—
Energy[b]	Rx1–Rx6: 0.4; 0.6; 0.8 J 1; 1.2 J 1.4; 1.6; 1.8; 2; 3; 4 J 5; 6; … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35 J 40◈ J	—	—
Pathway[a]	STD◈; REV	—	—
Burst therapy parameters			
Initial # Pulses	1; 2 … 8◈ … 15	—	—
R-S1 Interval=(%RR)	50; 53; 56; 59; 63; 66 … 84; 88◈; 91; 94; 97%	—	—
Interval Dec	0; 10◈ … 40 ms	—	—
# Sequences	1; 2 … 10 VT Therapies: 3◈ FVT Therapies: 1◈	—	—
Smart Mode[c]	On; Off◈	—	—
Ramp therapy parameters			
Initial # Pulses	1; 2 … 8◈ … 15	—	—
R-S1 Interval=(%RR)	50; 53; 56; 59; 63; 66 … 84; 88; 91◈; 94; 97%	—	—
Interval Dec	0; 10◈ … 40 ms	—	—
# Sequences	1; 2 … 10 VT Therapies: 3◈ FVT Therapies: 1◈	—	—
Smart Mode[c]	On; Off◈	—	—
Shared Settings…			
Shared V. ATP			
ATP Polarity	Ring 1 to Ring 2 (R1R2);	Coil 2 to Coil 1	Coil 2 to Coil 1

Table 9. Ventricular tachyarrhythmia therapy parameters (continued)

Parameter	Programmable values	Shipped	Reset
	Ring 1 to Coil 2(R1C2); Coil 2 to Coil 1 (C2C1)		
V. Amplitude	(R1R2, R1C2) 1; 2 … 8 V (C2C1) 10; 13; 16; 20; 30 V	10 V	10 V
V. Pulse Width	(R1R2, R1C2) 2; 4 ms (±100 µs); 6; 8 ms (±300 µs) (C2C1) 1; 2; 3; 4 ms	2 ms	2 ms
V-V Minimum ATP Interval	(R1R2, R1C2) 150; 160; 160 … 200 … 400 ms (±12 ms) (C2C1) 150; 160; 160 … 200 … 400 ms (±60 ms)	200 ms	200 ms
V. Pace Blanking	150; 160 … 250 … 450 ms (±5 ms)	250 ms	250 ms

[a] STD = Coils to Can; REV = Can to Coils.

[b] This parameter is for CV (cardioversion).

[c] Smart Mode is available only for Rx1– Rx4.

7.3.1 Delivered energy conditions and tolerances

This table lists the conditions and tolerances for delivered energy levels for high voltage therapies.

Table 10. Delivered energy conditions and tolerances

	30 Ω	50 Ω	75 Ω	200 Ω	250 Ω
22 °C (71.6 °F): 0.4 J - 35 J[a]	-35% / +20%	-30% / +20%	-30% / +20%	-30% / +20%	-50% / +50%
22 °C (71.6 °F): 40 J	-30% / +20%	-30% / +20%	-30% / +20%	-30% / +20%	-50% / +50%
37 °C (98.6 °F): 0.4 J - 4 J[a]	-30% / +20%	-30% / +20%	-30% / +20%	-30% / +20%	-50% / +50%
37 °C (98.6 °F): 5 J - 35 J	-30% / +20%	-20% / +20%	-20% / +20%	-30% / +20%	-50% / +50%
37 °C (98.6 °F): 40 J	-30% / +20%	-15% / +15%	-15% / +15%	-30% / +20%	-50% / +50%
45 °C (113 °F): 0.4 J - 40 J[a]	-30% / +20%	-30% / +20%	-30% / +20%	-30% / +20%	-50% / +50%

[a] Tolerance is ±0.25 J for energy levels for which ±0.25 J is greater than the listed tolerance range.

7.4 Post shock pacing parameters

Table 11. Post Shock pacing parameters

Parameter	Programmable values	Shipped	Reset
Post Shock Pacing Enable	On; Off	Off	Off
Pace Polarity	Ring 1 to Ring 2(R1R2); Ring 1 to Coil 2(R1C2); Coil 2 to Coil 1(C2C1)	Coil 2 to Coil 1	Coil 2 to Coil 1
Amplitude	(R1R2, R1C2) 1; 2 … 8 V (C2C1) 10; 13; 16; 20; 30 V	10 V	10 V

Table 11. Post Shock pacing parameters (continued)

Parameter	Programmable values	Shipped	Reset
Pulse Width	(R1R2, R1C2) 2; 4 ms (±100 µs); 6; 8 ms (±300 µs) (C2C1) 1; 2 … 10 ms	—	—
Lower Rate[a,b,c,d]	(R1R2, R1C2) 40 bpm (1500 ms) (±1.3 bpm (±50 ms) (C2C1) 40 bpm ±2.7 bpm (±100 ms) ≥10 V)	—	—
Therapy Duration[a]	30 s	—	—

[a] This parameter is nonprogrammable.

[b] The escape interval is 1500 ms.

[c] The corresponding pacing interval or escape interval can be calculated as follows: interval (in ms) = 60 000/Lower Rate (in bpm).

[d] The tolerance for the escape interval is +30/–2 ms.

7.5 Pause Prevention Detection — detection and pacing parameters

Table 12. Pause Prevention Detection — detection and pacing parameters

Parameter	Programmable values	Shipped	Reset
Setting			
Pause Prevention Detection Enable	On; Off; Monitor	Monitor	Monitor
Pause Prevention Detection Interval	5; 6 … 15 s	5 s	10 s
Pace Polarity	Ring 1 to Ring 2 (R1R2); Ring 1 to Coil 2 (R1C2); Coil 2 to Coil 1 (C2C1)	Coil 2 to Coil 1	Coil 2 to Coil 1
Amplitude	(R1R2, R1C2) 1 V; 2; 3 … 8 V (C2C1) 10; 13 V	—	—
Pulse Width	(R1R2, R1C2) 2; 4 ms (±100 µs); 6; 8 ms (±300 µs) (C2C1) 1; 2 … 10 ms	—	—
Lower Rate[a,b,c,d]	40 bpm (1500 ms) (±1.3 bpm (±50 ms) ≤8 V; ±2.7 bpm (±100 ms) ≥10 V)	—	—
Therapy Duration[b]	30 s	—	—

[a] Within ±10% for impedance ≥ 50 Ω and within ±20% for impedance < 50 Ω.

[b] This parameter is nonprogrammable.

[c] The corresponding pacing interval or escape interval can be calculated as follows: interval (in ms) = 60 000/Lower Rate (in bpm).

[d] The tolerance for the escape interval is +30 / –2 ms.

7.6 Miscellaneous operational parameters

Table 13. Modes

Parameter	Programmable values	Shipped	Reset
Mode	—	OVO	OVO

7.7 Sensing parameters

Table 14. Sensing parameters

Parameter	Programmable values	Shipped	Reset
Sensitivity[a,b,c]	0.075; 0.100; 0.150 (±75%); 0.200; 0.300; 0.450; 0.600 (±50%); 0.900; 1.200 mV (±30%)	0.300 mV	0.150 mV
Sense Polarity	Ring 1 to Ring 2; Ring 1 to Can; Ring 2 to Can	Ring 1 to Ring 2	Ring 1 to Ring 2
Blank after Sense	140; 150◈ … 200 ms	150 ms	150 ms
Sensing Threshold Decay Delay	210; 260 … 360◈ … 650 ms	360 ms	360 ms
Sensing Threshold Drop Time	500; 680; 1000; 1100 … 1500◈; 1600 … 2000; 2500 ms	1500 ms	1500 ms
Blank after Pace	200; 210 … 250◈ … 450 ms	250 ms	250 ms
Oversensing Prevention	Low - 1; 2; Medium - 3◈; 4; 5; High - 6	Medium - 3	Medium - 3

[a] **Warning:** Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity from its nominal setting to a more sensitive setting. When susceptibility to modulated interference is tested under the conditions specified in ISO 14708-6, ISO 14117, or EN 45502-2-2, the device is more susceptible to electromagnetic interference. The device will meet standard requirements when the sensitivity threshold is programmed to 0.3 mV or higher.

[b] There is no nominal value for this parameter.

[c] Programming Sense Polarity to a unipolar setting (Ring 1 to Can or Ring 2 to Can) will result in increased susceptibility to EMI. Consider programming Sense Polarity to a bipolar setting whenever possible.

Caution: Oversensing can cause inappropriate tachyarrhythmia detection and subsequent delivery of unnecessary therapy.

7.8 MRI SureScan parameters

Table 15. MRI SureScan parameters

Parameter	Programmable values	Shipped	Reset
MRI SureScan	On; Off	Off	Off
Timeout[a]	6 hr	—	—
Mode[a]	OVO	—	—
Detection/Therapies[a]	Off	—	—

[a] This parameter is nonprogrammable when the MRI SureScan feature is programmed to On.

7.9 Medtronic CareAlert parameters

Table 16. Clinical Management Alerts

Parameter	Programmable values	Shipped	Reset
Number of Shocks Delivered in an Episode…[a]			
Device Tone			
Alert Enable - Urgency	Off◈; On-Low; On-High	Off	Off
Number of Shocks Threshold[b]	1◈; 2; 3; 4; 5; 6	—	—
Patient Home Monitor[c]			
Alert Enable	Off◈; On	Off	Off
Number of Shocks Threshold[b]	1◈; 2; 3; 4; 5; 6	—	—

Table 16. Clinical Management Alerts (continued)

Parameter	Programmable values	Shipped	Reset
All Therapies in a Zone Exhausted for an Episode.			
Device Tone			
Alert Enable - Urgency	Off◈; On-Low; On-High	Off	Off
Patient Home Monitor			
Alert Enable	Off◈; On	Off	Off
Number of Pause Prevention Episodes…			
Device Tone			
Alert Enable - Urgency	Off◈; On-Low; On-High	Off	Off
Number of Pause Prevention Episodes Threshold[b]	1; 2; 3; 4; 5◈	—	—
Patient Home Monitor			
Alert Enable	Off; On	Off	Off
Number of Pause Prevention Episodes Threshold[b]	1; 2; 3; 4; 5◈	—	—
Alert Time (all others)…	00:00; 00:10 … 08:00◈ … 23:50	08:00	08:00

[a] Note that VF, VT, and FVT therapies could be delivered during a single episode (from initial detection until episode termination).

[b] This parameter is displayed only when its related alert is enabled; a single parameter is shared between the Device Tone and Patient Home Monitor alerts.

[c] Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

Table 17. Lead/Device Integrity Alerts

Parameter	Programmable values	Shipped	Reset
Lead Impedance Out of Range…			
Device Tone			
Alert Urgency[a]	Low; High◈	High	Off
Lead Impedance Enable			
Ring 1 to Ring 2	On; Off (Observation only)	On	Off (Observation only)
Ring 1 to Coil 2	On; Off (Observation only)	On	Off (Observation only)
High Voltage	On; Off (Observation only)	On	Off (Observation only)
Patient Home Monitor			
Lead Impedance Enable[b]			
Ring 1 to Ring 2	On; Off◈	Off	Off
Ring 1 to Coil 2	On; Off◈	Off	Off
High Voltage	On; Off◈	Off	Off
Low Battery Voltage RRT…			
Device Tone			
Alert Enable - Urgency	Off; On-Low; On-High◈	On-High	Off
Patient Home Monitor			
Alert Enable[b]	Off; On	On	Off

Table 17. Lead/Device Integrity Alerts (continued)

Parameter	Programmable values	Shipped	Reset
Excessive Charge Time EOS…			
Device Tone			
Alert Enable - Urgency	Off; On-Low; On-High◈	On-High	Off
Patient Home Monitor			
Alert Enable[b]	Off; On	On	Off
VF Detection Off, 3+ VF or 3+ FVT Rx Off.			
Device Tone			
Alert Enable	Off; On-High◈	On-High	On-High
Patient Home Monitor			
Alert Enable[b]	Off; On	On	Off

[a] This parameter is displayed only if an associated alert has been enabled.

[b] Alerts are programmable and transmittable to a monitor only when Patient Home Monitor is programmed to Yes.

Table 18. Shared parameters

Parameter	Programmable values	Shipped	Reset
Patient Home Monitor	Yes; No◈	No	No
Alert Time…[a]	00:00; 00:10 … 08:00◈ … 23:50	08:00	08:00

[a] This parameter is displayed only if an associated alert has been enabled.

7.10 Data collection parameters

Table 19. Data Collection Setup parameters

Parameter	Programmable values	Shipped	Reset
LECG Source [a]	Ring 1 to Ring 2; Ring 2 to Can◈; Coil 2 to Ring 2	Ring 2 to Can	Ring 2 to Can
LECG Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 1 Source	Ring 1 to Ring 2◈; Ring 1 to Can; Ring 2 to Can; Coil 2 to Coil 1	Ring 1 to Ring 2	Ring 1 to Ring 2
EGM 1 Range	±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 2 (Wavelet) Source	Ring 1 to Ring 2; Ring 1 to Coil 1; Ring 1 to Coil 2; Coil 2 to Can◈; Coil 1 to Can; Ring 1 to Can; Ring 2 to Can; Coil 2 to Coil 1	Coil 2 to Can	Coil 2 to Can
EGM 2 (Wavelet) Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
EGM 3 Source	Coil 2 to Coil 1◈; Ring 1 to Ring 2; Coil 2 to Ring 2	Coil 2 to Coil 1	Coil 2 to Coil 1
EGM 3 Range	±1; ±2; ±4; ±8◈; ±12; ±16; ±32 mV	±8 mV	±8 mV
Stored (Ventricular)	EGM1 and EGM2◈; EGM1 and EGM3; EGM1 and LECG; EGM2 and EGM3; EGM2 and LECG; EGM3 and LECG	EGM1 and EGM2	EGM1 and EGM2
Pre-arrhythmia EGM	Off◈; On - 1 month; On - 3 months; On Continuous	Off	Off

Table 19. Data Collection Setup parameters (continued)

Parameter	Programmable values	Shipped	Reset
Device Date/Time…[b]	(Enter time and date)	On	On
Holter Telemetry	Off◈; 0.5; 1; 2; 4; 8; 16; 24; 36; 46 hr	Off	Off

[a] LECG: this EGM channel displays morphology channel signals.

[b] The times and dates stored in episode records and other data are determined by the Device Date/Time clock.

7.11 System test parameters

Table 20. System Test parameters

Parameter	Selectable values
Tests – Sensing	
Mode	
Test Value	OVO
Permanent	OVO
Tests – Pacing Threshold	
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Mode	
Test Value	VVI
Permanent	OVO
Lower Rate	30; 35 … 60; 70; 75 … 150 bpm
Amplitude	Ring 1 to Ring 2, Ring 1 to Coil 2: 1.00; 1.50 … 8.00 V Coil 2 to Coil 1: 10; 13; 16; 20; 30 V
Pulse Width	Ring 1 to Ring 2, Ring 1 to Coil 2: 2.00; 4.00; 6.00; 8.00 ms Coil 2 to Coil 1: 0.50; 1.00; 2.00 … 10.00 ms
Additional Settings…	
V. Pace Blanking	150; 160 … 450 ms
Tests – Wavelet	
Wavelet enable	Off; On◈; Monitor
Match Threshold	40; 43 … 61◈ … 97
Auto Collection	On◈; Off
Mode	OVO

7.12 EP Study parameters

Table 21. T-Shock parameters

Parameter	Selectable values
Enable	(checked); (unchecked)◈
#S1	2; 3; 4; 5◈; 6 … 15
S1S1	300; 310 … 400◈ … 2000 ms
S1 Pathway	Ring 1 to Coil 2◈; Coil 2 to Coil 1
Delay	120; 130 … 300◈ … 600 ms
T Energy	1◈; 1.2; 1.4 … 2; 3 … 16; 18; 20 J
Waveform[a]	Monophasic

[a] This parameter is nonprogrammable.

Table 22. Burst Induction parameters

Parameter	Selectable values
Enable	(checked); (unchecked)◈

Table 23. PES parameters

Parameter	Selectable values
Enable	(checked); (unchecked)◈
#S1	1; 2 … 8◈; 9 … 15
S1S1	150; 160 … 600◈; 610 … 2000 ms
S1S2	150; 160 … 400◈; 410 … 600 ms
S2S3	150; 160 … 400◈; 410 … 600 ms[a]
S3S4	150; 160 … 400◈; 410 … 600 ms[a]
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Amplitude	Ring 1 to Ring 2, Ring 1 to Coil 2: 8 V Coil 2 to Coil 1: 10; 13; 16; 20; 30 V
Pulse Width	Ring 1 to Ring 2, Ring 1 to Coil 2: 2; 4; 6; 8 ms Coil 2 to Coil 1: 1; 2; 3; 4 ms

[a] Default value when parameter is On is 400 ms.

Table 24. Defibrillation parameters

Parameter	Selectable values
Enable	(checked); (unchecked)◈
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40◈ J
Waveform[a]	Biphasic
Pathway	STD◈; REV

[a] This parameter is nonprogrammable.

Table 25. Cardioversion parameters

Parameter	Selectable values
Enable	(checked); (unchecked)◈
Energy	0.4; 0.6 … 1.8; 2; 3 … 16; 18; 20; 22; 24; 25; 26; 28; 30; 32; 35; 40◈ J
Pathway	STD◈; REV

Table 26. Burst ATP parameters

Parameter	Selectable values
Enable	(checked); (unchecked)◈
#Pulses	1; 2 … 8◈ … 15
%RR Interval	50; 53; 56; 59; 63; 66 … 84; 88◈; 91; 94; 97%
Minimum Interval	150; 160 … 400 ms
Pace Polarity	Ring 1 to Ring 2; Ring 1 to Coil 2; Coil 2 to Coil 1
Amplitude[a]	Ring 1 to Ring 2, Ring 1 to Coil 2: 8 V Coil 2 to Coil 1: 10; 13; 16; 20; 30 V
Pulse Width	Ring 1 to Ring 2, Ring 1 to Coil 2: 2; 4; 6; 8 ms

Table 26. Burst ATP parameters (continued)

Parameter	Selectable values
	Coil 2 to Coil 1: 1; 2; 3; 4 ms

[a] This parameter is nonprogrammable.

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Medtronic

Aurora EV-ICD™ MRI SureScan™ DVEA3E4

MR Conditional digital single chamber implantable cardioverter defibrillator (ICD) with SureScan™ Technology

Reference Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Aurora EV-ICD™ MRI SureScan™ DVEA3E4

Reference Manual

A reference manual for the Medtronic Aurora EV-ICD MRI SureScan Model DVEA3E4 digital single chamber implantable cardioverter defibrillator (ICD).

Contents

1 Introduction

1.1 About the product literature

This manual describes the operation and intended use of features offered by the Medtronic Aurora EV-ICD MRI SureScan device.

Throughout this manual, the word “device” refers to the implanted ICD device.

The report images, button labels, and navigation instructions in this manual apply to the Medtronic Model SW041 software running on a Medtronic CareLink 2090 or a Medtronic CareLink Encore 29901. The details of the user interface are provided for reference only and may not match those of other applications.

The names of on-screen buttons and user interface controls are shown with bold text: **Button Name**. Navigation paths to software screens or programmable parameters are shown with a “>” character between each step in the path (for example, **Params** > **Sensing …** > **Sensitivity**).

1.1.1 Product literature

Before implanting the device, it is recommended that you take the following actions:

- Read the product literature for information about prescribing, implanting, and using the device and conducting a patient follow-up session.
- Thoroughly read the technical manuals for the lead used with the device. Also read the technical manuals for other system components.
- Discuss the device and implant procedure with the patient and any other interested parties, and give them any patient information materials packaged with the device.

Additional information about the device is provided in the following documents:

MRI technical manual – This manual provides MRI-specific procedures and warnings and precautions.

Device manual – This manual contains model-specific feature information, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, and parameter tables.

Programming guide – This manual explains how to use the programmer software to conduct a patient session.

Programmer reference manual – This manual contains information about the features of the programmer. There are separate programmer reference manuals for the Medtronic CareLink 2090 programmer and the Medtronic CareLink Encore 29901 programmer.

Medical Procedure and EMI Warnings, Precautions, and Guidance Manual for Health Care Professionals – This manual provides warnings, precautions, and guidance for health care professionals who perform medical therapies and diagnostic procedures on cardiac device patients. This manual also includes information about hazards from sources of electromagnetic interference (EMI) in the patient's home, recreational environments, and occupational environments.

Radio regulatory compliance information – This document provides compliance information related to the radio components of the device.

Explanation of symbols – This document defines the symbols that may appear on the device package. Refer to the package label to see which symbols apply specifically to this device.

1.1.2 Technical support

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products.

In addition, Medtronic maintains a professional staff of consultants to provide technical consultation to product users.

For more information, contact your local Medtronic representative or call or write Medtronic at the appropriate telephone number or address listed on the back cover.

2 Patient follow-up guidelines

2.1 In-clinic follow-up appointments and remote monitoring

Schedule regular in-clinic follow-up appointments with the patient throughout the service life of the device. If the Medtronic CareLink Network is available for Aurora EV-ICD MRI SureScan and patients are enrolled in the Medtronic CareLink Network, remote monitoring can replace the need for some in-clinic follow-up appointments. With remote monitoring, data from a patient's implanted device is sent to the Medtronic CareLink Network, and you can review the transmitted data on the Medtronic CareLink Network website. Schedule in-clinic follow-up appointments and CareLink transmissions as follows:

- Schedule an in-clinic follow-up appointment within 72 hours of implant so that the patient can be checked for lead dislodgment, wound healing, and postoperative complications.
- Schedule an in-clinic follow-up appointment within 2–12 weeks after implant to evaluate the condition of the patient, the device, and the lead, and to verify that the device is configured appropriately for the patient.
- Schedule routine CareLink transmissions or in-clinic follow-up appointments every 3–12 months, with in-clinic follow-up appointments occurring at least annually.
- When the device battery approaches Recommended Replacement Time (RRT), schedule CareLink transmissions or in-clinic follow-up appointments every 1–3 months.
- Schedule in-clinic follow-up appointments as needed (for example, if data from a CareLink transmission indicates that the patient's device requires adjustment).

2.1.1 Remote monitoring options

If the Medtronic CareLink network is available for Aurora EV-ICD MRI SureScan and the patient is enrolled, the device provides automatic wireless remote monitoring using a Medtronic patient monitor (if available). The transmissions occur automatically at a scheduled date and time. You can schedule automatic transmissions on the Medtronic CareLink Network website. In addition, automatic, unscheduled transmissions for specific clinical or device status events are provided by the CareAlert Monitoring feature (see *Section 3.2, Medtronic CareAlert events and notifications, page 20*). Patients can also send unscheduled transmissions manually.

Note: When viewing a CareLink transmission, the data collected since the last session is presented differently than it is for a programmer session. For a CareLink transmission, the last session is defined as either the last programmer session or the last CareLink transmission. During an in-clinic follow-up appointment, the programmer software defines the last session as the last programmer session.

2.1.2 Conducting a patient session with the programmer

2.1.2.1 How to start a patient session using wireless telemetry

1. Tap **Find Patient…** from the **Select Model** window.
2. Select the “Allow wireless communication” check box on the **Find Patient** window.
3. Use the Conexus Activator, or briefly place the programming head over the device to activate wireless telemetry in the device.

   Notes:
   - When the Conexus Activator is used to activate telemetry in the device, the programmer launches the patient session without suspending tachyarrhythmia detection. Placing a magnet near the device, however, suspends tachyarrhythmia detection.
   - When the programming head is used to activate telemetry in the device, the programmer automatically launches the patient session with tachyarrhythmia detection suspended. Detection remains suspended as long as the programming head is over the device. If tachyarrhythmia detection is programmed on, a warning reminds you that tachyarrhythmia detection is suspended.
4. Select the appropriate patient from the Patient Name list on the **Find Patient** window.

   Note: The programmer lists all patients with wireless-activated implantable devices within telemetry range.
5. Tap **Start**.

2.1.2.2 How to start a patient session using nonwireless telemetry

1. Tap **Find Patient…** from the **Select Model** window.
2. If you are using a Medtronic programmer with Conexus wireless telemetry, make sure that the “Allow wireless communication” check box on the **Find Patient** window is not selected. If you start a session with the programming head over the patient’s device and the “Allow wireless communication” check box is selected, the system initiates a wireless telemetry session and automatically interrogates the device. If you are using a Medtronic programmer without Conexus wireless telemetry, the “Allow wireless communication” check box does not appear on the **Find Patient** window.
3. Place the programming head over the device and the nonwireless session automatically begins.

2.1.2.3 Device and telemetry effects during a patient session

Tachyarrhythmia detection during a wireless telemetry session – If you place a programming head over the device, the magnet in the programming head always suspends tachyarrhythmia detection.

Tachyarrhythmia detection during a nonwireless telemetry session – If you place a programming head over the device and telemetry is established, the magnet in the programming head does not suspend tachyarrhythmia detection.

Episodes in progress during a wireless telemetry session – If you attempt to initiate a patient session when a detected arrhythmia episode is in progress, the device treats the arrhythmia normally. If telemetry has not been established, the magnet inside the programming head causes the device to suspend detection when the programming head is placed over the device.

Episodes in progress during a nonwireless telemetry session – After telemetry has been established and you position the programming head over the device when a detected arrhythmia episode is in progress, the device treats the arrhythmia normally. If telemetry has not been established and you position the programming head over the device, the magnet inside the programming head causes the device to suspend detection.

Capacitor charging during a wireless telemetry session – Interference caused by capacitor charging may affect telemetry between the device and the programmer. This interference could result in a temporary loss of telemetry indicator lights as shown on the programmer task bar and a temporary loss in Marker transmissions. It could also temporarily affect the ability to send programming commands. Ensure that the greatest number of telemetry strength indicator lights are illuminated on the programmer task bar to help improve telemetry reliability before any manual or automatic capacitor charging.

Capacitor charging during a nonwireless telemetry session – Interference caused by capacitor charging may affect telemetry between the device and the programmer. The programming head indicator lights may turn off during charging periods. It is normal for the lights to turn off on the programming head.

Note: The programming head “P” button is disabled during all EP study and manual system tests. During tachyarrhythmia inductions, the programming head “I” button is also disabled.

Marker transmissions during a wireless telemetry session – The device continuously transmits Marker Channel and supplementary marker data while telemetry is established. The device stops these transmissions when telemetry is interrupted. If Holter telemetry is programmed to On, the device transmits telemetry at all times except during a Conexus wireless telemetry session. To use Holter telemetry during a Conexus wireless telemetry session, you must first activate Standby mode.

Marker transmissions during a nonwireless telemetry session – The device continuously transmits Marker Channel and supplementary marker data while telemetry is

established and the programming head is positioned over the device. The device stops these transmissions when you lift the programming head, unless the Holter Telemetry feature is programmed to On. If Holter Telemetry is programmed to On, the device transmits Marker Channel and supplementary marker data regardless of the position of the programming head.

Device longevity and wireless telemetry – In typical patient session and device operation scenarios, wireless telemetry has no significant effect on device longevity.

2.1.3 Follow-up process

The process for conducting a follow-up evaluation, either during an in-clinic appointment or with a CareLink transmission, includes the following steps:

1. Review the patient's presenting rhythm.
2. Verify the status of the implanted system.
3. Verify the clinical effectiveness of the implanted system.
4. During an in-clinic follow-up appointment, adjust device parameters as necessary.
5. If evaluating data remotely, schedule an in-clinic follow-up appointment as necessary.

2.1.4 Reviewing the presenting rhythm

The presenting rhythm may indicate the presence of undersensing, oversensing, or loss of capture. These are basic pacing issues that can affect the delivery of therapy. These issues can often be resolved by making basic programming changes.

Review the presenting rhythm by viewing the Live Rhythm Monitor and by printing the EGM and Marker Channel traces. If you identify issues with the patient's presenting rhythm, review the device settings and reprogram the device to values that are appropriate for the patient.

2.1.5 Verifying the status of the implanted system

Perform the following tasks to verify the status of the implanted system:

- Assess the battery status.
- Check lead measurements and trend data.
- Review any Quick Look II Observations about the device and lead status.

2.1.5.1 How to review the Remaining Longevity estimate and device status indicators

Warning: Replace the device immediately if the programmer displays an EOS indicator. The device may lose the ability to pace, sense, and deliver therapy adequately after the EOS indicator appears.

Review the displayed Remaining Longevity estimate. If the programmer displays the RRT indicator, contact your Medtronic representative and schedule an appointment to replace the device. For more information, see *Section 3.3*.

2.1.5.2 How to assess the performance of the device and lead

1. To review trends in impedance and R-wave amplitude, tap the ⏭ button next to the lead trend graphs on the **Quick Look II** screen. The programmer displays a detailed history of automatic impedance and sensing measurements. For more information about viewing lead performance trends data, see *Section 3.3*.
2. If you also want to gather real-time information about the performance of the device and lead during the follow-up session, you can perform the following tests:

- Lead Impedance Test: Compare the results of the test to previous lead impedance measurements to determine if there have been significant changes since the last follow-up session. For more information, see the programming guide.
- Sensing Test: Compare the test results to previous R-wave amplitude measurements. For more information, see the programming guide.
- Pacing Threshold Test: Use the test to review the patient's capture thresholds. Determine the appropriate amplitude and pulse width settings to ensure capture and maximize device longevity. For more information, see the programming guide.

2.1.5.3 Reviewing Quick Look II Observations about the device and lead status

The Quick Look II data includes Observations that are based on an analysis of programmed parameters and collected data. Observations may include information about the status of the device and battery, the integrity of the implanted leads, or potential issues with programmed parameter settings. If Medtronic CareAlert Monitoring is enabled, any alert events detected by the device are presented as Quick Look II Observations. Review the Observations and check related reports for evidence of a problem with the device or leads.

2.1.6 Verifying the clinical effectiveness of the implanted system

Perform the following tasks to verify the clinical effectiveness of the implanted system:

- Review any Quick Look II Observations about the patient's clinical status.
- Check Pause Prevention episode records for appropriate detection.
- Check tachyarrhythmia episode records for appropriate detection and therapy.

2.1.6.1 Reviewing Quick Look II Observations about clinical status

The Quick Look II data includes Observations about noteworthy or abnormal patient conditions such as unexpectedly high rates or high arrhythmia burden. If Medtronic CareAlert Monitoring is enabled, any alert events detected by the device are presented as Quick Look II Observations. Review the Observations and check related data to help evaluate the clinical effectiveness of the implanted system.

2.1.6.2 How to assess accurate tachyarrhythmia detection

The system provides diagnostic episode records to help you accurately classify the patient's tachyarrhythmias. Review the tachyarrhythmia episode records since the last session and the Quick Look II observations. For more information, see *Section 3.5*.

Episode misidentification – If the episode records indicate that the device has misidentified the patient's rhythm, carefully review the tachyarrhythmia episode, the Cardiac Compass trend data, and the data stored for other episodes. Consider adjusting the detection parameters and the SVT detection criteria as needed.

Caution: Use caution when reprogramming the detection or sensing parameters to ensure that changes do not adversely affect VF detection. Ensure that appropriate sensing is maintained. For more information, see *Section 4.1*.

2.1.6.3 How to assess appropriate tachyarrhythmia therapy

1. Review any Medtronic CareAlert Notifications in the Quick Look II Observations section that relate to therapy delivery. To see detailed information about Medtronic CareAlert Notifications, tap **Data** > **Alert Events**.
2. Check tachyarrhythmia episode records to determine the effectiveness of therapies that have been delivered.
3. Adjust the therapy parameters as needed.

2.1.6.4 How to check for Pause Prevention Detection accuracy

1. Review any Medtronic CareAlert Notifications in the Quick Look II Observations section that relate to Pause Prevention Detection. To see detailed information about Medtronic CareAlert Notifications, tap **Data** > **Alert Events**.
2. Check Pause Prevention episode records to determine the accuracy of detection.
3. Adjust the Pause Prevention Detection parameters as needed.

2.2 Optimizing device longevity

Optimizing device longevity is a desirable goal because it may reduce the frequency of device replacement for patients. Optimizing device longevity requires balancing the benefit of device therapy and diagnostic features with the energy requirements placed on the battery as a result of these features.

To view the Remaining Longevity estimate for the device, refer to the Quick Look II screen.

The following sections describe strategies that may help reduce the energy requirements placed on the battery.

2.2.1 Managing pacing outputs

Manual optimization of amplitude and pulse width – You can optimize the patient's pacing output parameters manually. Perform a Pacing Threshold Test to determine the patient's pacing thresholds. Select amplitude and pulse width settings that provide an adequate safety margin above the patient's pacing threshold. These actions decrease the pacing outputs and preserve battery energy. Refer to the programming guide for more information about performing a Pacing Threshold Test.

2.2.2 Optimizing tachyarrhythmia therapy settings

Defibrillation – To treat ventricular fibrillation episodes, the device may deliver defibrillation therapy to end the episode and restore the patient's normal sinus rhythm. The device can be programmed to deliver a sequence of up to 6 defibrillation therapies. Although defibrillation therapy expends a high level of energy, VF therapies should be programmed to the maximum energy level. For more information, see *Section 5.1*.

Ventricular cardioversion – For VT and FVT detection, at least one cardioversion therapy must be programmed if ATP therapy is programmed. For more information, see *Section 5.3*.

FVT via VF detection – An FVT detection zone may be used to detect and treat a VT episode that is in the rate zone for VF. This approach may help maintain reliable detection of

VF while allowing ATP to be delivered for fast VT episodes. For more information, see *Section 4.3*.

Antitachycardia pacing (ATP) – ATP therapies interrupt the tachycardia episode and restore the patient's normal sinus rhythm. ATP therapies deliver pacing pulses instead of high-voltage shocks that are delivered in cardioversion therapy and defibrillation.

ATP therapy requires less battery energy than cardioversion or defibrillation. For some patients, you may be able to program the device to deliver ATP therapies before delivering high-voltage therapies.

2.2.3 Considering how diagnostic features with data storage impact longevity

Pre-arrhythmia EGM storage – Continual use of Pre-arrhythmia EGM storage reduces device longevity. For a patient with uniform tachyarrhythmia onset mechanisms, the greatest benefit of Pre-arrhythmia EGM storage is obtained after capturing a few episodes.

When Pre-arrhythmia EGM storage is on, the device collects up to 10 s of EGM data before the onset of VT/VF, VT Monitor, or the detection of SVT episodes.

To balance the benefit of using the Pre-arrhythmia EGM storage feature with optimizing device longevity, consider the following programming options:

- Set Pre-arrhythmia EGM storage to On to capture possible changes in the tachyarrhythmia onset mechanism following significant clinical adjustments such as device implant, medication changes, and surgical procedures. Pre-arrhythmia EGM storage may be set to On -1 month, On - 3 months, or On Continuous. Select the setting for the shortest time period that will provide the necessary data.
- Set Pre-arrhythmia EGM storage to Off after you have obtained the data of interest.

Note: When Pre-arrhythmia EGM storage is set to Off, the device begins to store EGM information for VT/VF, VT Monitor, and SVT episodes after the third tachyarrhythmia event occurs. Though EGM is not recorded before the start of the arrhythmia, the device still records up to 20 s of data before the onset or detection of the episode. This data includes interval measurements and Marker Channel annotations. In addition, Flashback Memory data is stored for the most recent tachyarrhythmia episodes.

Holter telemetry – Extended use of the Holter telemetry feature decreases device longevity. The Holter telemetry feature continues to transmit EGM and Marker Channel data for the programmed time duration, regardless of whether the programming head is positioned over the device.

Medtronic CareLink remote transmissions – When scheduling Medtronic CareLink remote transmissions, be aware that increasing the frequency of remote transmissions reduces implanted device service life by approximately 1 day for each additional

transmission. To conserve battery energy, schedule the lowest frequency of remote transmissions that still allows for the desired monitoring of your patient's device.

3 Diagnostic data features

3.1 Quick Look II summary data

At the start of a patient session, it is useful to quickly view summary information about device operation and the patient's condition. This overview can help you to determine whether you need to look more closely at diagnostic data or reprogram the device to optimize therapy for the patient.

The Quick Look II data summarizes the most important indicators of system operation and the patient's condition. These indicators include device and lead status data, Pause Prevention episode data, arrhythmia episode data, and system-defined observations.

You can view Quick Look II data on the **Quick Look II** screen, which is displayed on the programmer at the beginning of a patient session. To return to the **Quick Look II** screen from another screen, tap **Data** > **Quick Look II**. For more information about using the **Quick Look II** screen, refer to the programming guide.

3.1.1 Quick Look II device and lead status information

The Quick Look II data includes the following information about device and lead status:

- Estimate of remaining battery longevity
- Trends of the weekly average impedance and R-wave amplitude measurements
- Most recent measured values for impedance and R-wave amplitude

3.1.2 Quick Look II Pause Prevention episode information

The Quick Look II data includes the number of Pause Prevention episodes since the last patient session.

3.1.3 Quick Look II arrhythmia episode information

The Quick Look II data includes the following information about arrhythmia episodes since the last patient session:

- Number of treated arrhythmia episodes
- Number of monitored arrhythmia episodes
- Number of shocks delivered

- Number of episodes for which ventricular oversensing (VOS) was detected by the TWave Discrimination feature or the Noise Discrimination features

3.1.4 Quick Look II Observations

Observations are based on an analysis of programmed parameters and data collected since the last session.

Note: Conditions that prevent diagnostic data from being collected are reported as Quick Look II observations. When MRI SureScan is programmed to On, diagnostic data is not collected. If the device detects an MRI SureScan session, an observation like the following is reported: “MRI SureScan On: 23-April-2013 08:33:11. MRI SureScan Off: 23-April-2013 09:33:11. Data was not collected during MRI SureScan.” Refer to the MRI Technical Manual for additional information.

The following types of observations may occur:

- Device status observations inform you when the device is approaching RRT or End of Service (EOS). An observation is also reported if a charge circuit irregularity or device reset has occurred.
- Lead status observations report any potential issues with the sensing integrity of the lead, including possible lead dislodgments.
- Parameter observations warn of any inconsistencies in the programming of detection and therapy parameters. One example is if certain parameter settings result in a therapy being disabled.
- Diagnostic data observations report noteworthy arrhythmia episodes. Examples include arrhythmias of different types occurring together and episodes for which therapies were unsuccessful. Conditions that prevent diagnostic data from being collected are also reported.
- Medtronic CareAlert observations can report system or device performance conditions and certain heart rhythm conditions. For more information, see *Section 3.2, Medtronic CareAlert events and notifications, page 20*.
- Clinical status observations inform you of abnormal patient conditions, such as unexpectedly high heart rates or high arrhythmia burden.

On the **Quick Look II** screen, if you select one of the displayed observations and more information about the selected observation is available, the ⏭ button becomes active. You can use the ⏭ button to look at relevant details.

3.2 Medtronic CareAlert events and notifications

Important clinical management and system performance events may occur between scheduled patient sessions. These events may relate to clinical management data stored in device memory or to inappropriate programmed settings or system issues that should be investigated. The early detection and notification of these events, should they occur, enable you to intervene promptly with appropriate care for your patient.

The device continuously monitors for a specified set of clinical management and system performance events that may occur between scheduled follow-up sessions. If the device detects that such an event has occurred and if alerting parameters are turned on, it responds in the following ways:

- Wireless signal and network transmission of event information

  Medtronic CareAlert Monitoring continuously monitors for alert events. If an event occurs, CareAlert Monitoring sends a wireless alert signal to your patient's Medtronic patient monitor. Upon receiving a signal, the monitor transmits the alert data to the Medtronic CareLink Network, if programmed to do so.

- Notification of alert event

  Depending on the severity of the alert condition, you can set up Medtronic CareAlert Notifications through the CareLink Network (if available) to hold the alert for routine review at your office via email or the CareLink website or to notify you immediately via voice message, text message, pager, email, website, or live call.

- Patient alert

  The device emits 1 of 2 tones to alert your patient, depending on the type and urgency of the event that has occurred. The patient then responds according to your instructions.

3.2.1 Clinical management and system performance event alerts

3.2.1.1 Clinician-defined alerts (programmable)

Clinical Management Alerts	
Number of Shocks Delivered in an Episode	This alert indicates that the number of shocks delivered in a VT/VF episode is greater than or equal to the programmed Number of Shocks Threshold.
All Therapies in a Zone Exhausted	This alert indicates that a specific VF, VT, or FVT episode was redetected after all programmed therapies for that type of episode were delivered.
Number of Pause Prevention Episodes	This alert indicates that the number of pause prevention episodes is greater than or equal to the programmed Number of Pause Prevention Episodes Threshold.
Lead and Device Integrity Alerts	

VF Detection/Therapy Off	This alert indicates that one or more of the following conditions has occurred for at least 6 hours since the last programming: VF detection has been turned off; 3 or more VF therapies have been turned off; or FVT detection is programmed to FVT via VF and 3 or more FVT therapies have been turned off. Note that this alert sounds immediately and then every 6 hours until cleared.
Low Battery Voltage Recommended Replacement Time	This alert indicates that the daily automatic battery voltage measurement has been at or below the Recommended Replacement Time voltage level for 3 consecutive days.
Excessive Charge Time End of Service	This alert indicates that the charging period equals or exceeds the charge time threshold.
Lead Impedance Out of Range	This alert indicates that the daily lead impedance measurement for the lead is out of range. This could indicate that the lead has dislodged or is improperly connected. The device immediately sounds an alert tone. This tone repeats every 4 hours, beginning at the next scheduled 4-hour time interval, and at the programmed daily alert time.

For details about programmable settings for a particular parameter, see the device manual.

3.2.1.2 System-defined alerts (non-programmable)

Electrical Reset	This alert indicates that the device has been reset and may require reprogramming. The device immediately sounds a high-urgency alert tone that repeats every 20 hours or every 9 hours, depending on the type of electrical reset. Immediately contact your Medtronic representative if an Electrical Reset alert occurs. For electrical reset parameter values, see the device manual for the specific device.[a]
Charge Circuit Timeout	This alert indicates that a charging period has exceeded the maximum time allowed for capacitor charging. The device immediately sounds a high-urgency alert tone that repeats every 20 hours. Contact your Medtronic representative if a Charge Circuit Timeout alert occurs.

[a] An Electrical Reset alert sounds immediately and then every 20 hours thereafter. However, if the electrical reset disables tachyarrhythmia detection and therapy, the alert sounds immediately and then every 9 hours thereafter. Contact your Medtronic representative if an electrical reset alert sounds.

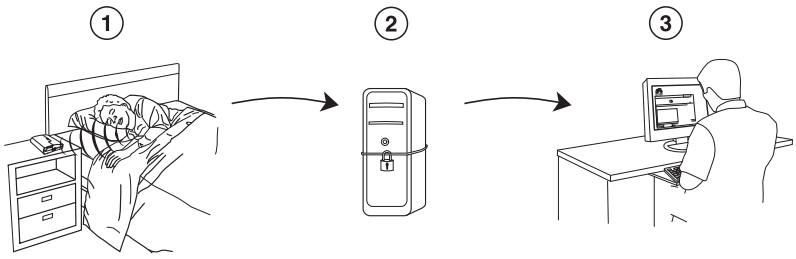
3.2.2 Operation of Medtronic CareAlert Monitoring and Medtronic CareAlert Notifications

If a clinical or system performance event occurs and the device is programmed to notify you over the CareLink Network (if the CareLink Network is available with your device), CareAlert Monitoring automatically attempts to establish wireless communication between the device and the monitor. Once communication is established, the monitor receives the alert data from the device. The monitor then transmits the alert data to the CareLink Network. The CareLink Network records the alert, and you are notified based on your preferences. The monitor communicates back to the device when the data transmission is successful. If a data transmission is unsuccessful at first, CareAlert Monitoring attempts to establish wireless communication with the monitor every 3 hours until the transmission is successful. If a transmission is still unsuccessful after 72 hours, the device emits a backup tone at the Alert Time that you select for your patient or at intervals unique to some alerts as described in *Section 3.2.1.1* and *Section 3.2.1.2*. A transmission includes data for all active alerts.

Note: After a wireless alert signal has been successfully transmitted, the device does not retransmit data for that particular alert until the alert is cleared, even if the threshold for the alert is met again in the interim. However, the device continues to emit alert tones each day for active alerts that have Device Tone set to On. There are no such tones emitted for alerts that have Device Tone set to Off.

The CareAlert Notification methods (any one or a combination of voice message, text message, pager, email, website, or live call) are set on a per-clinic basis according to alert urgency and time of day. You can assign the level of urgency to each alert for individual patients, so that the same alert can be high urgency for one patient and low urgency for another patient.

Figure 1. Process for transmitting Medtronic CareAlert Notifications



1 The device detects an alert condition and establishes wireless communication with the monitor.
2 The monitor sends the alert data to a secure server via the patient's telephone land line or cellular telephone connection.
3 If the CareLink Network is configured to do so, the clinician is notified via voice message, text message, pager, email, website, or live call. The clinician can then consult the network for detailed information.

3.2.3 Operation of Medtronic CareAlert events

Medtronic CareAlert events trigger patient alerts that are clinician-defined or system-defined and emit tones that can be differentiated using 2 levels of urgency:

- Clinician-defined alerts may be programmed as high-urgency or low-urgency and may be turned on or off.
- System-defined alerts are high-urgency, and they are always on.

High-urgency alerts emit a dual, high-low tone. Low-urgency alerts emit an intermittent on-off tone. High-urgency tones may indicate that there is a device problem that needs immediate attention. Alerts are displayed in the **Observations** window on the **Quick Look II** screen and on the **Medtronic CareAlert Events** screen of the Medtronic programmer.

When an alert is initiated, the device emits the tone pattern either at a selected time of day or at a fixed time interval. The tone then sounds each day at the selected time or interval until the alert is cleared (or until Device Tone is set to Off). Active tones also sound when the patient magnet is placed over the device. You can view alert details on a programmer during a patient session.

Notes:

- A CareLink transmission does not clear an alert tone from sounding. The tone will continue to sound until the alert is cleared (or until the Device Tone is set to Off).
- Once an alert has been successfully transmitted over the CareLink Network (if available), further transmissions for that alert condition will not occur until the alert is cleared.
- All alerts are cleared automatically when the device is interrogated with a programmer.

3.2.3.1 Patient alert process

If a clinical management or system performance event occurs and the device is programmed to sound a patient alert, the device emits alert tones at any or all of the following times, depending on the event: when the event occurs, at a programmed time of day, at fixed intervals. Instruct your patient to call the clinic if the patient hears tones coming from the device. Alert tones last for up to 30 s and are slightly louder than typical living room noise. If both high-urgency and low-urgency alerts are active at the same time, the high-urgency alert is given priority and sounds at the appropriate time or interval.

Although the system provides 2 types of alert tones for high-urgency and low-urgency clinical scenarios, it is important to remember that the patient may hear identical tones whether the alert is caused by a system performance issue or by a significant clinical event. Because the tones may be identical, a patient may not be able to distinguish between a system performance alert and a clinical event alert. The patient alert tone is only intended to prompt the patient to contact you. You should be aware that a patient who hears an alert tone will contact you to determine the type of alert that has occurred, the information the device has recorded, and how you interpret the data to assist in a plan of care. The details related to the alert, including the type of alert and detailed findings, are only available to the patient through discussion with you.

3.2.3.2 Selecting a patient alert time

The system allows you to select the time of day that a patient alert sounds. The alert tone continues to sound each day at the selected time until the alert is cleared (or until Device Tone is set to Off). Select a time when the patient or a companion is most likely to hear the tone. The following patient factors may influence your selection of the alert time:

- When the patient will be in a predictably quiet setting
- The patient's daily schedule; for example, medication routines that may affect alertness
- The patient's hearing acuity
- The presence or absence of companions who might also hear the tones

If the conditions that trigger an alert are intermittent, the alert event may not actually be present when the alert tone sounds. Also, the alert time is based on the internal device clock. It does not adjust for time zone changes.

3.2.3.3 Programming a patient alert time

Tones for some system alerts are synchronized to the time you program tones for clinician-defined alerts. To program an alert time, tap **Params** > **Alert…** > **Alert Time…**.

However, if you program all clinician-defined alerts to Off, the Alert Time field is not shown. In this situation, perform the following steps to program the Alert Time for these system alert tones:

1. Program one of the programmable alerts to On to display the Alert Time field.
2. Select an alert time to apply to system alerts.
3. Reprogram the alert to Off.

3.2.3.4 Instructing the patient

It is important that patients understand that they may hear alert tones emitted from implanted devices. They must know what to do when an alert sounds.

Warning: Make sure that patients understand that they must not carry, store, or leave the patient magnet positioned over the device. Device operation is temporarily impaired when the magnet is placed over the device and it must be moved away from the device to restore normal operation.

- Instruct patients to contact you immediately if they hear ANY tones from the device.
- Advise patients of the time of day that you have programmed an alert tone to sound. If a tone sounds, they should expect it to sound every day at that time until the alert is cleared (or until the Device Tone is set to Off).
- Make sure patients know that the alert time does not adjust for time zone changes.
- Advise patients that they may hear a steady test tone or any active alert tones if they are in the presence of a strong electromagnetic field, such as the field within a store theft detector. Advise patients that the device operation is temporarily impaired in these situations and that they should move away from the source of the interference to restore normal device operation.

Patients should also understand the purpose of the patient magnet and how and when to use it. Make sure that they know that current patient alerts sound when the patient magnet is placed over the device. Demonstrate how to place the patient magnet over the device to replay the alert tones, and review the patient magnet manual with them. Patients can use a folded patient magnet manual as a reference card.

3.2.3.5 Demonstrating alert tones

During a patient session, you can demonstrate high-urgency tones, low-urgency tones, and the test tone from the programmer as follows:

1. Tap **Params** > **Alert…** > **Demonstrate Tones…**.
2. Select **High-Urgency Condition Met**, **Low-Urgency Condition Met**, or **No Conditions Met**.

Note: Any active alert tones will sound when the patient magnet is placed over the device. If there are no active alerts, the steady test tone will sound.

3.2.4 Programming Alerts

Note: The **Medtronic CareAlert Setup** screen shows either a Lead/Device Integrity Alerts view or a Clinical Management Alerts view. To switch between views, tap either **Clinical Management Alerts…** or **Lead/Device Integrity Alerts…**.

Note: Programming each Device Tone alert includes setting the alert urgency. Alerts for the Patient Home Monitor do not have an urgency setting.

Table 1. How to navigate to CareAlert parameters

Parameters	Path
Clinical Management Alerts parameters: All Therapies in a Zone Exhausted for an Episode. Alert Enable - Urgency Alert Time…	**Params** > **Alert…**
Number of Shocks Delivered in an Episode parameters: Alert Enable - Urgency Number of Shocks Threshold	**Params** > **Alert…** > **Number of Shocks Delivered in an Episode…**
Number of Pause Prevention Episodes parameters: Alert Enable - Urgency Number of Pause Prevention Episodes Threshold	**Params** > **Alert…** > **Number of Pause Prevention Episodes…**

Table 1. How to navigate to CareAlert parameters (continued)

Parameters	Path
Lead/Device Integrity alert parameters: Low Battery Voltage RRT… Excessive Charge Time EOS… VF Detection OFF, 3+ VF or 3+ FVT Rx Off. Alert Time…	**Params** > **Alert…** > **Lead/Device Integrity Alerts…**
Lead Impedance Out of Range parameters: Alert Urgency Ring 1 to Ring 2 Ring 1 to Coil 2 High Voltage	**Params** > **Alert…** > **Lead/Device Integrity Alerts…** > **Lead Impedance Out of Range…**

Repetitive alerts – If a programmable alert is triggered so often that it loses its clinical value, you may want to consider adjusting the alert threshold, programming the device to improve therapy effectiveness, or turning off the alert.

3.2.5 Evaluation of alert events

The device stores alert events in the **Medtronic CareAlert Events** log. The programmer screen refers to alert events as Alert Events. For each alert event, a log entry includes the date and time of the alert, a description of the event, and the measurement or information that caused the event. Up to 15 Alert Events are stored.

To access alert events, tap **Data** > **Alert Events** > **Alert Events**.

3.3 Device and lead performance data

The device automatically measures and records device and lead performance data every day. This information can help you assess the status of the device battery and identify issues with lead position or lead integrity. The device records the following types of performance data:

- Remaining Longevity estimate and replacement indicators
- Capacitor charging and high-voltage therapy information
- Lead impedance measurements
- Sensing amplitude measurements

You can access device and lead performance data from several different screens on the programmer:

- **Quick Look II** screen: **Data** > **Quick Look II**
- **Battery and Lead Measurements** screen: **Data** > **Device/Lead Diagnostics** > **Battery and Lead Measurements** > **Open Data**
- **Lead Trends** screen: **Data** > **Device/Lead Diagnostics** > **Lead Impedance Trends** > **Open Data**

3.3.1 Remaining Longevity estimate and replacement indicators

The device measures the battery voltage automatically when telemetry is initiated at the start of a session, when a lead impedance test is performed, and every day at 02:15 as part of the automatic daily measurements. The battery voltage measurement at the start of a session is displayed on the **Battery and Lead Measurements** screen. The device uses this data to calculate a Remaining Longevity estimate. This estimate is based on the automatic daily battery voltage measurements, time since implant, programmed parameter settings, and device recorded events.

Note: You may see a temporary drop in the displayed battery voltage if high-voltage charging or high-voltage pacing has occurred within the past 7 days.

The calculation of the Remaining Longevity estimate provides maximum, minimum, and mean values for the amount of time remaining until the device reaches the Recommended Replacement Time (RRT). The mean value is reported as the Remaining Longevity estimate. The maximum and minimum remaining longevity estimates are 95th percentile values calculated from the distribution of this data. That is, approximately 95% of devices are expected to reach RRT before the reported maximum value, and approximately 95% of devices are expected to reach RRT after the reported minimum value. When scheduling the replacement of the device, do not use the estimate of remaining longevity. Instead, schedule the device replacement after the RRT condition is reached.

The device reaches RRT after 3 consecutive daily automatic measurements of < 2.73 V. After this occurs, the programmer displays the RRT symbol and the date when the battery reached RRT. Also, the programmer displays Replace Device instead of the Remaining Longevity estimate. If the programmer displays the RRT symbol, contact your Medtronic representative and schedule a replacement procedure with your patient.

The expected service life of the device after RRT, defined as the Prolonged Service Period (PSP), is 3 months (90 days).[1] After the 90-day PSP has expired or after 3 consecutive automatic daily measurements < 2.55 V, the device reaches End of Service (EOS) and the programmer displays the EOS indicator.[2]

[1] EOS may be indicated before the end of 90 days if the actual battery usage exceeds the expected conditions during the Prolonged Service Period.
[2] EOS may also be indicated if an excessive charge time occurs.

Warning: Replace the device immediately if the programmer displays an EOS indicator. The device may lose the ability to pace, sense, and deliver therapy adequately after the EOS indicator appears.

3.3.2 Capacitor charging and high-voltage therapy information

The **Battery and Lead Measurements** screen reports information about the last high-voltage charge and the last delivered high-voltage therapy. The Last Charge section displays the date, charge time, and energy range from the last time the high-voltage capacitors were charged (from any starting energy to any final energy). This information includes periodic charging (if necessary) to condition the battery. The Last High Voltage Therapy section reports the date, measured impedance, delivered energy, waveform, and pathway for the last delivered high-voltage therapy.

3.3.3 Lead impedance measurements

Every day at 03:00, the device automatically measures the lead impedance on the implanted lead using subthreshold electrical pulses. These pulses are synchronized to sensed or paced events and do not capture the heart.

The daily automatic lead impedance measurements are displayed on the **Lead Trends** screen, which plots the data as a graph. The graph displays up to 15 of the most recent measurements and up to 80 weekly summary measurements (showing minimum, maximum, and average values for each week). Significant or sudden changes in lead impedance may indicate a problem with the lead.

If the device is unable to perform automatic lead impedance measurements, gaps are present in the trend graph.

3.3.4 Sensing amplitude measurements

Every day at 02:15, the device begins to measure the amplitude of intrinsic sensed events. The device attempts to measure the amplitude of 9 normal intrinsic sensed events, and then records the median value from those events. If the device has not collected 9 amplitude measurements by 00:00 (midnight), no measurement is recorded. The sensing amplitude trend graph shows a gap for that day.

The daily automatic sensing amplitude measurements are displayed on the **Lead Trends** screen, which plots the data as a graph. The graph displays up to 15 of the most recent measurements and up to 80 weekly summary measurements (showing minimum, maximum, and average values for each week). Significant or sudden changes in sensing amplitude may indicate a problem with a lead.

Note: The sensing amplitude trend data is intended to show changes in sensing amplitude measurements that may be used to assess lead integrity. The adequacy of the ventricular sensing safety margin cannot be determined by the R-wave trend measurement and should be based on VF induction testing.

3.4 Cardiac Compass Trends

An analysis of clinical information collected over a long term can help you to follow changes in a patient's condition and correlate these changes with variations in device programming, medication, or symptoms.

Cardiac Compass Trends provides a picture of the patient's condition over the last 14 months. Graphs show trends in the frequency of arrhythmias, heart rates, and device therapies. Dates and event annotations allow you to correlate trends from different graphs. The trends can also help you to assess whether device therapies or antiarrhythmic drugs are effective.

The Cardiac Compass trends are based on data and measurements collected daily. Data storage for Cardiac Compass trends is automatic. No setup is required. The device begins storing data after the device is implanted. Each day thereafter, the device stores a set of Cardiac Compass trend data. Storage continues until the 14-month storage capacity is filled. At that point, the oldest stored data is overwritten with new data.

Notes:

- The time annotations displayed in the trends are based on the device clock.
- You cannot manually clear the Cardiac Compass trend data.

3.4.1 How to view and print Cardiac Compass Trends

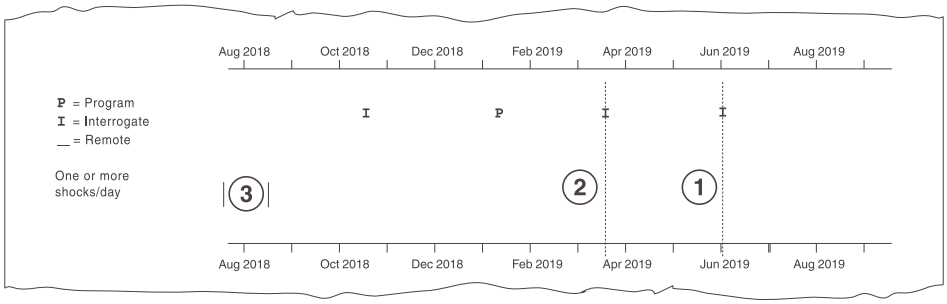
Cardiac Compass trend data is available on the **Cardiac Compass Trends** screen and in a printed report. To view the **Cardiac Compass Trends** screen, tap the » button next to Cardiac Compass on the **Quick Look II** screen, or tap **Data** > **Clinical Diagnostics** > **Cardiac Compass Trends** > **Open Data**. To print Cardiac Compass Trends, tap the **Print…** button on the **Cardiac Compass Trends** screen, or tap **Reports** > **Available Reports…** and select the check box for Cardiac Compass Trends before selecting one of the print options (**Print Now** or **Print Later**).

3.4.2 Information provided by Cardiac Compass Trends

Cardiac Compass Trends shows events that have occurred during the reporting period. It also provides trend graphs that can help you to assess the frequency of VT/VF arrhythmias.

3.4.2.1 Event information

Figure 2. Event annotations



1 Current session indicator
2 Last session indicator
3 High-voltage therapy indicator

Programming and interrogation events – Cardiac Compass Trends shows when the device was interrogated or programmed to allow possible correlations between device parameter changes and other clinical trends.

When the patient is evaluated during an office visit, the report records an “I” for a day on which the device is interrogated and a “P” for a day on which any programmable parameter is changed (except for temporary changes). If the device is interrogated and programmed on the same day, only a “P” is displayed.

When the patient is evaluated during a Medtronic patient monitor session, the report records an “I” with a line beneath it.

Two vertical lines run through all the graphs to indicate the beginning of the current session and the beginning of the last session, if applicable.

One or more shocks per day – Cardiac Compass Trends indicates a shock for any day on which the device delivered a high-voltage therapy (an automatic defibrillation therapy or cardioversion therapy). Each annotation indicates delivery of one or more ventricular (V) high-voltage therapies on a single day.

3.4.2.2 Assessing VT/VF arrhythmia information

Treated VT/VF episodes per day – The history of ventricular tachyarrhythmias may be helpful in revealing correlations between clusters of episodes and other clinical trends.

Each day, the device records the total number of spontaneous VT and VF episodes for which a therapy was started. This count may include therapies that were started and aborted. It does not include episodes that were only monitored.

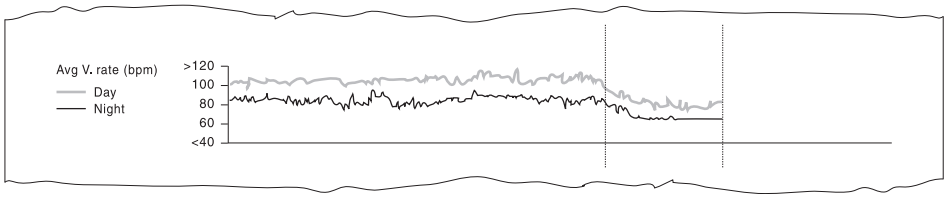
Ventricular rate during VT/VF – This trend may provide an indication of the effects of antiarrhythmic drugs on VT and VF rates and gives a better understanding of the safety margins for detection.

The graph displays the median ventricular rate during spontaneous VT and VF episodes. Multiple points on one day represent multiple episodes with different median rates. The horizontal lines indicate the programmed VF, VT, and FVT detection rates, if applicable.

Non-sustained VT episodes per day – This trend may help you to correlate patient symptoms (such as palpitations) to non-sustained VT episodes and may indicate a need for further investigation of the status of the patient.

3.4.2.3 Assessing ventricular rate information

Figure 3. Average ventricular rate trend graphs

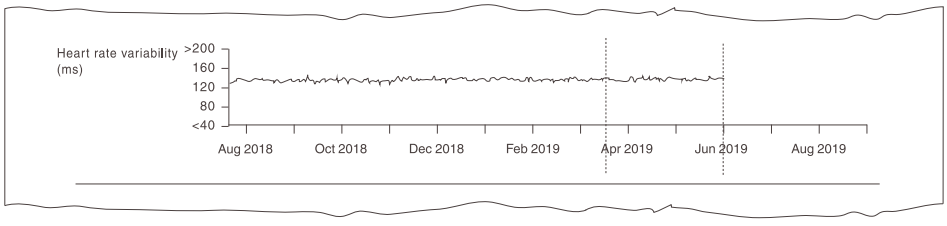


Average ventricular rate – The day and night heart rates provide information that may have the following clinical uses:

- Objective data to correlate with patient symptoms
- Indications of autonomic dysfunction or symptoms of heart failure
- Information regarding diurnal variations

For this trend, “day” is defined as the 12-hour period between 08:00 and 20:00 and “night” as the 4-hour period between 00:00 (midnight) and 04:00 (as indicated by the device clock).

Figure 4. Heart rate variability trend graph



Heart rate variability – The device measures each ventricular interval and calculates the median ventricular interval every 5 min. It then calculates and plots a variability value (in milliseconds) for each day.

Note: The heart rate variability calculation does not include events that occur during arrhythmia episodes.

3.5 Arrhythmia Episodes data

The system provides a clinically-oriented arrhythmia episode log that enables you to quickly view summary and detailed diagnostic data for arrhythmia episodes. Episode information is available in several formats, including interval plot diagrams, EGMs, and text summaries. Various filtering tools are available to give you precise control over the types of data displayed.

3.5.1 Episode log

The episode log is displayed in the upper portion of the **Arrhythmia Episodes** screen. It provides the following summary information for the episodes currently being stored in device memory:

- Type of episode
- The number of ATP sequences delivered (if any)
- The number of shocks or the energy delivered (if any)
- Whether the last therapy delivered was successful
- The date, time, and duration of the episode
- The average ventricular beats per minute
- The maximum ventricular beats per minute
- Whether EGM data is available for the episode

Avg bpm V – For VT Monitor and VT-NS episodes, the Avg bpm V is an average of ventricular cycle length throughout the entire episode. For VT/VF, SVT, and VOS episodes, the Avg bpm V is an average of the 4 beats at detection or just prior to withholding detection.

Max V bpm – For VT-NS episodes, the maximum ventricular bpm value is not displayed.

Notes:

- Episodes that occur during a device session are not available to view in the episode records until an interrogation is performed. The interrogation must be performed after episode termination.
- If an interrogation is performed while an episode is in progress, the type, date, and time of the episode are provided. To view additional episode information, interrogate the device after episode termination.
- For most episode types, when the log capacity is reached, data from the most recent episode will overwrite the oldest episode data in the log.

3.5.2 Episode records

An episode record displays detailed information about the episode currently selected in the episode log. An episode record is initially displayed in the lower portion of the **Arrhythmia Episodes** screen and can be maximized for better viewing. For a particular episode, you can display the following information, if available:

- An interval plot
- A strip chart of the stored EGM (if available)
- A text summary
- A QRS display showing Wavelet template match scores. For more information, see *Section 4.4.1*.

3.5.3 Episode interval plot

When you first select an episode from the episode log, the programmer displays a graph that plots the V-V intervals versus time and indicates the following information:

- Programmed detection intervals
- Point of detection or detection withheld
- Points of therapy delivery
- Point of episode termination
- For VT-NS episodes VF Count
- Point of VF Count reset and VF Count at the time of reset (if occurred)

VF Count – This is the number of VF counts leading toward the VF Initial Beats to Detect at the point of termination of a VT-NS episode.

Note: The device may truncate data storage during an episode to conserve device memory. If so, the programmer may display time labels on the horizontal axis of the interval plot following the truncation as asterisks (*).

3.5.4 Episode EGM

When you select an episode from the episode log and then select the EGM option, the programmer displays the stored EGM data for the episode.

EGM data storage and device memory conservation – The device begins to store ventricular EGM data when 3 consecutive intervals have occurred in the VT, VT Monitor, or VF zone.

To conserve device memory, the EGM is stored only during specific parts of an episode.

Note: Long episodes may contain gaps in the EGM to save storage memory.

3.5.5 Episode text

When you select an episode from the episode log and then select the Text option, the programmer displays a text summary of the episode.

3.5.6 Episode QRS data

When you select an episode from the episode log and then select the QRS option, the programmer displays the QRS data stored by the Wavelet feature.

The QRS screen is available for SVT, VF, VT, VT Monitor, FVT, and VOS episodes if the Wavelet criterion is programmed to On or Monitor at the time when the episodes occur.

The QRS screen displays waveform diagrams of up to 8 recorded QRS complexes, with the current template overlaid on each waveform. For each QRS complex, the match percentage and classification (Match or No Match) are also displayed. For more information, see *Section 4.4.1*.

Note: If no template was available at the time the episode was recorded, the QRS complexes appear with no match percentages or classifications.

3.5.7 How to set data collection preferences

Data collection is automatic and cannot be turned off. However, several preference settings that are useful for controlling the display of episode data are available on the **Data Collection Setup** screen. These settings also control the Live Rhythm Monitor display.

EGM and LECG source – For each EGM channel and the LECG channel, define the source electrodes between which the device records EGM signals.

Note: The cardiac interval measurements of the device are always based on the signals sensed through the programmed sensing polarity (not the stored diagnostic EGM). Therefore, your selection of EGM sources does not affect tachyarrhythmia interval criteria, synchronization, and therapy.

EGM and LECG range – Select a range for each EGM channel and the LECG channel. The range setting affects the resolution of the signal; the lower the setting, the higher the resolution. If the signal is illegible or clipped, consider changing the range selection.

Pre-arrhythmia EGM – Indicate whether you want to store EGM data collected prior to an episode. When Pre-arrhythmia EGM storage is on, the device collects up to 10 s of EGM data before the onset of VT/VF, VT Monitor, or the detection of SVT episodes. If Pre-arrhythmia EGM is programmed to Off, the episode record stores only intervals and no EGM at the beginning of each episode.

Note: Pre-arrhythmia EGM storage works by keeping the EGM circuitry enabled at all times, and therefore it reduces device longevity. If you select On - 1 Month or On - 3 Months, Pre-arrhythmia EGM storage is automatically turned off after the time period expires.

Note: Cleared data is not recoverable.

3.5.7.1 Programming data collection preferences

Table 2. How to navigate to parameters for data collection preferences

Parameters	Path
LECG Source LECG Range	**Params** > **Data Collection Setup…**
EGM 1 Source EGM 1 Range	
EGM 2 (Wavelet) Source EGM 2 (Wavelet) Range	
EGM 3 Source EGM 3 Range	
Stored (Ventricular)	
Pre-arrhythmia EGM	
Device Date/Time…	
Holter Telemetry	

3.6 Episode and therapy counters

The programmer allows you to view stored data about the number of times VT/VF episodes, VT/VF therapies, and Pause Prevention episodes have occurred.

The count data includes the number of premature ventricular contractions (PVCs) and monitored and non-sustained episodes. The count data also includes the number of episodes for which detection and therapy were withheld due to the application of supraventricular tachycardia (SVT) and ventricular oversensing (VOS) discrimination features.

To access episode and therapy counters, tap **Data** > **Clinical Diagnostics** > **Counters** > **Open Data**.

3.6.1 VT/VF episode counters

The device records the following types of counter data related to ventricular arrhythmias since the last session, and for the lifetime of the device:

VF, FVT, and VT – The number of episodes of each tachyarrhythmia.

Monitored VT – The number of VT Monitor episodes.

VT-NS – The number of non-sustained ventricular tachyarrhythmias.

PVC Runs – The average number of runs per hour of premature ventricular contractions (PVCs) in which 2, 3, or 4 consecutive ventricular events are premature.

PVC Singles – The average number of single PVCs per hour. PVCs in PVC runs are not counted as PVC singles.

SVT: VT/VF Rx Withheld – The number of episodes initially detected for each supraventricular tachycardia (SVT) discrimination feature for which VT/FVT/VF detection and therapy were withheld.

Note: Only SVTs with rates in the treated zones are included.

V. Oversensing: VT/VF Rx Withheld – The number of episodes initially detected for each ventricular oversensing discrimination feature for which VT/FVT/VF detection and therapy were withheld.

3.6.2 VT/VF therapy counters

The device records the following types of counter data related to ventricular tachyarrhythmia therapies since the last session:

VT/VF Therapy Summary – The number of pace-terminated tachyarrhythmias, shock-terminated tachyarrhythmias, total VT/VF shocks, and aborted charges.

VT/VF Therapy Efficacy Since Last Session – The number and types of VF, FVT, and VT therapies delivered, whether they were successful (if no redetection occurred), and, for VT and FVT therapies, whether redetected episodes had accelerated (and were redetected as faster tachyarrhythmias). The 6 listed therapies refer to Rx1 through Rx6 for each episode type.

3.6.3 Pause Prevention Episode counters

The device records the number of Pause Prevention Episodes that occurred since the last session, and for the lifetime of the device.

3.7 Flashback Memory data

Flashback Memory records ventricular intervals that occur immediately prior to tachyarrhythmia episodes or the most recent interrogation. The feature plots the interval data over time and allows you to view and print a graph of the collected data. The graphed data may help you assess the patient's heart rhythm.

Flashback Memory records up to a total of 2000 V-V intervals and stored marker data for the following events:

- The most recent interrogation
- The most recent VF episode
- The most recent VT episode

If 2 or more episodes are detected within 15 min, the Flashback Memory data before the episodes may be truncated.

To access Flashback Memory data, tap **Data** > **Clinical Diagnostics** > **Flashback Memory** > **Open Data**.

3.8 Pause Prevention Episodes

Pause Prevention is a pacing feature that monitors the heart for significant pauses and responds by providing temporary bradycardia pacing support (see *Section 6.3, Pause Prevention Pacing, page 117*). When Pause Prevention is programmed to On or Monitor, the device records data about episodes that meet the programmed pause detection criteria. This data is useful for analyzing Pause Prevention episodes and the events leading up to them. You can view and print data for the last 5 episodes.

The device stores the following summary information for each Pause Prevention episode:

- Date and time of the episode
- Whether treatment was delivered for the episode
- Whether EGM data is available for the episode

The following detailed information is provided for each Pause Prevention episode:

- A strip chart view showing EGM and Marker Channel annotations for the events that occur prior to detection of the episode
- A text summary of the sensing and EGM settings that were in effect when the episode was detected

To access Pause Prevention episode data, tap **Data** > **Clinical Diagnostics** > **Pause Prevention Episodes** > **Open Data**.

Note: If the log capacity has been reached for Pause Prevention episodes and Pause Prevention Detection Enable is programmed to Monitor, no new episodes will be added to the Pause Prevention log. Additionally, no existing episodes will be overwritten until the device is interrogated. Overwriting of the oldest Pause Prevention episode data with new data resumes after the device is interrogated.

3.9 Rate Histograms

Information about heart rates recorded between patient sessions can help you to monitor a patient's condition to assess the effectiveness of therapies. Rate Histograms shows the distribution of ventricular rates recorded Since Last Session and Prior to Last Session. Rate histogram data is available on the programmer screen and as a printed report. The recording time spans from the start of a session to the start of the next session.

3.9.1 How to view and print Rate Histograms

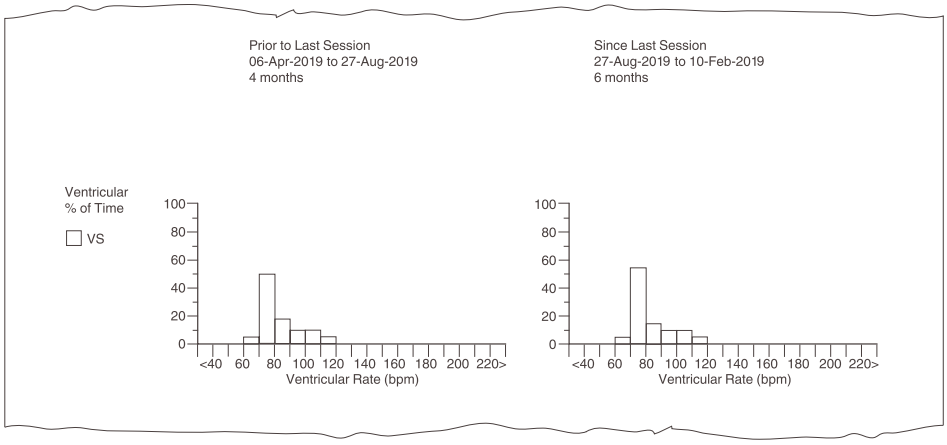
You can view Rate Histograms starting from the Data icon. Tap **Data** > **Clinical Diagnostics** > **Rate Histograms** > **Open Data**.

You can print Rate Histograms starting from either the Reports icon or the **Rate Histograms** screen. Tap **Reports** > **Available Reports…** > **Rate Histograms**, or tap **Print…** on the **Rate Histograms** screen.

3.9.2 Information provided by Rate Histograms

Rate Histograms report the ventricular event data stored by the device. Rate Histograms present the patient's heart rate data and a histogram showing the ventricular heart rate. The histograms include data from the current and previous collection periods. Data storage for Rate Histograms is automatic; no setup is required.

Figure 5. Rate Histograms



Rate histograms show the percentage of time that the device was sensing within rate ranges. There are 20 rate ranges that are each 10 bpm in length. Rates slower than 40 bpm are included in the "<40" range; rates faster than 220 bpm are included in the ">220" range.

Ventricular rate histogram – The ventricular rate histogram shows the rate distribution of ventricular sensed events.

3.10 Automatic device status monitoring

The device automatically and continuously monitors for adequate charge time performance, electrical reset, and disabled therapy conditions. During each interrogation, the device reports detected conditions that require attention as device status indicator warnings and then displays these warnings on the programmer screen. A device status indicator warning is displayed as a window on the programmer screen and is displayed also in the Observations box on the **Quick Look II** screen. A specific procedure about how to respond to the device status indicator warning for electrical reset is provided in *Section 3.10.2, How to respond to the device status indicator warning for electrical reset, page 42*.

Caution: The device status indicators are important. Please inform your Medtronic representative if any of the indicators are displayed on the programmer screen after interrogating a device.

To clear the displayed status indicator, tap **Clear** in the window that displays the device status indicator warning.

3.10.1 Definitions of device status indicator warnings

Warning - Charge Circuit Timeout – Indicates that the charging period has exceeded 36 s. The charge circuit is still active. Inform a Medtronic representative if this device status indicator is displayed on the programmer screen. **Immediate replacement of the device is recommended.**

Warning - Charge Circuit Inactive – Indicates that 3 consecutive charging periods have each exceeded 36 s. The charge circuit is inactive, and all automatic therapy functions, EP study functions, and manual system tests are disabled. Inform a Medtronic representative if this device status indicator is displayed on the programmer screen. **Immediate replacement of the device is recommended.**

Warning - Device Electrical Reset – Indicates that an electrical reset has occurred. An electrical reset can be either a full reset or a partial reset. When a full reset occurs, the programmed parameters are reset to the default electrical reset values. When a partial reset occurs, the reset does not affect any programmed parameters. For information about reset settings, see the device manual. Read the message accompanying the indicator, and follow the screen instructions carefully. See *Section 3.10.2* for instructions about what to do in the event of an electrical reset. If the warning message does not indicate that parameters have been reprogrammed, then the reset was a partial reset and did not affect any programmed parameters.

An electrical reset is a device-activated safety feature that can reset device parameters to values that provide basic device functionality. These basic parameters are considered safe for the majority of patients. In most electrical reset situations, VF detection is enabled. In rare cases, an electrical reset may disable tachyarrhythmia detection and therapy. If this occurs, the Medtronic CareAlert alarm for electrical reset sounds every 9 hours. Tachyarrhythmia detection and therapy can be reprogrammed after the electrical reset indicator has been cleared.

An electrical reset may occur when the device is exposed to extreme conditions, such as cold temperatures (before implant); intense, direct x-ray exposure; electrocautery; or external defibrillation. Inform a Medtronic representative if this device status indicator is displayed on the programmer screen.

After an electrical reset, the programmer and patient monitor may not be able to communicate with the device. If this occurs, inform a Medtronic representative. **Immediate replacement of the device is recommended.**

Note: If an electrical reset occurs while MRI SureScan is programmed to On, MRI SureScan operation is maintained.

SERIOUS DEVICE ERROR – Indicates an error has occurred from which the device cannot recover. Inform a Medtronic representative if this device status indicator is displayed on the programmer screen. **Immediate replacement of the device is recommended.**

3.10.2 How to respond to the device status indicator warning for electrical reset

If the programmer reports that an electrical reset occurred and the device is not yet implanted, do not implant the device. Contact a Medtronic representative. If the device is implanted, perform the following steps:

1. Remove any sources of electromagnetic interference (EMI).
2. Notify a Medtronic representative.
3. Tap **Clear** in the window to clear the reset indicator and the Medtronic CareAlert alarm. A confirmation window appears indicating that all previously interrogated data in the programmer will be cleared.
4. Tap **Continue**.

   Note: If an electrical reset occurs while MRI SureScan was programmed to On, MRI SureScan operation is maintained.

5. Interrogate the device.
   a. Note the time and date when counter data was last cleared because this indicates when the electrical reset occurred.
   b. Determine, if possible, what the patient was doing at the time and date the electrical reset occurred.
   c. Save your session data. You should give a copy of this saved data file to your Medtronic representative; it can be helpful in determining the events leading up to the reset. See the programming guide for more information about saving device data from a patient session.

6. Verify the programmed device parameters. If a full electrical reset occurred, the primary reprogrammed values are displayed in the warning message. If a full electrical reset occurred, reprogram the device parameters.

   After this type of reset, the device operates as a simple defibrillator (in VOE-OVO mode) until it is reprogrammed. For a list of electrical reset parameter settings, see the device manual for the specific device.
7. Verify that the device time and date are correct. If necessary, reprogram the time and date.
8. Check the Battery and Lead Measurements screen to verify that the battery voltage and charge time are acceptable.
9. Conduct lead impedance and pacing threshold tests as desired. See the programming guide for more information about conducting lead impedance and pacing threshold tests.

4 Tachyarrhythmia detection features

4.1 Sensing

The device must sense the occurrence of intrinsic cardiac events while avoiding oversensing so that it can deliver therapies appropriately. Effective sensing can reduce the effects of long depolarizations after paced events, oversensing the same event, and sensing T-waves, noise, and interference.

Effective sensing is essential for the safe and effective use of the device. The device senses cardiac signals using the sensing electrodes of the lead and can. You can adjust the sensitivity to cardiac signals. The sensitivity setting represents a threshold value that defines the minimum electrical amplitude recognized by the device as a sensed event.

Note: Selecting a higher value for the sensing threshold reduces the sensitivity to lower amplitude signals.

Programmable blanking periods help to screen out extraneous sensing or to prevent the device from responding to it. Blanking periods follow pacing pulses, sensed events, and shocks. Sensing is inhibited during blanking periods.

The sensing vector is programmable via the Sense Polarity parameter.

4.1.1 Operation of sensing thresholds

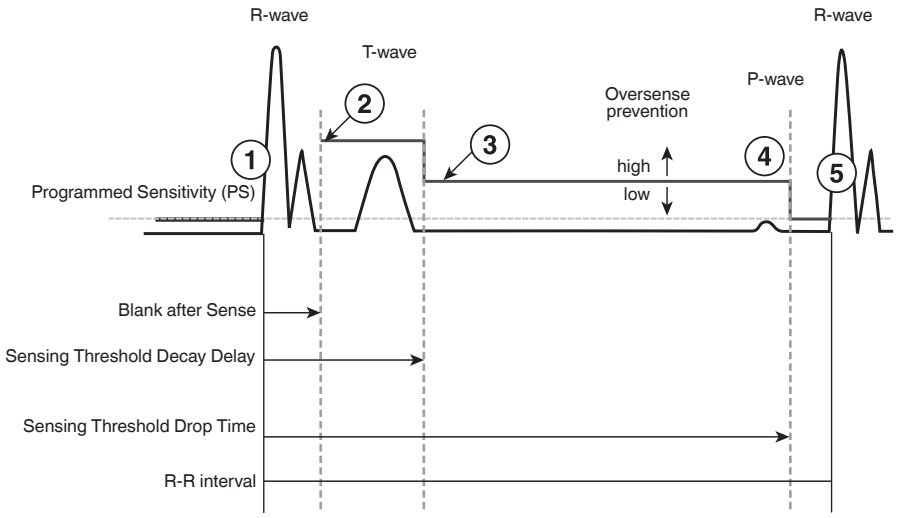
The device automatically adjusts the sensing threshold after certain sensed events to help reduce the oversensing of T-waves and P-waves. The threshold adjustment depends on the type of event that precedes the adjustment. During an automatic adjustment, the sensing threshold automatically increases, but it gradually decreases toward the programmed sensitivity value, which is the minimum amplitude that can be sensed. The threshold decrease is intended to be rapid enough to allow subsequent low-amplitude signals to be sensed.

Following a sensed event, the sensing threshold automatically adjusts to the values specified by three sensing threshold plateaus (see *Figure 6*). The values of the first 2 sensing threshold plateaus are related to the measured amplitude of the most recently sensed R-wave. The final plateau is the minimum threshold level, which is the programmed setting for Sensitivity. After a sensed R-wave, a blanking period begins and the sensing threshold is set to the first plateau level. The first plateau level is based on the peak amplitude of the last sensed R-wave. The sensing threshold stays at this value for a certain period of time to prevent T-wave sensing. If a new R-wave is not sensed before the Sensing Threshold Decay Delay, the sensing threshold automatically decays to the second plateau. The amount of decay to the second plateau is determined by the programmed setting for Oversensing Prevention. The sensing threshold decreases such that oversensing of P-waves is avoided, but the sensing of an R-wave is possible. If a new R-wave is not sensed before the Sensing Threshold Drop Time, the sensing threshold automatically decays to the third plateau at the programmed sensitivity setting. The sensing threshold never drops below the programmed sensitivity setting to avoid the sensing of noise or P-waves.

Notes:

- Selecting a higher programmed value for Oversensing Prevention reduces the sensitivity to lower amplitude signals.
- When high-amplitude sensed events occur, the sensitivity threshold is limited to prevent undersensing of subsequent intrinsic events.
- The Sensing Threshold Decay Delay, Sensing Threshold Drop Time, and Oversensing Prevention settings only apply to sensing thresholds following a sensed R-wave. The threshold adjustment following a pace or shock consists of three sensing threshold plateaus automatically calculated based on the programmed Sensitivity setting, rather than the sensed R-wave amplitude.
- The Oversensing Prevention settings only apply to the second plateau.

Figure 6. Automatic adjusting of the sensing threshold



1 After a sensed R-wave, a programmable blanking period is started. At the end of the blanking period, the sensing threshold is set to a percentage of the sensed R-wave peak.

2 The sensing threshold stays at this level during the programmed Sensing Threshold Decay Delay period.

3 After the Sensing Threshold Decay Delay period is finished, the sensing threshold decreases to a lower percentage of the R-wave peak amplitude. The severity of the sensing threshold decay is controlled by the Oversensing Prevention setting.

4 The sensing threshold stays at this level until the Sensing Threshold Drop Time has elapsed since the R-wave was initially sensed.

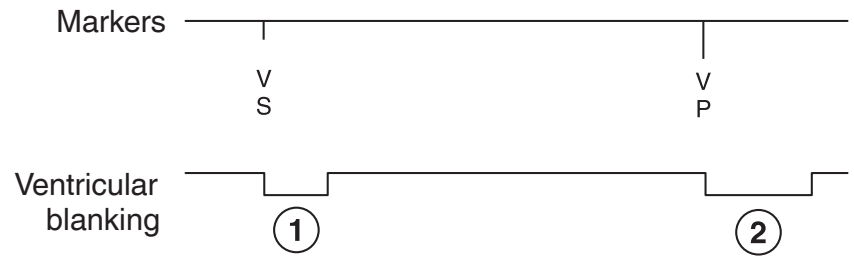
5 The sensing threshold then drops to the minimum threshold level, which is the programmed Sensitivity setting.

4.1.2 Operation of blanking periods

Blanking periods follow paced events, sensed events, and shocks. Blanking periods help to prevent the device from sensing pacing pulses, cardioversion and defibrillation pulses, post-pacing depolarization, T-waves, and oversensing of the same event. The blanking period after a paced event is longer than or equal to the blanking period after a sensed event to avoid sensing the ventricular depolarization.

Programmable parameters determine the lengths of the blanking periods that follow sensed events, paced events, and post-shock paced events.

Figure 7. Programmable blanking periods



1 For the duration of this ventricular blanking period, which is defined by the Blank after Sense parameter, ventricular sensing is disabled after a sensed ventricular event.

2 For the duration of this ventricular blanking period, which is defined by the Blank after Pace parameter, ventricular sensing is disabled after a paced ventricular event.

The post-shock blanking period is not programmable. After a cardioversion or defibrillation therapy is delivered, the ventricular blanking is 520 ms.

4.1.3 Programming sensing

Table 3. How to navigate to sensing parameters

Parameters	Path
Sensitivity and polarity parameters: Sensitivity Sense Polarity Blank after Sense Sensing Threshold Decay Delay Sensing Threshold Drop Time Blank after Pace Oversensing Prevention	**Params** > **Pacing…** > **Sensing…**

Sensing threshold – The sensing threshold, set by programming the Sensitivity parameter, applies to all features related to sensing, including detection, bradycardia pacing, and the Sensing Test.

High ventricular sensing threshold – Setting Sensitivity to a value greater than or equal to 0.6 mV is not recommended except for testing purposes. Doing this may cause undersensing, which may result in the following situations:

- Underdetection of tachyarrhythmias
- Delayed or aborted cardioversion therapy
- Delayed or aborted defibrillation therapy

Sensing during VF – Always verify that the device senses properly during VF. If the device is not sensing or detecting properly, disable detection and therapies and evaluate the system (making sure to monitor the patient for life-threatening tachyarrhythmias until you enable detection and therapies again). You may need to reposition or replace the lead to achieve proper sensing.

Sensing settings – If you change any sensing parameters, verify that the new settings provide adequate safety margins for the patient.

Carefully evaluate the possibility of increased susceptibility to EMI and oversensing before changing the sensitivity threshold to its minimum (most sensitive) setting of 0.075 mV.

Low sensing threshold – If you set the Sensitivity parameter to its most sensitive value, the device is more susceptible to electromagnetic interference (EMI) and oversensing.

Sensing to the Can electrode – Sensing polarities involving the Can electrode may be more susceptible to electromagnetic interference (EMI) and oversensing.

Testing sensitivity after reprogramming – If you change the sensing settings, evaluate for proper sensing. If appropriate, test for proper detection by inducing VF and allowing the device to automatically detect and treat the tachyarrhythmia.

4.1.4 Evaluation of sensing

4.1.4.1 Using the Sensing Test to evaluate sensing

The Sensing Test allows you to measure R-wave amplitudes. These measurements may be useful for assessing lead integrity and sensing performance. After the Sensing Test is complete, the test results are displayed on the test screen. You may view and print the results when desired. For more information, see the programming guide.

4.1.4.2 Viewing R-wave amplitude trends

To access R-wave amplitude trends, tap the » button next to R-Wave Amplitude on the **Quick Look II** screen, or tap **Data** > **Device/Lead Diagnostics** > **R Wave Amplitude Trends** > **Open Data**.

The daily automatic sensing amplitude measurements are displayed on the **Lead Trends** screen, which plots the data as a graph. The graph displays up to 15 of the most recent measurements and up to 80 weekly summary measurements (showing minimum, maximum, and average values for each week). You can compare recent amplitude measurements to the trends of daily automatic measurements. Significant or sudden changes in sensing amplitude may indicate a problem with a lead.

Note: The sensing amplitude trend data is intended to show changes in sensing amplitude measurements that may be used to assess lead integrity. The adequacy of the ventricular sensing safety margin cannot be determined by the R-wave trend measurement and should be based on VF induction testing.

4.2 Suspending and resuming tachyarrhythmia detection

It may be necessary to turn off tachyarrhythmia detection in some situations. For example, during emergency therapies and some EP study tests, therapies are delivered manually, and detection and episode storage are not needed. Also, certain types of surgery, including electrocautery surgery, RF ablation, and lithotripsy, can cause the device to detect tachyarrhythmias inappropriately and possibly deliver inappropriate therapy.

When detection is suspended, the device temporarily stops the process of classifying intervals for tachyarrhythmia detection. Sensing and Pause Prevention pacing remain active, and the programmed detection settings are not modified. When the device resumes detection, it does so at the previously programmed detection settings.

Note: If MRI SureScan is programmed to On, tachyarrhythmia detection and Medtronic CareAlert events (including audible alerts) are suspended.

4.2.1 Considerations for suspending detection

If you suspend detection during a tachyarrhythmia detection process but before detection has occurred, the initial detection never occurs. When you resume, detection starts over.

If you suspend detection after a tachyarrhythmia detection has occurred and resume detection before the tachyarrhythmia episode ends, redetection works differently for each type of episode, as follows:

VT/FVT/VF episodes – If you suspend detection while a therapy is being delivered, the device finishes delivering the therapy that is in progress but does not redetect until you resume detection. If you resume detection before the episode ends, the device begins redetection, and the episode is redetected if the programmed Beats to Redetect value is reached.

VT Monitor episodes – If you suspend detection during a detected VT Monitor episode, and then resume detection before the episode ends, there will be episode data storage for 2 episodes with the first episode ended while the rate is still fast.

4.2.2 How to suspend or resume detection with the programmer

The Suspend and Resume buttons can be used whenever there is telemetry with the device and the device software is running.

1. To suspend detection, tap **Suspend**. The programmer displays the word SUSPENDED.
2. To resume detection, tap **Resume**.

4.2.3 How to suspend or resume detection with a magnet

1. To suspend detection, place the magnet (such as the Model 9466 Tachy Patient Magnet) over the device.
2. To resume detection, remove the magnet from over the device.

Note: A magnet can be used to suspend detection only when there is no telemetry between the device and the programmer.

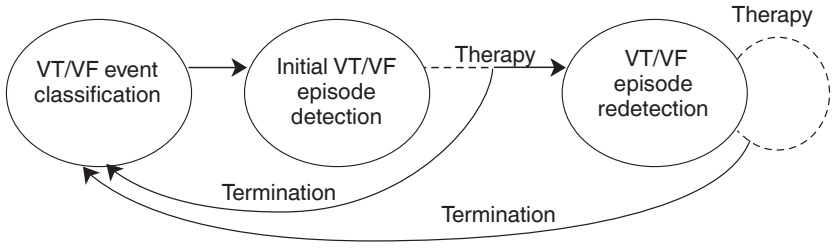
4.3 VT/VF detection

To provide the appropriate therapies for the patient, the device must first detect the presence of a tachyarrhythmia and classify it accurately. The device must be capable of detecting several types of ventricular tachyarrhythmias with differing characteristics. After delivering a therapy, the device must evaluate the effectiveness of the therapy and deliver additional therapy if the arrhythmia persists. Following episode termination, the device must continue to monitor for recurrence of the tachyarrhythmia. If an arrhythmia ends spontaneously following detection or if a fast ventricular rate is due to oversensing, therapy should be withheld.

Ventricular tachyarrhythmia detection is an ongoing process of classifying sensed ventricular events for tachyarrhythmia episode detection. Based on the results of the detection process, the device may deliver programmed therapy to the patient or withhold therapy from the patient. After delivering a therapy, the device continues to monitor the patient's rhythm to determine whether the tachyarrhythmia has ended or whether it persists or changes. The device can be programmed to monitor for slower, non-life-threatening VTs without providing therapy.

4.3.1 Operation of VT/VF detection

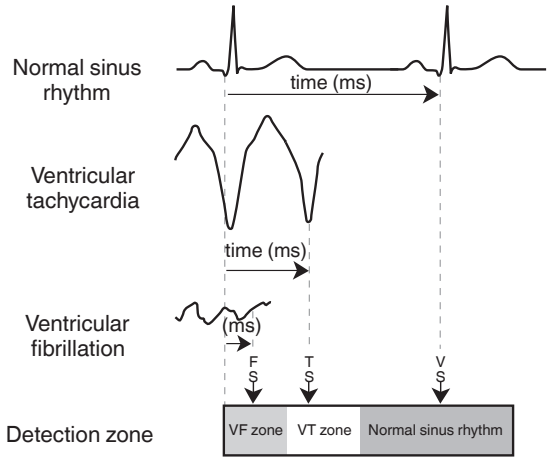
Figure 8. Overview of VT/VF detection



The device classifies the patient's heart rhythm by measuring each interval and counting the number of tachyarrhythmia events that occur within programmed tachyarrhythmia detection zones. There are 4 programmable detection zones: VF, Fast VT, VT, and Monitor. If the number of tachyarrhythmia events in a zone exceeds a programmed threshold, the device detects a ventricular tachyarrhythmia episode. Upon detection, the device may deliver a scheduled therapy, after which it reevaluates the patient's heart rhythm for episode termination or redetection.

4.3.1.1 Classifying ventricular events

Figure 9. VF and VT detection zones



The system uses programmable “detection zones” to classify ventricular events for tachyarrhythmia detection and therapy. A detection zone is a range of cycle lengths used to classify a sensed ventricular tachyarrhythmia event as VF or VT.

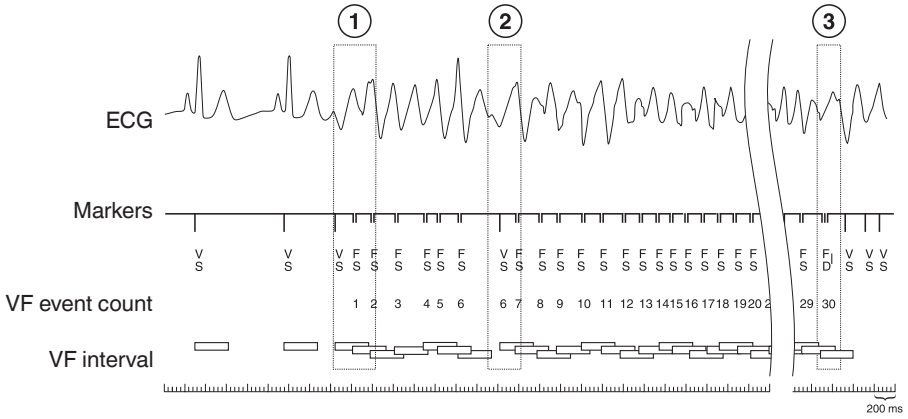
You program the detection zones by selecting a detection interval for each type of tachyarrhythmia that you want the device to detect. (The detection interval is called V. Interval (Rate) on the **V. Detection** window.) When you program a detection interval for VF, you are defining a zone for VF events. Intervals that are shorter than the VF detection interval fall in the VF detection zone and are classified as ventricular fibrillation events. In addition, when you program a VT detection interval, you are defining a zone for VT events. Intervals that are shorter than the VT detection interval and longer than or equal to the VF detection interval fall into the VT detection zone and are classified as ventricular tachycardia events.

4.3.1.2 Detecting VF and VT episodes

The system uses a programmable Initial Beats to Detect value to define how many beats a tachyarrhythmia must continue to be detected as an episode. The Initial Beats to Detect value operates differently for events in the VF zone as compared to events in the VT zone.

VF episodes have very fast, irregular intervals as a result of the chaotic nature of VF depolarizations. Some smaller VF signals may not be sensed and counted. Because of this, the system uses a ratio of VF events to consecutive events for VF detection. For example, if you program the VF Initial Beats to Detect value to 30/40, the device detects VF when at least 30 of the most recent 40 intervals have been classified as VF events.

Figure 10. Initial Beats to Detect calculation for VF



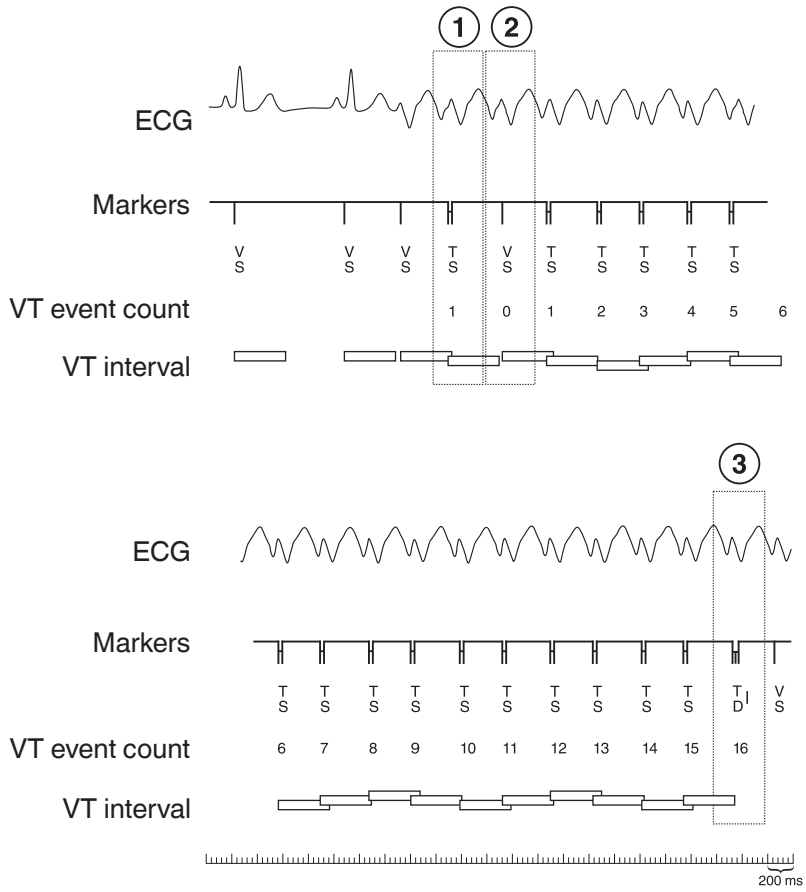
1 Ventricular fibrillation starts, and sensed intervals in the VF detection zone are classified as VF events (marked FS).

2 A sensed ventricular interval occurs outside the VF detection zone. This event is not classified as a VF event.

3 The programmed VF Initial Beats to Detect value of 30 events out of 40 is reached, and the device detects a VF episode (indicated by the FD marker).

VF detection uses a probabilistic counter to ensure that undersensing does not prevent detection. However, since VT rhythms are not as prone to undersensing, the system uses a count of consecutive events for VT detection. For example, if you program the VT Initial Beats to Detect value to 16, the device detects VT when 16 consecutive intervals have been classified as VT events. If an interval is longer than the VT zone, the detection process is restarted. If the interval is shorter than the VT detection interval and occurs in the VF zone, the device holds the count of consecutive VT events (neither resets nor increments it).

Figure 11. Initial Beats to Detect calculation for VT



1 Ventricular tachycardia starts, and sensed ventricular intervals in the VT detection zone are classified as VT events (marked TS).

2 A sensed ventricular interval occurs outside the VT detection zone. VT detection restarts.

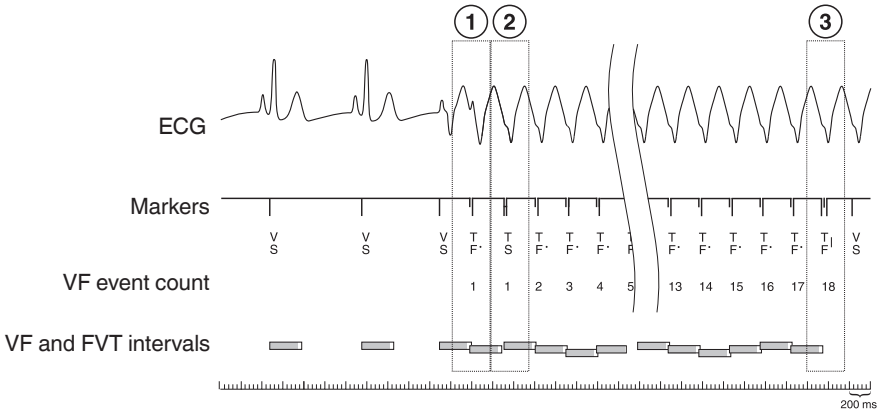
3 The programmed VT Initial Beats to Detect value of 16 events is reached, and the device detects VT (indicated by the TD marker).

4.3.1.3 Detecting a VT in the VF zone

A fast ventricular tachyarrhythmia (FVT) detection zone may be used to detect and treat a VT episode that is in the VF zone. This approach may help to ensure reliable detection of VF, while providing the ability to deliver a less aggressive therapy such as antitachycardia pacing for the patient's fast VT. To detect a VT in the VF zone, program FVT detection to via VF and select a V. Interval (Rate) value for FVT. To help ensure that the patient's fast ventricular tachycardia is classified as FVT, select a value that matches the shortest ventricular interval that typically occurs during the patient's fast VT.

The device detects a tachyarrhythmia episode when the number of recent VF or FVT events reaches the programmed Initial Beats to Detect value for VF. If all of the 8 most recent intervals were classified as FVT events, the device detects an FVT episode. If 1 or more of the 8 most recent intervals were classified as VF events, the device detects a VF episode.

Figure 12. Detecting an FVT via VF episode



1 Fast ventricular tachycardia starts. The first event has a cycle length in the FVT detection zone and is counted toward FVT or VF detection.

2 The second event has a cycle length that is longer than the VF detection interval. This event is not counted toward FVT or VF detection.

3 The programmed VF Initial Beats to Detect value is reached. Because all of the previous 8 events were classified as FVT events, the device detects a fast ventricular tachycardia episode (marked TF followed by a vertical bar).

4.3.1.4 Detecting ventricular tachyarrhythmia that fluctuates between zones: Combined Count detection

Combined Count detection is designed to prevent VF detection from being delayed when ventricular tachyarrhythmia fluctuates between the VF and VT zones. Combined Count detection occurs if the sum of the VT and VF events reaches 7/6 of the programmed VF Initial Beats to Detect value. For example, if the programmed VF Initial Beats to Detect value is 30/40, Combined Count detection takes place when the count reaches 7/6 of 30, which is 35. After Combined Count detection takes place, the last 8 events are examined. If any of the 8 events is classified as a VF event, VF is detected; otherwise, VT (or FVT) is detected. Combined Count detection also applies to redetection.

Notes:

- Combined Count detection is not programmable. It is automatically enabled when VT Detection is programmed to On. Combined Count detection begins when at least 6 VF events have occurred.
- Events in the Monitor zone are not included in Combined Count detection.

4.3.1.5 Monitoring ventricular tachyarrhythmias without delivering therapy

The Monitor rate zone may be used to program a range of rates for detecting ventricular tachycardia without delivering therapies.

When VT detection is programmed to On, the Monitor rate zone can function as a diagnostic zone to monitor for non-life-threatening VTs with cycle lengths longer than or equal to the VT detection interval.

When VT detection is programmed to OFF, a Monitor rate zone may be programmed to monitor any ventricular tachyarrhythmia with a cycle length longer than or equal to the VF detection interval.

Notes:

- Detection of a VF, VT, or FVT episode ends a VT monitor episode and suspends the VT monitoring operation until termination of the tachyarrhythmia.
- The programmed SVT discrimination features (Onset, Stability, Feature Match, and Wavelet) are applied in the VT monitor zone.

4.3.1.6 Detecting non-sustained ventricular tachyarrhythmia episodes

If at least 5 consecutive intervals fall within any programmed ventricular tachyarrhythmia detection zone (but fewer than the programmed Initial Beats to Detect), the episode is classified as a non-sustained VT (VT-NS). For example, if 5 or more consecutive intervals occur in the VT zone, but not enough to detect a VT episode, a VT-NS is detected.

After the device has been interrogated, VT-NS episodes can be selected from the Episode Log. For more information about the Episode Log, see *Section 3.5*.

4.3.1.7 Evaluating the ventricular rhythm after therapy

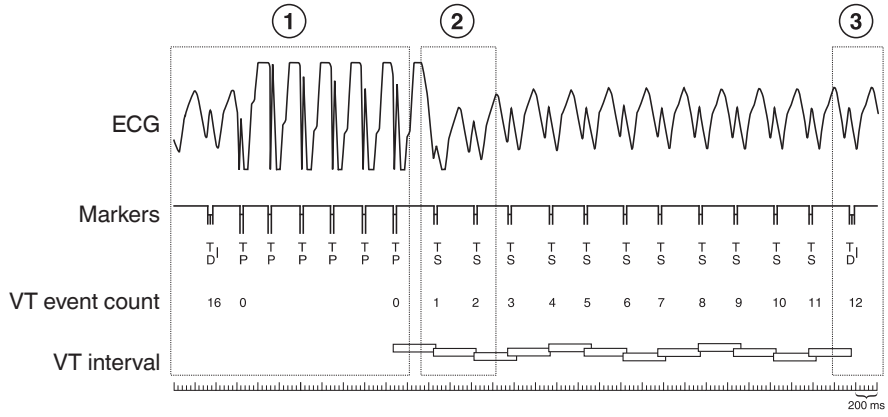
After delivering a therapy, the device evaluates the ventricular rhythm to determine if the episode is continuing.

Redetection – The device redetects the ventricular tachyarrhythmia if the programmed VF Beats to Redetect value or the programmed VT Beats to Redetect value is reached. The device then delivers the next programmed therapy sequence for the redetected ventricular tachyarrhythmia and again evaluates the rhythm for redetection or termination.

Notes:

- You can expedite redetection by programming the VF and VT Beats to Redetect values to values that are lower than the VF and VT Initial Beats to Detect value.
- The SVT discrimination features are not applied during redetection with the exception of the TWave Discrimination feature and the Stability feature, which are always applied after 3 consecutive VT events.

Figure 13. Redetecting a VT episode after therapy



1 A VT episode is detected, and the device delivers a Burst ATP therapy.

2 After the Burst ATP therapy, the device continues to identify VT events.

3 When the number of VT events reaches the programmed VT Beats to Redetect value, the device redetects the VT.

Zone merging – To ensure that the device delivers sufficiently aggressive therapies when FVT Detection is programmed, the device merges detection zones during redetection. If FVT Detection is programmed to FVT via VF and a VF episode is detected, the FVT zone

merges with the VF zone. After the zones have merged, the episode cannot be classified for redetection as the slower FVT rhythm. The merged zone configuration remains in effect until the episode ends.

4.3.1.8 Evaluating the ventricular rhythm for termination

The device determines that a VT episode has ended if 8 consecutive ventricular intervals are longer than or equal to the programmed VT detection interval or if 20 s elapse during which the median of the last 12 ventricular intervals is always longer than the VT detection interval.

If VT detection is off but VF detection is on, the device uses the programmed VF interval to end a VF episode. The episode ends when 8 consecutive ventricular intervals are longer than or equal to the programmed VF detection interval or when 20 s elapse during which the median of the last 12 ventricular intervals is always longer than the VF detection interval.

If VF Count reset is on, withheld episodes may terminate in less than 8 intervals when the VF Count reset criteria is met. For more information, see *Section 4.3.1.9*and *Section 4.3.1.10*.

4.3.1.9 SVT discrimination features for ventricular tachyarrhythmia detection

The device provides the following features designed to help prevent conducted supraventricular tachycardias (SVTs) from being treated as ventricular tachyarrhythmias:

Wavelet – The Wavelet feature withholds VT/VF detection if the rhythm displays characteristics of an SVT origin. For more information, see *Section 4.4.1*.

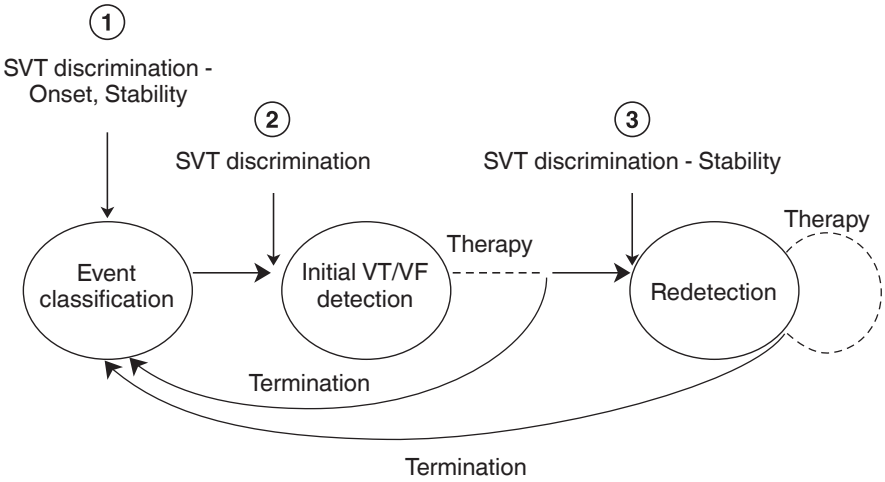
Feature Match – The Feature Match feature withholds VT/VF detection if the rhythm displays characteristics of an SVT origin. For more information see *Section 4.4.1.2.1, Operation of Feature Match, page 66*.

Rapid AF – The Rapid AF feature withholds VT/VF detection if the rhythm displays characteristics of an AF origin. For more information see *Section 4.4.1.2.2, Operation of Rapid AF, page 67*.

Onset – The Onset feature is designed to prevent sinus tachycardia from being treated as ventricular tachycardia. For more information, see *Section 4.5*.

Stability – The Stability feature is designed to prevent conducted atrial fibrillation episodes from being treated as ventricular tachycardia. For more information, see *Section 4.6*.

Figure 14. Overview of SVT discrimination



1 Onset and Stability withhold detection by preventing the programmed Initial Beats to Detect value from being reached.

2 Wavelet, Feature Match, and Rapid AF withhold detection and therapy after the programmed Initial Beats to Detect value has been reached.

3 Stability also applies to the Redetection phase.

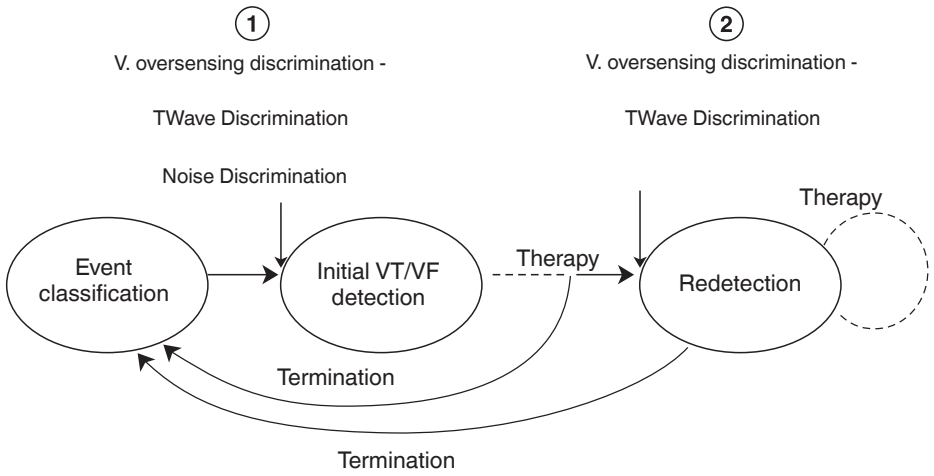
4.3.1.10 Ventricular oversensing (VOS) discrimination features for ventricular tachyarrhythmia detection

The device provides the following features designed to help prevent inappropriate ventricular tachyarrhythmia detection and therapy caused by ventricular oversensing (VOS).

TWave Discrimination – The TWave Discrimination feature withholds inappropriate ventricular tachyarrhythmia detection caused by the oversensing of T-waves. For more information, see *Section 4.8*.

Noise Discrimination – The Noise Discrimination features withhold inappropriate ventricular tachyarrhythmia detection caused by the oversensing of noise. For more information, see *Section 4.9, Noise Discrimination , page 82*.

Figure 15. Overview of ventricular oversensing (VOS) discrimination



1 The TWave Discrimination and Noise Discrimination features (Smart Sense, Morphology Noise, and Sensed EMI) withhold ventricular tachyarrhythmia detection and therapy after the programmed Initial Beats to Detect value has been reached.

2 The TWave Discrimination feature also applies to the Redetection phase.

4.3.2 Programming ventricular tachyarrhythmia detection

Table 4. How to navigate to VT/VF detection parameters

Parameters	Path
VF detection parameters: VF VF Initial VF Redetect VF V. Interval (Rate)	**Params** > **Detection (V.)…**
FVT detection parameters: FVT V. Interval (Rate)	
VT detection parameters: VT VT Initial VT Redetect VT V. Interval (Rate)	
VT Monitor parameters: Monitor Monitor Initial Monitor V. Interval (Rate)	
Other Enhancements parameters: Stability TWave	
FVT parameters: FVT Enable	**Params** > **Detection (V.)…** > **FVT**
Onset parameters: Onset Percent	**Params** > **Detection (V.)…** > **Onset…**
High Rate Timeout parameters: VF Zone Only All Zones	**Params** > **Detection (V.)…** > **High Rate Timeout…**
Noise parameters: Smart Sense Morphology Noise Sensed EMI Shared Noise Timeout	**Params** > **Detection (V.)…** > **Noise…**

VF, FVT, and VT detection intervals – To allow for normal variations in the patient's tachycardia interval, you should program the VF, FVT, and VT detection intervals at least 40 ms apart.

VF detection interval minimum setting – Programming the VF detection interval to a value less than 300 ms may increase the chance of underdetection of VF.

VF detection interval maximum setting – Programming the VF detection interval to a value greater than 350 ms may increase the chance of inappropriate detection of rapidly conducted atrial fibrillation as VF or FVT via VF.

VF detection backup – To ensure VF detection backup during VT, FVT, and VT Monitor episodes, if VT, FVT, or VT Monitor is programmed to On, VF Detection must also be programmed to On.

Monitored VT Beats to Detect – The Monitored VT Beats to Detect value must be greater than the VF and VT Initial Beats to Detect.

4.3.3 Evaluation of VT/VF detection

4.3.3.1 Quick Look II screen

To access Quick Look II VT/VF detection information, tap **Data** > **Quick Look II**. The **Quick Look II** screen shows the number of monitored and treated VT, FVT, and VF episodes since the last session.

For detailed information about viewing and interpreting all of the information available from the **Quick Look II** screen, see *Section 3.1, Quick Look II summary data, page 18*.

4.3.3.2 Arrhythmia Episodes screen

To access arrhythmia episode data, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data**.

The Plot view displays a plot diagram of the episode intervals and shows the detection and termination points. The EGM view displays EGM traces leading up to the detection point and through therapy and termination. The Text view provides a text summary of the episode.

4.3.3.3 Flashback Memory

To access Flashback Memory data, tap **Data** > **Clinical Diagnostics** > **Flashback Memory** > **Open Data**.

The **Flashback Memory** screen shows interval and marker data prior to the most recent occurrence of a VT or VF episode. Total elapsed time is plotted against interval length in milliseconds.

4.3.3.4 Cardiac Compass Trends

To view Cardiac Compass Trends data, tap **Data** > **Clinical Diagnostics** > **Cardiac Compass Trends** > **Open Data**. To print Cardiac Compass Trends, tap **Reports** > **Available Reports…** > **Cardiac Compass Trends** > **Print Now** or tap **Print…** directly from the **Cardiac Compass Trends** screen.

Cardiac Compass Trends data includes information about treated VT/VF episodes per day; ventricular rate during VF, FVT, or VT; and non-sustained VT episodes per day.

4.3.3.5 VT/VF episode counter

To access VT/VF episode data, tap **Data** > **Clinical Diagnostics** > **Counters** > **Open Data** > **VT/VF Episodes**.

The VT/VF episode counter provides a summary of VT/VF activity for last session, prior session, and device lifetime, including the number of VF, FVT, and VT episodes and the instances of therapy withheld by SVT and ventricular oversensing discrimination features.

4.4 SVT Discrimination

Patients who are experiencing supraventricular tachycardia (SVT) may exhibit ventricular rates in the VT/VF detection zone. If sustained and not correctly identified, such fast ventricular rates may cause an inappropriate delivery of a VT/VF therapy. Identifying and withholding detection for conducted SVT reduces the chance of delivering an inappropriate therapy for high ventricular rates that are not ventricular in origin.

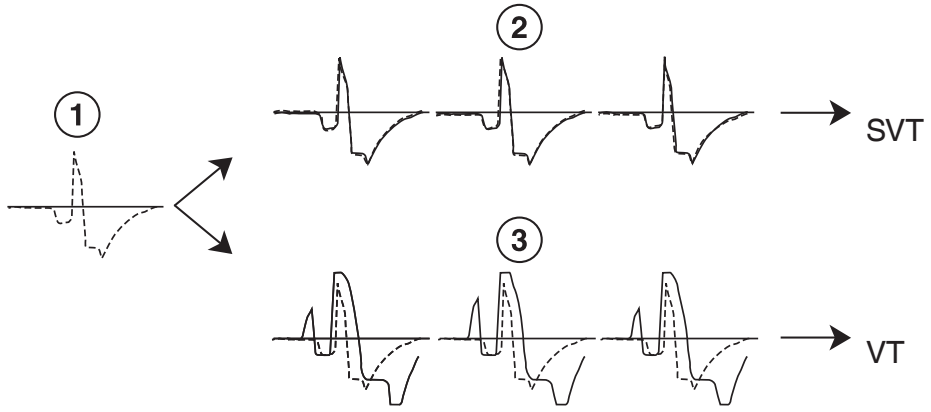
4.4.1 Wavelet

The Wavelet feature is designed to withhold inappropriate ventricular detection during episodes of rapidly conducted SVT.

Tachyarrhythmias of ventricular origin typically have different QRS morphologies than rhythms of supraventricular origin. The Wavelet feature compares the patient's current QRS waveform to a collected and stored template of the patient's QRS waveform in sinus rhythm. VT/VF detection is withheld if the current waveform sufficiently matches the template.

4.4.1.1 Operation of Wavelet

Figure 16. Using a Wavelet template to discriminate SVT from VT



1 Template
2 Rhythm matches template
3 Rhythm does not match template

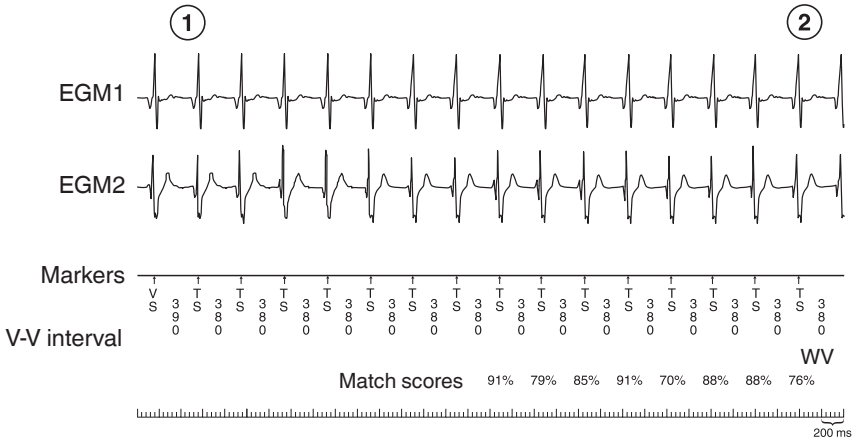
The device collects EGM data for sensed ventricular events and compares it to a stored template using the programmed Match Threshold value (nominally 61%). A QRS complex is classified as a “Match” if its match score is greater than or equal to the programmed Match Threshold value. If at least 3 of the last 8 QRS complexes sufficiently match the stored template, the device withholds detection. If fewer than 3 of the last 8 QRS complexes sufficiently match the stored template, the device allows detection and therapy.

After VT detection is withheld, the ventricular rhythm is continuously evaluated until VT detection occurs or the fast ventricular rate ends.

Notes:

- Wavelet uses the EGM2 channel for template creation and comparison.
- Ventricular events that are paced or that have intervals less than 210 ms are automatically classified as “Not Measured”.
- Wavelet applies to initial detection only.

Figure 17. Wavelet withholds detection



1 A fast sinus tachycardia begins with sensed ventricular intervals in the VT detection zone.

2 The VT Initial Beats to Detect criterion of 16 is reached, but detection is withheld because at least 3 of the previous 8 QRS complexes match the template (in this example, all match).

4.4.1.1.1 Collecting the Wavelet template: Auto Collection

You can program automatic device creation and maintenance of the template used to distinguish between VT and SVT. Alternatively, you can collect a template manually using the Wavelet test. For more information, see the programming guide.

When Auto Collection is programmed to On and the patient is not being paced, the device collects and confirms a Wavelet template and monitors it for consistency with the patient's QRS complexes in sinus rhythm. When the stored template is no longer consistent with the patient's QRS complexes (for example, due to lead maturation or changes in drug therapy), the device collects and confirms a new template.

After a template is calculated, the device performs a confirmation process before using the template for detection operations. Template confirmation takes a minimum of 12 min. If the intrinsic rhythm changes after the template is collected, template confirmation could take longer.

Notes:

- In creating and maintaining the Wavelet template, the device collects electrogram waveforms only for events with intervals longer than 600 ms or than the VT detection interval plus 60 ms, whichever is longer. It does not collect electrogram waveforms for paced events, for intrinsic events immediately following paced events, or for events classified as PVCs.
- The device stops any template collection or maintenance operations in progress and postpones them for one hour after a tachyarrhythmia episode, a system test, an EP study, or an emergency operation.

4.4.1.2 Additional SVT discrimination features

In addition to the SVT discrimination provided by the Wavelet feature, you can set the device to discriminate SVT rhythms from VT rhythms using two additional features, Feature Match and Rapid AF.

4.4.1.2.1 Operation of Feature Match

Feature Match withholds therapy for SVT that is monomorphic with a narrow R-wave width and the same polarity as the Wavelet template, but with match scores less than or equal to the programmed Match Threshold value for Wavelet. These rhythms may be missed by the SVT discrimination provided by Wavelet. Feature Match criteria will be assessed when the Wavelet algorithm suggests VT, but at least 6 of the 8 most recent beats have a Wavelet match score >19%. For the rhythm to be classified as monomorphic, the device will evaluate the stability of rhythm features of the most recent QRS complexes such as peak location, amplitude, and R-R interval.

After VT detection is withheld, the ventricular rhythm is continuously evaluated until VT detection occurs or the fast ventricular rate ends.

Notes:

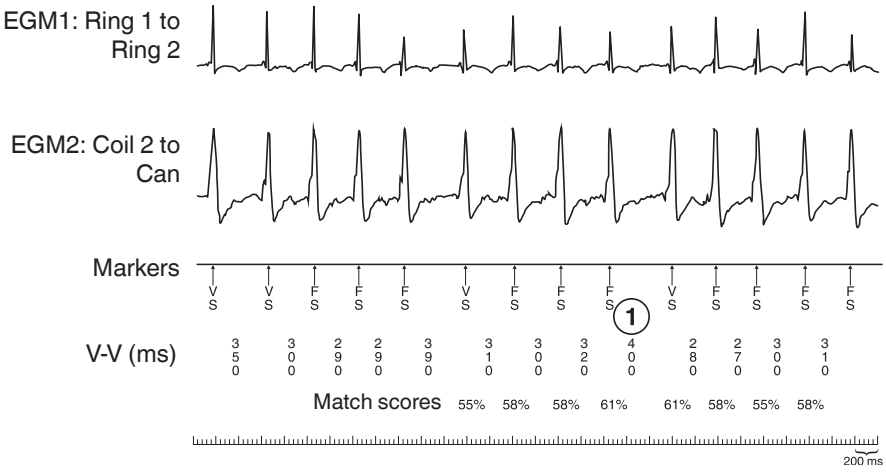
- Wavelet must be programmed to On to program Feature Match to On.
- Feature Match uses the EGM2 channel for comparison.
- Ventricular events that are paced or that have intervals less than 210 ms are automatically classified as “Not Measured.”
- Feature Match applies to initial detection only.

4.4.1.2.2 Operation of Rapid AF

The Rapid AF feature enhances the identification of rapidly-conducted atrial fibrillation (AF), a common reason for the delivery of inappropriate shocks. Rapid AF withholds detection for SVT rhythms conducted into the ventricles faster than the VF zone with the following characteristics:

- A periodically slow R-R interval (i.e., a long pause)
- A fairly good Wavelet match score between the evaluated pair of QRS complexes
- A fairly stable amplitude
- A rhythm that does not meet all of the criteria to be withheld by Wavelet

Figure 18. Rapid AF discrimination



1 Sensed event with an R-R interval longer than the VF detection interval with a fairly stable amplitude and fairly good Match scores.

Among the last 20 beats, if there is at least 1 beat with a detected long pause that meets the Rapid AF criteria, Rapid AF will withhold detection.

After VF detection is withheld, the ventricular rhythm is continuously evaluated until VF detection occurs or the fast ventricular rate ends.

Notes:

- Wavelet must be programmed to On to program Rapid AF to On.
- Ventricular events that are paced or that have intervals less than 210 ms are automatically classified as “Not Measured.”
- Rapid AF applies to initial detection only.

4.4.2 Programming SVT discrimination

Table 5. How to navigate to SVT discrimination parameters

Parameters	Path
Wavelet monitoring parameters: Match Threshold Auto Collection	**Params** > **Detection (V.)…** > **Wavelet…** > **Wavelet** > **Monitor**
Wavelet parameters: Rapid AF Feature Match SVT V. Limit	**Params** > **Detection (V.)…**

Note: SVT discrimination parameters are only accessible on the **V. Detection** window when Wavelet is programmed to On.

Programming an SVT V. Limit – The SVT V. Limit parameter allows you to program the highest rate for which the SVT discriminators will withhold therapies. When the median of the 12 most recent sensed ventricular intervals is shorter than the programmed SVT V. Limit, the SVT discriminator features do not withhold detection and therapy. The SVT V. Limit can be programmed to a value between 210 ms and the longest detection zone interval. The SVT V. Limit cannot be programmed longer than the VT detection interval.

Concomitant pacemaker – Use caution when programming Wavelet, Feature Match, or Rapid AF for patients who have a pacemaker concomitantly implanted. Caution is needed because the ICD cannot distinguish between intrinsic events and paced events from the pacemaker. Program Wavelet to Monitor and evaluate its effectiveness before enabling it for detection. In addition, it is strongly recommended that you disable Auto Collection and collect a template manually with the Wavelet test, making sure that the pacemaker is not pacing the heart during the collection process.

EGM2 Source and Range – It may be necessary to adjust the EGM2 Source and EGM2 Range to optimize SVT discriminator performance.

SVT discriminators are less effective at identifying SVTs and withholding detection in the following situations:

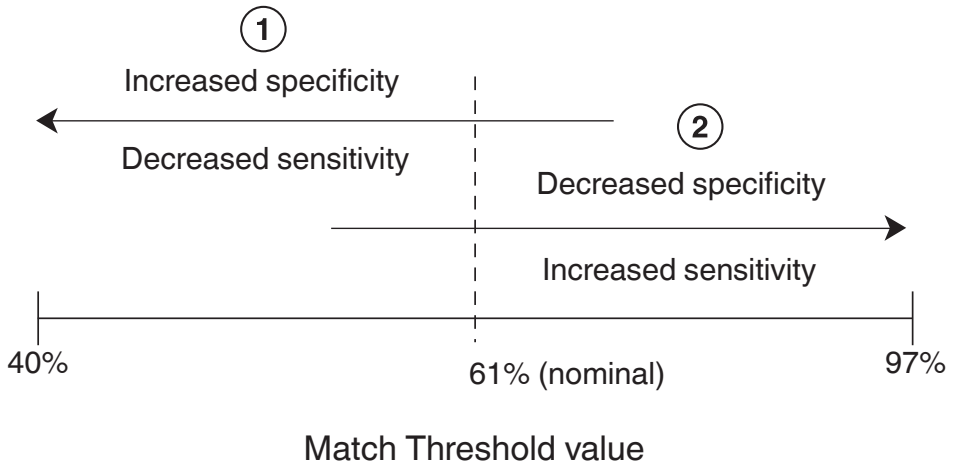
- R-wave amplitudes on the EGM2 signal are too small relative to myopotential interference.
- R-wave amplitudes on the EGM2 signal are so large during intrinsic rhythm or SVT that they exceed the maximum EGM range and are clipped.

You can assess the EGM2 signal using the programmer strip chart recorder or Electronic Strip Chart (eStrip) recorder, whichever is available. If the peak-to-peak R-wave amplitudes on the EGM2 trace are less than 1 mV, consider selecting a different EGM2 source. If the R-wave amplitudes are too large (either clipped or within 1 mV of the EGM2 Range), consider selecting a larger EGM2 Range value. If the R-wave amplitudes are too large at any EGM2 Range, try a different EGM2 Source and assess the R-wave amplitudes starting with an EGM2 Range value of ±8 mV.

Note: When the EGM2 Source or the EGM2 Range is programmed to a different value, the device clears the current template from memory and starts the template creation process.

Match Threshold – Incorrect programming of the Match Threshold may result in inappropriate therapies or delayed detection of tachyarrhythmias. The diagram in *Figure 19* shows the general relationship among Match Threshold, tachyarrhythmia detection, and SVT identification.

Figure 19. Wavelet performance with varying Match Threshold values



1 With a decrease in the Match Threshold value, the device is more likely to withhold detection of rapidly conducted SVTs (increased specificity) but is less likely to detect true VT (decreased sensitivity).

2 With an increase in the Match Threshold value, the device is less likely to withhold detection of rapidly conducted SVTs (decreased specificity) but is more likely to detect true VT (increased sensitivity).

Missing template – If SVT discriminators are enabled but no template is available, detection will occur as if SVT discriminators were disabled until a new template is stored.

4.4.3 Evaluation of SVT discrimination

4.4.3.1 Wavelet Test

You can use the Wavelet Test to evaluate the accuracy of the current Wavelet template and, if necessary, to manually collect an updated template.

For a full description of the Wavelet Test, see the programming guide.

4.4.3.2 Wavelet Monitor

You can use the Wavelet Monitor mode to evaluate the potential effectiveness of Wavelet for the patient without enabling it for detection. When Wavelet has been programmed to Monitor, the device records Wavelet-related data but does not use the Wavelet feature to withhold detection.

4.4.3.3 Arrhythmia Episodes screen

To access stored episode data related to the operation of SVT discrimination, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data**.

4.4.3.3.1 Wavelet episodes

The SVT-Wavelet episode type indicates an episode for which VT/VF detection is withheld due to Wavelet.

In the Decision Channel of the EGM display, ventricular events on which VT/VF detection was withheld by the Wavelet feature are indicated by the annotation “WV”.

4.4.3.3.2 Feature Match episodes

The SVT-FeatureMatch episode type indicates an episode for which VT/VF detection is withheld due to Feature Match.

In the Decision Channel of the EGM display, ventricular events on which VT/VF detection was withheld by the Feature Match feature are indicated by the annotation “FM”.

4.4.3.3.3 Rapid AF episodes

The SVT-RapidAF episode type indicates an episode for which VT/VF detection is withheld due to Rapid AF.

In the Decision Channel of the EGM display, ventricular events on which VT/VF detection was withheld by the Rapid AF feature are indicated by the annotation“RA”.

4.4.3.4 QRS complex match scores

QRS Snapshot data shows the template match scores for the QRS complexes recorded during an episode. To view the QRS complex match scores for an episode, select the QRS view for the episode on the **Arrhythmia Episodes** screen.

Note: Wavelet must be programmed to On or Monitor to collect QRS Snapshot data.

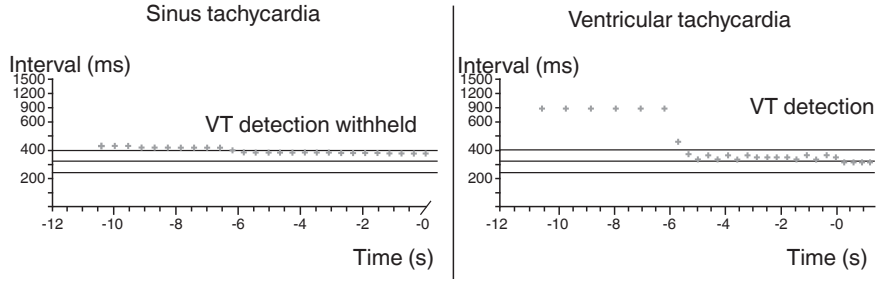
4.5 Onset

Patients experiencing sinus tachycardia can exhibit ventricular rates in the VT detection zone. If sustained, such fast ventricular rates can cause an inappropriate delivery of a ventricular tachyarrhythmia therapy. Sinus tachycardia can generally be distinguished from ventricular tachycardia by the speed of the ventricular rate increase. Typically, sinus tachycardia is characterized by a gradual ventricular rate increase, while ventricular tachycardia exhibits a sudden ventricular rate increase.

The Onset feature can help prevent detection of sinus tachycardia as VT by evaluating the acceleration of the ventricular rate. If the ventricular rate increases gradually, as typically happens during sinus tachycardia, the device does not classify sensed ventricular events that occur in the VT detection zone as VT events. If the ventricular rate increases rapidly, as typically happens during a ventricular tachycardia episode, the device does classify sensed ventricular events that occur in the VT detection zone as VT events.

4.5.1 Operation of the Onset feature

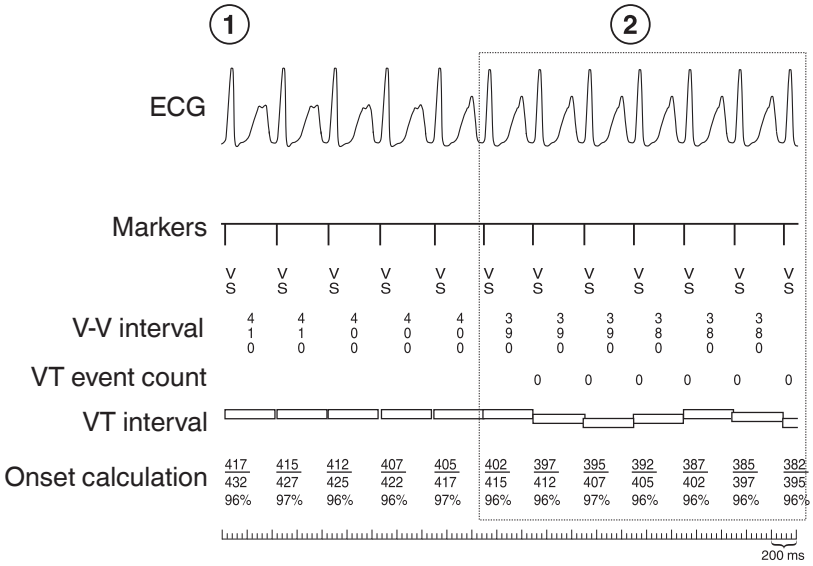
Figure 20. Gradual vs sudden rate acceleration



A programmable Onset Percent value is used to evaluate the suddenness or gradualness of the change in average cycle length from one set of 4 intervals to the next. If you program the Onset Percent value lower, a larger rate acceleration is required for the device to detect VT. If you program the Onset Percent value higher, a smaller rate acceleration is required for the device to detect VT.

If the ventricular rate accelerates gradually, as shown in *Figure 21*, then the Onset feature prevents sensed ventricular intervals that occur in the VT detection zone from being classified as VT events.

Figure 21. Operation of Onset during a gradually accelerating ventricular rate

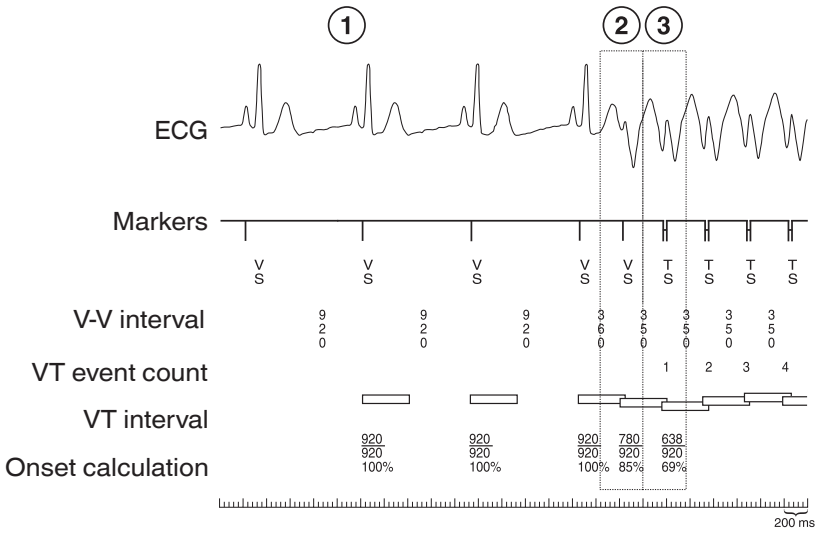


1 The ventricular rate is accelerating (interval cycle lengths are decreasing).

2 The ventricular rate is now in the VT detection zone, but the acceleration is gradual. The average cycle length of any set of 4 intervals is never 81% or less of the previous set of 4 intervals. (81% is the Onset Percent value in this example.)

If the ventricular rate accelerates rapidly, as shown in *Figure 22*, then the Onset feature permits sensed ventricular intervals that occur in the VT detection zone to be classified as VT events.

Figure 22. Operation of Onset during a rapidly accelerating ventricular rate



1 The ventricular rate is slow and steady.

2 The ventricular rate increases suddenly, with the first interval occurring in the VT detection zone. However, because the average ventricular interval is 85% of the average of the previous 4 intervals (slower than the programmed Onset Percent of 81%), this interval is not classified as a VT event.

3 The average ventricular interval is now 69% of the average of the previous 4 intervals (faster than the programmed Onset Percent of 81%), so this interval is classified as a VT event.

4.5.1.1 VT Monitor events and the Onset feature

The Onset feature applies to both VT detection and VT monitoring.

4.5.1.2 Ensuring appropriate detection of VT and VF events

Continuing arrhythmia episodes – The Onset feature does not affect redetection of ventricular tachyarrhythmias. If a VT, FVT, or VF episode is detected, the Onset feature is suspended until the episode ends.

VF detection – The Onset feature does not affect VF detection. The Onset feature can prevent sensed ventricular events in the VT detection zone from being classified as VT events, and therefore it affects VT detection and Combined Count detection.

4.5.2 Programming the Onset feature

To access Onset parameters, tap **Params** > **Detection (V.)…** > **Onset…**.

Exercise-induced VT episodes – Onset may delay detection of true VT in patients who experience exercise-induced ventricular tachycardia episodes.

Decreased VT detection sensitivity – With lower settings for the Onset Percent value, the device is less likely to inappropriately detect sinus tachycardia episodes as ventricular tachycardia. However, there may be a reduced likelihood of detecting true ventricular tachycardia.

4.5.3 Evaluation of the Onset feature

The **Arrhythmia Episodes** screen and the Onset Monitor option may help you assess the performance of the Onset feature.

4.5.3.1 Arrhythmia Episodes screen

To access Arrhythmia Episodes EGM data, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data** > **EGM**.

Notes:

- The SVT-Onset episode type indicates an episode for which VT/VF detection is withheld.
- In the Decision Channel of the EGM display, ventricular events on which VT detection was withheld by the Onset feature are indicated by the annotation “Reset: Onset”.

4.5.3.2 Onset Monitor option

You can use the Monitor setting to test the potential effectiveness of the Onset feature for the patient without programming it to On.

When the Onset feature is set to Monitor, the device performs all of the calculations associated with the Onset feature, but the calculations do not affect the classification of VT intervals. If the device detects a VT episode for which detection would have been withheld if the Onset feature had been programmed to On, the episode is noted in the episode text.

4.6 Stability

Atrial fibrillation can cause a patient's ventricular rate to accelerate into the VT detection zone, possibly triggering an inappropriate delivery of a ventricular tachyarrhythmia therapy. Atrial fibrillation is typically associated with a fast and irregular (unstable) ventricular rate. True ventricular tachycardia is typically fast but regular (stable).

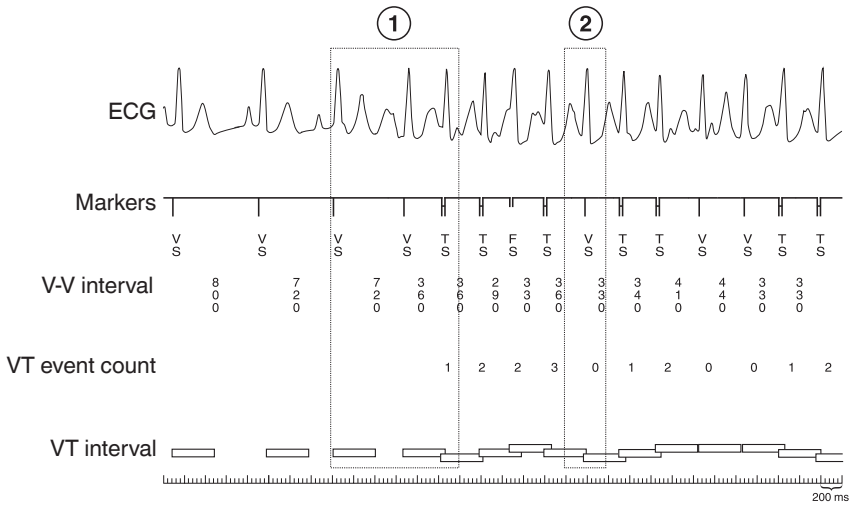
The Stability feature can help prevent detection of atrial fibrillation as ventricular tachyarrhythmia by evaluating the stability of the ventricular rate. When the device determines that the ventricular rate is not stable, it does not classify ventricular intervals as VT events, even if they occur in the VT detection zone.

4.6.1 Operation of the Stability feature

The Stability feature is applied when the device has counted at least 3 consecutive VT events. The device classifies an interval as unstable if the difference between it and any of the 3 previous intervals is greater than the programmed Stability interval. If the device classifies an interval as unstable, the system marks it as a sensed ventricular event and resets the VT event count to zero.

Note: The Stability feature operates throughout initial detection and redetection of VT.

Figure 23. Operation of Stability during atrial fibrillation



1 Atrial fibrillation starts and is conducted into the ventricle at a rapid rate.

2 After 3 VT events, the device applies the Stability feature. Because the 360 ms interval differs from the 290 ms interval by more than the programmed Stability interval (50 ms, in this case), the device resets the VT event count.

4.6.1.1 Stability criterion for VT Monitor events

The VT Monitor zone has a non-programmable stability criterion that can reset the VT Monitor event count, but it does so independently from the VT event count. The VT Monitor event count must be at least 3 before this stability criterion is applied to events in the VT Monitor zone. Note that no data is recorded for this operation.

4.6.2 Programming the Stability feature

To access the Stability feature, tap **Params** > **Detection (V.)…**.

Stability interval – A small Stability value may not allow for normal VT interval variation and may decrease the sensitivity of the device to detect ventricular tachycardia.

4.6.3 Evaluation of the Stability feature

To access Arrhythmia Episodes EGM data that can help you assess the performance of the Stability feature, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data**.

Notes:

- The SVT-Stability episode type indicates an episode for which VT/VF detection is withheld.
- In the Decision Channel of the EGM display, ventricular events on which detection was withheld by the Stability feature are indicated by the annotation “Reset: Stability”.

4.7 High Rate Timeout

The SVT discrimination features (Wavelet, Feature Match, Rapid AF, Onset, and Stability) are designed to withhold detection and therapy for ventricular rates classified by the device as having a supraventricular origin. For some patients, there may be a need to override the SVT discrimination features and allow therapy to be delivered when a ventricular tachyarrhythmia continues beyond a programmed length of time. For some patients, there may be a need for a separate SVT discrimination override for arrhythmias in the VF zone.

The High Rate Timeout feature allows the device to deliver therapy for any ventricular tachyarrhythmia that continues beyond a programmed length of time.

4.7.1 Operation of High Rate Timeout

You can program separate timeout periods for All Zones and for the VF Zone Only.

All Zones – The device starts the programmed High Rate Timeout period when VF, FVT, or VT detection occurs or is withheld by an SVT discrimination feature. If the tachyarrhythmia continues beyond the programmed timeout period, the device suspends all SVT discrimination features and allows the device to deliver therapy.

VF Zone Only – The device starts the programmed High Rate Timeout period when VF or FVT detection occurs or is withheld by an SVT discrimination feature. If the tachyarrhythmia continues beyond the programmed timeout period, the device suspends all SVT discrimination features and allows the device to deliver therapy.

Notes:

- When a VF Zone Only timeout occurs and the tachyarrhythmia leaves the VF zone before the timeout period expires, the timeout period is reset. If the tachyarrhythmia reenters the VF zone, the timeout starts over from the beginning.
- If, during either High Rate Timeout period, the device determines that the SVT discrimination feature no longer applies, detection occurs and therapy is delivered, regardless of the High Rate Timeout feature.
- High Rate Timeout is not applied to rates in the VT Monitor zone.

4.7.2 Programming High Rate Timeout

Table 6. How to navigate to High Rate Timeout parameters

Parameters	Path
High Rate Timeout parameters: VF Zone Only All Zones	**Params** > **Detection (V.)…** > **High Rate Timeout…**

Programming both High Rate Timeout periods – If both timeout periods are programmed, the shorter timeout is applied first. The VF Zone Only timeout would normally be programmed with the shorter duration.

High Rate Timeout and inappropriate therapies – After the programmed High Rate Timeout period elapses and the SVT discrimination features are suspended, it is possible that the device may detect a ventricular tachyarrhythmia that is actually a conducted SVT. If so, inappropriate tachyarrhythmia therapy may be delivered.

4.7.3 Evaluation of High Rate Timeout

4.7.3.1 Arrhythmia Episodes screen

High Rate Timeout information is located on the **Arrhythmia Episodes** screen.

When viewing an Arrhythmia Episode in EGM view, the stored EGM for that episode includes an “HT” annotation in the Decision Channel at the point when the High Rate Timeout period expired if a High Rate Timeout period expires during the episode.

When viewing an Arrhythmia Episode in Text view, the Initial Type field in the episode text includes the text High Rate Timeout–All Zones if the High Rate Timeout–All Zones period expires during the episode.

If the High Rate Timeout–VF Zone Only period expires during an episode, the Initial Type field in the episode text includes the text High Rate Timeout–VF Zone Only.

4.8 TWave Discrimination

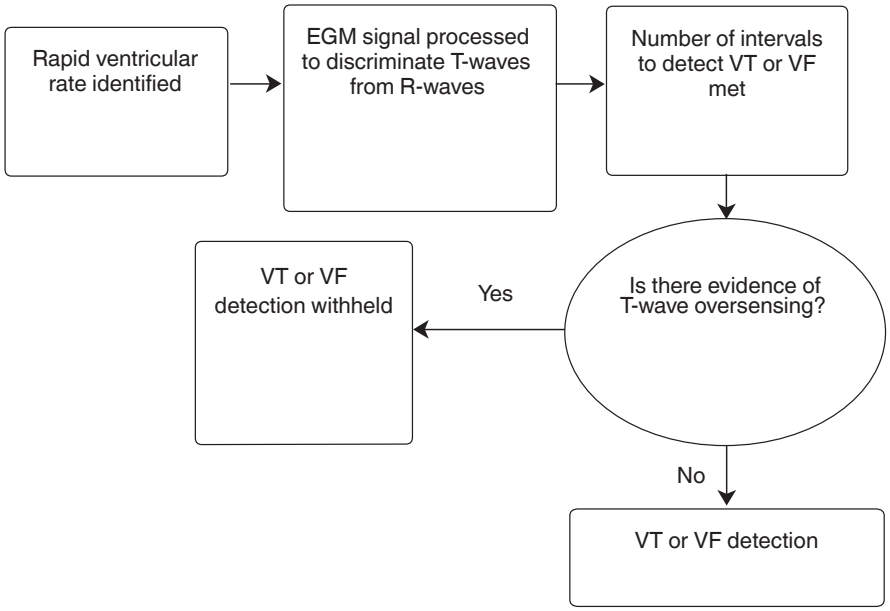
T-wave oversensing occurs when a device senses T-waves in addition to R-waves. This double-counting of ventricular events can push the ventricular rate into the VT/VF zone, leading to incorrect detection of VT or VF and delivery of inappropriate therapy.

When VT or VF is suspected, TWave Discrimination processes the sensed signal and the EGM2 signal to determine if both R-waves and T-waves are being sensed. If both waves are sensed, detection is withheld. If only fast R-waves are sensed, VT or VF detection occurs.

4.8.1 Operation of TWave Discrimination

The TWave Discrimination feature withholds VT/VF detection when a fast ventricular rate is detected due to oversensed T-waves. The feature operates on the assumption that R-waves and T-waves are clinically different, where R-waves generally have a higher slew rate (higher frequency) than T-waves and where R-waves match the Wavelet template better than T-waves. Also, when T-wave oversensing is present, R- and T-waves alternate, allowing the feature to recognize the 2 waves effectively.

Figure 24. Overview of TWave Discrimination



The TWave Discrimination feature has 2 components:

1. Wavelet-based analysis
2. Sensed pattern and frequency-based analysis

If either component determines that T-wave oversensing is present, detection is withheld.

Wavelet-based analysis – The Wavelet-based analysis uses the EGM2 signal to find R-T wave or T-R wave pairs based on the fact that R-waves should have high Wavelet match scores, but T-waves should match the template poorly. The Wavelet match threshold used for TWave Discrimination is a modified value of the Wavelet Match Threshold. The T-wave oversensing pattern is further confirmed by differences in differential sensed signal amplitude between beat pairs of sensed events.

Sensed pattern and frequency-based analysis – The sensed pattern and frequency-based analysis uses the sensing signal to identify T-waves by processing the EGM to highlight differences in frequency between R-waves and T-waves. It analyzes differences in amplitude, rate, and pattern to differentiate R-waves from T-waves. It then applies additional criteria to distinguish R and T patterns from VT/VF. This analysis reduces the potential to deliver inappropriate therapy for high rates that are attributable to T-wave oversensing, yet it does not compromise sensitivity to VT/VF detection.

Notes:

- TWave Discrimination using Wavelet-based analysis is performed for intervals greater than or equal to 210 ms. For intervals less than 210 ms, only sensed pattern and frequency-based analysis is applied.
- If Wavelet is programmed to Off or Monitor, TWave Discrimination using Wavelet-based analysis will not be performed.
- TWave Discrimination using Wavelet-based analysis is only applied on initial detection and will not be performed on redetection.
- TWave Discrimination using the sensed pattern and frequency-based analysis is applied both on initial detection and on redetection.

4.8.2 Programming TWave Discrimination

To access TWave Discrimination, tap **Params** > **Detection (V.)…**.

VT and VF redetection – If the programmed VT Redetect is less than 12 and VF Redetect values are less than 12/16, TWave Discrimination may not have enough data to distinguish T-waves from R-waves.

TWave Discrimination uses the Wavelet settings for the Wavelet-based analysis. For more information, see *Section 4.4.1*.

4.8.3 Evaluation of TWave Discrimination

The device stores T-wave oversensing episodes in the V. Oversensing T-wave log. The episode contains the interval plot, EGM detail, episode text, and QRS snapshots. The date, time, duration, and average ventricular rate, including T-wave oversensing, are also recorded.

4.8.3.1 Episode plot

To access Arrhythmia Episodes plots, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data** > **Plot**.

Episode Plots showing a T-wave oversensing episode are labeled as V. Oversensing-TWave.

4.8.3.2 Episode EGM

To access Arrhythmia Episodes EGM data, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data** > **EGM**.

In the EGM view, the annotation “TW” is displayed in the Decision Channel when the TWave Discrimination feature withholds VT/VF detection. This annotation appears upon the initial detection of T-wave oversensing and indicates T-wave oversensing on a per-event basis.

The Marker Channel shows each ventricular event is counted twice when T-wave oversensing occurs.

4.8.3.3 Episode text

To access Arrhythmia Episodes text, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data** > **Text**.

For T-wave oversensing episodes, the Text view lists the following types of information:

- Episode Summary for V. Oversensing-TWave including:

– Duration

– V. Max Rate

– V. Median rate

- List of other detection criteria triggered (Other Criteria Triggered) for this episode and programmed values for all other detection features
- Description of Wavelet activity, if triggered
- Programmed values for VF, FVT, and VT detection and redetection at time of episode
- Status of SVT discrimination features at time of episode

4.8.3.4 Quick Look II observations

Ventricular oversensing episodes since the last session are listed in Observations on the **Quick Look II** screen. To check the Quick Look II Observations list to verify T-wave oversensing episodes, tap **Data** > **Quick Look II**.

For detailed information about viewing and interpreting all of the information available from the **Quick Look II** screen, see *Section 3.1, Quick Look II summary data, page 18*.

4.9 Noise Discrimination

Noise oversensing is caused by sensing of both cardiac events and sensing of non-cardiac events such as electromagnetic interference (EMI), electrical activity in the muscle, or sensing artifacts. If the oversensing is not identified, it may cause the device to sense non-cardiac noise or cardiac oversenses (such as P-waves) as rapid ventricular events. If the oversensing is sustained, such rapid ventricular rates may cause inappropriate delivery of a ventricular tachyarrhythmia therapy.

The device has 3 types of noise discrimination: Smart Sense Noise Discrimination, Morphology Noise Discrimination, and Sensed EMI Noise Discrimination.

4.9.1 Operation of Smart Sense Noise Discrimination

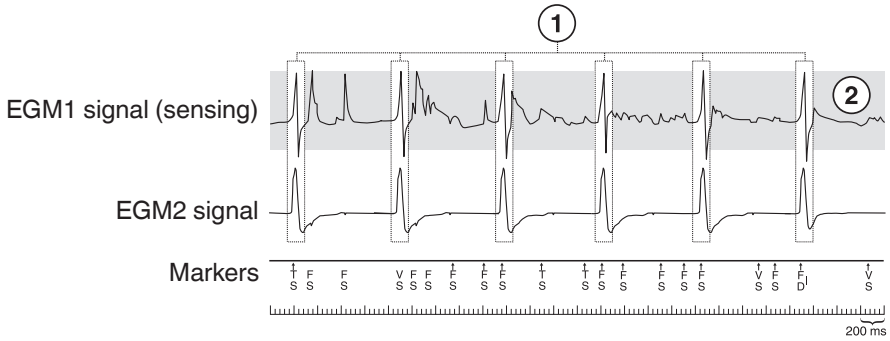
The Smart Sense Noise Discrimination feature compares the EGM2 signal to the sensing signal to differentiate noise from VT/VF. The feature also examines the EGM2 signal to look for evidence of P-waves. If noise or P-waves are identified in the EGM2 signal, VT/VF detection and therapy are withheld.

4.9.1.1 Discrimination of noise oversensing

When VT or VF is suspected, the device compares the sense signal to the EGM2 signal. When there is no noise oversensing, these signals match. If the sense signal shows persistent activity in the VT/VF zone that is not shown on the EGM2 signal, noise on the sense channel is determined and therapy for VT/VF is withheld.

Note: Smart Sense Noise Discrimination is applied only to initial detection.

Figure 25. Smart Sense Noise Discrimination



1 True events are seen simultaneously by the sensing and EGM2 signals.

2 Noise (shaded area) is indicated by activity on the sensing signal only.

In *Figure 25*, noise is identified on the sensing signal when compared to the EGM2 signal, which remains at baseline.

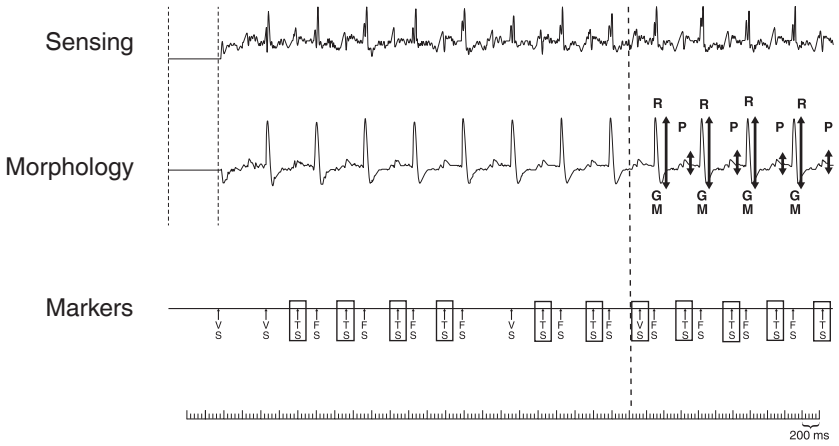
4.9.1.2 Discrimination of P-wave oversensing

When VT or VF is suspected, the device examines the EGM2 signal to detect the presence of P-waves by comparing the amplitudes of alternating sensed events. Normal sinus R-waves will exhibit amplitude stability when measured over a relatively short time interval. Similarly, P-waves will also exhibit amplitude stability. In addition to amplitude stability, P-waves also tend to have lower amplitudes than R-waves.

The Smart Sense Noise Discrimination feature also looks for a continual pattern of low-amplitude followed by high-amplitude signals indicating the presence of alternating P-waves and R-waves. The feature also examines the R-wave EGM2 signal to confirm a morphology dissimilar to VT/VF, as well as a narrow QRS complex.

If the sense signal shows alternating P-waves and R-waves, stable amplitude for P-waves and R-waves, and QRS morphology similar to normal sinus rhythm, P-wave oversensing on the sense channel is determined and therapy for VT/VF is withheld.

Figure 26. Smart Sense — P-wave Oversensing



In *Figure 26*, P-wave oversense events are denoted with a box in the Markers strip. P-wave oversensing is identified on the sensing signal and VT/VF therapy is withheld.

4.9.2 Morphology Noise Discrimination

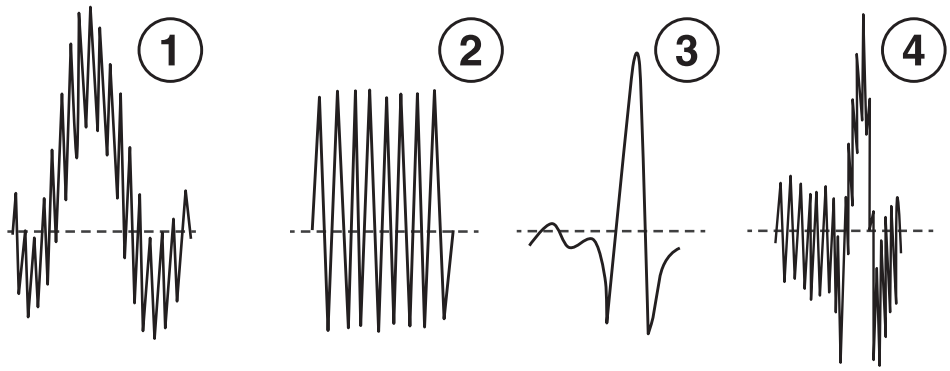
The Morphology Noise Discrimination feature uses the EGM2 signal to differentiate noise oversensing from VT/VF. If noise is identified and confirmed by the morphology of the EGM2 channel, VT/VF detection and therapy are withheld.

4.9.2.1 Operation of the Morphology Noise Discrimination feature

When VT or VF is suspected, the device evaluates the EGM2 signal to determine the level of noise on the signal and how similar the signal is to the typical VF rhythm morphology. If the EGM2 signal is noisy and the morphology is sufficiently dissimilar from VF, presence of noise is determined and therapy for VT/VF is withheld. If the device determines that the morphology of the EGM2 signal is indicative of VF and the EGM2 signal is not noisy, the device allows detection and delivery of therapy.

Note: Morphology Noise Discrimination is applied on initial detection only.

Figure 27. Morphology Noise discrimination



1 Beat not classified as noisy because the EGM2 morphology is similar to VF.
2 Beat classified as noisy because it is dissimilar from VF.
3 Beat not classified as noisy because of insufficient noise levels on EGM2.
4 Beat classified as noisy because it is dissimilar from VF.

4.9.3 Sensed EMI Noise Discrimination

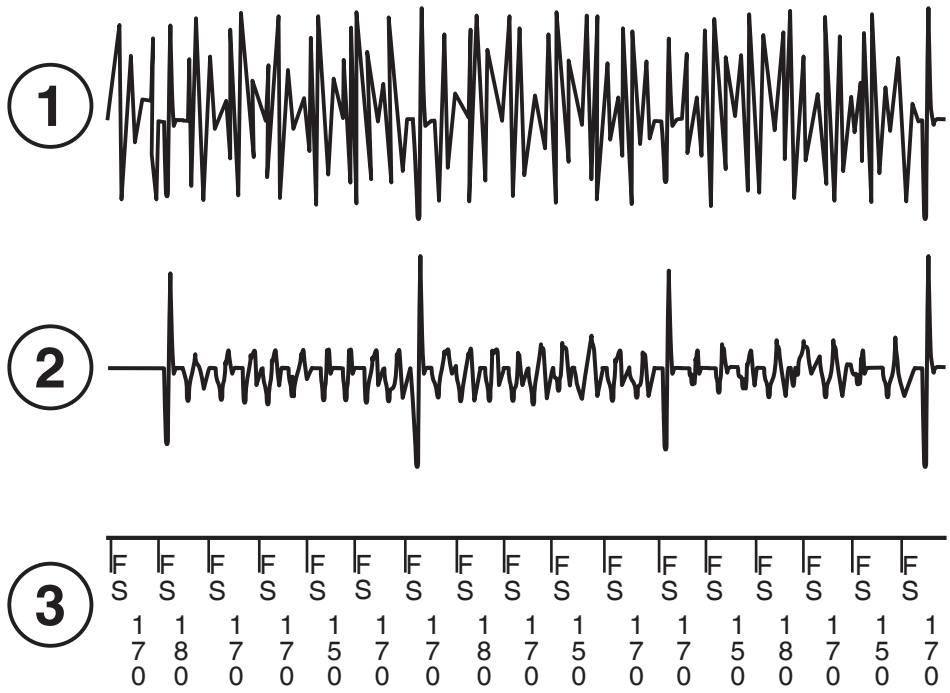
The Sensed EMI Discrimination feature differentiates high-frequency EMI noise oversensing from VT/VF. If EMI noise is identified, VT/VF detection and therapy are withheld.

4.9.3.1 Operation of the Sensed EMI Noise Discrimination feature

When VT or VF is suspected, the device evaluates the sense signal for presence of sustained high-frequency noise. If high-frequency noise is detected on the sense channel and the EGM2 morphology is sufficiently dissimilar from VF, the signal is classified as EMI noise and VT/VF therapy is withheld. If the high-frequency signal on the sense channel is not consistent or the morphology of EGM2 signal is indicative of VF, the device allows detection and delivery of therapy.

Note: Sensed EMI Noise Discrimination is applied on initial detection only.

Figure 28. Sensed EMI noise discrimination



1 EGM 1 signal (sensing)
2 EGM2 signal
3 Marker Channel

4.9.4 Programming the Noise Discrimination features

To access Noise Discrimination parameters, tap **Params** > **Detection (V.)…** > **Noise…**. Select **Smart Sense**, **Morphology Noise**, or **Sensed EMI** to access the parameters for a particular Noise Discrimination feature.

4.9.4.1 Shared Noise timeout

The Noise Discrimination features provide a programmable Shared Noise Timeout interval. During a noise event, the device withholds therapy for the duration of this interval. If the noise event persists longer than the programmed interval, therapy is delivered. The timeout interval ranges from 15 s to 4 min with an option to disable the timeout by turning it off.

4.9.5 Evaluation of Noise events

If the programmer indicates that a Noise oversensing event has occurred, evaluate the diagnostic data.

Note: The device records noise oversensing episode summaries for a particular type of noise discrimination only if that noise discrimination feature is programmed to On.

4.9.5.1 Quick Look II observations

To check the Quick Look II Observations list to verify that there is a Noise observation, tap **Data** > **Quick Look II**.

For detailed information about viewing and interpreting all of the information available from the **Quick Look II** screen, see *Section 3.1, Quick Look II summary data, page 18*.

4.9.5.2 Episode plot

To access the episode plots for stored noise episodes and arrhythmia episodes, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data** > **Plot**.

Episode Plots showing a noise episode are labeled as V. Oversensing-Noise.

Episode Plots showing the point a VF Count reset has occurred will show the annotation R##, where ## represents the value of the VF Count at the time of the reset.

4.9.5.3 Episode EGM

To access the EGM data for stored noise episodes, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data** > **EGM**.

The Decision Channel displays when the feature withholds ventricular tachyarrhythmia detection. The following annotations are used for each type of Noise Discriminator:

- The annotation “N” indicates Smart Sense Noise discrimination
- The annotation “NM” indicates Morphology Noise discrimination
- The annotation “NE” indicates EMI Noise discrimination
- The annotation “NT” is displayed when the Shared Noise Timeout period has expired
- The annotation “R##” is displayed when a VF Count reset has occurred. The ## represents VF Count at the time of the reset.

4.9.5.4 Episode text

To access the text for stored noise episodes, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data** > **Text**.

For noise oversensing episodes, the episode text screen offers the following types of information:

- Episode summary for V. Oversensing-Noise including:
  - Initial Type
  - Duration
  - V. Max Rate
  - V. Median rate
- List of other detection criteria triggered for this episode
- Description of Wavelet activity, if Wavelet is enabled
- Programmed values for VF, FVT, and VT detection and redetection at time of the episode
- Status (On/Off) of SVT discrimination features at the time of episode

To access the text for non-sustained VT episodes, tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data** > **Text**.

For non-sustained VT episodes, the episode text screen offers the following types of information:

- Episode summary for non-sustained VT including:
  - Initial Type
  - Duration
  - V. Median rate
  - VF Count at time of termination
- List of sensing criteria triggered for this episode
- Programmed values for VF, VT, and Monitor at time of the episode
- Status (On/Off) of VF, FVT, VT and Monitor at the time of episode

4.10 VF Count reset

The device will monitor events that accumulate counts toward initial detection and that occur prior to therapy delivery to discriminate events that are not cardiac in nature. The device will determine if 2 out of 8 beats meet the rate and morphology criteria that represent normal sinus rhythm. If these conditions are met, the detect counts will be reset to 3. The VF Count reset feature is automatically enabled if the Feature Match, Morphology Noise, and Wavelet features are enabled.

5 Tachyarrhythmia therapy features

5.1 VF therapies

Ventricular fibrillation (VF) is recognized by the presence of a grossly irregular ventricular rhythm. VF is life-threatening if it is not treated promptly with defibrillation therapy.

The device can respond to ventricular tachyarrhythmia episodes detected in the VF zone (VF episodes) by delivering defibrillation therapy to the patient's heart. The defibrillation therapy is intended to stop the episode by simultaneously depolarizing the heart tissue and restoring the patient's normal sinus rhythm.

For more information, see *Section 4.3*.

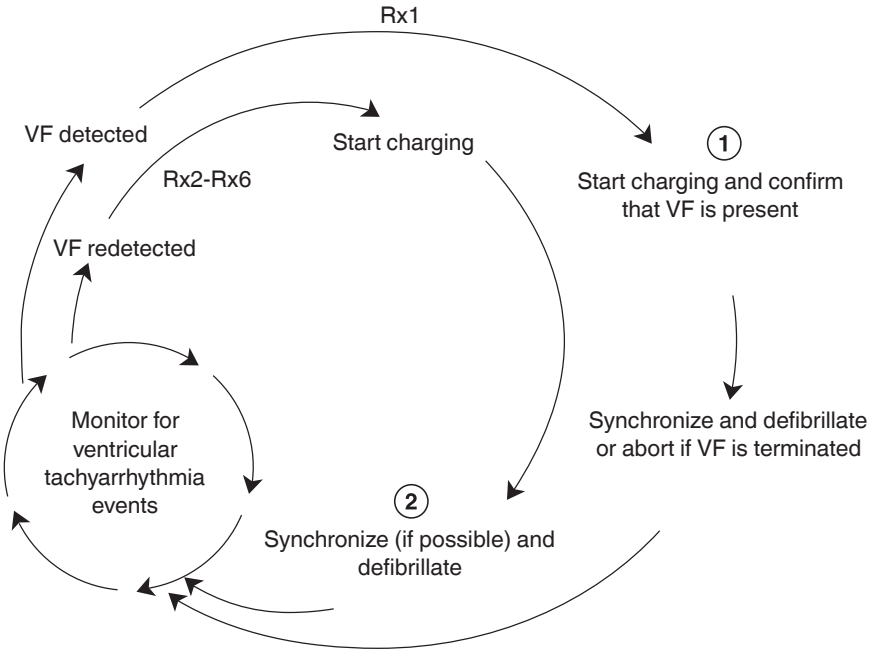
5.1.1 Operation of VF therapies

The device can be programmed to deliver a sequence of up to 6 therapies to treat VF episodes, each with specific energy and pathway settings. If the first therapy (labeled Rx1) is successful in ending the episode, the device continues monitoring for subsequent VF episodes. If the device redetects the VF episode after the first therapy delivery, it delivers the second VF therapy (labeled Rx2). It continues this process until either the episode ends or the last programmed therapy has been delivered. If therapy is successful, the device continues monitoring for subsequent VF episodes.

During charging for Rx1, the device attempts to confirm the continued presence of VF before delivering the shock. If the VF has stopped spontaneously, the device cancels the therapy and resumes monitoring.

If the VF episode resumes, the device redetects. This process continues until the VF episode ends, whether spontaneously or through device intervention.

Figure 29. Overview of VF therapies



1 The device confirms that VF is present prior to delivery of VF Rx1.

2 The device attempts to synchronize defibrillation to a ventricular event. If this is not possible, it delivers defibrillation asynchronously.

5.1.1.1 Delivering high-voltage therapies

To deliver a defibrillation therapy, the device must first charge its high-voltage capacitors to the programmed energy level. The length of time required to charge the capacitors depends on the programmed energy level and battery depletion. The delivered energy level is programmed independently for each defibrillation therapy. Defibrillation pulses use a biphasic waveform in which the current pathway for the high-voltage pulse is reversed midway through the pulse delivery.

For information about typical full-energy capacitor charging periods and a comparison of delivered and stored energy levels, see the device manual for the specific device.

5.1.1.2 Selecting the high-voltage current pathway

The Pathway parameter specifies the direction of current flow for defibrillation and cardioversion pulses.

The settings for the Pathway parameter are STD and REV. The Pathway setting defines direction of current flow during the initial segment of the biphasic waveform. If the parameter is set to STD, current flows from the Coils to the Can. If the parameter is set to REV, this current flow is reversed and current flows from the Can to the Coils.

Warning: REV (Can to Coils) pathway is not recommended for this device. Devices programmed in the REV pathway may experience sub-therapeutic energy (reduced or no energy) delivery during high-voltage therapy in the presence of an unintended current pathway (a short circuit). Refer to *Section 5.4*.

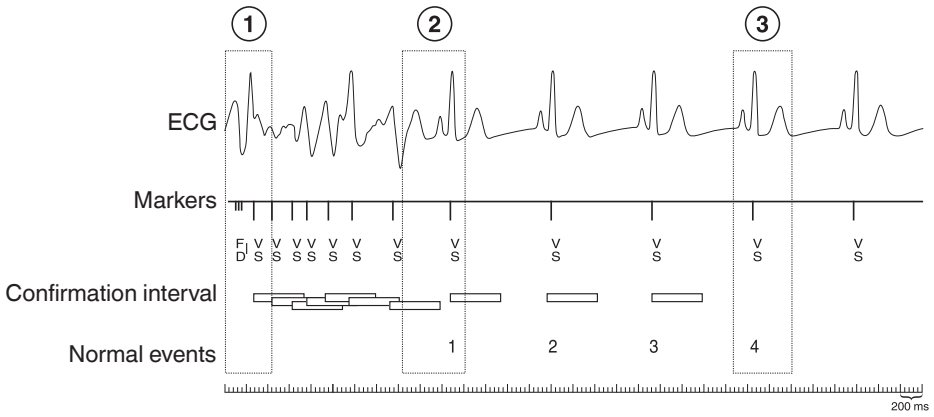
5.1.1.3 Confirming VF for the first defibrillation

Before the device delivers the first defibrillation shock for a VF episode, it monitors cardiac rhythm to confirm the presence of VF. VF is confirmed using a confirmation interval calculated from the ventricular cycle length + 60 ms, if this interval is at least as long as the programmed VF detection interval.

The device classifies any ventricular event that occurs within the confirmation interval as an “arrhythmic event” and any event that occurs outside the interval as a “normal event”.

With each ventricular event, the device reviews the previous 5 ventricular events. If the previous 5 ventricular events include 4 “normal events”, the device aborts the therapy.

Figure 30. Example of an aborted defibrillation therapy



1 The device detects VF, starts charging, and begins to confirm the tachyarrhythmia using the confirmation interval.

2 The VF spontaneously ends, and normal sinus rhythm resumes.

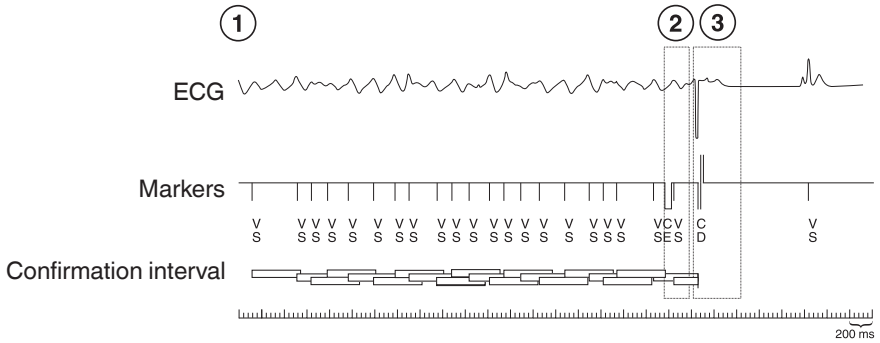
3 When 4 of the last 5 events are “normal events”, the device aborts the therapy and stops charging its capacitors.

5.1.1.4 Synchronizing the initial defibrillation therapy

After charging is complete, the device continues to confirm the presence of VF. If VF persists after charging ends and 1 ventricular tachyarrhythmic event has been sensed, the device attempts to synchronize the defibrillation therapy to the next ventricular tachyarrhythmic event that is outside the refractory period.

The device continues to attempt to synchronize until it delivers the defibrillation therapy or it fails to confirm the presence of VF and aborts the therapy.

Figure 31. Synchronous delivery of defibrillation



1 The device has detected VF. It charges its capacitors for defibrillation and confirms VF using the confirmation interval.

2 The device completes charging and starts synchronization while continuing VF confirmation.

3 On the second tachyarrhythmic event after charging, the device delivers the defibrillation therapy.

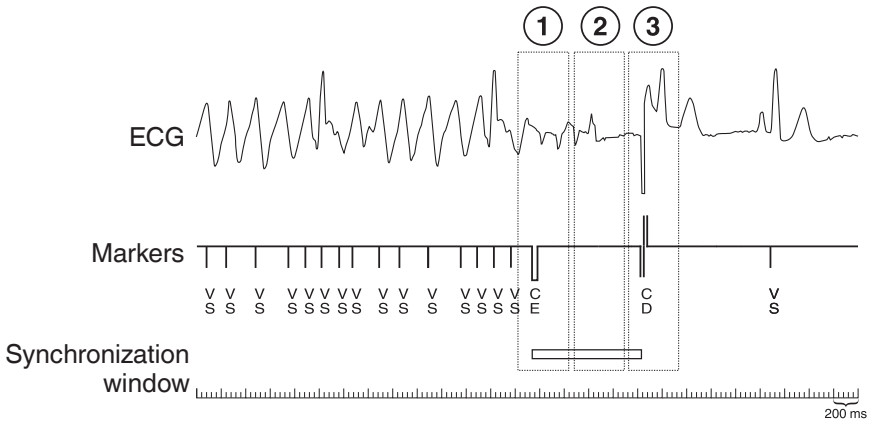
5.1.1.5 Synchronizing subsequent defibrillation therapies

If the first defibrillation therapy fails to end a VF episode, the device attempts to synchronize each subsequent defibrillation therapy to a sensed ventricular event. If synchronization is not possible, the device delivers the defibrillation therapy asynchronously.

Once the capacitors are charged to the programmed energy, the device starts a 900 ms synchronization window. If a qualified sensed ventricular event occurs during this window, the device delivers the defibrillation therapy synchronized to the event. Otherwise, the device delivers the therapy asynchronously after 900 ms (see *Figure 32*).

Any sensed ventricular event qualifies for therapy delivery unless it occurs in the refractory period. If an event occurs in the refractory period, the device continues to attempt to synchronize.

Figure 32. Asynchronous delivery of defibrillation



1 After redetecting VF, the device completes charging and starts a 900 ms synchronization window.

2 Several low-amplitude VF events go unsensed.

3 After 900 ms, the device delivers the defibrillation therapy asynchronously.

5.1.1.6 Device operation during and after a defibrillation therapy

After the defibrillation therapy is delivered, the device monitors for the end of the episode or redetection. The device suspends VT detection and Combined Count detection for 17 events following a defibrillation therapy that is delivered in response to a detected VF. Suspending VT detection helps avoid detecting transient VTs that can follow high-voltage therapies. For information about Combined Count detection, see *Section 4.3*.

Immediately after delivering the shock, the device starts a post-shock blanking period of 520 ms.

After the post-shock blanking period, the device resumes operation in the programmed pacing mode. If Post Shock Pacing is programmed to On, the Post Shock Pacing parameters are applied. For more information, see *Section 6.2*.

5.1.1.7 Device operation after an aborted defibrillation therapy

If the device aborts a defibrillation therapy, it resumes monitoring for ventricular tachyarrhythmias after the next sensed ventricular event. If VF is redetected before the episode ends, the first programmed defibrillation therapy that was aborted (Rx1) is reconfirmed and synchronized prior to delivery. If VF persists, Rx2 through Rx6 is delivered as needed without synchronization or confirmation. If the episode ends at any time, the device resumes monitoring.

Note: If the device aborts the defibrillation therapy leaving energy stored on the capacitors, the delivered energy of the next high-voltage therapy may be higher than the programmed value.

5.1.2 Programming VF therapies

Table 7. How to navigate to VF therapies parameters

Parameters	Path
VF Therapies parameters (Rx1 through Rx6): VF Therapy Status Energy Pathway	**Params** > **VF Therapies…**

Energy – Programming VF therapies to the maximum energy level is recommended.

Energy level availability – Energy levels below 10 J are available for VF therapies Rx1 and Rx2. For VF therapies Rx3–Rx6, the energy level cannot be programmed below 10 J. Likewise, a VF therapy cannot be followed by another VF therapy that has a lower energy setting.

VT and FVT therapies – VT and FVT therapies cannot be programmed to On unless at least one VF therapy is also programmed to On.

5.1.3 Evaluation of VF therapies

5.1.3.1 The Quick Look II screen

To access **Quick Look II** screen information about VT/VF therapies, tap **Data** > **Quick Look II**.

Treated VT/VF episodes – This section includes a count of treated VT/VF episodes. You can tap the ⏭ button next to Treated to view data for the treated episodes.

Quick Look II observations – The Quick Look II observations are based on an analysis of interrogated data since the last session and programmed parameters. If related information about an observation is available, you can select the observation and then tap the ⏭ button next to Observations to view the related information.

For detailed information about viewing and interpreting all of the information available from the **Quick Look II** screen, see *Section 3.1, Quick Look II summary data, page 18*.

5.1.3.2 VT/VF therapy counters

The VT/VF therapy counters provide information that helps you to evaluate the efficacy of defibrillation. The VT/VF therapy counters include the VT/VF Therapy Summary for the previous session, the last session, and the device lifetime. The VT/VF therapy counters also include the VT/VF Therapy Efficacy Since Last Session.

To access VT/VF therapy counter information, tap **Data** > **Clinical Diagnostics** > **Counters** > **Open Data** > **VT/VF Rx**.

The following VT/VF therapy counter data is available:

VT/VF Therapy Summary – This section reports the number of pace-terminated ventricular tachyarrhythmias, shock-terminated ventricular tachyarrhythmias, total VT/VF shocks, and aborted charges for the prior session, the last session, and the device lifetime.

VT/VF Therapy Efficacy Since Last Session – For VF, FVT, and VT therapies, the counters report the number and types of therapies that were delivered and successful. The VT Therapy counter includes VT episodes that accelerated during the therapy or were redetected as an FVT or VF episode. The FVT therapy counter includes FVT episodes that were redetected as a VF episode.

5.2 Ventricular ATP therapies

The device detects sustained ventricular tachycardia as a ventricular tachycardia (VT) episode or a fast ventricular tachycardia (FVT) episode. Treatments for these episodes are intended to interrupt the ventricular tachycardia and restore the patient's normal sinus rhythm. Pacing therapy can be a treatment option for ending a VT or an FVT episode that may not require high-voltage therapy.

The device can respond to a VT or FVT episode by delivering ventricular antitachycardia pacing (ATP) therapies to the patient's heart. Ventricular ATP therapies are designed to interrupt the VT or FVT reentrant activation pattern and restore the patient's normal sinus rhythm. ATP therapies deliver pacing pulses instead of high-voltage shocks delivered in cardioversion therapy.

For related information, see *Section 4.3*, and *Section 5.3*.

5.2.1 Operation of ventricular ATP therapies

The device can deliver up to 6 therapies to treat a VT or FVT episode. You can program the device to deliver ATP therapies before delivering the first cardioversion therapy for each type of episode. This may allow the device to end a ventricular tachycardia episode using an ATP therapy, delivering cardioversion therapy only if the ATP therapy is unsuccessful.

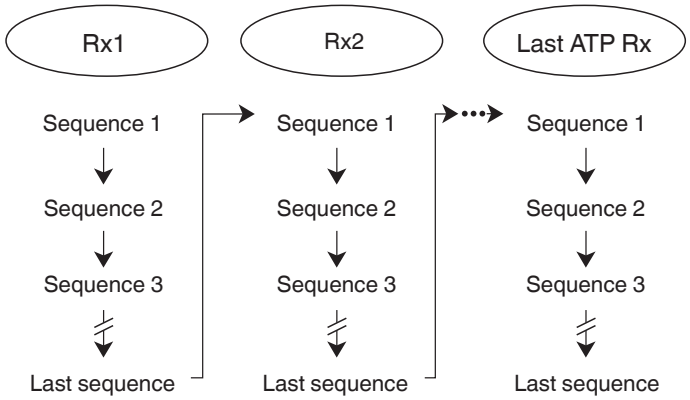
ATP therapy options are Burst and Ramp pacing, each with a programmable number of sequences. When a VT or FVT episode is detected and the first programmed therapy is an ATP therapy, the device delivers the first sequence of the ATP therapy. After the first ATP sequence, it continues to monitor for the presence of the ventricular tachycardia episode. If the device redetects the ventricular tachycardia episode, it delivers the next sequence and repeats this cycle until the episode ends or all sequences in the therapy are exhausted.

If all sequences in an ATP therapy are unsuccessful, the device starts delivering the next ATP or cardioversion therapy. If it detects that the current VT episode has accelerated (by at least 60 ms) or redetects the VT as FVT, the device skips the remaining sequences of an ATP therapy and starts the next programmed therapy for the episode.

If the device redetects the VT episode as VF, it delivers VF therapy. For more information, see *Section 5.1*.

During an ongoing ventricular tachyarrhythmia episode, the ventricular rate may also decelerate, which can cause the device to redetect the episode as a different type of tachyarrhythmia. If deceleration occurs, all subsequent therapies within the current episode are as aggressive or more aggressive than the preceding therapies.

Figure 33. Overview of ventricular ATP therapy delivery



The V-V Minimum ATP Interval, V. Amplitude, V. Pulse Width, ATP Polarity, and V. Pace Blanking parameters are the same for all ventricular ATP therapies. These parameters are programmable independently of the Pause Prevention and the Post Shock Pacing pulse width, amplitude, polarity, and pace blanking period.

5.2.1.1 Ventricular ATP therapy pacing rate

The ATP pacing interval is based on the ventricular tachycardia cycle length, which is calculated as the average of the last 4 ventricular intervals prior to VT or FVT detection (or redetection). The programmable parameter V-V Minimum ATP Interval limits the pacing interval at which the ATP pulses are delivered within a sequence. If the ATP pacing interval is shorter than the programmed V-V Minimum ATP Interval, the pulses are delivered at the programmed V-V Minimum ATP Interval.

If the intrinsic ventricular tachycardia interval is shorter than or equal to the programmed V-V Minimum ATP Interval, the device skips the rest of the ATP therapy and delivers the first programmed cardioversion therapy. If no cardioversion therapy is programmed, no therapy is delivered.

If the intrinsic ventricular tachycardia interval is longer than the programmed V-V Minimum ATP Interval but all the intervals of an ATP therapy sequence have been delivered at the V-V Minimum ATP Interval, the device skips the rest of the ATP therapy and delivers the next programmed ATP or cardioversion therapy. If the device detects an FVT episode, it delivers the next programmed cardioversion therapy.

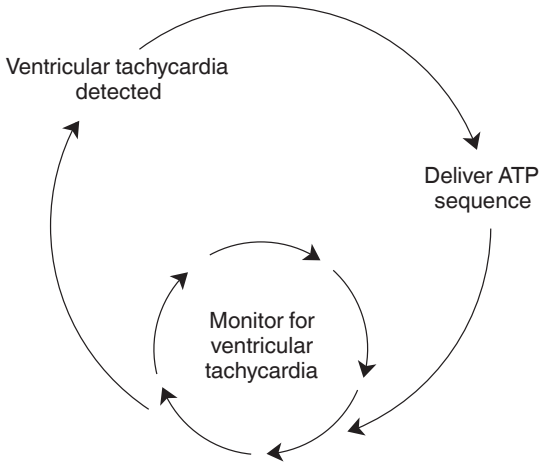
5.2.1.2 Ventricular ATP pacing polarity

When a VT or FVT episode is detected, the device will immediately deliver ATP therapy when the next programmed therapy is ATP pacing and ATP Polarity is programmed to either Ring 1 to Ring 2 or Ring 1 to Coil 2 polarity.

For an overview of ventricular ATP sequence delivery from Ring 1 to Ring 2 or Ring 1 to Coil 2 polarities, see *Figure 34*.

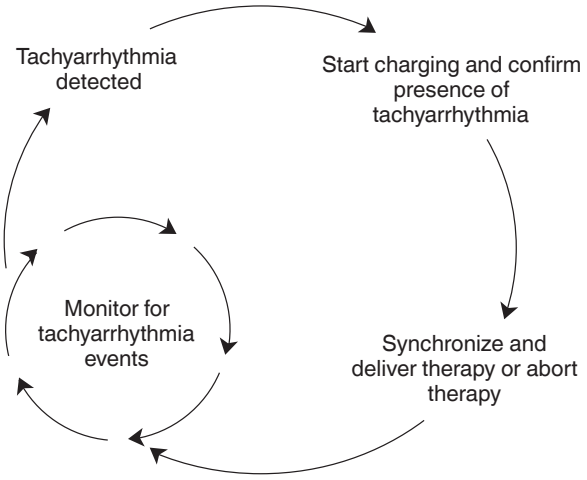
See *Figure 37* for an example of Ring 1 to Ring 2 or Ring 1 to Coil 2 ATP pacing therapy delivery.

Figure 34. Overview of ventricular ATP sequence delivery using Ring 1 to Ring 2 or Ring 1 to Coil 2 polarity



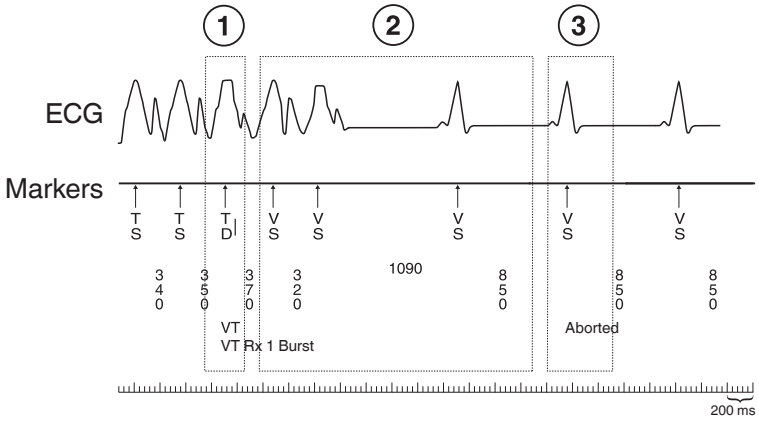
When a VT or FVT episode is detected, the device begins charging its high-voltage capacitors when the next programmed therapy is ATP pacing and ATP Polarity is programmed to Coil 2 to Coil 1. The device attempts to confirm the continued presence of the tachyarrhythmia. There will be at least a 1-second delay between VT or FVT detection and the first ATP pulse. The delay allows the device to accumulate sufficient charge for the high-voltage ATP therapy. For an overview of ventricular ATP sequence delivery using Coil 2 to Coil 1 ATP polarity, see *Figure 35*.

Figure 35. Overview of ventricular ATP sequence delivery using Coil 2 to Coil 1 ATP polarity



If the tachyarrhythmia is still present when the capacitors are charged to the programmed energy level, the device delivers ATP therapy synchronized to a sensed ventricular event. The device will attempt to synchronize the ATP therapy until it delivers the therapy or it fails to confirm the presence of VT or FVT and aborts the therapy. For an example of a canceled ATP therapy, see *Figure 36*.

Figure 36. Example of a canceled ATP therapy using the Coil 2 to Coil 1 ATP polarity



1 The device detects VT, starts charging, and begins to confirm the tachyarrhythmia using the confirmation interval.

2 The VT spontaneously ends, and normal sinus rhythm resumes.

3 When 2 “normal events” are sensed, the device aborts the therapy and stops charging the capacitors.

If a Coil 2 to Coil 1 ATP therapy aborts due to synchronization, upon re-detection the first therapy sequence will be delivered if it was the first sequence that failed synchronization. If the aborted sequence was not sequence 1, the next sequence will be selected on redetection. For example, if Rx1, sequence 1 was aborted, it will be reattempted on redetection. If Rx1 sequence 2 is aborted, the device will deliver Rx1 sequence 3 (if enabled) or Rx2 (if there are no more sequences in Rx1) on redetection.

In the event of continuing VT or FVT detection, if the energy on the high-voltage capacitors exceeds the programmed ATP V. Amplitude, ATP therapy may be skipped, and the next therapy will be attempted to avoid delivering excessive voltage to the patient.

5.2.1.3 Burst pacing therapy

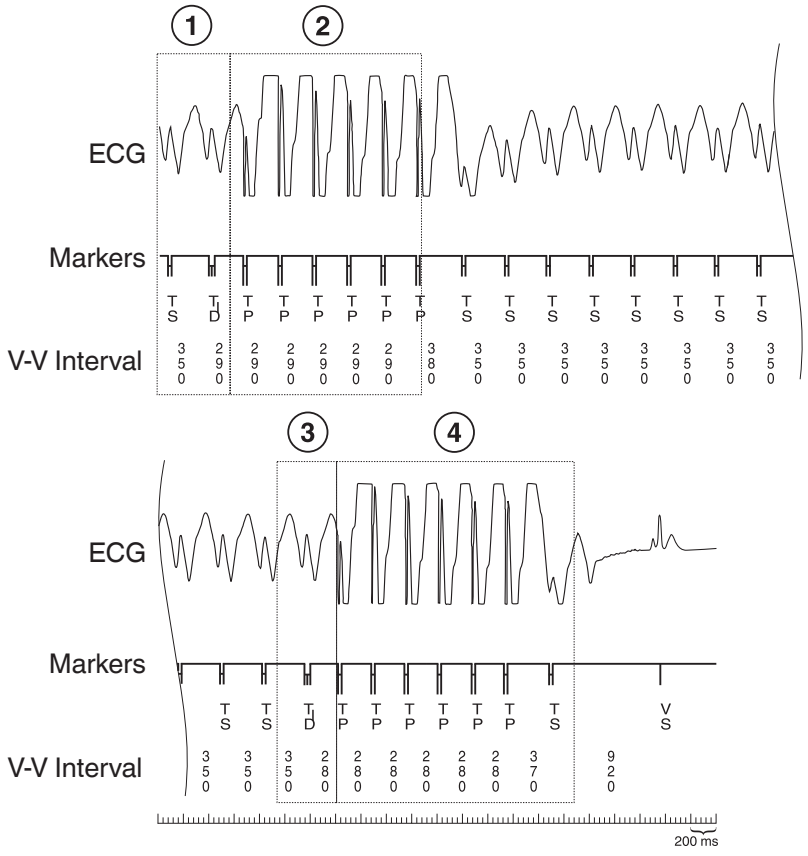
The programmable parameter Initial # Pulses sets the number of pulses in all sequences of a Burst therapy. R-S1 Interval=(%RR) and Interval Dec are programmable parameters that control Burst pacing intervals.

The first Burst sequence is delivered at a pacing interval determined by the R-S1 Interval=(%RR) parameter as a percentage of the ventricular tachycardia cycle length. Each pulse in the sequence is delivered at the same pacing interval. Each time the ventricular tachycardia is redetected after an unsuccessful sequence, the device applies the programmed Burst percentage to the new ventricular tachycardia cycle length. It then subtracts the Interval Dec value (once per sequence) to determine the pacing interval of the next Burst sequence.

Note: Burst pacing therapy is delivered in the VOO pacing mode.

In the example of Burst pacing operation in *Figure 37*, two Burst therapy sequences are delivered. The second therapy sequence ends the VT episode.

Figure 37. Example of Burst pacing operation



[3] This example is pertinent to ATP programmed to either the Ring 1 to Ring 2 or Ring 1 to Coil 2 polarities.

1 The device detects a VT episode.
2 The first Burst sequence is delivered with a pacing interval of 290 ms, but this sequence fails to end the VT episode.
3 The device redetects the VT episode.
4 The second Burst sequence is delivered with a pacing interval of 280 ms (the interval decrement being 10 ms per sequence). This sequence ends the VT episode.

5.2.1.4 Ramp pacing therapy

The programmable parameter Initial # Pulses sets the number of pulses in the first Ramp sequence. Ramp pacing intervals are controlled by the programmable parameters R-S1 Interval=(%RR) and Interval Dec.

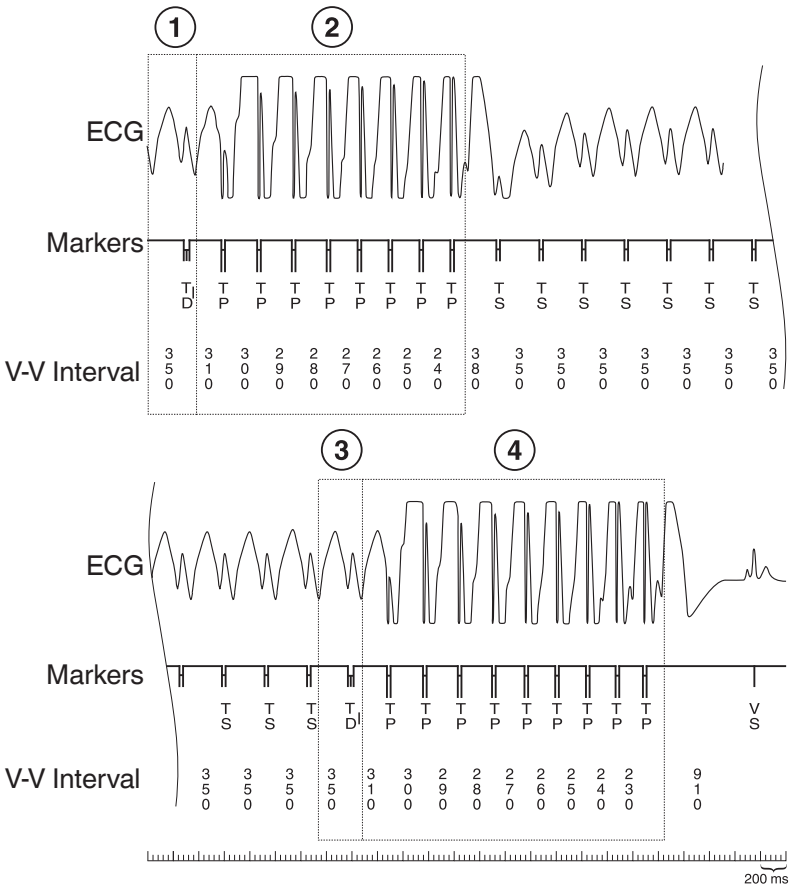
In each Ramp sequence, the first pulse is delivered at a pacing interval determined by the R-S1 Interval=(%RR) parameter as a percentage of the ventricular tachycardia cycle length. The remaining pulses in this sequence are delivered at progressively shorter pacing intervals by subtracting the Interval Dec value for each pulse.

Each time the ventricular tachycardia is redetected after an unsuccessful sequence, the device applies the programmed Ramp percentage to the new ventricular tachycardia cycle length to calculate the initial pacing interval for the next sequence. Each sequence adds one pacing pulse. Sensed ventricular events are counted as individual pulses of the Ramp sequence, even though they are not output pulses.

Note: Ramp pacing therapy is delivered in the VOO pacing mode.

In the example of Ramp pacing operation in *Figure 38*, 2 Ramp therapy sequences are delivered. The second therapy sequence ends the VT episode.

Figure 38. Example of Ramp pacing operation



1 The device detects a VT episode.

2 The first Ramp sequence is delivered with an initial pacing interval of 310 ms. Each subsequent interval is decremented 10 ms per pulse. Eight pacing pulses are delivered, but the VT episode does not end.

3 The device redetects the VT episode.

4 The second Ramp sequence is delivered with an initial pacing interval of 310 ms. Each subsequent interval is decremented 10 ms per pulse. Nine pacing pulses are delivered, and the VT episode ends.

[4] This example is pertinent to ATP programmed to either the Ring 1 to Ring 2 or Ring 1 to Coil 2 parameters.

5.2.1.5 Optimizing ventricular ATP therapies with Smart Mode

Smart Mode is a programmable option for ventricular ATP therapies. You can program Smart Mode to On for all or selected ATP therapies for the first 4 VT or FVT therapies.

When Smart Mode is programmed to On for a ventricular ATP therapy, the device monitors the outcome of that therapy. If there are 4 consecutive episodes in which all sequences of the ATP therapy are delivered but are unsuccessful, Smart Mode cancels that ATP therapy. This action allows the device to treat subsequent episodes more quickly, using ATP therapies that may have been effective previously.

If Smart Mode cancels a ventricular ATP therapy, you can either select a different therapy or modify the current therapy settings to improve the therapy effectiveness. An ATP therapy canceled by Smart Mode is indicated by the label “Off-SM” on the VT/VF therapy counters screen.

5.2.2 Programming ventricular ATP therapies

Navigation to parameters for ventricular ATP therapies for VT episodes is shown in *Table 8*. To navigate to parameters for ventricular ATP therapies for FVT episodes, tap **Params** > **FVT Therapies…**.

Table 8. How to navigate to parameters for ventricular ATP therapies

Parameters	Path
VT Therapies parameters (Rx1 through Rx6): VT Therapy Status Therapy Type	**Params** > **VT Therapies…**
Burst Therapy Type parameters: Initial # Pulses R-S1 Interval=(%RR) Interval Dec # Sequences Smart Mode	**Params** > **VT Therapies…** > **Therapy Type** > **Burst**
Ramp Therapy Type parameters: Initial # Pulses R-S1 Interval=(%RR) Interval Dec # Sequences Smart Mode	**Params** > **VT Therapies…** > **Therapy Type** > **Ramp**

Table 8. How to navigate to parameters for ventricular ATP therapies (continued)

Parameters	Path
Shared Settings parameters: V-V Minimum ATP Interval V. Amplitude V. Pulse Width V. Pace Blanking	**Params** > **VT Therapies…** > **Shared Settings…**
ATP Polarity parameters: Ring 1 to Ring 2 Ring 1 to Coil 2 Coil 2 to Coil 1	**Params** > **VT Therapies…** > **Shared Settings…** > **ATP Polarity**

VT and FVT therapies – You should not use ATP therapies exclusively to treat VT or FVT episodes. At least one VT therapy and one FVT therapy should be programmed to a maximum energy cardioversion.

Cardioversion therapies for VT and FVT – You cannot program all VT and FVT therapies as ATP therapies. If any VT or FVT therapies are programmed on, at least one of the therapies must be programmed to cardioversion therapy. The final VT or FVT therapy must always be programmed to cardioversion therapy.

Therapy aggressiveness – VT and FVT therapies must be programmed to be increasingly aggressive. For example, you cannot program one VT therapy as cardioversion and a subsequent VT therapy as a ventricular ATP therapy. Likewise, a VT cardioversion therapy cannot be followed by another VT cardioversion therapy with a lower energy setting.

VF therapies – You cannot program VT and FVT therapies to On unless at least one VF therapy is also programmed on.

Smart Mode – You can reset a ventricular ATP therapy canceled by Smart Mode by programming the Therapy Status parameter for that therapy to On. Smart Mode is not available for the last two VT or FVT therapies.

5.2.3 Evaluation of ventricular ATP therapies

5.2.3.1 The Quick Look II screen

To access **Quick Look II** screen information about VT/VF therapies, tap **Data** > **Quick Look II**.

Treated VT/VF episodes – This section includes a count of treated VT/VF episodes. You can tap the » button next to Treated to view data for the treated episodes.

Quick Look II observations – The Quick Look II observations are based on an analysis of interrogated data since the last session and programmed parameters. If related information

about an observation is available, you can select the observation and then tap the ⏭ button next to Observations to view the related information.

For detailed information about viewing and interpreting all of the information available from the **Quick Look II** screen, see *Section 3.1, Quick Look II summary data, page 18*.

5.2.3.2 VT/VF therapy counters

The VT/VF therapy counters provide information that helps you to evaluate the efficacy of ventricular ATP therapies. The VT/VF therapy counters include the VT/VF Therapy Summary for the prior session, the last session, and the device lifetime. VT/VF therapy counters also include VT/VF Therapy Efficacy Since Last Session.

To access VT/VF therapy counter information, tap **Data** > **Clinical Diagnostics** > **Counters** > **Open Data** > **VT/VF Rx**.

The following VT/VF therapy counter data is available:

VT/VF Therapy Summary – This counter reports the number of pace-terminated tachyarrhythmias, shock-terminated tachyarrhythmias, total VT/VF shocks, and aborted charges for the prior session, the last session, and the device lifetime.

VT/VF Therapy Efficacy Since Last Session – This counter reports the number and types of VF, FVT, and VT therapies that were delivered and successful. The VT Therapy counter includes VT episodes that accelerated during the therapy or were redetected as an FVT or VF episode. The FVT therapy counter includes FVT episodes that were redetected as a VF episode.

5.2.3.3 Smart Mode operation indicators

To access VT/VF therapy counter information about the operation of Smart Mode, tap **Data** > **Clinical Diagnostics** > **Counters** > **VT/VF Rx**.

Information about Smart Mode operation is also available from the **VT Therapies** screen or the **FVT Therapies** screen.

The Off-SM label for the Rx1 Therapy Status indicates that Smart Mode canceled an unsuccessful ATP therapy.

5.3 Ventricular cardioversion

A VT episode or an FVT episode is detected when sustained ventricular tachycardia occurs. Treatments for these episodes are intended to interrupt the tachyarrhythmia and restore sinus rhythm. Ventricular ATP therapies may end these episodes. If the ATP therapies are ineffective, a high-voltage shock is required.

The device can respond to a VT or FVT episode by delivering ventricular cardioversion therapy to the patient's heart. Cardioversion, like defibrillation, is intended to end the episode by simultaneously depolarizing the heart tissue and restoring the patient's normal sinus rhythm. However, unlike defibrillation, cardioversion requires that the device synchronizes the therapy to a sensed ventricular event.

Note: For the device to respond to a VT or FVT episode, at least one therapy must be programmed to cardioversion.

For more information, see *Section 4.3*.

5.3.1 Operation of ventricular cardioversion

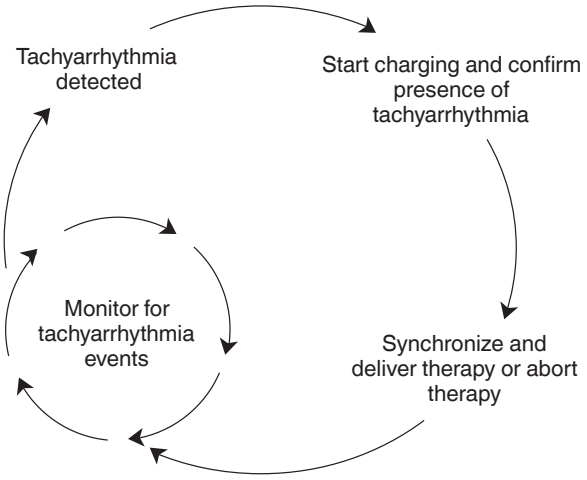
When a VT or FVT episode is detected and the next programmed therapy is a cardioversion, the device begins charging its high-voltage capacitors and attempts to confirm the continued presence of the tachyarrhythmia. If the tachyarrhythmia ends, the device cancels the therapy.

If the tachyarrhythmia is still present when the capacitors are charged to the programmed energy level, the device delivers the cardioversion pulse synchronized to a sensed ventricular event. If synchronization is not possible, the device cancels the therapy.

If the cardioversion therapy is unsuccessful, the device starts delivering the next cardioversion therapy. If the device redetects the VT episode as VF, it delivers therapy. See *Section 5.1*.

During an ongoing ventricular tachyarrhythmia episode, the ventricular rate may accelerate or decelerate, which can cause the device to redetect the episode as a different type of tachyarrhythmia. If redetection occurs, the device delivers all subsequent therapies within the current episode as aggressive as or more aggressive than the preceding therapies.

Figure 39. Overview of ventricular cardioversion



5.3.1.1 Delivering high-voltage therapies

To deliver a cardioversion therapy, the device must first charge its high-voltage capacitors to the programmed energy level. The length of time required to charge the capacitors depends on the programmed energy level and battery depletion. The delivered energy level is programmed independently for each cardioversion therapy. Cardioversion pulses use a biphasic waveform in which the current pathway for the high-voltage pulse is reversed midway through the pulse delivery.

See the device manual for the following information:

- Typical full-energy capacitor charging periods
- Comparison of delivered and stored energy levels

5.3.1.2 Selecting the high-voltage current pathway

The Pathway parameter specifies the direction of current flow for defibrillation and cardioversion pulses.

The settings for the Pathway parameter are STD and REV. The Pathway setting defines direction of current flow during the initial segment of the biphasic waveform. If the parameter is set to STD, current flows from the Coils to the Can. If the parameter is set to REV, this current flow is reversed and current flows from the Can to the Coils.

Warning: REV (Can to Coils) pathway is not recommended for this device. Devices programmed in the REV pathway may experience sub-therapeutic energy (reduced or no energy) delivery during high-voltage therapy in the presence of an unintended current pathway (a short circuit). Refer to *Section 5.4*.

5.3.1.3 Confirming VT or FVT after detection

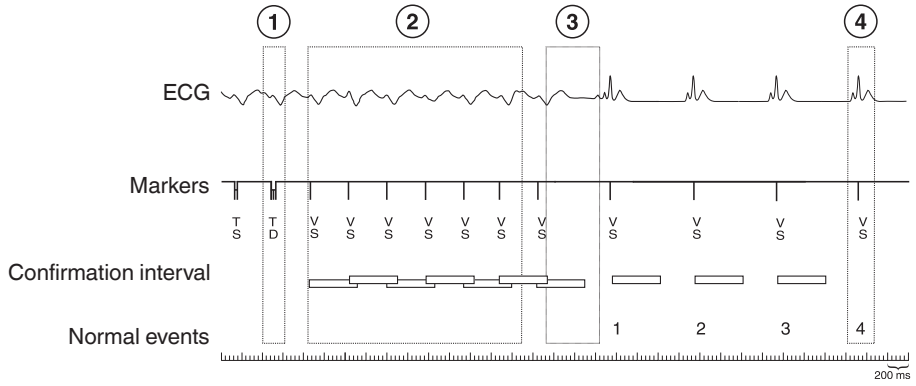
When the device begins charging its capacitors for a cardioversion therapy, it monitors the cardiac rhythm to ensure that the tachyarrhythmia remains present before delivering the therapy.

The device confirms the continued presence of the tachyarrhythmia using the ventricular cycle length + 60 ms, if this interval is at least as long as the programmed VF detection interval. This is the default confirmation interval.

The device classifies any ventricular event that occurs within either confirmation interval as an “arrhythmic event” and any event that occurs outside the interval as a “normal event”.

On each ventricular event during charging, the device reviews the last 5 events since charging started. If the last 5 ventricular events included 4 “normal events”, the device stops charging and cancels the therapy.

Figure 40. Example of a canceled cardioversion therapy



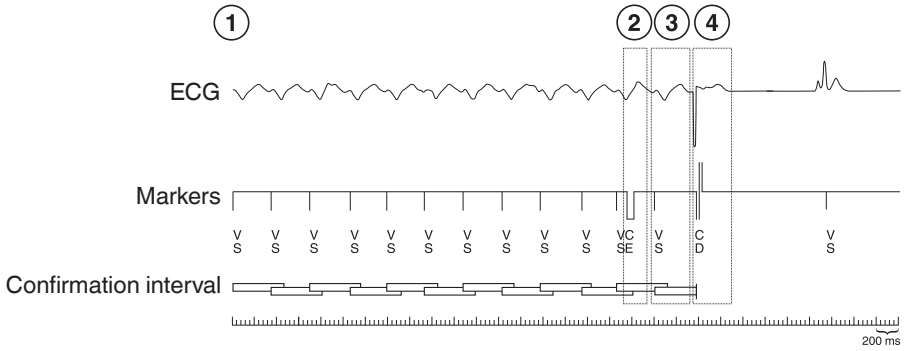
1 The device has detected VT and starts charging its capacitors for cardioversion.
2 The device confirms the tachyarrhythmia using the confirmation interval.
3 The VT spontaneously ends, and normal sinus rhythm resumes.
4 When 4 of the last 5 events are “normal events”, the device stops charging its capacitors.

5.3.1.4 Synchronizing cardioversion after charging

After charging ends, the device continues to confirm the presence of the tachyarrhythmia. If the tachyarrhythmia persists, the device attempts to synchronize the cardioversion therapy to the second nonrefractory tachyarrhythmic ventricular event after charging.

The device continues to attempt to synchronize until it delivers the cardioversion therapy or it fails to confirm the presence of the tachyarrhythmia and cancels the therapy.

Figure 41. Example of synchronous delivery of cardioversion



1 The device has detected VT. It charges its capacitors for cardioversion and confirms that the tachyarrhythmia is still present.

2 The device completes charging while continuing confirmation.

3 A tachyarrhythmic ventricular event occurs.

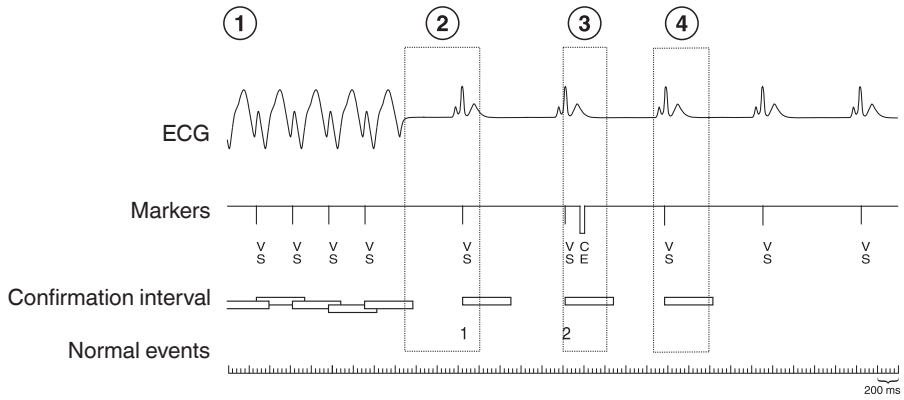
4 On the second tachyarrhythmic event after charging, the device delivers the cardioversion therapy.

The device confirms the presence of the detected tachyarrhythmia differently after charging than it does during charging. After charging, the device aborts the cardioversion therapy if one of the following events occurs:

- A normal event in the ventricle
- 3 consecutive ventricular-sensed intervals less than 200 ms

The presence of short ventricular-sensed intervals during synchronization indicates that the rhythm has either accelerated since initial detection or that significant oversensing is present. In either case, cardioversion may no longer be an appropriate therapy.

Figure 42. Example of an aborted cardioversion therapy



1 The device has detected VT. It charges its capacitors for cardioversion and confirms that the tachyarrhythmia is still present.

2 The VT spontaneously ends, and normal sinus rhythm resumes.

3 The charging period ends, and synchronization starts. At this point, the device stops the confirmation process.

4 The cardioversion therapy aborts when a “normal event” occurs during synchronization.

5.3.1.5 Device operation during and after a cardioversion therapy

After the cardioversion therapy is delivered, the device monitors for the end of the episode or redetection. Immediately after delivering the shock, the device starts a post-shock blanking period of 520 ms and resumes operation in the programmed pacing mode.

If Post Shock Pacing is programmed to On, the Post Shock Pacing parameters are applied. For more information, see *Section 6.2*.

5.3.1.6 Sequence after a canceled cardioversion therapy

If the device cancels a cardioversion therapy, Post Shock Pacing is not applied.

The device resumes monitoring for arrhythmias after the next sensed ventricular event. If the device redetects VT (or FVT) before the episode ends, it attempts to synchronize and deliver the programmed therapy that was aborted. However, if the episode ends, the device resumes normal detection.

Note: If the device cancels the cardioversion therapy, leaving energy stored on the capacitors, the delivered energy of the next high-voltage therapy may be higher than the programmed value.

5.3.2 Programming ventricular cardioversion

Navigation to parameters for ventricular cardioversion (CV) therapies for VT episodes is shown in *Table 9*. To navigate to parameters for ventricular cardioversion therapies for FVT episodes, tap **Params** > **FVT Therapies…**.

Table 9. How to navigate to ventricular cardioversion therapies parameters

Parameters	Path
CV Therapy Type parameters: Energy Pathway	**Params** > **VT Therapies…** > **Therapy Type** > **CV**

Energy – Programming the cardioversion therapy energy level to an optimized value can end the tachyarrhythmia with an appropriate safety margin and without wasting energy. At least 1 VT therapy and 1 FVT therapy should be programmed to a maximum energy cardioversion.

Cardioversion therapies for VT and FVT – If VT or FVT therapies are programmed to On, at least 1 VT or FVT therapy must be programmed to cardioversion (at any energy level). The final VT or FVT therapy must always be programmed to cardioversion.

Therapy aggressiveness – VT and FVT therapies must be programmed to be increasingly aggressive. For example, you cannot program 1 VT therapy to cardioversion and a subsequent VT therapy to an ATP therapy. Likewise, a VT cardioversion therapy cannot be followed by another VT cardioversion therapy with a lower energy setting.

VF therapies – VT and FVT therapies cannot be programmed to On unless at least 1 VF therapy is also programmed to On.

5.3.3 Evaluation of ventricular cardioversion

5.3.3.1 The Quick Look II screen

To access **Quick Look II** screen information about VT/VF therapies, tap **Data** > **Quick Look II**.

Treated VT/VF episodes – This section includes a count of treated VT/VF episodes. You can tap the ⏭ button next to Treated to view data for the treated episodes.

Quick Look II observations – The Quick Look II observations are based on an analysis of interrogated data since the last session and programmed parameters. If related information about an observation is available, you can select the observation and then tap the ⏭ button next to Observations to view the related information.

For detailed information about viewing and interpreting all of the information available from the **Quick Look II** screen, see *Section 3.1, Quick Look II summary data, page 18*.

5.3.3.2 VT/VF therapy counters

The VT/VF therapy counters provide information that helps you to evaluate the efficacy of ventricular cardioversion. The VT/VF therapy counters include the VT/VF Therapy Summary for the prior session, the last session, and the device lifetime. The VT/VF therapy counters also include the VT/VF Therapy Efficacy Since Last Session.

To access VT/VF therapy counter information, tap **Data** > **Clinical Diagnostics** > **Counters** > **Open Data** > **VT/VF Rx**.

VT/VF Therapy Summary – This section reports the number of pace-terminated arrhythmias, shock-terminated arrhythmias, total VT/VF shocks, and aborted charges for the prior session, the last session, and the device lifetime.

VT/VF Therapy Efficacy Since Last Session – For VF, FVT, and VT therapies, the counters report the number and types of therapies that were delivered and successful. The VT Therapy counter includes VT episodes that accelerated during the therapy or were redetected as an FVT or VF episode. The FVT therapy counter includes FVT episodes that were redetected as a VF episode.

5.4 Short Circuit Protection

5.4.1 Operation of Short Circuit Protection

Short Circuit Protection (SCP) is a safety feature that can only occur during high-voltage (HV) therapy. SCP is designed to truncate energy delivery to protect the device when an unintended current pathway (a short circuit) is detected during a shock. An SCP event can occur when an unintended current pathway develops in either the lead or in the device. Contact a Medtronic representative for additional guidance if you believe an SCP event occurred.

Warning: REV (Can to Coils) pathway is not recommended for this device. Devices programmed in the REV pathway may experience sub-therapeutic energy (reduced or no energy) delivery during high-voltage therapy in the presence of an unintended current pathway (a short circuit).

5.4.2 Identifying Short Circuit Protection events

If an SCP event occurred, the delivered energy will be less than the programmed energy in the displayed Episode Text. The lead impedance in the Episode Text will also display <30 ohms. If an SCP event occurs during a manual shock delivery, there will be no episode data. For manual shock deliveries, review the shock impedance and the delivered energy from the **Last High Voltage Therapy** section on the **Battery and Lead Measurements** screen of the programmer.

6 Pacing features

6.1 Operation of pacing

The device operates in OVO pacing mode, with the exception of Pause Prevention pacing therapy and Post Shock Pacing, which provide temporary VVI pacing. In OVO mode the device does not deliver ventricular pacing regardless of the intrinsic rate. When operating in the VVI mode, the heart is paced if no intrinsic events are sensed.

6.1.1 Programming pacing therapies

Table 10. How to navigate to basic pacing parameters

Parameters	Path
Setting Amplitude Pulse Width Pace Polarity	**Params** > **Pacing…**

Pacing safety margins – Pacing pulses must be delivered at an adequate safety margin above the stimulation thresholds.

High pacing output levels – The pulse width and amplitude settings affect the longevity of the device.

6.2 Post Shock Pacing

After the heart receives a high-voltage therapy, there may be a temporary bradycardia or asystole.

The device can be configured to deliver temporary Post Shock Pacing following a high-voltage therapy.

6.2.1 Operation of Post Shock Pacing

The device allows you to enable Post Shock Pacing and program separate Post Shock Pacing amplitude and pulse width settings that apply after any high-voltage therapy. If Post Shock Pacing is programmed On, VVI pacing will be delivered at 40 bpm for up to 30 s following any high-voltage therapy delivery.

Note: If Pace Polarity is configured to Coil 2 to Coil 1, there may be up to a 6 s delay between high-voltage therapy and start of post shock pacing.

6.2.2 Programming Post Shock Pacing

Table 11. How to navigate to Post Shock Pacing parameters

Parameters	Path
Post Shock Pacing parameters: Setting Amplitude Pulse Width Pace Polarity	**Params** > **Pacing…**

6.3 Pause Prevention Pacing

This feature has 2 modes of operation. Monitor is the first, and the device monitors for a ventricular pause but does not provide therapy. On is the second mode in which the device provides VVI therapy.

Pause Prevention Pacing provides temporary bradycardia pacing support after detection of a ventricular asystole of a programmed duration (5-15 s).

6.3.1 Operation of Pause Prevention Pacing

The device allows you to program Pause Prevention Pacing amplitude, pulse width, and polarity settings for the 30 s of VVI pacing administered during a Pause Prevention episode. The rate and duration of pacing during a Pause Prevention episode are not programmable. The rate is set at 40 bpm.

For more information on Pause Prevention, see *Section 3.8, Pause Prevention Episodes, page 38*.

6.3.2 Programming Pause Prevention Pacing

Table 12. How to navigate to Pause Prevention Pacing parameters

Parameters	Path
Pause Prevention Detection parameters: Pause Prevention Detection Enable Pause Prevention Detection Interval	**Params** > **Pacing…** > **Pause Prevention Setting**
Pause Prevention Pacing parameters: Setting Amplitude Pulse Width Pace Polarity	**Params** > **Pacing…**

Glossary

Antitachycardia pacing (ATP) – therapies that deliver rapid sequences of pacing pulses to terminate tachyarrhythmias.

Arrhythmia episode data – system that compiles an arrhythmia episode log that the clinician can use to view summary and detailed diagnostic data quickly, including stored EGM, for the selected arrhythmia episode.

blanking period – time interval during which sensing in a chamber is disabled to avoid oversensing.

Burst pacing – antitachycardia pacing (ATP) therapy that delivers sequences of ventricular pacing pulses with an interval that is a programmable percentage of the tachycardia cycle length. With each sequence of Burst pacing delivered, the device shortens the pacing interval by a programmable interval.

capacitor – component in the device that stores electrical energy so that high-voltage therapies can be delivered from a relatively small battery.

Cardiac Compass Trends – overview of the patient's condition over the last 14 months with graphs that display long-term clinical trends in heart rhythm, such as frequency of arrhythmias, heart rates, and device therapies.

Combined Count detection – feature designed to prevent a delay in VF detection when ventricular tachyarrhythmia fluctuates between the VF and VT zones.

Decision Channel annotations – annotations to stored and telemetered EGM that document details about tachyarrhythmia detection operations.

device status indicators – programmer warnings, such as "Warning - Device Electrical Reset," that describe problems with device memory or operation.

electrical reset – automatic device operation to recover from a disruption in device memory and control circuitry. Programmed parameters may be set to electrical reset values. This operation triggers a device status indicator and an automatic Medtronic CareAlert tone.

electromagnetic interference (EMI) – energy transmitted from external sources by radiation, conduction, or induction that can interfere with device operations, such as sensing, or can potentially damage device circuitry.

EOS (End of Service) – battery status indicator displayed by the programmer to indicate that the device should be replaced immediately and that it may not operate per specifications.

event – a sensed or paced beat.

Feature Match – feature designed to prevent ventricular tachyarrhythmia detection for rapidly conducted SVTs whose morphology features are similar to a template collected during sinus rhythm.

Flashback Memory – diagnostic feature that records the intervals that immediately preceded tachyarrhythmia episodes or that preceded the last interrogation of the device and plots the interval data over time.

High Rate Timeout – feature that allows the device to delivery therapy for any ventricular tachyarrhythmia that continues beyond the programmed length of time.

Holter telemetry – telemetry feature that transmits EGM and Marker Channel data continuously for a programmable number of hours, regardless of whether telemetry actually exists between the device and programmer.

Interrogate – command to transmit the device parameter settings and stored data to the programmer.

last session – refers to the last time the device was successfully interrogated before the current interrogation. A session ends 8 hours after the last interrogation.

median ventricular interval – the seventh in a numerically ordered list of the 12 most recent V-V intervals.

Medtronic CareAlert Monitoring – the continuous monitoring for, and silent, wireless transmission of, alert data between an implanted device and the Medtronic CareLink Network.

Medtronic CareAlert notifications – alert information sent via the Medtronic CareLink Network that notifies clinics and clinicians of events that impact patients or their implanted devices.

Medtronic CareLink Network – Internet-based service that allows a patient to transmit cardiac device information from home or other locations to the physician over a secure server. The CareLink Network may be unavailable in some geographic locations.

Medtronic patient monitor – instrument used in the patient's home that receives data from an implanted device via telemetry and transmits that data to the Medtronic CareLink Network.

Morphology Noise – feature that withholds detection of ventricular tachyarrhythmias when the morphology on the EGM2 channel shows noise.

MR Conditional – an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions for use.

MRI SureScan – a feature that permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine.

non-sustained VT (VT-NS) – ventricular rhythm that is fast enough to fall within the programmed VT and VF zones for at least 5 consecutive intervals but does not meet any episode detection criteria.

Onset – feature that helps prevent detection of sinus tachycardia as VT by evaluating the acceleration of the ventricular rate.

oversensing – inappropriate sensing of cardiac events or noncardiac signals. Examples include T-waves, myopotentials, and electromagnetic interference.

patient alert – a tone emitted from an implanted device to notify the patient of an alert condition.

Pause Prevention Pacing – feature that provides temporary bradycardia pacing support after detection of ventricular asystole of a programmed duration by providing a short duration of VVI pacing.

Post Shock Pacing – feature that provides temporary pacing support after a high-voltage therapy.

Pre-arrhythmia EGM storage – programmable option to record EGM from before the onset or detection of a tachyarrhythmia. While this feature is operating, the device records EGM continuously. If a tachyarrhythmia episode occurs, the most recently collected EGM is added to the episode record to document the rhythm at onset.

PVC (premature ventricular contraction) – a sensed ventricular event that has a shorter than expected interval, based on the intervals of the 4 most recent events.

Quick Look II – programmer screen that presents overview data about device operation and patient rhythms collected since the last patient session. It includes links to more detailed status and diagnostic information stored in the device, such as arrhythmia episodes and therapies provided.

Ramp pacing – antitachycardia pacing (ATP) therapy that delivers pacing pulses with progressively shorter pacing intervals per pulse. Each sequence of Ramp pacing that is delivered during a therapy includes an additional pacing pulse.

Rapid AF – feature designed to withhold detection for rapid atrial fibrillation conducted into the ventricles with periodic slow intervals that have consistent morphology and amplitudes.

Rate Histograms – diagnostic feature that shows range distributions for a patient's heart rate.

Remaining Longevity estimate – an estimate of remaining device longevity that is displayed on the Quick Look II and Battery and Lead Measurements screens. On both screens, this information includes a graphical display for easy reference and the estimated number of years or months of remaining longevity. On the Battery and Lead Measurements screen, the Minimum and Maximum number of years or months of remaining device longevity are also provided.

Resume – programming command that reinstates automatic tachyarrhythmia detection.

RRT (Recommended Replacement Time) – battery status indicator displayed by the programmer to indicate when replacement of the device is recommended.

Sensed EMI – feature that withholds ventricular tachyarrhythmia detection when noise is sensed during the blanking periods.

sensed event – electrical activity across the sensing electrodes that exceeds the programmed sensitivity threshold and is identified by the device as a cardiac event.

sequence, ATP – one programmable set of antitachycardia pacing (ATP) therapy pulses.

Short Circuit Protection (SCP) – safety feature that can only occur during high-voltage (HV) therapy. SCP is designed to truncate energy delivered to protect the device when an unintended current pathway (a short circuit) is detected during a shock. An SCP event can occur when an unintended current pathway develops either in the lead or in the device.

Smart Mode – feature that disables an ATP therapy that has been unsuccessful in 4 consecutive episodes so the device can treat subsequent episodes more quickly with therapies that have been effective.

Smart Sense – feature that withholds ventricular tachyarrhythmia detection in the presence of P-wave oversensing or when the device senses noise, but the EGM2 signal is free of noise.

Stability – feature that helps prevent detection of atrial fibrillation as ventricular tachyarrhythmia by evaluating the stability of the ventricular rate. If the device determines that the ventricular rate is not stable, it withholds VT detection.

Suspend – programming command that temporarily deactivates the tachyarrhythmia detection functions.

synchronization – period during tachyarrhythmia therapies when the device attempts to deliver the therapy shock simultaneously with a sensed ventricular event.

TWave Discrimination – feature that withholds VT/VF detection when a fast ventricular rate is detected because of oversensed T-waves.

undersensing – failure of the device to sense intrinsic cardiac activity.

ventricular antitachycardia pacing (ATP) – therapies that respond to a VT episode or an FVT episode with rapid sequences of pacing pulses to end detected ventricular tachyarrhythmias.

ventricular cardioversion – therapy that delivers a high-voltage shock to treat a VT or an FVT episode. Therapy is synchronized to a sensed ventricular event.

ventricular fibrillation (VF) therapies – therapies that deliver automatic defibrillation shocks to treat VF episodes. The first defibrillation therapy requires VF confirmation before delivery. After the first shock has been delivered, shocks are delivered asynchronously if synchronization fails.

VF confirmation – device operation that confirms the presence of VF after initial detection but before a defibrillation therapy is delivered. This feature applies only to the first programmed VF therapy.

VF Count reset – feature that monitors events that accumulate counts toward initial detection and that occur prior to therapy delivery to discriminate events that are not cardiac in nature.

VT/VF detection – feature that uses programmable detection zones to classify ventricular events. Depending on programming, the device delivers a scheduled therapy, re-evaluates the patient's heart rhythm, and ends or redetects the episode.

VT monitoring – programmable option that allows the device to detect fast rhythms as VT and record episode data without delivering VT therapy.

Wavelet – feature designed to prevent detection of rapidly conducted SVTs as ventricular tachyarrhythmias by comparing the shape of each QRS complex during a fast ventricular rate to a template.

wireless telemetry – transmission of data between the device and the programmer by radio waves.

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V

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Z

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Medtronic

Epsila EV™ MRI SureScan™ EV2401

Extravascular quadripolar lead with shaped passive fixation, designed for sensing, cardioversion, defibrillation, and pacing therapies

Technical Manual

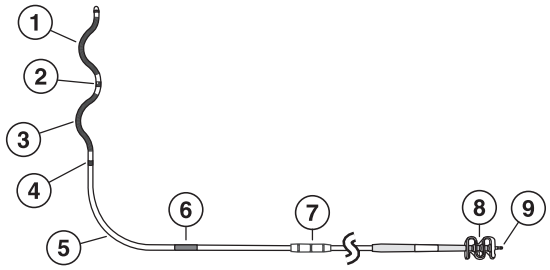
Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Contents

1 Description

The Medtronic Epsila EV Model EV2401 lead is an extravascular quadripolar lead with shaped passive fixation, designed for sensing, cardioversion, defibrillation, and pacing therapies. The lead has been tested for use in the magnetic resonance imaging (MRI) environment. All lead lengths for this lead model are MR Conditional.

Figure 1. Lead components and accessories

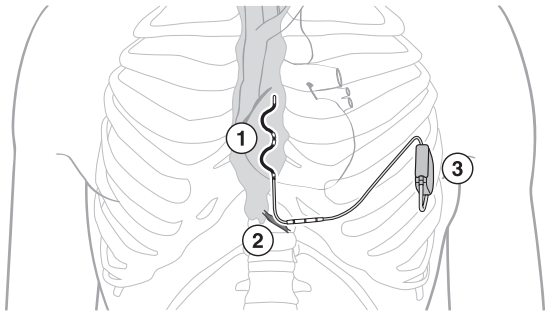


1 Coil 1 electrode (defibrillation)
2 Ring 1 electrode (sensing)
3 Coil 2 electrode (defibrillation)
4 Ring 2 electrode (sensing)
5 Preformed bend
6 Blue insertion indicator
7 Anchoring sleeve
8 AccuRead analyzer cable interface (ACI) tool
9 Connector pin

The lead has the ability to pace and sense between the ring and coil electrodes. In addition, the Coil 1 and Coil 2 electrodes deliver cardioversion and defibrillation therapy. The EV4-LLHH[1] four-pole inline connector facilitates connection to an EV4 device during implant.

Figure 2 shows the implanted lead connected to the device.

Figure 2. Implanted lead



1 Passive fixation in the anterior mediastinum
2 Anchored at the xiphoid incision
3 Connected to the device

1.1 Medtronic SureScan system

A complete SureScan system is required for use in the MR environment. A complete SureScan system includes a Medtronic SureScan device with the appropriate number of Medtronic SureScan leads. Any other combination may result in a hazard to the patient during an MRI scan. The Model EV2401 lead is part of the Medtronic SureScan system. Labeling for SureScan system components displays the MR Conditional symbol.

MR Conditional symbol. The Medtronic SureScan system is MR Conditional and is designed to allow implanted patients to undergo an MRI scan under the specified MR conditions for use.

The MRI SureScan feature permits a mode of operation that allows a patient with a SureScan device to be safely scanned by an MRI machine. When programmed to On, MRI SureScan operation disables arrhythmia detection and all user-defined diagnostics. **Before performing an MRI scan, refer to the SureScan system MRI technical manual for important information about procedures and MRI-specific warnings and precautions.**

1.2 Package contents

The lead and accessories are supplied sterile. Each package contains the following items:

- 1 lead with a radiopaque anchoring sleeve and AccuRead analyzer cable interface (ACI) tool
- 1 additional AccuRead ACI tool
- Product documentation

[1] EV4-LLHH is a Medtronic proprietary design that defines the lead connector contacts as low voltage (L) and high voltage (H).

1.3 Accessory descriptions

Dispose of all single-use accessories according to local environmental requirements.

AccuRead analyzer cable interface (ACI) tool – The ACI tool facilitates accurate electrical measurements during implant and prevents possible connector damage.

Anchoring sleeve – An anchoring sleeve secures the lead to prevent it from moving and protects the lead insulation and conductors from damage caused by tight sutures.

Lead introducer – A lead introducer facilitates the passage of a lead into the desired anatomical location during lead implant.

Sternal tunneling tool – A sternal tunneling tool delivers an introducer sheath and an extravascular lead into the anterior mediastinum during lead implant.

Transverse tunneling tool – A transverse tunneling tool delivers the proximal portion of an extravascular lead to the device pocket during implant of an extravascular implantable device system.

2 Indications

The Epsila EV MRI SureScan Model EV2401 extravascular lead is indicated for use in the anterior mediastinum for pacing therapies, cardioversion, and defibrillation when an extravascular implantable cardioverter defibrillator is indicated to treat patients who have experienced, or are at significant risk of developing, life-threatening ventricular tachyarrhythmias. For more information, refer to the product documentation supplied with the extravascular implantable cardioverter defibrillator (EV-ICD).

3 Contraindications

The Epsila EV MRI SureScan Model EV2401 lead is contraindicated for any application that is not specified in the Indications.

4 Warnings and precautions

A complete SureScan system is required for use in the MR environment. Before performing an MRI scan, refer to the MRI technical manual for MRI-specific warnings and precautions.
A complete SureScan system only includes components that have been certified by Medtronic as being MR conditional.

Note: Medical procedure warnings and precautions that pertain to the Medtronic implanted system are provided in the manual that is packaged with the device or on the Medtronic Manual Library website (www.medtronic.com/manuals).

Prior sternotomy – Use of the EV2401 lead has not been evaluated in patients who have undergone a prior sternotomy.

Post-implant sternotomy – Performing a sternotomy on a patient with an implanted EV2401 lead has not been evaluated.

Inspecting the sterile package – Inspect the sterile package with care before opening it.

- Contact a Medtronic representative if the seal or package is damaged.
- Do not use the product after its expiration date.

Storage temperature – Store at 25 °C (77 °F). Excursions from this storage temperature are permitted in the range of 15 °C to 30 °C (59 °F to 86 °F). Transient spikes ranging from –35 °C up to 58 °C (–31 °F up to 136 °F) are permitted.

Do not use the product after its expiration date.

Checking and opening the package – Before opening the sterile package tray, visually check for any signs of damage that might invalidate the sterility of the package contents.

Single use – This product is intended for single use only. Do not resterilize and re-implant the explanted product. Reuse may compromise the structural integrity of the product or create a risk of contamination of the product that could result in patient injury, illness, or death.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment.

Connector compatibility – Use the lead only with a Medtronic EV4 implantable cardioverter defibrillator system. The known potential adverse consequences of using any other combination may include undersensing of cardiac activity, failure to deliver necessary therapy, or an intermittent electrical connection.

Medtronic EV4 devices – The EV4 connector is a Medtronic proprietary design, not an industry standard. No claims of safety and efficacy can be made with regard to devices that are not labeled as EV4 by Medtronic.

Implant tools – Do not implant the lead using any tools other than the Medtronic tunneling tools designed for implanting the extravascular ICD system.

Handling the lead – Handle the lead with care at all times.

- Do not implant the lead if it is damaged. Return the lead to a Medtronic representative.
- Protect the lead from materials that shed small particles such as lint and dust. Lead insulators attract these particles.
- Handle the lead with sterile surgical gloves that have been rinsed in sterile water or a comparable substance.
- Do not severely bend, kink, or stretch the lead.
- Do not immerse the lead in mineral oil, silicone oil, or any other liquid, except blood, at the time of implant.
- Do not use surgical instruments to grasp the lead.

If the package is damaged – The device packaging consists of an outer tray and inner tray. Do not use the device or accessories if the outer packaging tray is wet, punctured, opened, or damaged. Return the device to Medtronic because the integrity of the sterile packaging or the device functionality may be compromised. This device is not intended to be resterilized.

Additional hazards – Refer to the Medical Procedure and EMI Precautions manual for information about hazards related to medical therapies and diagnostic procedures on patients with cardiac devices.

External defibrillation equipment – Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the implant procedure, or whenever arrhythmias are possible or intentionally induced during post-implant testing.

Line-powered and battery-powered equipment – During lead implant and testing, use only battery-powered equipment or line-powered equipment specifically designed for this purpose to protect against fibrillation that may be caused by alternating currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. The lead connector pin must be insulated from any leakage currents that may arise from line-powered equipment.

Magnetic resonance imaging (MRI) – An MRI is a type of medical imaging that uses magnetic fields to create an internal view of the body. If certain criteria are met and the warnings and precautions provided by Medtronic are followed, patients with an MR Conditional device and lead system are able to undergo an MRI scan; for details, refer to the MRI technical manual that Medtronic provides for an MR Conditional device.

Removal of a chronic lead and the SureScan system – When implanting a SureScan system, consider the risks associated with removing previously implanted leads before doing so. Abandoned leads or previously implanted non-SureScan labeled leads compromise the ability to safely scan the SureScan system during MRI scans.

AccuRead tool – The AccuRead tool reduces the risk of connector damage, and reduces the risk of bridging and shorting that may occur while taking electrical measurements during implant. The potential for connector damage, bridging, and shorting is due to variations in analyzer cable terminals, as well as to the connector ring width and the proximity of the rings on the EV4 connector.

Electrophysiologic testing – Electrophysiologic evaluation and testing should be performed at the discretion of the physician, taking into consideration the current clinical guidelines.

5 Potential adverse events

The following are known potential adverse events associated with the use of this product.

Note: Implant and usage of this product may result in adverse events, which may lead to injury, death, or other serious adverse reactions.

- Acute tissue trauma
- Allergic reaction
- Bradyarrhythmia
- Cardiac arrest
- Cardiac inflammation
- Cardiac perforation
- Cardiac tamponade
- Death
- Discomfort
- Dizziness
- Dyspnea
- Erosion
- Extracardiac stimulation
- Fever
- Hematoma
- Hemorrhage
- Hemothorax
- Hiccups
- Hospitalization
- Inappropriate shock
- Infection
- Insulation failure
- Lead abrasion
- Lead fracture
- Lead migration or dislodgement
- Lethargy
- Mental anguish
- Organ damage (liver, mammary arteries, diaphragmatic arteries)
- Palpitations
- Pericardial effusion
- Pneumothorax
- Return of cardiac symptoms
- Seroma
- Syncope
- Tachyarrhythmia
- Toxic reaction
- Wound dehiscence

6 Clinical study

Information regarding clinical studies that are applicable to the Model EV2401 lead is available on the Medtronic Manual Library website:

1. Point your browser to http://www.medtronic.com/manuals.
2. Select the geography/language, and then search for the EV2401 lead model. The lead technical manual and any applicable clinical studies are listed.

If you do not have web access, you can order a printed copy of the Clinical Study Summaries from your Medtronic representative or by calling the toll-free number located on the back cover.

7 Directions for use

Warning: Before implanting a SureScan system, consider the risks associated with removing previously implanted leads. Abandoned leads or previously implanted leads not tested for MRI compatibility compromise the ability to safely scan the SureScan system during MRI scans.

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. The following procedures are provided for information only. Some implant techniques vary according to physician preference and the patient's anatomy or physical condition. Each physician must apply the information in these instructions according to professional medical training and experience.

7.1 Tunneling under the sternum

Warning: Do not place the distal portion of the EV2401 lead using a tool other than the Medtronic sternal tunneling tool. Use of a different tool could result in patient harm.

1. Prepare a 3.0 mm (9 Fr) percutaneous lead introducer that contains a hemostatic valve. Refer to the product documentation packaged with the introducer for instructions.
2. Using the Medtronic sternal tunneling tool, tunnel under the sternum according to the instructions in the product documentation supplied with the tunneling tool.
3. Remove the tunneling tool while keeping the introducer in place and minimizing air ingress. Refer to the product documentation supplied with the tunneling tool for instructions.

7.2 Opening the package

1. Within the sterile field, open the sterile package and remove the lead.
2. Inspect the lead to verify that there is an anchoring sleeve on the lead body.

7.3 Inserting and positioning the lead

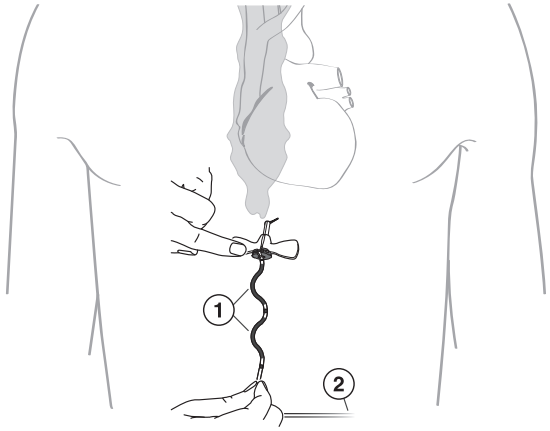
Caution: Use care when handling the lead during insertion and positioning.

- Do not severely bend, kink, or stretch the lead.
- Do not use surgical instruments to grasp the lead or connector.

Perform the following steps to insert the lead:

1. Orient the lead as shown in *Figure 3* and insert the lead into the introducer.

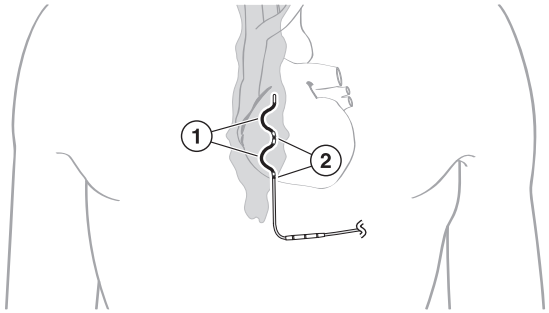
Figure 3. Lead insertion orientation



1 Coil 1 and Coil 2 electrodes are oriented toward the patient's right.
2 Proximal end of the lead is lying toward the patient's left.

2. Advance the lead through the introducer into the anterior mediastinum to the top of the cardiac silhouette until the blue insertion indicator on the lead body is at the hemostasis valve on the introducer.
   Note: The blue insertion indicator is not a predictor of lead orientation. Use fluoroscopy to confirm the correct lead orientation throughout the procedure.
3. Retract the introducer to expose enough of the Coil 1 electrode to determine its orientation.
4. Using fluoroscopy, confirm that the Coil 1 electrode is oriented toward the patient's right chest. If it is not, see *Section 7.4* for instructions on reinserting the lead.
5. Retract the introducer far enough to expose the Ring 2 electrode of the lead.
6. Using fluoroscopy, confirm that the lead is oriented correctly, as shown in *Figure 4*.

Figure 4. Correct lead orientation



1 The Coil 1 and Coil 2 electrodes must be oriented toward the patient's right chest.
2 The Ring 1 and Ring 2 electrodes must be oriented toward the patient's left chest.

Note: If the lead is not oriented as shown in *Figure 4*, see *Section 7.4* for instructions on reinserting the lead.

7.4 Reinserting the lead, if needed

Caution: If more than 5 insertions are required, it is recommended to use a new lead.

If the lead is not oriented as shown in *Figure 4*, perform the following steps:

1. Readvance the introducer over the lead body to the distal tip.
2. Withdraw the lead and reinsert it, ensuring that it is oriented correctly.

7.5 Taking electrical measurements

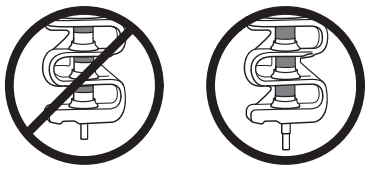
Caution: Prior to taking electrical or defibrillation efficacy measurements, move objects made from conductive materials away from all electrodes. Metal objects can short a lead and an active implantable device, causing electrical current to bypass the heart and possibly damage the implantable device and lead.

Caution: The ACI tool reduces the risk of connector damage, and reduces the risk of bridging and shorting that may occur while taking electrical measurements during implant. The potential for connector damage, bridging, and shorting is due to variations in analyzer cable terminals, as well as to the connector ring width and the proximity of the rings on the EV4 connector.

Perform the following steps to take electrical measurements:

1. Ensure that the lead connector is fully inserted into the ACI tool. The connector pin will be completely accessible if the ACI tool is properly attached (see *Figure 5*).

Figure 5.



1 When properly attached, all 3 contacts are visible through the ACI tool openings.

2. Attach a surgical cable to the ACI tool. Line up the cable clips with the contacts on the ACI tool to ensure that accurate readings are obtained. (See *Figure 13* for specific contacts.)
3. Use a testing device, such as a pacing system analyzer, for obtaining electrical measurements. For information on the use of the testing device, consult the product documentation for that device. See below for acceptable lead measurements.
4. After the electrical measurements are complete, remove the surgical cable from the ACI tool and remove the tool from the lead.
5. Remove the introducer. Refer to the product documentation packaged with the introducer for instructions.

For more information about obtaining electrical measurements, consult the product documentation supplied with the testing device.

Note: In the event that lead measurements are unacceptable, repositioning or re-tunneling is required. Refer to the tunnelling tool instructions for use.

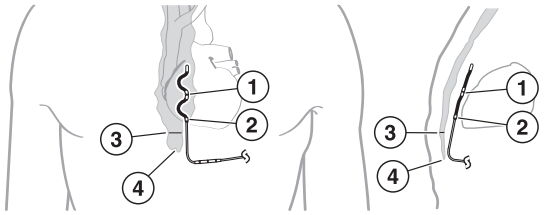
Acceptable lead measurements must meet either of the following criteria in the Ring 1 to Ring 2 vector:

- R-wave ≥1 mV and P-wave <0.2 mV through a respiratory cycle measured by the analyzer or the device.
- If P-waves are measured ≥0.2 mV but less than 0.3 mV, the R-Wave Amplitude must be greater than 10 times the P-Wave Amplitude through a respiratory cycle measured by the device.

Caution: If unable to meet the criteria above, attempt repositioning the lead or re-tunneling. If still unable to meet the criteria above, there is a potential for undersensing R-waves or oversensing P-waves and the implant of an alternative ICD system should be considered.

Warning: Ensure that the Ring 2 electrode on the lead is not located caudal to the xiphoid tip (see *Figure 6*) to avoid possible lead damage. **Note:** If the xiphoid tip is unidentifiable, do not implant the Ring 1 electrode caudal to the xiphisternal junction (see *Figure 6*).

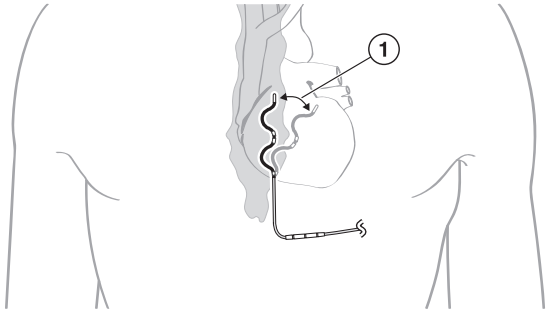
Figure 6. Example of final lead placement



1 Ring 1
2 Ring 2
3 Xiphisternal junction
4 Xiphoid tip

Warning: If the distal portion of the lead is moving significantly (see *Figure 7*), attempt repositioning or re-tunneling the lead to avoid possible damage.

Figure 7. Example of significant distal lead motion



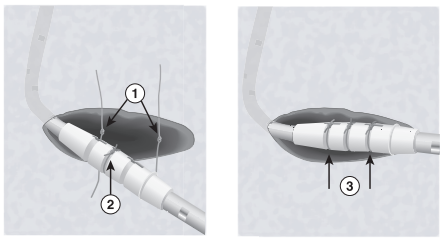
1 Example of significant distal lead motion

7.6 Anchoring the lead

Caution: Use care when anchoring the lead.

- Use only nonabsorbable sutures to anchor the lead.
- Do not attempt to remove or cut the anchoring sleeve from the lead body.
- During lead anchoring, take care to avoid dislodging the lead tip.
- Do not secure sutures so tightly that they damage the fascia, lead, or anchoring sleeve (*Figure 8*).
- Do not tie a suture directly to the lead body (*Figure 8*).

Figure 8.



1 Secure sutures to fascia.
2 Secure anchoring sleeve to lead.
3 Secure anchoring sleeve to fascia.

Note: The anchoring sleeve contains a radiopaque substance, which allows visualization of the anchoring sleeve on a standard x-ray and may aid in follow-up examinations.

Perform the following steps to anchor the lead:

1. Ensure the anchoring sleeve is distal of the blue indicator and over the indented tubing.
2. Position the anchoring sleeve in the xiphoid incision.
3. Tie two non-necrosing knots to the fascia that are correctly spaced for the two anchoring sleeve grooves.
4. Fixate with high tension force one knot around the anchoring sleeve groove and lead body only. Do not tie this knot to tissue.
5. Fixate with high tension force two knots in the remaining open grooves with the suture strands from the fascia knots.

7.7 Creating the pocket

Create a surgical pocket for the implantable device in the mid-axillary line between the fifth and sixth intercostal spaces.

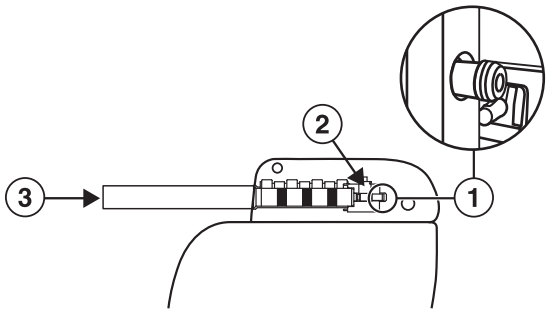
7.8 Tunneling to the pocket

1. Using the Medtronic transverse tunneling tool, tunnel from the xiphoid incision to the pocket according to the instructions in the product documentation supplied with the tunneling tool.
2. Pull the proximal end of the lead through the pocket according to the instructions in the product documentation supplied with the tunneling tool.

7.9 Connecting the lead to the device

Push the lead into the header block until the tip of the lead connector pin is visible in the pin viewing area (see *Figure 9*). Consult the product documentation packaged with the implantable device for instructions on proper lead connection.

Figure 9. Lead connector pin viewing area



1 Lead tip extends past setscrew block; lead connector pin is visible in pin viewing area
2 Setscrew block, located behind grommet
3 Lead

7.10 Placing the device and lead into the pocket

Caution: Use care when placing the device and lead into the pocket.

- Ensure that the lead does not leave the device at an acute angle.
- Do not grip the lead or device with surgical instruments.
- Do not coil the lead. Coiling the lead can twist the lead body and may result in lead dislodgment (*Figure 10*).

Figure 10.

Perform the following steps to place the device and lead into the pocket:

1. To prevent undesirable twisting of the lead body, rotate the device to loosely wrap the excess lead length (*Figure 11*).

Figure 11.

2. Insert the device and lead into the pocket.

3. Verify sensing, pacing, cardioversion, and defibrillation efficacy.
   Warning: If the implanted lead system fails to terminate a VF episode, rescue the patient promptly with an external defibrillator. At least 5 min should elapse between VF inductions.
4. Secure the device into the pocket.
5. Close the pocket and the xiphoid incision.

7.11 Post-implant evaluation

After implant, monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.

Recommendations for verifying proper lead positioning include x-rays, and pacing and sensing threshold measurements.

In the event of a patient death, explant all implanted leads and devices and return them to Medtronic with a completed Product Information Report form. Call the appropriate phone number on the back cover if there are any questions on product handling procedures.

8 Specifications

8.1 Detailed device description

Table 1. Specifications

Parameter		Model EV2401
Type		Quadripolar
Position		Anterior mediastinum
Fixation		Shaped passive fixation
Length		52 cm, 63 cm (20.47 in, 24.8 in)
Connector	Type:	EV4-LLHH
	Length (distal end to proximal end):	24.3 mm (0.96 in)
	Diameter:	3.2 mm (9.6 Fr)
Materials	Conductors:	MP35N (silver cored) composite cables
	Insulation:	Polyurethane, ETFE
	Overlay:	Polyurethane
	Ring electrodes (pace, sense):	Titanium nitride coated platinum iridium
	Coil electrodes (defibrillation):	Platinum iridium, tantalum
	Connector pin:	MP35N
Conductor resistances	Pacing (unipolar):	1.5 Ω (52 cm, 63 cm) (max)
	Defibrillation:	1.5 Ω (52 cm, 63 cm) (max)

Table 1. Specifications (continued)

Parameter		Model EV2401
Diameters	Lead body:	2.9 mm (8.7 Fr)
	Tip:	3.0 mm (9.0 Fr)
Lead introducer (recommended size)		3.0 mm (9.0 Fr)

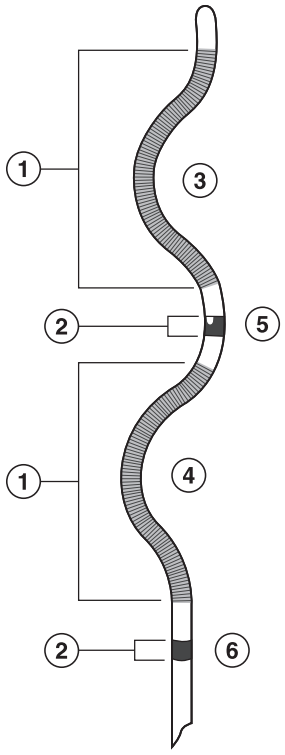
Table 2. Respective electrode distances

Coil 1 to Ring 1	4.3 mm (0.17 in)
Ring 1 to Coil 2	4.3 mm (0.17 in)
Coil 2 to Ring 2	5 mm (0.2 in)

Table 3. Pacing vectors

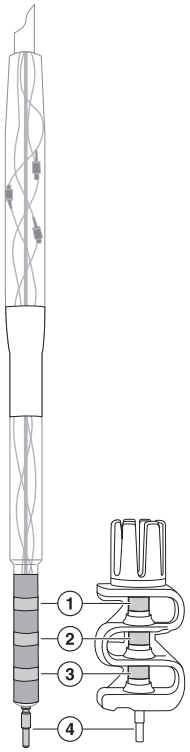
Cathode (–)	Anode (+)
Ring 1	Ring 2
Ring 1	Coil 2
Coil 2	Coil 1

Figure 12. Model EV2401 distal lead components



1 Coil 1 and Coil 2 electrode surface area: 281 mm^2 each
2 Ring 1 and Ring 2 electrode surface area: 23.8 mm^2 each
3 Coil 1 electrode
4 Coil 2 electrode
5 Ring 1 electrode
6 Ring 2 electrode

Figure 13. Model EV2401 proximal lead components



1 Coil 1 connection (defibrillation)
2 Coil 2 connection (defibrillation)
3 Ring 2 connection (sensing)
4 Ring 1 connection (sensing)

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AURORA EV-ICD™ MRI SURESCAN™ SW041

MR Programmer software

Programming Guide

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

AURORA EV-ICD™ MRI SURESCAN™ SW041

Programming Guide

A guide to programming the Medtronic Aurora EV-ICD MRI SureScan Model DVEA3E4 implantable cardioverter defibrillator using the Medtronic SW041 application software on a Medtronic programmer

Contents

1 Software overview

1.1 Introduction

This manual describes the Aurora EV-ICD MRI SureScan SW041 programmer software and explains how to use a programmer to conduct a patient session.

Throughout this manual, the word “device” refers to the implanted Aurora EV-ICD MRI SureScan defibrillator. The names of screen titles and interactive screen elements are in **bold** type. Navigation paths to software screens or programmable parameters are shown with a “>” character between steps in the path (for example, **Data** > **Clinical Diagnostics** > **Counters** > **Open Data**).

If you have a printed copy of this manual and any part of it is illegible, contact a Medtronic representative to request a replacement manual.

The following manuals and documents contain additional information about the programmer and implanted device:

MRI technical manual – This manual provides MRI-specific procedures and warnings and precautions.

Reference manual – This manual contains information about device features.

Programmer reference manual – This manual contains information about the features of the programmer. There are separate programmer reference manuals for the Medtronic CareLink 2090 programmer and the Medtronic CareLink Encore 29901 programmer.

Medical Procedure and EMI Warnings, Precautions, and Guidance Manual for Health Care Professionals – This manual provides warnings, precautions, and guidance for health care professionals who perform medical therapies and diagnostic procedures on cardiac device patients. This manual also includes information about hazards from sources of electromagnetic interference (EMI) in the patient’s home, recreational environments, and occupational environments.

Device manual – This manual contains model-specific feature information, indications and contraindications, warnings and precautions, instructions for implanting the device, quick reference specifications, parameter tables, and an explanation of package symbols.

Radio regulatory compliance information – This document provides compliance information related to the radio components of the device.

Explanation of symbols – This document defines the symbols that may appear on the device package. Refer to the package label to see which symbols apply specifically to this device.

1.2 Software description

The Aurora EV-ICD MRI SureScan SW041 software runs on the Medtronic CareLink 2090 and Medtronic CareLink Encore 29901 programmers and communicates with an implanted Aurora EV-ICD MRI SureScan device to program settings and view stored data.

The programmer and software should be used only by healthcare professionals or Medtronic personnel in a clinical or hospital environment.

Note: Do not use the **Patient Information** screen in the place of the patient's medical chart. The **Patient Information** screen of the programmer software application is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Medtronic makes no representation as to the accuracy or completeness of the patient information that end users enter into the **Patient Information** screen. MEDTRONIC SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULT FROM THE USE OF THE PATIENT INFORMATION SUPPLIED BY END USERS TO THE SOFTWARE.

1.3 Intended purpose

The Aurora EV-ICD MRI SureScan SW041 software is intended to provide information which is used to make decisions with the implanted Aurora EV-ICD MRI SureScan Model DVEA3E4 system. For information about indications for the implantable Aurora EV-ICD MRI SureScan device, refer to the device manual.

1.4 Contraindications

No contraindications related to the use of this software are known. Contraindications related to the use of the implantable device and programmers that are compatible with this software can be found in the appropriate manual for the compatible device.

1.5 Warnings and precautions

There are no general warnings or precautions related to the use of this software. Specific warnings and precautions are listed in the sections to which they pertain.

For information regarding warnings and precautions related to the use of the implantable device and programmers that are compatible with this software, refer to the appropriate manual for the compatible device.

1.6 Potential adverse events

There are no known potential adverse events related to the use of this software.

For information regarding potential adverse events related to the use of the implantable device and programmers that are compatible with this software, refer to the appropriate manual for the compatible device.

2 Patient session

2.1 Conducting a patient session

During a patient session, you can use the programmer to view or enter information about the patient and device, and to program the device.

Use the programmer to perform the following tasks:

- Review the presenting rhythm.
- Verify the status and clinical effectiveness of the implanted system.
- View or enter patient information.
- Program parameters.
- Print, save, or export data.

2.2 Starting a patient session

You can use a Medtronic programmer in wireless telemetry mode without a programming head, or in conventional telemetry mode with a programming head. Once you start a patient session using either wireless or conventional telemetry, you must terminate the session before you can switch between telemetry modes.

If you are having trouble maintaining consistent, reliable telemetry between a patient's implanted device and the programmer, remove any sources of electromagnetic interference (EMI) that can affect the telemetry signal. For more information about EMI, see the device manual.

If EMI or loss of telemetry disrupts programming, you must reestablish telemetry and program the device again.

Caution: A programmer failure (for example, a faulty touch pen) could result in inappropriate programming or the inability to stop an action or activity in progress. If a programmer fails, immediately turn off the programmer power to deactivate telemetry and stop any programmer-controlled activity in progress.

2.2.1 How to start a patient session using wireless telemetry

Caution: During a wireless telemetry session, verify that you have selected the appropriate patient before proceeding with the session, and maintain visual contact with the patient for the duration of the session. If you select the wrong patient and continue with the session, you may inadvertently program the wrong patient's device.

Caution: Do not leave the programmer unattended while a wireless telemetry session is in progress. Maintain control of the programmer during the session to prevent inadvertent communication with the patient's device.

1. Tap **Find Patient…** from the **Select Model** window.
2. Select the Allow wireless communication check box on the **Find Patient** window.
3. Briefly place the programming head over the device to activate wireless telemetry in the device. The programmer launches the patient session with tachyarrhythmia detection suspended. Detection remains suspended as long as the programming head is over the device. If tachyarrhythmia detection is programmed on, a warning reminds you that tachyarrhythmia detection is suspended.
4. Select your patient's name from the Patient Name list on the **Find Patient** window.

   Note: The programmer lists all patients with wireless-activated implantable devices within telemetry range.

5. Tap **Start**.

2.2.2 How to start a patient session using nonwireless telemetry

1. Tap **Find Patient…** from the **Select Model** window.
2. Make sure that the Allow wireless communication check box on the **Find Patient** window is not selected. If you start a session with the programming head over the patient's device and the Allow wireless communication check box is selected, the system initiates a wireless telemetry session and automatically interrogates the device.
3. Place the programming head over the device to begin the nonwireless session.

   Note: For the device to transmit EGM traces and Marker Channel data, you must keep the programming head over the device during the patient session.

2.3 Interrogating the device during a patient session

You can manually interrogate the device at any time during the patient session.

1. Tap **Interrogate…** or press the **I** button on the programming head.

   The **Interrogate How Much?** window is displayed.
2. Choose the data you would like to gather:
   - To gather information collected since the last patient session, tap **Since Last Session**.
   - To gather all the information stored in the device, tap **All**.
3. Tap **Start**.

2.4 Responding to device status indicator warnings

The device automatically monitors for internal conditions that affect device operation and require attention. If any such conditions occur, a device status indicator is recorded in memory, and a device status indicator warning is displayed on the programmer screen when the device is interrogated.

Device status indicator warnings are displayed both as a window on the programmer screen and in the Observations box on the Quick Look II screen.

Take the following actions to respond to device status indicator messages:

Indicator warning	Action
Warning - Device Electrical Reset	If the device is not yet implanted, do not implant the device. Contact a Medtronic representative. If the device is implanted, follow the procedure in *Section 2.4.1*.
SERIOUS DEVICE MEMORY FAILURE	Contact a Medtronic representative. **Immediate replacement of the device is recommended.**
SERIOUS DEVICE ERROR	Contact a Medtronic representative. **Immediate replacement of the device is recommended.**

Caution: Inform your Medtronic representative if a device status indicator warning is displayed.

2.4.1 Responding to a device reset warning for an implanted device

A device reset is a safety feature that can automatically change parameter values or clear diagnostic data in response to a problem with device memory. If a device status indicator warning for a reset is displayed, you must clear the device status indicator and may need to reprogram the device to desired parameters.

Note: Notify a Medtronic representative to report a device reset.

After a device reset, a device status indicator is recorded. For a device reset that requires attention, the device status indicator displays a warning message that describes how the reset affected device data. Follow carefully the screen instructions that are included with the warning message. If the message indicates that the reset affected device parameters, you must reprogram the device to restore the previous settings.

If the programmer displays a device reset message for an implanted device, perform the following steps:

1. Remove any sources of electromagnetic interference (EMI).
2. Tap **Clear** to clear the device status indicator.

   A confirmation window appears to indicate that all previously interrogated data in the programmer will be cleared.
3. Tap **Continue**.

   Note: If a device reset occurred while the MRI SureScan parameter was programmed to On, the **MRI SureScan** window appears. Program the MRI SureScan parameter to Off before continuing with the next step.
4. Interrogate the device.
5. The time and date that the device reset occurred can be found in the CareAlert Events log.
6. Save your session data to a disk or a USB flash drive.

   Give a copy of this saved data file to your Medtronic representative; it helps to determine the events leading up to the reset.
7. Verify the programmed device parameters and reprogram them as necessary.
8. Verify that the device date and time are correct. If you need to change the date and time, see *Section 2.9.6, Setting data collection preferences, page 28*.
9. To verify that the battery voltage is acceptable, check the **Battery and Lead Measurements** screen.
10. Conduct lead impedance and pacing threshold tests as desired.

2.5 Quick Look II screen

The **Quick Look II** screen provides a summary of the most important indicators of the system's operation and patient's condition since the last patient session. It includes links to more detailed status and diagnostic information stored in the device.

The **Quick Look II** screen provides the following information:

- Device and lead status information indicating how the system is operating.
- Information about arrhythmia episodes and delivered therapies to help assess the patient's clinical status since the last follow up appointment.
- System-defined Observations alert you to unexpected conditions, providing suggestions of how to optimize the device settings.

Note: The **Quick Look II** screen shows information collected since the last patient session and stored in the device memory. Programming changes made during the current session can also affect the Quick Look II Observations.

You can update the Quick Look II data during a session by reinterrogating the device.

The **Quick Look II** screen is displayed at the beginning of a patient session. To access the **Quick Look II** screen from another screen, tap **Data** > **Quick Look II**.

2.5.1 Information on the Quick Look II screen

The **Quick Look II** screen provides a summary of the most important indicators of the system operation and patient's condition. It includes links to more detailed status and diagnostic information stored in the device.

Available information

To view relevant details about a section of the screen, tap its ⏭ button.

Remaining Longevity – The Remaining Longevity estimate shows the estimated time remaining until Recommended Replacement Time (RRT).

To access the **Battery and Lead Measurements** screen, tap the ⏭ button to the left of the Remaining Longevity label.

Lead status and trends – The lead status section helps you to assess the performance and integrity of leads and to identify any unusual conditions. The lead status section shows the lead impedance trends. To see additional information, tap the ⏭ button to the left of the Last Measured label.

The lead trend graphs show lead impedance and R-wave amplitude measurements recorded over the last 12 months. To see more details, tap the ⏭ button to the left of either lead trend graph.

Arrhythmia episode information – This section shows the number of treated and monitored arrhythmia episodes that have occurred since the last patient session. To access the **Arrhythmia Episodes** window, tap the ⏭ button to the right of either the Treated or Monitored labels.

Pause Prevention episodes – This section shows the number of treated pause prevention episodes that have occurred since the last patient session. To see details for each episode, tap the ⏭ to the right of the Pause Prevention label.

Cardiac Compass trend data – The Cardiac Compass trend data provides a picture of the patient's condition during the last 14 months. The trend information can help to assess whether device therapies or antiarrhythmic drugs are effective. To access the **Cardiac Compass Trends** window, tap the ⏭ button to the right of the Cardiac Compass label.

Observations – Observations are based on an analysis of programmed parameters and data collected since the last session. Observations alert you to unexpected conditions related to device and lead status, parameter settings, arrhythmia episodes, and clinical status.

If you select one of the displayed observations, the ⏭ button to the right of the Observations label becomes active if additional information about the selected observation is available. To see relevant details, tap the ⏭ button.

2.6 Programmer screen

The programmer screen is divided into areas to view information, navigate among screens, and perform tasks.

The screen includes the following areas:

- Task bar at the top of the screen (See the programmer reference manual for information about the task bar.)
- Status bar below the task bar
- Live Rhythm Monitor area
- Task area that changes according to the task or function you select
- Navigation icons on the right

2.6.1 Status bar

The status bar is at the top of the display screen, below the task bar. It is available following device interrogation. Use the status bar to perform some basic functions and to note the current status of the device.

The status bar displays the following items:

- Current pacing mode
- Programmed detection and therapy configuration
- **Resume** and **Suspend** buttons, to resume or suspend detection

- The word SUSPENDED, when automatic detection is suspended
- Either the current episode, therapy, or manual operation status, or the device name and model number

2.6.2 Live Rhythm Monitor window

The Live Rhythm Monitor window displays ECG waveform traces, Marker Channel telemetry with marker annotations and intervals, and telemetered EGM waveform traces.

You can view live waveform traces, freeze waveform traces, record live waveform traces to the programmer strip chart recorder or Electronic Strip chart (eStrip) recorder, whichever is available. You can then recall any saved waveform strips before you end a patient session. In addition to waveform traces, the Live Rhythm Monitor window shows the following information:

- If telemetry has been established with the device, heart rate and interval are displayed.
- If parameters are programmed, an annotation appears above the waveform trace showing the point at which programming occurred.

The Live Rhythm Monitor window appears in partial-screen view by default. To expand this window to full-screen view, tap the small square button in the upper-right corner of the window or tap the **Adjust…** button. The display of waveform traces in the Live Rhythm Monitor window varies depending on which sources you select during data collection setup and how you arrange traces in the full-screen view.

2.6.2.1 About the Live Rhythm Monitor

The Live Rhythm Monitor can display up to 6 different waveforms during a patient session.

Waveforms are available from ECG and EGM signals:

- The ECG Lead I, ECG Lead II, and ECG Lead III waveforms display ECG signals that are detected using skin electrodes attached to the patient. The ECG cable attached to these electrodes must be connected to the programmer.
- The LECG, EGM1, EGM2, and EGM3 signals are telemetered from the device and are selected from programmable EGM sources. You can choose the signal sources for LECG, EGM1, EGM2, and EGM3 when you set up data collection. See *Section 2.9.6, Setting data collection preferences, page 28* for more information.

2.6.2.2 Adjusting the Live Rhythm Monitor display

Use the Live Rhythm Monitor **Adjust…** window selections to change the waveform display.

1. Tap **Adjust…**.

   The full-screen Live Rhythm Monitor window and the **Adjust…** window are displayed.

2. Adjust the size, source, and print selection options for each waveform trace using the waveform adjustment buttons to the left of each waveform trace.

Button	Description
	Increase the size of the waveform trace.
	Restore the waveform trace to its default size.
	Decrease the size of the waveform trace.
	Display a waveform trace, marker annotation, or marker intervals.
	Indicates which waveform traces have been selected for printing. Tap the button to clear the selection and choose a different trace.
	Select the waveform trace for printing. You can select 1 or 2 waveform traces for printing.
	Change the color of the waveform trace.

3. Adjust the appearance of all waveform traces by using the controls in the **Adjust…** window.

Optional adjustment	Steps
Truncate the tops and bottoms of waveform traces at a 22 mm boundary.	Tap **Clipping**.
Change the bandwidth of waveforms to improve the clarity of the displayed ECG in the presence of interference.	Tap **ECG Filter** and select the check box to set the bandwidth to 0.5 to 40 Hz, or clear the check box to set the bandwidth to 0.05 to 100 Hz.
Display pacing artifacts superimposed over waveform traces.	Tap **Show Artifacts**.

Optional adjustment	Steps
Control how quickly the waveform is drawn across the display.	Tap **Sweep Speed** and select a speed (12.5, 25, 50, or 100 mm/s). Selecting a fast Sweep Speed produces a wide waveform. Selecting a slow Sweep Speed produces a narrow waveform.
Equalize the spacing between the waveform traces and resize each trace to its default setting.	Tap **Normalize**.
Add a reference signal to the analog output, the screen, or the real-time strip recorder or Electronic Strip Chart (eStrip) recorder, whichever is available.	Tap  (Calibrate).

4. Tap **OK**.

   The **Adjust…** window closes and the Live Rhythm Monitor window returns to its previous size.

2.6.2.3 Marker Channel data

Marker Channel annotations on the waveform trace indicate events such as pacing, sensing, detection, and delivered therapies.

The device continuously transmits Marker Channel data and supplementary marker data while telemetry is established and the programming head is positioned over the device. Marker Channel annotations appear as 2 characters above or below the Marker Channel waveform trace.

Real-time printed waveform recordings also display symbols that appear above or below their associated Marker Channel annotations. The symbols sometimes appear compressed, depending on the printout speed of the programmer strip chart recorder. The symbols do not appear on screens or in episode recordings.

Notes:

- Any interruption in telemetry with the device can result in missing marker annotations and symbols on the waveform trace display.
- If you are using non-wireless telemetry, the device stops transmitting marker data when you lift the programming head, unless the Holter telemetry feature is programmed to On. If Holter telemetry is programmed to On, the device transmits Marker Channel data and supplementary marker data regardless of the position of the programming head.

2.6.2.4 Live waveform trace recordings

At any time during a patient session, you can record a continuous, live waveform trace of the patient's ECG and EGM in one of two ways:

1. On an internal strip chart recorder, if available on your Medtronic programmer.

   Note: The printed waveform strip is of a higher resolution than the programmer display and may show artifacts and events that do not appear on the programmer display.

2. On an Electronic Strip Chart (eStrip) recorder, if available on your Medtronic programmer.

Depending on the Medtronic programmer model used, a printout of the live waveform trace includes the following information:

- ECG and EGM traces
- An indication of an executed command when confirmation of the command is received
- Test values during system tests
- Telemetry markers that show telemetry from the programmer to the device (programming the device) and telemetry from the device to the programmer (confirming the programming)
- Decision Channel annotations

EGM waveform trace

The programmer cannot display or record an EGM waveform trace until the current EGM Range setting has been interrogated from the device. If you program an EGM Range setting during a recording, the programmer marks the change with a vertical dotted line on the paper recording. EGM and Marker Channel telemetry can be momentarily interrupted during interrogation or programming.

Simultaneous report printing and live waveform trace recording

If you attempt to print a report to the strip chart printer while performing a live waveform trace recording, the report is sent to the print queue. Printing to an external printer is not affected.

2.6.2.5 Freezing live waveform traces

The Freeze feature enables you to freeze the last 15 s of all waveform traces displayed in the Live Rhythm Monitor window.

You can use controls in the frozen strip viewer to view earlier or later portions of the strip, see frozen waveform strips that are not visible in the window, and measure a time interval.

1. Tap **Freeze**.

   The live waveform trace is frozen and displayed in the frozen strip viewer.

2. To modify or navigate the frozen strip viewer, select from the following options in the frozen strip viewer:

Optional task	Steps
Open the **Adjust…** window for the frozen strip viewer.	Tap **Adjust…** to open the **Adjust…** window. The **Adjust…** window offers display options for the frozen strip viewer that are similar to the **Adjust…** window for the Live Rhythm Monitor.
Normalize or resize the trace, or change the waveform source.	Use the waveform adjustment buttons.
Measure time intervals on the waveform trace.	Use the caliper controls. The caliper measurement is the time interval, in milliseconds, between the on-screen calipers. The arrow buttons move the on-screen calipers to show the beginning and the end of a time interval.
Open a list of other frozen strips.	Tap **Strips…** to open a list of other frozen strips. Tap a strip to view and tap **Open** to display the selected strip.
Delete the on-screen frozen strip (if it was previously saved).	Tap **Delete**.
Print the on-screen frozen strip.	Tap **Print…**.
View earlier or later portions of the strip.	Scroll horizontally using the horizontal scroll bar.
View frozen waveform strips that are not visible in the window.	Scroll vertically using the vertical scroll bar.
Save the on-screen frozen strip.	Tap **Save**.

3. To close the frozen strip viewer, tap **Close**.

2.6.2.6 Recalling saved waveform strips

Before ending a patient session, you can recall any waveform strip collected and saved during the session in order to view, adjust, and print the waveform strip.

1. Tap **Strips…** on the main screen or in the frozen strip viewer.

   The **Strips…** window is displayed.

2. Tap a strip to view.

3. Tap **Open**.

   The frozen strip viewer displays the selected strip.

2.6.3 Navigation icons

Navigation icons on the right side of the screen provide access to the main programmer screens.

Table 1. Navigation icons

	Displays options for viewing device information and diagnostic data.
	Displays the **Parameters** screen for viewing and programming device parameters.
	Displays options for performing system tests and EP studies.
	Displays options for printing reports.
	Displays the **Patient Information** screen.
	Displays options for adjusting preferences, viewing parameter changes made during the session, saving data, and ending the session.

2.7 Delivering an emergency tachyarrhythmia therapy

You can use emergency defibrillation or cardioversion to treat ventricular tachyarrhythmia episodes during a patient session:

- Emergency defibrillation therapy delivers a high-voltage biphasic shock at the selected energy level.
- Emergency cardioversion therapy delivers a high-voltage biphasic shock at the selected energy level that is synchronized to a ventricular event.

2.7.1 Considerations for emergency tachyarrhythmia therapies

Tachyarrhythmia detection during emergency tachyarrhythmia therapies – The device suspends the tachyarrhythmia detection when an emergency defibrillation or cardioversion is delivered. Tap **Resume** to resume tachyarrhythmia detection.

Temporary parameter values – Emergency tachyarrhythmia therapies use temporary parameter values that do not change the programmed parameters of the device. The device reverts to its programmed parameter values after a tachyarrhythmia therapy is delivered.

Aborting an emergency tachyarrhythmia therapy – To abort an emergency defibrillation or emergency cardioversion, tap **ABORT**.

Emergency tachyarrhythmia therapies and MRI SureScan – If the MRI SureScan feature is programmed to On, it is programmed to Off for an emergency tachyarrhythmia therapy.

2.7.2 How to deliver an emergency tachyarrhythmia therapy

1. Tap **Emergency**.
2. Tap **Defibrillation** or **Cardioversion**.
3. Tap the **Energy** field if you want to select an energy level lower than 40 J.
4. Tap **DELIVER**.

2.8 Patient information

You can enter patient-related information and program it into device memory. This information can then be viewed and printed during a patient session.

Patient information is typically entered at the time of implant and can be revised at any time. After you enter the patient's information and program it into device memory, patient information is used in the following ways:

- Clinical conditions are available for follow up appointments.
- Clinical conditions are included in the initial interrogation report and in the Save to Media file.
- Clinical conditions can be printed from the **Patient Information** screen.
- The patient's name and ID and the device serial number are included on all reports.

Some entries may appear shortened after they are entered. For example, the **Patient** field can display most but not all of the characters that can be entered. The full entry is provided on the Patient Information Report. When displayed or printed from other screens, the text entry may be shortened.

Note: Do not use the **Patient Information** screen in the place of the patient's medical chart. The **Patient Information** screen of the programmer software application is provided as an informational tool for the end user. The user is responsible for accurate input of patient information into the software. Medtronic makes no representation as to the accuracy or completeness of the patient information that end users enter into the **Patient Information** screen. MEDTRONIC SHALL NOT BE LIABLE FOR ANY DIRECT, INDIRECT, INCIDENTAL, OR CONSEQUENTIAL DAMAGES TO ANY THIRD PARTY WHICH RESULT FROM THE USE OF THE PATIENT INFORMATION SUPPLIED BY END USERS TO THE SOFTWARE.

2.8.1 Entering and viewing patient information

Enter information about the patient, the device, and the lead into the **Patient Information** screen.

1. Tap **Patient** > **Patient Information**.

   The **Patient Information** screen is displayed.

2. Tap each text field to enter or change its content:

Field	Description
Patient	Enter the patient's name (up to 29 characters).
ID	Enter the patient ID (up to 15 characters).
Date of Birth	Select the patient's date of birth.
Serial Number	Displays the serial number of the implanted device. This field is not selectable.
Lead 1…	Enter detailed information for the lead.
Implant…	Enter the defibrillation testing data and lead analysis data.
MRI SureScan System/Other Hardware…	Select this field to access the **MRI SureScan System/Other Hardware** screen. This screen includes information about leads and other hardware that can affect the decision to perform an MRI scan of this patient.
Notes	Enter notes about the patient or other information (up to 80 characters).
History…	Enter the patient's clinical conditions. This information will be available for follow up appointments.
EF, on	Select the ejection fraction from a table of values and select the measurement date.

Field	Description
Physician, **Phone**, **Hospital**	Use these fields to select the physician's name, phone number, and hospital from a list. To add a physician, phone number, or hospital information to the list, tap the corresponding field, tap **Modify List…** > **Add…**, then enter the information.
Last Update	Displays the last date that changes made to patient information were programmed into memory. This field is not selectable.

3. Tap **PROGRAM**.

2.8.2 Entering and viewing information about the MRI SureScan system and other implanted hardware

Enter information about the leads and other implanted hardware, such as abandoned devices and leads, lead extenders, or lead adaptors into the **MRI SureScan System/Other Hardware** screen.

1. Tap **Patient** > **Patient Information** > **MRI SureScan System/Other Hardware…**.

   The **MRI SureScan System/Other Hardware** screen is displayed.

2. Tap each text field to enter or change its content:

Field	Description
MRI SureScan System	
MR Conditional Device Implanted	Displays the MR Conditional status of the implanted device. This field is not selectable.
MR Conditional Lead 1 Implanted	Specify whether Lead 1 is MR Conditional by selecting **Yes**, **No**, or **Unknown**. **Note:** You can enter lead information in either the **Patient Information** screen or the **MRI SureScan System/Other Hardware** screen.
Lead 1 Model	Select a lead model from the drop-down list.
Other Hardware	
Other Devices	Enter information about any other in-use or abandoned devices.
Other Leads	Enter information about any other in-use or abandoned leads.
Lead Extenders/Adaptors	Enter information about any in-use or abandoned lead extenders or adaptors.

Field	Description
Other Hardware Notes	Enter information about other implanted hardware. This field is limited to 50 characters. **Note:** The presence of other hardware in the patient may determine if the patient can have an MRI scan.
Last Update	Displays the most recent date that changes to patient information were programmed into memory. This field is not selectable.

3. Tap **OK**.

   The **Patient Information** screen is displayed.

4. Tap **PROGRAM**.

2.9 Parameters

Parameters are settings that control device functions and data collection. You view and program parameters from the **Parameters** screen.

All device parameters that you can view and program appear as active fields. Some active fields pertain to only 1 parameter, while other fields provide access to groups of parameters. If a parameter cannot be programmed, no active field appears next to its name. All permanent parameter changes can be programmed from the **Parameters** screen.

After you select new values for parameters, the new values are designated as pending values. A field containing a pending value has a dashed rectangle as its border. Values remain pending until you program them to device memory.

2.9.1 Parameter sets

Parameter sets are collections of parameter values that have been stored for quick retrieval. They include the following types:

Medtronic Nominals – Parameter values suggested for the device by Medtronic. The Medtronic Nominals cannot be customized or deleted.

Initial Interrogation Values – The permanently programmed parameter values as determined by the first interrogation of the device during the patient session. The Initial Interrogation Values cannot be customized or deleted.

Custom sets of values – Sets of parameter values that you create for a particular clinical situation. For example, you can save a set of parameter values for an initial implant setting, for a specific disease state, or for situations in which you need to program particular parameters. The set of parameter values that you save can include both programmed and

pending values. To delete a custom parameter set, use the **Delete** button in the **Get Parameter Set** window.

See *Section 2.9.4* for additional information.

2.9.2 Accessing and programming parameters

Use the **Parameters** screen to view and program parameters.

1. Tap the **Params** icon.

   The **Parameters** screen is displayed.

2. Make the desired parameter selections.

   New values are displayed as pending values.

3. Tap **PROGRAM**.

   The pending values are programmed to device memory.

2.9.3 Parameter symbols

Symbols can appear next to parameter values to convey their status or other information.

Table 2. Symbols that appear with parameter values

Symbol	Explanation
	**Interlock –** Indicates that the parameter value conflicts with the setting of another present or pending value. Select another value or resolve the conflicting parameter value before programming the parameter.
	**Warning –** Indicates that a warning message is available regarding that value. The message can be viewed either by tapping the message button or by reselecting that parameter. In the latter case, the warning is displayed as a warning note in the selection window. These parameter values can be programmed.
	**Adaptive –** Indicates that the programmed value can be changed automatically by the device. The symbol does not necessarily indicate that the parameter value has been adapted from a previously programmed value, only that it is able to be adapted.
	**Nominal –** Indicates that the value is the Medtronic nominal value. **Note:** If the nominal value is also the programmed value, the Programmed symbol is displayed instead of the Nominal symbol.
	**Programmed –** Indicates that the value is the programmed value.

The programmer may display a message button next to the **PROGRAM** button that, when tapped, provides access to additional information about the pending parameters. The message button has one of the symbols described in the following table. When the message button is tapped, the programmer opens a second window displaying one or more messages. If there are multiple messages regarding the pending parameter values, the most significant message determines which symbol appears on the button.

Table 3. Symbols that appear on the message button

Symbol	Explanation
	**Interlock –** Indicates that a parameter interlock exists. Programming is restricted until you resolve the conflict. Tap this button for a message that describes the conflict.
	**Warning –** Indicates that there is a warning associated with programming one or more of the pending parameter values. Tap this button to view the warning message and recommendations.
	**Informational –** Indicates that there is an informational message regarding one or more of the parameter values. Tap this button to view the message.

2.9.4 Creating a custom parameter set

You can create and save sets of parameter values to the programmer and retrieve them at any time.

This capability allows you to save or quickly access a custom set of parameter values for a particular clinical situation. For example, you can save a set of parameter values for an initial implant setting, for a specific disease state, or for situations in which you must always reprogram particular parameters. The set of parameter values that you save can include both programmed and pending values.

1. Tap **Params**.

   The **Parameters** screen is displayed.

2. Make the desired parameter selections.
3. Tap **Save…**.

   The **Parameter Set Name** window is displayed.

4. Enter a name for the parameter set, and tap **OK**.

   If a parameter set exists with that name, confirm that you want to replace the existing set with a new set or change the name of the new parameter set.

The parameter set is saved for future retrieval and the parameter values appear as pending values on the **Parameters** screen.

2.9.5 Retrieving a parameter set

Use the **Get…** button to retrieve a Medtronic Nominals parameter set, an Initial Interrogation Values parameter set, or a custom parameter set.

1. Tap **Params** > **Get…**.

   The **Get Parameter Set** window opens.

2. Use the following optional tasks to manage parameter sets:

Optional task	Steps
Retrieve a parameter set.	Tap the parameter set you want to retrieve.
Program the selected parameter set.	Tap **Set Pending** to use the parameters from the selected set. The **Get Parameter Set** window closes and the new parameter values appear as pending values on the **Parameters** screen. Tap **PROGRAM** to program the pending values to device memory.
Remove an unneeded parameter set from the list.	Select the parameter set you want to remove and tap **Delete**.

2.9.6 Setting data collection preferences

Use the **Data Collection Setup** screen to control the collection of EGM data for arrhythmia episodes, to adjust the device clock, to set Observation Conditions, and to enable telemetry features.

To navigate to these parameters, tap **Params** > **Data Collection Setup**.

Notes:

- Data collection is automatic and cannot be turned off.
- The sources for the LECG, EGM1, EGM2 (Wavelet), and EGM3 signals that are displayed on the Live Rhythm Monitor are set up through the fields located under the Source and Range labels.
- Pre-arrhythmia EGM storage can affect longevity. See the reference manual for more information.

1. Tap **Params** > **Data Collection Setup…**.
2. Set your preferences using the following fields and controls:

Field	Description
EGM Source	For each EGM channel, define the source electrodes between which the device records EGM signals. **Note:** The cardiac interval measurements of the device are always based on the signals sensed through the programmed sensing polarity (not the stored diagnostic EGM). Therefore, your selection of EGM sources does not affect Post Shock pacing or Pause Prevention pacing; but your selection for the EGM 2 (Wavelet) source can affect tachyarrhythmia detection. See the reference manual for more information.
EGM Range	For each EGM channel, select a range. The EGM range setting affects the resolution of the EGM signal; the lower the setting, the higher the resolution. If the EGM signal is illegible or clipped, consider changing the range selection.
Stored (Ventricular)	Select a set of 2 sources to be used for tachyarrhythmia or Pause Prevention episode record storage.
Pre-arrhythmia EGM	Indicate if you want to store EGM data prior to an episode.
Device Date/Time…	To set the current date and time for the device, tap this field.
Holter Telemetry	Select a duration for the Holter telemetry feature to operate, or disable Holter telemetry. When Holter telemetry is enabled, the device continuously transmits EGM and Marker Channel data for the selected duration regardless of the presence of the programming head.

3. Tap **OK**.

   The **Data Collection Setup** window closes and new values are displayed as pending values.

4. Tap **PROGRAM**.

2.10 Printing reports

You can print reports at the beginning of a session, during a session, at the end of a session, and after a session. By setting printing preferences, you can identify the reports to print, whether to print them now or later, and which printer to use.

During a patient session, you can print a report on a specific programmer screen by tapping the **Print…** button or the printer icon. If the printing preferences window appears, select printing preferences as desired. If the printing preferences window does not appear, the report prints according to the previously set printing preferences.

2.10.1 Setting printing preferences

Use the **Preferences** window to select print options, such as number of copies, printer type, and whether to print now or later.

1. After starting a patient session, tap **Reports** > **Preferences…** > **Printing**.
2. Select or deselect the check box next to Pop up these options when any Print button is selected:
   - To apply the printing preferences automatically whenever you print a report, leave the check box blank.
   - To be prompted to set printing preferences each time you print a report, select the check box.
3. Select the number of copies, choose a printer, and tap **OK**.

   Note: If you select Adobe PDF from the list of available printers, you can save reports as PDF files. Reports are saved to a connected USB flash drive. If your programmer has a disk drive, you can save to a disk if a USB flash drive is not connected.

Your preferences take effect immediately.

2.10.2 Enabling printing of an Initial Interrogation Report

You can set a preference to have the software application print an Initial Interrogation Report automatically after the first interrogation in a patient session. You can also specify the data to include in the report.

Initial Report preferences take effect at the start of a new session and remain in effect until you change them and start a new session.

1. After starting a patient session, tap **Reports** > **Preferences…** > **Initial Report**.
2. Select the check box next to Print Initial Interrogation Report after first interrogation.
3. Select the reports that you want to include in the Initial Interrogation Report and tap **OK**.

   Notes:
   - The Quick Look II report is always included in the Initial Interrogation Report and cannot be deselected.
   - To print an Initial Interrogation Report for a patient session that is in progress, end and restart the patient session.

   The selected preferences are stored and the **Preferences** window closes. The Initial Interrogation Report prints automatically after interrogation.

2.10.3 Printing a set of reports during a patient session

To specify a customized set of reports for printing, use the **Reports - Available Reports** window.

1. Tap **Reports** > **Available Reports…**.
2. Select the reports you want to print.

   Note: A report can be printed only if its data has been collected. If no data has been collected, the name of the report appears gray.

   a. If a report is available, tap **Print Options…** to view the **Print - Options** window.

   b. Select your printing options and tap **OK**.
3. Tap **Print Options…** if it is available, and select printing preferences as desired.
4. Tap one of the following buttons:
   - **Print Now** prints the reports immediately.
   - **Print Later** adds the print request to the print queue.

2.10.4 Printing a Final Report for the patient session

You can print a Final Report summarizing selected data at the end of a patient session.

The Session Summary Report is always included in the Final Report. You can select additional reports to include in the Final Report using the **Preferences** window.

- Tap **Reports** > **Final Report…**.

  The result depends on the following print preference you have specified in the **Preferences** window.

Print Preference	Result
Pop up these options when any Print button is selected box is checked.	The **Reports - Final Report** window is displayed. • Specify the number of copies to print and select the printer. If you select **Full Size** for the printer, select the file format from the list of available options. • Tap **Print Now** to print the Final Report immediately. • Tap **Print Later** to add the Final Report to the print queue.
Pop up these options when any Print button is selected box is unchecked.	The Final Report prints immediately.

2.10.4.1 Setting Final Report preferences

Use the **Preferences** window to select the reports you want printed as part of the Final Report.

Your Final Report preferences remain in effect between sessions and across all applications.

Note: The Session Summary is always included in the Final Report and cannot be deselected.

1. Before ending a patient session, tap **Reports** > **Preferences…** > **Final Report**.
2. Select the reports to include in the Final Report.
3. If this is the first time you are establishing Final Report preferences, select **All Settings** in the Parameters section.
4. Select **OK**.

2.10.5 Print Queue window

The **Reports - Print Queue** window indicates the status of print jobs. It is available during a patient session and outside of a patient session.

The Reports - Print Queue window during a patient session

The **Reports - Print Queue** window indicates the printing status of reports that you select to print as you progress through a patient session. To display the **Reports - Print Queue** window during a patient session, select **Reports** > **Print Queue**.

The Reports - Print Queue window outside of a patient session

When you end a patient session, the **Reports - Print Queue** window is still available. It lists any reports held from that session and other sessions. To display the **Reports - Print Queue** window when you are not in a patient session, select the **Print Queue** icon from the **Select Model** screen.

Printing or deleting a print job

You can print or delete a print job from the queue. A report cannot be deleted if its status is Printing or Waiting.

A status of Hold-Later indicates one of the following situations:

- A report is on hold until you request that it be printed (using the **Print** button).
- The printing of a report was interrupted by the start of a recording.
- The printer is not operational (because it is out of paper, for example).

2.11 Exporting data to the Paceart system

The SessionSync feature, if available, provides network connectivity between the programmer and the Medtronic Paceart data management system. Using your clinic's network, the programmer can send downloaded device data through the SessionSync feature to the data management system for later analysis and patient management.

For information about the SessionSync feature, see the programmer reference manual.

2.12 Saving and retrieving device data

You can save interrogated device data from a patient session to a disk or to a USB flash drive. Following the patient session, you can use the Read From Media application on the programmer to retrieve, view, and print previously saved data.

The Save to Media feature stores session data in a format that can only be retrieved using the Read From Media application.

Note: You can also save reports and frozen waveform strips as PDF files by checking the **Save to PDF File** option when printing.

The Medtronic CareLink 2090 Programmer has a disk drive for 90 mm (3.5 inch) disks and a USB port. The Medtronic CareLink Encore 29901 Programmer has a USB port.

If a USB flash drive is inserted into a Medtronic CareLink 2090 Programmer, it overrides the disk drive for saving and retrieving device data. Disks can be used only when no USB flash drive is inserted.

Interrogate the device before saving data to a USB flash drive or a disk because the programmer saves only the data it has interrogated. If the **Interrogate How Much?** window is displayed, tap **All** to save a record of all the information from the device. If an issue needs to be investigated, selecting the **All** option provides more data for analysis.

During the save operation, the **Emergency** button remains displayed, and the emergency function is available. If an error occurs during a save operation, there may be a delay in initiating the Emergency screen. Do not save to media during EP studies or when it is possible that the emergency function will be needed immediately. If the emergency function is used during a save operation, the device aborts the save operation.

Do not insert or remove a USB flash drive during the following operations:

- Programming a device
- Performing a Save To Media operation
- Performing a Read From Media operation
- Saving a report or a frozen waveform strip as a PDF file

2.12.1 Saving device data

You can save interrogated device data from a patient session to a disk or to a USB flash drive.

To ensure the integrity and security of patient information, use a USB flash drive or a disk that is reserved for storing programmer data.

If you are saving to a USB flash drive, insert only one writable USB flash drive at a time. Inserting additional USB flash drives results in an error during data-saving operations and the USB indicator becomes unavailable. Insert a USB flash drive only if the programmer is turned on.

You can save to a disk if your programmer has a disk drive. If you are saving to a disk, the disk must be a formatted, IBM-compatible, 90 mm (3.5 inch) disk. If you save data to a disk that is corrupt or is not IBM-formatted, the programmer may become unresponsive. If this situation occurs, remove the disk, turn off the programmer, and then turn it on again. Normal operation should resume. Inform your Medtronic representative of this occurrence.

1. Tap **Interrogate** to interrogate the device.
2. Tap **Session** > **Save to Media…**.
3. Insert a USB flash drive into any available USB port on the programmer or insert a disk into the programmer disk drive.
4. Tap **Save**.

   If you are saving to a USB flash drive, a slight delay may occur while the USB flash drive is authorized. The USB indicator on the task bar turns green to indicate that the USB flash drive is available for use and the disk icon becomes unavailable.

While a Save To Media action is in progress, the progress indicator and the message “Save To Media - In Progress” are displayed. Before removing a USB flash drive, wait a few seconds after the progress indicator shows 100%.

2.12.2 Retrieving device data

Use the Read From Media application on the programmer to view saved data, print reports, and display all programmed parameter values.

You can use the Read From Media application only outside of a patient session. When you retrieve stored data, the programmer presents the data in a slightly different way than what is seen during a patient session. Because you are not in a live patient session, the Live Rhythm Monitor window is replaced with the device model and the words Read From Media.

Note: You cannot use the programmer to view reports that have been saved using the **Save to PDF File** option. Reports that have been saved using the **Save to PDF File** option can only be viewed on a computer equipped to display PDF files.

Warning: The Read From Media application is designed only for viewing saved data while no patient session is in progress. You cannot program a device or deliver emergency therapies from the Read From Media application.

Use the following steps to retrieve device data:

1. Insert a USB flash drive or a disk that contains information saved during a patient session.
2. From the **Select Model** screen, select the product category from the **View** list.
3. Select the Read From Media version of the device application.
4. Tap **Start**.

   A warning message is displayed informing you that programming a device and emergency operations are not possible while you are in the Read From Media application.
5. Tap **OK**.
6. Tap **Open File…**.
7. Select the data record that displays the desired device serial number, date, and time and tap **Open File**.

   The Read From Media application displays information from the saved session.

2.13 Ending a patient session

Use the **Session** icon to review changes made during a session, and use the **End Session…** button to save session data or end the patient session.

Note: Session data may be lost once a session has ended. Print session data or save the session data to a USB flash drive or disk prior to ending the session to avoid permanent loss of session data.

1. To review or print a list of changes made during this session, tap **Session** > **Changes This Session**.

   Note: Selecting **Print…** will allow you to print the list of changes made during this session.
2. Tap **End Session…**.

   The **End Session?** window is displayed.

3. Choose one of the following options:
   - To save the session data to a USB flash drive or a disk, tap **Save To Media…**.
   - To end the session and return to the **Select Model** screen, tap **End Now**.

3 Diagnostic data

3.1 Diagnostic data overview

The implanted device collects and stores a variety of data about the patient's condition and the performance of the implanted system. The programmer software allows you to access the stored data and use it to help manage patient care.

The following categories of data are available:

- CareAlert events, which include both clinical status events and system performance events
- Clinical diagnostic data
- Device and lead performance data

3.2 CareAlert Events

Important clinical management and system performance events can occur between scheduled patient sessions, eliciting CareAlert patient alerts or a CareAlert notification (if remote monitoring is available). You can program CareAlert patient alerts, delivered as device tones, or CareAlert Notifications for certain clinical management events and lead and device integrity events.

CareAlert Patient Alert and CareAlert notification settings can be programmed during implant, at patient discharge, or during a patient follow up appointment. CareAlert patient alerts can be programmed **Off**, **On-Low**, or **On-High**. Changes to CareAlert patient alerts and CareAlert notification settings take effect immediately in the implanted device upon successful completion of programming.

Note: The CareAlert Patient Alert and CareAlert notification for a device reset occur automatically and cannot be programmed.

3.2.1 Viewing alert events

The implanted device stores alert events. When you interrogate the device, downloaded alert events are logged as **Alert Events** in the **Data - Medtronic CareAlert Events** screen.

For each event, a log entry includes the date and time of the alert, a description of the event, and the measurement or information that caused the event. Up to 15 events are stored.

To view Medtronic CareAlert events, tap **Data** > **Alert Events** > **Alert Events**.

3.3 Clinical diagnostic data

You can use a variety of diagnostic data that has been collected and stored by the device to help you assess the patient's clinical condition and the effectiveness of therapies.

3.3.1 Viewing Arrhythmia Episodes data

Use the **Data - Arrhythmia Episodes** window to view summary and detailed diagnostic data for arrhythmia episodes.

1. Tap **Data** > **Clinical Diagnostics** > **Arrhythmia Episodes** > **Open Data**.

   The **Data - Arrhythmia Episodes** window displays episodes, listed in the log in the upper section of the window.

   Note: Data is not available for episodes that occur during a device session. These episodes are labeled as Episode in progress and cannot be viewed in the episode records until an interrogation is performed. To view the episode information for an Episode in progress, interrogate the device after the episode has ended.

2. Use the following filtering tools to specify which data you want to see:

Filtering tool	Steps
Specify the types of episodes (**VT/VF**, **SVT**, and **VOS**) you want to see.	Select the applicable check boxes to display the episodes.
Display episodes with specific characteristics, choosing from **All Selected Types**, **Treated**, **Shocked**, **Any Rx Failed**, **All Rx Failed**, **Monitored**, **Symptom**, or **EGM**.	Tap the box next to **View** to display a type of episode.
Display episodes that are longer than a specific amount of time.	Tap the box to the right of the **>** and choose the minimum episode duration.

   Note: For each episode type, when the log capacity is reached, data from the most recent episodes overwrites the oldest episode data in the log.

3. To view detailed information about an episode, tap the episode in the episode log.

   Details about the episode are displayed in the episode record area, in the lower portion of the **Data - Arrhythmia Episodes** window.

4. Use the following options to control the data displayed in the episode record area:

Action	Steps
Move to a specific area of the EGM view.	Use the horizontal scroll bar to change the displayed area.
Select a specific portion of an episode for which to view EGM data.	Tap **Plot**. Use the arrow buttons to adjust the location of the yellow box to select a portion of the episode. Tap **EGM** to see the selected data in the EGM format.
Change the format of the data for the selected episode.	Tap **Plot**, **EGM**, or **Text** to view the data in that format.
Maximize or minimize the plot, EGM, or text display.	Use the or buttons to change the size of the displayed episode in the window.
Switch the y-axis between interval and rate.	Tap the white **Interval/Rate** box (in Plot view) at the top of the y-axis.

3.3.2 Viewing Pause Prevention Episodes data

Use the **Data - Pause Prevention Episodes** window to analyze Pause Prevention episodes and the device therapies delivered to treat those episodes.

1. Tap **Data** > **Clinical Diagnostics** > **Pause Prevention Episodes** > **Open Data**.

   The **Data - Pause Prevention Episodes** window is displayed.

2. Tap an episode from the episode log.

   Details about the episode are displayed in the episode record area.

3. Use the following options to control the data displayed in the episode record area:

Action	Steps
Move to a specific area of the EGM view.	Use the horizontal scroll bar to change the displayed area.
Sort by Date/Time or Treated.	Use the Sorted by field to sort by **Date/Time** or **Treated**.
Change the format of the data for the selected episode.	Tap **EGM** or **Text** to view the data in that format.
Maximize or minimize the plot, EGM, or text display.	Use the or buttons to change the size of the displayed episode in the window.

3.3.3 Viewing Flashback Memory data

Use the **Data - Flashback Memory** window to view a graph showing ventricular intervals that occur immediately prior to VT/VF episodes or the most recent interrogation. This data may help to assess the patient's heart rhythm and the performance of device therapies.

Note: Flashback memory is not available for SVT or VOS episodes.

1. Tap **Data** > **Clinical Diagnostics** > **Flashback Memory** > **Open Data** or tap the **Flashback** button on the record detail view for the most recent VT/VF episodes on the **Data - Arrhythmia Episodes** window.
2. Use the following options to control how the data is displayed:

Action	Steps
Select the interval to view.	Select an option under **View Intervals Prior to:**.
Switch the y-axis between interval and rate.	Tap the box at the top of the y-axis to toggle between episode **Interval (ms)** and **Rate (bpm)**.
Shrink or enlarge the region to display when the view is maximized.	Use the zoom region resize buttons to adjust the location of the yellow box to select a portion of the interval. Tap to shrink the region to display and tap to enlarge the region to display. Tap to maximize the view of the selected data in the yellow box.
Reposition the region to display when the view is maximized.	Use the arrow buttons to adjust the location of the yellow box to select a portion of the interval. Tap to maximize the view of the data in the yellow box.
Maximize or minimize the view of the selected region.	Use the or buttons to change the size of the displayed interval in the window.

3.3.4 Viewing Cardiac Compass Trends data

Use the **Cardiac Compass Trends** window to view data about the patient's condition during the last 14 months. The trend information can help you to assess whether device therapies or antiarrhythmic drugs are effective.

- Tap **Data** > **Clinical Diagnostics** > **Cardiac Compass Trends** > **Open Data**.

  The **Cardiac Compass Trends** data is displayed.

3.3.5 Viewing Rate Histograms data

Use the **Rate Histograms** window to view information about heart rates recorded between patient sessions. This data can help you to monitor a patient's condition and assesses the effectiveness of therapies.

- Tap **Data** > **Clinical Diagnostics** > **Rate Histograms** > **Open Data**.

  The **Rate Histograms** data is displayed.

3.3.6 Viewing Counters data

Use Counters data for information about the number of times VT/VF episodes and therapies and Pause Prevention episodes have occurred.

1. Tap **Data** > **Clinical Diagnostics** > **Counters** > **Open Data**.

   The **Data - Counters** screen is displayed.

2. Use the options near the top of the screen to specify which counters to display (VT/VF Episodes, VT/VF Rx, or Pause Prevention Episodes).

3.4 Device and lead performance data

The device automatically measures and records device and lead performance data every day. Detailed views of this data are available from the **Data - Battery and Lead Measurements** screen and the **Data - Lead Trends** screen.

3.4.1 Viewing battery and lead measurements

Use the **Data - Battery and Lead Measurements** window to view the most recent values for key measures of device and lead performance.

Warning: Replace the device immediately if the programmer displays an End of Service (EOS) indicator. The device can lose the ability to pace, sense, and deliver therapy adequately after the EOS indicator appears.

Note: If the programmer displays the Recommended Replacement Time (RRT) indicator, contact your Medtronic representative and your patient to schedule a replacement procedure.

1. Tap **Data** > **Device/Lead Diagnostics** > **Battery and Lead Measurements** > **Open Data**.

   The **Data - Battery and Lead Measurements** window is displayed.

   - For lead impedance measurements, the window displays the most recent manual measurements or the most recent daily automatic measurements.
   - For sensing amplitude measurements, the window displays the most recent daily automatic measurements. Measurements performed with the manual Sensing test are not displayed on the **Data - Battery and Lead Measurements** window.

2. Optionally, tap the ⏭ button to the right of the Lead Impedance label or the Sensing label to compare the most recent measurements to the trends of daily automatic measurements.

   The **Data - Lead Trends** window is displayed.

3.4.2 Viewing lead impedance trends

Use the **Data - Lead Trends** screen to view a graph displaying the automatic daily lead impedance measurements. Significant or sudden changes in lead impedance may indicate a problem with the lead.

The graph displays up to 15 of the most recent automatic daily measurements and up to 60 weekly summary measurements. Gaps in the trend graph occur if the device was unable to perform automatic lead impedance measurements.

1. Tap **Data** > **Device/Lead Diagnostics** > **Lead Impedance Trends** > **Open Data**.

   The **Data - Lead Trends** screen is displayed.

2. Select the measurement trend that you want to display.

3.4.3 Viewing sensing amplitude trends

Use the **Data - Lead Trends** screen to view a graph displaying the automatic daily sensing amplitude measurements. Significant or sudden changes in sensing amplitude may indicate a problem with the lead.

The sensing amplitude graph displays up to 15 of the most recent automatic daily measurements and up to 60 weekly summary measurements. The daily measurements are the median values of the amplitudes of 9 normal intrinsic sensed events. Gaps in the trend graph occur if the device was unable to collect 9 amplitude measurements on a given day.

1. Tap **Data** > **Device/Lead Diagnostics** > **R Wave Amplitude Trends** > **Open Data**.

   The **Data - Lead Trends** screen is displayed.

2. R-wave amplitude measurement is displayed.

4 System test and EP study features

4.1 Overview of system test and EP study features

System test features include manual tests of the patient's condition and the device's functionality. Electrophysiology (EP) study features include arrhythmia induction protocols and manual therapy delivery.

System test features

- Sensing test: measure R-wave amplitudes.
- Pacing Threshold test: determine the patient's pacing stimulation thresholds.
- Lead Impedance test: test the integrity of the implanted lead system.
- Charge/Dump test: measure the time needed to charge (and dump) capacitors for cardioversion or defibrillation therapy.
- Wavelet test: test the Wavelet dynamic discrimination feature to evaluate the existing template and collect a new template, if necessary.

Electrophysiology (EP) study features

- Arrhythmia induction protocols: T-Shock, Burst Induction, and Programmed Electrical Stimulation (PES).
- Manual therapies: Defibrillation, Cardioversion, and Burst ATP.

4.1.1 Setting test preferences for the Live Rhythm Monitor

You can choose to allow the live rhythm display to arrange the order of the waveforms, or to keep the waveform arrangement unchanged.

1. Tap **Reports** > **Preferences** > **Tests**

   Waveform display options become available on the **Preferences** screen.

2. Select one of the following options:

Option	Steps
Allow the programmer to determine the top-to-bottom order of waveforms for tests.	Select **Auto-arrange waveforms**.
Leave the waveform display unchanged during a test.	Select **Do not auto-arrange waveforms**.

3. Tap **OK**.

   Test preferences are saved and the **Preferences** screen closes.

4.2 Performing a Sensing Test

The sensing test enables you to measure R-wave amplitude on the programmed Sense Polarity. This test is used to assess lead integrity and sensing performance.

Sensing amplitude measurements taken during a sensing test can include events that are atypical or result from oversensing. These events are excluded from the daily automatic sensing amplitude measurements, which the device collects and reports in the sensing amplitude trends. Because of this difference in measurement operations, sensing test amplitude results can differ from amplitudes reported in the sensing amplitude trend data.

Considerations for performing a sensing test:

- If no intrinsic events occur, the sensing test ends after a few seconds.
- Tachyarrhythmia detection is suspended during the sensing test.

Use the following steps to perform a sensing test:

1. Tap **Tests** > **Sensing**.
2. Tap **START Measurement**.
3. Observe the Live Rhythm Monitor for an intrinsic rhythm.

   Notes:

   - To abort the test, tap **STOP and Restore**.
   - The device measures amplitudes only on intrinsic events. The maximum amplitude value that the sensing test can measure is 10 mV. If the amplitude is over 10 mV, the results are displayed as >10 mV.
   - The measured amplitude for 3 to 5 sensed events will be annotated in the real time waveform area while the test is in progress.

The sensing test ends when it has measured 5 intrinsic events. When the test is complete, the R-Wave Amplitude value is updated on the test screen. This value represents the median measured R-wave amplitude.

To compare the sensing test measurements with the automatic daily sensing amplitude measurements, tap the R Wave Amplitude Trends » button.

4.3 Measuring pacing thresholds

The Pacing Threshold test enables you to monitor patient response to changes in pacing outputs, and to determine when loss of capture occurs. To ensure capture while minimizing output to maximize battery longevity, this test enables you to optimize pulses delivered for Post Shock pacing, Pause Prevention pacing, and ATP therapies.

Considerations for measuring pacing thresholds:

- The Model DVEA3E4 device is permanently programmed to OVO mode, but the Pacing Threshold test is delivered in VVI mode.
- After performing a Pacing Threshold test, make sure that the permanently programmed pulse amplitude and width parameters for all pacing features provide an adequate safety margin above the pacing threshold.
- Tachyarrhythmia detection is suspended during the Pacing Threshold test.

1. Tap **Tests** > **Pacing Threshold**.
2. Review the displayed values in the **Tests - Pacing Threshold** screen and consider the following options:

Optional task	Steps
Change the Pace Polarity, Lower Rate, Amplitude, Pulse Width, or Sensitivity.	Tap the field next to the parameter to change its value.
Change the value for V. Pace Blanking.	Tap **Additional Settings…** and then tap the field next to V. Pace Blanking. Select your desired temporary V. Pace Blanking value.

3. Check the **Enable** check box.
4. Press and hold **TEST Press and Hold**.
5. Observe the Live Rhythm Monitor for loss of capture.
6. When capture/loss of capture is assessed with current settings, release **TEST Press and Hold**. The programmer displays the **Pacing Threshold Test - Results** window.
7. Note when capture is determined.
8. View the data in the **Pacing Threshold Test - Results** window:

Optional task	Steps
View the pending value and permanent value for the V. Pace Blanking parameter. **Note:** V. Pace Blanking permanent value will only appear if a pacing feature is enabled.	Tap **Additional Settings…** to view the values. Tap **OK** to return to the **Pacing Threshold Test - Results** window.
View a test strip from the most recent pacing threshold test.	Tap the **Test Strip** icon to view the test strip. Tap **Close** to return to the **Pacing Threshold Test - Results** window.
Print a Pacing Threshold Test Report.	Tap **Print…**.

9. When you have finished viewing data on the **Pacing Threshold Test - Results** window, tap **Close** to return to the **Tests - Pacing Threshold** screen.

4.4 Measuring lead impedance

The Lead Impedance test allows you to test the integrity of the implanted lead by measuring the impedance of its electrodes.

These are considerations for measuring lead impedance:

- The device takes measurements with low-voltage, subthreshold pulses that do not capture the heart.
- The test pulses may cause very small variations on one or more of the EGM channels or the LECG channel.
- Tachyarrhythmia detection is suspended during the Lead Impedance test.

You can compare the measured impedance values to the impedance values reported on the **Data - Lead Trends** window. You can also compare the measured impedance values to the values measured and recorded during previous follow-up appointments.

1. Tap **Tests** > **Lead Impedance**.
2. Tap **START Measurement**.
   a. The message Measurement in progress… and a test progress indicator display on the programmer.
   b. If necessary, tap **STOP** to terminate the test. Lead impedance measurements are not updated from a test that is stopped.

   When the test is complete, the new measured impedance values for the tested polarities are displayed.

4.5 Performing a charge/dump test

The Charge/Dump Test allows you to test the charge time of the capacitors and dump any charge remaining on the capacitors. After the capacitors are charged, the charge remains on the capacitors until the charge is dumped, delivered by a cardioversion or defibrillation therapy, or allowed to dissipate. The Charge/Dump Test screen displays the date, time, charge time, and energy values for the last time the device capacitors were charged (from any starting energy to any final energy).

Note: Tachyarrhythmia detection is suspended during the Charge portion of the Charge/Dump Test.

4.5.1 How to perform a Charge/Dump Test

1. Tap **Tests** > **Charge/Dump**.
2. Tap **DUMP Capacitors**. This dumps any residual charge from the capacitors.
3. Wait 30 s for the charge to dump.
4. Tap **CHARGE Capacitors**. As the capacitors charge, the message “Manual operation charging” displays on the device status line. If necessary, tap **ABORT Test** to abort the charge.

   When the capacitors are fully charged, a CE (charge end) symbol displays on the Marker Channel. Also, the message “Manual operation charging“ no longer displays on the device status line.
5. To retrieve the charge time data, tap **RETRIEVE Data**.

Note: Charging the capacitors reduces device longevity by approximately 1 month.

4.6 Performing a wavelet test

The Wavelet feature is designed to discriminate between rapid SVT and VT/VF episodes by comparing a patient’s QRS waveforms to a stored template collected during normal sinus rhythm. The Wavelet test allows you to evaluate the current template and collect a new template, if necessary.

For a full description of the Wavelet feature, including automatic template collection, see the reference manual.

4.6.1 Evaluating the current template

You can use the Wavelet test to evaluate the accuracy of the current Wavelet template. As the test is conducted, intrinsic QRS waveforms are assigned match scores (percentages) in the Live Rhythm Monitor area. The higher the percentage, the closer the template event matches the patient's intrinsic event. Waveforms that fall below the programmable Match Threshold value are determined to be non-match events.

Note that changes to the Match Threshold value can adversely affect Wavelet operation. For information about Wavelet and the impact of increasing or decreasing the Match Threshold value, see the reference manual.

4.6.1.1 Considerations for evaluating a template

Patient comfort – Reduce the pacing rate gradually to minimize symptoms associated with abrupt changes in heart rate.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended when you tap **SHOW Match Scores** to evaluate a Wavelet template.

4.6.1.2 How to evaluate the current template

1. Interrogate the device.
2. Tap **Tests** > **Wavelet**.
3. Tap **SHOW Match Scores**.
4. Observe the Live Rhythm Monitor for the intrinsic rhythm and the match scores for each compared event. The higher the percentage shown for the match scores, the more likely the template reflects the patient's intrinsic morphology.
5. If necessary, tap **ABORT** to abort the test.
6. After the test completes, tap **Details** to view details about the stored template.

4.6.2 Collecting a template

You can use the Wavelet test to collect a template manually if one does not exist or if the existing template no longer matches the patient's intrinsic QRS morphology. Certain factors, such as a change in the patient's medication or disease progression, may have affected the appropriateness of the currently stored template. See *Section 4.6.1*.

After you successfully collect a template, the template goes into effect immediately and does not go through a confirmation process.

4.6.2.1 Considerations for collecting a new template

Intrinsic events – There must be a sufficient number of intrinsic events that occur during the template collection process in order to collect a template. If no intrinsic events occur, the test ends automatically after several seconds and restores the programmed settings.

High or low EGM amplitude – Ensure that the EGM 2 range closely matches the amplitude of the patient's EGM signals so that a template can be collected. If the EGM signal exceeds the EGM 2 programmed range, you can increase the EGM 2 range to prevent clipping of the signal. If the EGM signal occupies only a small fraction of the EGM amplitude range, decrease the EGM 2 range so that the signal uses a larger portion of the range. You can access the EGM 2 range by tapping **Params** > **Data Collection Setup…**. After adjusting the EGM 2 range, you will need to collect a new template.

Tachyarrhythmia detection suspended – Tachyarrhythmia detection is suspended when you tap **COLLECT Template** to collect a new Wavelet template.

4.6.2.2 How to collect a new template

1. Interrogate the device.
2. Tap **Tests** > **Wavelet**.
3. Tap **COLLECT Template**.
4. After a template is collected, observe the Live Rhythm Monitor for the patient's intrinsic rhythm and the match scores for each compared event. If necessary, tap **ABORT** to abort the test.

   If the **Wavelet** test cannot collect enough matching EGM signals, the programmer displays the **Template Collection Problem** window, which is then used to manually collect a template.

   a. Tap **Close**, and try to collect the template again. If you cannot collect a template, use the **Template Collection Problem** window to select a set of waveforms for the template.

   b. Refine the template by clearing the check box next to the color bar for each waveform sample that you do not want to include in the new template.

   c. Tap **Calculate Template**.

   d. Tap **SHOW Match Scores** to evaluate the newly collected template.

4.7 EP Study arrhythmia inductions

The system provides several electrophysiology study (EP Study) test functions that can be used to induce arrhythmias in order to evaluate the effectiveness of tachyarrhythmia therapies.

The available arrhythmia induction methods are manual therapies. These therapies include T-Shock, Burst Induction, and Programmed Electrical Stimulation (PES).

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

Considerations for inducing an arrhythmia

Telemetry – Ensure that there is a telemetry link between the device and the programmer before performing an EP Study function. Successful interrogation or programming confirms proper communication between the device and the programmer.

Detection resumes – Tachyarrhythmia detection is automatically suspended during all EP Study tests, and it automatically resumes when a test has ended or if a test is aborted.

Aborting an induction or therapy – As a safety measure, the EP Study screen provides an **ABORT** button to abort any induction or tachyarrhythmia therapy in progress. In addition to the **ABORT** button, Burst Induction is aborted when the **BURST Press and Hold** button is released. When a manual therapy is delivered, the device automatically aborts any induction or automatic therapy in progress.

Temporary parameter values – The EP Study functions use test values that do not change the programmed parameters of the device. The test values take effect when the induction or therapy begins.

Programming head buttons – The programming head buttons are disabled during the following situations:

- The Program button on the programming head is disabled during EP Study inductions and manual therapies. Use the appropriate button on the programmer screen to deliver an induction or manual therapy.
- The Interrogate button on the programming head is disabled during EP Study inductions only. To interrogate the device while the EP Study induction screen is active, use the **Interrogate…** button on the programmer screen.

4.7.1 Inducing VF with T-Shock

The T-Shock test is a defibrillation threshold test that delivers from 2 to 15 VOO pulses, followed by a high-voltage shock, to induce VF. The VOO pulses make the T-Wave timing more predictable so that the high-voltage shock is delivered simultaneously with the T-Wave. You can specify the characteristics of the pacing pulses and high-voltage shock, and you can program a 120 ms – 600 ms delay between the final pacing pulse and the shock.

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia can degenerate to ventricular fibrillation.

To induce tachyarrhythmia with T-Shock, perform the following steps:

1. Tap **Tests** > **EP Study** > **T-Shock**.
2. Accept the displayed test values, or select new test values.
3. To view and change VF detection and therapy parameters, tap **Adjust Permanent…**.
   a. If you adjust any VF detection and therapy parameters in the **Adjust Permanent** window, tap **PROGRAM** to program the changes.
   b. Tap **Close** to close the **Adjust Permanent** window.
4. Check the **Enable** check box.

   Note: If the energy on the capacitors is higher than the energy level you selected for the T Energy parameter, the programmer displays a warning when you check the **Enable** check box. To clear this warning, tap either **Dump** or **Cancel**.

5. Tap **DELIVER T-Shock**.

   Note: If necessary, tap **ABORT** to stop a therapy in progress.

6. To review the T-Shock therapy data, tap **Retrieve Data…**. The data is recorded under Last High Voltage Therapy.

4.7.2 Inducing a tachyarrhythmia with Burst Induction

The Burst Induction test delivers high-voltage VOO pacing pulses for a duration of your choosing, up to 10 s. The pulses are delivered at an amplitude of 40 V, a pulse width of 2 ms, and a rate of approximately 20 pulses per s.

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

To induce tachyarrhythmia with a Burst Induction, perform the following steps:

1. Tap **Tests** > **EP Study** > **Burst Induction**.
2. Check the **Enable** check box.

   Note: If the energy on the capacitors is higher than the energy level you selected, the programmer displays a warning when you check the **Enable** check box. To clear this warning, tap either **Dump** or **Cancel**.

3. Press and hold **BURST Press and Hold**.

   Note: If necessary, tap **ABORT** to abort a therapy in progress.

4. To terminate the induction, release the button.

   If you do not release the button, the induction times out after 10 s.

4.7.3 Inducing a tachyarrhythmia with a Programmed Electrical Stimulation (PES)

To induce a tachyarrhythmia, a Programmed Electrical Stimulation (PES) delivers a selectable number of pacing pulses at individually-selectable intervals.

Warning: Monitor the patient carefully when using an EP study function. Have an external defibrillator ready for use when inducing any tachyarrhythmia. An induced tachyarrhythmia may degenerate to ventricular fibrillation.

PES delivers a selectable number of pacing pulses at the S1S1 interval and then delivers up to 3 asynchronous pacing pulses at S1S2, S2S3, and S3S4 intervals. You can specify the pace polarity, pulse width, and pacing intervals for the induction. When the Pace Polarity is programmed to Coil 1 to Coil 2, you can also specify the pacing amplitude for the induction.

To induce a tachyarrhythmia with a PES, perform the following steps:

1. Tap **Tests** > **EP Study** > **PES**.
2. Check the **Enable** check box.
3. Verify the displayed test values. If needed, select new test values by tapping the value you want to change.
4. Tap **DELIVER PES**.

   Note: If necessary, tap **ABORT** to stop a therapy in progress.

4.8 EP Study manual therapies

During EP testing, you can deliver tachyarrhythmia therapies from the programmer.

Warning: Monitor the patient carefully when delivering a manual therapy. Have an external defibrillator nearby and ready for immediate use. Potentially harmful tachyarrhythmias can occur during device testing.

During follow up appointments, manual therapies can be helpful in assessing therapy effectiveness and making any necessary adjustments as part of chronic care. The available manual therapies include Defibrillation, Cardioversion, and Burst ATP.

Considerations for manual therapies

Aborting a Burst ATP therapy – As a safety precaution, you can tap **ABORT** to stop a Burst ATP therapy in progress.

A Defibrillation therapy or Cardioversion therapy cannot be stopped after it has been initiated.

Detection suspended during manual therapies – Tachyarrhythmia detection is suspended when delivering a manual therapy. Detection stays suspended until you tap **Resume** or the telemetry session between the programmer and device terminates.

Temporary parameter values – The test values that you select for the EP Study manual therapies do not change the programmed parameters of the device. The test values take effect when a therapy begins. After the therapy, the device reverts to its programmed parameter values for tachyarrhythmia therapies.

Programming head buttons – The program button on the programming head is disabled during manual therapies. To deliver a manual therapy, tap **DELIVER** on the programmer.

Telemetry – Ensure that there is a telemetry link between the device and the programmer before performing a manual therapy. Successful interrogation or programming confirms proper communication between the device and the programmer.

Operation of manual therapies

Manual therapies deliver the selected therapy one time. Each therapy provides a set of adjustable parameters to apply during therapy delivery.

Defibrillation therapy – Manual defibrillation therapy delivers a defibrillation shock at the selected energy level and pathway.

Cardioversion therapy – Manual cardioversion therapy delivers a cardioversion shock at the selected energy level and pathway.

Burst ATP therapy – Manual Burst ATP pacing therapy delivers the selected number of pacing pulses in VOO mode. The pacing interval for the pulse sequence is determined as a percentage of the tachycardia cycle length using the selected **%RR interval** value. The pulses within the sequence are delivered at the same pacing interval.

4.8.1 Delivering a manual therapy

You can perform device therapies manually to assess their effectiveness, or to provide backup therapy during EP episode induction tests.

1. Tap **Tests** > **EP Study**.
2. Tap **Defibrillation**, **Cardioversion**, or **Burst ATP**.
3. Verify the displayed test values. If needed, select new test values by tapping the value you want to change.
4. Select the **Enable** check box.

   Note: If the energy on the capacitors is higher than the Energy level you selected to deliver for a Defibrillation or Cardioversion induction test, the programmer displays a warning when you check the **Enable** check box. To clear this warning, tap either **Dump** or **Cancel**.

5. Tap **DELIVER**.

   Note: If necessary, tap **ABORT** to stop the manual therapy.

Glossary

Antitachycardia pacing (ATP) – therapies that deliver rapid sequences of pacing pulses to terminate tachyarrhythmias.

Burst pacing – manual antitachycardia pacing (ATP) therapy that delivers ventricular pacing pulses with an interval that is a programmable percentage of the tachycardia cycle length.

Cardiac Compass Trends – overview of the patient's condition over the last 14 months with graphs that display long-term clinical trends in heart rhythm, such as frequency of arrhythmias, heart rates, and device therapies.

Charge/Dump Test – feature that tests the charge time of the capacitors and dumps any charge remaining on the capacitors.

Decision Channel annotations – annotations to stored and telemetered EGM that document details about tachyarrhythmia detection operations.

device reset – automatic device operation to recover from a disruption in device memory and control circuitry. Programmed parameters may be set to default reset values. This operation triggers a device status indicator.

device status indicator – value recorded in device memory to signify a condition or problem that may affect device operation and that requires attention.

electromagnetic interference (EMI) – energy transmitted from external sources by radiation, conduction, or induction that can interfere with device operations, such as sensing, or can potentially damage device circuitry.

Emergency therapies – Defibrillation or cardioversion that can be administered manually to treat ventricular tachyarrhythmia episodes.

EOS (End of Service) – battery status indicator displayed by the programmer to indicate that the device should be replaced immediately and that it may not operate per specifications.

event – a sensed or paced beat.

Flashback Memory – diagnostic feature that records the intervals that immediately preceded tachyarrhythmia episodes or that preceded the last interrogation of the device and plots the interval data over time.

Holter telemetry – telemetry feature that transmits EGM and Marker Channel data continuously for a programmable number of hours, regardless of whether telemetry actually exists between the device and programmer.

last session – refers to the last time the device was successfully interrogated before the current interrogation. A session ends 8 hours after the last interrogation.

Marker Channel recording – a feature that annotates pacing, sensing, and therapy operations on the ECG record, as they occur.

MR Conditional – an item that has been demonstrated to pose no known hazards in a specified MR environment with specified conditions for use.

MRI SureScan – a feature that permits a mode of operation that allows a patient with a SureScan system to be safely scanned by an MRI machine.

oversensing – inappropriate sensing of cardiac events or noncardiac signals. Examples include T-waves, myopotentials, and electromagnetic interference.

pacing threshold – minimum pacing output that consistently captures the heart.

Quick Look II data – overview data summarizing the most important indicators of system operation and the patient's condition, including information about device and lead status, arrhythmia episodes, and system-defined observations.

Rate Histograms – diagnostic feature that shows range distributions for a patient's heart rate.

Remaining Longevity estimate – an estimate of remaining device longevity that is displayed on the **Quick Look II** screen and **Battery and Lead Measurements** window. This information includes a graphical display for easy reference and the estimated number of years or months of remaining longevity. On the **Battery and Lead Measurements** window, the Minimum and Maximum number of years or months of remaining device longevity are also provided.

Resume – programming command that reinstates automatic tachyarrhythmia detection.

RRT (Recommended Replacement Time) – battery status indicator displayed by the programmer to indicate when replacement of the device is recommended.

sensed event – electrical activity across the sensing electrodes that exceeds the programmed sensitivity threshold and is identified by the device as a cardiac event.

Suspend – programming command that temporarily deactivates the tachyarrhythmia detection functions.

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ExtraVascular Implantable Cardioverter Defibrillator (EV ICD) Pivotal Clinical Study

Summary of clinical results

Clinical Study Summary

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician

Table of Contents

1. Clinical Summary

Study Title:	ExtraVascular Implantable Cardioverter Defibrillator (EV ICD) Pivotal Study
Number of Centers:	46 centers across 17 countries, including: Australia, Austria, Canada, Denmark, France, Hong Kong, Hungary, Italy, the Netherlands, New Zealand, Norway, Poland, Saudi Arabia, Spain, Switzerland, The United Kingdom, and the United States
Number of Subjects:	356 subjects were enrolled in the study, of which 316 underwent an implant attempt with the EV ICD System. Of the 316 subjects who underwent an implant attempt, the substernal lead was positioned in 315. A total of 299 subjects were successfully implanted with the full system.

2. Study Purpose

The purpose of the EV ICD Pivotal clinical study was to demonstrate the safety and efficacy of the EV ICD System: a complete single-chamber extravascular ICD system with the lead implanted substernally.

3. Study Scope, Design, and Methods

The EV ICD Pivotal clinical study was a prospective, multi-center, single-arm, pre-market clinical study. The purpose of this clinical study was to demonstrate the safety and efficacy of the EV ICD System.

The study design allowed for up to 400 enrollments at up to 60 sites worldwide, to allow at least 292 subjects to, in the case of the safety objective, undergo an implant attempt of the EV ICD System, and in the case of the efficacy objective, complete the pre-specified defibrillation testing protocol.

Maximum number of subjects enrolled at each site was capped at 35, which is approximately 10% of the total number of subjects enrolled.

Subjects indicated for single-chamber ICD therapy were recruited and implanted with the Medtronic EV ICD System. Once enrolled, a subject was assessed at the following visits:

- Baseline
- Implant
- Pre-Hospital Discharge (PHD)
- 2 Weeks (2WK)
- 3 Months (3M)
- 6 Months (6M)
- Long-term: Every 6 months thereafter until study closure (12, 18, 24… Months)
- Unscheduled (as they occur)
- System Modifications (as they occur)
- Exit

Refer to Table 1 for the schedule of events for the Pivotal study visits.

The sponsor consulted with the Steering Committee before and during the study.

A Clinical Events Committee (CEC) consisting of physicians independent of the study was used to review and adjudicate adverse events (AEs) for their relationship to the EV ICD Pivotal system and/or procedure.

A Data Monitoring Committee (DMC) consisting of members independent of the study was used to periodically review the total incidence of AEs and follow trends of these events in the study, and to make recommendations to Medtronic and/or the Steering Committee regarding study conduct and subject safety.

An Episode Review Committee (ERC) consisting of independent physicians and Medtronic experts was used to evaluate device-treated ventricular episodes according to an ERC Charter.

Table 1. EV ICD Pivotal Study schedule of events

Study procedure	Baseline	Implant	PHD	2 Weeks	3 Months	6 Months	Long-Term (12, 18, 24… months)	Unsched.	Sys. Mod.	Exit
Informed Consent	X									
Inclusion/Exclusion Assessment	X									
Physical Exam, Demographics, Cardiovascular Medical History, Surgical History	X									
SF-12 quality of life survey	X					X				
Florida Patient Acceptance Survey (FPAS)[1]						X				
System and procedure information		X							X	
Pre-procedure Transesophageal Echocardiogram (TEE)[2]		X[2]								
CT or MRI scan	X[3]									
Fluoroscopy recordings during tunneling procedure		X							X[6]	
Fluoroscopy (AP and Lateral cine) of final ICD generator and lead position		X							X[6]	
Sensing, Impedance & Pacing Tests		X	X	X	X	X	X	X[5]	X[6]	
Defibrillation Testing		X				Subset[4]			X[6]	
Chest Radiographs – (PA/Lateral)	X		X			X				
Echocardiographic data within the last 6 months	X									
Save-to-media files		X	X	X	X	X	X	X	X	X
Medications (for subjects implanted with any device)	X	X	X	X	X	X	X	X	X	X
Adverse Events[7] (including AEs with fatal outcome), Device Deficiencies, HCUs, Study Deviations, and Other Cardiac Imaging	As they occur									

[1] Only for subjects who complete their Informed Consent Form (ICF) in English.

[2] Required for subjects presenting in persistent atrial fibrillation to confirm the absence of Left Atrium (LA) or Left Ventricular (LV) thrombus.

[3] Taken within the last year. Recommended for first 3 subjects at minimum, for each implanter. If collected/reviewed, send CT-scan and/or MRI to Medtronic.

[4] Only for subjects participating in chronic defibrillation testing, see CIP Addendum for 6-Month Defibrillation Testing.

[5] Optional. If electrical testing conducted, print the Testing Reports to PDF or paper and send a copy of the reports to Medtronic

[6] System modification where a subject leaves the procedure with an EV ICD System.

[7] Recommended to collect incision photographs if an infection related to the EV ICD System is suspected.

3.1. Inclusion and Exclusion Criteria

Enrollment in the EV ICD Pivotal study was limited to patients who met the following inclusion criteria:

	Inclusion Criteria
1.	Patient has a Class I or IIa indication for implantation of an ICD according to the ACC/AHA/HRS Guidelines[1], or ESC guidelines[2].
2.	Patient is at least 18 years of age and meets age requirements per local law.
3.	Patient is geographically stable and willing and able to complete the study procedures and visits for the duration of the follow-up.

Patients were not permitted to enroll in the EV ICD Pivotal study if they met any of the following exclusion criteria:

	Exclusion Criteria
1.	Patient is unwilling or unable to personally provide Informed Consent.
2.	Patient has indications for bradycardia pacing[3] or Cardiac Resynchronization Therapy (CRT)[4] (Class I, IIa, or IIb indication).
3.	Patients with an existing pacemaker, ICD, or CRT device or leads.
4.	Patients with these medical interventions are excluded from participation in the study: 1. Prior sternotomy 2. Any prior medical condition or procedure that leads to adhesions in the anterior mediastinal space (i.e., prior mediastinal instrumentation, mediastinitis) 3. Prior abdominal surgery in the epigastric region 4. Planned sternotomy 5. Prior chest radiotherapy Or any other prior/planned medical intervention not listed that precludes their participation in the opinion of the Investigator.

1 Al-Khatib SM, Stevenson WG, Ackerman MJ, et al. 2017 AHA/ACC/HRS guideline for management of patients with ventricular arrhythmias.

2 Priori SG, Blomstrom-Lundqvist C, Mazzanti A, et al. 2015 ESC guidelines for the management of patients with ventricular arrhythmias and the prevention of sudden cardiac death. European Heart Journal 2015 36:41 (2793-2867). https://doi.org/10.1093/eurheartj/ehv316

3 2015 HRS/EHRA/APHRS/SOLAECE expert consensus statement on optimal implantable cardioverter-defibrillator programming and testing).

4 ACC/AHA/HRS guidelines for Cardiac Resynchronization Therapy

	Exclusion Criteria
5.	Patient has previous pericarditis that: • Was chronic and recurrent, or • Resulted in pericardial effusion[5], or Resulted in pericardial thickening or calcification.[6]
6.	Patients with these medical conditions or anatomies are excluded from participation in the study: – Hiatal hernia that distorts mediastinal anatomy – Marked sternal abnormality (e.g., pectus excavatum) – Decompensated heart failure – COPD with oxygen dependence – Gross hepatosplenomegaly Or any other known medical condition or anatomy type not listed that precludes their participation in the opinion of the Investigator.
7.	Patients with a medical condition that precludes them from undergoing defibrillation testing: — Severe aortic stenosis — Current Intracardiac Left Atrium (LA) or Left Ventricular (LV) thrombus — Severe proximal three-vessel or left main coronary artery disease without revascularization — Hemodynamic instability — Unstable angina — Recent stroke or transient ischemic attack (within the last 6 months) — Known inadequate external defibrillation — Left Ventricular Ejection Fraction (LVEF) < 20% — Left Ventricular End Diastolic Diameter (LVEDD) >70 mm Or any other known medical condition not listed that precludes their participation in the opinion of the Investigator.
8.	Patient with any evidence of active infection or undergoing treatment for an infection.
9.	Patient is contraindicated from temporary suspension of oral/systemic anticoagulation
10.	Patient with current implantation of neurostimulator or any other chronically implanted device that delivers current in the body.
11.	Patient meets ACC/AHA/HRS or ESC clinical guideline Class III criteria for an ICD (e.g., life expectancy of less than 12 months).
12.	Patient is enrolled or planning to enroll in a concurrent clinical study that may confound the results of this study, without documented pre-approval from a Medtronic study manager.
13.	Patient with any exclusion criteria as required by local law (e.g., age or other).

5 As documented on echo or MRI
6 As documented on CT scan or MRI

	Exclusion Criteria
14.	Pregnant women or breastfeeding women, or women of child bearing potential and who are not on a reliable form of birth regulation method or abstinence.[7]

4. Study Endpoints

4.1. Primary Endpoints

4.1.1. Primary Safety Endpoint

The primary safety objective was to demonstrate the freedom from major complications related to the EV ICD System and/or procedure at 6 months post-implant exceeds 79% Performance Goal (PG). The endpoint was defined as a subject's first occurrence of a major complication related to the EV ICD System and/or procedure, as determined by an independent Clinical Events Committee (CEC), that occurs on or prior to 6 months (182 days) post-implant.

For an adverse event to meet the endpoint, the event must have occurred within 182 days (inclusive) of the EV ICD System implant and be adjudicated by the CEC as being a major complication related (causal relationship) to the EV ICD System and/or procedure. Major complications were those complications resulting in:

- Death
- Permanent loss of defibrillation function (specifically shock) due to mechanical or electrical dysfunction of the device
- Hospitalization
- Prolongation of an existing hospitalization by at least 48 hours
- System revision (reposition, replacement, explant)

4.1.2. Primary Efficacy Endpoint

With regards to effectiveness, the primary efficacy objective was to demonstrate the defibrillation efficacy at implant of the EV ICD System exceeds 88% (PG). The endpoint, defibrillation testing success, was defined as:

- Single sustained shockable ventricular arrhythmia (SSVA) conversion at 20J, or
- Conversion of two consecutive episodes of SSVA at 30J in final system configuration.

4.2. Sample Size

Two primary objectives each require at least 292 subjects to, in the case of the safety objective, undergo an implant attempt of the EV ICD System, and in the case of the efficacy objective, complete the pre-specified defibrillation testing protocol. Since the defibrillation protocol would not be initiated until an implant attempt occurs, the overall sample size requirement was derived from the efficacy objective; and at least 292 subjects were to undergo the defibrillation testing protocol, which would result in more than 292 subjects undergoing an implant attempt to satisfy this requirement. To further account for subjects who enrolled in the study but exited prior to an implant attempt, the protocol allowed for enrollment of up to 400 subjects.

7 If required by local law, women of child-bearing potential must undergo a pregnancy test within seven days prior to EV ICD Pivotal Study procedures

4.3. Study Populations for Analysis

Enrollment included up to 400 subjects at up to 60 sites worldwide. The maximum number of subjects enrolled at each site was capped at 35, which was approximately 10% of the total number of subjects enrolled.

5. Results

The first worldwide subject was enrolled in the EV ICD Pivotal Clinical Study on 16 September 2019 and underwent an EV ICD implant the same day. On 15 October 2021, the last subject underwent an implant attempt, completing the enrollment and implant phase of the study. On 28 April 2022, the final 6-month follow-up visit was completed, triggering the visit cutoff date for this report analysis. Case report form data analyzed for this report was collected on or before 28 April 2022 and was received at Medtronic on or before 13 May 2022. The study database was frozen for analysis on 7 June 2022.

As of the 28 April 2022 visit cutoff date, 356 subjects were enrolled in the study, of which 316 underwent an implant attempt with the EV ICD System. Of the 316 subjects who underwent an implant attempt, the substernal lead was positioned in 315. A total of 299 subjects were successfully implanted with the full system by 55 physicians at 46 centers across 17 countries.

5.1. Subject Accountability

Among 356 enrolled subjects, 40 exited the study without having an implant attempt and 316 underwent an implant attempt of the EV ICD System. Of the 316 subjects who underwent an implant attempt, 315 subjects had the lead positioned and proceeded to electrical testing during the implant procedure. In total, 299 (94.6%) had the EV ICD System fully implanted and 17 did not. Reasons for not having a successful implant included:

- Failed defibrillation testing (4)
- Inadequate R-wave sensing (7)
- Incomplete defibrillation testing protocol (4)
- Other reasons (2)
    - Tunneling stopped due to resistance
    - Oversensing of atrial fibrillation in all lead positions attempted

All 17 subjects with an unsuccessful implant exited the study following the instructions in the Clinical Investigational Protocol (CIP). Of them, 15 subjects exited between 28-36 days post implant attempt and two subjects exited 54 and 70 days post implant attempt, respectively.

Subject disposition is presented using a flow diagram (refer to Figure 1) where completed visits, missed visits, and attrition due to exit and death are indicated.

Figure 1: Subject Disposition Diagram

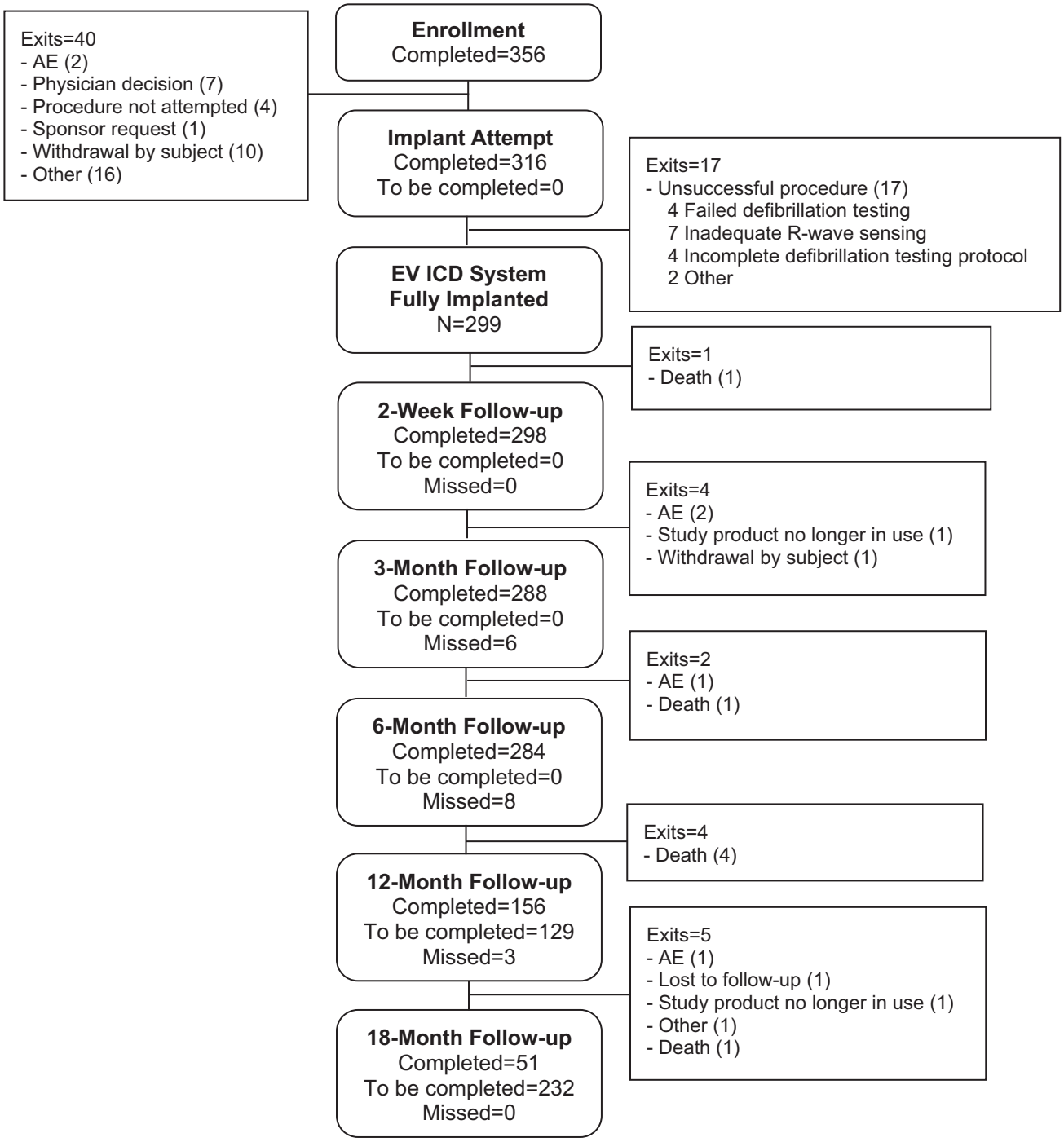
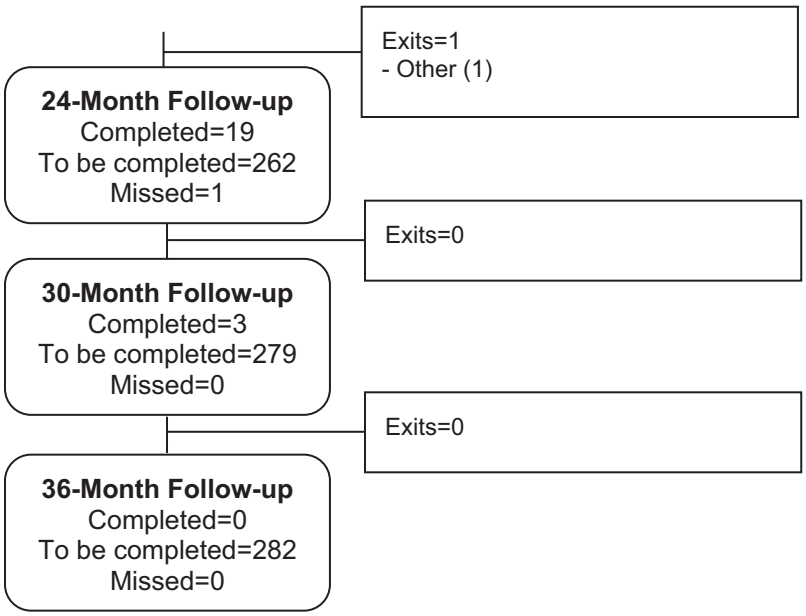


Figure 1 Continued:



5.2. Subject Baseline Characteristics and Demographics

The demographics of the study population are younger than typical ICD recipients, with a high frequency of hypertrophic cardiomyopathy.

Baseline characteristics are summarized in Table 2 – Table 12.

Among 356 subjects enrolled, 343 had baseline forms completed at the time of this report, and all subjects without a baseline form have been exited. There were 316 subjects with an implant attempt; of these, 74.7% were male, the average age was 53.8 ± 13.1 years, the average BMI was 28.0 ± 5.6, 23.7% were known to be NYHA Class I and 65.5% were known to be NYHA Class II/III.

Of those with an implant attempt, 258 (81.6%) were indicated for primary prevention as defined in Table 5, 57 (18.0%) were indicated for secondary prevention and 1 (0.3%) did not provide enough information to classify as primary or secondary.

Of the 18 subjects with an explanted device indicated in cardiovascular surgical history (Table 10), ten had their explant within two weeks prior to enrollment, seven had their explant more than two weeks prior to enrollment with a maximum of 258 days, and one had their explant occur 33 days after enrollment but seven days prior to EV ICD implant.

Table 2: Subject Demographics

	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Sex (N,%)			
Male	236 (74.7%)	22 (81.5%)	258 (75.2%)
Female	80 (25.3%)	5 (18.5%)	85 (24.8%)
Age (years)			
Mean ± Standard Deviation	53.8 ± 13.1	53.3 ± 14.7	53.8 ± 13.2
Median	55.0	55.0	55.0
25^{th} Percentile - 75^{th} Percentile	46 - 64	43 - 68	46 - 64
Minimum - Maximum	18 - 84	19 - 76	18 - 84
Number Of Subjects With Measure Available (N, %)	316 (100.0%)	27 (100.0%)	343 (100.0%)
Number of Subjects 90 Years or Older	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ethnicity (N,%)			
Not Reported due to local requirements (Non-US)	197 (62.3%)	10 (37.0%)	207 (60.3%)
Not Reported for other reasons	2 (0.6%)	0 (0.0%)	2 (0.6%)
Not Hispanic or Latino	110 (34.8%)	17 (63.0%)	127 (37.0%)
Hispanic or Latino	7 (2.2%)	0 (0.0%)	7 (2.0%)
Unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)
Race (N,%)			
Not Reported due to local requirements (Non-US)	197 (62.3%)	10 (37.0%)	207 (60.3%)
Not Reported for other reasons	0 (0.0%)	0 (0.0%)	0 (0.0%)
American Indian or Alaska Native	2 (0.6%)	0 (0.0%)	2 (0.6%)
Asian	7 (2.2%)	1 (3.7%)	8 (2.3%)
Black or African American	16 (5.1%)	1 (3.7%)	17 (5.0%)
Native Hawaiian or Other Pacific Islander	1 (0.3%)	0 (0.0%)	1 (0.3%)
White	87 (27.5%)	15 (55.6%)	102 (29.7%)
Other	6 (1.9%)	0 (0.0%)	6 (1.7%)

Table 3: Physical Exam Results

Status	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Height (cm)			
Mean ± Standard Deviation	173.8 ± 9.4	172.9 ± 10.0	173.8 ± 9.4
Median	174.0	172.7	174.0
25th Percentile – 75th Percentile	167 - 180	165 - 182	167 - 180
Minimum – Maximum	145 - 203	147 - 188	145 - 203
Number of Subjects With Measure Available (N,%)	316 (100.0%)	27 (100.0%)	343 (100.0%)
Weight (kg)			
Mean ± Standard Deviation	85.1 ± 19.7	83.8 ± 20.7	85.0 ± 19.8
Median	83.0	85.3	83.0
25th Percentile – 75th Percentile	70 - 96	69 - 93	70 - 96
Minimum – Maximum	48 - 148	49 - 137	48 - 148
Number of Subjects With Measure Available (N,%)	316 (100.0%)	27 (100.0%)	343 (100.0%)
BMI (kg/m^2)			
Mean ± Standard Deviation	28.0 ± 5.6	27.9 ± 5.7	28.0 ± 5.6
Median	27.7	27.5	27.7
25th Percentile – 75th Percentile	24 - 31	24 - 33	24 - 32
Minimum – Maximum	18 - 46	17 - 41	17 - 46
Number of Subjects With Measure Available (N,%)	316 (100.0%)	27 (100.0%)	343 (100.0%)

Table 4: Cardiac Disease Classification Characteristics

Status	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
New York Heart Association (N,%)			
Class I	75 (23.7%)	5 (18.5%)	80 (23.3%)

Status	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Class II	184 (58.2%)	17 (63.0%)	201 (58.6%)
Class III	23 (7.3%)	4 (14.8%)	27 (7.9%)
Class IV	0 (0.0%)	0 (0.0%)	0 (0.0%)
NYHA classification not available	34 (10.8%)	1 (3.7%)	35 (10.2%)

Table 5: Summary of ICD Indication

	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Primary prevention	**258 (81.6%)**	**25 (92.6%)**	**283 (82.5%)**
LVEF<=35% due to prior MI, NYHA Class II or III	94 (29.7%)	9 (33.3%)	103 (30.0%)
Nonischemic dilated cardiomyopathy, LVEF <=35%, NYHA Class II/III	76 (24.1%)	8 (29.6%)	84 (24.5%)
LV dysfunction due to prior MI, LVEF <=30%, NYHA Class I	14 (4.4%)	2 (7.4%)	16 (4.7%)
NSVT due to prior MI, LVEF<40%, inducible VT/VF	1 (0.3%)	1 (3.7%)	2 (0.6%)
Hypertrophic cardiomyopathy, 1 or more major risk factors for SCD	33 (10.4%)	2 (7.4%)	35 (10.2%)
Arrhythmogenic RV dysplasia/cardiomyopathy, 1 or more risk factor for SCD	5 (1.6%)	0 (0.0%)	5 (1.5%)
Brugada syndrome and has had syncope	1 (0.3%)	0 (0.0%)	1 (0.3%)
Brugada syndrome and has documented VT that has not resulted in cardiac arrest	1 (0.3%)	0 (0.0%)	1 (0.3%)
Cardiac sarcoidosis, giant cell myocarditis, or Chagas disease	3 (0.9%)	0 (0.0%)	3 (0.9%)
Nonischemic heart disease, LVEF <=35%, NYHA functional Class I	9 (2.8%)	0 (0.0%)	9 (2.6%)
Long-QT Syndrome and risk factors for SCD	1 (0.3%)	0 (0.0%)	1 (0.3%)

	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Familial cardiomyopathy associated with sudden death	13 (4.1%)	1 (3.7%)	14 (4.1%)
LV noncompaction	0 (0.0%)	2 (7.4%)	2 (0.6%)
Other primary prevention*	7 (2.2%)	0 (0.0%)	7 (2.0%)
Secondary prevention	**57 (18.0%)**	**2 (7.4%)**	**59 (17.2%)**
Cardiac arrest due to VF/hemodynamically unstable sustained VT	40 (12.7%)	1 (3.7%)	41 (12.0%)
Structural heart disease and spontaneous sustained VT	6 (1.9%)	1 (3.7%)	7 (2.0%)
Syncope with induced sustained VT/VF	1 (0.3%)	0 (0.0%)	1 (0.3%)
Unstable VT and/or VT with syncope and LVEF<=40%	4 (1.3%)	0 (0.0%)	4 (1.2%)
Sustained VT and normal ventricular function	6 (1.9%)	0 (0.0%)	6 (1.7%)
Other**	**1 (0.3%)**	**0 (0.0%)**	**1 (0.3%)**

** Other primary prevention indications for subjects with an Implant Attempt included "FAMILIAL IDIOPATHIC VF (DPP6 GENE)" (2), "ISCHAEMIC CARDIOMYOPATHY, LVEF 30%, NYHA II" (1), "ISCHEMIC CARDIOMYOPATHY AND HAS AN LVEF LESS THAN OR EQUAL TO 35% AND IS IN NYHA FUNCTIONAL CLASS II OR III" (1), "ISCHEMIC CARDIOMYOPATHY, HAS AN LVEF LESS THAN OR EQUAL TO 30% AND IS IN NYHA FUNCTIONAL CLASS I(WITHOUT MYOCARDIAL INFRACTION DOCUMENTED" (1), "ISCHEMIC CARDIOPATHY, ELF 35%, NYHA II" (1), and "ISCHEMIC HEART DISEASE, LVEF LESS THAN 35%, NYHA II"(1).*

*** Other unclassified indication included "STRUCTURAL HEART DISEASE WITH NON-SUSTAINED VT" (1).*

Table 6: EP Testing and ECG Characteristics

Status	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
EP Testing Within Last 180 Days (N,%)			
Not done	308 (97.5%)	26 (96.3%)	334 (97.4%)
Non-inducible ventricular arrhythmias	2 (0.6%)	0 (0.0%)	2 (0.6%)
Inducible, specify	**6 (1.9%)**	**1 (3.7%)**	**7 (2.0%)**
Sustained VF	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-sustained VF	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular flutter	1 (0.3%)	0 (0.0%)	1 (0.3%)

Status	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Ventricular fibrillation	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sustained monomorphic VT	2 (0.6%)	1 (3.7%)	3 (0.9%)
Sustained polymorphic VT	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sustained VT, morphology unknown	0 (0.0%)	0 (0.0%)	0 (0.0%)
Non-sustained VT (5 beats or less)	1 (0.3%)	0 (0.0%)	1 (0.3%)
Torsades de Pointes	0 (0.0%)	0 (0.0%)	0 (0.0%)
Other*	2 (0.6%)	0 (0.0%)	2 (0.6%)

** Other indications included "NON DIAGNOSTIC STUDY – NO ARRHYTHMIAS INDUCED" (1) and "NON INDUCIBLE SVT ON MONITOR > 3 MIN" (1).*

Table 7: Imaging Testing Results

Status	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Methods Used for LVEF Measurement (%)			
Transthoracic Echocardiography	303 (95.9%)	27 (100.0%)	330 (96.2%)
Stress Echocardiography	1 (0.3%)	0 (0.0%)	1 (0.3%)
Transesophageal Echocardiography	11 (3.5%)	0 (0.0%)	11 (3.2%)
Other	1 (0.3%)	0 (0.0%)	1 (0.3%)
Echo Not Done	0 (0.0%)	0 (0.0%)	0 (0.0%)
LV Ejection Fraction (%)			
Mean ± Standard Deviation	38.9 ± 15.4	36.0 ± 12.5	38.7 ± 15.2
Median	33.0	35.0	33.0
25th Percentile – 75th Percentile	27 - 53	28 - 45	27 - 51
Minimum – Maximum	20 - 85	15 - 70	15 - 85
Number of Subjects With Measure Available (N,%)	316 (100.0%)	27 (100.0%)	343 (100.0%)
LV End Diastolic Volume (mL)			
Mean ± Standard Deviation	158.7 ± 69.9	146.4 ± 57.0	157.7 ± 69.0
Median	150.0	136.2	150.0
25th Percentile – 75th Percentile	110 - 197	116 - 194	110 - 196
Minimum – Maximum	5 - 503	38 - 255	5 - 503
Number of Subjects With Measure Available (N,%)	244 (77.2%)	20 (74.1%)	264 (77.0%)
LV End Diastolic Diameter (mm)			
Mean ± Standard Deviation	55.8 ± 9.2	56.1 ± 10.3	55.8 ± 9.2

Status	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Median	57.0	58.0	57.0
25th Percentile – 75th Percentile	50 - 62	50 - 61	50 - 62
Minimum – Maximum*	22 - 72	31 - 75	22 - 75
Number of Subjects With Measure Available (N,%)	314 (99.4%)	27 (100.0%)	341 (99.4%)
LA Systolic Diameter (mm)			
Mean ± Standard Deviation	40.4 ± 11.8	44.2 ± 10.9	40.7 ± 11.8
Median	41.0	44.0	41.0
25th Percentile – 75th Percentile	35 - 46	38 - 50	35 - 46
Minimum – Maximum	3 - 93	21 - 72	3 - 93
Number of Subjects With Measure Available (N,%)	260 (82.3%)	23 (85.2%)	283 (82.5%)
RA Size (N,%)			
Normal	223 (70.6%)	14 (51.9%)	237 (69.1%)
Enlarged	69 (21.8%)	9 (33.3%)	78 (22.7%)
Measure not available	24 (7.6%)	3 (11.1%)	27 (7.9%)

** LVEDD > 70 is an exclusion criterion for this study. Two deviations have been completed for the two patients with an implant attempt and an LVEDD of 71 and 72.*

Table 8: Spontaneous Arrhythmia History

Status*	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
None	**127 (40.2%)**	**7 (25.9%)**	**134 (39.1%)**
Supraventricular tachycardia			
Atrial fibrillation	**44 (13.9%)**	**8 (29.6%)**	**52 (15.2%)**
Paroxysmal	28 (8.9%)	2 (7.4%)	30 (8.7%)
Persistent	8 (2.5%)	6 (22.2%)	14 (4.1%)
Long-standing persistent	4 (1.3%)	1 (3.7%)	5 (1.5%)
Permanent	5 (1.6%)	1 (3.7%)	6 (1.7%)
Atrial flutter	7 (2.2%)	4 (14.8%)	11 (3.2%)
Atrial tachycardia	7 (2.2%)	1 (3.7%)	8 (2.3%)
Sinus node dysfunction (any of the following)	**34 (10.8%)**	**5 (18.5%)**	**39 (11.4%)**
Bradycardia-tachycardia syndrome	0 (0.0%)	0 (0.0%)	0 (0.0%)

Status*	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Chronotropic incompetence	0 (0.0%)	0 (0.0%)	0 (0.0%)
Sinus arrest/pause/exit block	1 (0.3%)	0 (0.0%)	1 (0.3%)
Sinus bradycardia	19 (6.0%)	3 (11.1%)	22 (6.4%)
Sinus tachycardia	16 (5.1%)	2 (7.4%)	18 (5.2%)
Ventricular arrhythmias	**135 (42.7%)**	**9 (33.3%)**	**144 (42.0%)**
Premature ventricular complexes	41 (13.0%)	1 (3.7%)	42 (12.2%)
Torsades de pointes	2 (0.6%)	0 (0.0%)	2 (0.6%)
Ventricular fibrillation	32 (10.1%)	1 (3.7%)	33 (9.6%)
Ventricular flutter	0 (0.0%)	0 (0.0%)	0 (0.0%)
Ventricular tachycardia non-sustained	70 (22.2%)	7 (25.9%)	77 (22.4%)
Ventricular tachycardia, sustained monomorphic	14 (4.4%)	0 (0.0%)	14 (4.1%)
Ventricular tachycardia, sustained polymorphic	4 (1.3%)	1 (3.7%)	5 (1.5%)
Ventricular tachycardia, sustained unknown	10 (3.2%)	0 (0.0%)	10 (2.9%)
AV block	**12 (3.8%)**	**2 (7.4%)**	**14 (4.1%)**
1st degree AV block	12 (3.8%)	2 (7.4%)	14 (4.1%)
2nd degree AV block	3 (0.9%)	0 (0.0%)	3 (0.9%)
3rd degree AV block	0 (0.0%)	0 (0.0%)	0 (0.0%)
Bundle branch blocks	**22 (7.0%)**	**2 (7.4%)**	**24 (7.0%)**
Left bundle branch block	5 (1.6%)	0 (0.0%)	5 (1.5%)
Intraventricular conduction delay	9 (2.8%)	1 (3.7%)	10 (2.9%)
Right bundle branch block	11 (3.5%)	1 (3.7%)	12 (3.5%)

** Categories in medical history tables may not be mutually exclusive.*

Table 9: Cardiovascular History

Status*	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
None of the following	**4 (1.3%)**	**0 (0.0%)**	**4 (1.2%)**
Cardiac arrest	45 (14.2%)	2 (7.4%)	47 (13.7%)
Cardiomyopathy	**265 (83.9%)**	**25 (92.6%)**	**290 (84.5%)**
Ischemic	128 (40.5%)	12 (44.4%)	140 (40.8%)
Non-ischemic	102 (32.3%)	12 (44.4%)	114 (33.2%)

Status*	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
Hypertrophic	41 (13.0%)	2 (7.4%)	43 (12.5%)
Coronary artery disease	147 (46.5%)	16 (59.3%)	163 (47.5%)
Hypertension	155 (49.1%)	12 (44.4%)	167 (48.7%)
Hypotension	8 (2.5%)	0 (0.0%)	8 (2.3%)
Idiopathic structural heart disease	9 (2.8%)	2 (7.4%)	11 (3.2%)
Left ventricular hypertrophy	52 (16.5%)	4 (14.8%)	56 (16.3%)
Myocardial infarction	132 (41.8%)	13 (48.1%)	145 (42.3%)
Primary/idiopathic electrical disease (of the following)	**24 (7.6%)**	**2 (7.4%)**	**26 (7.6%)**
Arrhythmogenic RV dysplasia	6 (1.9%)	0 (0.0%)	6 (1.7%)
Brugada syndrome	2 (0.6%)	0 (0.0%)	2 (0.6%)
Long Q/T syndrome	5 (1.6%)	0 (0.0%)	5 (1.5%)
Unknown type	2 (0.6%)	1 (3.7%)	3 (0.9%)
Other	9 (2.8%)	1 (3.7%)	10 (2.9%)
Stroke and stroke-related events	**24 (7.6%)**	**3 (11.1%)**	**27 (7.9%)**
Stroke, ischemic	14 (4.4%)	1 (3.7%)	15 (4.4%)
Stroke, hemorrhagic	1 (0.3%)	0 (0.0%)	1 (0.3%)
Thromboembolism	6 (1.9%)	1 (3.7%)	7 (2.0%)
Transient ischemic attack	8 (2.5%)	1 (3.7%)	9 (2.6%)
Syncope	**32 (10.1%)**	**4 (14.8%)**	**36 (10.5%)**
Due to arrhythmia	13 (4.1%)	3 (11.1%)	16 (4.7%)
Due to no arrhythmia causes	3 (0.9%)	1 (3.7%)	4 (1.2%)
Unexplained/unknown	17 (5.4%)	0 (0.0%)	17 (5.0%)
Vascular disease	28 (8.9%)	2 (7.4%)	30 (8.7%)

** Categories in medical history tables may not be mutually exclusive.*

Table 10: Cardiovascular Surgical History

Status*	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
None of the following	**190 (60.1%)**	**14 (51.9%)**	**204 (59.5%)**
Ablation (of the following)	**4 (1.3%)**	**1 (3.7%)**	**5 (1.5%)**

Status*	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
AV node	0 (0.0%)	1 (3.7%)	1 (0.3%)
HIS bundle	0 (0.0%)	0 (0.0%)	0 (0.0%)
VT	4 (1.3%)	0 (0.0%)	4 (1.2%)
Coronary artery bypass graft(CABG)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Coronary artery intervention	**110 (34.8%)**	**12 (44.4%)**	**122 (35.6%)**
Balloon angioplasty	46 (14.6%)	4 (14.8%)	50 (14.6%)
Stent	102 (32.3%)	12 (44.4%)	114 (33.2%)
Other	7 (2.2%)	1 (3.7%)	8 (2.3%)
Previous CIED System Implanted	**18 (5.7%)**	**2 (7.4%)**	**20 (5.8%)**
Pacemaker	1 (0.3%)	0 (0.0%)	1 (0.3%)
S-ICD	9 (2.8%)	0 (0.0%)	9 (2.6%)
TV ICD	10 (3.2%)	2 (7.4%)	12 (3.5%)
CRT-P	0 (0.0%)	0 (0.0%)	0 (0.0%)
CRT-D	0 (0.0%)	0 (0.0%)	0 (0.0%)
Days Since Most Recent Explant Procedure			
Mean ± Standard Deviation	42.22 ± 69.06	87.00 ± 2.83	46.70 ± 66.77
Median	13.00	87.00	13.50
25th Percentile - 75th Percentile	7.0 - 56.0	85.0 - 89.0	7.0 - 77.5
Minimum - Maximum	-33.0† - 258.0	85.0 - 89.0	-33.0 - 258.0
Number Of Subjects With Measure Available (N, %)	18 (5.70%)	2 (7.41%)	20 (5.83%)

** Categories in medical history tables may not be mutually exclusive.*

† One subject had their previous CIED system explanted 33 days after enrollment but seven days prior to the EV ICD implant attempt.

Table 11: Other Medical History

Status	Subjects with EV ICD Implant Attempted (N = 316)	Subjects without EV ICD Implant Attempted (N = 27)	Total Subjects with Baseline Form (N = 343)
None	**204 (64.6%)**	**13 (48.1%)**	**217 (63.3%)**
Asthma	21 (6.6%)	2 (7.4%)	23 (6.7%)
Chronic obstructive pulmonary disease	13 (4.1%)	3 (11.1%)	16 (4.7%)
Chronic bronchitis	3 (0.9%)	0 (0.0%)	3 (0.9%)
Diabetes	66 (20.9%)	8 (29.6%)	74 (21.6%)
Emphysema	0 (0.0%)	2 (7.4%)	2 (0.6%)
Pleural effusion	13 (4.1%)	2 (7.4%)	15 (4.4%)
Renal dysfunction	30 (9.5%)	4 (14.8%)	34 (9.9%)

Table 12: Baseline Medications

Anatomical Group	Medication Type	Subjects with EV ICD Implant Attempt (N=316)	Subjects without EV ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
Alimentary Tract And Metabolism	Antacids	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	Antiemetics And Antinauseants	3 (2, 0.6%)	0 (0, 0%)	3 (2, 0.6%)
	Ascorbic Acid (Vitamin C), Incl. Combinations	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Blood Glucose Lowering Drugs, Excl. Insulins	78 (55, 17.4%)	8 (4, 14.8%)	86 (59, 17.2%)
	Calcium	7 (7, 2.2%)	1 (1, 3.7%)	8 (8, 2.3%)
	Drugs For Constipation	6 (6, 1.9%)	0 (0, 0%)	6 (6, 1.7%)
	Drugs For Functional Gastrointestinal Disorders	0 (0, 0%)	0 (0, 0%)	1 (1, 0.3%)
	Drugs For Peptic Ulcer And Gastro-Oesophageal Reflux Disease (GORD)	97 (96, 30.4%)	4 (4, 14.8%)	102 (101, 29.4%)
	Insulins And Analogues	20 (16, 5.1%)	1 (1, 3.7%)	21 (17, 5.0%)
	Intestinal Antiinflammatory Agents	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Multivitamins, Combinations	4 (4, 1.3%)	1 (1, 3.7%)	5 (5, 1.5%)

Anatomical Group	Medication Type	Subjects with EV ICD Implant Attempt (N=316)	Subjects without EV ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
	Other Alimentary Tract And Metabolism Products	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Other Drugs For Acid Related Disorders	5 (5, 1.6%)	0 (0, 0%)	5 (5, 1.5%)
	Other Mineral Supplements	7 (7, 2.2%)	0 (0, 0%)	7 (7, 2.0%)
	Other Plain Vitamin Preparations	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
	Other Vitamin Products, Combinations	14 (12, 3.8%)	3 (3, 11.1%)	17 (15, 4.4%)
	Potassium	27 (27, 8.5%)	1 (1, 3.7%)	28 (28, 8.2%)
	Propulsives	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Vitamin A And D, Incl. Combinations Of The Two	19 (19, 6.0%)	1 (1, 3.7%)	20 (20, 5.8%)
	Vitamin B1, Plain And In Combination With Vitamin B6 And B12	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
Antiinfectives For Systemic Use	Direct Acting Antivirals	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
	Other Antibacterials	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Other Beta-Lactam Antibacterials	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Sulfonamides And Trimethoprim	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
Antineoplastic And Immunomodulating Agents	Hormone Antagonists And Related Agents	0 (0, 0%)	1 (1, 3.7%)	1 (1, 0.3%)
	Immunosuppressants	13 (9, 2.8%)	0 (0, 0%)	13 (9, 2.6%)
Blood And Blood Forming Organs	Antithrombotic Agents	259 (183, 57.9%)	20 (14, 51.9%)	280 (198, 57.7%)
	I.V. Solution Additives	0 (0, 0%)	1 (1, 3.7%)	2 (2, 0.6%)
	Iron Preparations	9 (9, 2.8%)	0 (0, 0%)	10 (10, 2.9%)
	Vitamin B12 And Folic Acid	12 (11, 3.5%)	0 (0, 0%)	12 (11, 3.2%)
Cardiovascular System	ACE Inhibitors, Combinations	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	ACE Inhibitors, Plain	95 (95, 30.1%)	7 (7, 25.9%)	102 (102, 29.7%)
	Angiotensin II Receptor Blockers (ARBs), Combinations	68 (67, 21.2%)	4 (4, 14.8%)	73 (72, 21.0%)

Anatomical Group	Medication Type	Subjects with EV ICD Implant Attempt (N=316)	Subjects without EV ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
	Angiotensin II Receptor Blockers (ARBs), Plain	37 (37, 11.7%)	0 (0, 0%)	37 (37, 10.8%)
	Antiadrenergic Agents, Centrally Acting	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Antiadrenergic Agents, Peripherally Acting	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
	Antiarrhythmics, Class I And III	16 (16, 5.1%)	3 (3, 11.1%)	19 (19, 5.5%)
	Arteriolar Smooth Muscle, Agents Acting On	7 (7, 2.2%)	0 (0, 0%)	8 (8, 2.3%)
	Beta Blocking Agents	239 (236, 74.7%)	14 (14, 51.9%)	254 (251, 73.2%)
	Beta Blocking Agents And Thiazides	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
	Beta Blocking Agents, Other Combinations	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Cardiac Glycosides	6 (6, 1.9%)	1 (1, 3.7%)	7 (7, 2.0%)
	Diuretics And Potassium-Sparing Agents In Combination	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	High-Ceiling Diuretics	113 (110, 34.8%)	8 (8, 29.6%)	123 (120, 35.0%)
	Lipid Modifying Agents, Combinations	6 (6, 1.9%)	2 (2, 7.4%)	8 (8, 2.3%)
	Lipid Modifying Agents, Plain	182 (163, 51.6%)	6 (6, 22.2%)	188 (169, 49.3%)
	Low-Ceiling Diuretics, Excl. Thiazides	3 (3, 0.9%)	0 (0, 0%)	4 (4, 1.2%)
	Low-Ceiling Diuretics, Thiazides	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	Other Antihypertensives	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	Other Cardiac Preparations	18 (14, 4.4%)	0 (0, 0%)	18 (14, 4.1%)
	Other Diuretics	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Potassium-Sparing Agents	125 (124, 39.2%)	3 (3, 11.1%)	129 (128, 37.3%)
	Selective Calcium Channel Blockers With Direct Cardiac Effects	5 (5, 1.6%)	0 (0, 0%)	5 (5, 1.5%)
	Selective Calcium Channel Blockers With Mainly Vascular Effects	17 (16, 5.1%)	0 (0, 0%)	17 (16, 4.7%)

Anatomical Group	Medication Type	Subjects with EV ICD Implant Attempt (N=316)	Subjects without EV ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
	Vasodilators Used In Cardiac Diseases	26 (24, 7.6%)	2 (1, 3.7%)	29 (26, 7.6%)
Dermatologicals	Anti-Acne Preparations For Topical Use	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Antipruritics, Incl. Antihistamines, Anesthetics, Etc.	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Corticosteroids, Plain	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Other Dermatological Preparations	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
Genito Urinary System And Sex Hormones	Androgens	1 (1, 0.3%)	1 (1, 3.7%)	2 (2, 0.6%)
	Drugs Used In Benign Prostatic Hypertrophy	13 (12, 3.8%)	0 (0, 0%)	13 (12, 3.5%)
	Estrogens	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Hormonal Contraceptives For Systemic Use	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Progestogens And Estrogens In Combination	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Urologicals	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
Musculo-Skeletal System	Antigout Preparations	26 (23, 7.3%)	2 (1, 3.7%)	28 (24, 7.0%)
	Antiinflammatory And Antirheumatic Products, Non-Steroids	7 (7, 2.2%)	1 (1, 3.7%)	8 (8, 2.3%)
	Muscle Relaxants, Centrally Acting Agents	4 (4, 1.3%)	1 (1, 3.7%)	7 (6, 1.7%)
Nervous System	Anesthetics, General	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Anesthetics, Local	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Antidepressants	30 (27, 8.5%)	1 (1, 3.7%)	32 (29, 8.5%)
	Antiepileptics	3 (2, 0.6%)	0 (0, 0%)	3 (2, 0.6%)
	Antimigraine Preparations	7 (7, 2.2%)	0 (0, 0%)	7 (7, 2.0%)
	Antipsychotics	3 (3, 0.9%)	0 (0, 0%)	3 (3, 0.9%)
	Antivertigo Preparations	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Anxiolytics	11 (11, 3.5%)	1 (1, 3.7%)	12 (12, 3.5%)
	Drugs Used In Addictive Disorders	4 (3, 0.9%)	2 (2, 7.4%)	6 (5, 1.5%)

Anatomical Group	Medication Type	Subjects with EV ICD Implant Attempt (N=316)	Subjects without EV ICD Implant Attempt (N=27)	Total Subjects with Baseline Form (N=343)
	Hypnotics And Sedatives	13 (13, 4.1%)	0 (0, 0%)	14 (14, 4.1%)
	Opioids	13 (11, 3.5%)	0 (0, 0%)	13 (11, 3.2%)
	Other Analgesics And Antipyretics	27 (25, 7.9%)	0 (0, 0%)	27 (25, 7.3%)
	Psychostimulants, Agents Used For ADHD And Nootropics	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
Respiratory System	Adrenergics For Systemic Use	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Adrenergics, Inhalants	22 (15, 4.7%)	0 (0, 0%)	24 (17, 5.0%)
	Antihistamines For Systemic Use	15 (13, 4.1%)	0 (0, 0%)	15 (13, 3.8%)
	Cough Suppressants, Excl. Combinations With Expectorants	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Expectorants, Excl. Combinations With Cough Suppressants	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
	Other Drugs For Obstructive Airway Diseases, Inhalants	9 (9, 2.8%)	0 (0, 0%)	9 (9, 2.6%)
	Other Systemic Drugs For Obstructive Airway Diseases	4 (4, 1.3%)	0 (0, 0%)	4 (4, 1.2%)
Sensory Organs	Antiglaucoma Preparations And Miotics	2 (2, 0.6%)	0 (0, 0%)	2 (2, 0.6%)
Systemic Hormonal Preparations, Excl. Sex Hormones And Insulins	Anti-Parathyroid Agents	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Corticosteroids For Systemic Use, Plain	6 (6, 1.9%)	0 (0, 0%)	6 (6, 1.7%)
	Thyroid Preparations	16 (16, 5.1%)	0 (0, 0%)	16 (16, 4.7%)
Various	All Other Therapeutic Products	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Homeopathic Preparation	5 (5, 1.6%)	0 (0, 0%)	5 (5, 1.5%)
	Magnetic Resonance Imaging Contrast Media	1 (1, 0.3%)	0 (0, 0%)	1 (1, 0.3%)
	Other Nutrients	0 (0, 0%)	1 (1, 3.7%)	1 (1, 0.3%)
	Unspecified Herbal And Traditional Medicine	3 (2, 0.6%)	0 (0, 0%)	3 (2, 0.6%)
Total		**1860 (278, 88.0%)**	**102 (17, 63.0%)**	**1981 (297, 86.6%)**

5.3. Primary Endpoint Results

5.3.1. Primary Safety Results

Of the 316 subjects that underwent an implant attempt, 23 subjects had a total of 25 major EV ICD System and/or procedure-related complication through 182 days post-implant.

The freedom from the first major EV ICD System/procedure-related complication through 182 days post implant was estimated using the Kaplan-Meier method. Table 13 shows that the Kaplan-Meier estimated major EV ICD System/procedure-related complication free rate through 182 days post implant was 92.6%, with a lower confidence bound of two-sided 95% confidence interval of 89.0%. This was greater than the PG of 79%, hence the primary safety objective was met ($p<0.0001$).

Table 13: Results of Primary Safety Objective

Number of subjects with an implant attempt	Number of subjects with major EV ICD System/procedure-related complications through 182 days post implant attempt	Kaplan-Meier estimate of major EV ICD System/procedure-related complication free rate through 182 days post implant attempt	Lower confidence bound of two-sided 95% confidence interval
316	23	92.6%	89.0%

Figure 2 is the Kaplan-Meier plot for the freedom from EV ICD System and/or procedure-related major complications through 182 days post implant. Among the 23 subjects that experienced at least one major EV ICD System and/or procedure-related complication within 182 days post implant, 15 subjects experienced it within 30 days post implant attempt.

Figure 2: Kaplan-Meier Plot of EV ICD System/procedure-related Major Complication Free Rate Through 182 Days Post Implant

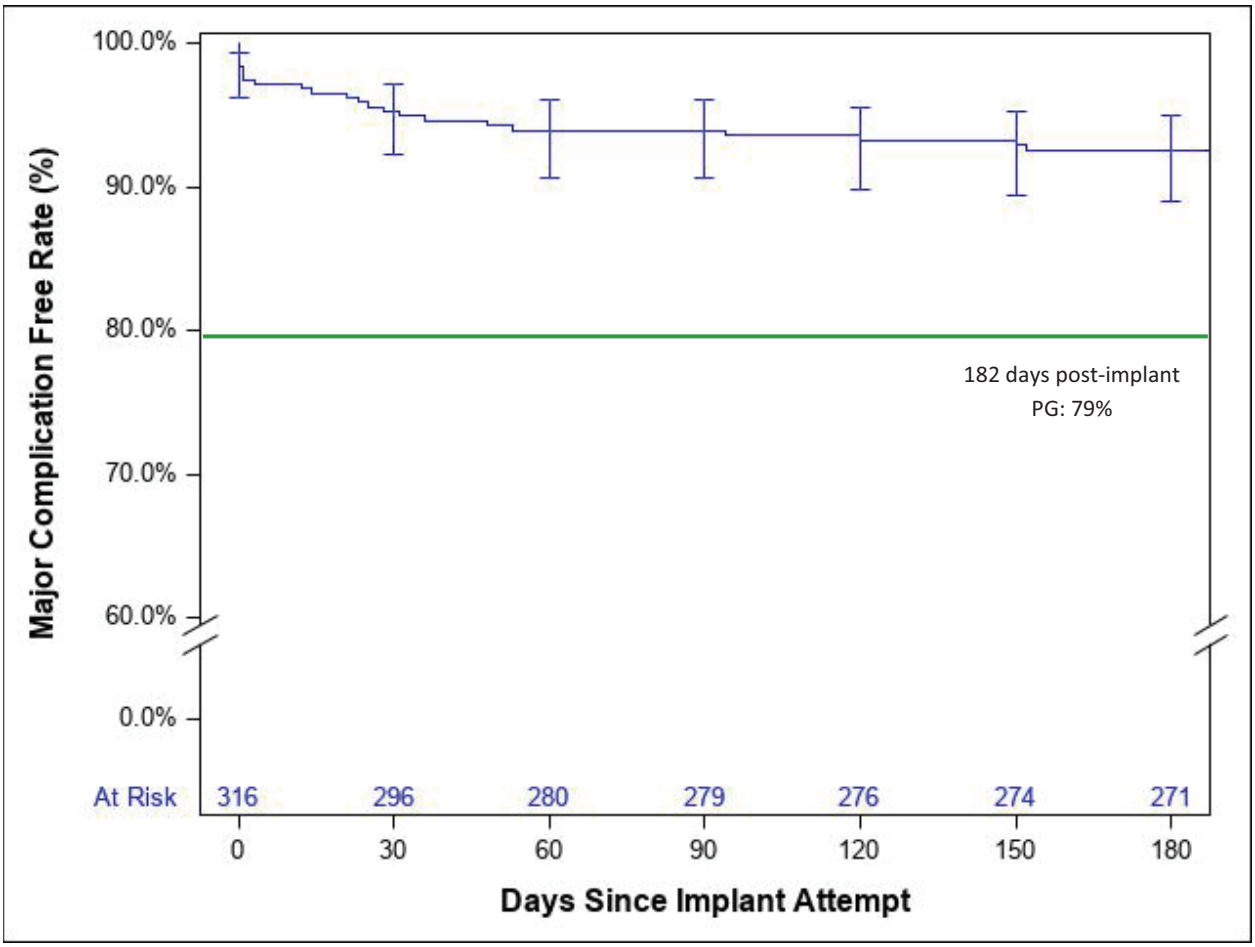
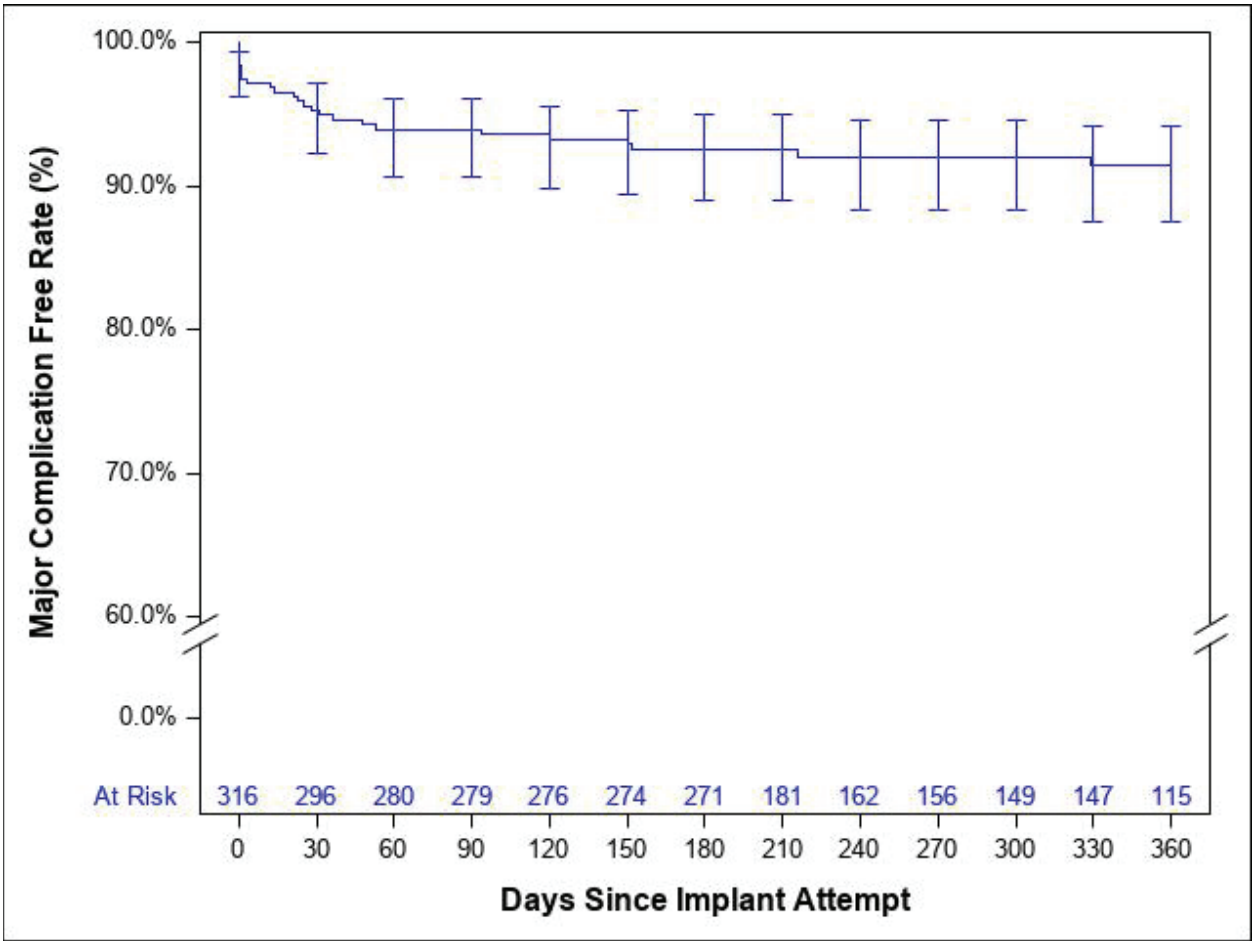


Figure 3 is the Kaplan-Meier plot for the freedom from EV ICD System and/or procedure-related major complications through 360 days post implant. The longest follow-up duration among the 299 subjects who underwent an implant attempt without having a major EV ICD System and/or procedure-related complication was 924 days from implant attempt to the last documented contact.

Figure 3: Kaplan-Meier Plot of EV ICD System/procedure-related Major Complication Free Rate Through 360 Days Post Implant



The cumulative number of subjects with major EV ICD System and/or procedure-related complications over time are listed in Table 14. The EV ICD System and/or procedure-related major complication free rate estimated by the Kaplan-Meier method was 98.4% at the day of implant attempt, 95.2% at 30 days post implant attempt, and 92.6% from 180 days through 210 days post implant attempt.

Table 14. Major EV ICD System/procedure-related Complications Free Rate

Days since implant attempt	Cumulative number of subjects with major EV ICD System/procedure-related complications	Major EV ICD System/procedure-related complication free rate
0	5	98.4%
30	15	95.2%
60	19	93.9%
90	19	93.9%

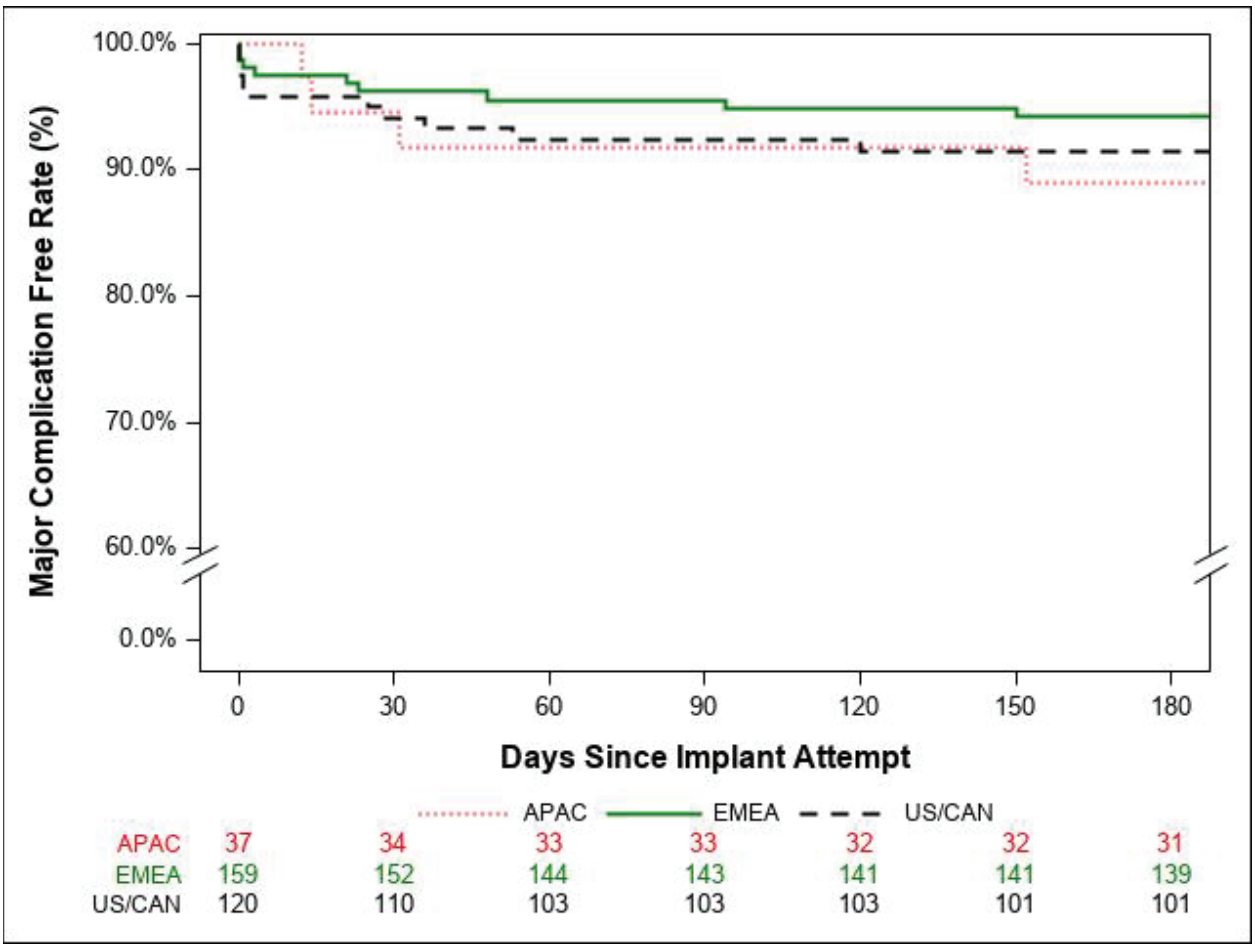
Days since implant attempt	Cumulative number of subjects with major EV ICD System/procedure-related complications	Major EV ICD System/procedure-related complication free rate
120	21	93.2%
150	22	92.9%
180	23	92.6%
210	23	92.6%
240	24	92.0%
270	24	92.0%
300	24	92.0%
330	25	91.4%
360	25	91.4%

A poolability analysis was performed to compare the results of the primary safety endpoint between different geographic regions using a log-rank test. Table 15 shows that there were no statistical differences in the major EV ICD System and/or procedure-related complication free rate through 182 days post implant attempt among APAC, EMEA and US/Canada regions (p=0.3330). Figure 4 is the Kaplan-Meier plot by region.

Table 15: Poolability Analysis of Primary Safety Endpoint on Region

Region	Number of subjects with an implant attempt	Number of subjects with major EV ICD System/procedure-related complications through 182 days post implant attempt	Kaplan-Meier estimate of major EV ICD System/procedure-related complication free rate through 182 days post implant attempt (95% CI)	Log-Rank Test p-Value
APAC	37	4	88.9% (73.1%, 95.7%)	0.3330
EMEA	159	9	94.2% (89.2%, 97.0%)	
US/CAN	120	10	91.5% (84.7%, 95.3%)	

Figure 4: Kaplan-Meier Plot of EV ICD System/procedure-related Major Complication Free Rate Through 182 Days Post Implant by Region



Adverse effects that occurred in the Pivotal clinical study:

In the EV ICD Pivotal study, the CEC adjudicates Adverse Event (AE) relatedness into Causal Relationship, Possible and Not Related. The CEC also classifies system- or procedure-related AEs into complication (major, minor) or observation. Seriousness of AE and whether an AE is an Unanticipated (Serious) Adverse Device Effect (U(S)ADE) are determined by Medtronic. Adverse events are coded using the MedDRA, Medical Dictionary for Regulatory Activities, which is organized with a five-level hierarchy, The highest or broadest level is System Organ Class (SOC), further divided into High-Level Group Terms (HLGT), High-Level Terms (HLT), Preferred Terms (PT), and finally into the most granular Lowest Level Terms (LLT). Preferred Terms (i.e., AE Key Terms) are used in this report.

Table 16 provides a high-level summary of AE seriousness, U(S)ADE, AE relatedness, and complication/observation. All AEs in this report have been evaluated by Medtronic and fully adjudicated by the CEC. Adverse events that were adjudicated by the CEC as Causal Relationship or Possible to the EV ICD system, to a procedure or to an accessory were regarded as system-, procedure- or accessory-related, respectively. Note that the categories of AE relatedness were not mutually exclusive as an AE could be related to more than one category (e.g., an AE could be system-, procedure- and accessory-related).

There were 756 AEs from 243 enrolled subjects, including 731 AEs from 231 subjects who underwent an EV ICD implant attempt and 25 AEs from 12 subjects who did not undergo an EV ICD implant attempt. Among all the adverse events, 331 were serious, three were U(S)ADE, 144 were system- and/or procedure-related (90 procedure-related and 92 EV ICD System-related), and 31 were accessory-related. Of the 144 system- and/or procedure-related AEs, 50 were complications (27 major and 23 minor complications) and 94 were observations.

Table 16: Overall Summary of Adverse Events

	Number of Events (Number of Subjects, % of Subjects)		
Adverse Event Classification	**Subjects with EV ICD Implant Attempt (N = 316)**	**Subjects without EV ICD Implant Attempt (N = 40)**	**Total Subjects (N = 356)**
Serious[*]			
Yes	318 (164, 51.9%)	13 (8, 20.0%)	331 (172, 48.3%)
No	413 (162, 51.3%)	12 (6, 15.0%)	425 (168, 47.2%)
U(S)ADE[**]	**3 (3, 0.9%)**	**0 (0, 0.0%)**	**3 (3, 0.8%)**
Complications/Observations[***]	**144 (108, 34.2%)**	**0 (0, 0.0%)**	**144 (108, 30.3%)**
Complication	50 (45, 14.2%)	0 (0, 0.0%)	50 (45, 12.6%)
Major Complication	27 (25, 7.9%)	0 (0, 0.0%)	27 (25, 7.0%)
Minor Complication	23 (22, 7.0%)	0 (0, 0.0%)	23 (22, 6.2%)
Observation	94 (76, 24.1%)	0 (0, 0.0%)	94 (76, 21.3%)
Relatedness[****]			
System and/or Procedure Relatedness			
Causal Relationship	140 (106, 33.5%)	0 (0, 0.0%)	140 (106, 29.8%)
Probable	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Possible	4 (4, 1.3%)	0 (0, 0.0%)	4 (4, 1.1%)
Unlikely	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	587 (200, 63.3%)	25 (12, 30.0%)	612 (212, 59.6%)
Procedure Relatedness			
Causal Relationship	88 (77, 24.4%)	0 (0, 0.0%)	88 (77, 21.6%)
Probable	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Possible	2 (2, 0.6%)	0 (0, 0.0%)	2 (2, 0.6%)

	Number of Events (Number of Subjects, % of Subjects)		
Adverse Event Classification	**Subjects with EV ICD Implant Attempt (N = 316)**	**Subjects without EV ICD Implant Attempt (N = 40)**	**Total Subjects (N = 356)**
Unlikely	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	641 (216, 68.4%)	25 (12, 30.0%)	666 (228, 64.0%)
System Relatedness			
Causal Relationship	88 (67, 21.2%)	0 (0, 0.0%)	88 (67, 18.8%)
Probable	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Possible	4 (4, 1.3%)	0 (0, 0.0%)	4 (4, 1.1%)
Unlikely	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	639 (212, 67.1%)	25 (12, 30.0%)	664 (224, 62.9%)
Accessory Relatedness			
Causal Relationship	6 (5, 1.6%)	0 (0, 0.0%)	6 (5, 1.4%)
Probable	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Possible	25 (23, 7.3%)	0 (0, 0.0%)	25 (23, 6.5%)
Unlikely	0 (0, 0.0%)	0 (0, 0.0%)	0 (0, 0.0%)
Not Related	700 (228, 72.2%)	25 (12, 30.0%)	725 (240, 67.4%)
Total Adverse Events	**731 (231, 73.1%)**	**25 (12, 30.0%)**	**756 (243, 68.3%)**

* AE seriousness collected by investigators and determined by Medtronic.

** U(S)ADE determined by Medtronic.

*** Complications or observations per CEC adjudication for system- or procedure-related AEs.

**** AE relatedness per CEC adjudication; categories of AE relatedness were not mutually exclusive.

Table 17 summarizes system- and/or procedure-related complications by preferred term. There were 50 system- and/or procedure-related complications from 45 subjects with an implant attempt. Of them, 45 complications from 40 subjects were serious. The most common preferred term for complications was lead dislodgement (11).

Table 17. System- and/or Procedure-related Complications by Preferred Term

	Number of Events (Number, % of Subjects with Events) (Denominator = 316 Subjects with Implant Attempt)	
AE Preferred Term	**Event**	**Serious Events**
Lead dislodgement	11 (10, 3.2%)	11 (10, 3.2%)
Postoperative wound infection	5 (5, 1.6%)	4 (4, 1.3%)
Device inappropriate shock delivery	4 (4, 1.3%)	4 (4, 1.3%)
Device inversion	4 (4, 1.3%)	4 (4, 1.3%)
Implant site infection	4 (4, 1.3%)	2 (2, 0.6%)
Chest pain	2 (2, 0.6%)	2 (2, 0.6%)
Device lead damage	2 (2, 0.6%)	2 (2, 0.6%)
Implant site pain	2 (2, 0.6%)	2 (2, 0.6%)
Oversensing	2 (2, 0.6%)	2 (2, 0.6%)
Suture related complication	2 (2, 0.6%)	1 (1, 0.3%)
Device computer issue	1 (1, 0.3%)	1 (1, 0.3%)
Device placement issue	1 (1, 0.3%)	1 (1, 0.3%)
Implant site haemorrhage	1 (1, 0.3%)	1 (1, 0.3%)
Incision site impaired healing	1 (1, 0.3%)	1 (1, 0.3%)
Incision site pain	1 (1, 0.3%)	1 (1, 0.3%)
Medical device site discomfort	1 (1, 0.3%)	1 (1, 0.3%)
Muscle injury	1 (1, 0.3%)	1 (1, 0.3%)
Musculoskeletal chest pain	1 (1, 0.3%)	1 (1, 0.3%)
Postoperative wound complication	1 (1, 0.3%)	1 (1, 0.3%)
Procedural pain	1 (1, 0.3%)	1 (1, 0.3%)
Pulseless electrical activity	1 (1, 0.3%)	1 (1, 0.3%)
Impaired healing	1 (1, 0.3%)	0 (0, 0.0%)
Total	**50 (45, 14.2%)**	**45 (40, 12.7%)**

The three U(S)ADEs included one with device software interaction and two with high-voltage lead fractures.

There was one report of a device computer issue due to previously unknown software-hardware interaction which could cause the high voltage circuit to “lock-up”. In this case, following two successful

VT/VF defibrillation tests at implant, a subsequent cardioversion was attempted to resolve an atrial arrhythmia. At the time the cardioversion was attempted, the programmer presented an error message indicating the capacitors could not be charged. The device was explanted and replaced without sequelae and an adverse event report was submitted. Due to the rate of occurrence of this issue being higher than anticipated, this event was classified as a U(S)ADE. A clinical communication was disseminated to sites and ethics committees in March 2021 which included programming recommendations to prevent this interaction. Since a malfunction resulting in failure to deliver high voltage therapy was previously identified as a risk in the protocol and informed consent, there were no changes to the pre-specified risks listed in the study protocol or in the patient's informed consent document. Medtronic developed a software update to permanently eliminate the risk for this interaction. In November 2021, the FDA approved the updated software (v8.3.1), and the software was subsequently provided to subjects globally, following local submissions and approvals as applicable.

There were two reports of a lead fracture, which were both classified as a U(S)ADEs. In both cases, the fracture was discovered following explant due to a high voltage lead impedance out of range alert. While lead fracture is identified as a potential adverse event associated with the use of this product, these two events were classified as an Unanticipated Adverse Device Effect due to the unanticipated degree of incidence (event occurring within a limited number of implants and early in the lifecycle of the lead). There were no changes to the pre-specified risks listed in the study protocol or in the patient's informed consent document. The location of the lead fracture was the same in both subjects, at the proximal end of the proximal defibrillation coil. After further investigation, it was determined that both fractures were due to excessive lead bending motions, which were not previously observed in pre-clinical or human feasibility studies. Both lead extractions were performed without further clinical sequelae. Notifications were provided (October 2021 and January 2022) to global competent authorities, where required, and Medtronic notified investigating centers and Ethics Committees. There were no new patient management recommendations for previously implanted patients, and physicians were reminded to continue to maintain standard clinical follow-up for patients in the EV ICD Pivotal Study. At the time of the first communication, enrollments and implants in the Pivotal clinical trial were complete. Subsequent to these observations, updates were made to the lead implant guidance to: 1) define the lower limit for lead location to ensure all electrodes are located under (posterior to) the sternum and 2) define the upper limit for lead motion and specify when repositioning should be performed at implant.

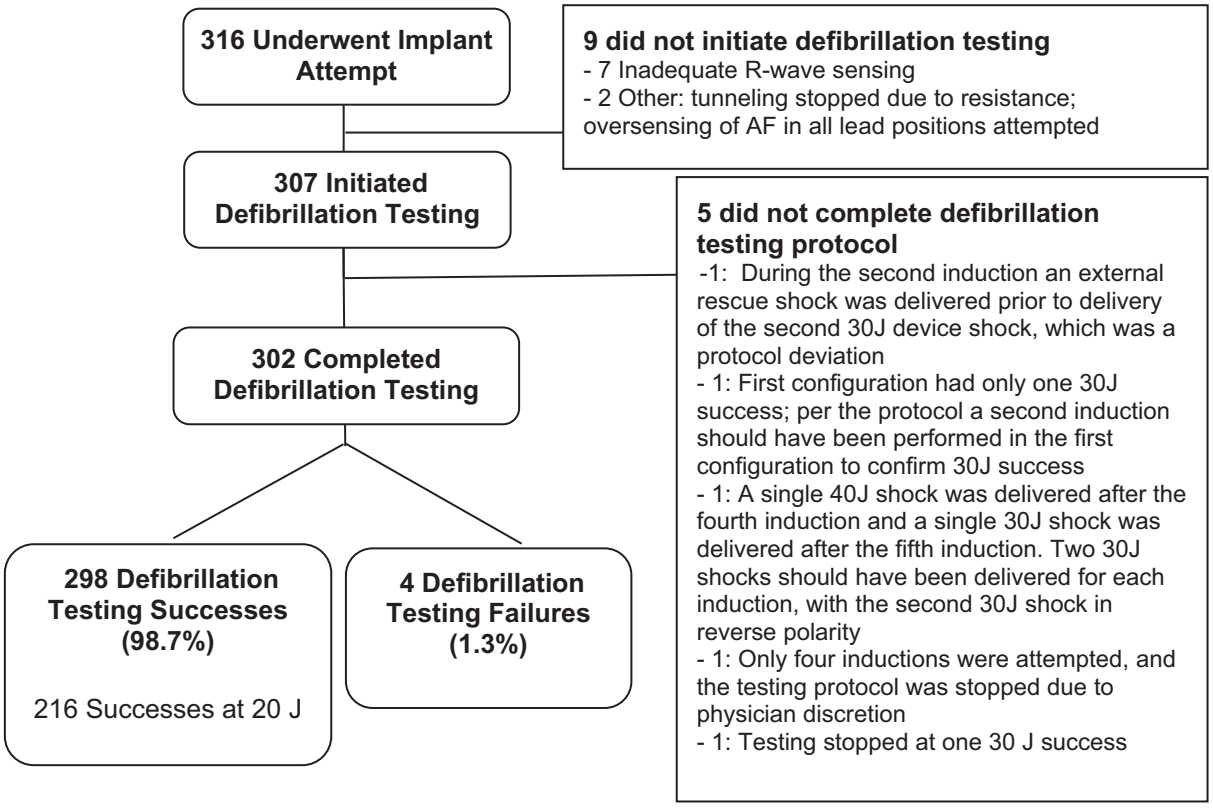
NOTE: There was one additional lead fracture confirmed on a lead explanted from a subject enrolled in the Pivotal study which occurred after the database freeze for this report. This event was classified as a U(S)ADE, bringing the total number of U(S)ADEs to four: one device software interaction and three high-voltage lead fractures. In this case, the patient contacted their clinic to report that their device alarm was sounding, which was 34 months post-implant. The alarm sounded due to a high voltage lead impedance out of range measurement. The patient had a system revision and underwent successful lead extraction and replacement of a new EV ICD system without sequelae. The fracture was at the connection between the proximal defibrillation coil and the conductor cable. Notifications were provided (January 2023) to global competent authorities, where required, and Medtronic notified investigating centers and Ethics Committees. There were no new patient management

recommendations, and physicians were reminded to continue to maintain standard clinical follow-up for patients in the EV ICD Pivotal Study.

5.3.2. Primary Effectiveness Results

The defibrillation testing status of subjects with an implant attempt is shown in Figure 5. Among the 316 subjects with an implant attempt, 9 did not initiate defibrillation testing at implant, 5 did not complete defibrillation testing, and 302 subjects completed defibrillation testing including 298 successes and 4 failures.

Figure 5: Defibrillation Testing Status of Subjects with Implant Attempt



Of the 307 subjects that initiated defibrillation testing at implant, all had at least one ventricular fibrillation (VF) episode that was device-detected in the final lead position at ≥ 0.2mV for the Ring 1 to Ring 2 sensing vector, and all but ten subjects had the defibrillation testing completed on the date of implant.

Table 18 summarizes the implant defibrillation testing status of 316 subjects that underwent an implant attempt. There were 302 subjects who completed the implant defibrillation testing, including 298 successes and 4 failures. Of the 298 subjects with implant defibrillation testing success, 216 (72.5%) had the first SSVA episode terminated successfully with one 20J shock and 82 (27.5%) had two consecutive SSVA episodes terminated with 30J shocks.

Of the 216 subjects that had the first SSVA episode terminated successfully with a 20J shock, 212 subjects had a second SSVA episode tested with a 15J shock including 154 (72.6%) subjects with a 15J success, 58 (27.4%) subjects with a 15J failure. Four subjects were not tested at 15J after a defibrillation success at 20J.

Of the 82 subjects that had two consecutive SSVA episodes terminated with 30J shocks, 68 (82.9%) subjects met this defibrillation criterion after 3 induced SSVA episodes, 7 (8.5%) met it after 4 induced SSVA episodes, 2 (2.4%) after 5 induced SSVA episodes, and 5 (6.1%) after 6 induced SSVA episodes.

Table 18: Implant Defibrillation Testing Status

Implant defibrillation testing status	EV ICD System fully implanted?	Reason EV ICD System not fully implanted	Energy level with defibrillation testing success	Number of subjects (Total=316)
Did not initiate implant DFT	N	INADEQUATE R-WAVE SENSING	-	7
Did not initiate implant DFT	N	OTHER: OVERSENSING OF ATRIAL FIBRILLATION IN ALL LEAD POSITION ATTEMPTED.	-	1
Did not initiate implant DFT	N	OTHER: TUNNELING STOPPED DUE TO RESISTENCE	-	1
Initiated implant DFT but did not complete	N	INCOMPLETE DEFIBRILLATION TESTING PROTOCOL	-	4
Initiated implant DFT but did not complete	Y	-	-	1
Completed implant DFT with failure	N	FAILED DEFIBRILLATION TESTING	-	4

Implant defibrillation testing status	EV ICD System fully implanted?	Reason EV ICD System not fully implanted	Energy level with defibrillation testing success	Number of subjects (Total=316)
Completed implant DFT with success	Y	-	20J	216
Completed implant DFT with success	Y	-	30J	82

Among subjects who completed the defibrillation testing protocol at implant, the proportion of those who had a defibrillation testing success was 98.7% (298/302), with a lower confidence bound of two-sided 95% confidence interval being 96.6%. This was greater than the PG of 88%, hence the primary efficacy objective was met (p<0.0001). Results are summarized in Table 19.

Table 19: Results of Primary Efficacy Objective

Number of subjects completed implant DFT	Number of subjects with implant DFT success	Implant DFT success rate	Lower confidence bound of two-side 95% confidence interval	p-Value
302	298	98.68%	96.64%	<.0001

Table 20 summarizes the number of rescue shocks received among subjects that underwent implant defibrillation testing. Of the 307 subjects that initiated implant defibrillation testing, 156 (50.8%) subjects did not receive a rescue shock, and 151 (49.2%) subjects received at least one rescue shock including:

- 112 subjects had 1 rescue shock
- 21 subjects each had 2 rescue shocks
- 7 subjects each had 3 rescue shocks
- 7 subjects had 4-5 rescue shocks
- 2 subjects had 6-8 rescue shocks (Subject 100270911 and 1002692806 with DFT protocol not completed)
- 2 subjects had 10 rescue shocks (Subject 104235106 with DFT spanned for 3 days to complete the protocol; Subject 200878022 with DFT protocol not completed)

Table 20: Summary of Number of Rescue Shocks Received

Number of Rescue Shocks Received	Implant DFT Status	Implant DFT Result	Energy Level at Final DFT Success	Number of subjects (Total=307)
0	Completed implant DFT with success	Success	20J	155
			30J	1
1	Completed implant DFT with success	Success	20J	52

Number of Rescue Shocks Received	Implant DFT Status	Implant DFT Result	Energy Level at Final DFT Success	Number of subjects (Total=307)
			30J	60
2	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
	Completed implant DFT with success	Success	20J	7
			30J	13
3	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
	Completed implant DFT with success	Success	20J	2
			30J	4
4	Completed implant DFT with failure	Failure	-	1
	Completed implant DFT with success	Success	30J	1
5	Completed implant DFT with failure	Failure	-	3
	Completed implant DFT with success	Success	30J	2
6	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
8	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
10	Initiated implant DFT but did not complete	DFT Protocol Not Completed	-	1
	Completed implant DFT with success	Success	30J	1

A poolability analysis was performed to compare the results of the primary efficacy endpoint between different geographic regions using a Fisher's exact test. As shown in Table 21, there was no significant difference in implant defibrillation testing success rate among APAC, EMEA and US/Canada regions (p=0.7806).

Table 21: Poolability Analysis of Primary Efficacy Endpoint on Region

Region	Number of subjects completed implant DFT	Number of subjects with implant DFT success	Implant DFT success rate	Fisher's Exact Test p-Value
APAC	35	35	100.0%	0.7806
EMEA	154	151	98.1%	
US/CAN	113	112	99.1%	

Subgroup Analyses

The cohort included all enrolled subjects who underwent the study procedures unless the subject did not complete the required testing, and there were no pre-specified subgroups for assessment. However, poolability analyses were performed to compare the results of the primary objectives between different geographic regions; no statistically significant differences were observed.

6. Study Conclusions

The prospective global EV ICD Study was conducted to demonstrate the safety and effectiveness of the EV ICD System, and confirmed the following:

- The EV ICD System is safe, as demonstrated by the major system- and procedure-related complication-free rate (92.6%).
- The EV ICD System using a substernal lead is effective at terminating ventricular arrhythmias, as demonstrated by the defibrillation efficacy at implant (98.7%).

The study exceeded the pre-specified PG of 79% for the freedom from major complications related to the EV ICD System and/or procedure at 6 months post-implant, with a lower confidence bound of two-sided 95% confidence interval of 89.0%. Therefore, the primary safety objective was met. There were no unique major complications observed related to the extravascular ICD system or procedure that have not been observed in subcutaneous and transvenous devices previously.[1-4] The most common major complication observed through 182 days post-implant was lead dislodgement, accounting for 10 major complications from 9 subjects. Through post-hoc analysis, Medtronic attributed lead dislodgement to either lead location in the pleural cavity (n=3/9) or suboptimal suturing (n=6/9). As a result, Medtronic will emphasize tunnelling along the midline or just left of the sternal midline to reduce the risk of pleural lead placement during training for new implanters. Emphasis will also be placed on fixating the lead using a minimum of 3 sutures (2 non-necrosing sutures tied in the rectus fascia and 1 suture tied directly around the lead anchoring the sleeve to secure to the lead body).

The study exceeded the pre-specified PG of 88% for the EV ICD defibrillation testing success rate at implant, with a lower confidence bound of two-sided 95% confidence interval of 96.6%. Therefore, the primary efficacy objective was also met. Furthermore, the study demonstrated that defibrillation can be achieved with adequate (≥10J) safety margin at implant, with defibrillation efficacy at ≤20J in 216/302 (72.5%) subjects and ≤15J in 154/212 (72.6%), among subjects tested at these energies. The median energy for defibrillation was 15J at implant, which is comparable to that of transvenous ICDs, and approximately half of that reported with the subcutaneous ICD.[5]

Furthermore, these results demonstrate that through a robust training program, the EV ICD implant procedure could be safely performed by a non-surgical physician specialty (EP/Cardiology), along with initial collaboration from cardiac surgeons. Implant procedures were successfully performed by 55 implanting physicians at 46 sites in 17 countries. Physicians rated the ease of deploying the lead in the intended location as “very easy” or “easy” in the majority (82.6%) of implant attempts, and 99.7% of patients had the substernal lead positioned. There were no major intraprocedural complications. Average procedure time (first incision to final device pocket procedure suture) of the EV ICD procedure (74.6±33.2 min) was similar to early experience with the subcutaneous ICD (69±27 min).[6]

The EV ICD System can detect and treat life-threatening arrythmias following implant. Among discrete spontaneous true VT/VF events treated with appropriate shocks, 100% (18/18 episodes) were successfully converted to sinus rhythm. Furthermore, 36 of 36 patients enrolled in the chronic defibrillation study with inducible arrhythmias were successfully defibrillated, and chronic defibrillation

testing was successful in all 18 subjects when performed chronically per physician discretion. Importantly, there were no arrhythmic deaths due to unsuccessful device therapy.

The most common reason for inappropriate shocks in the extravascular ICD was from P-wave oversensing (n=34/81; 42.0%). P-wave oversensing is a function of lead location relative to the right atrial appendage. The incidence of inappropriate shocks due to P-wave oversensing decreased with experience over the trial duration (28 episodes in 6 patients implanted among the first half of study implants versus 6 episodes in 4 patients implanted among the second half of study implants, respectively).

Overall, the incidence of first inappropriate shock was 10.8% at 360 days post-implant, which is comparable to the incidence of first inappropriate shock observed in the S-ICD IDE trial (13.1% through 11-month average follow-up[7]). Algorithms to mitigate inappropriate shocks have been developed and deployed, but not yet well studied clinically.[8] Additionally, the rate of inappropriate shocks may improve with experience, as demonstrated by the EFFORTLESS post-market S-ICD study.[4]

Electrical performance, including sensing amplitudes, impedance, and pacing capture thresholds, were characterized over time and were relatively stable.

Extracardiac pacing sensation was characterized over time, as measured by pacing therapies being turned OFF due to pacing sensation. At the 6-month visit, fewer than 5% of subjects had therapies programmed off due to pacing sensation not tolerated (4.9% for ATP, 1.3% for pause prevention pacing [programmed off or to monitor mode], and 1.8% for post shock pacing). No patient had their device explanted due to pacing sensation.

The EV ICD System is capable of delivering asystole (pause prevention) pacing. This feature was required to be set to MONITOR at pre-hospital discharge per the CIP and could be turned to ON or OFF modes per physician discretion; thus, experience was limited. However, two patients experienced 7 episodes of asystole that were detected and treated with between 1 and 19 paces delivered.

The EV ICD System is capable of delivering terminating arrhythmias using ATP therapy, thus, avoiding a potential shock. By programming ATP “ON”, 29 true VT/VF episodes were terminated by ATP alone.

Medtronic plans to enroll patients with an EV ICD System in a post-market registry to further characterize the system performance. The Product Surveillance Registry (PSR) is Medtronic’s active global post market surveillance platform. The PSR platform is designed to conduct non-randomized, prospective, multi-center post-market surveillance and provides continuing evaluation and periodic reporting of the long-term reliability, safety, and performance of Medtronic market-released products. The objectives of the post-market registry are outlined in a separate analysis plan.

The EV ICD Pivotal trial has demonstrated the safety and efficacy of the system through a global prospective trial. The data from the EV ICD Pivotal trial show that the EV ICD system utilizing a substernal lead can be implanted safely and effectively detects and terminates induced and spontaneous ventricular arrhythmias, retaining the benefits of extravascular placement while providing pause prevention pacing, anti-tachycardia pacing and low-energy defibrillation.

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AURORA EV-ICD™ MRI SURESCAN™ DVEA3E4

MRI procedural information for MRI SureScan cardioverter defibrillators with MRI SureScan leads

MRI Technical Manual

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Contents

1 Introduction

1.1 About the system

The Medtronic Aurora EV-ICD™ MRI SureScan™ system is MR Conditional and, as such, is designed to allow patients to be safely scanned by an MRI machine when used according to the specified MR conditions for use. When programmed to On, the MRI SureScan feature allows the patient to be safely scanned. The MRI SureScan feature must be programmed using the Medtronic Model SW041 software on a Medtronic CareLink 2090 Programmer or a Medtronic CareLink Encore 29901 Programmer.

It is important to read this MRI Technical Manual before conducting an MRI scan on a patient with an implanted SureScan system. Contact a Medtronic representative if you have further questions.

Note: The button labels and navigation instructions in this manual apply to the Medtronic Model SW041 software on a Medtronic CareLink 2090 Programmer or a Medtronic CareLink Encore 29901 Programmer. The details of the user interface are provided for reference only and may not match those of other applications.

Refer to the appropriate Medtronic device and reference manuals or lead technical manuals for non-MRI related instructions for use.

2 MR conditions for use

A complete SureScan system is required for use in the MR environment. A complete SureScan system includes an extravascular SureScan VR ICD with an extravascular SureScan defibrillation lead. To verify that components are part of a SureScan system, visit http://www.mrisurescan.com. Any other combination may result in a hazard to the patient during an MRI scan.

Warning: Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan system.

Note: The MRI SureScan mode cannot be programmed to On if the device is recommended for replacement.

2.1 Cardiology requirements

Patients and their implanted systems must be screened to meet the following requirements:

- The patient has no implanted lead extenders, lead adaptors, or abandoned leads.
- The patient has no broken leads or leads with intermittent electrical contact, as confirmed by lead impedance history.
- The SureScan device is operating within the projected service life.

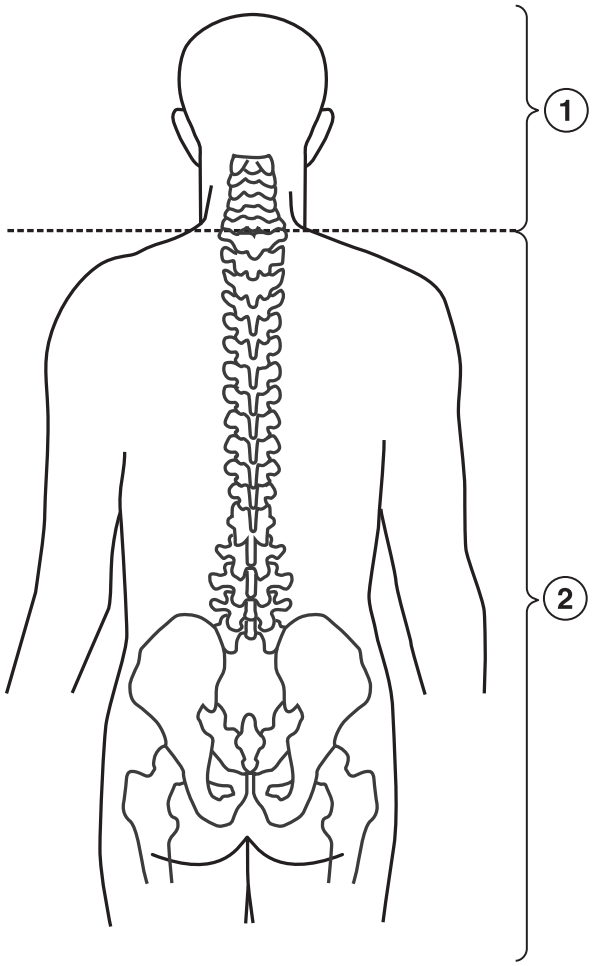
2.2 Radiology requirements

The safety and reliability of the SureScan system has been evaluated for scanning patients using MRI equipment that has the following operating characteristics:

Scanner type	Horizontal field, cylindrical bore, clinical system for hydrogen proton imaging
Scanner characteristics	• Static magnetic field of one of the following strengths: – 1.5 T – 3 T • Maximum spatial field gradient of ≤ 20 T/m (2000 gauss/cm) • Gradient systems with maximum gradient slew rate performance per axis of ≤ 200 T/m/s

Scanner operation	**1.5 T –** MRI radio frequency (RF) power – Normal Operating Mode. • The whole body averaged specific absorption rate (SAR) must be ≤ 2.0 W/kg. • The head SAR must be ≤ 3.2 W/kg.
	3 T – MRI radio frequency (RF) power – First Level Controlled Operating Mode or Normal Operating Mode: • B_{1+RMS} must be ≤ 2.0 µT when the isocenter (center of the MRI bore) is inferior to the C7 vertebra. • Scans can be performed without B_{1+RMS} restriction when the isocenter is at or superior to the C7 vertebra (see *Figure 1*).

Figure 1. 3 T Scan location requirements



1 No B_{1+RMS} restrictions
2 B_{1+RMS} not to exceed 2.0 µT

2.3 Patient monitoring and rescue requirements

Continuous patient monitoring is required during the MRI scan.

In the event that patient rescue is required, an external defibrillator must be immediately available.

2.4 Training requirements

- A health professional who has completed cardiology SureScan training must be present during the programming of the MRI SureScan feature.
- A health professional who has completed radiology SureScan training must be present during the MRI scan.

3 MRI warnings and precautions

Warnings:

- Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan system.
- Do not leave the device in MRI SureScan mode after the scan is complete. While MRI SureScan mode is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. Be sure to program MRI SureScan mode to Off as soon as the scan is complete.
- Do not scan patients who do not have a complete SureScan system, which includes an EV ICD MRI SureScan ICD with an EV ICD SureScan defibrillation lead. Any other combination may result in a hazard to the patient during an MRI scan.
- Do not scan patients with broken, abandoned, or intermittent leads. Lead fractures or other damage to the leads may cause changes in the electrical properties of the SureScan system that will make the system unsafe for an MRI scan. Patients with damaged leads may be harmed if an MRI scan is performed.

Cautions:

- Do not scan patients in a 1.5 T magnetic field with a whole body averaged SAR level > 2.0 W/kg. A scan above 2.0 W/kg may increase the risk of lead electrode heating resulting in patient discomfort.
- Do not scan patients in a 3 T magnetic field with a B_{1+RMS} value > 2.0 µT when the isocenter (center of the MRI bore) is inferior to the C7 vertebra. A scan above 2.0 µT may increase the risk of MRI-related hazards, including patient discomfort due to lead electrode heating.
- Do not scan patients with lead extenders or lead adaptors. Lead extenders and lead adaptors may increase the risk of MRI-related hazards, including patient discomfort due to lead electrode heating.
- It is not recommended to perform MRI scans during the lead maturation period (approximately 6 weeks) because MRI scans during this period have not been prospectively studied by Medtronic.
- Scanning patients who have multiple MR Conditional devices present is acceptable as long as the MR labeling conditions for all implants can be satisfied.
- Do not bring the Medtronic programmer, Patient Assistant, or patient monitor into Zone 4 (MRI magnet room), as defined by the American College of Radiology. They are MR Unsafe.
- It is not recommended to perform an MR examination near the RF exposure limits for periods exceeding 60 min of active scan duration, as this may increase the risk for localized tissue damage from heating around the lead electrodes.

4 Potential adverse events

The SureScan system is designed to minimize the potential adverse events that may cause patient harm. The following potential adverse events may occur in the MRI environment:

- lead electrode heating resulting in tissue damage near the lead electrodes or patient discomfort or both
- spontaneous tachyarrhythmia occurring during the scan that is not detected and treated because tachyarrhythmia detection is suspended while MRI SureScan mode is programmed to On
- device heating resulting in tissue damage in the implant pocket or patient discomfort or both
- MR-induced muscle stimulation resulting in patient discomfort

- damage to the device or leads causing the system to fail to detect or treat irregular heartbeats or causing the system to treat the patient's condition incorrectly
- damage to the functionality or mechanical integrity of the device resulting in the inability of the device to communicate with the programmer
- movement or vibration of the device or leads resulting in dislodgment

5 Patient monitoring requirements

While the MRI SureScan mode is programmed to On, tachyarrhythmia detection and therapy are suspended, leaving the patient at risk of death from untreated spontaneous tachyarrhythmia. Therefore, proper patient monitoring is required during the entire time when the MRI SureScan mode is programmed to On.

Proper patient monitoring must be provided during the MRI scan and includes all of the following actions:

- Continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography
- Continuous visual monitoring of the patient, maintaining verbal contact if the patient can communicate

Preparation for patient rescue – In the event that patient rescue is required, an external defibrillator must be immediately available.

Note: If the patient's hemodynamic function is compromised during the MRI scan, discontinue the scan, remove the patient from the magnet room, and take the proper measures to restore the patient's hemodynamic function.

6 Cardiology-specific considerations

Lead maturation – MRI scans during the lead maturation period (approximately 6 weeks) have not been prospectively studied by Medtronic and are not recommended.

Spontaneous tachyarrhythmia – Tachyarrhythmia detection and therapy are suspended while the MRI SureScan mode is programmed to On. Be sure to program the MRI SureScan mode to Off as soon as the MRI scan is complete.

System information and records – All pertinent information about the components of the implanted SureScan system such as model names, model numbers, and serial numbers should be recorded in the patient record and on the Patient Information screen on the programmer. This information will help with system identification in the future.

Patient ID card – Reference materials, such as an ID card, should be provided to all patients with an implanted SureScan system. These reference materials should indicate that the patient has a SureScan defibrillation device and SureScan leads.

Note: Be sure to advise the patient to notify medical personnel that they have an ICD before entering the MR environment and to present their patient ID card.

7 Radiology-specific considerations

7.1 MRI considerations

3 T whole-body transmit coil RF excitations – 3 T MRI systems using 2 transmit channels (or fewer) may operate in the following RF excitations: 2 transmit channels (known as Multichannel-2 (MC-2)) or Circularly Polarized (CP). Systems that use more than 2 transmit channels have not been studied, but such systems could be operated in CP or MC-2, if available.

Use of transmit/receive and receive-only coils – There are no restrictions on the use of local transmit/receive coils for MRI scanning of the head or of the extremities, and there are no restrictions on the placement of receive-only coils.

Image artifact and distortion – SureScan leads have demonstrated minimal MRI scan distortion for areas surrounding the implanted leads when the device is out of the field of view. Significant MRI scan distortion will result from the presence of the device within the field of view. MRI scan artifacts and distortion resulting from the presence of the device and the leads within the field of view must be considered when selecting the field of view and the MRI scanning parameters. These factors must also be considered when interpreting the MRI scans.

Patient sensation during MRI – The device has been evaluated to ensure no risk of tissue damage. However, the patient may feel sensations of warmth or vibration in the implant site during the MRI scan. Tolerable levels of these sensations do not indicate that patient safety has been compromised.

8 Pre-MRI scan operations

The steps in the following sections are required before performing an MRI scan.

8.1 Identification of SureScan system components

Use the following methods to verify that a patient has a SureScan system:

- **Patient records or patient ID card (if applicable):** Patient records and the patient ID card, if applicable, are the most reliable record of the medical devices that have been implanted in the patient. These records are available to clinicians other than the device clinician and can be accessed without the presence of the patient or the use of a programmer. These records must be complete and accurate if they are to be used to determine whether the patient has a SureScan system.
- **Patient information on the programmer:** The programmer Patient Information feature is intended to be used by the implanting clinician to document the components of the patient's SureScan system. If the implanting clinician has entered the needed information completely and accurately, you can use the Patient Information feature to determine whether the patient has a SureScan system. The patient may have other implanted devices that are not approved for use in the MRI environment, but not noted in the patient information on the programmer.
    1. Tap **Patient > Patient Information > MRI SureScan System/Other Hardware…**.
       The **MRI SureScan System/Other Hardware** window appears.
    2. View the **MRI SureScan System** fields for information about the patient's leads and whether or not they are MR Conditional.
    3. View the **Other Hardware** fields for information about other lead extenders, lead adaptors, and abandoned leads.

8.2 Required patient care

Before programming the MRI SureScan mode to On, perform the following actions to help ensure patient safety:

Prepare to provide proper patient monitoring while the MRI SureScan mode is programmed to On. – Proper patient monitoring includes maintaining continuous visual and verbal contact with the patient, if the patient can communicate, and continuous monitoring of the patient's heart rate using instrumentation such as pulse oximetry (plethysmography) or electrocardiography.

Prepare for patient rescue. – In the event that patient rescue is required, an external defibrillator must be immediately available.

9 Performing an MRI scan

Warning: Do not scan a patient without first programming the MRI SureScan mode to On. Scanning the patient without programming the MRI SureScan mode to On may result in patient harm or damage to the SureScan system.

Warning: Do not leave the device in MRI SureScan mode after the scan is complete. While the MRI SureScan mode is programmed to On, arrhythmia detection and therapies are suspended, leaving the patient at risk of death

from untreated spontaneous tachyarrhythmia. Be sure to program the MRI SureScan mode to Off as soon as the scan is complete.

Note: The system automatically programs the MRI SureScan mode to Off 6 hours after it is programmed to On. Before you program the MRI SureScan mode to On, ensure that the MRI scan will be completed before this 6-hour timeout occurs. Refer to the MRI SureScan Parameters report or the Quick Look II report for information about when the MRI SureScan mode was programmed to On.

Caution: Do not bring the Medtronic programmer, the Patient Assistant, or the patient monitor into Zone 4 (MRI magnet room), as defined by the American College of Radiology. They are MR Unsafe.

Sensed events will be ignored by the device when the MRI SureScan mode is programmed to On, regardless of the programmed mode. The device maintains the selected parameters until the MRI SureScan mode is programmed to Off after the MRI scan has been completed. After the MRI SureScan mode is programmed to Off, the permanent device parameters are restored.

9.1 SureScan system integrity verification

The SureScan system provides for an acceptable impedance range of the lead vectors for patient safety during an MRI scan. The acceptable impedance ranges for the lead vectors are as follows:

- Ring 1 to Ring 2: 100 - 1500 Ω
- Ring 1 to Coil 2: 100 - 1500 Ω
- Coil 2 to Coil 1: 30 - 250 Ω
- Coil 2 to Can: 30 - 250 Ω

If any vector impedance falls outside these ranges, then MRI SureScan mode cannot be programmed On.

9.2 Programming the MRI SureScan feature to On

When programmed to On, the MRI SureScan feature allows patients to be safely scanned by an MRI machine.

Perform the following steps to program the MRI SureScan feature to On.

1. Tap **Params** > **MRI SureScan…**.
   The **MRI SureScan Checklist** screen appears.
2. Review the MRI SureScan Checklist and select the check box if all items are satisfied for the patient.
   Note: Tap **Print…** to print a copy of the MRI SureScan Checklist if desired.
3. Tap **OK**.
   The **MRI SureScan** screen appears.
4. Tap the **MRI SureScan** field.
   The MRI SureScan feature settings become available.
5. Set the **MRI SureScan** parameter to On.
6. Tap **PROGRAM**.
   The implanted device is now ready for the MRI scan.
   Notes:
   - After the device is programmed for an MRI scan, available options are **Print…**, **End Session…**, and **Emergency**. The MRI SureScan parameter can also be programmed to Off.
   - Selecting the **Emergency** button while in MRI SureScan mode programs the MRI SureScan parameter to Off.
   - The status of the MRI SureScan mode and the programmed parameters may be confirmed by printing the MRI SureScan Parameters report. The MRI SureScan Parameters report may be printed by tapping **Print…**.

9.3 Device considerations

Suspension of diagnostic data – When the MRI SureScan mode is programmed to On, all device diagnostic measurements and collection are suspended.

Suspension of wireless telemetry and Medtronic CareAlert Monitoring – Wireless telemetry and the Medtronic CareAlert Monitoring feature are disabled when MRI SureScan mode is programmed to On.

Automatic canceling of the MRI SureScan mode with Emergency programming – If you deliver any emergency therapy when the MRI SureScan mode is programmed to On, the MRI SureScan mode is automatically programmed to Off. After an Emergency feature is programmed, the MRI SureScan mode must be programmed to On again before the patient can be scanned safely.

Suspension of tachyarrhythmia detection – When MRI SureScan mode is programmed to On, the device does not detect ventricular tachyarrhythmias.

Note: When MRI SureScan mode is programmed to On, the message All Off appears on the Device Status Line to indicate that all detection and therapy features are suspended.

Suspension of tachyarrhythmia therapies – When MRI SureScan mode is programmed to On, tachyarrhythmia therapies are disabled.

10 Following the MRI scan

Program the MRI SureScan mode to Off – Program the MRI SureScan mode to Off as soon as the scan is complete to restore tachyarrhythmia therapies. If the device is inadvertently left in MRI SureScan mode after the scan, the device will remain in MRI SureScan mode until 6 hours have elapsed. After 6 hours, MRI SureScan mode will be changed to Off, and the device parameter values will be restored to the pre-MRI SureScan mode configuration.

10.1 Returning the device to the pre-MRI configuration

After the MRI scan is complete, the MRI SureScan mode must be programmed to Off using the Medtronic programmer. Programming the MRI SureScan mode to Off restores the device parameter values to the pre-MRI SureScan mode configuration.

Perform the following steps to program the MRI SureScan mode to Off:

1. Tap the **MRI SureScan** field of the **MRI SureScan** screen, changing the value to **Off**.
2. Tap **PROGRAM**.
3. Tap **Close**.

   The **MRI SureScan** screen closes and the programmer returns to the **Parameters** screen. The device parameter values are now restored to the pre-MRI SureScan configuration.

Note: During each interrogation, the device is monitored for possible electrical reset conditions and disabled therapies. If a condition is detected that requires attention, the programmer displays a Device Status Indicator warning in a pop-up window and on the Quick Look II screen.

11 Medtronic warranty information

Please see the literature enclosed with the products for information regarding the product warranty or disclaimer of warranty as applicable.

12 Explanation of MRI symbols

The following symbols are related to the magnetic resonance (MR) environment and are used to indicate the safety of devices and components in the MR environment.

MR Conditional symbol. The Medtronic SureScan system is MR Conditional and, as such, is designed to allow implanted patients the ability to undergo an MRI scan under the specified MR conditions for use.

13 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For more information, contact your local Medtronic representative or call or write Medtronic at the appropriate telephone number or address listed on the back cover.

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Medtronic

Medical Procedure and EMI Warnings, Precautions, and Guidance

for implanted pacemakers and defibrillators

Manual for Health Care Professionals

Contents

1 Introduction

This manual is for physicians and other health care professionals who treat patients who have the following Medtronic implanted cardiac devices:

- Pacemakers, including cardiac resynchronization therapy pacemakers (CRT-P)
- Cardioverter defibrillators (ICD), including cardiac resynchronization therapy defibrillators (CRT-D)

Note: The warnings, precautions, and guidance in this manual do not apply to patients who have leadless transcatheter cardiac devices or implantable cardiac monitors.

To view or download this manual online, see the Medtronic eManuals website at www.medtronic.com/manuals.

Chapter 2 provides a short overview of electromagnetic interference (EMI).

Chapter 3 describes the most common device responses to electromagnetic interference (EMI).

Chapter 4 provides EMI guidelines for clinicians to discuss with their patients.

Chapter 5 provides guidance for the perioperative care of patients with implanted devices for medical procedures.

Chapter 6 provides information related to EMI for health care professionals who perform medical procedures on patients with Medtronic implanted cardiac device systems, in consultation with patient cardiologists. This section provides warnings, precautions, and guidance for medical therapies and diagnostic procedures that present potential risk to the patient or to the operation or physical integrity of the Medtronic system. Some common medical procedures that pose no risk for EMI are also listed. This chapter also includes technical and procedural information for the application of a Medtronic Model 9466 patient magnet. The patient magnet can mitigate the effects of EMI on an implanted device. Use of the patient magnet is suggested for a number of the medical therapies and diagnostic procedures described in this chapter.

Chapter 7 provides precautions and other information related to EMI that is helpful to patients in their daily living. Health care professionals can review the information with their patients and use it as a reference for post-implant consultations.

For guidance on medical procedures or potential EMI scenarios that are not documented in this manual, customers can contact the following Medtronic resources:

- Customers in the USA can contact Medtronic Technical Services at +1 800 505 4636 for pacemakers and CRT-Ps or +1 800 723 6243 for ICDs and CRT-Ds. You can also submit questions to tshelp@medtronic.com or to your Medtronic representative.
- Customers outside of the USA can contact a Medtronic representative.

2 Overview of electromagnetic interference (EMI)

This chapter details the types of EMI and lists the electromagnetic field intensity limits for Medtronic implanted pacemakers and ICDs.

2.1 Types of EMI

Medtronic pacemakers and ICDs comply with standards for testing of implanted cardiac devices in the presence of EMI. These devices operate properly when a patient is exposed to the electromagnetic fields commonly encountered at work, at home, or in other environments. Medtronic advises patients, their clinicians, and their employers to consult with each other to consider EMI safety before the patient returns to work after receiving a pacemaker or an ICD.

Note: See *Section 2.2, Applicable standards for safety and electromagnetic compatibility, page 5* for more information.

There are 3 principal types of EMI:

- **Conducted interference** occurs when the patient is in direct contact with the electrical source. The greatest risk occurs from poorly maintained or ungrounded electrical equipment or items. Patients with an implanted pacemaker or ICD must avoid conducted current.
- **Radiated fields** are signals propagated through the air. They can induce current that is detectable by an implanted pacemaker or ICD. Common sources of these fields include high-voltage power lines, radio transmission towers, or two-way wireless communication equipment.
- **Static magnetic fields** are produced by permanent magnets or direct current (DC) electro-magnets. Permanent magnets are the most common type of magnet in consumer products.

See *Chapter 3, Device responses to EMI, page 5* for details on how EMI affects implanted pacemakers and ICDs.

2.2 Applicable standards for safety and electromagnetic compatibility

Medtronic pacemakers and ICDs conform to the following industry standards for active implantable medical devices for safety and electromagnetic compatibility:

- ANSI/AAMI/ISO 14117
- EN 45502-1
- EN 45502-2-1
- EN 45502-2-2
- ISO 14708-1
- ISO 14708-2
- ISO 14708-6

3 Device responses to EMI

This chapter describes the most common device responses to electromagnetic interference (EMI).

Potential EMI impact on implanted pacemakers and ICDs – *Table 1* describes the potential impact of EMI on implanted pacemakers and ICDs.

Note: If you remove the source of EMI or if the patient moves away from or turns off the source of EMI, the implanted cardiac device resumes normal operation.

Table 1. Potential EMI impact on implanted pacemakers and ICDs

EMI source	Potential impact on a pacemaker	Potential impact on an ICD
Conducted interference; radiated electric / magnetic fields	Inhibition of pacing therapy[a]; noise reversion[b]; high-rate pacing[c]	Inhibition of pacing therapy[a]; suspension of tachyarrhythmia detection, and suspension of therapy[d]; high-rate pacing[c]; delivery of inappropriate high-voltage therapy
Static magnetic fields (direct current)	Asynchronous pacing[e]; suspension of tachyarrhythmia detection, and suspension of anti-tachyarrhythmia pacing therapy[f]	Suspension of tachyarrhythmia detection which will prevent tachyarrhythmia therapy delivery[d,g]

[a] EMI oversensing can cause both pacemakers and ICDs to provide insufficient pacing support. If pacing therapy is inhibited, pacemaker-dependent patients can be deprived of adequate cardiac output.

[b] See *Section 3.3, Reversion, page 6* for more information.

[c] Application of pacing therapy at an excessive rate such that it causes symptoms or compromised cardiac hemodynamics.

[d] Inadequate tachyarrhythmia therapy (failure to provide anti-tachyarrhythmia pacing, cardioversion, or defibrillation therapy).

[e] Pacemakers will switch their operating mode and rate in the presence of a strong magnet. For pacemakers that have not reached recommended replacement time (RRT) or elective replacement indication (ERI), the device will operate in an asynchronous mode at 85 min^{-1}. For pacemakers that have reached RRT or ERI, the pacemaker will operate in an asynchronous mode at 65 min^{-1}. Asynchronous pacing can induce an arrhythmia.

[f] Tachyarrhythmia detection and anti-tachyarrhythmia pacing therapy are available in some models of pacemakers. Exposure to static magnetic fields can result in inadequate tachyarrhythmia therapy.

[g] Static magnetic fields do not affect pacing in ICDs.

3.1 Oversensing

Oversensing is the most common consequence of device overexposure to EMI. Oversensing occurs when a device detects EMI in addition to intrinsic cardiac signals. Several factors can trigger oversensing, such as the duration of EMI exposure or the path of the electrical or magnetic current.

Inappropriate sensing of tachyarrhythmias – Some medical procedures use equipment that can create EMI that an implanted pacemaker or ICD does not filter out but interprets as a rapid heart rate. If this interference persists, it can meet the criteria for tachyarrhythmia detection for which the device can deliver inappropriate tachyarrhythmia therapy.

Inhibition of pacing and cardiac resynchronization therapy – Oversensing can inhibit pacing or cardiac resynchronization therapy in pacemakers and ICDs. If a patient is pacemaker-dependent, prolonged pacing inhibition can cause hemodynamic instability.

3.2 Device reset

Device reset, also known as a power on reset (POR) or an electrical reset, is a recovery response to an unexpected device event. Device reset is a rare response to EMI or to ambient radiation. A device reset can also occur in response to the direct exposure to some types of therapeutic ionizing radiation.

Device reset settings are safe for most patients, but they can be therapeutically suboptimal. Perform the following steps if an implanted device reports a device reset:

1. Schedule an immediate clinic appointment with your patient.
2. Restore the patient's parameter values for pacing, arrhythmia detection, and arrhythmia therapy with a Medtronic programmer or a Medtronic device manager.
3. Download the saved device data file according to the procedure provided in the instructions for use for your Medtronic programmer or Medtronic device manager. This file includes the device memory image that Medtronic uses to analyze the device.
4. Contact Medtronic Technical Services for further guidance.

3.3 Reversion

Reversion, also known as noise reversion, initiates asynchronous pacing in the presence of strong EMI. It minimizes the effect of EMI that can inhibit pacing. During reversion, a pacemaker responds as follows:

- Pacing occurs at the sensor-indicated rate for all rate responsive modes (excludes VVIR and VDIR).
- Pacing occurs at the programmed lower rate for all non-rate responsive modes (includes VVIR and VDIR).

The device resumes normal operation when the EMI source is removed.

4 General guidelines for patients in the presence of EMI

Advise patients to observe the following general guidelines in the presence of EMI:

- Area restrictions – consult with your clinician before entering an area where signs are posted that warn persons with an implanted pacemaker or ICD.
- Symptoms of EMI – if you become dizzy or feel rapid or irregular heartbeats while using an electrical item, release whatever you are touching or move away from the item. The implanted cardiac device should immediately return to normal operation. If symptoms do not improve when you move away from the item, notify your clinician. If you have an ICD and you receive a therapy shock while using an electrical item, release the item or move away from it, then notify your clinician.
- Proper grounding of electrical items – To avoid interference from electrical current that can leak from improperly grounded electrical items and pass through the body, observe the following precautions:
  - Confirm that all electrical items are properly wired and grounded.

– Confirm that electrical supply lines for swimming pools and hot tubs are properly installed and grounded according to local and national electrical code requirements.

5 Perioperative management of patients with implanted pacemakers or ICDs

Perioperative care of a patient with an implanted pacemaker or an implanted ICD requires thorough communication between the procedure team and the device team. The procedure team includes the clinicians who perform the medical procedure. The device team includes the clinicians who monitor the device function. The device team leader is an electrophysiologist, a cardiologist, an anesthesiologist, or a surgeon with expertise in device management. If the patient's device team is not available, a resident device team can evaluate the patient and provide recommendations to the procedure team.

Observe these general precautions:

- The perioperative management of devices must consider the health of the patient, the type of device, and the procedure.
- The procedure team informs the device team of the type of procedure and any sources for EMI.
- The device team gives the procedure team a prescription for the perioperative management of the patient in consideration of the potential to the device for EMI. For most patients, the prescription can be made from a review of records maintained by the device clinic. Consult with device specialists if clinic records are not available.

6 Warnings and precautions for medical procedures and equipment

This chapter describes the potential for EMI from medical procedures and equipment to patients with a Medtronic implanted pacemaker or a Medtronic implanted ICD.

Table 2. Acceptability of medical equipment and procedures for patients with an implanted pacemaker or an implanted ICD

Acceptability	Acceptability criteria
Acceptable	The equipment and procedure have a low potential for EMI with an implanted device, and they are safe if the equipment is in proper working condition and used as intended.
Acceptable with precautions	The equipment and procedure have some potential for EMI with an implanted device. You can mitigate the effects of the EMI if the equipment is in proper working condition and used as intended, and if you follow the precautions in this document.
Not recommended	The equipment and procedure have a high potential for EMI with an implanted device, and they are not safe. You cannot mitigate the effects of the EMI.

Note: The off-label use of any medical equipment or procedure described in this document voids these acceptability criteria.

6.1 Medical procedures and equipment that require warnings, precautions, and guidance for health care professionals

This section describes medical procedures and equipment that require precautions for patients with a Medtronic implanted pacemaker or ICD:

- A pacemaker can be a single-chamber pacemaker, a dual-chamber pacemaker, or a CRT-P.
- An ICD can be a single-chamber ICD, a dual-chamber ICD, or a CRT-D.

For a list of commonly performed medical procedures that are acceptable without precautions for patients with implanted cardiac devices, see *Section 6.2, Medical procedures and devices that are acceptable for patients with implanted pacemakers and ICDs, page 19*.

Ablation

Cryogenic ablation – Acceptable. Cryogenic ablation is indicated for the treatment of atrial fibrillation. This procedure creates lesions in the cardiac tissue near the pulmonary veins with cryothermal energy (pressurized liquid nitrous oxide).

Radiofrequency (RF) or microwave ablation – Acceptable with precautions. RF or microwave ablation is a surgical technique in which energy creates heat to destroy cells. Common types of ablation include, but are not limited to, intracardiac ablation and endometrial ablation.

RF or microwave ablation used for cardiac device patients can result in, but is not limited to, ventricular tachyarrhythmias, oversensing, unintended tissue damage, or unintended device function.

Observe the following precautions when you administer RF or microwave ablation to a patient with an implanted pacemaker or ICD:

- Make sure that temporary pacing and defibrillation equipment is available.
- Avoid direct contact between the ablation catheter and the implanted system.
- Consider using at least 2 methods to monitor the patient during ablation. These methods can include arterial pressure display, ECG, manual monitoring of patient rhythm (taking pulse), ear or finger pulse oximetry, or Doppler pulse detection.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Acupuncture, alternating current (AC)

Acceptable with precautions. AC acupuncture, also known as electroacupuncture, passes a small electrical current between pairs of acupuncture needles.

AC acupuncture introduces electrical current into the body that can cause oversensing in a pacemaker or an ICD. Patients should consult with their clinicians to determine if their cardiac condition allows them to undergo exposure to AC acupuncture.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Bone growth stimulators

A bone growth stimulator provides supplemental therapy to promote bone healing. There are 3 types of bone growth stimulators:

Stimulator that introduces direct current (DC) into the body – Acceptable. A DC bone growth stimulator generates insufficient EMI to affect an implanted pacemaker or an ICD.

Stimulator that introduces alternating current (AC) into the body – Acceptable with precautions. An AC bone growth stimulator uses electrodes to introduce electrical current into the body. There is a potential for EMI with an implanted pacemaker or ICD with the electrodes attached to the torso. When the electrodes are attached to an extremity, the stimulator generates insufficient EMI to affect an implanted pacemaker or ICD.

Bone growth stimulators

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Stimulator that produces an alternating magnetic field – Acceptable with precautions. This bone growth stimulator delivers a short, high-intensity pulse to a coil in an insulated cuff to produce a therapeutic magnetic field. This therapy does not introduce conducted current into the body. When the insulated cuff is on a patient's leg, the stimulator generates insufficient EMI to affect an implanted pacemaker or ICD. However, when the insulated cuff is on a patient's wrist or arm, maintain a 30 cm (12 in) distance between the cuff and the implanted pacemaker or ICD.

Bone scan

Bone scans are used to diagnose and evaluate bone diseases and conditions. There are 3 types of bone scans.

X-ray bone scan (skeletal scintigraphy) – Acceptable. An x-ray bone scan uses small amounts of a radiopharmaceutical to show contrast between abnormal and healthy bone tissue. An x-ray bone scan generates insufficient EMI to affect an implanted pacemaker or ICD.

Ultrasound bone scan (sonography or musculoskeletal ultrasound) – Acceptable. An ultrasound bone scan uses a transducer to transmit high-frequency sound waves to create an image of bone tissue. An ultrasound bone scan generates insufficient EMI to affect an implanted pacemaker or ICD.

Bone densitometry (dual-energy x-ray absorptiometry – DEXA) – Acceptable with precautions. Bone densitometry is an enhanced form of x-ray technology used to measure bone density. It uses a small dose of ionizing radiation to produce images used to diagnose osteoporosis and to assess patient risk for developing fractures. These images are usually of the lower spine and the pelvis.

The accumulated dose of radiation from DEXA is insufficient to damage or interfere with the operation of an implanted pacemaker or ICD. However, do not allow an implanted pacemaker or ICD to undergo direct exposure to the radiation beam.

Capsule endoscopy

Contact Medtronic Technical Services. Capsule endoscopy, also known as *video capsule endoscopy*, uses an ingestible digital camera that captures a video record of the patient's digestive tract. The camera is in a capsule with light-emitting diodes, a battery, and a transmitter. Transmission of the video data occurs in short bursts of radiofrequency energy, approximately 2 per s, for an 8-hour diagnostic period.

Note: Contact Medtronic Technical Services to confirm that your capsule endoscopy system is safe for your patient.

Central venous access catheter

Acceptable with precautions. Also known as a central line or a central venous line, a central venous access catheter is placed into a large vein or into the heart. It administers medication or fluids that cannot be taken orally or that can harm a smaller peripheral vein.

If transvenous leads are acute (within 30 days of implant), verify that they are actively fixed in the endocardium. Confirm lead fixation with an x-ray or through a review of the stored device lead impedance and short interval count data (if available). If a lead has dislodged, do not insert a central venous access catheter into the patient's heart.

Observe these precautions when you insert the guide wire of a central venous access catheter into the heart of a patient who has an implanted pacemaker or ICD:

Central venous access catheter

- The presence of a guide wire can trigger an arrhythmia in the patient, independent of the implanted cardiac device.
- Contact between a guide wire and sensing electrodes can cause inappropriate pacing or oversensing in an implanted cardiac device.
- Contact between a guide wire and a coil can cause inappropriate shock or an electrical short in an implanted ICD.

To mitigate the potential effects of a central venous access catheter, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Dental equipment

Acceptable with precautions. Dental procedures that use equipment such as apex locators, ultrasonic scalers, drills, and pulp testers, pose no potential for EMI with an implanted pacemaker or ICD.

Accessories, such as office pillows or headrests, can contain magnets that can affect sensing or initiate asynchronous pacing in an implanted pacemaker or ICD. Keep an implanted pacemaker or ICD at least 15 cm (6 in) from these magnets.

Note: See “Electrosurgery” for guidance with electrosurgery used in periodontal surgery.

Diagnostic radiology (CT scans, fluoroscopy, mammograms, x-rays)

Diagnostic radiology includes the following procedures: computerized axial tomography (CT or CAT scan), fluoroscopy, mammograms, and x-rays.

Normally, the accumulated dose of radiation from diagnostic radiology is insufficient to damage an implanted pacemaker or ICD. If the implanted pacemaker or ICD is not directly in the radiation beam, there is no potential for EMI, except where noted here.

CT scan – Acceptable with precautions. Oversensing can occur only when the implanted pacemaker or ICD is directly in the CT scan beam.

Pacemakers	If the device is in the CT scan beam for more than 4 s, see *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	If the device is in the CT scan beam for more than 4 s, see *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Fluoroscopy at < 1 cGy/min – Acceptable. Fluoroscopy at < 1 cGy/min generates insufficient EMI to affect an implanted pacemaker or ICD.

Fluoroscopy at ≥ 1 cGy/min – Not recommended. EMI from fluoroscopy at ≥ 1 cGy/min can cause oversensing in an implanted pacemaker or ICD.

Mammography – Acceptable. Mammography generates insufficient EMI to affect an implanted pacemaker or ICD.

X-ray – Acceptable. X-rays generate insufficient EMI to affect an implanted pacemaker or ICD.

Diagnostic ultrasound

Acceptable. Diagnostic ultrasound is an imaging technique that visualizes muscles and internal organs, their size, structures, and motion, as well as any pathological lesions. It can also monitor a fetus, and it can detect and measure blood flow. Diagnostic ultrasound generates insufficient EMI to affect an implanted pacemaker or ICD. For precautions about therapeutic ultrasound, see “Diathermy (3 types)”.

Diathermy (3 types)

Diathermy involves the therapeutic heating of body tissues. There are 3 types of diathermy: shortwave diathermy, microwave diathermy, and ultrasonic diathermy, also known as therapeutic ultrasound. Shortwave diathermy or microwave diathermy can cause serious injury, or they can damage an implanted pacemaker or ICD. Do not use shortwave diathermy or microwave diathermy. Ultrasonic diathermy is acceptable, with precautions.

Shortwave diathermy – Not recommended. Shortwave diathermy can cause serious patient injury. It can damage an implanted pacemaker or ICD. Do not perform shortwave diathermy on patients who have an implanted pacemaker or ICD.

Microwave diathermy – Not recommended. Microwave diathermy can cause serious patient injury. It can damage an implanted pacemaker or ICD. Do not perform microwave diathermy on patients who have an implanted pacemaker or ICD.

Therapeutic ultrasound – Acceptable with precautions. Therapeutic ultrasound (including physiotherapy, high intensity therapeutic ultrasound, and high intensity focused ultrasound) uses ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Therapeutic ultrasound does not produce EMI fields capable of inducing significant energy levels in pacing leads; however, the mechanical energy can physically damage internal device components.

Therapeutic ultrasound is acceptable with a minimum separation distance of 15 cm (6 in) between the applicator and the implanted device and lead system. Also, point the ultrasonic beam away from the device and lead system.

EECP (enhanced external counterpulsation therapy)

Acceptable with precautions. EECP is a noninvasive outpatient therapy for treatment of angina. It uses inflatable cuffs to compress the blood vessels in the lower limbs to increase blood flow to the heart. If the rate response feature of an implanted pacemaker or an implanted ICD is programmed to On, the pacing rate can increase if the implanted device detects EECP-induced vibration.

Consider programming an implanted pacemaker or an implanted ICD to a non-rate-responsive pacing mode before you administer EECP.

Enteral magnetic navigation

Acceptable with precautions. Enteral magnetic navigation allows a clinician to steer catheter-based diagnostic and therapeutic devices throughout the digestive system.

An enteral magnetic navigation procedure can initiate asynchronous pacing in a pacemaker or suspend tachyarrhythmia detection in an ICD.

To mitigate the effects of oversensing EMI during an enteral magnetic navigation procedure, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

ECT (electroconvulsive therapy)

Acceptable with precautions. ECT, also known as electroshock therapy, provides relief from psychiatric illnesses. ECT delivers a measured electrical pulse to induce a seizure that can last for several minutes. The electrical current that this procedure introduces into the body can affect an implanted pacemaker or an implanted ICD. Clinicians who administer ECT to patients with an implanted pacemaker or an implanted ICD should consult with their cardiologists to evaluate the potential for EMI.

A pacemaker or an ICD will respond in the following ways during a typical 1 to 2 s ECT electrical pulse:

ECT (electroconvulsive therapy)	
Pacemakers	The electrical pulse can inhibit pacing for 1 to 2 s. If the rate response feature is programmed to On, the pacing rate can increase during the seizure period. If an ECT electrical pulse is longer than 8 s, reversion can occur.
ICDs	An ICD will inhibit pacing for the duration of the electrical pulse. If the rate response feature is programmed to On, the pacing rate can increase during the seizure period. The potential is low that an ICD will deliver a shock during a 1 to 2 s electrical pulse. If an ECT electrical pulse is longer than 8 s, an ICD can deliver a shock.

EMG (electromyography)

Acceptable. EMG records muscle response to electrical stimuli during muscle rest and during muscle contraction. It helps to diagnose a number of muscular or neuromuscular conditions.

EMG is typically administered with an NCS (nerve conduction study), where an NCS measures nerve response to electrical stimuli. See “NCS (nerve conduction study)” for more information and precautions.

There are 2 types of EMG:

- **sEMG**: surface electromyography. sEMG delivers electrical stimuli to a single patch electrode or to an array of patch electrodes attached via a skin adhesive over the tested muscle.
- **NEMG**: needle electromyography. NEMG delivers electrical stimuli to a single needle electrode or to an array of needle electrodes inserted into the tested muscle.

EMG is acceptable for patients with an implanted pacemaker or ICD.

Electrolysis

Acceptable with precautions. Electrolysis permanently removes hair by inserting an electrified needle (AC or DC) into the hair follicle. Electrolysis introduces electrical current into the body, which can cause oversensing. Patients should consult with their clinicians to determine if their cardiac condition allows them to undergo electrolysis.

To mitigate the effects of EMI during electrolysis, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Electrosurgery

Acceptable with precautions. Electrosurgery (including electrocautery, argon plasma coagulation, electrosurgical cautery, advanced energy surgical technology, and hyfrecator) uses an electric probe to control bleeding, cut tissue, or remove unwanted tissue. Electrosurgery performed on patients with an implanted pacemaker or ICD can result in, but is not limited to, the following complications:

- Potential pacing interruption during and up to 5 s immediately after exposure to electrosurgery.
- Oversensing.
- Unintended tissue damage.
- Tachyarrhythmias.
- Lead or device damage.
- Device malfunction.

If electrosurgery is required, consider the following precautions:

- Ensure that temporary pacing and defibrillation equipment is immediately available.
- If possible, use a bipolar electrosurgery system or advanced energy surgical technology. If a unipolar electrosurgery system is used, position the return electrode patch so that the electrical current pathway passes

Electrosurgery

no closer than 15 cm (6 in) from the device and leads. Contact Medtronic Technical Services for further guidance with unipolar electrosurgery.

- Use short, intermittent, and irregular bursts at the lowest clinically appropriate energy levels.
- Always monitor the patient during electrosurgery. If the ECG tracing is not clear due to interference, manually monitor the patient's rhythm (take pulse); alternatively, monitor by some other means such as ear or finger pulse oximetry, Doppler pulse detection, or arterial pressure display.

To mitigate the effects of oversensing during electrosurgery, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

External defibrillation and cardioversion

Acceptable with precautions. External defibrillation and cardioversion are therapies that deliver an electrical shock to the heart to convert an abnormal heart rhythm to a normal rhythm.

Medtronic pacemakers and ICDs are designed to withstand exposure to external defibrillation and cardioversion. While damage to an implanted pacemaker or ICD from an external shock is rare, the probability increases with increased energy levels. These procedures can also temporarily or permanently elevate pacing thresholds or temporarily or permanently damage the myocardium.

Follow these precautions when you deliver external defibrillation or cardioversion:

- Use the lowest clinically appropriate energy.
- Position the patches or paddles at least 15 cm (6 in) from the implanted pacemaker or ICD.
- Use a Medtronic programmer or a Medtronic device manager to evaluate the implanted pacemaker or ICD if you deliver external defibrillation or cardioversion.

Hearing aids and cochlear implants, in ear or hardwired

Acceptable. Hearing aids or cochlear implants worn in the ear or hardwired to an acoustical detector have no potential for EMI with an implanted pacemaker or ICD.

Hearing aids with transmitting loop antenna

Acceptable with precautions. A hearing aid with a transmitting loop antenna, worn around the neck, radiates a magnetic field that is coupled with the T-coil in the earpiece. Advise patients to keep the loop antenna at least 15 cm (6 in) from an implanted pacemaker or ICD.

If the loop antenna is closer than 15 cm (6 in) to a pacemaker or ICD, there is a potential for pacemaker reversion, pacing inhibition, or ICD shock.

Advise patients to reposition the loop antenna to the shoulder opposite the implant site. If that is not possible, advise patients to use an alternative transmitting antenna that can be worn at least 15 cm (6 in) from the implant site.

Note: This precaution also applies to transmitting loop antennae attached to audio equipment.

Note: Bluetooth hearing aids without a transmitting loop antenna are acceptable.

Hyperbaric therapy (including hyperbaric oxygen therapy, or HBOT)

Acceptable with precautions. Hyperbaric therapy is the medical use of air or 100% oxygen at a higher pressure than atmospheric pressure. Hyperbaric therapy treats several conditions, including decompression sickness, carbon monoxide poisoning, serious infections, and persistent wounds. Hyperbaric therapies with pressures exceeding 4.0 ATA, approximately 30 m (100 ft) of seawater, can affect the function of or damage an implanted

Hyperbaric therapy (including hyperbaric oxygen therapy, or HBOT)

pacemaker or ICD. To avoid or mitigate risks to an implanted pacemaker or ICD, do not expose patients to pressures exceeding 4.0 ATA.

Interferential current therapy

Acceptable with precautions. Physical therapists use interferential current therapy to relieve pain and to promote soft-tissue healing. If interferential current therapy is administered on the torso, it introduces an electrical current that can affect an implanted pacemaker or ICD. Patients should consult with their clinicians to determine if their cardiac condition allows them to undergo interferential current therapy.

Note: The potential is low for a pacemaker or an ICD to detect interferential current therapy when it is administered to the extremities.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Lithotripsy

Acceptable with precautions. Lithotripsy uses mechanical shock waves to break up kidney stones or gallbladder stones. Lithotripsy can damage an implanted pacemaker or ICD if it is at the focal point of the lithotripter beam. Keep the focal point of the lithotripter beam at least 2.5 cm (1 in) away from the implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Magnetic resonance imaging (MRI)

A Medtronic implanted pacemaker, ICD, or lead is either **MR Conditional** or **MR Unsafe**.

Use any of the following resources to confirm if a pacemaker, an ICD, or a lead is MR Conditional or MR Unsafe:

- See the Medtronic MR Conditional Product Search for Cardiac Devices at www.medtronic.com/mrc.
- See the Medtronic MRI Resource Library at http://manuals.medtronic.com/manuals/mri/region.
- If you are in the USA, you can call +1 877 674 7677 for MRI technical consultation.
- If you are outside of the USA, you can contact a Medtronic representative for MRI technical consultation.

Patients with an implanted pacemaker system or an implanted ICD system (implanted device, implanted leads, and any abandoned leads) that is **MR Conditional** can undergo an MRI scan under specified conditions. For details, refer to the MRI technical manual for the pacemaker or ICD, or contact the listed Medtronic resources.

An implanted pacemaker system or ICD system (implanted device, implanted leads, and any abandoned leads) is **MR Unsafe** if any system component or item poses unacceptable risks to the patient, medical staff or other persons within the MR environment. Patients with an implanted pacemaker system or ICD system that is MR Unsafe cannot undergo an MRI scan. An MRI scan on a patient with an MR Unsafe system can result in serious patient injury or induction of tachyarrhythmias. An MRI scan on an MR Unsafe system can damage or impact the function of the implanted pacemaker system or the implanted ICD system.

MET (microcurrent electrical therapy)

Not recommended. MET is an in-home treatment for acute, chronic, and postoperative or post-traumatic pain. MET delivers an electrical current that can affect an implanted pacemaker or ICD, depending on where MET is applied to the body.

The potential is low that an implanted pacemaker or ICD will detect an MET pulse if the pulse is applied to the cranium or extremities. However, if MET is applied to the torso, it can inhibit pacing in a pacemaker or an ICD, or it can cause pacemaker reversion or ICD shock. Because MET is marketed for use in the home, its misapplication cannot be anticipated. MET, therefore, has a high potential to affect an implanted pacemaker or ICD.

NCS (nerve conduction study)

Acceptable with precautions. An NCS, also known as a nerve conduction velocity (NCV) test, records the speed that an electrical pulse is conducted through a nerve. This study can determine nerve damage or nerve destruction that causes abnormal muscle response. An NCS delivers mild electrical pulses between 2 patch electrodes. These electrodes are attached over the tested nerve with a conductive skin adhesive. One electrode delivers the pulse, and the other electrode records the pulse and calculates its speed along the tested nerve.

An NCS is typically administered with EMG (electromyography), where EMG measures muscle response to electrical stimuli. See “EMG (electromyography)” for more information.

Type 1: manual test – During a manual NCS, the clinician applies discretionary electrical pulses. If an implanted pacemaker or ICD detects a pulse, it can inhibit pacing for 1 to 2 s. If the clinician separates pulses by > 10 s, the inhibited pacing does not cause symptoms in most patients. If it is necessary to apply pulses more frequently than once every 10 s, the implanted pacemaker or ICD can mistake the therapy for oversensing. However, if both NCS electrodes are on the same extremity and not on the torso, the pulses are unlikely to affect an implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during a manual NCS, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Type 2: automated test – An automated NCS applies a programmed sequence of pulses to a nerve that can affect an implanted pacemaker or ICD.

In an automated NCS, the pulse sequence is sent from the sending patch electrode to the receiving patch electrode at a rate of 2 to 5 pulses/s for 250 pulses. If an implanted pacemaker or ICD detects the pulse sequence, there is the potential for pacemaker reversion or pacing inhibition, or for an inappropriate ICD shock. However, if both NCS electrodes are on the same extremity and not on the torso, the pulses are unlikely to affect an implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during an automated NCS, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Ocular procedures

A patient must remain motionless during critical junctures of an ocular procedure. A cardiac event or implanted cardiac device therapy that is delivered during an ocular procedure can cause a patient to move and sustain injury to the eye.

Pacemakers – Acceptable. Ocular procedures are acceptable for patients with pacemakers.

ICDs (monitored patients) – Acceptable with precautions. Suspend tachyarrhythmia detection with a Medtronic patient magnet (see *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a*

Ocular procedures

Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20), a Medtronic programmer, or a Medtronic device manager. If appropriate for the patient, program the ICD to an asynchronous pacing mode. Remove the magnet or restore ICD parameters with the programmer or the device manager after completing the ocular procedure.

ICDs (unmonitored patients) – Not recommended. A cardiac event or a device therapy delivered during an ocular procedure can cause a patient to move and sustain trauma to the eye. It is more important that the patient receive the appropriate arrhythmia therapy if needed. Therefore, the occurrence of VT or VF in an unmonitored ICD patient with tachyarrhythmia detection suspended would result in unexpected patient motion and, potentially, sudden cardiac death.

PEMF (pulsed electromagnetic field therapy)

Not recommended. PEMF generates a pulsed magnetic field that can cause serious injury, induction of tachyarrhythmias, or implanted system malfunction or damage. Patients with an implanted pacemaker or ICD should not use PEMF devices or therapies.

PET (positron emission tomography) / SPECT (single photon emission computed tomography)

Acceptable. PET and SPECT are noninvasive nuclear imaging technologies. They scan radioactive tracers injected into the bloodstream to produce three-dimensional images.

PET and SPECT generate insufficient EMI to affect an implanted pacemaker or an implanted ICD.

RFID (radiofrequency identification devices)

Acceptable with precautions. RFID is an autoidentification technology used to decrease cost and improve patient safety, particularly in an operating room. Wireless technology used in this setting has the potential to interfere with implanted pacemakers and ICDs. EMI from RFID technology depends on distance and frequency of the RF source. It is stronger at lower frequencies and at closer distances, and it peaks with direct contact between an RFID reader and an RFID tag. Do not place an RFID tag within 30 cm (12 in) of an implanted pacemaker or ICD.

If an RFID tag is placed more than 30 cm (12 in) from an implanted pacemaker or ICD, the generated EMI is insufficient to interfere with the device.

Standard autoidentification systems, like systems used in consumer merchandising, present a low potential for EMI with an implanted pacemaker or ICD.

Stereotaxis

Acceptable with precautions. Stereotaxis allows clinicians to steer catheter-based diagnostic and therapeutic devices throughout the body by using magnetic navigation. During a stereotaxis procedure, the magnetic field can initiate magnet mode (asynchronous pacing) in a pacemaker or suspend tachyarrhythmia detection in an ICD. The implanted pacemaker or ICD resumes normal programmed operation after the stereotaxis procedure.

Clinicians should consult with cardiologists to determine if a stereotaxis procedure is safe for their patients with an implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Therapeutic radiation (radiosurgery and radiotherapy)

Radiosurgery – Acceptable with precautions. Also known as stereotactic radiosurgery, radiosurgery delivers intense doses of radiation from a linear accelerator to destroy tumors with submillimeter precision.

Therapeutic radiation (radiosurgery and radiotherapy)

Do not subject an implanted pacemaker or ICD to direct radiosurgery exposure. Accumulated radiation dosage must not exceed 500 cGy.

Radiotherapy – Acceptable with precautions. Radiotherapy is a cancer treatment that uses radiation to control cell growth and destroy tumors. Types of radiotherapy include high-energy photon radiation and proton beam therapy (PBT).

Do not subject an implanted pacemaker or ICD to direct radiotherapy exposure. Accumulated radiation dosage must not exceed 500 cGy.

Note: Contact your Medtronic representative for additional guidance to monitor the implanted pacemaker or ICD during radiosurgery or radiotherapy.

Pacemaker and ICD shielding and radiation modeling – Discuss a shielding plan with the radiation oncologist and physicist responsible for treating the patient. The plan includes modeling of the radiation to be absorbed by the implanted pacemaker or ICD — the accumulated radiation dosage must not exceed 500 cGy.

Pacemaker and ICD repositioning – If the modeling of the radiation indicates that the accumulated radiation dosage will be > 500 cGy, consider repositioning the implanted pacemaker or ICD. If you must reposition the implanted pacemaker or ICD, use lead extenders to implant the device in an alternate location. If possible, implant the pacemaker or ICD in its original location after you deliver the therapy.

Pacemaker and ICD interference from radiosurgery or radiotherapy – If a patient undergoes radiosurgery or radiotherapy, an implanted pacemaker or ICD can sense direct or scattered radiation as cardiac activity for the duration of the procedure. Average dose rates at the pacemaker or ICD of less than 1 cGy/min are unlikely to produce pacemaker or ICD interference. Decreasing the dose rate (for example, by increasing the distance between the beam and the implanted pacemaker or ICD) decreases the potential for interference.

The programmer or device manager can detect pacemaker or ICD interference during the initial therapy, shown as unexpected activity in the programmer marker channel or the device manager event markers. If interference does not occur, it is unlikely to occur during future treatments with the same therapy.

Note: Interrogate the implanted pacemaker or ICD to evaluate it following radiosurgery or radiotherapy.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

Device reset following radiation – A device reset (also called an electrical reset) does not indicate damage to the implanted pacemaker or ICD; however, a reset requires device interrogation. In rare cases, a device reset can occur several days following exposure to radiation.

Report a device reset to Medtronic Technical Services. Download the device data file with your programmer's save-to-media function and include it with your report. This file contains the device memory image.

How to evaluate a pacemaker or ICD for a device reset – If an implanted pacemaker or ICD has had a device reset, a device reset warning message displays immediately upon interrogation. Reprogram the device to restore normal operation.

Inform your Medtronic representative if your patient's device has reset.

Pacemaker or ICD damage from radiosurgery or radiotherapy – Radiation can affect electronic circuitry, so an accumulated radiation dosage of > 500 cGy can damage an implanted pacemaker or ICD. However, radiation damage is sometimes not immediately apparent. If a patient requires radiosurgery or radiotherapy from any source, do not expose an implanted pacemaker or ICD to an accumulated radiation dosage that exceeds the recommended limit. Record and monitor the accumulated radiation dosage to implanted devices for patients who undergo multiple radiosurgeries or courses of radiation treatment.

Tests have shown damage to implanted Medtronic pacemakers and ICDs with accumulated radiation dosage > 500 cGy. Medtronic therefore cannot predict the operation of implanted pacemakers and ICDs that have with-

Therapeutic radiation (radiosurgery and radiotherapy)

stood radiation overdose. Monitor devices exposed to radiation overdose after each radiosurgery or radiotherapy treatment and consider them for replacement. Consider an augmented follow-up schedule following the completion of all procedures.

TENS (transcutaneous electrical nerve stimulation)

Not recommended. TENS (including NMES – neuromuscular electrical stimulation) is a pain control technique that uses electrical impulses passed through the skin to stimulate nerves. A TENS device is not recommended for in-home use by cardiac device patients due to a potential for oversensing, inappropriate therapy, inhibition of pacing, or asynchronous pacing. If a TENS device is determined to be medically necessary, contact a Medtronic representative for more information.

Tissue expanders with magnetic aiming guides

Not recommended. Tissue expanders are used by plastic surgeons to prepare for reconstructive breast surgery. Some tissue expanders incorporate magnets to direct a needle that is used to fill the expander with fluid. These magnets are often close enough to initiate magnet mode in a pacemaker or suspend tachyarrhythmia detection in an ICD.

Do not use tissue expanders with magnetic aiming guides on patients with pacemakers or ICDs. Instead, use tissue expanders that do not have magnetic aiming guides.

TMS (transcranial magnetic stimulation)

Acceptable with precautions. TMS is a treatment that provides relief from major depressive disorder. TMS therapy delivers rapid magnetic pulses over an extended period to stimulate nerve cells in areas of the brain thought to control mood. TMS produces an effect similar to electroconvulsive therapy but with minimal side effects. The magnetic current that TMS introduces into the body can affect an implanted pacemaker or ICD.

To mitigate the effects of oversensing EMI during therapy, consider the following procedures if patient condition allows:

Pacemakers	See *Section 6.3, How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet, page 19*.
ICDs	See *Section 6.4, How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet, page 20*.

TUNA (transurethral needle ablation), TUMT (transurethral microwave therapy), and TURP (transurethral resection of the prostate)

Acceptable with precautions. TUNA, TUMT, and TURP are surgical procedures that treat urinary symptoms caused by benign prostatic hyperplasia (BPH). These procedures use precisely focused energy to ablate prostate tissue. Patients with implanted cardiac devices can conditionally undergo procedures that use a TUNA, TUMT, or TURP system. To avoid affecting an implanted pacemaker or ICD when performing a TUNA, TUMT, or TURP procedure, position the return electrode on the lower back or lower extremity at least 15 cm (6 in) away from the implanted pacemaker or ICD.

Virtual colonoscopy (CT scan)

Acceptable with precautions. This procedure diagnoses colon and bowel disease, including polyps, diverticulosis, and cancer. The procedure is performed with a CAT scan. See “Diagnostic radiology” for more information on this procedure.

Virtual colonoscopy (MRI)

Acceptable with precautions. This procedure diagnoses colon and bowel disease, including polyps, diverticulosis, and cancer. As this procedure is performed with an MRI, it can only be performed on patients with implanted cardiac devices and leads that are MR Conditional. See magnetic resonance imaging (MRI) for more information.

6.2 Medical procedures and devices that are acceptable for patients with implanted pacemakers and ICDs

The following medical procedures and devices, when in proper working condition and used as intended, generate insufficient EMI to affect an implanted pacemaker or an ICD.

Acceptable procedures and devices for patients with implanted pacemakers and ICDs	
Acupuncture, direct current (DC)	DC acupuncture is safe for patients with an implanted pacemaker or ICD.
Colonoscopy	Diagnostic colonoscopy is safe for patients with an implanted pacemaker or ICD.
Digital infrared thermal imaging (DITI)	Digital infrared thermal imaging is an imaging technique. It monitors the infrared radiation that the skin surface emits. It uses a passive device that does not introduce electrical current into the body.
Dysphagia treatment devices	Dysphagia treatment devices apply neuromuscular electrical stimulation to the throat to treat swallowing disorders.
Echocardiography	Echocardiography uses diagnostic ultrasound to examine the heart.
Electrocardiography (ECG)	Electrocardiography senses the electrical activity of the heart.
Electroencephalography (EEG)	Electroencephalography detects electrical activity in the brain.
Electronystagmography (ENG)	Electronystagmography is a diagnostic test that uses passive electrodes on the head to record involuntary movements of the eye caused by nystagmus. This test helps to diagnose the causes of vertigo, dizziness, or balance disorders.
Esophageal pH test	An esophageal pH test measures and records esophageal pH to assess for gastroesophageal reflux disease. The test works by temporarily attaching a small capsule to the wall of the esophagus to measure pH levels. The capsule transmits data to a receiver that the patient wears on a belt.
Iontophoresis	Transdermal drug delivery via iontophoresis (also known as electromotive drug administration – EMDA) relies on delivering a small level of localized DC current.
Laser surgery	Laser (light energy only) is safe for patients with an implanted pacemaker or ICD. See the precautions for performing electrocautery if you plan to combine laser surgery with electrocautery.
Motion sickness relief band	A motion sickness relief band prevents motion sickness. This device delivers a small electrical pulse at the wrist area.
Photodynamic therapy (PDT)	Photodynamic therapy is a cancer treatment that uses a drug, called a photosensitizer or photosensitizing agent. The photosensitizing agent interacts with a specific wavelength of light to produce a form of oxygen that kills nearby cells.
Sleep apnea therapy — CPAP machine	CPAP (continuous positive airway pressure) keeps airways open in patients with moderate to severe obstructive sleep apnea. If the CPAP mask uses magnetic clips, keep the magnets at least 15 cm (6 in) from the implanted pacemaker or ICD.

6.3 How to initiate asynchronous pacing in a Medtronic pacemaker with a Medtronic Model 9466 patient magnet

All Medtronic pacemakers, including all MR Conditional and MR Unsafe models, enter “magnet operation” with the application of a magnet. During magnet operation, a pacemaker paces in an asynchronous mode at either

85 min^{-1} or 65 min^{-1}, depending upon whether the pacemaker battery voltage is above or below its elective replacement threshold. Sensing is suspended during asynchronous pacing to prevent pacing inhibition by EMI.

Note: As an alternative, you can program asynchronous pacing during a telemetry session with a Medtronic programmer or with a Medtronic device manager. If telemetry is established with an implanted pacemaker, a Medtronic Model 9466 patient magnet will not initiate magnet operation.

Note: Tap the [End Now] button to end a programmer session with a Kappa, EnPulse, Adapta, Versa, Sensia, or Relia pacemaker. If you do not tap the [End Now] button, a 1-hour period must elapse before you can initiate asynchronous pacing with a Medtronic Model 9466 patient magnet.

Review pacemaker labeling, available at www.medtronic.com/manuals, for information on specific pacemaker response to a Medtronic magnet.

6.3.1 Magnet application procedure

If appropriate for the patient, perform the following steps to initiate asynchronous pacing in an implanted pacemaker with a Medtronic Model 9466 patient magnet:

1. Locate the implanted pacemaker by gently feeling for the device under the skin. The typical location is in the left or right pectoral area.
2. Place the patient magnet directly over the pacemaker. This action initiates asynchronous pacing in the device.
3. To return the pacemaker to its programmed operation, remove the patient magnet.

6.3.2 Magnet operation in a pacemaker

When you position a Medtronic Model 9466 patient magnet over a pacemaker, magnet operation implements the following changes:

- Single-chamber atrial pacing modes switch to AOO asynchronous pacing.
- Single-chamber ventricular pacing modes switch to VOO asynchronous pacing.
- Dual-chamber pacing modes, including MVP modes, switch to DOO asynchronous pacing.
- The pacing rate switches to 85 min^{-1} (700 ms) if the pacemaker has not reached Recommended Replacement Time (RRT).
- The pacing rate switches to 65 min^{-1} (920 ms) if an RRT indicator or a device reset has occurred.
- Tachyarrhythmia detection, available in some models, is suspended.

When you remove the patient magnet, the pacemaker resumes operation as programmed.

Note: Some pacemakers deliver the first 3 paces in magnet operation at 100 min^{-1}, followed by 85 min^{-1}.

Note: Magnet operation does not occur if telemetry is established between the pacemaker and a Medtronic programmer or a Medtronic device manager, or if the MRI SureScan feature is programmed to On.

6.4 How to suspend tachyarrhythmia detection and therapies in a Medtronic ICD with a Medtronic Model 9466 patient magnet

All Medtronic ICDs, including all MR Conditional and MR Unsafe models, enter “magnet operation” with the application of a magnet. In magnet operation, an ICD sounds a steady magnet alert tone, suspends tachyarrhythmia detection, and suspends therapy delivery. With magnet application, suspension of tachyarrhythmia detection and suspension of therapy delivery prevent inappropriate shock therapy.

Review ICD labeling, available at www.medtronic.com/manuals, for information on specific ICD model response to a Medtronic Model 9466 patient magnet.

Warning: An ICD suspends tachyarrhythmia detection and therapy delivery while the patient magnet is in place. A patient magnet does not affect bradycardia pacing in an ICD. Remove the magnet to restore the ICD to its programmed operation.

See *Section 6.4.3, How to program asynchronous pacing in an ICD, page 21* for additional information.

Warning: To ensure the availability of needed tachyarrhythmia therapy, the patient should not carry, store, or leave the patient magnet positioned over the ICD. The patient should be careful to avoid sources of electromagnetic interference (EMI) while applying the patient magnet.

6.4.1 Magnet application procedure

1. To suspend tachyarrhythmia detection and therapies, place the patient magnet over the ICD.
2. To resume tachyarrhythmia detection and therapies, remove the patient magnet from the ICD.

Note: You can also suspend and resume tachyarrhythmia detection and therapies with a Medtronic programmer or a Medtronic device manager.

6.4.2 ICD device tones

There are 2 types of ICD or CRT-D tones, the magnet tone, and the patient alert tone.

Magnet tone – The magnet tone is a steady tone. It sounds when an ICD or CRT-D senses a magnetic field. If a patient hears a magnet tone, instruct them to look for a magnetic object on them or near them. If a patient is ambulatory when they hear the tone, instruct them to move away from the magnetic source, or to move to a different location if they cannot identify the magnetic source.

Patient alert tone – The patient alert tone is either a beeping tone or an alternating high/low tone. If a patient alert tone is programmed to On, the tone sounds when its related alert is triggered. The patient alert tone continues to sound as scheduled, either once every 4 hours or once every 24 hours, until you interrogate the device. A patient alert tone will also sound if an alert is in effect and the ICD or CRT-D senses a magnetic field. Tell your patient to contact you if they hear a patient alert tone.

If you hear an alert tone when you apply a Medtronic Model 9466 patient magnet, interrogate the ICD or CRT-D for alert conditions, for device errors, or for a device reset.

Note: ICD or CRT-D tones sound in the presence of EMI that includes a magnetic field.

Note: Magnets are designed into many consumer products, including clothing and clothing accessories. Patients may not be aware of these magnets because they can be difficult to locate. If a patient is unsure if a product has a magnet, the patient can contact the product manufacturer for further information. Patients can also search consumer products with a ferrous metal object, such as a paper clip, to see if any magnets attract it.

6.4.3 How to program asynchronous pacing in an ICD

Some medical procedures and therapies generate enough EMI to inhibit pacing in an ICD. If your ICD patient is pacemaker-dependent, use a Medtronic programmer or Medtronic device manager to program an asynchronous pacing mode (AOO, VOO, or DOO).

Note: A Medtronic Model 9466 patient magnet will not initiate asynchronous pacing in a Medtronic ICD.

When you have finished the medical procedure or therapy, use a Medtronic programmer or Medtronic device manager to restore device parameters.

6.5 Medtronic Model 9466 patient magnet

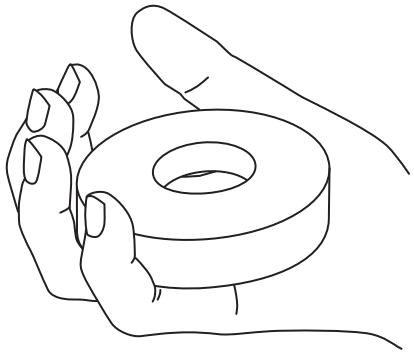
Table 3. Model 9466 patient magnet specifications

Shape	ring
Size	
Diameter	75 mm (3 in)
Thickness	16 mm (5/8 in)

Table 3. Model 9466 patient magnet specifications (continued)

Materials	ferrous alloys, coated with epoxy
Minimum field strength	90 gauss, at 40 mm (1.5 in) from magnet surface

Figure 1. Model 9466 patient magnet



Patient magnet storage and handling – Observe the following precautions when storing and handling the Medtronic Model 9466 patient magnet:

- The patient magnet can damage some electronic devices if it is stored too close to those devices.
- Keep the patient magnet at least 15 cm (6 in) from electronic devices and recordings: VCRs, televisions, and videotapes; bank cards and credit cards, cordless telephones and mobile telephones, computers, diskettes, calculators, and similar devices.
- Keep the patient magnet at least 5 cm (2 in) from wristwatches and clocks.
- If soiled, the patient magnet can be wiped clean with a soft cloth or a sponge, or it can be washed with a non-abrasive cleanser. The patient magnet is not damaged by being submerged in water.

7 Warnings, precautions, and guidance for EMI for patients with an implanted pacemaker or ICD

This chapter provides guidance for you to share with your patients to help them remain safe in or near environments and devices that can generate EMI.

7.1 Items with no distance restriction from an implanted pacemaker or ICD

The following table represents items that, when used as intended and in good working condition, have no distance restriction from an implanted pacemaker or ICD.

Table 4. Examples of household items with no distance restriction for EMI

Bed, adjustable	Garage door opener, remote control	Medical alert necklace or pendant
Battery charger for household batteries	GPS (global positioning system)	Microwave oven
Blender / food processor	Guitar, electric	Radio, AM/FM
Bluetooth technology	Hair shaver / trimmer, battery powered[a]	Refrigerator
Can opener	Hair straightener	Remote control, infrared, for CD/DVD player, television, and so on.
CD/DVD/DVR player or recorder, without speakers	Heart rate monitor, chest band	Residential power line

Table 4. Examples of household items with no distance restriction for EMI (continued)

Clothes iron	Heating pad	Satellite dish, receiving
Curling iron	Home security system, infrared or ultrasonic	Sauna, electric
Digital music player (for example, iPod)	Hot tub[b]	Smart scale with WiFi or Bluetooth connectivity[c]
Dishwasher	House arrest anklet[d]	Stove, kitchen[e]
Electric blanket or electric mattress pad	Ionized bracelet	Swimming pool[b]
Electronic weight scale	Kiln, 115-120 V AC or 220-240 V AC	Television[f]
Flashlight	Massage bed / chair / pad	Toaster

[a] Compare to hair shaver / trimmer in *Table 9, page 25*.

[b] Hot tub and swimming pool must be properly grounded.

[c] Smart scales that measure body composition (BMI) using an electrical current are not recommended.

[d] Compare to house arrest bracelet. See *Table 7, page 24*.

[e] 60 cm (24 in) distance restriction from induction cooktops.

[f] Maintain a 15 cm (6 in) distance from television speakers.

Table 5. Examples of professional and vocational items with no distance restriction for EMI

Anti-theft detection pedestals / electronic article surveillance equipment for retail loss prevention[a]	Calipers, battery powered	Laser level, battery operated	Pager, receiver only
Automobiles, electric[b]	Diesel engines	Office calculator	Polygraph / lie detector test[c]
Automobiles, hybrid[d]	Facsimile (fax) machine	Office printer	Soldering iron[f]
Barcode scanner	Hooded hair dryer, salon[e]	Photocopier / copy machine	Stud finder, battery operated

[a] Safe when walking between the pedestals at normal walking speed. Do not linger near the detection equipment.

[b] 30 cm (12 in) distance from electric automobile battery charger.

[c] A polygraph test introduces direct current into the body. This direct current poses a low risk of affecting a pacemaker or ICD.

[d] Compare to hybrid automobiles in *Section 7.3.1, Vehicles with engines fueled by gasoline or petrol, page 26*.

[e] Compare to hair dryer, handheld in *Table 7, page 24*.

[f] Compare to soldering gun; see *Table 12, page 26*.

Table 6. Examples of recreational items with no distance restriction for EMI

Casino slot machine	Motorcycle vest, heated	Tanning booth, electrostatic
Electric golf cart[a]	Tanning bed	

[a] Maintain a 15 cm (6 in) distance from battery during charging.

7.2 Items with a 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

The following table represents items that, when used as intended and in good working condition, have a 15 cm (6 in) distance restriction from an implanted pacemaker or ICD.

Table 7. Examples of household items with 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

Air filter, ionized	Magnet, small	Static electricity generator, "plasma ball"[a]
Amateur radio, ham radio, and marine radio, < 3 W, from antenna	Magnetic back brace or belt	Stereo speakers, from magnet
Canine shock collar for electric pet containment fence, including remote control and base with antenna	Magnetic cover for tablet computer	Television audio headset, from transmitter near television
Clasp, magnetic	Magnetic chair pad	Tools, battery powered
Electric guitar speakers	Magnetic therapy products	Tools, small electric, from motor
Electric kitchen appliances, hand-held	Massager, handheld	Toothbrush, electric, from charging base
Exercise bicycle, wheel magnet	Model cars, airplanes, video drones — remote controlled, from controller antenna	Toy train, electric, from transformer and rails
Hair dryer, handheld[b]	Refrigerator door, from magnetic closure strip	Treadmill, from electric motor
Home security system, microwave, from transmitter	Sewing machine or serger, from motor	Ultrasonic or radio frequency pest control device
House arrest bracelet[c]	Smart meter (used by utility companies)	Vacuum cleaner, from motor

[a] Do not touch this item.

[b] Compare to hooded hair dryer, salon in *Table 5, page 23*.

[c] Compare to house arrest anklet; see *Table 4, page 22*.

Table 8. Examples of household wireless electronic devices with 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

Activity band or wearable fitness monitor, if device contains magnets	Earbuds, wireless (from magnet)	Remote control, radiofrequency (RF), for CD/DVD player, television, and so on
Cellular adaptor for laptop computer	eReader	Remote keyless entry and remote car starter key fob
Computer keyboard, wireless	Gaming console and controllers	Radiofrequency (RF) wireless charger
Computer: personal, laptop, or tablet	Headphones, from magnets	Smart watch
Cordless telephone, < 3 W, from antenna and base station[a]	Network router	Wi-Fi or cellular modem, from transmitter/receiver
CD/DVD/DVR player and recorder with speakers	Qi inductive mobile telephone charger	

[a] See also cordless telephone, 3 to 15 W, in *Table 11, page 25*

Caution: Do not carry a wireless device in a pocket or in a shoulder bag near a pacemaker or an ICD.

Table 9. Examples of professional and vocational items with 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

Badge (name tag) with magnetic clasp	OnStar Technology, from antenna	Tools, handheld battery powered
Badge (security) with externally activated electronic circuit	Pager, 2-way, ≤ 3 W, from antenna	Tools, handheld electric, from motor
Citizens band (CB) radio, ≤ 3 W, from antenna	Personal scooter / electric grocery cart, from battery, during charging	Security badge wall scanner
Cordless microphone, from transmitter	Piconet wireless computer connector, from antenna	Tattoo machine
Extractor wand, for automobile mechanics	Portable radio (walkie-talkie), ≤ 3 W, from antenna	Telephone headset, cordless
Hair shaver / trimmer, corded[a]	—	—

[a] Compare to hair shaver / trimmer, battery powered in *Table 4*.

Mobile telephones
Keep mobile telephones, cellular telephones, or smartphones at least 15 cm (6 in) from an implanted pacemaker or ICD.
Keep magnetic accessories for mobile telephones at least 15 cm (6 in) from an implanted pacemaker or ICD. Accessories with magnets can include wireless earbuds, plug-in earbuds, or cases with magnetic clasps.

Table 10. Sample of recreational items with 15 cm (6 in) distance restriction from an implanted pacemaker or ICD

Bingo wand	Golf cart, electric, from battery during charging	Marine radio, < 3 W, from antenna
Disney MagicBand reader[a]	Laser tag, from magnet or transmitter in some vests	

[a] No distance restriction for Disney MagicBand.

7.3 Items with a 30 cm (12 in) distance restriction from an implanted pacemaker or ICD

The following table represents items that, when used as intended and in good working condition, have a 30 cm (12 in) distance restriction from an implanted pacemaker or ICD.

Table 11. Examples of household items with 30 cm (12 in) distance restriction from an implanted pacemaker or ICD

Amateur radio, cordless telephone[a], ham radio, or 2-way portable radio, 3 to 15 W, from antenna and base station	Automobile battery charger / charging station for electric automobiles	Lawn and garden tools powered by gasoline / petrol, from ignition system (for example, backpack leaf blowers, snow blowers, chainsaws)
Automobile battery charger for gasoline engines	Electrical transformer / transformer box, residential	

[a] Compare to cordless telephone, < 3 W, in *Table 8, page 24*.

Table 12. Examples of professional and vocational items with 30 cm (12 in) distance restriction from an implanted pacemaker or ICD

Cattle prod / stock prod, from electrodes	Marine radio, 3 to 15 W, from antenna	Transmitters, portable 3 to 15 W, from antenna
Degausser / demagnetizer	Pagers, 2-way, 3 to 15 W, from antenna	UPS (uninterruptible power source – commercial power failure back-up system) up to 200 A
Generators, electric, portable AC/DC, up to 20 kW	Soldering gun[a]	

[a] Compare to soldering iron, see *Table 5, page 23*.

7.3.1 Vehicles with engines fueled by gasoline or petrol

Observe the following precautions when using vehicles fueled with gasoline / petrol:

- Do not repair or perform maintenance work on an engine while it is running or when its ignition switch is on. Repair or perform maintenance work on an engine when both the engine and its ignition switch are off.
- Maintain a 30 cm (12 in) distance between the implanted cardiac device and an engine that is running or that has its ignition switch turned on.

Note: Diesel engines are safe for patients with an implanted pacemaker or ICD.

Table 13. Examples of vehicles with gasoline / petrol engines with a 30 cm (12 in) distance restriction from an implanted pacemaker or ICD

All-terrain vehicle (ATV)	Equipment / vehicles used for agriculture or construction	Motorcycle
Automobile / hybrid automobile[a]	Forklift – also fueled by propane or natural gas	Snowmobile or snow machine
Boat motor	Jet ski	Truck / lorry

[a] Automobile / hybrid automobile have no distance restriction for drivers or passengers.

7.4 Items with a 60 cm (24 in) distance restriction from an implanted pacemaker or ICD

The following table represents items that, when used as intended and in good working condition, have a 60 cm (24 in) distance restriction from an implanted pacemaker or ICD.

Table 14. Examples of items with a 60 cm (24 in) distance restriction from an implanted pacemaker or ICD

Household items	
Amateur radio, ham radio, or walkie-talkie, 15 to 30 W, from antenna	Stove, induction cooktop
Jumper cables, during use	Residential satellite dish, 2-way
Professional and vocational items	
Anti-theft tag deactivator	GPS survey equipment
Bench-mounted / free-standing tools with motors ≤ 400 horsepower	Radio transmitters, vehicle-mounted, 15 to 30 W – from antenna
Forklift, battery powered, from motor	Welding equipment with less than 160 A (see *Section 7.4.1, Welding safety precautions, page 27*)
Recreational items	
Beach comber / metal detector, from detector head	Marine radio, single side band, 20–25 W, from antenna

7.4.1 Welding safety precautions

Patients must observe the follow precautions with welding equipment at currents less than 160 A. (It is not recommended that patients work with welding equipment at currents greater than 160 A.)

- Work in a dry area with dry gloves and shoes.
- Maintain a 60 cm (24 in) distance between the welding arc and the implanted device.
- Keep the welding cables close together and as far as possible from the implanted device. Place the welding unit approximately 150 cm (5 ft) from the work area.
- Connect the ground clamp to the metal as close to the point of welding as possible. Arrange the work area so that if the handle and rod are dropped, they will not contact the metal being welded.
- Wait several seconds between attempts when having difficulty starting a weld.
- Work in an area that offers firm footing and room for movement.
- Work with an informed person who understands these precautions.
- The patient must immediately stop welding and step away from the area if the patient becomes light-headed or dizzy, or if an implanted ICD delivers a shock.

Note: Aprons or vests will not effectively shield a pacemaker or an ICD from EMI generated by welding equipment.

7.5 Items with low potential for EMI at extended distances from an implanted pacemaker or ICD

The following table lists communications items that have low potential for EMI when used as intended and in good working condition. These items are safe for patients when their antennae are at, or greater than, the listed distance from an implanted pacemaker or ICD.

Note: These distances assume free space and an unobstructed line-of-sight.

Table 15. Items with low potential for EMI at extended distances from an implanted pacemaker or ICD

Communications	
1 m (3 ft)	2-way portable radio, from antenna – 30 to 50 W.
2 m (6 ft)	2-way portable radio, from antenna – 50 to 125 W.
3 m (9 ft)	Amateur radio, ham radio, marine radio, or 2-way portable radio, from antenna – 125 to 250 W. Cellular tower – ≤ 250 W. Commercial broadcast towers – 125 to 250 W. For transmitters with power levels > 250 W, avoid restricted areas that contain the antenna.
4 m (12 ft)	Amateur or ham radio, from antenna – 250 to 500 W.
6 m (20 ft)	Amateur or ham radio, from antenna – 500 to 1000 W.
9 m (30 ft)	Amateur or ham radio, from antenna – 1000 to 2000 W.

7.6 Items and environments with special considerations for EMI for patients with implanted pacemakers and ICDs

The information in this section discusses electrical equipment and environments that generate EMI that can affect an implanted pacemaker or ICD. Share this information with patients who work with this equipment or in these environments, or who can encounter these sources of EMI. Contact Medtronic Technical Services for additional guidance regarding these environments.

Industrial equipment – The following industrial equipment and environments include high-voltage current, magnetic fields, or other EMI sources that can affect device operation. Patients may need to avoid using or working near the following categories of industrial equipment. Medtronic recommends that the employers of patients with pacemakers or ICDs consult with clinicians before their employees return to work in these environments.

- Electric furnaces used in the manufacturing of steel
- Induction heating equipment and induction furnaces, such as kilns
- Industrial magnets such as those used in surface grinding and electromagnetic cranes
- Dielectric heaters to heat plastic and dry glue in furniture manufacturing
- Electric arc and resistance welding equipment operating at greater than 160 A (see *Section 7.4, Items with a 60 cm (24 in) distance restriction from an implanted pacemaker or ICD, page 26* for guidance with welding equipment operating at less than 160 A)
- Broadcasting antennas for AM, FM, shortwave radio, and TV stations
- Microwave transmitters
- Power plants, power generators, and transmission power lines

  Note: Lower-voltage distribution power lines for homes and businesses are unlikely to affect implanted cardiac devices.

Anti-theft and security systems

Anti-theft systems – Anti-theft systems are unlikely to affect an implanted pacemaker or ICD. However, as a precaution, do not linger near or lean against these systems. Walk past or through them at a normal pace. If you experience symptoms, move away from the equipment. After you move away from the equipment, the device resumes its previous state of operation.

Security systems – Metal detectors (walk-through archways and handheld wands) and full-body imaging scanners (millimeter wave scanners, three-dimensional imaging scanners, or backscatter full body scanners) are unlikely to affect an implanted pacemaker or ICD. These detectors and scanners are common in airports, courthouses, and other high-security facilities.

When you encounter security systems, observe the following guidelines:

- Always carry your cardiac device ID card. If your cardiac device sets off a metal detector or a security system, your card is helpful for security staff.
- To minimize the risk of temporary interference with your implanted pacemaker or ICD while going through the security screening process, do not touch metal surfaces around any screening equipment.
- Do not stop or linger in a walk-through archway; simply walk through the archway at a normal pace.
- If a handheld wand is used, ask the security operator not to hold it over or wave it back and forth over your implanted pacemaker or ICD.
- If you have concerns about security screening methods, show your cardiac device ID card to the security operator, request alternative screening, and then follow the security operator's instructions.

Shock from an electrical outlet (110 V / 220 V)

A momentary shock from an electrical outlet can inhibit pacing in a pacemaker or an ICD. A momentary shock can reset some parameters to their nominal values. Any parameter changes that occur can be reprogrammed during an office visit. There is a low risk of permanent damage to a pacemaker or an ICD from a momentary shock from an electrical outlet.

A prolonged shock greater than 8 s can inhibit pacing in a pacemaker or an ICD, or it can cause delivery of a shock in an ICD. A prolonged external shock greater than 2 s can cause reversion in a pacemaker. There is a low risk of permanent damage to a pacemaker, ICD, or leads from a prolonged shock from an electrical outlet.

7.7 Non-EMI environments with special consideration for patients with implanted pacemakers and ICDs

This section includes important information to share with patients about home or work environments that can affect an implanted pacemaker or ICD. Contact Medtronic Technical Services for additional guidance regarding these environments.

Air travel

Air travel in a pressurized cabin is safe for patients with an implanted pacemaker or ICD.

High altitude environments and activities

Medtronic implantable pacemakers and ICDs can withstand air pressure levels equivalent to an altitude limit of 6,000 m (20,000 ft). The following activities are safe for patients with an implanted pacemaker or ICD:

- Hiking, trekking, skiing or vehicle travel up to the altitude limit.
- Camping or extended stays up to the altitude limit.

Rifles, shotguns

Patients should consult their physician for advice and limitations for the use of rifles and shotguns. A rifle or shotgun should be used on the shoulder that is opposite from the implant location.

Scuba diving, recreational diving

Medtronic implantable pacemakers and ICDs are rated for pressure levels up to 4.0 ATA (atmospheres absolute). 4.0 ATA is approximate to a seawater depth of 30 m (100 ft).

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Medtronic

Epsila EV™ EAZ101

Sternal tunneling tool

Technical Manual

! USA **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

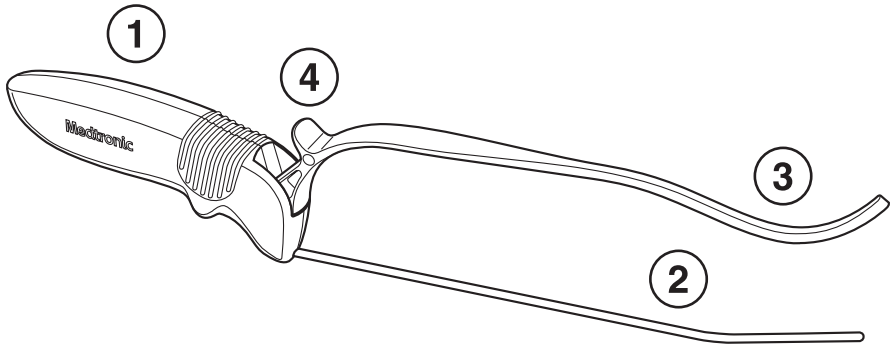
1 Device description

The Medtronic Epsila EV Model EAZ101 sternal tunneling tool is designed to deliver an introducer and an extravascular lead into the anterior mediastinum during implant of an extravascular implantable device system.

The sternal tunneling tool, shown in *Figure 1*, consists of the following components:

- A handle.
- A stainless steel tunneling rod that delivers an introducer to the anterior mediastinum. (See *Chapter 11* for the recommended introducer size.) The tunneling rod has a preformed bend and is malleable to accommodate patient anatomy.
- An external guide that remains above the skin and indicates the distance and direction of the tunneling rod. The external guide is hinged and removable to accommodate physician preference and patient anatomy.
- A thumb tab that can be used to raise and lower the external guide.

Figure 1. Model EAZ101 sternal tunneling tool



1 Handle
2 Stainless steel tunneling rod
3 External guide (removable)
4 Thumb tab

1.1 Package contents

The tunneling tool is supplied sterile. Each package contains the following items:

- 1 sternal tunneling tool
- Product documentation

2 Indications

The Epsila EV Model EAZ101 sternal tunneling tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

3 Contraindications

The Epsila EV Model EAZ101 sternal tunneling tool is contraindicated for use in patients with a prior sternotomy.

4 Intended purpose

The Medtronic Model EAZ101 sternal tunneling tool is a sterile, single-use only medical device intended for use in the implantation of a compatible anterior mediastinum defibrillation lead.

5 Intended users

The users of the Model EAZ101 sternal tunneling tool are individuals trained in the operation and handling of the tool.

6 Warnings and precautions

Note: Medical procedure warnings and precautions that pertain to the Medtronic implanted system are included in the manual that is provided with the implantable device.

Product compatibility – This tool has not been tested for use with non-Medtronic products.

Pediatric use – The tool has not been tested specifically for pediatric use.

Inspecting the sterile package – Inspect the sterile package before opening it.

- If the package is damaged or opened, do not use the product and contact a Medtronic representative.
- Do not transport the package or contents of the package above 58°C (136°F) or below –35°C (–31°F). Do not store the package or contents of the package above 30°C (86°F) or below 15°C (59°F).
- Do not use the product after its expiration date.

Single use – This tool is for single use only. Reuse may compromise the structural integrity of the tool or create a risk of contamination of the tool that could result in patient injury, illness, or death.

Sterilization – Medtronic has sterilized the package contents using irradiation before shipment. This tool is for single use only and is not intended to be resterilized.

Implantation and system management – Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the system and must be in compliance with procedures described in the appropriate technical instructions. Inadequate training or failure to follow instructions may result in harm to the patients.

Disposal – Dispose of the single-use tool according to local environmental requirements.

7 Potential adverse events

The following are foreseeable potential adverse events associated with the use of the sternal tunneling tool:

- Acute tissue trauma
- Allergic reaction
- Cardiac perforation
- Cardiac tamponade
- Death
- Discomfort
- Hematoma
- Hemorrhage
- Hemothorax
- Infection
- Organ damage (liver, mammary arteries, diaphragmatic arteries)
- Pain
- Pericardial effusion
- Pericarditis
- Pneumothorax
- Seroma

Note: If a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.

8 Adverse events and clinical trial data

The following information applies only to use of the tool in the United States. For information regarding clinical studies and adverse events related to this tool, see the US device manual for the extravascular implantable cardioverter defibrillator.

9 Summary of safety and clinical performance

The Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed. Search for the SSCP using the manufacturer and device name, and any of the following elements, as applicable: device model, reference number, catalog number, or the Basic Unique Device Identification (Basic UDI-DI) number — 0763000B000082586.

10 Directions for use

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. The following procedures are provided for information only. Some implant techniques vary according to physician preference and the patient's anatomy or physical condition. Each physician must apply the information in these instructions according to professional medical training and experience.

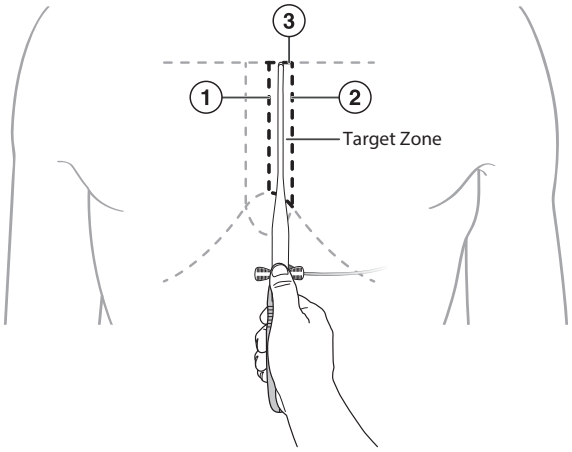
10.1 Preparing to tunnel

1. Prepare the introducer for lead implant according to the instructions in the product documentation packaged with the introducer. Leave the saline-filled syringe attached to the introducer side port and open the stopcock.
2. If needed, manually bend the tunneling rod of the sternal tunneling tool to a curvature suitable for the patient's anatomy. The angle must allow for the tunneling rod tip to remain in contact with (or as close as possible to) the posterior of the sternum during tunneling.

   Note: Inspect the introducer for damage before use.
3. Backload the introducer onto the tunneling rod.
4. Draw landmarks on the patient's skin. Recommended landmarks include the following locations:
   - Xiphoid process
   - Rib borders
   - Sternal midline
   - Sternal left lateral border
   - Top of cardiac silhouette
   - Location of incision
   - Location of device pocket

   Note: The spine is not a recommended landmark.

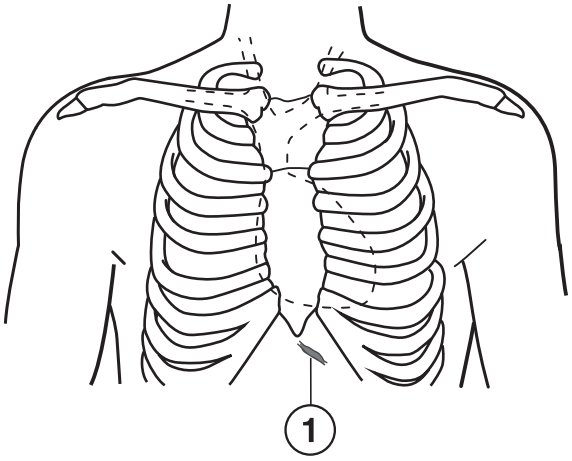
Figure 2. Target tunneling zone



1 Sternal midline
2 Sternal left lateral border
3 Top of cardiac silhouette

5. Incise the skin below the xiphoid process, slightly left of midline, as shown in *Figure 3*. To avoid potential adverse events due to organ contact, choose an incision location that accommodates the appropriate angle of the sternal tool insertion based on the patient's anatomy. Make the incision large enough to accommodate fixation of the anchoring sleeve.

Figure 3. Incision site



1 Incision site

6. Perform blunt dissection of the diaphragmatic attachments, using lateral fluoroscopy as guidance. Start blunt dissection by using a finger to traverse the diaphragmatic attachments. Confirm the correct tissue plane using a finger.

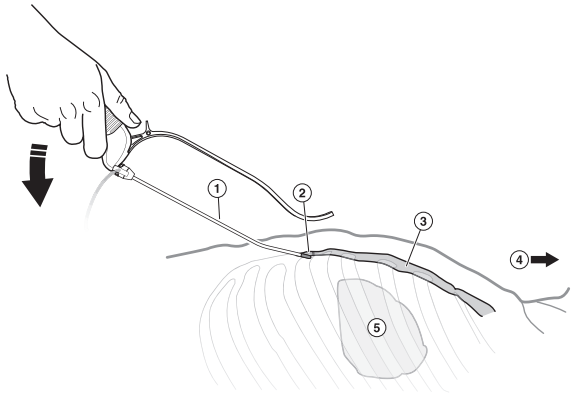
10.2 Tunneling under the sternum

Notes:

- If the patient has challenging anatomical features, such as thick subcutaneous tissue, a curved sternum, or a prominent xiphoid process, raise the external guide as needed so it does not interfere with initial insertion. Once the tunneling rod is inserted, you can lower the external guide for use as a visual indicator of lateral direction and cranial distance as you tunnel.
- Before inserting the tunneling rod, optionally remove the external guide. To remove the external guide, pull it all the way up until it clicks, then pull it off the handle in the direction opposite the tunneling rod.
  - **Note:** Do not remove the external guide while tunneling.

1. With lateral fluoroscopy as guidance, insert the tunneling rod and introducer into the incision. Advance the tip of the tunneling rod to make contact with the xiphisternal junction.
2. Once the tunneling rod tip is under the sternum, immediately lower the handle towards the abdomen so the tunneling rod is parallel to the sternum. To avoid potential adverse events due to organ contact, keep the tunneling rod tip in contact with (or as close as possible to) the posterior of the sternum. (See *Figure 4*.) Use lateral fluoroscopy as guidance.

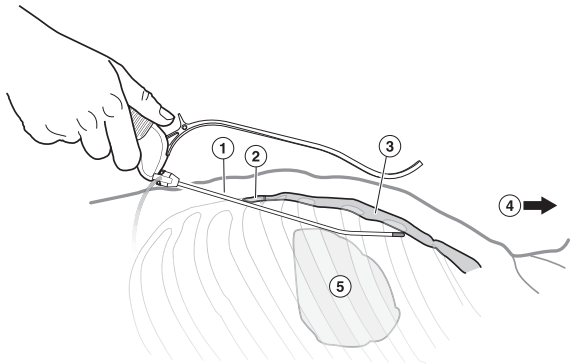
Figure 4. Lateral view: Tunneling rod tip in contact with the xiphisternal junction



1 Tunneling rod
2 Xiphisternal junction
3 Sternum
4 Head
5 Heart

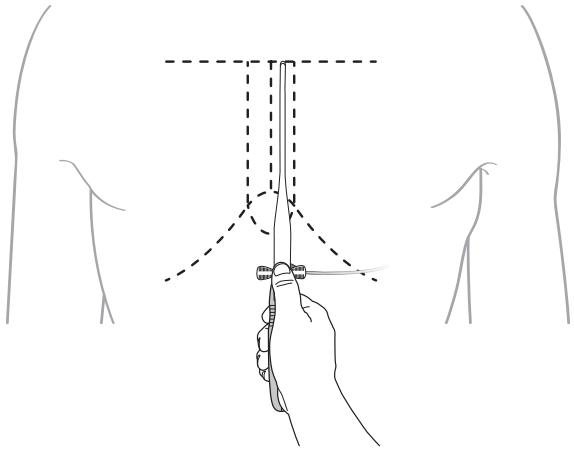
3. While tunneling must occur in lateral view, confirmation of the tool direction should occur in AP view to ensure the tool remains in the target tunneling zone. Advance the tunneling tool to the top of the cardiac silhouette, frequently adjusting between lateral and AP view to confirm the trajectory of the tool. See *Figure 5*. While tunneling, consider using the external guide to ensure that the tunneling rod remains between the sternal borders, as shown in *Figure 6*.

Figure 5. Lateral view: Tunneling rod tip at the top of the cardiac silhouette



1 Tunneling rod
2 Xiphisternal junction
3 Sternum
4 Head
5 Heart

Figure 6. External view: Tunneling rod tip at the top of the cardiac silhouette



Note: If you feel resistance when tunneling, stop tunneling and confirm the location of the tunneling rod using another fluoroscopic view. Then, using fluoroscopy, perform the following steps:

a. Slightly retract the tunneling rod together with the introducer.
b. Reposition the tunneling rod, ensuring that it is in contact with (or as close as possible to) the posterior of the sternum and inside the target tunneling zone, as shown in *Figure 2*.
c. If the introducer is damaged, use a new introducer and start the tunneling process again.

4. Confirm the tunneling rod placement using either the external guide or a different fluoroscopic view.

10.3 Removing the tunneling rod and inserting the lead

1. To minimize air ingress, ensure that the saline-filled syringe is attached to the introducer side port and the stopcock is open.
2. Hold the introducer in place while removing the tunneling rod.
   Note: Do not advance the introducer without the tunneling rod inserted.
3. Insert the lead into the introducer according to the instructions in the lead technical manual.

11 Specifications

Parameter	Model EAZ101
Length	Overall length: 35.5 cm (14 in) Tunneling rod length: 22.3 cm (8.8 in)
Tunneling rod diameter	3.0 mm (9 Fr)
Material	Tunneling rod: 304 stainless steel External guide: acrylonitrile butadiene styrene (ABS) Handle: polycarbonate
Recommended introducer	Diameter: 3.0 mm (9 Fr) Length: 19.13 cm (7.53 in)

12 CE mark of conformity

CE 0344

13 Explanation of symbols on package labeling

Refer to the package labels to see which symbols apply to this product.

Table 1. Explanation of symbols on package labeling

Symbol	Explanation
CE 0344	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
	Do not use if package is damaged
	Do not reuse
	Temperature limit
	Transit temperature limit
	Storage temperature limit
	Open here
STERILE R	Sterilized using irradiation
	Caution
	Consult instructions for use
	Date of manufacture
	Manufacturer
	Importer
EC REP	Authorized representative in the European community
	Use-by date
REF	Reorder number
LOT	Lot number
#	Model number
	Manufactured in

Table 1. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Package contents
	Product documentation
	Lead introducer
	Inner diameter
	Single sterile barrier system
! USA	For US audiences only
MD	Medical device
PIN	PIN number
	Sternal tunneling tool

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
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www.medtronic.com
+1 763 514 4000

EC REP

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
+31 45 566 8000

Canada
Medtronic Canada ULC
99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
1 800 268 5346

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Medtronic

Epsila EV™ EAZ101

Sternal tunneling tool
Herramienta de tunelización esternal
Alat tunneling sternum
Инструмент для туннелирования под грудиной
Sternalni alat za pravljenje prolaza
Інструмент для грудинного тунелювання

Technical Manual • Manual técnico • Panduan Teknis • Техническое руководство • Tehnički priručnik • Технічне керівництво

! USA **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

Epsila EV™

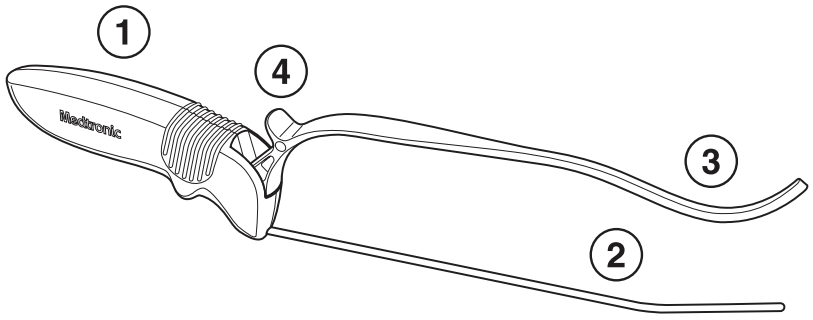
1 Device description

The Medtronic Epsila EV Model EAZ101 sternal tunneling tool is designed to deliver an introducer and an extravascular lead into the anterior mediastinum during implant of an extravascular implantable device system.

The sternal tunneling tool, shown in *Figure 1*, consists of the following components:

- A handle.
- A stainless steel tunneling rod that delivers an introducer to the anterior mediastinum. (See *Chapter 11* for the recommended introducer size.) The tunneling rod has a preformed bend and is malleable to accommodate patient anatomy.
- An external guide that remains above the skin and indicates the distance and direction of the tunneling rod. The external guide is hinged and removable to accommodate physician preference and patient anatomy.
- A thumb tab that can be used to raise and lower the external guide.

Figure 1. Model EAZ101 sternal tunneling tool



1 Handle
2 Stainless steel tunneling rod
3 External guide (removable)
4 Thumb tab

1.1 Package contents

The tunneling tool is supplied sterile. Each package contains the following items:

- 1 sternal tunneling tool
- Product documentation

2 Indications

The Epsila EV Model EAZ101 sternal tunneling tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

3 Contraindications

The Epsila EV Model EAZ101 sternal tunneling tool is contraindicated for use in patients with a prior sternotomy.

4 Intended purpose

The Medtronic Model EAZ101 sternal tunneling tool is a sterile, single-use only medical device intended for use in the implantation of a compatible anterior mediastinum defibrillation lead.

5 Intended users

The users of the Model EAZ101 sternal tunneling tool are individuals trained in the operation and handling of the tool.

6 Warnings and precautions

Note: Medical procedure warnings and precautions that pertain to the Medtronic implanted system are included in the manual that is provided with the implantable device.

Product compatibility – This tool has not been tested for use with non-Medtronic products.

Pediatric use – The tool has not been tested specifically for pediatric use.

Inspecting the sterile package – Inspect the sterile package before opening it.

- If the package is damaged or opened, do not use the product and contact a Medtronic representative.
- Do not transport the package or contents of the package above 58°C (136°F) or below –35°C (–31°F). Do not store the package or contents of the package above 30°C (86°F) or below 15°C (59°F).
- Do not use the product after its expiration date.

Single use – This tool is for single use only. Reuse may compromise the structural integrity of the tool or create a risk of contamination of the tool that could result in patient injury, illness, or death.

Sterilization – Medtronic has sterilized the package contents using irradiation before shipment. This tool is for single use only and is not intended to be resterilized.

Implantation and system management – Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the system and must be in compliance with procedures described in the appropriate technical instructions. Inadequate training or failure to follow instructions may result in harm to the patients.

Disposal – Dispose of the single-use tool according to local environmental requirements.

7 Potential adverse events

The following are foreseeable potential adverse events associated with the use of the sternal tunneling tool:

- Acute tissue trauma
- Allergic reaction
- Cardiac perforation
- Cardiac tamponade
- Death
- Discomfort
- Hematoma
- Hemorrhage
- Hemothorax
- Infection
- Organ damage (liver, mammary arteries, diaphragmatic arteries)
- Pain
- Pericardial effusion
- Pericarditis
- Pneumothorax
- Seroma

Note: If a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.

8 Adverse events and clinical trial data

The following information applies only to use of the tool in the United States. For information regarding clinical studies and adverse events related to this tool, see the US device manual for the extravascular implantable cardioverter defibrillator.

9 Summary of safety and clinical performance

The Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed. Search for the SSCP using the manufacturer and device name, and any of the following elements, as applicable: device model, reference number, catalog number, or the Basic Unique Device Identification (Basic UDI-DI) number — 0763000B000082586.

10 Directions for use

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. The following procedures are provided for information only. Some implant techniques vary according to physician preference and the patient's anatomy or physical condition. Each physician must apply the information in these instructions according to professional medical training and experience.

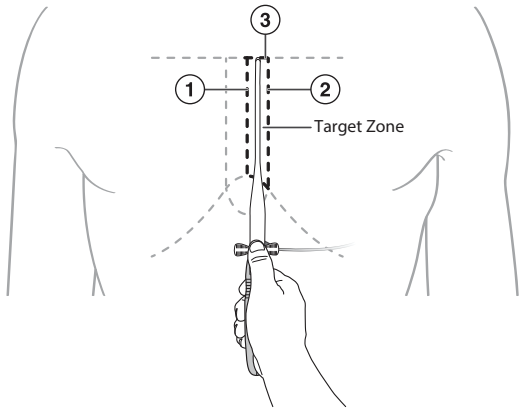
10.1 Preparing to tunnel

1. Prepare the introducer for lead implant according to the instructions in the product documentation packaged with the introducer. Leave the saline-filled syringe attached to the introducer side port and open the stopcock.
2. If needed, manually bend the tunneling rod of the sternal tunneling tool to a curvature suitable for the patient's anatomy. The angle must allow for the tunneling rod tip to remain in contact with (or as close as possible to) the posterior of the sternum during tunneling.

   Note: Inspect the introducer for damage before use.
3. Backload the introducer onto the tunneling rod.
4. Draw landmarks on the patient's skin. Recommended landmarks include the following locations:
   - Xiphoid process
   - Rib borders
   - Sternal midline
   - Sternal left lateral border
   - Top of cardiac silhouette
   - Location of incision
   - Location of device pocket

   Note: The spine is not a recommended landmark.

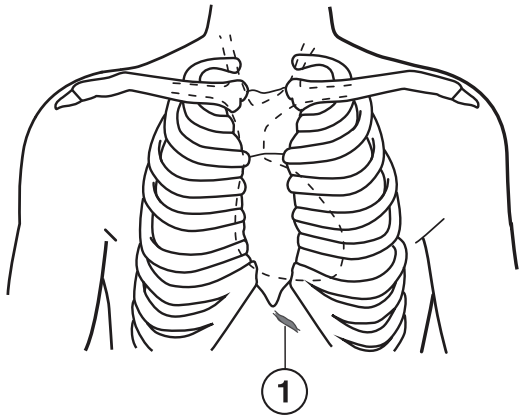
Figure 2. Target tunneling zone



1 Sternal midline
2 Sternal left lateral border
3 Top of cardiac silhouette

5. Incise the skin below the xiphoid process, slightly left of midline, as shown in *Figure 3*. To avoid potential adverse events due to organ contact, choose an incision location that accommodates the appropriate angle of the sternal tool insertion based on the patient's anatomy. Make the incision large enough to accommodate fixation of the anchoring sleeve.

Figure 3. Incision site



1 Incision site

6. Perform blunt dissection of the diaphragmatic attachments, using lateral fluoroscopy as guidance. Start blunt dissection by using a finger to traverse the diaphragmatic attachments. Confirm the correct tissue plane using a finger.

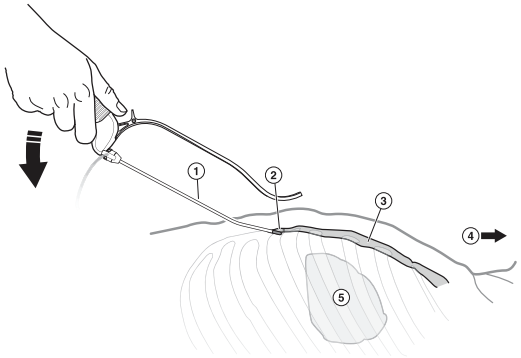
10.2 Tunneling under the sternum

Notes:

- If the patient has challenging anatomical features, such as thick subcutaneous tissue, a curved sternum, or a prominent xiphoid process, raise the external guide as needed so it does not interfere with initial insertion. Once the tunneling rod is inserted, you can lower the external guide for use as a visual indicator of lateral direction and cranial distance as you tunnel.
- Before inserting the tunneling rod, optionally remove the external guide. To remove the external guide, pull it all the way up until it clicks, then pull it off the handle in the direction opposite the tunneling rod.
  - **Note:** Do not remove the external guide while tunneling.

1. With lateral fluoroscopy as guidance, insert the tunneling rod and introducer into the incision. Advance the tip of the tunneling rod to make contact with the xiphisternal junction.
2. Once the tunneling rod tip is under the sternum, immediately lower the handle towards the abdomen so the tunneling rod is parallel to the sternum. To avoid potential adverse events due to organ contact, keep the tunneling rod tip in contact with (or as close as possible to) the posterior of the sternum. (See *Figure 4*.) Use lateral fluoroscopy as guidance.

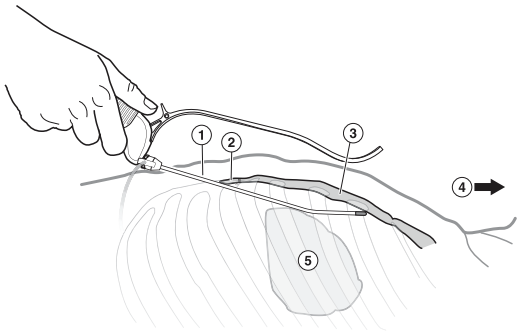
Figure 4. Lateral view: Tunneling rod tip in contact with the xiphisternal junction



1 Tunneling rod
2 Xiphisternal junction
3 Sternum
4 Head
5 Heart

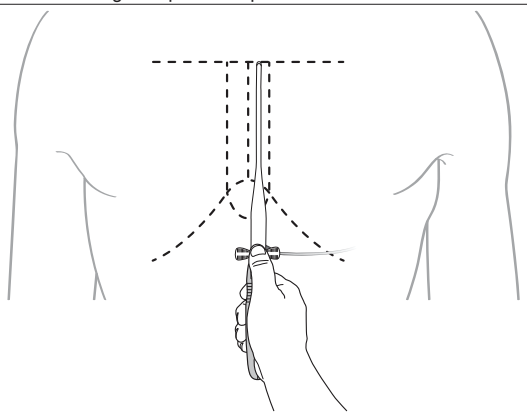
3. While tunneling must occur in lateral view, confirmation of the tool direction should occur in AP view to ensure the tool remains in the target tunneling zone. Advance the tunneling tool to the top of the cardiac silhouette, frequently adjusting between lateral and AP view to confirm the trajectory of the tool. See *Figure 5*. While tunneling, consider using the external guide to ensure that the tunneling rod remains between the sternal borders, as shown in *Figure 6*.

Figure 5. Lateral view: Tunneling rod tip at the top of the cardiac silhouette



1 Tunneling rod
2 Xiphisternal junction
3 Sternum
4 Head
5 Heart

Figure 6. External view: Tunneling rod tip at the top of the cardiac silhouette



Note: If you feel resistance when tunneling, stop tunneling and confirm the location of the tunneling rod using another fluoroscopic view. Then, using fluoroscopy, perform the following steps:

a. Slightly retract the tunneling rod together with the introducer.
b. Reposition the tunneling rod, ensuring that it is in contact with (or as close as possible to) the posterior of the sternum and inside the target tunneling zone, as shown in *Figure 2*.
c. If the introducer is damaged, use a new introducer and start the tunneling process again.

4. Confirm the tunneling rod placement using either the external guide or a different fluoroscopic view.

10.3 Removing the tunneling rod and inserting the lead

1. To minimize air ingress, ensure that the saline-filled syringe is attached to the introducer side port and the stopcock is open.
2. Hold the introducer in place while removing the tunneling rod.
   Note: Do not advance the introducer without the tunneling rod inserted.
3. Insert the lead into the introducer according to the instructions in the lead technical manual.

11 Specifications

Parameter	Model EAZ101
Length	Overall length: 35.5 cm (14 in) Tunneling rod length: 22.3 cm (8.8 in)
Tunneling rod diameter	3.0 mm (9 Fr)
Material	Tunneling rod: 304 stainless steel External guide: acrylonitrile butadiene styrene (ABS) Handle: polycarbonate
Recommended introducer	Diameter: 3.0 mm (9 Fr) Length: 19.13 cm (7.53 in)

12 CE mark of conformity

CE 0344

13 Explanation of symbols on package labeling

Refer to the package labels to see which symbols apply to this product.

Table 1. Explanation of symbols on package labeling

Symbol	Explanation
CE 0344	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
	Do not use if package is damaged
	Do not reuse
	Temperature limit
	Transit temperature limit
	Storage temperature limit
	Open here
STERILE R	Sterilized using irradiation
	Caution
	Consult instructions for use
	Date of manufacture
	Manufacturer
	Importer
EC REP	Authorized representative in the European community
	Use-by date
REF	Reorder number
LOT	Lot number
#	Model number
	Manufactured in

Table 1. Explanation of symbols on package labeling (continued)

Symbol	Explanation
	Package contents
	Product documentation
	Lead introducer
	Inner diameter
	Single sterile barrier system
	For US audiences only
	Medical device
	PIN number
	Sternal tunneling tool

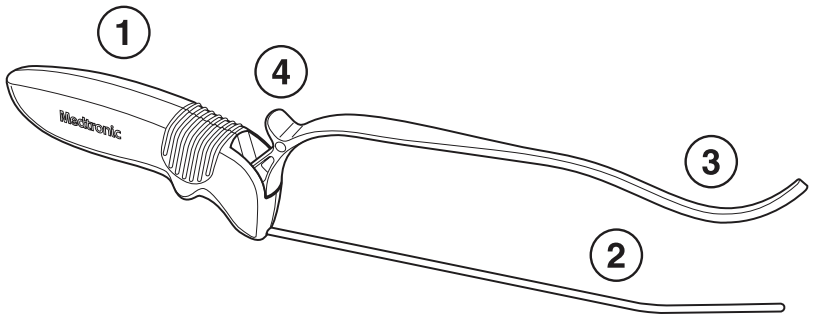
1 Descripción del dispositivo

La herramienta de tunelización esternal Modelo EAZ101 de Medtronic Epsila EV está diseñada para colocar un introductor y un cable extravascular en el mediastino anterior durante la implantación de un sistema de dispositivo implantable extravascular.

La herramienta de tunelización esternal, que se muestra en la *Figura 1*, consta de los componentes siguientes:

- Un mango.
- Una varilla de tunelización de acero inoxidable que coloca un introductor en el mediastino anterior. (Consulte el *Capítulo 11* para ver el tamaño de introductor recomendado). La varilla de tunelización tiene una curvatura preformada y se puede moldear para adaptarla a la anatomía del paciente.
- Una guía externa que permanece sobre la piel e indica la distancia y la dirección de la varilla de tunelización. La guía externa tiene una bisagra y se puede extraer para adaptarla a la preferencia del médico y la anatomía del paciente.
- Una pestaña para el pulgar que se puede utilizar para subir y bajar la guía externa.

Figura 1. Herramienta de tunelización esternal Modelo EAZ101



1 Mango
2 Varilla de tunelización de acero inoxidable
3 Guía externa (extraíble)
4 Pestaña para el pulgar

1.1 Contenido del envase

La herramienta de tunelización se suministra estéril. Cada envase contiene el siguiente material:

- 1 herramienta de tunelización esternal
- Documentación del producto

2 Indicaciones

La herramienta de tunelización esternal Epsila EV Modelo EAZ101 está indicada para utilizarse en la implantación de un cable de desfibrilación compatible en el mediastino anterior.

3 Contraindicaciones

La herramienta de tunelización esternal Epsila EV Modelo EAZ101 está contraindicada para utilizarse en pacientes con una esternotomía previa.

4 Fin previsto

La herramienta de tunelización esternal Modelo EAZ101 de Medtronic es un dispositivo médico estéril de un solo uso que está indicado para utilizarse en la implantación de un cable de desfibrilación compatible en el mediastino anterior.

5 Usuarios previstos

Los usuarios de la herramienta de tunelización esternal Modelo EAZ101 deben tener formación en el funcionamiento y la manipulación de la herramienta.

6 Advertencias y medidas preventivas

Nota: En el manual que se incluye con el dispositivo implantable se proporcionan advertencias y medidas preventivas sobre procedimientos médicos que son aplicables al sistema implantado de Medtronic.

Compatibilidad del producto – Esta herramienta no se ha probado en productos que no son de Medtronic.

Uso pediátrico – La herramienta no se ha probado específicamente para uso pediátrico.

Inspección del envase estéril – Examine el envase estéril antes de abrirlo.

- Si el envase está dañado o abierto, no utilice el producto y póngase en contacto con el representante de Medtronic.
- No transporte el envase o el contenido del envase a temperaturas superiores a 58°C (136°F) o inferiores a –35°C (–31°F). No almacene el envase o el contenido del envase a temperaturas superiores a 30°C (86°F) o inferiores a 15°C (59°F).
- No utilice el producto pasada la fecha de caducidad.

Un solo uso – Esta herramienta es de un solo uso. La reutilización de la herramienta puede poner en peligro su integridad estructural y generar un riesgo de contaminación de la herramienta que podría provocar al paciente lesiones, enfermedades o la muerte.

Esterilización – Medtronic ha esterilizado el contenido del envase mediante irradiación antes de su envío. Esta herramienta es de un solo uso y no se debe volver a esterilizar.

Implantación y gestión del sistema – La implantación y la gestión continua del sistema deben ser realizadas por personas con formación en el funcionamiento y la manipulación del sistema, conforme a los procedimientos descritos en las instrucciones técnicas correspondientes. Una formación inadecuada o el incumplimiento de las instrucciones puede causar lesiones a los pacientes.

Eliminación – Deseche la herramienta de un solo uso conforme a los requisitos medioambientales locales.

7 Posibles eventos adversos

A continuación se indican los posibles efectos adversos previsibles asociados al uso de la herramienta de tunelización esternal:

- Traumatismo tisular agudo
- Reacción alérgica
- Perforación cardíaca
- Taponamiento cardíaco
- Muerte
- Molestias
- hematoma
- hemorragia
- Hemotórax
- Infección
- Daños orgánicos (hígado, arterias mamarias, arterias diafragmáticas)
- Dolor
- Derrame pericárdico
- Pericarditis
- Neumotórax
- Seroma

Nota: Si ocurre un incidente grave relacionado con el dispositivo, notifíquelo inmediatamente a Medtronic y a la autoridad u organismo regulador competente correspondiente.

8 Datos de ensayos clínicos y acontecimientos adversos

La información siguiente es de aplicación únicamente al uso de la herramienta en Estados Unidos. Si desea obtener información sobre los ensayos clínicos y los acontecimientos adversos relacionados con la herramienta, consulte el manual del desfibrilador automático implantable extravascular para Estados Unidos.

9 Resumen de seguridad y rendimiento clínico

El Resumen de seguridad y rendimiento clínico (Summary of Safety and Clinical Performance, SSCP) puede encontrarse en https://ec.europa.eu/tools/eudamed. Busque el SSCP utilizando el fabricante y el nombre del dispositivo, así como cualquiera de los elementos siguientes según proceda: modelo de dispositivo, número de referencia, número de catálogo o número de identificación único del dispositivo básico (UDI-DI básico) — 0763000B000082586.

10 Instrucciones de uso

Los procedimientos quirúrgicos y las técnicas de esterilización adecuadas son responsabilidad del profesional médico. Los procedimientos que se describen a continuación son meramente informativos. Algunas técnicas de implantación varían en función de las preferencias del médico y de la anatomía del paciente o de su estado físico. Cada médico debe aplicar la información contenida en estas instrucciones de acuerdo con su formación y experiencia médica profesional.

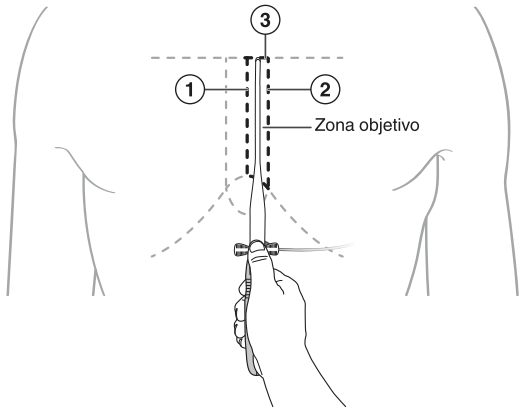
10.1 Preparación del túnel

1. Prepare el introductor para la implantación del cable de acuerdo con las instrucciones descritas en la documentación del producto que se incluye con el introductor. Deje la jeringa llena de solución salina conectada al puerto lateral del introductor y abra la lleve de paso.
2. Si es necesario, doble manualmente la varilla de tunelización de la herramienta de tunelización esternal hasta conseguir la curvatura apropiada para la anatomía del paciente. Su ángulo debe permitir que la punta de la varilla de tunelización permanezca en contacto con la parte posterior del esternón o lo más cerca posible de esta durante la tunelización.

   Nota: Examine el introductor en busca de daños antes de utilizarlo.
3. Cargue el introductor en la parte posterior de la varilla de tunelización.
4. Dibuje puntos de referencia en la piel del paciente. Entre los puntos de referencia recomendados se incluyen los lugares siguientes:
   - apófisis xifoides
   - bordes de las costillas
   - línea media esternal
   - borde lateral izquierdo del esternón
   - borde superior de la silueta cardíaca
   - lugar de la incisión
   - lugar de la bolsa del dispositivo

   Nota: La columna vertebral no es un punto de referencia recomendado.

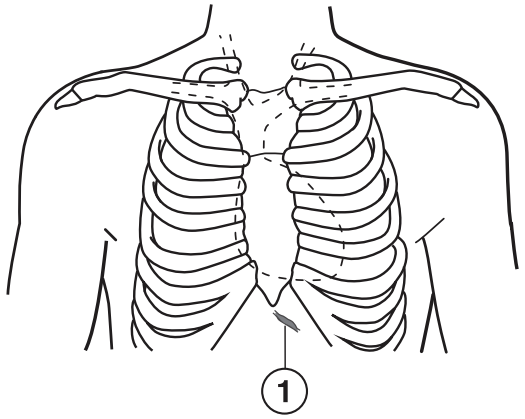
Figura 2. Zona de tunelización objetivo



1 línea media esternal
2 borde lateral izquierdo del esternón
3 borde superior de la silueta cardíaca

5. Haga una incisión en la piel por debajo de la apófisis xifoides, ligeramente a la izquierda de la línea media, tal como se muestra en la *Figura 3*. A fin de evitar posibles efectos adversos debidos al contacto con órganos, elija un lugar de incisión que permita el ángulo apropiado de la inserción de la herramienta esternal en función de la anatomía del paciente. Practique una incisión suficientemente grande para permitir la fijación del manguito de fijación.

Figura 3. Área de incisión



1 Área de incisión

6. Realice una disección roma de las uniones diafragmáticas utilizando fluoroscopia lateral como guía. Comience la disección roma con un dedo para atravesar las uniones diafragmáticas. Compruebe con el dedo que el plano de tejido es correcto.

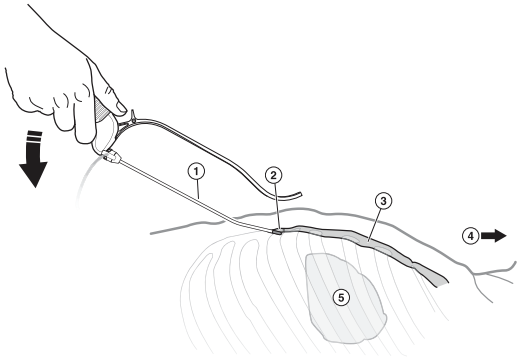
10.2 tunelización bajo el esternón

Notas:

- Si el paciente presenta características anatómicas complicadas, como tejido subcutáneo grueso, un esternón curvado o una apófisis xifoides saliente, eleve la guía externa tanto como sea necesario para que no interfiera con la inserción inicial. Una vez que se haya insertado la varilla de tunelización, puede bajar la guía externa para utilizarla como indicador visual de la dirección lateral y la distancia craneal a medida que tunelice.
- Antes de insertar la varilla de tunelización, puede retirar la guía externa si lo desea. Para retirar la guía externa, tire de ella por completo hacia arriba hasta que oiga un chasquido y después tire de ella fuera del mango en dirección contraria a la varilla de tunelización.
  - **Nota:** No retire la guía externa durante la tunelización.

1. Utilizando fluoroscopia lateral como guía, inserte la varilla de tunelización y el introductor en la incisión. Haga avanzar la punta de la varilla de tunelización para que entre en contacto con la unión xifoesternal.
2. Una vez que la punta de la varilla de tunelización se encuentre bajo el esternón, baje inmediatamente el mango hacia el abdomen de forma que la varilla de tunelización quede paralela al esternón. Para evitar posibles efectos adversos debidos al contacto con algún órgano, mantenga la punta de la varilla de tunelización en contacto con la parte posterior del esternón y lo más cerca posible de ella. (Consulte *Figura 4*). Utilice fluoroscopia lateral como guía.

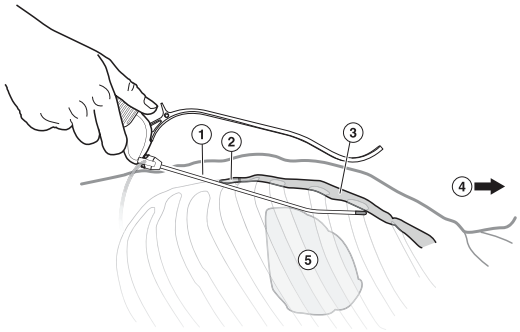
Figura 4. Vista lateral: punta de la varilla de tunelización en contacto con la unión xifoesternal



1 Varilla de tunelización
2 Unión xifoesternal
3 Esternón
4 Cabeza
5 Corazón

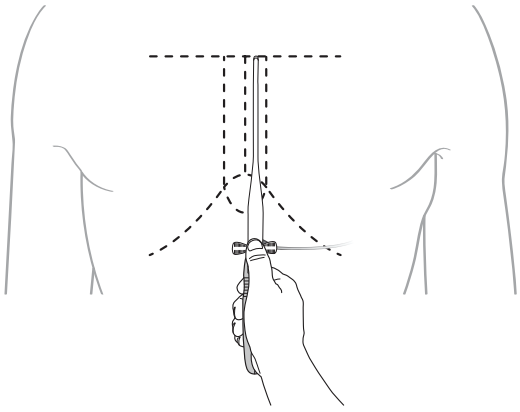
3. Aunque la tunelización debe realizarse en la vista lateral, es necesario confirmar la dirección de la herramienta en la vista AP para garantizar que la herramienta permanece en la zona de tunelización objetivo. Haga avanzar la herramienta de tunelización hasta la parte superior de la silueta cardíaca, realizando ajustes frecuentes entre las vistas lateral y AP para confirmar la trayectoria de la herramienta. Consulte la *Figura 5*. Durante la tunelización, considera la conveniencia de utilizar la guía externa para asegurar que la varilla de tunelización permanezca entre los bordes esternales, tal como se muestra en la *Figura 6*.

Figura 5. Vista lateral: punta de la varilla de tunelización en la parte superior de la silueta cardíaca



1 Varilla de tunelización
2 Unión xifoesternal
3 Esternón
4 Cabeza
5 Corazón

Figura 6. Vista externa: punta de la varilla de tunelización en la parte superior de la silueta cardíaca



Nota: Si nota resistencia durante la tunelización, deje de tunelizar y confirme la ubicación de la varilla de tunelización utilizando otra vista fluoroscópica. Después, bajo fluoroscopia, lleve a cabo los pasos siguientes:

a. Haga retroceder ligeramente la varilla de tunelización junto con el introductor.

b. Cambie de posición la varilla de tunelización, asegurando que esté en contacto con la parte posterior del esternón o lo más cerca posible de ella, y dentro de la zona de tunelización objetivo, tal y como se muestra en la *Figura 2*.
c. Si el introductor está dañado, utilice uno nuevo y comience de nuevo el proceso de tunelización.

4. Confirme la colocación de la varilla de tunelización utilizando la guía externa o una vista fluoroscópica diferente.

10.3 Retirada de la varilla de tunelización e inserción del cable

1. Para reducir al mínimo la entrada de aire, compruebe que la jeringa llena de solución salina esté conectada al puerto lateral del introductor y que la llave de paso esté abierta.
2. Sujete el introductor en su posición mientras extrae la varilla de tunelización.
   Nota: No haga avanzar el introductor sin la varilla de tunelización insertada.
3. Inserte el cable por el introductor siguiendo las instrucciones facilitadas en el manual técnico del cable.

11 Especificaciones

Parámetro	Modelo EAZ101
Longitud	Longitud total: 35,5 cm (14 in) Longitud de la varilla de tunelización: 22,3 cm (8,8 in)
Diámetro de la varilla de tunelización	3,0 mm (9 Fr)
Material	Varilla de tunelización: acero inoxidable 304 Guía externa: acrilonitrilo butadieno estireno (ABS) Mango: policarbonato
Introductor recomendado	Diámetro: 3,0 mm (9 Fr) Longitud: 19,13 cm (7,53 in)

12 Símbolo de conformidad CE

CE 0344

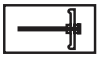
13 Explicación de los símbolos en el etiquetado del envase

Consulte las etiquetas del envase para comprobar qué símbolos se utilizan con este producto.

Tabla 1. Explicación de los símbolos que aparecen en la etiqueta del envase

Símbolo	Explicación
CE 0344	Conformité Européenne (Conformidad Europea). Este símbolo indica que el dispositivo cumple totalmente las leyes vigentes de la Unión Europea.
	No utilizar si el envase está dañado
	No reutilizar
	Límite de temperatura
	Límite de temperatura de transporte
	Límite de temperatura de almacenamiento
	Abrir aquí
STERILE R	Esterilizado mediante irradiación
	Precaución
	Consultar las instrucciones de uso
	Fecha de fabricación
	Fabricante
	Importador
EC REP	Representante autorizado en la Comunidad Europea
	Fecha de caducidad
REF	Número para pedidos

Tabla 1. Explicación de los símbolos que aparecen en la etiqueta del envase (continuación)

Símbolo	Explicación
LOT	Número de lote
#	Número del modelo
	Fabricado en
	Contenido del envase
	Documentación del producto
	Introductor del cable
	Diámetro interno
	Sistema de barrera estéril única
! USA	Solo aplicable en EE. UU.
MD	Dispositivo médico
PIN	Número PIN
	Herramienta de tunelización esternal

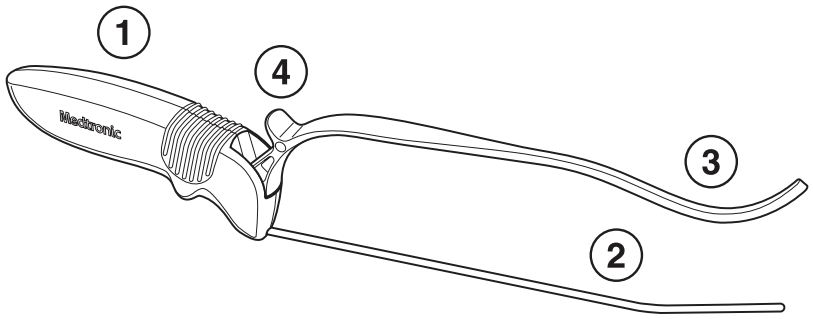
1 Deskripsi perangkat

Alat tunneling Epsila EV Model EAZ101 Medtronic dirancang untuk mengirimkan pengantar dan sadapan ekstravaskular ke dalam mediastinum anterior selama proses implan sistem perangkat ekstravaskular yang dapat diimplan.

Alat tunneling sternum, ditampilkan di *Gambar 1*, berisi komponen berikut:

- Pegangan.
- Tangkai tunneling stainless steel yang mengirimkan pengantar ke mediastinum anterior. (Lihat *Bab 11* untuk ukuran pengantar yang direkomendasikan.) Tangkai tunneling memiliki lengkungan yang telah dibentuk sebelumnya dan lentur untuk mengakomodasi anatomi pasien.
- Pemandu eksternal yang tetap berada di atas kulit dan mengindikasikan jarak dan arah tangkai tunneling. Pemandu eksternal memiliki engsel dan dapat dilepas untuk mengakomodasi preferensi dokter dan anatomi pasien.
- Bilah jempol dapat digunakan untuk menaikkan dan menurunkan pemandu eksternal.

Gambar 1. Alat tunneling sternum Model EAZ101



1 Pegangan
2 Tangkai tunneling stainless steel
3 Pemandu eksternal (dapat dilepas)
4 Bilah jempol

1.1 Isi kemasan

Alat tunneling yang disediakan steril. Setiap kemasan berisi item berikut:

- 1 alat tunneling sternum
- Dokumen produk

2 Indikasi

Alat tunneling sternum Epsila EV Model EAZ101 diindikasikan untuk penggunaan pada implan sadapan defibrilasi mediastinum anterior.

3 Kontraindikasi

Alat tunneling sternum Epsila EV Model EAZ101 dikontraindikasikan untuk penggunaan pada pasien dengan sternotomi sebelumnya.

4 Tujuan yang dimaksudkan

Alat tunneling sternum Medtronic Model EAZ101 merupakan alat medis sekali pakai yang steril, untuk digunakan pada implantasi sadapan defibrilasi mediastinum anterior yang kompatibel.

5 Pengguna yang dituju

Pengguna alat tunneling sternum Model EAZ101 merupakan individu yang terlatih dalam operasi dan penanganan alat.

6 Peringatan dan tindakan pencegahan

Catatan: Peringatan dan tindakan pencegahan prosedur medis yang berkaitan dengan sistem implan Medtronic disertakan di panduan yang disediakan bersama dengan perangkat terimplan.

Kompatibilitas produk – Alat ini belum diuji untuk penggunaan dengan produk non-Medtronic.

Penggunaan pediatri – Alat ini belum diuji secara spesifik untuk penggunaan pediatri.

Memeriksa kemasan steril – Periksa kemasan steril sebelum membukanya.

- Jika kemasan rusak atau terbuka, jangan gunakan produk dan hubungi perwakilan Medtronic.
- Jangan bawa kemasan atau isi kemasan pada suhu di atas 58°C (136°F) atau di bawah –35°C (–31°F). Jangan simpan kemasan atau isi kemasan pada suhu di atas 30°C (86°F) atau di bawah 15°C (59°F).
- Jangan gunakan produk setelah tanggal kedaluwarsa.

Sekali pakai – Alat ini hanya untuk sekali pakai. Penggunaan ulang dapat membahayakan integritas struktural alat atau menimbulkan risiko kontaminasi pada alat yang dapat berakibat pada cedera, penyakit, atau kematian pasien.

Sterilisasi – Medtronic telah mensterilkan isi kemasan menggunakan penyinaran sebelum pengiriman. Alat ini hanya untuk sekali pakai dan tidak dimaksudkan untuk disterilkan ulang.

Manajemen sistem dan implantasi – Implantasi dan manajemen sistem berkelanjutan harus dilakukan oleh orang yang terlatih dalam pengoperasian dan penanganan sistem dan harus tunduk dengan prosedur yang dijelaskan di instruksi teknis yang sesuai. Tidak cukupnya pelatihan dan kegagalan dalam mengikuti instruksi dapat membahayakan pasien.

Petunjuk pembuangan – Pembuangan alat sekali pakai sesuai dengan persyaratan lingkungan setempat.

7 Potensi efek samping

Berikut ini adalah potensi kejadian yang tidak diharapkan yang diketahui terkait dengan alat tunneling sternum:

- Trauma jaringan akut
- Reaksi alergi
- Perforasi jantung
- Tamponade jantung
- Kematian
- Rasa tidak nyaman
- Hematoma
- Perdarahan
- Hemotoraks
- Infeksi
- Kerusakan organ (hati, arteri mamaria, arteri diafragma)
- Nyeri
- Efusi perikardial
- Perikarditis
- Pneumotoraks
- Seroma

Catatan: Jika terjadi insiden serius terkait perangkat ini, segera laporkan insiden tersebut ke Medtronic dan badan pengawas atau otoritas yang berwajib.

8 Peristiwa yang tidak diharapkan dan data uji klinis

Informasi berikut hanya berlaku untuk penggunaan alat di Amerika Serikat. Untuk informasi tentang studi klinis dan peristiwa yang tidak diinginkan terkait alat ini, lihat panduan perangkat AS untuk defibrilator kardioverter ekstravaskular yang dapat diimplan.

9 Ringkasan keselamatan dan kinerja klinis

Ringkasan Keselamatan dan Kinerja Klinis (SSCP) dapat ditemukan di https://ec.europa.eu/tools/eudamed. Cari SSCP menggunakan nama produsen dan perangkat, dan salah satu elemen berikut, jika relevan: model perangkat, nomor referensi, nomor katalog, atau Identifikasi Perangkat Unik Dasar (UDI-DI Dasar) — 0763000B000082586.

10 Petunjuk penggunaan

Prosedur bedah dan teknik steril yang tepat merupakan tanggung jawab petugas medis. Prosedur berikut disediakan hanya untuk informasi. Beberapa teknik impan dapat berbeda-beda sesuai dengan preferensi dokter dan anatomi atau kondisi fisik pasien. Setiap dokter harus menerapkan informasi dalam petunjuk ini menurut pelatihan dan pengalaman medis profesional.

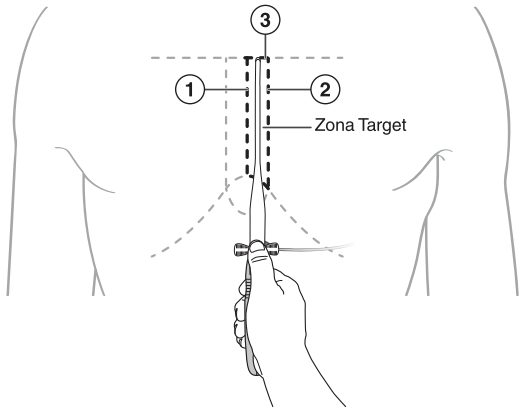
10.1 Mempersiapkan untuk melakukan tunneling

1. Siapkan pengantar untuk mengimplan sadapan sesuai petunjuk di dokumen produk yang dikemas dengan pengantar. Tempelkan alat suntik yang terisi dengan larutan garam ke port samping pengantar dan buka sumbat.
2. Jika diperlukan, tekuk tangkai tunneling pada alat tunneling sternum secara manual sampai membentuk lengkungan yang sesuai dengan anatomi pasien. Sudutnya harus memungkinkan ujung tangkai tunneling untuk tetap menyentuh (atau sedekat mungkin dengan) posterior sternum selama proses tunneling.

   Catatan: Periksa pengantar akan adanya kerusakan sebelum penggunaan.
3. Muat kembali pengantar ke tangkai tunneling.
4. Gambar titik penting pada kulit pasien. Titik penting yang direkomendasikan termasuk lokasi berikut:
   - Proses xiphoid
   - Batas tulang rusuk
   - Garis tengah sternum
   - Batas lateral kiri sternum
   - Atas siluet jantung
   - Lokasi sayatan
   - Lokasi kantong perangkat

   Catatan: Tulang belakang bukan titik penting yang direkomendasikan.

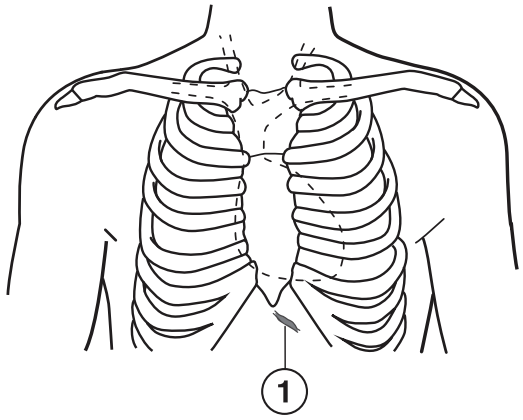
Gambar 2. Zona tunneling target



1 Garis tengah sternum
2 Batas lateral kiri sternum
3 Atas siluet jantung

5. Sayat kulit di bawah proses xiphoid, sedikit di kiri garis tengah, sesuai yang ditampilkan di *Gambar 3*. Untuk menghindari potensi peristiwa yang tidak diinginkan karena sentuhan dengan organ, pilih lokasi sayatan yang mengakomodasi sudut untuk memasukkan alat sternum yang benar berdasarkan anatomi pasien. Buat sayatan cukup besar untuk mengakomodasi fiksasi lengan penahan.

Gambar 3. Tempat sayatan



1 Tempat sayatan

6. Lakukan diseksi tumpul pada lokasi diafragma, mengunakan fluoroskopi lateral sebagai pemandu. Mulai diseksi tumpul dengan menggunakan jari untuk melintasi lokasi diafragma. Konfirmasi bahwa bidang jaringan sudah benar menggunakan jari.

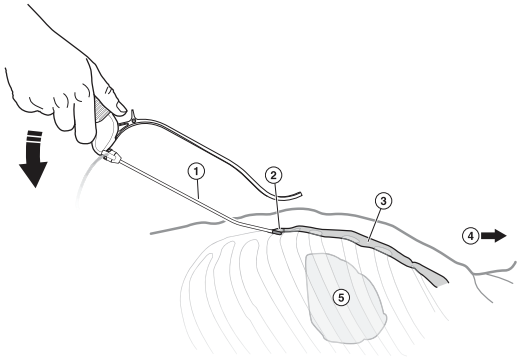
10.2 Melakukan tunneling di bawah sternum

Catatan:

- Jika pasien memiliki fitur anatomi yang sulit, seperti jaringan subkutan yang tebal, sternum melengkung, atau proses xiphoid menonjol, naikkan pemandu eksternal sesuai yang diperlukan sehingga tidak mengganggu proses awal masuknya. Setelah tangkai tunneling dimasukkan, Anda dapat menurunkan pemandu eksternal untuk digunakan sebagai indikator visual arah lateral dan jarak kranial selagi Anda melakukan tunneling.
- Sebelum memasukkan tangkai tunneling, Anda dapat memilih untuk melepas pemandu eksternal. Untuk melepas pemandu eksternal, tarik ke atas sepenuhnya sampai terdengar bunyi klik, lalu tarik dari pegangan dengan arah berkebalikan dari tangkai tunneling.
  - **Catatan:** Jangan melepas pemandu eksternal saat melakukan tunneling.

1. Dengan fluoroskopi lateral sebagai pemandu, masukkan tangkai tunneling dan pengantar ke sayatan. Majukan ujung tangkai tunneling agar menyentuh persimpangan xiphisternal.
2. Setelah tangkai tunneling berada di bawah sternum, segera turunkan pegangan ke bawah perut sehingga tangkai tunneling sejajar dengan sternum. Untuk menghindari potensi peristiwa yang tidak diinginkan karena sentuhan organ, jaga agar ujung tangkai tunneling tetap menyentuh (atau sedekat mungkin dengan) posterior sternum. (Lihat *Gambar 4*.) Gunakan fluoroskopi lateral sebagai pemandu.

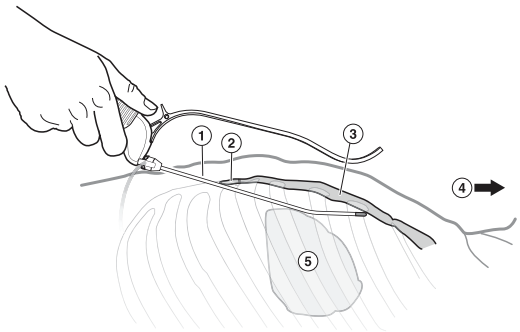
Gambar 4. Tampilan lateral: Ujung tangkai tunneling bersentuhan dengan persimpangan xiphisternal



1 Tangkai tunneling
2 Persimpangan xiphisternal
3 Sternum
4 Kepala
5 Jantung

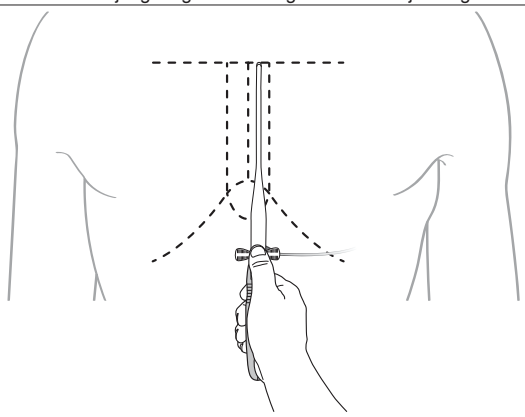
3. Meski tunneling harus terjadi di tampilan lateral, konfirmasi arah alat harus terjadi di tampilan AP untuk memastikan alat tetap berada di zona tunneling target. Majukan alat tunneling ke atas siluet jantung, dengan sering-sering menyesuaikan antara tampilan lateral dan AP untuk mengonfirmasi trajektori alat. Lihat *Gambar 5*. Saat melakukan tunneling, pertimbangkan menggunakan pemandu eksternal untuk memastikan bahwa tangkai tunneling tetap berada di antara batas sternum, sesuai yang ditampilkan di *Gambar 6*.

Gambar 5. Tampilan lateral: Ujung tangkai tunneling di atas siluet jantung



1 Tangkai tunneling
2 Persimpangan xiphisternal
3 Sternum
4 Kepala
5 Jantung

Gambar 6. Tampilan eksternal: Ujung tangkai tunneling di atas siluet jantung



Catatan: Jika Anda merasakan resistansi saat melakukan tunneling, berhenti dan pastikan lokasi tangkai tunneling menggunakan tampilan fluoroskopi lain. Kemudian, lakukan langkah berikut menggunakan fluoroskopi:

a. Tarik sedikit tangkai tunneling bersama dengan pengantar.
b. Posisikan ulang tangkai tunneling untuk memastikan bahwa tangkai bersentuhan (atau sedekat mungkin dengan) posterior sternum dan bagian dalam zona tunneling target, seperti yang ditunjukkan di *Gambar 2*.
c. Jika pengantar rusak, gunakan pengantar baru dan mulai proses tunneling lagi.

4. Pastikan tempat tangkai tunneling menggunakan pemandu eksternal atau tampilan fluoroskopik lain.

10.3 Melepas tangkai tunneling dan memasukan sadapan

1. Untuk meminimalkan masuknya udara, pastikan bahwa alat suntik yang berisi larutan garam menempel pada port samping pengantar dan sumbat terbuka.
2. Tahan pengantar di tempatnya saat melepas tangkai tunneling.
   Catatan: Jangan majukan pengantar tanpa tangkai tunneling di dalam.
3. Masukkan sadapan ke pengantar sesuai petunjuk di panduan teknis sadapan.

11 Spesifikasi

Parameter	Model EAZ101
Panjang	Panjang keseluruhan: 35,5 cm (14 in) Panjang tangkai tunneling: 22,3 cm (8,8 in)
Diameter tangkai tunneling	3,0 mm (9 Fr)
Bahan	Tangkai tunneling: stainless steel 304 Pemandu eksternal: akrilonitril butadiena stiren (ABS) Pegangan: polikarbonat
Pengantar yang direkomendasikan	Diameter: 3,0 mm (9 Fr) Panjang: 19,13 cm (7,53 in)

12 Tanda kesesuaian CE

CE 0344

13 Penjelasan simbol pada pelabelan kemasan

Lihat label kemasan untuk melihat simbol yang digunakan untuk produk ini.

Tabel 1. Penjelasan simbol pada pelabelan kemasan

Simbol	Penjelasan
CE 0344	Conformité Européenne (European Conformity/Kesesuaian untuk Uni Eropa). Simbol ini berarti bahwa perangkat sepenuhnya mematuhi undang-undang yang berlaku di Uni Eropa.
	Jangan gunakan jika kemasan rusak
	Jangan dipakai ulang
	Batas suhu
	Batas suhu transit
	Batas suhu penyimpanan
	Buka di sini
STERILE R	Disterilkan menggunakan penyinaran
	Perhatian
	Lihat petunjuk penggunaan
	Tanggal produksi
	Produsen
	Pengimpor
EC REP	Perwakilan resmi di negara-negara Eropa
	Tanggal "gunakan paling lambat"
REF	Nomor pesan ulang
LOT	Nomor lot
#	Nomor model
	Diproduksi di

Tabel 1. Penjelasan simbol pada pelabelan kemasan (lanjutan)

Simbol	Penjelasan
	Isi kemasan
	Dokumen produk
	Pengantar sadapan
	Diameter bagian dalam
	Sistem pembatas steril tunggal
	Hanya untuk audiens di AS
	Perangkat medis
	Nomor PIN
	Alat tunneling sternum

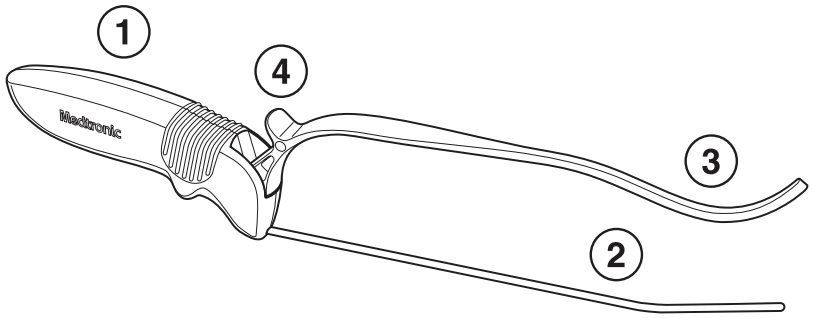
1 Описание устройства

Инструмент для туннелирования под грудиной модели EAZ101 компании Medtronic Epsila EV предназначен для доставки интродьюсера и экстраваскулярного электрода в переднее средостение при имплантации системы экстраваскулярного имплантируемого устройства.

Инструмент для туннелирования под грудиной, показанный на *Рис. 1*, состоит из следующих компонентов:

- Рукоятка.
- Стержень для туннелирования из нержавеющей стали, доставляющий интродьюсер в переднее средостение. (рекомендуемый размер интродьюсера см. в *Гл. 11*). Стержень для туннелирования имеет предварительно сформированный изгиб и может дополнительно изгибаться в соответствии с особенностями анатомии пациента.
- Наружный направитель, который остается над кожей и указывает дальность введения и направление стержня для туннелирования. Наружный направитель можно откинуть или снять с учетом предпочтений врача и анатомии пациента.
- Упор для большого пальца, с помощью которого можно поднять и опустить наружный направитель.

Рисунок 1. Инструмент для туннелирования под грудиной модели EAZ101



1 Рукоятка
2 Стержень для туннелирования из нержавеющей стали
3 Наружный направитель (съемный)
4 Упор для большого пальца

1.1 Содержимое упаковки

Инструмент для туннелирования поставляется стерильным. В каждой упаковке содержатся следующие компоненты:

- 1 инструмент для туннелирования под грудиной
- Документация по продукту

2 Показания

Инструмент для туннелирования под грудиной Epsila EV модели EAZ101 показан для применения при имплантации совместимого электрода для дефибрилляции через переднее средостение.

3 Противопоказания

Инструмент для туннелирования под грудиной Epsila EV модели EAZ101 противопоказан для применения у пациентов, ранее перенесших стернотомию.

4 Предусмотренное назначение

Инструмент для туннелирования под грудиной модели EAZ101 компании Medtronic представляет собой одноразовое стерильное медицинское изделие, показанное для применения при имплантации совместимого электрода для дефибрилляции через переднее средостение.

5 Предполагаемые пользователи

К использованию инструмента для туннелирования под грудиной модели EAZ101 допускаются лица, прошедшие подготовку по работе и обращению с ним.

6 Предупреждения и меры предосторожности

Примечание. Предупреждения и меры предосторожности касательно медицинских процедур, относящихся к имплантированной системе компании Medtronic, включены в руководство, которое поставляется с имплантируемым устройством.

Совместимость продукта – Использование этого инструмента с продуктами, произведенными не компанией Medtronic, не проверялось.

Применение в детском возрасте – Специальные исследования применения инструмента у детей не проводились.

Осмотр стерильной упаковки – Перед открытием осмотрите стерильную упаковку.

- Если упаковка имеет повреждения или была открыта, не используйте изделие и обратитесь в представительство компании Medtronic.

- Не транспортируйте упаковку или ее содержимое при температуре выше 58°C (136°F) или ниже –35°C (–31°F). Не храните упаковку или ее содержимое при температуре выше 30°C (86°F) или ниже 15°C (59°F).
- Не используйте изделие после окончания срока годности.

Однократное использование – Этот инструмент предназначен только для однократного использования. Повторное использование может нарушить структурную целостность инструмента или создать риск его заражения, что может привести к травме, заболеванию или смерти пациента.

Стерилизация – Перед поставкой компания Medtronic стерилизовала содержимое упаковки облучением. Этот инструмент является одноразовым и не предназначен для повторной стерилизации.

Имплантация и управление системой – Имплантация и непрерывное управление системой должны выполнятся врачами, обученными управлению системой и обращению с ней, и ознакомившимися с процедурами, описанными в соответствующих технических руководствах. Ненадлежащая подготовка или несоблюдение инструкций могут привести к причинению вреда пациентам.

Утилизация – Утилизируйте одноразовый инструмент в соответствии с требованиями местного законодательства по защите окружающей среды.

7 Возможные нежелательные явления

Далее перечислены предсказуемые возможные нежелательные явления, связанные с применением инструмента для туннелирования под грудиной:

- Острое травмирование тканей
- Аллергическая реакция
- Перфорация сердца
- Тампонада сердца
- Смерть
- Дискомфорт
- Гематома
- Кровоизлияние
- Гемоторакс
- Инфицирование
- Повреждение органов (печень, маммарные артерии, диафрагмальные артерии)
- Боль
- Перикардиальный выпот
- Перикардит
- Пневмоторакс
- Серома

Примечание. В случае серьезного происшествия, связанного с работой устройства, немедленно сообщите о произошедшем компании Medtronic и уполномоченному регулирующему органу.

8 Нежелательные явления и данные клинических исследований

Следующая информация относится только к применению инструмента в США. Информацию о клинических исследованиях и нежелательных явлениях, связанных с этим инструментом, см. в руководстве по экстраваскулярному имплантируемому кардиовертеру-дефибриллятору для пользователей в США.

9 Сводные данные по безопасности и клинической эффективности

Краткий отчет о безопасности и клинической эффективности (SSCP) представлен на веб-сайте https://ec.europa.eu/tools/eudamed. Вы можете найти отчет SSCP по названию изготовителя и наименованию изделия, а также по следующим данным (если применимо): модель изделия, учетный номер, номер по каталогу или основной уникальный идентификационный номер изделия (основной UDI-DI): 0763000B000082586.

10 Указания по применению

За надлежащее выполнение хирургических процедур и применения правил асептики и антисептики несут ответственность медицинские работники. Ниже, исключительно с информационной целью, описаны некоторые процедуры. Некоторые методы имплантации могут изменяться в зависимости от предпочтений врача, анатомических особенностей пациента и его физического состояния. Каждый врач должен применять информацию, содержащуюся в этих инструкциях, согласно профессиональной медицинской подготовке и полученному опыту.

10.1 Подготовка к туннелированию

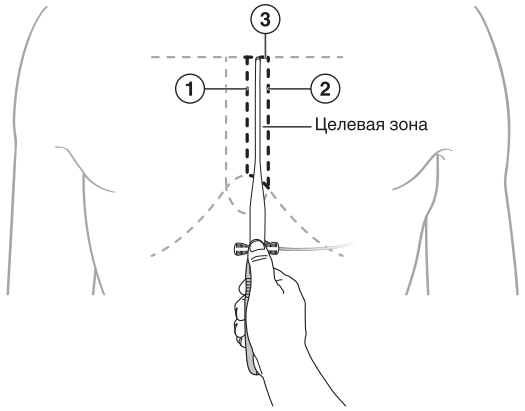
1. Подготовьте интродьюсер для имплантации электрода согласно инструкциям, которые приведены в документации, поставляемой вместе с интродьюсером. Оставьте заполненный физиологическим раствором шприц подсоединенным к боковому порту интродьюсера и откройте запорный кран.
2. При необходимости вручную придайте стержню инструмента для туннелирования под грудиной изгиб сообразно анатомии пациента. При туннелировании угол должен позволять кончику стержня для туннелирования оставаться в контакте с задней поверхностью грудины или быть как можно ближе к ней.

   Примечание. Перед использованием осмотрите интродьюсер на предмет повреждения.
3. Поместите интродьюсер на стержень для туннелирования с проксимального конца.

4. Нанесите ориентировочные метки на кожу пациента. Рекомендуемые метки включают следующие места:
   - Мечевидный отросток
   - Границы ребер
   - Срединная линия грудины
   - Левый край грудины
   - Верх тени сердца
   - Расположение разреза
   - Расположение "кармана" устройства

   Примечание. Позвоночник не рекомендуется использовать в качестве анатомического ориентира.

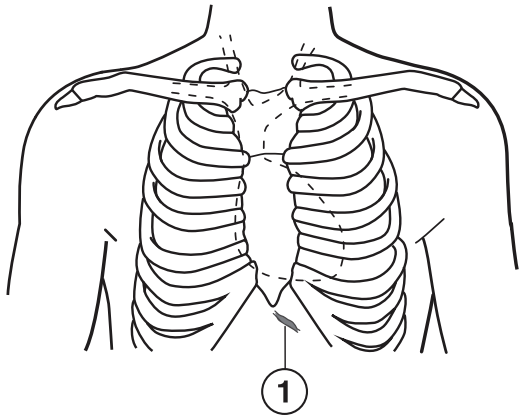
   Рисунок 2. Целевая зона туннелирования



1 Срединная линия грудины
2 Левый край грудины
3 Верх тени сердца

5. Разрежьте кожу ниже мечевидного отростка, чуть левее срединной линии, как показано на *Рис. 3*. Чтобы избежать возможных нежелательных явлений вследствие контакта с органами, выбирайте расположение разреза с учетом надлежащего угла введения инструмента для туннелирования под грудиной на основании анатомии пациента. Сделайте разрез достаточного размера для размещения фиксирующей муфты.

   Рисунок 3. Место разреза



1 Место разреза

6. Выполните тупую диссекцию прикреплений диафрагмы под контролем боковой рентгеноскопии. Начните тупое разделение тканей, используя палец для прохождения креплений диафрагмы. Используя палец, подтвердите нахождение в нужной плоскости ткани.

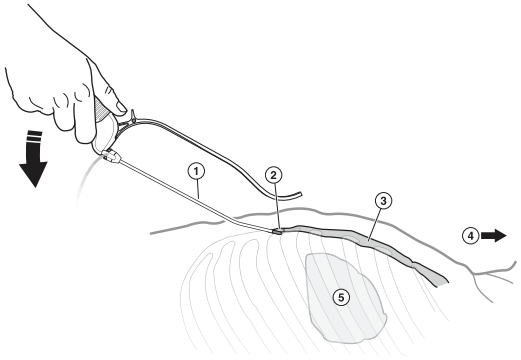
10.2 Туннелирование под грудиной

Примечания.

- Если у пациента имеются сложные анатомические особенности, например толстая подкожная клетчатка, изогнутая грудина или выступающий мечевидный отросток, поднимите наружный направитель насколько необходимо, чтобы он не мешал первоначальному введению. Когда стержень для туннелирования будет введен, можно опустить наружный направитель, чтобы использовать его как визуальный индикатор бокового отклонения и краниального расстояния по мере туннелирования.
- Перед введением стержня для туннелирования, при желании, отсоедините наружный направитель. Чтобы отсоединить наружный направитель, потяните его вверх до щелчка, затем снимите его с рукоятки в направлении, противоположном стержню для туннелирования.
  - **Примечание.** Не отсоединяйте наружный направитель во время туннелирования.

1. Под контролем боковой рентгеноскопии введите стержень для туннелирования и интродьюсер в разрез. Продвиньте кончик стержня для туннелирования до контакта с синхондрозом мечевидного отростка.
2. Как только кончик стержня для туннелирования окажется под грудиной, немедленно опустите рукоятку к животу, чтобы стержень для туннелирования был параллелен грудине. Чтобы избежать возможных нежелательных явлений вследствие контакта с органами, удерживайте кончик стержня для туннелирования в контакте с задней поверхностью грудины или как можно ближе к ней (см. *Рис. 4*). Используйте боковую рентгеноскопию для контроля.

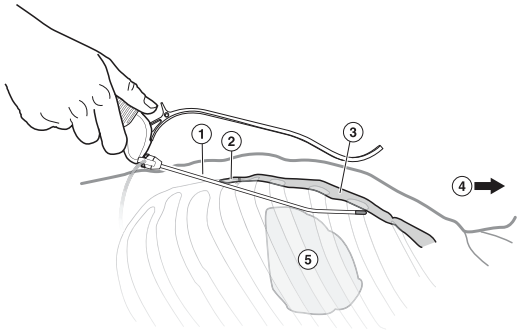
Рисунок 4. Вид сбоку: кончик стержня для туннелирования в контакте с синхондрозом мечевидного отростка



1 Стержень для туннелирования
2 Синхондроз мечевидного отростка
3 Грудина
4 Голова
5 Сердце

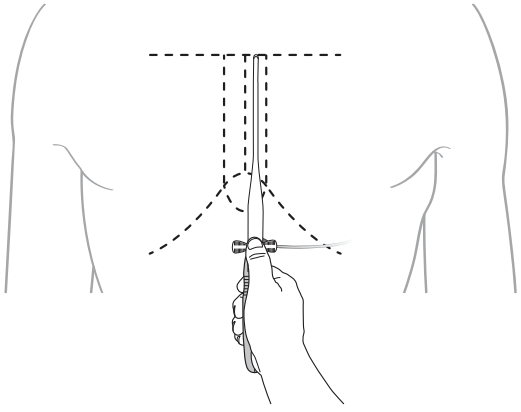
3. Хотя во время самого туннелирования визуализацию выполняют в латеральной проекции, для определения направления инструмента с целью подтверждения его нахождения в целевой зоне туннелирования используется визуализация в переднезадней проекции. Проводите инструмент для туннелирования к вершине силуэта сердца, периодически сменяя латеральную проекцию на переднезаднюю с целью подтверждения траектории инструмента. См. *Рис. 5*. Во время туннелирования рассмотрите возможность использования наружного направителя, чтобы обеспечить нахождение стержня для туннелирования в пределах границ грудины, как показано на *Рис. 6*.

Рисунок 5. Вид сбоку: кончик стержня для туннелирования у верхней части тени сердца



1 Стержень для туннелирования
2 Синхондроз мечевидного отростка
3 Грудина
4 Голова
5 Сердце

Рисунок 6. Вид снаружи: кончик стержня для туннелирования у верхней части тени сердца



Примечание. Если при туннелировании ощущается сопротивление, прекратите туннелирование и проверьте положение стержня для туннелирования, используя другую рентгеноскопическую проекцию. Затем под рентгеноскопическим контролем выполните следующие действия:

a. Немного отведите назад стержень для туннелирования вместе с интродьюсером.
b. Измените положение стержня для туннелирования таким образом, чтобы обеспечить его контакт с задней поверхностью грудины или максимально возможную близость к ней, так, чтобы он находится в пределах целевой зоны туннелирования, как показано в *Рис. 2*.
c. Если интродьюсер поврежден, используйте новый интродьюсер и начните процесс туннелирования снова.

4. Подтвердите положение стержня для туннелирования, используя наружный направитель или другую рентгеноскопическую проекцию.

10.3 Удаление стержня для туннелирования и введение электрода

1. Чтобы максимально ограничить вхождение воздуха, убедитесь, что заполненный физиологическим раствором шприц подсоединен к боковому порту интродьюсера и запорный кран открыт.
2. Удерживайте интродьюсер на месте при удалении стержня для туннелирования.
   Примечание. Не продвигайте интродьюсер вперед без введенного стержня для туннелирования.
3. Введите электрод в интродьюсер, соблюдая инструкции из технического руководства к электроду.

11 Технические характеристики

Параметр	Модель EAZ101
Длина	Общая длина: 35,5 см (14 in) Длина стержня для туннелирования: 22,3 см (8,8 in)
Диаметр стержня для туннелирования	3,0 мм (9 Fr)
Материал	Стержень для туннелирования: нержавеющая сталь марки 304 Наружный направитель: акрилонитрилбутадиенстирол (АБС) Рукоятка: поликарбонат
Рекомендуемый интродьюсер	Диаметр: 3,0 мм (9 Fr) Длина: 19,13 см (7,53 in)

12 Знак соответствия CE

CE 0344

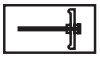
13 Объяснение символов, приведенных на упаковке

См. на этикетках упаковки, какие символы применимы к данному продукту.

Таблица 1. Объяснение символов, приведенных на этикетке упаковки

Символ	Объяснение
CE 0344	Conformité Européenne (Европейское соответствие). Этот символ обозначает, что изделие полностью соответствует требованиям применимых директив Европейского союза.
	Не использовать при повреждении упаковки
	Запрет на повторное применение
	Температурный диапазон
	Диапазон температуры транспортировки
	Диапазон температуры хранения
	Открывать здесь
	Радиационная стерилизация
	Предостережение
	Обратитесь к инструкции по применению
	Дата изготовления
	Изготовитель

Таблица 1. Объяснение символов, приведенных на этикетке упаковки (продолжение)

Символ	Объяснение
	Импортер
EC REP	Уполномоченный представитель в Европейском сообществе
	Срок годности
REF	Номер для заказа
LOT	Номер партии
#	Номер модели
	Произведено в
	Содержимое упаковки
	Документация по продукту
	Интродьюсер электрода
	Внутренний диаметр
	Система с единственным стерильным барьером
! USA	Только для США
MD	Медицинское устройство
PIN	Номер ПИН
	Инструмент для туннелирования под грудиной

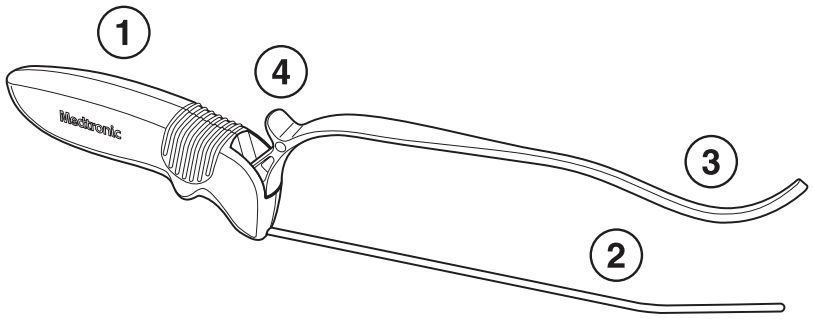
1 Opis uređaja

Medtronic Epsila EV model EAZ101 sternalnog alata za pravljenje prolaza je namenjen da dovede uvodnik i ekstravaskularni provodnik u prednji medijastinum, prilikom implantacije ekstravaskularnog implantabilnog sistema uređaja.

Sternalni alat za pravljenje prolaza prikazan na *sl. 1* se sastoji od sledećih komponenti:

- Ručica.
- Šipka za pravljenje prolaza od nerđajućeg čelika koja dovodi uvodnik u prednji medijastinum. (Više o preporučenoj veličini uvodnika nudi *pogl. 11*.) Šipka za pravljenje prolaza ima fabrički napravljenu krivinu i može se savijati da bi se prilagodila pacijentovoj anatomiji.
- Eksterni vodič koji ostaje iznad kože i koji pokazuje na kojoj se udaljenosti nalazi i kako je usmerena šipka za pravljenje prolaza. Eksterni vodič je pričvršćen šarkom i može se postavljati i skidati shodno željama lekara i pacijentovoj anatomiji.
- Jezičak koji se pomera palcem i koji služi za podizanje i spuštanje eksternog vodiča.

Slika 1. Model EAZ101 sternalnog alata za pravljenje prolaza



1 Drška
2 Šipka za pravljenje prolaza od nerđajućeg čelika
3 Eksterni vodič (uklonjiv)
4 Jezičak koji se pomera palcem

1.1 Sadržaj pakovanja

Alatka za pravljenje prolaza isporučuje se sterilna. Svako pakovanje sadrži sledeće stavke:

- 1 Sternalni alat za pravljenje prolaza
- Dokumentacija o proizvodu

2 Indikacije

Epsila EV model EAZ101 sternalnog alata za pravljenje prolaza je indikovan za primenu prilikom implantacije kompatibilnog provodnika za defibrilaciju u prednji medijastinum.

3 Kontraindikacije

Primena Epsila EV modela EAZ101 sternalnog alata za pravljenje prolaza je kontraindikovana kod pacijenata, kod kojih je ranije vršena sternotomija.

4 Predviđena namena

Medtronic model EAZ101 sternalnog alata za pravljenje prolaza predstavlja sterilno medicinsko sredstvo za jednokratnu upotrebu, namenjeno za primenu prilikom implantacije kompatibilnog provodnika za defibrilaciju u prednji medijastinum.

5 Predviđeni korisnici

Korisnici sternalnog alata za pravljenje prolaza model EAZ101 su osobe obučene za rad i rukovanje ovim alatom.

6 Upozorenja i mere predostrožnosti

Napomena: Medicinska upozorenja i mere predostrožnosti koje se odnose na Medtronic implantirani sistem obuhvaćeni su priručnikom koji je dostavljen uz implantabilni uređaj.

Kompatibilnost proizvoda – Ovaj alat nije ispitan za primenu sa proizvodima koje ne proizvodi kompanija Medtronic.

Primena kod dece – Alat nije posebno testiran za primenu kod dece.

Provera sterilnog pakovanja – Pregledajte sterilno pakovanje pre otvaranja.

- Ako je pakovanje oštećeno ili otvoreno, nemojte koristiti proizvod i obratite se predstavniku preduzeća Medtronic.
- Nemojte transportovati pakovanje ni sadržaj pakovanja na temperaturama iznad 58°C (136°F), kao ni ispod -35°C (-31°F). Nemojte čuvati pakovanje ni sadržaj pakovanja na temperaturama iznad 30°C (86°F), kao ni ispod 15°C (59°F).
- Ne koristite proizvod posle isteka roka važenja.

Jednokratna upotreba – Ovaj alat je namenjen samo za jednokratnu upotrebu. Ponovljena upotreba može ugroziti strukturni integritet alata i stvoriti rizik od kontaminacije alata, koja može dovesti do povrede, bolesti ili smrti pacijenta.

Sterilizacija – Medtronic je sterilisao sadržaj pakovanja primenom jonizujućeg zračenja pre isporuke. Ovaj alat je namenjen samo za jednokratnu upotrebu i nije predviđena ponovna sterilizacija.

Implantacija i upravljanje sistemom – Implantaciju i tekuće upravljanje sistemom moraju da vrše pojedinci obučeni za rad i rukovanje sistemom i moraju da budu usklađeni sa procedurama opisanim u odgovarajućim tehničkim uputstvima. Neodgovarajuća obuka ili propust u poštovanju uputstava mogu da dovedu do povrede pacijenata.

Odlaganje – Alat za jednokratnu upotrebu odložite u otpad shodno lokalnim ekološkim propisima.

7 Mogući neželjeni događaji

Ovde navodimo moguće neželjene događaje povezane sa primenom sternalnog alata za pravljenje prolaza koji se mogu predvideti:

- Akutna povreda tkiva
- Alergijska reakcija
- Srčana perforacija
- Srčana tamponada
- Smrt
- Nelagodnost
- Hematom
- Krvarenje
- Hemotoraks
- Infekcija
- Oštećenje organa (jetre, torakalnih arterija, freničnih arterija)
- Bol
- Perikardijalna efuzija
- Perikarditis
- Pneumotoraks
- Serom

Napomena: Ako dođe do ozbiljnog incidenta u vezi sa ovim sredstvom, odmah prijavite incident kompaniji Medtronic i nadležnoj službi ili regulatornom telu.

8 Neželjeni događaji i podaci dobijeni kliničkim ispitivanjem

Sledeće informacije se odnose isključivo na korišćenje alata u Sjedinjenim Američkim Državama. Informacije koje se odnose na kliničke studije i neželjene događaje povezane sa ovim alatom možete pronaći u priručniku medicinskog sredstva za tržište SAD ekstravaskularnog implantabilnog kardioverter defibrilatora.

9 Sažeti prikaz bezbednosti i kliničkog učinka

Sažetak bezbednosnih i kliničkih performansi (SSCP) možete pronaći na https://ec.europa.eu/tools/eudamed. SSCP potražite na osnovu imena proizvođača i naziva sredstva, kao i na osnovu bilo kog od sledećih elemenata, kako je primereno: model sredstva, referentni broj, kataloški broj ili osnovni jedinstveni identifikacioni broj uređaja (osnovni UDI-DI) broj – 0763000B000082586.

10 Uputstva za upotrebu

Medicinsko osoblje je odgovorno za sprovođenje ispravnih hirurških procedura i sterilnih tehnika. Sledeće procedure se pružaju isključivo u informativne svrhe. Neke tehnike implantacije razlikuju se u zavisnosti od ličnog načina rada lekara, kao i anatomije i fizičkog stanja pacijenta. Svaki lekar mora da primeni informacije iz ovih uputstava u skladu sa stručnom medicinskom obukom i iskustvom.

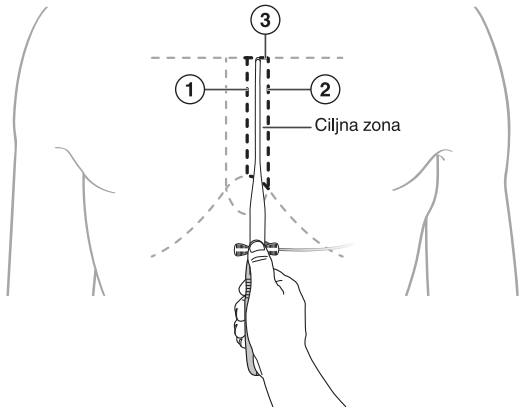
10.1 Priprema za pravljenje prolaza

1. Pripremite uvodnik za implantat provodnika prema uputstvima iz dokumentacije o proizvodu koja se isporučuje u paketu sa uvodnikom. Neka špric napunjen fiziološkim rastvorom ostane pripojen na bočni ulaz uvodnika i otvorite slavinu.
2. Prema potrebi, ručno savijte šipku sternalnog alata za pravljenje prolaza u oblik koji odgovara pacijentovoj anatomiji. Dobijeni ugao mora omogućavati da vrh šipke za pravljenje prolaza ostane u kontaktu sa zadnjom stranom sternuma tokom pravljenja prolaza (ili da joj bude što je bliže moguće).

   Napomena: Pre korišćenja pregledajte da li na uvodniku ima oštećenja.
3. Navucite uvodnik na šipku za pravljenje prolaza.
4. Nacrtajte orijentire na pacijentovoj koži. Preporučeni orijentiri obuhvataju sledeće lokacije:
   - Ksifoidni nastavak
   - Ivice rebara
   - Srednja linija sternuma (prednja središnja linija)
   - Leva parasternalna linija
   - Vrh srčane senke
   - Mesto reza
   - Mesto džepa za uređaj

   Napomena: Kičma nije preporučeni orijentir.

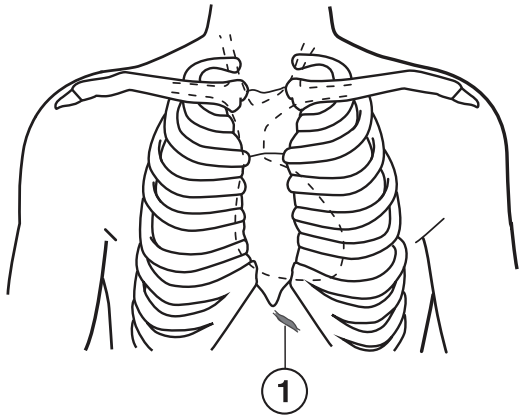
Slika 2. Ciljna zona za pravljenje prolaza



1 Srednja linija sternuma (prednja središnja linija)
2 Leva parasternalna linija
3 Vrh srčane senke

5. Napravite rez na koži ispod ksifoidnog nastavka, blago ulevo od prednje središnje linije, kao što je prikazano na *sl. 3*. Da bi se izbegli eventualni neželjeni događaji usled kontakta sa organima, odaberite mesto za rez koje omogućava uvođenje sternalnog alata pod određenim uglom, shodno pacijentovoj anatomiji. Napravite dovoljno veliki rez, kako bi bilo moguće pričvrstiti navlaku za fiksiranje.

Slika 3. Mesto reza



1 Mesto reza

6. Obavite disekciju dijafragmalnih pripoja tupim instrumentom, orijentišući se pomoću lateralne fluoroskopije. Počnite tupu disekciju koristeći prst za prolaz pored dijafragmatičnih pripoja. Prstom potvrdite da ste u odgovarajućoj tkivnj ravni.

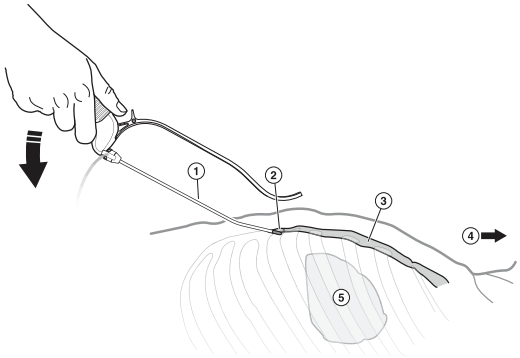
10.2 Pravljenje prolaza ispod sternuma

Napomene:

- Ako kod pacijenta postoje problematična anatomska svojstva, poput debelog potkožnog tkiva, izražene krivine sternuma ili izraženog ksifoidnog nastavka, prema potrebi podignite eksterni vodič kako ne bi ometao inicijano uvođenje. Nakon ubacivanja šipke za pravljenje prolaza, možete da spustite eksterni vodič kako bi vam služio kao vizuelni indikator lateralnog pravca i kranijalne daljine tokom pravljenja prolaza.
- Ako je potrebno, uklonite eksterni vodič pre ubacivanja šipke za pravljenje prolaza. Da biste uklonili eksterni vodič, povucite ga sasvim prema gore, sve dok ne „klikne", a zatim ga skinite sa drške u smeru suprotnom od šipke za pravljenje prolaza.
  - **Napomena:** Nemojte uklanjati eksterni vodič za vreme pravljenja prolaza.

1. Koristeći lateralnu fluoroskopiju za orijentaciju, ubacite šipku za pravljenje prolaza i uvodnik u rez. Gurajte vrh šipke za pravljenje prolaza, dok ne dođete u kontakt sa ksifosternalnim spojem.
2. Kad se vrh šipke za pravljenje prolaza nađe ispod sternuma, odmah spustite dršku prema abdomenu, tako da šipka za pravljenje prolaza bude paralelna grudnoj kosti. Da bi se izbegli eventualni neželjeni događaji usled kontakta sa organima, odaberite mesto za rez koje omogućava uvođenje sternalnog alata pod određenim uglom, shodno pacijentovoj anatomiji. (Pogledajte odeljak *sl. 4*.) Za orijentaciju koristite lateralnu fluoroskopiju.

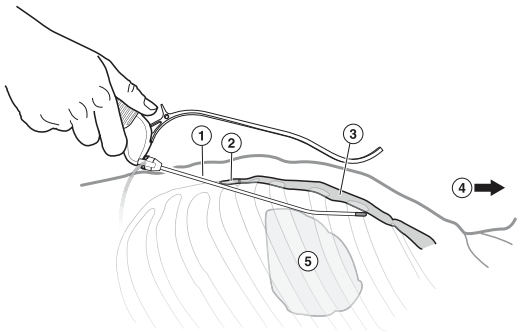
Slika 4. Bočni prikaz: Štap za pravljenje prolaza u kontaktu sa ksifosternalnim spojem



1 Šipka za pravljenje prolaza
2 Ksifosternalni spoj
3 Sternum
4 Glava
5 Srce

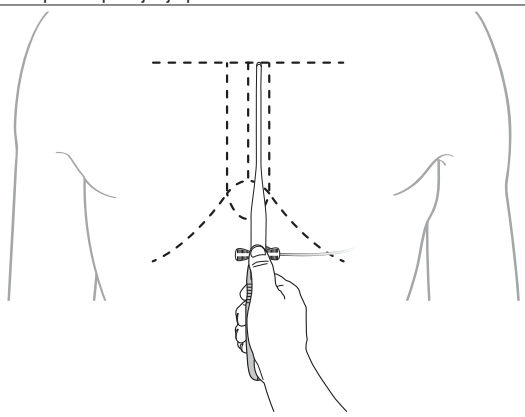
3. Iako se postupak pravljenja prolaza mora pratiti u bočnoj projekciji (profil), potvrdu usmerenosti alata treba vršiti u AP projekciji kako biste bili sigurni da se alat nalazi u ciljnoj zoni za pravljenje prolaza. Gurajte alat za pravljenje prolaza do vrha srčane senke, uz često prebacivanje između bočne i AP projekcije kako bi se uverili da je putanja alata odgovarajuća. Pogledajte *sl. 5*. Da biste bili sigurni da se šipka za pravljenje prolaza nalazi u granicama grudne kosti, razmotrite primenu eksternog vodiča, kao što je prikazano na *sl. 6*.

Slika 5. Bočni prikaz: šipka za pravljenje prolaza na vrhu srčane senke



1 Šipka za pravljenje prolaza
2 Ksifosternalni spoj
3 Sternum
4 Glava
5 Srce

Slika 6. Spoljni prikaz: šipka za pravljenje prolaza na vrhu srčane senke



Napomena: Ako za vreme pravljenja prolaza osetite otpor, prekinite sa pravljenjem prolaza i potvrdite lokaciju šipke za pravljenje prolaza pomoću fluoroskopskog prikaza iz drugog ugla. Nakon toga, obavite sledeće korake uz pomoć fluoroskopije:

a. Neznatno izvucite šipku za pravljenje prolaza zajedno sa uvodnikom.
b. Premestite šipku za pravljenje prolaza, vodeći računa da ostane u kontaktu sa zadnjom stranom sternuma (ili da joj bude što je bliže moguće) i unutar ciljne zone za pravljenje prolaza, kao što je prikazano na *sl. 2*.
c. Ako je uvodnik oštećen, upotrebite novi uvodnik i započnite postupak pravljenja prolaza od početka.

4. Potvrdite položaj šipke za pravljenje prolaza, koristeći spoljašnji vodič ili fluoroskopski prikaz iz drugog ugla.

10.3 Uklanjanje šipke za pravljenje prolaza i ubacivanje provodnika

1. Kako bi se smanjilo prodiranje vazduha, vodite računa da špric napunjen fiziološkim rastvorom bude pripojen na bočni ulaz uvodnika i da slavina bude otvorena.
2. Držite uvodnik na mestu dok uklanjate šipku za pravljenje prolaza.
   Napomena: Nemojte gurati uvodnik, ako šipka za pravljenje prolaza nije ubačena.
3. Umetnite provodnik u uvodnik u skladu sa uputstvima koje nudi tehnički priručnik za provodnik.

11 Specifikacije

Parametar	Model EAZ101
Dužina	Ukupna dužina: 35,5 cm (14 in) Dužina šipke za pravljenje prolaza: 22,3 cm (8,8 in)
Prečnik šipke za pravljenje prolaza	3,0 mm (9 Fr)
Materijal	Šipka za pravljenje prolaza: nerđajući čelik 304 Eksterni vodič: akrilonitril butadien stiren (ABS) Drška: polikarbonat
Preporučeni uvodnik	Prečnik: 3,0 mm (9 Fr) Dužina: 19,13 cm (7,53 in)

12 CE oznaka za usklađenost

CE 0344

13 Objašnjenje simbola na oznakama na pakovanju

Pogledajte oznake na pakovanju da biste videli koji se simboli odnose na ovaj proizvod.

Tabela 1. Objašnjenje simbola na oznakama na pakovanju

Simbol	Objašnjenje
CE 0344	Conformité Européenne (usklađenost sa evropskim standardima). Ovaj simbol označava da je uređaj u potpunosti usklađen sa važećim zakonima Evropske unije.
	Nemojte koristiti ako je pakovanje oštećeno
	Nemojte ponovo koristiti
	Ograničenje temperature
	Ograničenje temperature pri transportu
	Ograničenje temperature skladištenja
	Ovde otvoriti
STERILE R	Sterilizovano zračenjem
	Oprez
	Postupite u skladu s uputstvom za upotrebu
	Datum proizvodnje
	Proizvođač
	Uvoznik
EC REP	Ovlašćeni predstavnik za Evropsku uniju
	Datum „Upotrebljivo do”
REF	Broj za naknadnu narudžbinu
LOT	Broj serije
#	Broj modela
	Proizvedeno u

Tabela 1. Objašnjenje simbola na oznakama na pakovanju (nastavak)

Simbol	Objašnjenje
	Sadržaj pakovanja
	Dokumentacija o proizvodu
	Uvodnik provodnika
	Unutrašnji prečnik
	Sistem jednostruke sterilne barijere
	Samo za korisnike u SAD-u
	Medicinsko sredstvo
	PIN broj
	Sternalni alat za pravljenje prolaza

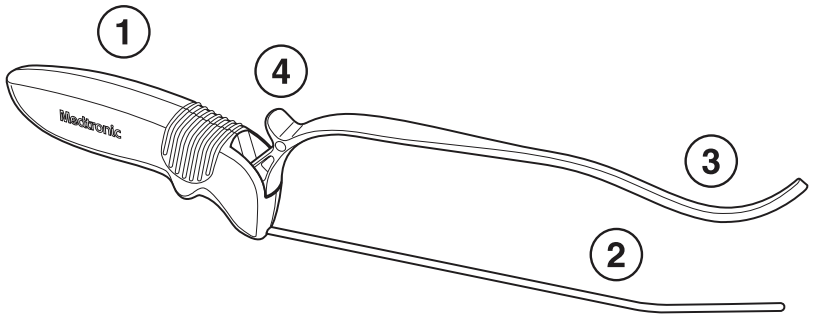
1 Опис пристрою

Інструмент для грудинного тунелювання моделі EAZ101 компанії Medtronic Epsila EV призначений для введення інтрод'юсера і позасудинного електрода в переднє середостіння в ході імплантації позасудинної системи пристрою, який імплантується.

Інструмент для грудинного тунелювання, показаний на *Мал. 1*, складається з наступних компонентів:

- Рукоятка.
- Стрижень для тунелювання з нержавіючої сталі, який забезпечує введення інтрод'юсера в переднє середостіння. (Див. *Гл. 11* для отримання інформації про рекомендований розмір інтрод'юсера.) Стрижень для тунелювання має заздалегідь заданий вигин і є еластичним для відповідності анатомії пацієнта.
- Зовнішній направляючий пристрій, який залишається над шкірою та вказує відстань і напрямок стрижня для тунелювання. Зовнішня напрямна має шарнірне з'єднання і її можна знімати відповідно до вподобань лікаря і анатомічних особливостей пацієнта.
- Накладка для великого пальця, яка може використовуватися для підйому і опускання зовнішнього направляючого пристрою.

Малюнок 1. Інструмент для грудинного тунелювання моделі EAZ101



1 Рукоятка
2 Стрижень для тунелювання з нержавіючої сталі
3 Зовнішній направляючий пристрій (знімний)
4 Накладка для великого пальця

1.1 Вміст упаковки

Інструмент для тунелювання постачається в стерильному вигляді. У кожній упаковці містяться наступні компоненти:

- 1 інструмент для грудинного тунелювання
- Документація на продукт

2 Показання

Інструмент для грудинного тунелювання Epsila EV моделі EAZ101 показаний для використання під час імплантування сумісного електрода для дефібриляції в переднє середостіння.

3 Протипоказання

Інструмент для грудинного тунелювання Epsila EV моделі EAZ101 протипоказаний для застосування серед пацієнтів зі стернотомією в анамнезі.

4 Цільове призначення

Інструмент для грудинного тунелювання Medtronic моделі EAZ101 є стерильним, одноразовим медичним пристроєм, показаним для використання під час імплантування сумісного електрода для дефібриляції в переднє середостіння.

5 Передбачені користувачі

Користувачі інструмента для грудинного тунелювання моделі EAZ101 – це люди, навчені роботі з інструментом.

6 Попередження та запобіжні заходи

Примітка. Застереження і запобіжні заходи щодо медичних процедур, які відносяться до імплантованої системи компанії Medtronic, включені в керівництво, яке надається з пристроєм, що імплантується.

Сумісність продукту – Цей інструмент не був протестований для використання з іншими продуктами, крім продуктів компанії Medtronic.

Застосування серед дітей – Спеціальні дослідження застосування пристрою в дітей не проводились.

Огляд стерильної упаковки – Перед відкриттям огляньте стерильну упаковку.

- Якщо упаковка пошкоджена або відкрита, не використовуйте продукт і зверніться до представництва компанії Medtronic.

- Перевозити упаковку або її вміст при температурі вище 58°C (136°F) або нижче –35°C (–31°F) заборонено. Зберігати упаковку або її вміст при температурі вище 30°C (86°F) або нижче 15°C (59°F) заборонено.
- Не використовуйте даний продукт після закінчення терміну придатності.

Одноразове застосування – Цей інструмент призначений лише для одноразового використання. Повторне використання може порушити структурну цілісність інструмента або створити ризик його забруднення, що може призвести до травмування, захворювання або смерті пацієнта.

Стерилізація – Перед постачанням фахівці компанії Medtronic стерилізували вміст упаковки опроміненням. Інструмент є одноразовим і не призначений для повторної стерилізації.

Імплантація та управління системою – Імплантація та поточне управління системою повинні виконуватися лікарями, навченими управлінню системою та поводженню з нею, і які ознайомилися з процедурами, описаними у відповідних технічних посібниках. Неналежна підготовка або недотримання інструкцій можуть призвести до заподіяння шкоди пацієнтам.

Утилізація – Утилізуйте одноразовий інструмент відповідно до вимог чинного законодавства з охорони навколишнього середовища.

7 Можливі небажані явища

Нижче наводяться передбачувані потенційні небажані явища, пов'язані з використанням інструмента для грудинного тунелювання:

- Гостра травма тканин
- Алергічна реакція
- Перфорація серця
- Тампонада серця
- Смерть
- Дискомфорт
- Гематома
- Крововилив
- Гемоторакс
- Інфекція
- Пошкодження органів (печінки, артерій молочної залози, діафрагмальних артерій)
- Біль
- Перикардіальний випіт
- Перикардит
- Пневмоторакс
- Серома

Примітка. у разі серйозного випадку, пов'язаного з пристроєм, негайно повідомте про випадок компанії Medtronic і вповноваженому чи регулюючому органу.

8 Небажані явища й дані клінічного дослідження

Нижченаведена інформація застосовується лише в разі використання інструмента в США. Для отримання інформації про клінічні дослідження й небажані явища, пов'язані з цим інструментом, див. посібник з експлуатації пристрою для США для позасудинного імплантованого кардіовертер-дефібрилятора.

9 Зведені дані з безпеки і клінічної ефективності

Короткий звіт про безпеку й клінічну ефективність (SSCP) наведено за адресою https://ec.europa.eu/tools/eudamed. Для пошуку короткого звіту про безпеку й клінічну ефективність (SSCP) використовуйте назву виробника та пристрою, а також будь-який із цих відповідних елементів: модель пристрою, обліковий номер (REF), номер за каталогом або базовий унікальний ідентифікатор виробу (базовий UDI-DI) — 0763000B000082586.

10 Вказівки щодо застосування

Відповідальність за правильність виконання хірургічних процедур і застосування стерильних методів несуть медичні працівники. Нижче, виключно з інформаційною метою, описані деякі процедури. Деякі методи імплантації можуть змінюватися залежно від уподобань лікаря, анатомічних особливостей пацієнта і його фізичного стану. Кожен лікар повинен застосовувати інформацію, що міститься в цих інструкціях, згідно з професійним медичним досвідом та отриманими навичками.

10.1 Підготовка до тунелювання

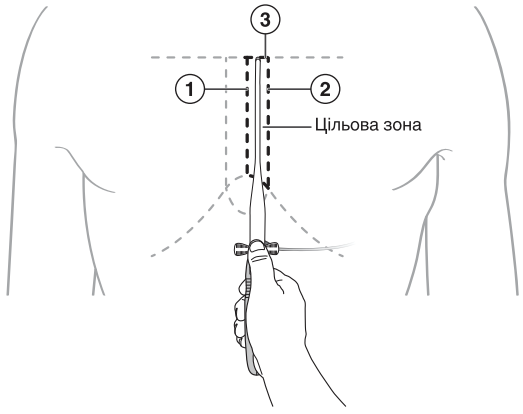
1. Підготуйте інтрод'юсер для імплантації електрода відповідно до інструкцій в документації з використання продукту, що входить в комплект поставки інтрод'юсера. Залиште шприц, заповнений фізіологічним розчином, прикріпленим до бічного порту інтрод'юсера і відкрийте запірний кран.
2. При необхідності вручну надайте стрижню для тунелювання інструмента для грудинного тунелювання вигин згідно з анатомічними особливостями пацієнта. Кут повинен дозволяти кінчику стрижня для тунелювання залишатися в контакті з задньою частиною грудини або якомога ближче до неї під час тунелювання.

   Примітка. Оглядайте інтрод'юсер перед використанням, щоб переконатися в тому, що він не пошкоджений.
3. Знову вставте інтрод'юсер в стрижень для тунелювання.

4. Намалюйте орієнтири на шкірі пацієнта. Рекомендовані орієнтири включають в себе наступні місця:
   - Мечоподібний відросток
   - Межі ребер
   - Середню лінію грудини
   - Лівий латеральний край грудини
   - Верхню частину тіні серця
   - Розташування розрізу
   - Розташування «кишені» для пристрою

   Примітка. Хребет не рекомендується використовувати як анатомічний орієнтир.

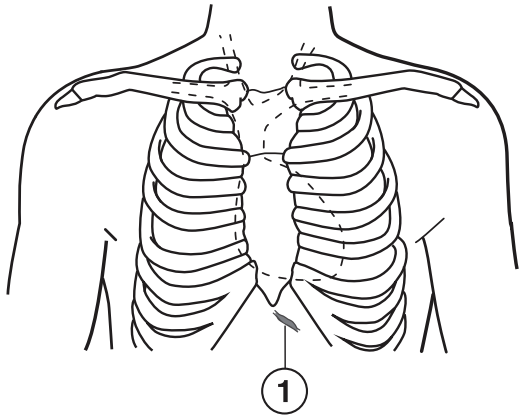
   Малюнок 2. Цільова зона тунелювання



1 Середня лінія грудини
2 Лівий латеральний край грудини
3 Верхня частина тіні серця

5. Надріжте шкіру нижче мечоподібного відростка, трохи лівіше від середньої лінії, як показано на *Мал. 3*. Щоб уникнути потенційних небажаних явищ через контакт з органами, виберіть місце розрізу, яке забезпечує відповідний кут введення грудинного інструмента на підставі анатомії пацієнта. Зробіть розріз досить великим, щоб забезпечити кріплення фіксуючої муфти.

   Малюнок 3. Місце розрізу



1 Місце розрізу

6. Виконайте тупу дисекцію кріплень діафрагми, використовуючи в якості допоміжного засобу латеральну рентгеноскопію. Почніть тупу дисекцію тканин, використовуючи палець для проходження кріплень діафрагми. Використовуючи палець, підтвердьте знаходження у потрібній площині тканини.

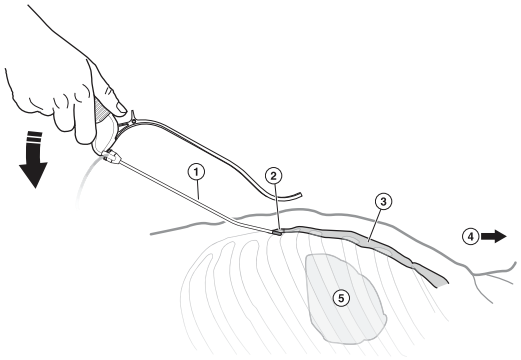
10.2 Тунелювання під грудиною

Примітки.

- Якщо у пацієнта зустрічаються складні анатомічні особливості, такі як товста підшкірна фасція, вигнута грудна клітка або виступаючий мечоподібний відросток, підійміть зовнішній направляючий пристрій на необхідний рівень, щоб він не заважав первинному введенню. Після введення стрижня для тунелювання ви можете опустити зовнішній направляючий пристрій для використання в якості візуального індикатора бічного напрямку і краніальної дистанції при тунелюванні.
- Перед введенням стрижня для тунелювання додатково видаліть зовнішній направляючий пристрій. Для виймання зовнішнього направляючого пристрою потягніть його вгору до клацання, потім потягніть його за рукоятку в напрямку, протилежному стрижню для тунелювання.
  - **Примітка:** не виймайте зовнішній направляючий пристрій під час тунелювання.

1. Використовуючи рентгеноскопію в бічній проекції в якості допоміжного пристрою, введіть у розріз стрижень для тунелювання та інтрод'юсер. Просувайте кінчик стрижня для тунелювання для досягнення контакту зі з'єднанням мечоподібного відростка.
2. Як тільки кінчик стрижня для тунелювання буде перебувати під грудиною, негайно опустіть рукоятку в бік живота, щоб стрижень для тунелювання був розташований паралельно до грудної клітки. Щоб уникнути виникнення потенційних небажаних явищ через контакт з органами, тримайте кінчик стрижня для тунелювання в контакті із задньою частиною грудної клітки або якомога ближче до неї. (Див. *Мал. 4*.) У якості допоміжного пристрою використовуйте рентгеноскопію в бічній проекції.

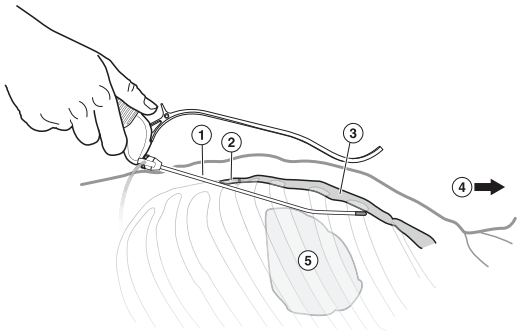
Малюнок 4. Бічна проекція: кінчик стрижня для тунелювання контактує зі з'єднанням мечоподібного відростка



1 Стрижень для тунелювання
2 З'єднання мечоподібного відростка
3 Грудина
4 Голова
5 Серце

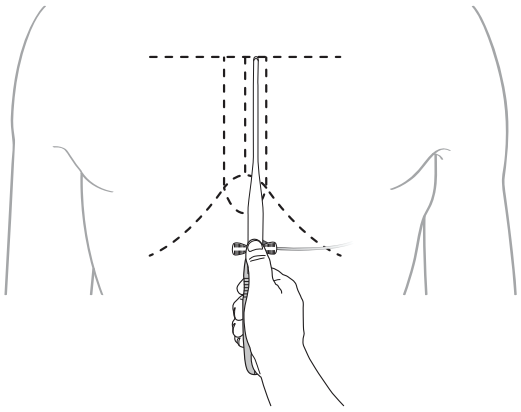
3. Хоча під час тунелювання візуалізацію виконують в латеральній проекції, для визначення напрямку інструменту з метою підтвердження його знаходження в цільовій зоні тунелювання використовується візуалізація в передньо-задній проекції. Проводьте інструмент тунелювання до вершини силуету серця, періодично змінюючи латеральну проекцію на передньо-задню з метою підтвердження траєкторії інструменту. Див. *Мал. 5*. Під час тунелювання розгляньте можливість використання зовнішнього направляючого пристрою, щоб переконатися, що стрижень для тунелювання залишається між межами грудини, як показано на *Мал. 6*.

Малюнок 5. Бічна проекція: кінчик стрижня для тунелювання в верхній частині тіні серця



1 Стрижень для тунелювання
2 З'єднання мечоподібного відростка
3 Грудина
4 Голова
5 Серце

Малюнок 6. Зовнішня проекція: кінчик стрижня для тунелювання в верхній частині тіні серця



Примітка. Якщо ви відчуваєте опір при тунелюванні, припиніть його і підтвердіть розташування стрижня для тунелювання за допомогою іншої рентгеноскопічної проекції. Після цього виконайте наступні дії за допомогою рентгеноскопії:

a. Трохи відведіть стрижень для тунелювання разом з інтрод'юсером.
b. Змініть положення стрижня для тунелювання таким чином, щоб забезпечити його контакт із задньою поверхнею грудини або максимально можливу близькість до неї так, щоб він знаходився в межах цільової зони тунелювання, як показано на *Мал. 2*.
c. Якщо інтрод'юсер пошкоджений, використовуйте новий інтрод'юсер і знову почніть процес тунелювання.

4. Підтвердіть розташування стрижня для тунелювання за допомогою зовнішньої направляючої або іншої рентгеноскопічної проекції.

10.3 Виймання стрижня для тунелювання і введення електрода

1. Щоб звести до мінімуму потрапляння повітря, впевніться, що шприц, заповнений фізіологічним розчином, прикріплений до бічного порту інтрод'юсера і запірний кран відкритий.
2. Утримуйте інтрод'юсер на місці під час виймання стрижня для тунелювання.
   Примітка. Не просувайте інтрод'юсер без введеного стрижня для тунелювання.
3. Введіть електрод в інтрод'юсер відповідно до інструкцій у технічному керівництві електрода.

11 Технічні характеристики

Параметр	Модель EAZ101
Довжина	Загальна довжина: 35,5 см(cm) (14 in) Довжина стрижня для тунелювання: 22,3 см(cm) (8,8 in)
Діаметр стрижня для тунелювання	3,0 мм(mm) (9 Fr)
Матеріал	Стрижень для тунелювання: нержавіюча сталь 304 Зовнішній направляючий пристрій: акрилонітрилбутадієнстирол (АБС) Рукоятка: полікарбонат
Рекомендований інтрод'юсер	Діаметр: 3,0 мм(mm) (9 Fr) Довжина: 19,13 см(cm) (7,53 in)

12 Знак відповідності CE

CE 0344

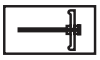
13 Пояснення символів на маркуванні упаковки

Див. етикетки упаковки, які умовні позначки застосовуються до цього продукту.

Таблиця 1. Роз'яснення умовних позначок на маркуванні упаковки

Символ	Пояснення
CE 0344	Conformité Européenne (відповідність вимогам ЄС). Цей символ означає, що пристрій повністю відповідає вимогам застосовних директив Європейського Союзу.
	Не використовувати у разі пошкодження пакування
	Повторно використовувати заборонено
	Температурне обмеження
	Обмеження температури транспортування
	Обмеження температури зберігання
	Відкривати тут
	Стерилізовано із застосуванням випромінювання
	Увага!
	Ознайомтеся з інструкціями із застосування
	Дата виготовлення
	Виробник
	Імпортер

Таблиця 1. Роз'яснення умовних позначок на маркуванні упаковки (продовження)

Символ	Пояснення
EC REP	Уповноважений представник Європейського Союзу
	Термін придатності
REF	Номер для повторного замовлення
LOT	Номер партії
#	Номер моделі
	Місце виготовлення
	Вміст упаковки
	Документація на продукт
	Інтрод'юсер електрода
	Внутрішній діаметр
	Система одинарного стерильного бар'єра
! USA	Лише для користувачів у США
MD	Медичний виріб
PIN	PIN-номер
	Інструмент для грудинного тунелювання

Medtronic

Medtronic, Inc.
710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

EC REP

Medtronic B.V.
Earl Bakkenstraat 10
6422 PJ Heerlen
The Netherlands
+31 45 566 8000

Canada
Medtronic Canada ULC
99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
1 800 268 5346

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M999188A003 B
2022-01-27

M999188A003

Medtronic

Epsila EV™ EAZ201

Transverse tunneling tool

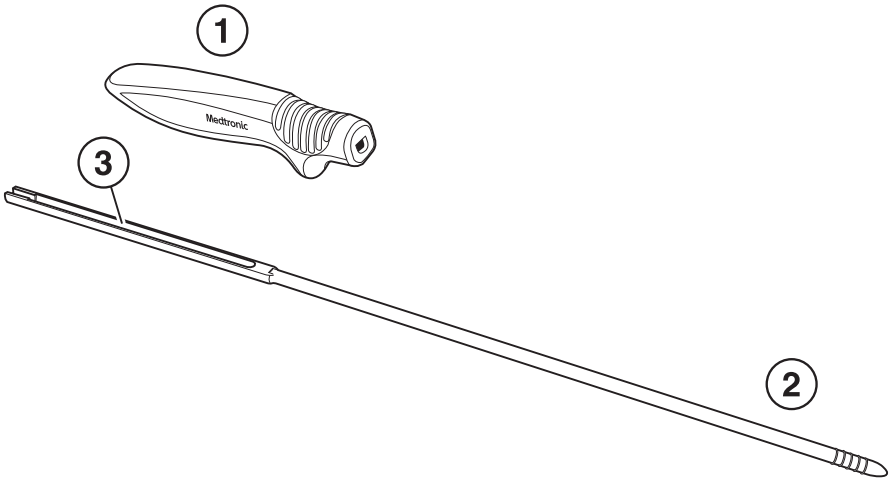
Technical Manual

! USA **Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

1 Description

The Medtronic Epsila EV Model EAZ201 transverse tunneling tool is designed to deliver the proximal portion of an extravascular lead to the device pocket during implant of an extravascular implantable device system. The tunneling tool is shown in *Figure 1*.

Figure 1. Model EAZ201 tunneling tool



1 Handle
2 Tunneling rod
3 Channel for lead delivery

2 Package contents

The tunneling tool is supplied sterile. Each package contains the following items:

- 1 handle
- 1 tunneling rod
- Product documentation

3 Indications

The Epsila EV Model EAZ201 transverse tunneling tool is indicated for use in the implant of a compatible anterior mediastinum defibrillation lead.

4 Contraindications

The Epsila EV Model EAZ201 transverse tunneling tool is contraindicated for any application that is not specified in the Indications.

5 Intended purpose

The Medtronic Model EAZ201 transverse tunneling tool is a sterile, single-use only medical device intended for use in the implantation of a compatible anterior mediastinum defibrillation lead.

6 Intended users

The users of the Model EAZ201 transverse tunneling tool are individuals trained in the operation and handling of the tool.

7 Warnings and precautions

Note: Medical procedure warnings and precautions that pertain to the Medtronic implanted system are included in the manual that is provided with the implantable device.

Product compatibility – This tool has not been tested for use with non-Medtronic products.

Pediatric use – The tool has not been tested specifically for pediatric use.

Inspecting the sterile package – Inspect the sterile package before opening it.

- If the package is damaged or opened, do not use the product and contact a Medtronic representative.
- Do not transport the package or contents of the package above 58°C (136°F) or below –35°C (–31°F). Do not store the package or contents of the package above 30°C (86°F) or below 15°C (59°F).
- Do not use the product after its expiration date.

Single use – This tool is for single use only. Reuse may compromise the structural integrity of the tool or create a risk of contamination of the tool that could result in patient injury, illness, or death.

Sterilization – Medtronic has sterilized the package contents using irradiation before shipment. This tool is for single use only and is not intended to be resterilized.

Prior sternotomy – Use of the EAZ201 tunneling tool has not been evaluated in patients who have undergone a prior sternotomy.

Implantation and system management – Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the system and must be in compliance with procedures

described in the appropriate technical instructions. Inadequate training or failure to follow instructions may result in harm to the patients.

Disposal – Dispose of the single-use tool according to local environmental requirements.

8 Potential adverse events

The following are foreseeable potential adverse events associated with the use of the transverse tunneling tool:

- Acute tissue trauma
- Allergic reaction
- Death
- Discomfort
- Hematoma
- Hemorrhage
- Infection
- Pain
- Seroma

Note: If a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.

9 Adverse events and clinical trial data

The following information applies only to use of the tool in the United States. For information regarding clinical studies and adverse events related to this tool, see the US device manual for the extravascular implantable cardioverter defibrillator.

10 Summary of safety and clinical performance

The Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed. Search for the SSCP using the manufacturer and device name, and any of the following elements, as applicable: device model, reference number, catalog number, or the Basic Unique Device Identification (Basic UDI-DI) number — 0763000B000082586.

11 Directions for use

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. The following procedures are provided for information only. Some implant techniques vary according to physician preference and the patient's anatomy or physical condition. Each physician must apply the information in these instructions according to professional medical training and experience.

Use the following instructions after positioning and securing the distal end of the lead and creating the device pocket, as described in the extravascular lead technical manual.

1. Insert the tunneling rod into the handle and push the tunneling rod all the way to the end of the handle.
2. Insert the tunneling rod tip into the xiphoid incision above the costal rib margin, as shown in *Figure 2*.

   Figure 2. Inserting the tunneling rod

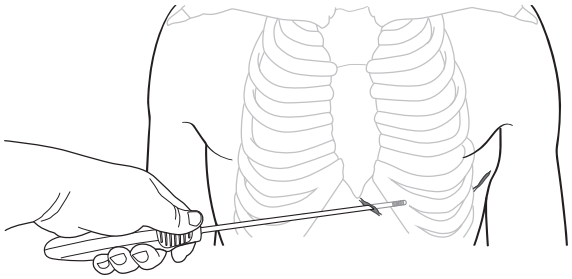
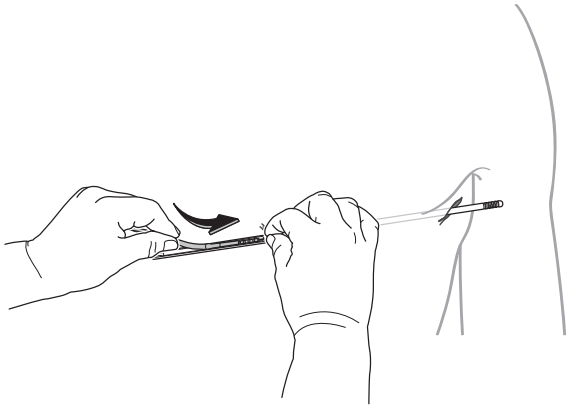
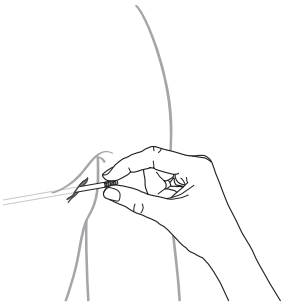
   
3. Tunnel subcutaneously to the device pocket.
4. When the tunneling rod tip exits the device pocket, remove the handle from the tunneling rod, keeping the tunneling rod in place.
5. Set the handle aside for later disposal.
6. Insert the proximal end of the lead into the channel of the tunneling rod, as shown in *Figure 3*.

Figure 3. Inserting the proximal end of the lead into the channel



7. Pull the tunneling rod and lead through the subcutaneous tunnel and out through the device pocket, as shown in *Figure 4*.

Figure 4. Pulling out the tunneling rod through the device pocket



8. Remove the lead from the tunneling rod channel and dispose of the tunneling tool components.

12 Specifications

Parameter		Model EAZ201
Device length		
	Overall length	36.1 cm (14.2 in)
	Tunneling length	22.9 cm (9.0 in)
Material		
	Handle	Polycarbonate
	Tunneling rod	Polyetherimide

13 CE mark of conformity

CE 0344

14 Explanation of symbols

Table 1. Explanation of symbols on package labeling

Refer to the package labels to see which symbols apply to this product.

CE 0344	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
EC REP	Authorized representative in the European community
	Date of manufacture
	Manufacturer
	Importer
	Use-by date
LOT	Lot number
REF	Reorder number
STERILE R	Sterilized using irradiation

Table 1. Explanation of symbols on package labeling (continued)

	Do not reuse
	Do not use if package is damaged
	Temperature limit
	Transit temperature limit
	Storage temperature limit
	Open here
	Consult instructions for use
	Model number
	Manufactured in
	Package contents
	Product documentation
	Single sterile barrier system
	For US audiences only
	Medical device
	PIN number
	Transverse tunneling tool

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M999195A001 D
2022-01-10

M999195A001

Medtronic

Epsila EV™ EAZ201

Transverse tunneling tool
Herramienta de tunelización transversal
Alat tunneling transversal
Инструмент для поперечного туннелирования
Alat za poprečno pravljenje prolaza
Інструмент для поперечного тунелювання

Technical Manual • Manual técnico • Panduan Teknis • Техническое руководство • Tehnički priručnik • Технічне керівництво

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Epsila EV™

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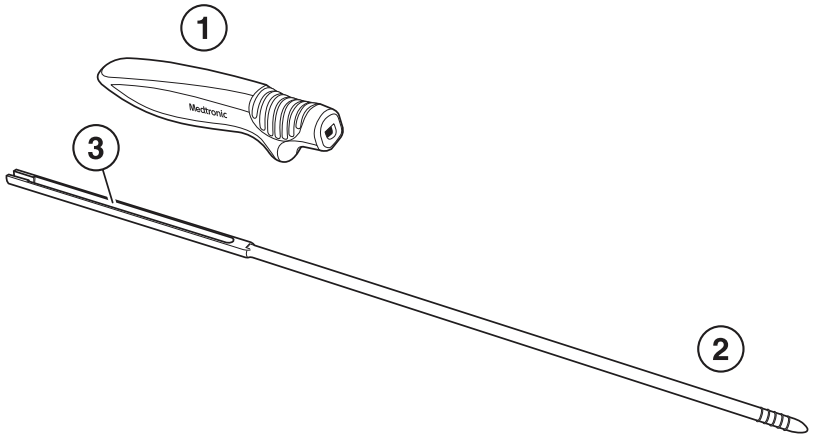

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Note: Medical procedure warnings and precautions that pertain to the Medtronic implanted system are included in the manual that is provided with the implantable device.

Product compatibility – This tool has not been tested for use with non-Medtronic products.

Pediatric use – The tool has not been tested specifically for pediatric use.

Inspecting the sterile package – Inspect the sterile package before opening it.

- If the package is damaged or opened, do not use the product and contact a Medtronic representative.
- Do not transport the package or contents of the package above 58°C (136°F) or below –35°C (–31°F). Do not store the package or contents of the package above 30°C (86°F) or below 15°C (59°F).
- Do not use the product after its expiration date.

Single use – This tool is for single use only. Reuse may compromise the structural integrity of the tool or create a risk of contamination of the tool that could result in patient injury, illness, or death.

Sterilization – Medtronic has sterilized the package contents using irradiation before shipment. This tool is for single use only and is not intended to be resterilized.

Prior sternotomy – Use of the EAZ201 tunneling tool has not been evaluated in patients who have undergone a prior sternotomy.

Implantation and system management – Implantation and ongoing system management must be performed by individuals trained in the operation and handling of the system and must be in compliance with procedures

described in the appropriate technical instructions. Inadequate training or failure to follow instructions may result in harm to the patients.

Disposal – Dispose of the single-use tool according to local environmental requirements.

8 Potential adverse events

The following are foreseeable potential adverse events associated with the use of the transverse tunneling tool:

- Acute tissue trauma
- Allergic reaction
- Death
- Discomfort
- Hematoma
- Hemorrhage
- Infection
- Pain
- Seroma

Note: If a serious incident related to the device occurs, immediately report the incident to Medtronic and the applicable competent authority or regulatory body.

9 Adverse events and clinical trial data

The following information applies only to use of the tool in the United States. For information regarding clinical studies and adverse events related to this tool, see the US device manual for the extravascular implantable cardioverter defibrillator.

10 Summary of safety and clinical performance

The Summary of Safety and Clinical Performance (SSCP) can be found at https://ec.europa.eu/tools/eudamed. Search for the SSCP using the manufacturer and device name, and any of the following elements, as applicable: device model, reference number, catalog number, or the Basic Unique Device Identification (Basic UDI-DI) number — 0763000B000082586.

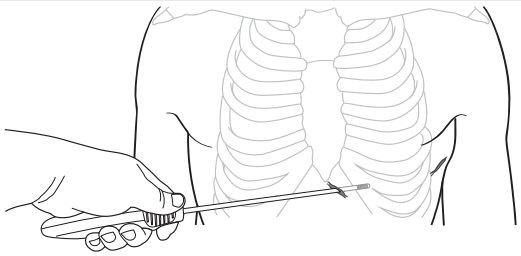
11 Directions for use

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. The following procedures are provided for information only. Some implant techniques vary according to physician preference and the patient's anatomy or physical condition. Each physician must apply the information in these instructions according to professional medical training and experience.

Use the following instructions after positioning and securing the distal end of the lead and creating the device pocket, as described in the extravascular lead technical manual.

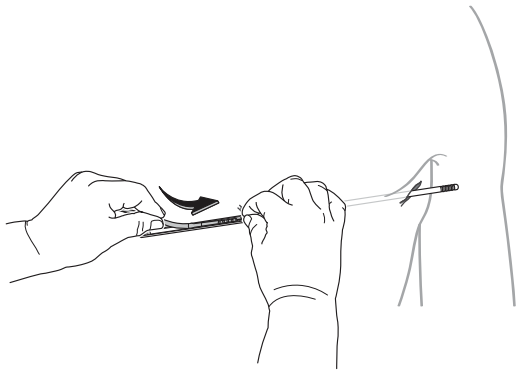
1. Insert the tunneling rod into the handle and push the tunneling rod all the way to the end of the handle.
2. Insert the tunneling rod tip into the xiphoid incision above the costal rib margin, as shown in *Figure 2*.

Figure 2. Inserting the tunneling rod



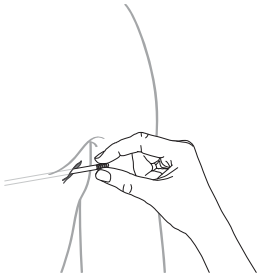
3. Tunnel subcutaneously to the device pocket.
4. When the tunneling rod tip exits the device pocket, remove the handle from the tunneling rod, keeping the tunneling rod in place.
5. Set the handle aside for later disposal.
6. Insert the proximal end of the lead into the channel of the tunneling rod, as shown in *Figure 3*.

Figure 3. Inserting the proximal end of the lead into the channel



7. Pull the tunneling rod and lead through the subcutaneous tunnel and out through the device pocket, as shown in *Figure 4*.

Figure 4. Pulling out the tunneling rod through the device pocket



8. Remove the lead from the tunneling rod channel and dispose of the tunneling tool components.

12 Specifications

Parameter		Model EAZ201
Device length		
	Overall length	36.1 cm (14.2 in)
	Tunneling length	22.9 cm (9.0 in)
Material		
	Handle	Polycarbonate
	Tunneling rod	Polyetherimide

13 CE mark of conformity

CE 0344

14 Explanation of symbols

Table 1. Explanation of symbols on package labeling

Refer to the package labels to see which symbols apply to this product.

CE 0344	Conformité Européenne (European Conformity). This symbol means that the device fully complies with applicable European Union acts.
EC REP	Authorized representative in the European community
	Date of manufacture
	Manufacturer
	Importer
	Use-by date
LOT	Lot number
REF	Reorder number
STERILE R	Sterilized using irradiation

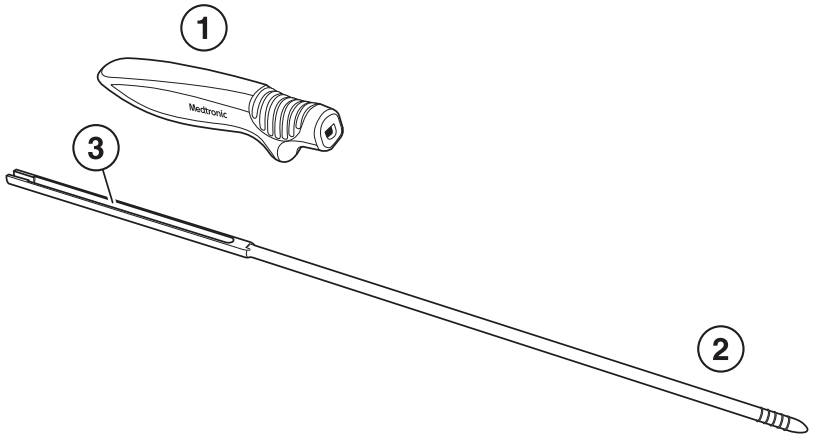
Table 1. Explanation of symbols on package labeling (continued)

	Do not reuse
	Do not use if package is damaged
	Temperature limit
	Transit temperature limit
	Storage temperature limit
	Open here
	Consult instructions for use
	Model number
	Manufactured in
	Package contents
	Product documentation
	Single sterile barrier system
	For US audiences only
	Medical device
	PIN number
	Transverse tunneling tool

1 Descripción

La herramienta de tunelización transversal Epsila EV Modelo EAZ201 de Medtronic está diseñada para colocar la parte proximal de un cable extravascular en la bolsa del dispositivo durante la implantación de un sistema de dispositivo implantable extravascular. La herramienta de tunelización se muestra en la *Figura 1*.

Figura 1. Herramienta de tunelización Modelo EAZ201



1 Mango
2 Varilla de tunelización
3 Canal para colocación del cable

2 Contenido del envase

La herramienta de tunelización se suministra estéril. Cada envase contiene el siguiente material:

- 1 mango
- 1 varilla de tunelización
- Documentación del producto

3 Indicaciones

La herramienta de tunelización transversal Epsila EV Modelo EAZ201 está indicada para utilizarse en la implantación de un cable de desfibrilación compatible en el mediastino anterior.

4 Contraindicaciones

La herramienta de tunelización transversal Epsila EV Modelo EAZ201 está contraindicada para cualquier aplicación que no esté especificada en la sección Indicaciones.

5 Fin previsto

La herramienta de tunelización transversal Modelo EAZ201 de Medtronic es un dispositivo médico estéril de un solo uso que está indicado para utilizarse en la implantación de un cable de desfibrilación compatible en el mediastino anterior.

6 Usuarios previstos

Los usuarios de la herramienta de tunelización transversal Modelo EAZ201 deben tener formación en el funcionamiento y la manipulación de la herramienta.

7 Advertencias y medidas preventivas

Nota: En el manual que se incluye con el dispositivo implantable se proporcionan advertencias y medidas preventivas sobre procedimientos médicos que son aplicables al sistema implantado de Medtronic.

Compatibilidad del producto – Esta herramienta no se ha probado en productos que no son de Medtronic.

Uso pediátrico – La herramienta no se ha probado específicamente para uso pediátrico.

Inspección del envase estéril – Examine el envase estéril antes de abrirlo.

- Si el envase está dañado o abierto, no utilice el producto y póngase en contacto con el representante de Medtronic.
- No transporte el envase o el contenido del envase a temperaturas superiores a 58°C (136°F) o inferiores a –35°C (–31°F). No almacene el envase o el contenido del envase a temperaturas superiores a 30°C (86°F) o inferiores a 15°C (59°F).
- No utilice el producto pasada la fecha de caducidad.

Un solo uso – Esta herramienta es de un solo uso. La reutilización de la herramienta puede poner en peligro su integridad estructural y generar un riesgo de contaminación de la herramienta que podría provocar al paciente lesiones, enfermedades o la muerte.

Esterilización – Medtronic ha esterilizado el contenido del envase mediante irradiación antes de su envío. Esta herramienta es de un solo uso y no se debe volver a esterilizar.

Esternotomía previa – No se ha evaluado el uso de la herramienta de tunelización EAZ201 en pacientes que se han sometido a una esternotomía previa.

Implantación y gestión del sistema – La implantación y la gestión continua del sistema deben ser realizadas por personas con formación en el funcionamiento y la manipulación del sistema, conforme a los procedimientos descritos en las instrucciones técnicas correspondientes. Una formación inadecuada o el incumplimiento de las instrucciones puede causar lesiones a los pacientes.

Eliminación – Deseche la herramienta de un solo uso conforme a los requisitos medioambientales locales.

8 Posibles eventos adversos

A continuación se indican los posibles efectos adversos previsibles asociados al uso de la herramienta de tunelización transversal:

- Traumatismo tisular agudo
- Reacción alérgica
- Muerte
- Molestias
- hematoma
- hemorragia
- Infección
- Dolor
- Seroma

Nota: Si ocurre un incidente grave relacionado con el dispositivo, notifíquelo inmediatamente a Medtronic y a la autoridad u organismo regulador competente correspondiente.

9 Datos de ensayos clínicos y acontecimientos adversos

La información siguiente es de aplicación únicamente al uso de la herramienta en Estados Unidos. Si desea obtener información sobre los ensayos clínicos y los acontecimientos adversos relacionados con la herramienta, consulte el manual del desfibrilador automático implantable extravascular para Estados Unidos.

10 Resumen de seguridad y rendimiento clínico

El Resumen de seguridad y rendimiento clínico (Summary of Safety and Clinical Performance, SSCP) puede encontrarse en https://ec.europa.eu/tools/eudamed. Busque el SSCP utilizando el fabricante y el nombre del dispositivo, así como cualquiera de los elementos siguientes según proceda: modelo de dispositivo, número de referencia, número de catálogo o número de identificación único del dispositivo básico (UDI-DI básico) — 0763000B000082586.

11 Instrucciones de uso

Los procedimientos quirúrgicos y las técnicas de esterilización adecuadas son responsabilidad del profesional médico. Los procedimientos que se describen a continuación son meramente informativos. Algunas técnicas de implantación varían en función de las preferencias del médico y de la anatomía del paciente o de su estado físico. Cada médico debe aplicar la información contenida en estas instrucciones de acuerdo con su formación y experiencia médica profesional.

Siga las instrucciones que se indican a continuación después de colocar y sujetar el extremo distal del cable y de crear la bolsa del dispositivo, tal como se describe en el manual técnico del cable extravascular.

1. Inserte la varilla de tunelización en el mango y empújela completamente hasta el extremo del mango.
2. Inserte la punta de la varilla de tunelización en la incisión practicada en el xifoides, por encima del margen costal de la costilla, tal como se muestra en la *Figura 2*.

   Figura 2. Inserción de la varilla de tunelización

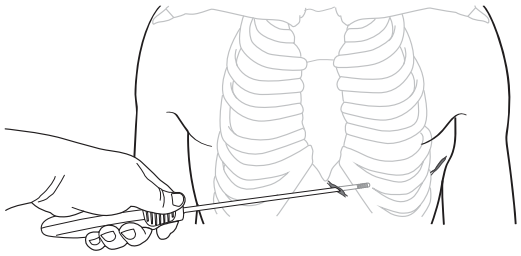
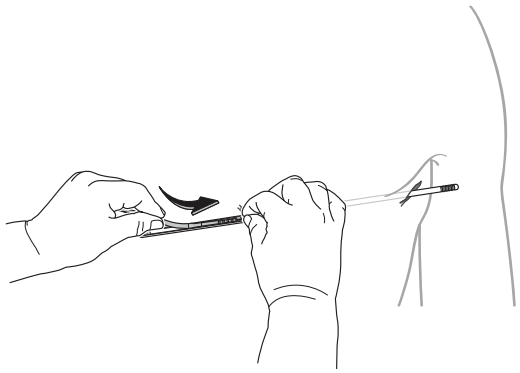
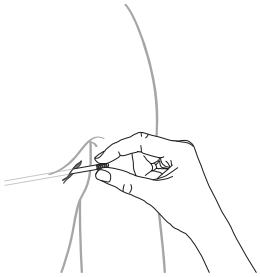
   
3. Tunelice subcutáneamente hasta la bolsa del dispositivo.
4. Cuando la punta de la varilla de tunelización salga de la bolsa del dispositivo, retire el mango de la varilla de tunelización, manteniendo la varilla colocada.
5. Deje el mango a un lado para su posterior eliminación.
6. Inserte el extremo proximal del cable en el canal de la varilla de tunelización, tal como se muestra en la *Figura 3*.

Figura 3. Inserción del extremo proximal del cable en el canal



7. Tire de la varilla de tunelización y el cable a través del túnel subcutáneo y sáquelos a través de la bolsa del dispositivo, tal como se muestra en la *Figura 4*.

Figura 4. Tracción de la varilla de tunelización a través de la bolsa del dispositivo



8. Retire el cable del canal de la varilla de tunelización y deseche los componentes de la herramienta de tunelización.

12 Especificaciones

Parámetro	Modelo EAZ201
Longitud del dispositivo	
Longitud total	36,1 cm (14,2 in)
Longitud de tunelización	22,9 cm (9,0 in)
Material	
Mango	Policarbonato
Varilla de tunelización	Polieterimida

13 Símbolo de conformidad CE

CE 0344

14 Explicación de los símbolos

Tabla 1. Explicación de los símbolos en la etiqueta del envase

Consulte las etiquetas del envase para comprobar qué símbolos se utilizan con este producto.

CE 0344	Conformité Européenne (Conformidad Europea). Este símbolo indica que el dispositivo cumple totalmente las leyes vigentes de la Unión Europea.
EC REP	Representante autorizado en la Comunidad Europea
	Fecha de fabricación
	Fabricante
	Importador
	Fecha de caducidad
LOT	Número de lote
REF	Número para pedidos
STERILE R	Esterilizado mediante irradiación

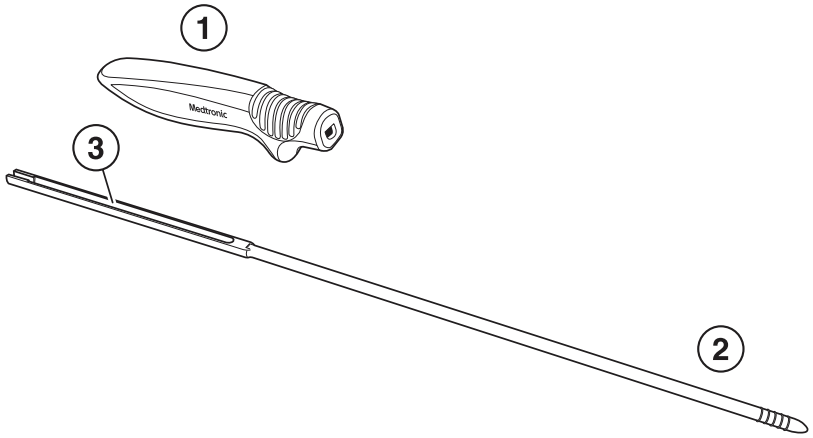
Tabla 1. Explicación de los símbolos en la etiqueta del envase (continuación)

	No reutilizar
	No utilizar si el envase está dañado
	Límite de temperatura
	Límite de temperatura de transporte
	Límite de temperatura de almacenamiento
	Abrir aquí
	Consultar las instrucciones de uso
	Número del modelo
	Fabricado en
	Contenido del envase
	Documentación del producto
	Sistema de barrera estéril única
	Solo aplicable en EE. UU.
	Dispositivo médico
	Número PIN
	Herramienta de tunelización transversal

1 Keterangan

Alat tunneling transversal Epsila EV Model EAZ201 Medtronic dirancang untuk mengirimkan bagian proksimal sadapan ekstravaskular ke kantong perangkat selama implan sistem perangkat ekstravaskular yang dapat diimplan. Alat tunneling ditampilkan di *Gambar 1*.

Gambar 1. Alat tunneling Model EAZ201



1 Pegangan
2 Tangkai tunneling
3 Channel untuk pengiriman sadapan

2 Isi kemasan

Alat tunneling yang disediakan steril. Setiap kemasan berisi item berikut:

- 1 pegangan
- 1 tangkai tunneling
- Dokumen produk

3 Indikasi

Alat tunneling transversal Epsila EV Model EAZ201 diindikasikan untuk penggunaan pada implan sadapan defibrilasi mediastinum anterior.

4 Kontraindikasi

Alat tunneling transversal Epsila EV Model EAZ201 dikontraindikasikan untuk penggunaan pada semua aplikasi yang tidak dispesifikasikan pada Indikasi.

5 Tujuan yang dimaksudkan

Alat tunneling transversal Medtronic Model EAZ201 merupakan alat medis sekali pakai yang steril, untuk digunakan pada implantasi sadapan defibrilasi mediastinum anterior yang kompatibel.

6 Pengguna yang dituju

Pengguna alat tunneling transversal Model EAZ201 merupakan individu yang terlatih dalam operasi dan penanganan alat ini.

7 Peringatan dan tindakan pencegahan

Catatan: Peringatan dan tindakan pencegahan prosedur medis yang berkaitan dengan sistem implan Medtronic disertakan di panduan yang disediakan bersama dengan perangkat terimplan.

Kompatibilitas produk – Alat ini belum diuji untuk penggunaan dengan produk non-Medtronic.

Penggunaan pediatri – Alat ini belum diuji secara spesifik untuk penggunaan pediatri.

Memeriksa kemasan steril – Periksa kemasan steril sebelum membukanya.

- Jika kemasan rusak atau terbuka, jangan gunakan produk dan hubungi perwakilan Medtronic.
- Jangan bawa kemasan atau isi kemasan pada suhu di atas 58°C (136°F) atau di bawah –35°C (–31°F). Jangan simpan kemasan atau isi kemasan pada suhu di atas 30°C (86°F) atau di bawah 15°C (59°F).
- Jangan gunakan produk setelah tanggal kedaluwarsa.

Sekali pakai – Alat ini hanya untuk sekali pakai. Penggunaan ulang dapat membahayakan integritas struktural alat atau menimbulkan risiko kontaminasi pada alat yang dapat berakibat pada cedera, penyakit, atau kematian pasien.

Sterilisasi – Medtronic telah mensterilkan isi kemasan menggunakan penyinaran sebelum pengiriman. Alat ini hanya untuk sekali pakai dan tidak dimaksudkan untuk disterilkan ulang.

Sternotomi sebelumnya – Penggunaan alat tunneling EAZ201 belum dievaluasi pada pasien yang telah menjalankan sternotomi sebelumnya.

Manajemen sistem dan implantasi – Implantasi dan manajemen sistem berkelanjutan harus dilakukan oleh orang yang terlatih dalam pengoperasian dan penanganan sistem dan harus tunduk dengan prosedur yang dijelaskan di instruksi teknis yang sesuai. Tidak cukupnya pelatihan dan kegagalan dalam mengikuti instruksi dapat membahayakan pasien.

Petunjuk pembuangan – Pembuangan alat sekali pakai sesuai dengan persyaratan lingkungan setempat.

8 Potensi efek samping

Berikut ini adalah potensi kejadian yang tidak diharapkan yang diketahui terkait dengan alat tunneling transversal:

- Trauma jaringan akut
- Reaksi alergi
- Kematian
- Rasa tidak nyaman
- Hematoma
- Perdarahan
- Infeksi
- Nyeri
- Seroma

Catatan: Jika terjadi insiden serius terkait perangkat ini, segera laporkan insiden tersebut ke Medtronic dan badan pengawas atau otoritas yang berwajib.

9 Peristiwa yang tidak diharapkan dan data uji klinis

Informasi berikut hanya berlaku untuk penggunaan alat di Amerika Serikat. Untuk informasi tentang studi klinis dan peristiwa yang tidak diinginkan terkait alat ini, lihat panduan perangkat AS untuk defibrilator kardioverter ekstravaskular yang dapat diimplan.

10 Ringkasan keselamatan dan kinerja klinis

Ringkasan Keselamatan dan Kinerja Klinis (SSCP) dapat ditemukan di https://ec.europa.eu/tools/eudamed. Cari SSCP menggunakan nama produsen dan perangkat, dan salah satu elemen berikut, jika relevan: model perangkat, nomor referensi, nomor katalog, atau Identifikasi Perangkat Unik Dasar (UDI-DI Dasar) — 0763000B000082586.

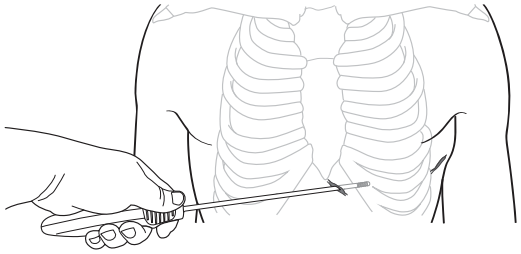
11 Petunjuk penggunaan

Prosedur bedah dan teknik steril yang tepat merupakan tanggung jawab petugas medis. Prosedur berikut disediakan hanya untuk informasi. Beberapa teknik impan dapat berbeda-beda sesuai dengan preferensi dokter dan anatomi atau kondisi fisik pasien. Setiap dokter harus menerapkan informasi dalam petunjuk ini menurut pelatihan dan pengalaman medis profesional.

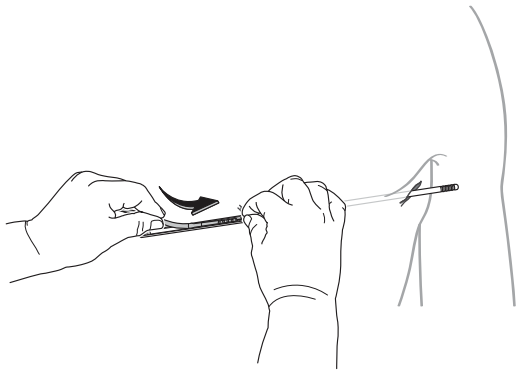
Gunakan petunjuk berikut setelah memosisikan dan mengamankan ujung distal sadapan dan membuat kantong perangkat, seperti yang dijelaskan di panduan teknis sadapan ekstravaskular.

1. Masukkan tangkai tunneling ke pegangan dan dorong tangkai tunneling seluruhnya ke ujung pegangan.
2. Masukkan ujung tangkai tunneling ke sayatan xiphoid di atas margin tulang rusuk kostal, sebagaimana ditampilkan di *Gambar 2*.

   Gambar 2. Memasukkan tangkai tunneling

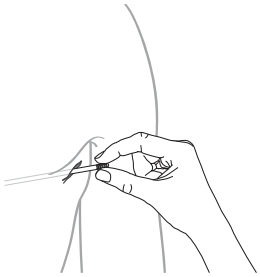
   
3. Lakukan tunneling secara subkutan ke kantong perangkat.
4. Saat ujung tangkai tunneling keluar dari kantong perangkat, lepaskan pegangan dari tangkai tunneling, memastikan tangkai tunneling berada di tempatnya.
5. Taruh pegangan untuk dibuang.
6. Masukkan ujung proksimal sadapan ke channel tangkai tunneling, sebagaimana ditampilkan di *Gambar 3*.

Gambar 3. Memasukkan ujung proksimal sadapan ke channel



7. Tarik tangkai tunneling dan sadapan melalui tunnel subkutan dan keluar melalui kantong perangkat, sebagaimana ditampilkan di *Gambar 4*.

Gambar 4. Menarik tangkai tunneling keluar dari kantong perangkat



8. Lepas sadapan dari channel tangkai tunneling dan buang komponen alat tunneling.

12 Spesifikasi

Parameter	Model EAZ201
Panjang perangkat	
Panjang keseluruhan	36,1 cm (14,2 in)
Panjang tunneling	22,9 cm (9,0 in)
Bahan	
Pegangan	Polikarbonat
Tangkai tunneling	Polieterimida

13 Tanda kesesuaian CE

CE 0344

14 Penjelasan simbol

Tabel 1. Penjelasan simbol pada pelabelan kemasan

Lihat label kemasan untuk melihat simbol yang digunakan untuk produk ini.

CE 0344	Conformité Européenne (European Conformity/Kesesuaian untuk Uni Eropa). Simbol ini berarti bahwa perangkat sepenuhnya mematuhi undang-undang yang berlaku di Uni Eropa.
EC REP	Perwakilan resmi di negara-negara Eropa
	Tanggal produksi
	Produsen
	Pengimpor
	Tanggal "gunakan paling lambat"
LOT	Nomor lot
REF	Nomor pesan ulang
STERILE R	Disterilkan menggunakan penyinaran

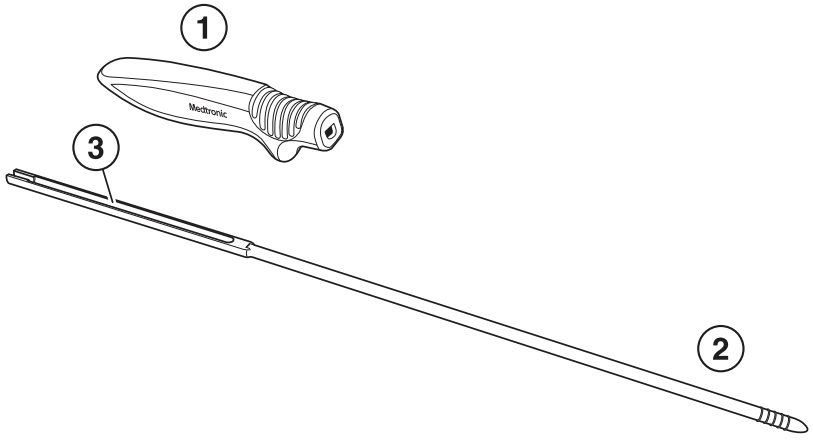
Tabel 1. Penjelasan simbol pada pelabelan kemasan (lanjutan)

	Jangan dipakai ulang
	Jangan gunakan jika kemasan rusak
	Batas suhu
	Batas suhu transit
	Batas suhu penyimpanan
	Buka di sini
	Lihat petunjuk penggunaan
	Nomor model
	Diproduksi di
	Isi kemasan
	Dokumen produk
	Sistem pembatas steril tunggal
	Hanya untuk audiens di AS
	Perangkat medis
	Nomor PIN
	Alat tunneling transversal

1 Описание

Инструмент для поперечного туннелирования Epsila EV модели EAZ201 компании Medtronic предназначен для доставки проксимальной части экстраваскулярного электрода в "карман" для устройства в ходе имплантации системы экстраваскулярного имплантируемого устройства. Инструмент для туннелирования показан на *Рис. 1*.

Рисунок 1. Инструмент для туннелирования модели EAZ201



1 Рукоятка
2 Стержень для туннелирования
3 Канал для доставки электрода

2 Содержимое упаковки

Инструмент для туннелирования поставляется стерильным. В каждой упаковке содержатся следующие компоненты:

- 1 рукоятка
- 1 стержень для туннелирования
- Документация по продукту

3 Показания

Инструмент для поперечного туннелирования Epsila EV модели EAZ201 показан для применения при имплантации совместимого электрода для дефибрилляции через переднее средостение.

4 Противопоказания

Инструмент для поперечного туннелирования Epsila EV модели EAZ201 противопоказан для любого применения, не описанного в показаниях.

5 Предусмотренное назначение

Инструмент для поперечного туннелирования модели EAZ201 компании Medtronic представляет собой одноразовое стерильное медицинское изделие, показанное для применения при имплантации совместимого электрода для дефибрилляции через переднее средостение.

6 Предполагаемые пользователи

К использованию инструмента для поперечного туннелирования EAZ201 допускаются лица, прошедшие подготовку по работе и обращению с ним.

7 Предупреждения и меры предосторожности

Примечание. Предупреждения и меры предосторожности касательно медицинских процедур, относящихся к имплантированной системе компании Medtronic, включены в руководство, которое поставляется с имплантируемым устройством.

Совместимость продукта – Использование этого инструмента с продуктами, произведенными не компанией Medtronic, не проверялось.

Применение в детском возрасте – Специальные исследования применения инструмента у детей не проводились.

Осмотр стерильной упаковки – Перед открытием осмотрите стерильную упаковку.

- Если упаковка имеет повреждения или была открыта, не используйте изделие и обратитесь в представительство компании Medtronic.
- Не транспортируйте упаковку или ее содержимое при температуре выше 58°C (136°F) или ниже –35°C (–31°F). Не храните упаковку или ее содержимое при температуре выше 30°C (86°F) или ниже 15°C (59°F).
- Не используйте изделие после окончания срока годности.

Однократное использование – Этот инструмент предназначен только для однократного использования. Повторное использование может нарушить структурную целостность инструмента или создать риск его заражения, что может привести к травме, заболеванию или смерти пациента.

Стерилизация – Перед поставкой компания Medtronic стерилизовала содержимое упаковки облучением. Этот инструмент является одноразовым и не предназначен для повторной стерилизации.

Предшествующая стернотомия – Применение инструмента для туннелирования модели EAZ201 не оценивалось у пациентов, которым ранее была проведена стернотомия.

Имплантация и управление системой – Имплантация и непрерывное управление системой должны выполнятся врачами, обученными управлению системой и обращению с ней, и ознакомившимися с процедурами, описанными в соответствующих технических руководствах. Ненадлежащая подготовка или несоблюдение инструкций могут привести к причинению вреда пациентам.

Утилизация – Утилизируйте одноразовый инструмент в соответствии с требованиями местного законодательства по защите окружающей среды.

8 Возможные нежелательные явления

Далее перечислены предсказуемые возможные нежелательные явления, связанные с применением инструмента для поперечного туннелирования:

- Острое травмирование тканей
- Аллергическая реакция
- Смерть
- Дискомфорт
- Гематома
- Кровоизлияние
- Инфицирование
- Боль
- Серома

Примечание. В случае серьезного происшествия, связанного с работой устройства, немедленно сообщите о произошедшем компании Medtronic и уполномоченному регулирующему органу.

9 Нежелательные явления и данные клинических исследований

Следующая информация относится только к применению инструмента в США. Информацию о клинических исследованиях и нежелательных явлениях, связанных с этим инструментом, см. в руководстве по экстраваскулярному имплантируемому кардиовертеру-дефибриллятору для пользователей в США.

10 Сводные данные по безопасности и клинической эффективности

Краткий отчет о безопасности и клинической эффективности (SSCP) представлен на веб-сайте https://ec.europa.eu/tools/eudamed. Вы можете найти отчет SSCP по названию изготовителя и наименованию изделия, а также по следующим данным (если применимо): модель изделия, учетный номер, номер по каталогу или основной уникальный идентификационный номер изделия (основной UDI-DI): 0763000B000082586.

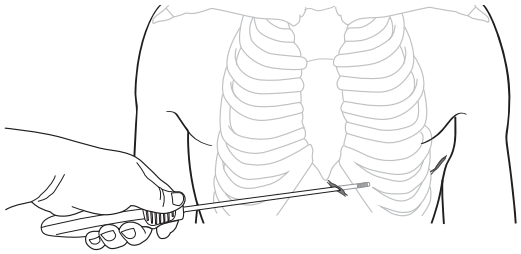
11 Указания по применению

За надлежащее выполнение хирургических процедур и применения правил асептики и антисептики несут ответственность медицинские работники. Ниже, исключительно с информационной целью, описаны некоторые процедуры. Некоторые методы имплантации могут изменяться в зависимости от предпочтений врача, анатомических особенностей пациента и его физического состояния. Каждый врач должен применять информацию, содержащуюся в этих инструкциях, согласно профессиональной медицинской подготовке и полученному опыту.

Используйте следующие инструкции после позиционирования и закрепления дистального конца электрода и создания "кармана" для устройства, как описано в техническом руководстве к экстраваскулярному электроду.

1. Вставьте стержень для туннелирования в рукоятку и продвиньте его до конца рукоятки.
2. Введите кончик стержня для туннелирования в разрез у мечевидного отростка над краем ребра, как показано на *Рис. 2*.

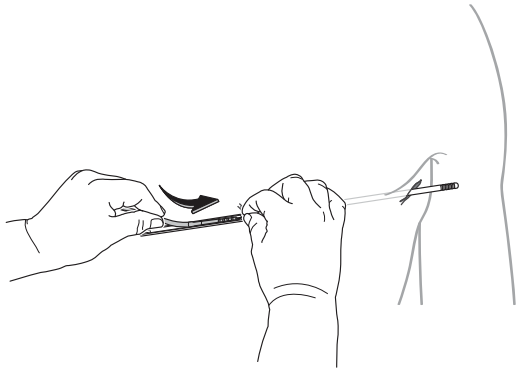
   Рисунок 2. Введение стержня для туннелирования

3. Выполните подкожное туннелирование в "карман" для устройства.
4. Когда кончик стержня для туннелирования выйдет через "карман" для устройства, снимите рукоятку со стержня для туннелирования, удерживая стержень для туннелирования на месте.

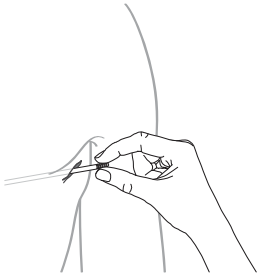
5. Отложите рукоятку в сторону, чтобы позже утилизировать.
6. Введите проксимальный конец электрода в канал стержня для туннелирования, как показано на *Рис. 3*.

Рисунок 3. Введение проксимального конца электрода в канал



7. Протяните стержень для туннелирования и электрод по подкожному туннелю наружу через "карман" для устройства, как показано на *Рис. 4*.

Рисунок 4. Вытягивание стержня для туннелирования из "кармана" для устройства



8. Выньте электрод из канала стержня для туннелирования и утилизируйте компоненты инструмента для туннелирования.

12 Технические характеристики

Параметр	Модель EAZ201
Длина устройства	
Общая длина	36,1 см (14,2 in)
Длина туннелирования	22,9 см (9,0 in)
Материал	
Рукоятка	Поликарбонат
Стержень для туннелирования	Полиэфиримид

13 Знак соответствия CE

CE 0344

14 Объяснение символов

Таблица 1. Объяснение символов, приведенных на этикетке упаковки

См. на этикетках упаковки, какие символы применимы к данному продукту.

CE 0344	Conformité Européenne (Европейское соответствие). Этот символ обозначает, что изделие полностью соответствует требованиям применимых директив Европейского союза.
EC REP	Уполномоченный представитель в Европейском сообществе
	Дата изготовления
	Изготовитель
	Импортер
	Срок годности
LOT	Номер партии

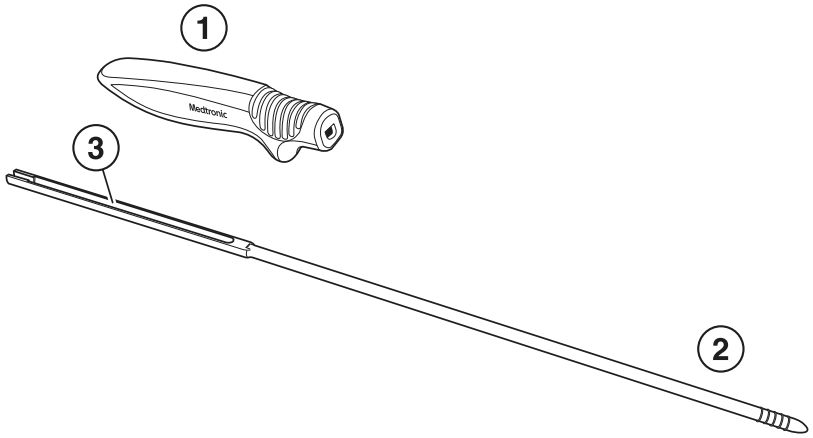
Таблица 1. Объяснение символов, приведенных на этикетке упаковки (продолжение)

REF	Номер для заказа
STERILE R	Радиационная стерилизация
	Запрет на повторное применение
	Не использовать при повреждении упаковки
	Температурный диапазон
	Диапазон температуры транспортировки
	Диапазон температуры хранения
	Открывать здесь
	Обратитесь к инструкции по применению
#	Номер модели
	Произведено в
	Содержимое упаковки
	Документация по продукту
	Система с единственным стерильным барьером
! USA	Только для США
MD	Медицинское устройство
PIN	Номер ПИН
	Инструмент для поперечного туннелирования

1 Opis

Medtronic Epsila EV model EAZ201 alata za poprečno pravljenje prolaza je namenjen da dovede proksimalni deo ekstravaskularnog provodnika do džepa za uređaj prilikom implantacije ekstravaskularnog implantabilnog sistema uređaja. Alat za pravljenje prolaza je prikazan na *sl. 1*.

Slika 1. Model EAZ201 alata za pravljenje prolaza



1 Drška
2 Šipka za pravljenje prolaza
3 Kanal za dovođenje provodnika

2 Sadržaj pakovanja

Alatka za pravljenje prolaza isporučuje se sterilna. Svako pakovanje sadrži sledeće stavke:

- 1 drška
- 1 šipka za pravljenje prolaza
- Dokumentacija o proizvodu

3 Indikacije

Epsila EV Model EAZ201 alata za poprečno pravljenje prolaza je indikovan za primenu prilikom implantacije kompatibilnog provodnika za defibrilaciju u prednji medijastinum.

4 Kontraindikacije

Epsila EV Model EAZ201 alata za poprečno pravljenje provodnika je isključivo indikovan za primene koje su navedene u indikacijama.

5 Predviđena namena

Medtronic model EAZ201 alata za poprečno pravljenje prolaza predstavlja sterilno medicinsko sredstvo za jednokratnu upotrebu, namenjeno za primenu prilikom implantacije kompatibilnog provodnika za defibrilaciju u prednji medijastinum.

6 Predviđeni korisnici

Korisnici alata za poprečno pravljenje prolaza model EAZ201 su osobe obučene za rad i rukovanje ovim alatom.

7 Upozorenja i mere predostrožnosti

Napomena: Medicinska upozorenja i mere predostrožnosti koje se odnose na Medtronic implantirani sistem obuhvaćeni su priručnikom koji je dostavljen uz implantabilni uređaj.

Kompatibilnost proizvoda – Ovaj alat nije ispitan za primenu sa proizvodima koje ne proizvodi kompanija Medtronic.

Primena kod dece – Alat nije posebno testiran za primenu kod dece.

Provera sterilnog pakovanja – Pregledajte sterilno pakovanje pre otvaranja.

- Ako je pakovanje oštećeno ili otvoreno, nemojte koristiti proizvod i obratite se predstavniku preduzeća Medtronic.
- Nemojte transportovati pakovanje ni sadržaj pakovanja na temperaturama iznad 58°C (136°F), kao ni ispod -35°C (-31°F). Nemojte čuvati pakovanje ni sadržaj pakovanja na temperaturama iznad 30°C (86°F), kao ni ispod 15°C (59°F).
- Ne koristite proizvod posle isteka roka važenja.

Jednokratna upotreba – Ovaj alat je namenjen samo za jednokratnu upotrebu. Ponovljena upotreba može ugroziti strukturni integritet alata i stvoriti rizik od kontaminacije alata, koja može dovesti do povrede, bolesti ili smrti pacijenta.

Sterilizacija – Medtronic je sterilisao sadržaj pakovanja primenom jonizujućeg zračenja pre isporuke. Ovaj alat je namenjen samo za jednokratnu upotrebu i nije predviđena ponovna sterilizacija.

Ranije sternotomije – Primena EAZ201 alata za pravljenje prolaza nije procenjena kod pacijenata, kod kojih je ranije vršena sternotomija.

Implantacija i upravljanje sistemom – Implantaciju i tekuće upravljanje sistemom moraju da vrše pojedinci obučeni za rad i rukovanje sistemom i moraju da budu usklađeni sa procedurama opisanim u odgovarajućim tehničkim uputstvima. Neodgovarajuća obuka ili propust u poštovanju uputstava mogu da dovedu do povrede pacijenata.

Odlaganje – Alat za jednokratnu upotrebu odložite u otpad shodno lokalnim ekološkim propisima.

8 Mogući neželjeni događaji

Ovde navodimo moguće neželjene događaje povezane sa primenom alata za poprečno pravljenje prolaza koji se mogu predvideti:

- Akutna povreda tkiva
- Alergijska reakcija
- Smrt
- Nelagodnost
- Hematom
- Krvarenje
- Infekcija
- Bol
- Serom

Napomena: Ako dođe do ozbiljnog incidenta u vezi sa ovim sredstvom, odmah prijavite incident kompaniji Medtronic i nadležnoj službi ili regulatornom telu.

9 Neželjeni događaji i podaci dobijeni kliničkim ispitivanjem

Sledeće informacije se odnose isključivo na korišćenje alata u Sjedinjenim Američkim Državama. Informacije koje se odnose na kliničke studije i neželjene događaje povezane sa ovim alatom možete pronaći u priručniku medicinskog sredstva za tržište SAD ekstravaskularnog implantabilnog kardioverter defibrilatora.

10 Sažeti prikaz bezbednosti i kliničkog učinka

Sažetak bezbednosnih i kliničkih performansi (SSCP) možete pronaći na https://ec.europa.eu/tools/eudamed. SSCP potražite na osnovu imena proizvođača i naziva sredstva, kao i na osnovu bilo kog od sledećih elemenata, kako je primereno: model sredstva, referentni broj, kataloški broj ili osnovni jedinstveni identifikacioni broj uređaja (osnovni UDI-DI) broj – 0763000B000082586.

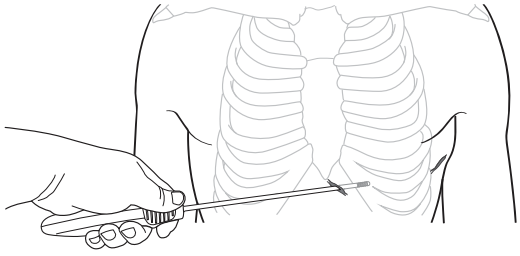
11 Uputstva za upotrebu

Medicinsko osoblje je odgovorno za sprovođenje ispravnih hirurških procedura i sterilnih tehnika. Sledeće procedure se pružaju isključivo u informativne svrhe. Neke tehnike implantacije razlikuju se u zavisnosti od ličnog načina rada lekara, kao i anatomije i fizičkog stanja pacijenta. Svaki lekar mora da primeni informacije iz ovih uputstava u skladu sa stručnom medicinskom obukom i iskustvom.

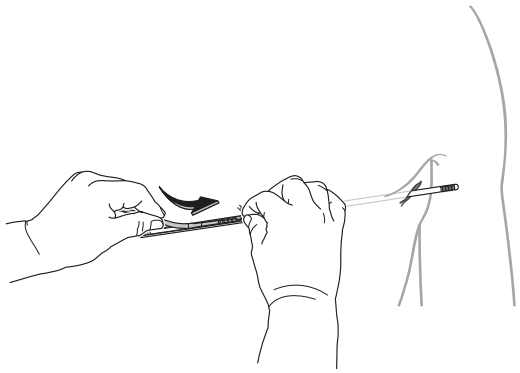
Pridržavajte se sledećih uputstava nakon postavljanja i pričvršćivanja distalnog kraja provodnika i pravljenja džepa za uređaj, kao što je opisano u tehničkom priručniku za ekstravaskularni provodnik.

1. Ubacite šipku za pravljenje prolaza u dršku i gurajte je do samog kraja drške.
2. Ubacite vrh šipke za pravljenje prolaza u ksifoidni rez, iznad ivice rebarnog luka, kao što je prikazano na *sl. 2*.

   Slika 2. Ubacivanje šipke za pravljenje prolaza

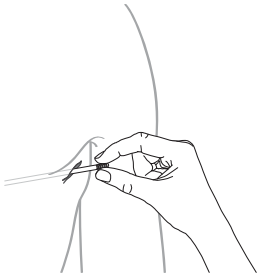
   
3. Napravite supkutani prolaz do džepa za uređaj.
4. Kada šipka za pravljenje prolaza izađe kroz džep za uređaj, skinite dršku sa šipke držeći pritom šipku na mestu.
5. Stavite dršku na stranu, kako biste je kasnije odložili u otpad.
6. Ubacite proksimalni kraj provodnika u kanal šipke za pravljenje prolaza, kao što je prikazano na *sl. 3*.

Slika 3. Ubacivanje proksimalnog kraja provodnika u kanal



7. Izvucite alat za pravljenje prolaza i provodnik kroz supkutani prolaz i napolje kroz džep za uređaj, kao što je prikazano na *sl. 4*.

Slika 4. Izvlačenje alata za pravljenje prolaza kroz džep za uređaj



8. Uklonite provodnik iz kanala alata za pravljenje prolaza i odložite komponente alata za pravljenje prolaza u otpad.

12 Specifikacije

Parametar	Model EAZ201
Dužina uređaja	
Ukupna dužina	36,1 cm (14,2 in)
Dužina za pravljenje prolaza	22,9 cm (9,0 in)
Materijal	
Drška	Polikarbonat
Šipka za pravljenje prolaza	Polieterimid

13 CE oznaka za usklađenost

CE 0344

14 Objašnjenje simbola

Tabela 1. Objašnjenje simbola na oznakama pakovanja

Pogledajte oznake na pakovanju da biste videli koji se simboli odnose na ovaj proizvod.

CE 0344	Conformité Européenne (usklađenost sa evropskim standardima). Ovaj simbol označava da je uređaj u potpunosti usklađen sa važećim zakonima Evropske unije.
EC REP	Ovlašćeni predstavnik za Evropsku uniju
	Datum proizvodnje
	Proizvođač
	Uvoznik
	Datum „Upotrebljivo do”
LOT	Broj serije
REF	Broj za naknadnu narudžbinu

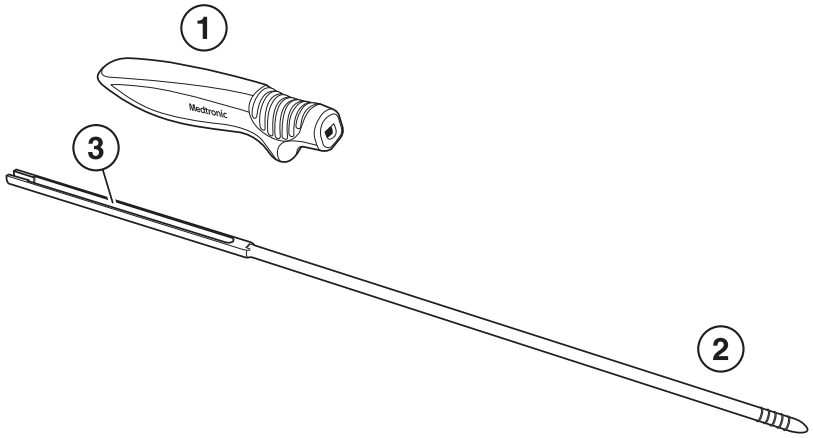
Tabela 1. Objašnjenje simbola na oznakama pakovanja (nastavak)

STERILE R	Sterilizovano zračenjem
	Nemojte ponovo koristiti
	Nemojte koristiti ako je pakovanje oštećeno
	Ograničenje temperature
	Ograničenje temperature pri transportu
	Ograničenje temperature skladištenja
	Ovde otvoriti
	Postupite u skladu s uputstvom za upotrebu
#	Broj modela
	Proizvedeno u
	Sadržaj pakovanja
	Dokumentacija o proizvodu
	Sistem jednostruke sterilne barijere
! USA	Samo za korisnike u SAD-u
MD	Medicinsko sredstvo
PIN	PIN broj
	Alat za poprečno pravljenje prolaza

1 Опис

Інструмент для поперечного тунелювання Epsila EV моделі EAZ201 компанії Medtronic призначений для введення проксимальної частини позасудинного електрода в «кишеню» пристрою під час імплантації системи позасудинного пристрою, що імплантується. Інструмент для тунелювання показаний на *Мал. 1*.

Малюнок 1. Інструмент для тунелювання моделі EAZ201



1 Рукоятка
2 Стрижень для тунелювання
3 Канал для введення електрода

2 Вміст упаковки

Інструмент для тунелювання постачається в стерильному вигляді. У кожній упаковці містяться нижченаведені компоненти.

- 1 рукоятка
- 1 стрижень для тунелювання
- Документація на продукт

3 Показання

Інструмент для поперечного тунелювання Epsila EV моделі EAZ201 показаний для використання під час імплантування сумісного електрода для дефібриляції в переднє середостіння.

4 Протипоказання

Інструмент для поперечного тунелювання Epsila EV моделі EAZ201 не призначений для будь-якого використання, яке не зазначено в показаннях.

5 Цільове призначення

Інструмент для поперечного тунелювання Medtronic моделі EAZ201 є стерильним, одноразовим медичним пристроєм, показаним для використання під час імплантування сумісного електрода для дефібриляції в переднє середостіння.

6 Передбачені користувачі

Користувачі інструмента для поперечного тунелювання моделі EAZ201 – це люди, навчені роботі з інструментом.

7 Попередження та запобіжні заходи

Примітка. Застереження і запобіжні заходи щодо медичних процедур, які відносяться до імплантованої системи компанії Medtronic, включені в керівництво, яке надається з пристроєм, що імплантується.

Сумісність продукту – Цей інструмент не був протестований для використання з іншими продуктами, крім продуктів компанії Medtronic.

Застосування серед дітей – Спеціальні дослідження застосування пристрою в дітей не проводились.

Огляд стерильної упаковки – Перед відкриттям огляньте стерильну упаковку.

- Якщо упаковка пошкоджена або відкрита, не використовуйте продукт і зверніться до представництва компанії Medtronic.
- Перевозити упаковку або її вміст при температурі вище 58°C (136°F) або нижче –35°C (–31°F) заборонено. Зберігати упаковку або її вміст при температурі вище 30°C (86°F) або нижче 15°C (59°F) заборонено.
- Не використовуйте даний продукт після закінчення терміну придатності.

Одноразове застосування – Цей інструмент призначений лише для одноразового використання. Повторне використання може порушити структурну цілісність інструмента або створити ризик його забруднення, що може призвести до травмування, захворювання або смерті пацієнта.

Стерилізація – Перед постачанням фахівці компанії Medtronic стерилізували вміст упаковки опроміненням. Інструмент є одноразовим і не призначений для повторної стерилізації.

Стернотомія в анамнезі – Використання інструмента для тунелювання EAZ201 не оцінювалося у пацієнтів, які перенесли попередню стернотомію.

Імплантація та управління системою – Імплантація та поточне управління системою повинні виконуватися лікарями, навченими управлінню системою та поводженню з нею, і які ознайомилися з процедурами, описаними у відповідних технічних посібниках. Неналежна підготовка або недотримання інструкцій можуть призвести до заподіяння шкоди пацієнтам.

Утилізація – Утилізуйте одноразовий інструмент відповідно до вимог чинного законодавства з охорони навколишнього середовища.

8 Можливі небажані явища

Нижче вказано передбачувані потенційні небажані явища, пов'язані з використанням інструмента для поперечного тунелювання.

- Гостра травма тканин
- Алергічна реакція
- Смерть
- Дискомфорт
- Гематома
- Крововилив
- Інфекція
- Біль
- Серома

Примітка. у разі серйозного випадку, пов'язаного з пристроєм, негайно повідомте про випадок компанії Medtronic і вповноваженому чи регулюючому органу.

9 Небажані явища й дані клінічного дослідження

Нижченаведена інформація застосовується лише в разі використання інструмента в США. Для отримання інформації про клінічні дослідження й небажані явища, пов'язані з цим інструментом, див. посібник з експлуатації пристрою для США для позасудинного імплантованого кардіовертер-дефібрилятора.

10 Зведені дані з безпеки і клінічної ефективності

Короткий звіт про безпеку й клінічну ефективність (SSCP) наведено за адресою https://ec.europa.eu/tools/eudamed. Для пошуку короткого звіту про безпеку й клінічну ефективність (SSCP) використовуйте назву виробника та пристрою, а також будь-який із цих відповідних елементів: модель пристрою, обліковий номер (REF), номер за каталогом або базовий унікальний ідентифікатор виробу (базовий UDI-DI) — 0763000B000082586.

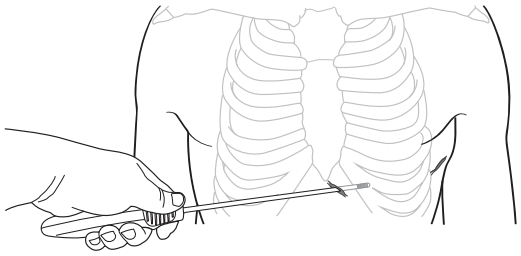
11 Вказівки щодо застосування

Відповідальність за правильність виконання хірургічних процедур і застосування стерильних методів несуть медичні працівники. Нижче, виключно з інформаційною метою, описані деякі процедури. Деякі методи імплантації можуть змінюватися залежно від уподобань лікаря, анатомічних особливостей пацієнта і його фізичного стану. Кожен лікар повинен застосовувати інформацію, що міститься в цих інструкціях, згідно з професійним медичним досвідом та отриманими навичками.

Використовуйте наступні інструкції після позиціонування і кріплення дистального кінця електрода і створення «кишені» для пристрою, як описано в технічному керівництві для позасудинного електрода.

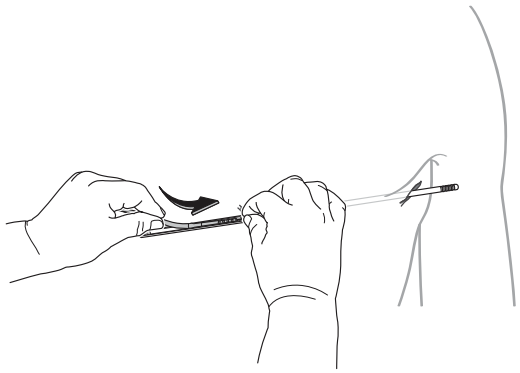
1. Вставте стрижень для тунелювання в рукоятку й проштовхніть стрижень для тунелювання до кінця рукоятки.
2. Вставте стрижень для тунелювання в розріз біля мечоподібного відростка вище краю ребра, як показано на *Мал. 2*.

   Малюнок 2. Введення стрижня для тунелювання

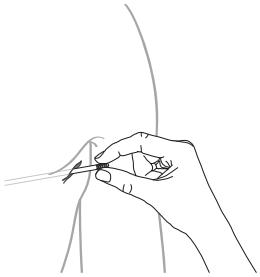
3. Виконайте підшкірне тунелювання в «кишеню» пристрою.
4. Коли кінчик стрижня для тунелювання виходить з «кишені» пристрою, зніміть рукоятку зі стрижня для тунелювання, утримуючи стрижень для тунелювання на місці.
5. Відкладіть рукоятку для подальшої утилізації.
6. Введіть проксимальний кінець електрода в канал стрижня для тунелювання, як показано на *Мал. 3*.

Малюнок 3. Введення проксимального кінця електрода в канал



7. Протягніть стрижень для тунелювання й електрод через підшкірний тунель і вийміть через «кишеню» пристрою, як показано на *Мал. 4*.

Малюнок 4. Виймання стрижня для тунелювання через «кишеню» для пристрою



8. Вийміть електрод з каналу стрижня для тунелювання і утилізуйте компоненти інструменту для тунелювання.

12 Технічні характеристики

Параметр	Модель EAZ201
Довжина пристрою	
Загальна довжина	36,1 см(cm) (14,2 in)
Довжина тунелювання	22,9 см(cm) (9,0 in)
Матеріал	
Рукоятка	Полікарбонат
Стрижень для тунелювання	Поліефірімід

13 Знак відповідності CE

CE 0344

14 Роз'яснення умовних позначок

Таблиця 1. Роз'яснення умовних позначок на маркуванні упаковки

Див. етикетки упаковки, які символи застосовні до даного продукту.

CE 0344	Conformité Européenne (відповідність вимогам ЄС). Цей символ означає, що пристрій повністю відповідає вимогам застосовних директив Європейського Союзу.
EC REP	Уповноважений представник Європейського Союзу
	Дата виготовлення
	Виробник
	Імпортер
	Термін придатності
LOT	Номер партії
REF	Номер для повторного замовлення

Таблиця 1. Роз'яснення умовних позначок на маркуванні упаковки (продовження)

STERILE R	Стерилізовано із застосуванням випромінювання
	Повторно використовувати заборонено
	Не використовувати у разі пошкодження пакування
	Температурне обмеження
	Обмеження температури транспортування
	Обмеження температури зберігання
	Відкривати тут
	Ознайомтеся з інструкціями із застосування
#	Номер моделі
	Місце виготовлення
	Вміст упаковки
	Документація на продукт
	Система одинарного стерильного бар'єра
! USA	Лише для користувачів у США
MD	Медичний виріб
PIN	PIN-номер
	Інструмент для поперечного тунелювання

Medtronic

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710 Medtronic Parkway
Minneapolis, MN 55432
USA
www.medtronic.com
+1 763 514 4000

EC REP

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6422 PJ Heerlen
The Netherlands
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Canada
Medtronic Canada ULC
99 Hereford Street
Brampton, Ontario L6Y 0R3
Canada
1 800 268 5346

Technical manuals
www.medtronic.com/manuals

M999195A003 B
2022-01-27

M999195A003

Medtronic

IMPLANTED DEVICE IDENTIFICATION CARD

(IN USA AND CANADA) IF EMERGENCY, CALL 911. (For implantable cardioverter defibrillators [ICDs]) Perform CPR. Device therapeutic shocks may be felt but will not be harmful. EMT: Place the external defibrillator paddles 15 cm away from ICD. If ineffective, switch positions to posterior-anterior. Placing a magnet over the ICD will prevent delivery of tachy therapies but will not alter brady pacing.

IN CASE OF EMERGENCY, CONTACT PHYSICIAN(S):

NAME _____ **TEL** _____

NAME _____ **TEL** _____

This is your patient's temporary identification card. Please complete it and advise your patient to keep it where it may be readily located. (In USA and Canada) Upon receipt of registration, Medtronic will mail your patient a permanent identification card to replace this one.

TEMPORARY ID CARD

MY NAME _____ **TEL** _____

ADDRESS _____

_____

I HAVE AN IMPLANTED ☐**PACEMAKER** ☐**ICD** ☐**MONITOR**

MODEL / SERIAL NO. **IMPLANT DATE**

_____

_____

_____

Medtronic, Inc., Minneapolis, MN 55432, USA (800) 551-5544

Medtronic of Canada, Ltd., 6733 Kitimat Road, Mississauga, Ontario L5N 1W3 (800) 268-5346

Medtronic

IMPLANTED DEVICE IDENTIFICATION CARD

(IN USA AND CANADA) IF EMERGENCY, CALL 911. (For implantable cardioverter defibrillators [ICDs]) Perform CPR. Device therapeutic shocks may be felt but will not be harmful. EMT: Place the external defibrillator paddles 15 cm away from ICD. If ineffective, switch positions to posterior-anterior. Placing a magnet over the ICD will prevent delivery of tachy therapies but will not alter brady pacing.

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TEMPORARY ID CARD

MY NAME _____ **TEL** _____

ADDRESS _____

_____

I HAVE AN IMPLANTED ☐**PACEMAKER** ☐**ICD** ☐**MONITOR**

MODEL / SERIAL NO. **IMPLANT DATE**

_____

_____

_____

Medtronic, Inc., Minneapolis, MN 55432, USA (800) 551-5544
Medtronic of Canada, Ltd., 6733 Kitimat Road, Mississauga, Ontario L5N 1W3 (800) 268-5346

Medtronic

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Renuncia de responsabilidad y advertencia general

Uitsluiting van garantie en algemene waarschuwing

Esclusione dalla garanzia e avvertenza generale

Ansvarsfraskrivelse og generell advarsel

Friskrivning från ansvar och allmän varning

Παύση ισχύος της εγγύησης και γενική προειδοποίηση

Ansvarsfraskrivelse og generel advarsel

Renúncia de garantia e aviso geral

Felelősségkizárás és általános figyelmeztetés

Wyłączenie gwarancji i ostrzeżenie ogólne

Odmítnutí záruk a obecná varování

Ограниченная гарантия и предупреждения общего характера

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General warning

The PRODUCTS in this package are designed for use with other Medtronic products. Despite the exercise of all due care in design, component selection, manufacture, and testing prior to sale, PRODUCTS may be easily damaged by improper handling or use because of their unavoidably fragile character, which is dictated by the unusual requirements of their application. Consequently, no representation or warranty is made that failure or cessation of function of PRODUCTS will not occur.

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General warning

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Les clients des États-Unis peuvent avoir recours au présent déni de garantie et avertissement général :

Déni de garantie

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Les clients en dehors des États-Unis peuvent avoir recours au présent déni de garantie et avertissement général :

Déni de garantie

Bien que les accessoires de Medtronic® (ci-après, le « Produit ») aient été soigneusement conçus, fabriqués et testés avant sa mise en vente sur le marché, le Produit peut, pour diverses raisons, connaître des défaillances. Les avertissements décrits dans la documentation du Produit contiennent des informations détaillées et doivent être considérés comme faisant partie intégrante du présent DÉNI DE GARANTIE. En conséquence, Medtronic décline toute responsabilité, expresse ou implicite, relative au Produit. Medtronic ne sera pas tenu responsable de tous dommages fortuits ou indirects qui seraient provoqués par tous usages, défectuosités ou défaillances du Produit, et ce que la plainte soit fondée sur une garantie, une responsabilité contractuelle, délictueuse ou quasi-délictueuse.

Les exclusions et les limitations de garantie mentionnées ci-dessus ne sont pas, et ne doivent pas être interprétées comme contraires aux dispositions obligatoires des lois applicables. Si une partie ou une disposition du présent DÉNI DE GARANTIE devait être considérée illégale, non applicable ou contraire à la loi en vigueur par un tribunal compétent, la validité des autres dispositions du présent DÉNI DE GARANTIE n'en sera pas affectée. Dans ce cas, tous autres droits et obligations seront interprétés et appliqués, sans tenir compte de la partie ou la disposition considérée comme illégale.

Avertissement général

Les produits de cet emballage sont conçus pour être utilisés avec d'autres produits de Medtronic. En dépit de toute l'attention portée à la conception, au choix des composants, à la fabrication et aux essais précédant la mise en vente, les produits peuvent être facilement endommagés par une mauvaise manipulation ou par d'autres interventions en raison de leur caractère inévitablement fragile imposé par les exigences inhabituelles de leur application. Par conséquent, aucune déclaration, ni aucune garantie ne sont émises pour certifier qu’un défaut ou un arrêt de fonctionnement des produits ne se produira pas.

Der folgende Haftungsausschluss und der dazugehörige allgemeine Warnhinweis gelten nur für Kunden außerhalb der USA:

Haftungsausschluss

Trotz sorgfältiger Konstruktion, Herstellung und vor dem Verkauf durchgeführter Testdurchläufe ist es möglich, dass das Medtronic® Zubehörteil (nachfolgend als „Produkt“ bezeichnet) aus den verschiedensten Gründen nicht zufrieden stellend funktioniert. Die Hinweise in der Produktinformation enthalten weitere detaillierte Informationen und sollten als Teil des HAFTUNGSAUSSCHLUSSES gesehen werden. Medtronic schließt jede ausdrückliche oder stillschweigende Garantie in Bezug auf das Produkt aus. Medtronic haftet weder für unmittelbare noch mittelbare Folgeschäden, die durch den Gebrauch, durch Störungen oder Fehlfunktionen des Produktes entstehen, unabhängig davon, ob sich der Anspruch auf Schadensersatz auf eine Garantie, einen Vertrag, eine unerlaubte Handlung oder eine andere Anspruchsgrundlage stützt.

Die hier aufgeführten Haftungsausschlüsse und-beschränkungen sollen nicht gegen zwingende gesetzliche Bestimmungen verstoßen und sind nicht dahingehend auszulegen. Sollte ein zuständiges Gericht feststellen, dass dieser HAFTUNGSAUSSCHLUSS ganz oder teilweise unwirksam, nicht durchsetzbar oder im Widerspruch zu zwingendem Recht ist, berührt dies die Gültigkeit der restlichen Klauseln nicht und alle Rechte und Pflichten aus diesem HAFTUNGSAUSSCHLUSS sind so auszulegen und durchzusetzen, als sei der für ungültig erklärte Teil oder die ungültige Vorschrift in dem HAFTUNGSAUSSCHLUSS nicht enthalten.

Allgemeiner Warnhinweis

Die Produkte in dieser Packung sind zur Verwendung mit anderen Medtronic Produkten vorgesehen. Obwohl die Konstruktion der Produkte, die Auswahl ihrer Komponenten, ihre Fertigung und Erprobung vor dem Verkauf mit der gebotenen Sorgfalt erfolgt sind, können die Produkte aufgrund ihrer unvermeidlichen Zerbrechlichkeit, die sich aus den ungewöhnlichen Bedingungen ihres Einsatzes ergibt, durch falsche Behandlung oder Verwendung leicht beschädigt werden. Daher kann nicht zugesichert oder garantiert werden, dass es nicht zu einem Versagen oder einem Funktionsausfall der Produkte kommen kann.

La Renuncia de responsabilidad y la advertencia general siguientes se aplican a los clientes que se encuentran fuera de los Estados Unidos:

Renuncia de responsabilidad

Aunque el Accesorio de Medtronic®, al que nos referiremos en lo sucesivo como “Producto”, ha sido diseñado, fabricado y probado cuidadosamente antes de ponerlo a la venta, el Producto puede no cumplir sus funciones de forma satisfactoria por diversas razones. Las advertencias que contiene el etiquetado del Producto proporcionan información más detallada y se consideran como parte integrante de esta RENUNCIA DE RESPONSABILIDAD. Medtronic, por lo tanto, renuncia a toda garantía, tanto expresa como implícita, respecto al Producto. Medtronic no se hace responsable de los daños fortuitos o resultantes derivados de la utilización, defecto o malfuncionamiento del Producto, aun cuando la reclamación se base en una garantía, contrato, responsabilidad extracontractual u otras causas.

Las exclusiones y limitaciones arriba expresadas no revisten el propósito de contravenir las disposiciones obligatorias establecidas por la legislación vigente, ni deben interpretarse de dicha forma. En el supuesto de que cualquier parte o término de la presente Renuncia de responsabilidad sea declarado por cualquier tribunal competente como ilegal, inaplicable o contrario a la ley, ello no afectará a la validez del resto de la Renuncia de responsabilidad, interpretándose y aplicándose cuantos derechos y obligaciones se incluyen en ella como si la presente Renuncia de responsabilidad no contuviera la parte o condición considerada no válida.

Advertencia general

Los Productos contenidos en este envase están diseñados para utilizarse con otros productos de Medtronic. A pesar del debido cuidado puesto en el diseño, selección de componentes, fabricación y comprobación previos a la venta, es fácil que los Productos sufran daños causados por el manejo o uso inadecuados debido a su carácter inevitablemente frágil, el cual viene condicionado por los inusuales requisitos de su aplicación. Por consiguiente, no se ofrece representación ni garantía alguna de que no se produzca un fallo o cese del funcionamiento de los Productos.

De hiernavolgende uitsluiting van garantie en algemene waarschuwing gelden alleen voor klanten buiten de Verenigde Staten:

Uitsluiting van garantie

Hoewel het toebehoren van Medtronic®, hierna het "Product" genoemd, met veel zorg is ontworpen, vervaardigd en vóór de verkoop getest, kunnen er verschillende redenen zijn waarom het Product niet volgens de specificaties werkt. De waarschuwingen in de productdocumentatie bieden meer gedetailleerde informatie en vormen een integraal onderdeel van deze UITSLUITING VAN GARANTIE. Medtronic verleent daarom geen enkele garantie, noch expliciet noch impliciet, met betrekking tot het Product. Medtronic is niet aansprakelijk voor enige incidentele of gevolgschade, veroorzaakt door om het even welk gebruik, defect of falen van het Product, ongeacht of de vordering is gebaseerd op een garantie, contract, onrechtmatige daad of anderszins.

De uitsluitingen en beperkingen die hierboven uiteengezet zijn, zijn niet bedoeld, en moeten niet geïnterpreteerd worden als een inbreuk op dwingende bepalingen van de van toepassing zijnde wet. Indien enig onderdeel of enige bepaling van deze UITSLUITING VAN GARANTIE door een daartoe bevoegde rechtbank als illegaal, onuitvoerbaar of in strijd met de van toepassing zijnde wet beschouwd wordt, zal dit de geldigheid van het overige deel van deze UITSLUITING VAN GARANTIE niet aantasten en zullen alle rechten en plichten worden uitgelegd en ten uitvoer worden gebracht alsof deze UITSLUITING VAN GARANTIE het desbetreffende ongeldig verklaarde gedeelte niet bevatte.

Algemene waarschuwing

De Producten in deze verpakking zijn ontworpen voor gebruik met ander producten van Medtronic. De Producten kunnen, ondanks alle zorg die aan het ontwerp, de selectie van de componenten, de fabricage en de voorafgaand aan de verkoop uitgevoerde tests is besteed, gemakkelijk beschadigd raken door onjuiste hantering of onjuist gebruik. Dit komt door hun kwetsbare ontwerp waaraan vanwege hun toepassing bijzondere eisen zijn gesteld. Derhalve kan geen garantie worden gegeven dat de Producten correct zullen blijven functioneren.

L’Esclusione dalla garanzia e l’avvertenza generale riportate di seguito sono valide esclusivamente per i clienti non residenti negli Stati Uniti.

Esclusione dalla garanzia

Sebbene l'accessorio della Medtronic®, di seguito denominato “Prodotto”, sia stato accuratamente progettato, realizzato e testato prima di essere commercializzato, potrebbe non funzionare in modo soddisfacente per svariati motivi. Le avvertenze indicate nella documentazione del Prodotto forniscono informazioni più dettagliate a tale riguardo e sono da considerare come parte integrante della presente dichiarazione dell’ESCLUSIONE DALLA GARANZIA. Di conseguenza la Medtronic non rilascia alcuna garanzia, né espressa né tacita, relativa al Prodotto. La Medtronic declina ogni responsabilità per eventuali danni incidentali o indiretti derivanti dall'uso, dai difetti o dal mancato funzionamento del Prodotto, indipendentemente dal fatto che la richiesta di risarcimento si basi su garanzia, contratto, fatto illecito o altro.

Le esclusioni e le restrizioni di cui sopra non vanno intese, né devono essere interpretate in quanto tali, come contravvenenti alle disposizioni inderogabili della legislazione vigente. Nel caso in cui una parte od un termine della presente ESCLUSIONE DALLA GARANZIA venga dichiarato illegale, inefficace od in conflitto con la legislazione vigente da un organo giudiziario competente, la validità delle rimanenti parti della presente ESCLUSIONE DALLA GARANZIA non verrà compromessa e tutti i diritti e gli obblighi saranno interpretati ed applicati come se la presente ESCLUSIONE DALLA GARANZIA non contenesse la parte od i termini dichiarati non validi.

Avvertenza generale

I Prodotti contenuti in questa confezione sono stati progettati per essere utilizzati congiuntamente ad altri prodotti della Medtronic. Malgrado l'estrema attenzione dedicata alla progettazione, alla selezione dei componenti, alla fabbricazione ed al collaudo prevendita, i Prodotti possono facilmente subire dei danni a seguito di maneggiamento o uso inadeguato, a causa della loro natura inevitabilmente fragile dettata dalle particolari esigenze della loro applicazione. Di conseguenza, non viene fornita alcuna garanzia che esclude un eventuale malfunzionamento o la cessazione del funzionamento dei Prodotti.

Følgende ansvarsfraskrivelse og generelle advarsel gjelder for kunder utenfor USA:

Ansvarsfraskrivelse

Selv om tilbehøret fra Medtronic®, heretter kalt "Produktet", er nøye designet, produsert og testet før salg, kan det hende at Produktet ikke virker som det skal av en rekke årsaker. Advarslene på Produktets etiketter inneholder mer detaljert informasjon og skal betraktes som en integrerende del av denne ANSVARSFRASKRIVELSEN. Medtronic frasier seg derfor ethvert garantiansvar, både direkte og indirekte, for dette produktet. Medtronic skal ikke være ansvarlig for tilfeldige skader eller følgeskader som skyldes bruk av, feil eller svikt på Produktet, enten kravet er basert på garanti, kontrakt, forhold utenfor kontrakt eller annet.

Unntakene og begrensningene som er angitt ovenfor, er ikke ment som, og skal ikke tolkes som, brudd på ufravikelige bestemmelser i gjeldende rett. Hvis en kompetent domstol finner at en del eller betingelse i denne ANSVARSFRASKRIVELSEN er ulovlig, ikke kan håndheves eller er i strid med gjeldende rett, skal ikke gyldigheten av de øvrige delene av ANSVARSFRASKRIVELSEN berøres, og alle retter og plikter skal tolkes og håndheves som om denne ANSVARSFRASKRIVELSEN ikke inneholdt den bestemte delen eller betingelsen som ble funnet ugyldig.

Generell advarsel

Produktene i denne forpakningen er beregnet på å brukes sammen med andre Medtronic-produkter. Til tross for streng kontroll i forbindelse med design, valg av komponenter, produksjon og testing før salg, kan Produktene lett bli ødelagt ved feilaktig håndtering eller bruk ettersom de lett kan gå i stykker, noe som de uvanlige brukskravene tilsier. Det gis derfor ingen løfter eller garantier om at Produktene ikke vil svikte eller slutte å virke som de skal.

Nedanstående friskrivning från ansvar är endast tillämplig för kunder utanför USA.

Friskrivning från ansvar

Oaktat Medtronic® tillbehör, nedan Produkten, före försäljning blivit noggrant konstruerad, tillverkad och kontrollerad, kan det av olika skäl inträffa att Produkten är behäftad med fel eller inte fungerar tillfredsställande. Varningstexter på Produktetiketten innehåller mera detaljerade upplysningar och utgör en integrerad del av denna FRISKRIVNING FRÅN ANSVAR. Medtronic friskriver sig därför helt från ansvar för alla fel i Produkten. Inga garantier lämnas, vare sig uttryckligen eller underförstått. Medtronic skall därför inte vara skyldigt att ersätta någon skada, vare sig direkt eller indirekt, som uppkommer i anledning av Produktens utformning eller dess användning, oavsett om kravet grundar sig på påstående om garanti, avtalsbrott, skadegörande handling eller annat.

Ovan angiven friskrivning från ansvar är inte avsedd att stå i strid med tvingande regler i tillämplig lag, och de skall inte heller tolkas så. Skulle FRISKRIVNING FRÅN ANSVAR till någon del av behörig domstol anses ogiltig, verkningslös eller stridande mot tillämplig lag, skall FRISKRIVNING FRÅN ANSVAR gälla i övrigt, varvid alla rättigheter och skyldigheter skall bestå, som om avtalet inte innehöll den del av GARANTIN eller FRISKRIVNING FRÅN ANSVAR som underkänts.

Allmän varning

Produkterna i denna förpackning är tillverkade för att användas med andra Medtronic produkter. Dessutom, trots att de blivit noggrant konstruerade, tillverkade och kontrollerade före försäljning, kan produkten lätt skadas vid felaktig behandling eller annan typ av ovarsam hantering. Ömtåligheten är en ofrånkomlig konsekvens av dess funktion. Därför kan ingen garanti ges eller utfästelser göras om att produkten alltid fungerar som den ska och att inga fel uppstår.

Η παρακάτω παύση ισχύος της εγγύησης και γενική προειδοποίηση ισχύει για πελάτες εκτός των Ηνωμένων Πολιτειών:

Παύση ισχύος της εγγύησης

Αν και το Εξάρτημα της Medtronic®, το οποίο αναφέρεται εφεξής ως «Προϊόν», έχει σχεδιασθεί, κατασκευασθεί και δοκιμασθεί προσεκτικά πριν την πώλησή του, το Προϊόν μπορεί να αποτύχει να εκτελέσει ικανοποιητικά την προτιθέμενη λειτουργία του λόγω διάφορων αιτίων. Οι προειδοποιήσεις που περιέχονται στη σήμανση του Προϊόντος παρέχουν περισσότερο λεπτομερείς πληροφορίες και θεωρούνται αναπόσπαστο τμήμα αυτής της ΠΑΥΣΗΣ ΙΣΧΥΟΣ ΤΗΣ ΕΓΓΥΗΣΗΣ. Επομένως, η Medtronic αποποιείται κάθε εγγύηση, ρητή και σιωπηρή, σε σχέση με το Προϊόν. Η Medtronic δεν θα είναι υπεύθυνη για οποιεσδήποτε θετικές ή αποθετικές ζημίες προκαλούμενες από οποιαδήποτε χρήση, ελάττωμα ή βλάβη του Προϊόντος, είτε η απαίτηση βασίζεται σε εγγύηση, συμβατική υποχρέωση, αδικοπραξία ή άλλο.

Οι ως άνω εξαιρέσεις και περιορισμοί δεν αποσκοπούν να εναντιωθούν σε υποχρεωτικούς όρους της ισχύουσας νομοθεσίας και δεν θα πρέπει να ερμηνευθούν κατά αυτό τον τρόπο. Εάν μέρος ή όρος αυτής της ΠΑΥΣΗΣ ΙΣΧΥΟΣ ΤΗΣ ΕΓΓΥΗΣΗΣ θεωρείται από οιοδήποτε δικαστήριο ικανής δικαιοδοσίας παράνομο, μη εφαρμόσιμο ή σε αντίθεση με την ισχύουσα νομοθεσία, η ισχύς του υπολοίπου τμήματος της ΠΑΥΣΗΣ ΙΣΧΥΟΣ ΤΗΣ ΕΓΓΥΗΣΗΣ δεν θα επηρεασθεί και όλα τα δικαιώματα και οι υποχρεώσεις θα ερμηνευθούν και θα ισχύσουν σαν να μην περιέχει αυτή η ΠΑΥΣΗ ΙΣΧΥΟΣ ΤΗΣ ΕΓΓΥΗΣΗΣ το ιδιαίτερο τμήμα ή τον όρο που θεωρείται άκυρος.

Γενική προειδοποίηση

Τα Προϊόντα σε αυτήν τη συσκευασία έχουν σχεδιασθεί για χρήση με άλλα προϊόντα της Medtronic. Παρά την εφαρμογή της πρέπουσας φροντίδας στο σχεδιασμό, την επιλογή των εξαρτημάτων, την κατασκευή και τις δοκιμές πριν την πώληση, τα Προϊόντα μπορεί εύκολα να υποστούν βλάβη από ακατάλληλο χειρισμό ή χρήση λόγω της αναπόφευκτα εύθραυστης φύσης τους, η οποία επιβάλλεται από τις ασυνήθεις απαιτήσεις της εφαρμογής τους. Συνεπώς, δεν παρέχεται δέσμευση ή εγγύηση ότι δεν θα συμβεί βλάβη ή παύση της λειτουργίας των Προϊόντων.

Følgende ansvarsfraskrivelse og generelle advarsel gælder for kunder uden for USA:

Ansvarsfraskrivelse

Selvom Medtronic® tilbehør, i det følgende kaldet "Produktet", er omhyggeligt designet, fremstillet og afprøvet før salg, kan der af mange grunde være risiko for, at Produktet ikke fungerer tilfredsstillende efter hensigten. Advarslerne, som fremgår af Produktets mærkater, giver mere detaljerede oplysninger og betragtes som en integreret del af denne ANSVARSFRASKRIVELSE. Medtronic frasiger sig derfor alle garantier, udtrykkelige såvel som stiltiende, med hensyn til Produktet. Medtronic kan ikke holdes ansvarlig for tilfældige skader eller følgeskader som følge af brug af Produktet eller dets defekt eller fejlfunktion, uanset om kravet baseres på garanti, kontrakt, erstatning uden for kontrakt, eller andet.

Ovennævnte undtagelser og begrænsninger har ikke til hensigt at være og må ikke fortolkes som værende i modstrid med ufravigelige lovbestemmelser. Hvis nogen del af eller vilkår i denne ANSVARSFRASKRIVELSE af en retsinstans i nogen kompetent retskreds anses for ulovlig, uden retskraft eller i konflikt med den relevante lovgivning, berøres den resterende del af ANSVARSFRASKRIVELSEN ikke, og alle rettigheder og forpligtelser skal tolkes og håndhæves, som om denne ANSVARSFRASKRIVELSE ikke indeholdt det pågældende afsnit eller vilkår, der anses for ugyldigt.

Generel advarsel

Produkterne i denne pakke er beregnet til anvendelse sammen med andre Medtronic produkter. På trods af at der træffes omhyggelige forholdsregler ved design, valg af komponenter, fremstilling og test inden salget, bliver Produkterne let beskadiget ved forkert håndtering eller brug på grund af deres uundgåeligt sarte natur, der er fastsat ud fra de usædvanlige krav, som deres anvendelse stiller til dem. Følgelig fremsættes der ingen erklæring eller garanti om, at der ikke vil forekomme svigt eller ophør af produktets funktionsevne.

A renúncia de garantia e o aviso geral seguintes aplicam-se a clientes no exterior dos Estados Unidos:

Renúncia de garantia

Apesar do acessório da Medtronic®, aqui a seguir designado por “Produto”, ter sido cuidadosamente concebido, fabricado e testado antes da comercialização, o Produto poderá não desempenhar satisfatoriamente a sua função devido a uma variedade de motivos. Os avisos contidos nas etiquetas do Produto fornecem informações mais detalhadas e são considerados como parte integrante desta RENÚNCIA DE GARANTIA. Desta forma, a Medtronic renuncia a todas as garantias, tanto expressas como implícitas, relativas ao Produto. A Medtronic não será responsável por quaisquer danos acidentais ou indirectos causados por qualquer utilização, defeito ou falha do Produto, quer a reclamação se baseie na garantia, contrato, dano ou outros.

As exclusões e limitações acima definidas não se destinam a infringir disposições obrigatórias da lei aplicável, e não devem ser interpretadas como tal. Se alguma parte ou termo desta RENÚNCIA DE GARANTIA for considerado ilegal, não executável ou em conflito com a lei aplicável por parte de um tribunal da jurisdição competente, a validade da parte remanescente desta RENÚNCIA DE GARANTIA não deverá ser afectada, e todos os direitos e obrigações devem ser interpretados e executados como se esta RENÚNCIA DE GARANTIA não contivesse a parte ou termo particular considerado inválido.

Aviso geral

Os Produtos contidos nesta embalagem foram concebidos para utilização com outros produtos da Medtronic. Apesar de todo o cuidado colocado na concepção, selecção de componentes, fabrico e testes realizados antes da comercialização, os Produtos poderão ser facilmente danificados por um manuseamento ou utilização incorrectos, devido ao seu carácter inevitavelmente frágil que é ditado pelos requisitos invulgares da sua aplicação. Consequentemente, não é possível assegurar nem garantir que não possa ocorrer falha ou interrupção do funcionamento dos Produtos.

Az alábbi felelősségkizárás és általános figyelmeztetés az Egyesült Államok területén kívüli vásárlókra vonatkozik:

Felelősségkizárás

Bár a Medtronic® tartozék – a továbbiakban „termék” – tervezése, gyártása és értékesítés előtti ellenőrzése körültekintő módon történt, előfordulhat, hogy a termék különböző okokból esetleg nem látja el kielégítően a feladatát. A termék címkéin feltüntetett figyelmeztetések további információkkal szolgálnak, és a jelen FELELŐSSÉGKIZÁRÁS szerves részének tekintendőek. A Medtronic ezért a termékkel kapcsolatban semminemű kifejezett vagy hallgatólagos felelősséget nem vállal. A Medtronic nem felel a termék használatából, hibájából vagy működésképtelenségéből eredő semmilyen járulékos vagy ezek következtében keletkezett kárért, legyen a kárigény alapja szavatosság, jótállás, szerződés, kártérítésre vonatkozó jogszabály vagy egyéb.

A fenti felelősségkorlátozás és -kizárás nem a vonatkozó jogszabályok kötelező erejű rendelkezéseinek megszegésére irányul, azok akkénti értelmezésének nincs helye. Ha a jelen FELELŐSSÉGKIZÁRÁS bármely elemét vagy rendelkezését illetékes bíróság jogellenesnek, hatálytalannak vagy a vonatkozó jogszabályokkal ellentétesnek mondja ki, a FELELŐSSÉGKIZÁRÁS fennmaradó részét ez nem érinti, és minden jog és kötelezettség úgy értelmezendő és tartandó be, mintha a jelen FELELŐSSÉGKIZÁRÁS nem tartalmazná az érvénytelenített részt vagy pontot.

Általános figyelmeztetés

A csomagban találhatóTermékek a Medtronic egyéb termékeivel történő együttes használatra készültek. A lehető legalaposabb tervezés, alkatrészválasztás, gyártás és a forgalomba bocsátást megelőző tesztelés ellenére helytelen kezelés vagy használat esetén eredendő sérülékenységük következtében a Termékek könnyen megsérülhetnek. A sérülékenység a Termékekkel szembeni különleges alkalmazási követelményekből adódik. Következésképpen semmiféle garancia nincs arra, hogy a Termékek nem hibásodnak meg, vagy nem válnak használhatatlanná.

Poniższe Wyłączenie gwarancji i ostrzeżenie ogólne dotyczy klientów spoza terenu Stanów Zjednoczonych:

Wyłączenie gwarancji

Niezależnie od faktu, że akcesorium firmy Medtronic®, nazywane dalej „Produktem“, zostało przed wprowadzeniem do sprzedaży zaprojektowane, wytworzone i przetestowane z należytą starannością, produkt może z wielu powodów nie spełniać zamierzonych funkcji w zadowalający sposób. Ostrzeżenia podane na etykietach Produktu zawierają bardziej szczegółowe informacje i stanowią integralną część niniejszego WYŁĄCZENIA GWARANCJI. Firma Medtronic niniejszym wyłącza wszelkie gwarancje w odniesieniu do Produktu, zarówno wyraźne, jak i dorozumiane. Firma Medtronic nie odpowiada za jakiekolwiek przypadkowe lub wtórne szkody spowodowane dowolnym zastosowaniem, wadą lub awarią Produktu, bez względu na to, czy roszczenie zostanie wysunięte na podstawie gwarancji, umowy, odpowiedzialności za szkodę wyrządzoną czynem niedozwolonym lub w inny sposób.

Wyżej określone wyłączenia i ograniczenia nie mają na celu naruszania obowiązkowych uregulowań właściwego prawa i nie należy ich tak interpretować. Jeśli którakolwiek część lub warunek niniejszego WYŁĄCZENIA GWARANCJI zostanie uznany przez właściwy sąd za sprzeczny z prawem, niemożliwy do wyegzekwowania lub stojący w konflikcie z obowiązującym prawem, fakt ten nie wpłynie na ważność pozostałej części WYŁĄCZENIA GWARANCJI, a wszelkie prawa i zobowiązania będą interpretowane i egzekwowane tak, jak gdyby niniejsze WYŁĄCZENIE GWARANCJI nie zawierało danej części lub warunku uznanego za nieważny.

Ostrzeżenie ogólne

Produkty w tym opakowaniu są przeznaczone do użytku z innymi produktami firmy Medtronic. Mimo że podczas projektowania, doboru części, wytwarzania i testowania przed sprzedażą dochowano należytej staranności, Produkty mogą łatwo ulec uszkodzeniu w wyniku nieprawidłowego obchodzenia się z nimi lub ich użytkowania, ponieważ są z natury delikatne, co wynika z zastosowań, do jakich są przeznaczone.
W związku z tym nie można złożyć żadnego oświadczenia ani udzielić żadnej gwarancji, że nie wystąpi awaria lub zaprzestanie działania Produktów.

Následující odmítnutí záruk a obecná varování se vztahují na zákazníky mimo USA:

Odmítnutí záruk

Ačkoli je příslušenství Medtronic®, dále nazývanému „Výrobek“, před prodejem věnována pečlivá pozornost ve fázi jeho konstrukce, výroby i zkoušek, je možné, že u Výrobku selže z různých důvodů jeho zamýšlená funkce. Výstrahy na štítcích Výrobku poskytují podrobnější informace a jsou považovány za nedílnou součást tohoto ODMÍTNUTÍ ZÁRUK. Společnost Medtronic proto odmítá odpovědnost za jakékoliv záruky za tento Výrobek, ať už přímé nebo vyplývající. Společnost Medtronic neodpovídá za jakékoliv náhodné nebo následné škody způsobené použitím, vadou nebo selháním Výrobku, nehledě k tomu, vyplývá-li nárok ze záruky, smlouvy, osobnostních práv či z jiného důvodu.

Záměrem výše uvedených výjimek a omezení není porušování závazných nařízení příslušných právních předpisů a ani by tak neměly být interpretovány. Pokud bude kterákoli část nebo podmínka tohoto ODMÍTNUTÍ ZÁRUK shledána příslušným soudem jako protiprávní, nevynutitelná nebo v rozporu s příslušnými právními předpisy, nemá to vliv na platnost zbývající části tohoto ODMÍTNUTÍ ZÁRUK a všechna práva a závazky budou chápány a uplatněny tak, jako by toto ODMÍTNUTÍ ZÁRUK neobsahovalo tuto konkrétní část nebo podmínku, která byla shledána neplatnou.

Všeobecná varování

Výrobky v tomto balení jsou určeny pro použití s jinými výrobky společnosti Medtronic. I přes maximální možnou péči věnovanou vývoji, výběru komponent, výrobě a testování prováděného před prodejem lze Výrobky snadno poškodit nesprávnou manipulací nebo použitím z důvodu jejich křehkosti vyplývající z mimořádných nároků na jejich použití. V důsledku toho nelze poskytnout záruky, že nedojde k selhání nebo ztrátě funkčnosti Výrobků.

Следующая ограниченная гарантия предназначена для покупателей, находящихся за пределами США

Ограниченная гарантия

Хотя принадлежности корпорации Medtronic®, далее именуемые «Продукт», были тщательно спроектированы, произведены и прошли предпродажные испытания, существуют различные причины возможного отказа в работе Продукта. Предостережения, содержащиеся в обозначениях продукта, содержат более подробные сведения и являются составной частью данной ОГРАНИЧЕННОЙ ГАРАНТИИ. Поэтому корпорация Medtronic ограничивает все гарантийные обязательства, как прямые, так и опосредованные, по отношению к данному Продукту. Корпорация Medtronic не несет ответственности за любые случайные или опосредованные убытки, являющиеся следствием любого использования, дефекта или сбоя в функционировании Продукта, независимо от того, основана ли претензия на гарантийных обязательствах, контракте, гражданском правонарушении или на чем-либо другом.

Вышеизложенные исключения и ограничения не подразумеваются и не будут толковаться так, чтобы противоречить обязательным положениям їременяемых правовых норм. Если какая-либо часть или условие данной ОГРАНИЧЕННОЙ ГАРАНТИИ считается судом компетентной юрисдикции как незаконное, не имеющее возможности служить основанием для иска, или противоречит применяемым правовым нормам, оставшаяся часть ОГРАНИЧЕННОЙ ГАРАНТИИ будет считаться имеющей юридическую силу, и все права и обязательства будут толковаться и принудительно выполняются, как если бы данная ОГРАНИЧЕННАЯ ГАРАНТИЯ не содержала отдельных частей или условий, которые считаются юридически не имеющими силу.

Предупреждение общего характера

Находящиеся в этой упаковке Продукты предназначены для использования с другими продуктами корпорации Medtronic. Несмотря на тщательное проектирование, отбор компонентов, производство и предпродажную проверку, Продукты могут легко повреждаться при неправильном обращении или использовании, поскольку необычные условия их применения обуславливают их хрупкость. Следовательно, нельзя гарантировать невозможность поломки Продуктов или их выхода из строя.

Na zákazníkov mimo USA sa vzťahuje nasledujúce odmietnutie záruky a všeobecné upozornenie:

Odmietnutie záruky

Príslušenstvo od spoločnosti Medtronic® (ďalej len „produkt“) môže z rôznych príčin zlyhať pri uspokojivom vykonávaní činností, na ktoré bolo určené, a to aj napriek tomu, že bolo starostlivo navrhnuté, vyrobené a testované pred uvedením do predajnej siete. Upozornenia na štítkoch, ktorými je produkt označený, poskytujú používateľovi podrobnejšie informácie a považujú sa za neoddeliteľnú súčasť tohto ODMIETNUTIA ZÁRUKY. Spoločnosť Medtronic preto odmieta všetky záruky na tento produkt, či už výslovné alebo implicitné. Spoločnosť Medtronic nenesie zodpovednosť za žiadne náhodné ani následné škody spôsobené používaním, poruchou alebo zlyhaním produktu, či už na základe záruky, zmluvy, protiprávneho konania alebo inej právnej teórie.

Vyššie uvedené výnimky a obmedzenia by nemali byť v rozpore a ani by sa nemali považovať za výnimky a obmedzenia, ktoré sú v rozpore s povinnými nariadeniami relevantných právnych ustanovení. Ak ľubovoľný súd kompetentnej jurisdikcie vyhlási niektorú časť alebo podmienku tohto ODMIETNUTIA ZÁRUKY za nelegálnu, nevynútiteľnú alebo nezlučiteľnú s relevantnými právnymi ustanoveniami, vyhlásenie súdu nebude mať vplyv na platnosť zvyšku ODMIETNUTIA ZÁRUKY a všetky práva a povinnosti sa musia posudzovať a presadzovať tak, ako keby toto ODMIETNUTIE ZÁRUKY neobsahovalo časť alebo podmienku, ktorá bola vyhlásená za neplatnú.

Všeobecné upozornenie

Produkty obsiahnuté v tomto balení sú určené na použitie s inými produktmi spoločnosti Medtronic. Aj napriek tomu, že sme v oblasti návrhu, výberu komponentov, výroby a testovania pred uvedením do predaja vyvinuli maximálne úsilie, v dôsledku nesprávnej manipulácie alebo krehkosti (pozrite neobvyklé požiadavky týkajúce sa ich použitia) sa produkty môžu ľahko poškodiť. Z týchto dôvodov sa preto neposkytuje žiadna záruka, že nedôjde k zlyhaniu alebo ukončeniu funkčnosti produktov.

Aşağıdaki Garanti feragat beyannamesi ve genel uyarı Amerika Birleşik Devletleri dışındaki müşteriler için geçerlidir:

Garanti feragat beyannamesi

Bundan sonra “Ürün” olarak adı geçecek olan Medtronic® Aksesuarı özenle tasarlanmış, üretilmiş ve satıştan önce test edilmiş olsa da, Ürün çeşitli sebeplerden dolayı işlevlerini yeterince gerçekleştiremeyebilir. Ürün etiketindeki uyarılar daha ayrıntılı bilgi verebilir ve bu GARANTİ FERAGAT BEYANNAMESİNİN bir parçası sayılır. Medtronic, bu nedenle, Ürünle ilgili açık veya örtülü tüm garantilerden feragat eder. Medtronic Ürünün kullanımı, kusur veya bozukluğu sebebiyle oluşan herhangi bir tesadüfi veya dolaylı hasardan, iddia garanti belgesi, sözleşme veya haksız muameleye dayanıyor olsa da sorumlu değildir.

Yukarıda belirtilen istisnalar ve sınırlamalar tatbik kanununun uyulması zorunlu hükümlerini ihlal etme niyetiyle oluşturulmamıştır ve bu anlamda da yorumlanmamalıdır. Bu GARANTİ FERAGAT BEYANNAMESİNİN herhangi bir kısmının veya teriminin yetkili bir yargı mahkemesi tarafından yasadışı, uygulanamaz veya ilgili yasaya aykırı olduğu saptanırsa, GARANTİ FERAGAT BEYANNAMESİNİN diğer kısımlarının geçerliliği bundan etkilenmeyecektir ve tüm hak ve sorumluluklar, bu GARANTİ FERAGAT BEYANNAMESİ geçersiz sayılan söz konusu kısmı veya terimi içermiyormuş gibi yorumlanacak ve uygulanacaktır.

Genel uyarı

Bu ambalajdaki Ürünler diğer Medtronic ürünleriyle kullanılmak üzere tasarlanmıştır. Tasarım, bileşen seçimi, üretim ve satış öncesi testlerin tamamında gerekli özen gösterilmesine karşın, Ürünler uygulamalarının olağandışı gereksinimlerince belirlenen önüne geçilemez kırılganlıktaki yapıları nedeniyle yanlış kullanılmaları sonucu kolaylıkla hasar görebilir. Sonuç olarak, Ürünlerin işlevinin sona ermesi veya arızalanması gerçekleşmeyecek şeklinde bir temsil veya garanti verilmemiştir.

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If the product warranty information or the implanted system registration form is not contained in the product package, go to www.medtronic.com/manuals to download a copy.

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