FlexAbility™ Ablation Catheter, Sensor Enabled™

REF

A-FASE-D, A-FASE-F, A-FASE-J, A-FASE-DD, A-FASE-FF, A-FASE-JJ, A-FASE-DF, A-FASE-FJ

Instructions for Use

Abbott

Proposition 65, a State of California voter initiative, requires the following notice:

⚠ WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

EN: English
FlexAbility™ Ablation Catheter, Sensor Enabled™

Instructions for Use

Caution

- Federal law (U.S.A.) restricts this device to sale by or on order of a physician.
- Do not attempt to use the device before completely reading and understanding the instructions for use.

Description

The FlexAbility™ Ablation Catheter, Sensor Enabled™ is a sterile, single use catheter with a 7.5 F shaft and an 8 F distal section. It is constructed of thermoplastic elastomer material and noble metal electrodes. The catheter has a flexible tip electrode and magnetic sensor. It has a fluid lumen connected to open conduits at the flexible tip electrode for saline irrigation during the ablation procedure. For both bi-directional and uni-directional catheters, the tip curvature is manipulated by the control mechanism located on the handle at the catheter's proximal end. To adjust the curve of the distal tip on the uni-directional catheter, push or pull the thumb control located on the handle. To adjust the curve of the distal tip on the bi-directional catheter, use the actuator to deflect the catheter in either direction. The catheters are available in eight distal curve configurations listed in the table below. The curve is identified on the catheter label. The catheter is compatible with Abbott Medical visualization and 3D navigation systems.

Table 1. Catheter Curve Configurations

Catheter Type	Curve Type (Model Number)
Uni-directional	D (A-FASE-D)
	F (A-FASE-F)
	J (A-FASE-J)
Bi-directional	D-D (A-FASE-DD)
	F-F (A-FASE-FF)
	J-J (A-FASE-JJ)
	D-F (A-FASE-DF)
	F-J (A-FASE-FJ)

The catheter connects to the compatible RF cardiac ablation generators, irrigation pump, and visualization and navigation systems listed below. For information regarding their use, refer to the appropriate instructions for use.

Table 2. Compatible Systems

System Device	Connect via
Ampere™ RF Ablation Generator	Sensor Enabled™ Ablation Connection Cable (RO A-FASE-CBL4)
EnSite™ Velocity™ System	
EnSite Precision™ System	
EnSite™ X EP System*	
MediGuide™ System, v17.x	
Cool Point™ Irrigation Pump	Cool Point™ Tubing Set (RO 85785)

* Optional: Magnetic Extension 10 Pin EnSite™ X Cable (A-ENS-MAGEXT-CBL)

Indications

The FlexAbility™ Ablation Catheter, Sensor Enabled™, when used in conjunction with a compatible irrigation pump and compatible RF generator, is indicated for:

Endocardial mapping, stimulation, and ablation for the treatment of typical atrial flutter.

Endocardial or epicardial mapping, stimulation and ablation for the treatment of recurrent, drug-refractory, sustained monomorphic ventricular tachycardia in patients with non-ischemic structural heart disease, when used in conjunction with a compatible cardiac mapping system.

Contraindications

The catheter is contraindicated for:

- Patients with active systemic infection.
- Patients with intracardiac thrombus or myxoma, or interatrial baffle or patch via transeptal approach.

In addition, the following contraindications apply for treatment of ventricular tachycardia:

- Patients who have had a ventriculotomy or atriotomy within the preceding four weeks as the recent surgery may increase the risk of perforation.
- Patients with prosthetic valves as the catheter may damage the prosthesis.
- The use in coronary arterial vasculature due to risk of damage to the coronary arterial vasculature.
- The transseptal approach in a patient with an interatrial baffle or patch because the opening could persist and produce an iatrogenic atrial shunt.
- The retrograde trans-aortic approach in patients who have had aortic valve replacement.
- Patients unable to receive heparin or an acceptable alternative to achieve adequate anticoagulation.

Warnings

- Cases of delayed onset of atrioesophageal fistula (AEF) have been reported in association with radiofrequency catheter ablation procedures. While rare, AEF is associated with significant morbidity and mortality.
- Cardiac ablation procedures should be performed only by physicians thoroughly trained in the techniques of radiofrequency catheter ablation in a fully equipped electrophysiology laboratory.
- The temperature data transmitted by the sensor in this catheter is representative of the irrigated electrode only and does not provide tissue temperature data.
- Catheter ablation procedures present the potential for significant x-ray exposure, which can result in acute radiation injury as well as an increased risk for somatic and genetic effects, to both patients and laboratory staff due to the x-ray beam intensity and duration of the fluoroscopic imaging. Catheter ablation should only be performed after adequate attention has been given to the potential radiation exposure associated with the procedure and steps have been taken to minimize this exposure. The long-term risk of protracted fluoroscopy has not been established. Therefore, careful consideration must be given for the use of the device in pregnant women and prepubescent children.
- Pacemakers and implantable cardioverter/defibrillators can be adversely affected by RF signals. It is important to: a) have temporary external sources of pacing and defibrillation available during ablation, b) deactivate Intracardiac Defibrillators (ICDs) as they could discharge and injure the patient or be damaged by the ablation procedure, c) exercise extreme caution during ablation when in close proximity to permanent pacing or defibrillation leads, and d) perform complete implantable device system analysis on all patients after ablation.
- Caution should be taken when placing lesions in the proximity of the specialized conduction system.
- The long-term risks of RF ablation lesions have not been established, particularly with respect to lesions placed in proximity to the specialized conduction system.
- Ablation within and in close proximity to the coronary arterial vasculature has been associated with myocardial infarction and death.
- In accordance with your hospital's protocol, monitor the patient's fluid balance throughout the procedure to avoid fluid overload.
- Always verify that the tubing and catheter have been properly cleared of air prior to inserting the catheter into the vasculature since entrapped air can cause potential injury or fatality.
- Catheter materials are not compatible with magnetic resonance imaging (MRI).
- Catheter entrapment within the heart or blood vessels is a possible complication of electrophysiology procedures.
- Vascular perforation or dissection is an inherent risk of any electrode placement. Careful catheter manipulation must be performed in order to avoid cardiac damage, perforation, or tamponade.
- Do not use force to advance or withdraw catheter when resistance is encountered.
- When using an electrophysiology (EP) recording system, the equipment must be front-end isolated, or have an isolated patient cable.
- Ablation along the caval line may injure the right phrenic nerve.
- This device is intended for one time use only. Do not reprocess or reuse. Reuse can cause device failure, patient injury, and/or the communication of infectious disease(s) from one patient to another.

Precautions

- If the Cool Point™ Irrigation Pump alarm sounds, RF energy will be terminated. Communication and fluid flow must be evaluated. Inspect irrigation tubing for obstructions, such as kinks and air bubbles. Remove the catheter from the patient and inspect the catheter and the electrodes. If necessary, clean the electrodes with a sterile saline saturated gauze pad. Ensure that the irrigation ports are patent and flush the catheter prior to re-insertion.
- The catheter impedance display of the cardiac ablation generator should be continuously monitored during RF power delivery. If a sudden rise in impedance is noted that does not exceed the preset limit, or a steam pop is observed, power delivery should be manually discontinued. Clinically assess the situation. If necessary, the catheter should be removed from the patient and the distal tip of the catheter cleaned to eliminate any coagulum. If the catheter has defects, exchange it for a new one. Make sure fluid flows from the irrigations ports before reinserting into the patient. Relocate the catheter and attempt another RF application.
- There is a possibility of higher incidences of steam pops at power levels exceeding 40 watts and increased collateral damage when maximum power settings (50 watts) are used. Power should be increased to these levels only if lower energies do not achieve the intended result.
- Catheter advancement must be performed under fluoroscopic guidance in conjunction with internal electrograms and impedance monitoring to minimize the risk of cardiac damage, perforation, or tamponade.
- Always straighten the catheter before insertion or withdrawal.
- Always maintain constant irrigation to prevent coagulation within and around electrodes.
- Do not use if catheter appears damaged, kinked, or if there is difficulty in deflecting the distal section to achieve the desired curve. Do not use if the catheter does not hold its curve and/or if any of the irrigation ports are blocked.
- Excessive bending or kinking of the catheter may cause damage to the catheter. Manual pre-bending of the distal curve can damage the steering mechanism and may cause patient injury.
- Irrigated ablation systems have been shown to create larger lesions than standard radiofrequency ablation catheters. Care should be taken when ablating near electrically vulnerable, thin-walled or other arterial structures.
- Adequate filtering of mapping systems must be used to allow continuous monitoring of the surface or intracardiac electrocardiograms during radiofrequency power applications. Monitoring systems incorporating high frequency current-limiting devices are recommended.
- Needle monitoring electrodes are not recommended.
- Do not immerse the proximal handle or cable connectors in fluids; electrical performance could be affected.
- Position connecting cables such that contact with the patient and other electrical leads is avoided.
- If irrigation flow is interrupted, immediately inspect and re-flush the catheter outside of the patient. Re-establish irrigation flow prior to placing catheter in the body.
- Do not attempt ablation without using the Cool Point™ Irrigation Pump.
- Do not twist or pull the distal electrode. Excessive force may loosen the electrode from the catheter shaft.
- After use, dispose of product and packaging in accordance with hospital, administrative, and/or local government policy.

- Do not expose the catheter to organic solvents such as alcohol.

Potential Adverse Events

Potential adverse effects (e.g., complications) that may be associated with cardiac ablation using the device include:

Abnormal vision
Anaphylaxis
Anemia
Angina
Arrhythmia
Arterial/venous thrombus
Atypical flutter
AV fistula
Cardiac tamponade
Catheter insertion site hematoma
Chest pain (non-specific)
Congestive heart failure (CHF) exacerbation
Component damage to ICD or implantable pacemaker
Coronary artery dissection
Death
Dislodgement of implantable cardioverter defibrillator or permanent pacing lead
Dizziness
Endocarditis
Exacerbation of chronic obstructive pulmonary disease (COPD)
Exacerbation of pre-existing atrial fibrillation as evidence by hospitalization, cardioversion, or worsening of AF symptoms
Hemothorax
Hypotension
Hypoxia
Inadvertent AV block
Infection
Myocardial infarction/MI
Palpitations
Perforation (cardiac)
Pericardial effusion
Pericarditis
Peripheral venous thrombosis
Phrenic nerve damage
Pleural effusion
Pneumonia
Pneumothorax
Pseudoaneurysm
Pulmonary edema
Pulmonary embolism
Radiation injury resulting in dermatitis (inflammation of the skin), erythmia (redness), etc.
Respiratory failure
Seizure
Sepsis
Stroke/cerebrovascular accident
Syncope
Thromboembolic event
Transient ischemic attack (TIA)
Vasovagal reaction
Ventricular arrhythmia requiring defibrillation
Vessel wall/valvular damage or insufficiency (i.e. new tricuspid regurgitation)

Summary of Clinical Studies

The following information describes two clinical studies. The first is a clinical study conducted for the Therapy™ Cool Flex™ Ablation Catheter. The FlexAbility™ Ablation Catheter, Sensor Enabled™ was developed based on the Therapy™ Cool Flex™ Ablation Catheter and the FlexAbility™ Ablation Catheter. The clinical use of the FlexAbility™ Ablation Catheter, Sensor Enabled™ is supported by the St. Jude Medical electrophysiologic mapping and ablation clinical study using the Therapy™ Cool Flex™ Ablation Catheter, as the inclusion of the magnetic sensor and associated functionality does not affect the ablation therapy delivery or catheter operation because the use of fluoroscopy is still required to confirm device positioning prior to delivery of therapy. The second is the LESS-VT clinical study using the FlexAbility™ Ablation Catheter, Sensor Enabled™.

Therapy™ Cool Flex™ Ablation Catheter Clinical Evaluation

Objective

A multi-center clinical study was conducted using the Therapy™ Cool Flex™ Cardiac Ablation System. The purpose of the clinical study was to demonstrate the safety and effectiveness of the use of the Therapy™ Cool Flex™ Cardiac Ablation System for the treatment of typical atrial flutter (cavotricuspid isthmus dependent).

Study Design

This was a prospective, multi-center, and non-randomized study. The subjects who signed informed consent and were verified to meet the inclusion/exclusion criteria received ablation therapy for typical atrial flutter using the Therapy™ Cool Flex™ Cardiac Ablation System. The study was designed to demonstrate that the use of the Therapy™ Cool Flex™ Cardiac Ablation System for the treatment of typical atrial flutter did not result in unacceptable risk of intra-procedural composite serious adverse events and did not affect efficacy of the ablation procedure.

Historical data from combined published Atrial Flutter studies (PMA P060019 Therapy™ Cool Path™ and PMA P110016 Therapy™ Cool Path™ Duo) were used to determine performance goals for the study endpoints.

Clinical Endpoints

Primary Safety was defined as the incidence of composite, serious adverse events (SAEs) within 7 days post-procedure, regardless of whether a determination can be made regarding device relatedness.

Primary Efficacy or acute success was defined as the achievement of bi-directional block in the cavo-tricuspid isthmus and non-inducibility of typical atrial flutter at least 30 minutes following the last RF application with the Therapy™ Cool Flex™system.

Secondary Efficacy or chronic success was defined as freedom from recurrence of typical atrial flutter three months post ablation. Repeat ablations and new or increased dosage of existing anti-arrhythmic medication (Class Ia, Ic, or III) during the three month follow-up were considered chronic failures.

Subjects Studied

Table 3. Subject Accountability

Consented subjects (Enrolled)	200

Table 3. Subject Accountability

Withdrawn prior to introduction of the investigational device	21
Screen fail prior to insertion of the investigational device	14
Subject/Family Request	2
Investigators Request	2
Other	3
Treated with the investigational device	179
Acute failures	2
Acute success, chronic failure	23
Lost to follow up	2
Discontinued – patient / family request	1
Death	1
Chronic success	150

Demographics

A total of 200 subjects were consented at 24 investigational sites (22 in the U.S. and 2 in Canada). Twenty-one (21) subjects were withdrawn from the study prior to the use of the investigational device.

Of the 179 subjects treated, 143 subjects (79.89%) were male and 36 subjects (20.11%) were female. The mean age of the treated subjects was 66.28 years and the mean weight of treated subjects was 211.64 pounds.

Cardiac history of treated subjects is summarized in the table below. The most commonly reported cardiac history for subjects treated with the investigational system were Hypertension (60.89%), Atrial Fibrillation (45.81%), and Coronary Artery Disease (27.93%)

Table 4. Cardiac history of treated subjects

Cardiac Condition	**Therapy™ Cool Flex™ Ablation Catheter (n=179)**
Hypertension	60.89% (n=109)
Atrial Fibrillation	45.81% (n=82)
Coronary Artery Disease	28.49% (n=51)
Coronary Artery Intervention	15.08% (n=27)
Valve Disease	14.53% (n=26)
Myocardial Infarction	11.73% (n=21)
Pacemaker/ICD Implant	11.17% (n=20)
Congestive Heart Failure	10.61% (n=19)
Stroke/TIA	8.38% (n=15)
Valve Surgery	7.82% (n=14)
Ventricular Tachycardia	6.15% (n=11)
Pericarditis	1.68% (n=3)
Atypical Atrial Flutter 0.00%	(n=0)

Procedural Data

Procedural Data

The table below summarizes ablation parameters during the procedure for subjects treated with the Therapy™ Cool Flex™ Ablation Catheter.

Table 5. Procedural Parameters

Parameter	**N**	**Mean ± SD**
# of Applications per Procedure	179	12.40 ± 12.35
RF Time (Sec) per Application	2,212*	85.98 ± 99.78
RF Time (Min) per Procedure	179	17.71 ± 12.64
Procedure Time (Min) per Patient	179	98.73 ± 42.99
Temperature (°C) per Application	2,211*	* 28.35 ± 3.13
Mean Power (Watts) per Application	2,211*	31.78 ± 6.02
Impedance (Ohms) per Application	2,211*	93.64 ± 15.60
Total Fluid Administered (mL) per Patient	178¥	931.08 ± 497.53
Total Pump Saline (mL) per Patient	179	414.41 ± 314.42

* A total of 2,220 RF applications were delivered, however, the procedural data could not be collected on some RF applications. The percentage of such instances is less than 0.5%.

¥ A total of 179 subjects were treated with the investigational system, however the total fluid administered could not be collected for some subjects.

Results

Safety

Of the 179 subjects treated with the investigational catheter, 5 subjects had composite serious adverse events (SAEs) within 7 days of the procedure. No unanticipated adverse device effects (UADE) were reported. The key safety outcomes for this study are presented in Table 4 and Table 5.

Table 6. Primary Safety Comparison

Measure	Therapy™ Cool Flex™ Ablation Catheter	Hypothesis	95% CL[1]	Decision	Conclusion
Composite SAE within 7 days post procedure (Primary Safety)	5/179 (2.79%)	H0: $\prod \geq 14\%$ HA: $\prod < 14\%$	5.78%	Reject H0	Equivalent Safety

[1] Based on exact binomial confidence limits.

Table 7. Composite SAEs that occurred within 7 days post-procedure

Event Description	Number of Subjects	Percent
Congestive Heart Failure (CHF) Exacerbation	2/179	1.12%
Arrhythmia	1/179	0.56%
Death*	1/179	0.56%
Stroke/Cerebrovascular Accident	1/179	0.56%

* Primary Cause: Ventricular Fibrillation Cardiac Arrest. Secondary Cause: Acute Pulmonary Edema Congenital Heart Disease Atrial Flutter

There was one subject death reported during the course of the clinical study, the causality of which was related to the subject's concomitant procedure by the clinical events committee. Below is the description of this event:

The subject was a 62 year old male who had two (2) previous corrective surgeries for a congenital disease - Tetralogy of Fallot – a palliative procedure in childhood and a complete repair in 1987. Additional history includes ventricular dilatation, atrial fibrillation, aortic insufficiency, valve disease, hypertension, and dyslipidemia. At the time of enrollment in the study, the subject presented with problems of fatigue, significant bradycardia and very slow ventricular rates noted on Holter monitoring. The subject was noted to have intermittent atrial flutter, consistent with isthmus-dependent flutter and was enrolled in the study on April 16, 2012. Due to the long-standing history of significant conduction problems, it was anticipated that the subject would receive a dual chamber pacemaker implant following the flutter procedure. The patient tolerated the flutter procedure and pacemaker implant and initially maintained hemodynamic stability, however, later developed ventricular fibrillation cardiac arrest.

The major complication rate (of composite serious adverse events) was 2.79% (5/179). This was compared to the pre-defined performance goal of 14%. Thus, based on the quantitative assessment, the pivotal study demonstrated that the Therapy™ Cool Flex™ Ablation Catheter met the pre-defined performance goal of 14% major complication rate.

Primary Effectiveness

Out of 179 subjects treated with the investigational system, 2 subjects were acute failures. The acute procedural success rate in this study was 98.88% (177/179).

This was compared against the pre-specified performance goal of 88%. Thus, based on a quantitative assessment, the pivotal study demonstrated that the Therapy™ Cool Flex™ Ablation Catheter met the pre-defined performance goal of 88% acute procedural success. Table 6 illustrates the primary effectiveness results.

Table 8. Primary Effectiveness Comparison

Measure	Therapy™ Cool Flex™ Ablation Catheter	Hypothesis	95% CL[1]	Decision	Conclusion
Acute Procedural Success (Primary Effectiveness)	177/179 (98.88%)	H0: $\prod \geq 88\%$ HA: $\prod < 88\%$	96.52%	Reject H0	Equivalent Effectiveness

[1] Based on exact binomial confidence limits.

Secondary Effectiveness

One hundred seventy-nine (179) subjects treated with the investigational system were evaluated for the chronic endpoint, 175 had evaluable chronic outcome data at 3 months. One hundred fifty (150) of these subjects met the chronic success endpoint criteria. Multiple imputation modeling was used to evaluate the chronic success endpoint. The model derived chronic success rate was 85.47%. The 95% confidence limit was 81.10% which was compared against the pre-specified performance goal of 72%.

Thus, based on a quantitative assessment, the pivotal study demonstrated the Therapy™ Cool Flex™ Ablation Catheter met the pre-defined performance goal of 72% chronic success. Table 7 illustrates the secondary effectiveness results.

Table 9. Secondary Effectiveness Comparison

Measure	Therapy™ Cool Flex™ Ablation Catheter	Hypothesis	95% CL[1]	Decision	Conclusion
Freedom from recurrence of typical AFL or increase/new dosage of Class I/III AAD for any arrhythmia (Secondary Efficacy)[2]	(85.47%)	H0: $\prod \geq 72\%$ HA: $\prod < 72\%$	81.10%	Reject H0	Equivalent Effectiveness

[1] Based on exact binomial confidence limits.

[2] PROC MI used to obtain outcome for acute failures and subjects who discontinued prior to availability of 3 month data.

Patient Selection and Treatment

The patient should be prepared for ablation procedure in accordance with standard clinical practice. The safety and effectiveness of Therapy™ Cool Flex™ Cardiac Ablation Catheter has not been studied in pregnant patients.

LESS-VT IDE (NICM Clinical Cohort)

Study Objective

The objective of the clinical investigation was to demonstrate that substrate ablation with FlexAbility™ Ablation Catheter, Sensor Enabled™ (FlexAbility™ SE) is safe and effective in reducing the occurrence of sustained monomorphic ventricular tachycardia (MMVT) in patients in whom ventricular tachycardia (VT) recurs despite antiarrhythmic drug (AAD) therapy or when AADs are not tolerated or desired.

Study Design

The study was a prospective, single-arm, open-label, multi-center trial designed to evaluate the safety and effectiveness of the FlexAbility™ SE catheter for the treatment of non-ischemic ventricular tachycardia. The study was designed to enroll 182 subjects with drug refractory sustained MMVT and non-ischemic cardiomyopathy (NICM) at up to 35 centers worldwide.

Study Population

The intended population of this study was patients with drug refractory sustained MMVT (i.e., AADs are not effective, not tolerated or not desired) of NICM origin, who had at least one episode of MMVT within 6 months prior to enrollment.

Key Study Endpoints

There were two primary endpoints and twelve descriptive endpoints for this study.

Primary Safety Endpoint:

The primary safety endpoint is a composite of cardiovascular-related and procedure-related major complications through 7 days post index ablation procedure. Major complication was defined as an adverse event that led to prolongation of hospital stay or to another hospitalization, required additional intervention for treatment, and/or resulted in significant injury or death.

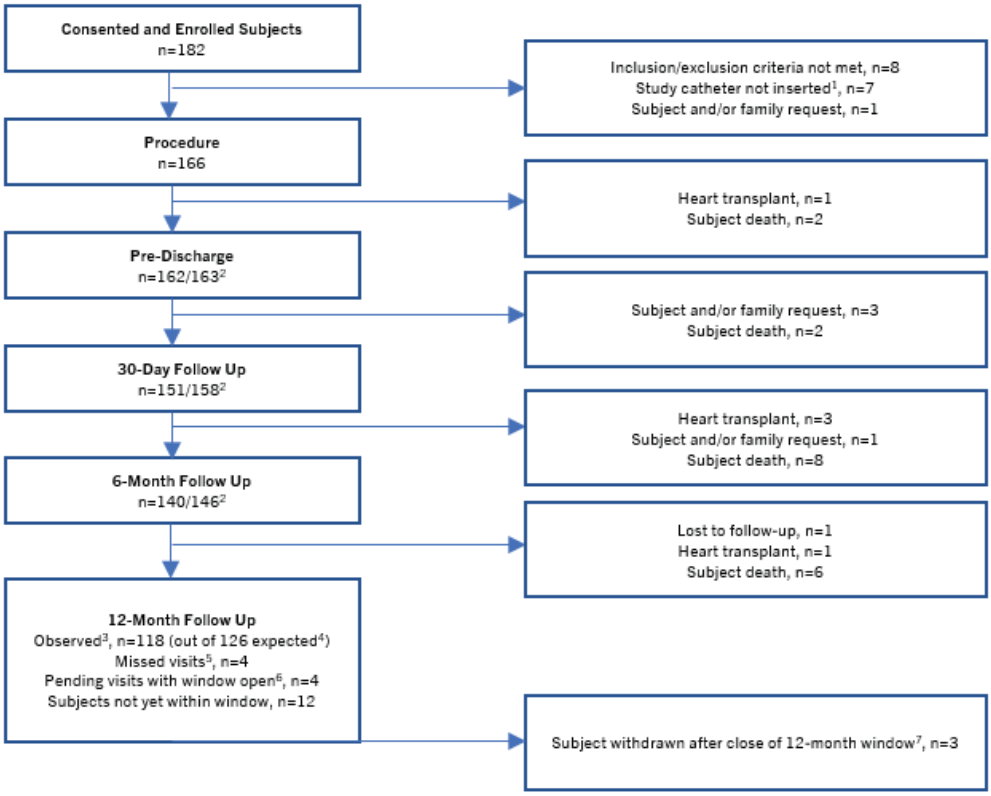
Primary Effectiveness Endpoint:

The primary effectiveness endpoint is freedom from recurrent sustained MMVT at 6 months and a new or increased dose Class I or III AAD at 6 months following the index ablation procedure, where sustained MMVT is defined as a continuous MMVT for >30 seconds, or MMVT requiring intervention for termination regardless of its duration.

Enrollment

There were 182 subjects enrolled in the NICM cohort at 24 investigational sites. Enrollment in the NICM cohort began on June 11, 2018 and completed on June 09, 2021. The last 6-month follow-up visit for the NICM cohort occurred on December 21, 2021 and long-term follow-up of enrolled subjects will continue through 12 months.

Figure 1. Subject Disposition



For follow-up visits, data are presented as n = [number of observed visits] / [number of expected visits].

[1] Withdrawal due to study catheter not inserted was counted as pre-procedure withdrawal.

[2] n is displayed as the number of observed visits / number of expected visits.

[3] n is the number of visits observed at the time of this report that occurred within the visit window, excluding deaths and withdrawals.

[4] Number of visits expected at the time of this report. A subject is considered expected at the given visit if they have not died or withdrawn by the end of the visit window, and the visit window has opened by the cutoff date.

[5] A visit is considered missed if the visit window is closed at the time of this report and the visit has not occurred or has not been entered in the database, excluding deaths and withdrawals.

[6] A visit is considered pending if the visit window is open at the time of this report, but the visit has not occurred or has not been entered in the database, excluding deaths and withdrawals.

[7] Withdrawal case report forms were submitted for three (3) NICM subjects after missing the 12-month visit and after the close of the 12-month visit window. For these subjects, the reason for withdrawal was documented as lost to follow-up (n=2) and subject and/or family request (n=1). These subjects are also counted as having missed visits for the 12-month follow-up.

Study Visits and Length of Follow-Up

Study visits consisted of baseline, procedure, and pre-discharge, as well as 30-day, 6-month, and 12-month follow-up visits scheduled after completion of the index procedure. The scheduled visit windows were calculated from the date of the index (first) ablation procedure (Day 0). Additional ablation procedures did not affect this schedule.

Demographics

The tables below summarize the demographic information.

Table 10.

Population	Abbreviation for Analysis Population	Description	Subjects
Enrolled	ENR	Signed written informed consent	182
Catheter-Inserted	CIN	Investigational catheter inserted into the vasculature	166
Primary Safety Endpoint	SAF	Catheter inserted subjects who completed 7 days of follow-up or experienced a primary safety endpoint failure	166
Treated	TRT	Investigational catheter inserted and RF energy delivered	165
Primary	EFF	Treated subjects who have completed a 6 or 12 Month visit	146

Table 10.

Population	Abbreviation for Analysis Population	Description	Subjects
Effectiveness Endpoint		with ICD interrogation or experienced a primary effectiveness endpoint failure	

RF denotes radiofrequency and ICD implantable cardioverter defibrillator or cardiac resynchronization therapy-defibrillator.

Table 11. Demographics

Demographic Variable	CIN Population (N=166)
Age	
Mean ± SD (n)	60.2 ± 13.8 (166)
Range (Min, Max)	(22.0, 88.0)
Sex, n (%)	
Female	16.3% (27/166)
Male	83.7% (139/166)
Ethnicity, n (%)	
Hispanic or Latino	2.0% (3/152)
Not Hispanic or Latino	98.0% (149/152)
Race, n (%)	
American Indian or Alaskan Native	0.7% (1/152)
Asian	2.0% (3/152)
Black or African American	13.2% (20/152)
Native Hawaiian or Other Pacific Islander	0.0% (0/152)
White	84.2% (128/152)
Height (cm)	
Mean ± SD (n)	175.4 ± 9.6 (165)
Range (Min, Max)	(150.0, 198.0)
Weight (kg)	
Mean ± SD (n)	89.4 ± 22.4 (165)
Range (Min, Max)	(45.0, 155.6)

Note: Denominator in percentages is the number of subjects with available data.

Table 12. Cardiovascular History and Baseline LVEF (CIN Population)

Demographic Variable	CIN Population (N=166)
Cardiovascular History, n (%)	
Structural Heart Disease	100.0% (166/166)
Ischemic Cardiomyopathy	0.0% (0/166)
Non-Ischemic Cardiomyopathy	100.0% (166/166)
Coronary Artery Disease	16.3% (27/166)
Diastolic Dysfunction	27.7% (46/166)
Heart Failure	61.4% (102/166)
NYHA[1] Class I	17.6% (18/102)
NYHA[1] Class II	52.0% (53/102)
NYHA[1] Class III	30.4% (31/102)
NYHA[1] Class IV	0.0% (0/102)
Not Specified	0.0% (0/102)
Hypercholesterolemia	27.7% (46/166)
Hyperlipidemia	45.8% (76/166)
Hypertension	48.2% (80/166)
Infective Endocarditis	1.2% (2/166)
Myocardial Infarction	5.4% (9/166)
Percutaneous Coronary Intervention	7.2% (12/166)
Valvular Heart Disease	19.9% (33/166)
LVEF[1] (%)	38.1 ± 12.9 (163) (15.0, 70.0)

Note: Denominator in percentages is the number of subjects with available data.
1NYHA denotes New York Heart Association, ARVC/D arrhythmogenic right ventricular cardiomyopathy/dysplasia, and LVEF left ventricular ejection fraction.

Table 13.

Non-Ischemic Heart Disease Type	Catheter-Inserted Subjects (N=166)
Arrhythmogenic Right Ventricular Cardiomyopathy / Dysplasia	21.7% (36/166)
Cardiac Sarcoidosis	10.2% (17/166)
Congenital Heart Disease	3.6% (6/166)
Hypertrophic Cardiomyopathy	6.6% (11/166)
Dilated Cardiomyopathy and/or Non-Ischemic Left Ventricular Cardiomyopathy	54.2% (90/166)
Other	9.0% (15/166)
Genetic Cardiomyopathy	1.2% (2/166)
Other Cardiomyopathy	3.0% (5/166)
Myocarditis	2.4% (4/166)
Previous Cardiac Surgery	0.6% (1/166)
Unknown	1.8% (3/166

Summary of Study Results

Table 14. Primary Safety Endpoint Analysis

Primary Safety Endpoint			
Population	Number of Subjects	95% One-Sided Confidence Interval Upper Bound	Performance Goal
Safety Population	16.3% (27/166)	21.7%	<26.9%

[2]The analysis population for the primary safety endpoint includes subjects with an inserted investigational catheter who have completed 7 days of follow-up or experienced a primary safety endpoint failure.

Table 15. Primary Safety Endpoint Events (SAF Population)

		PSAE within 7 Days of Index Procedure (N=166)
Primary Safety Endpoint Event Criteria	Number of Events	Number of Subjects
Acute Myocardial Infarction	0	0.0% (0/166)
Acute Pulmonary edema requiring reintubation	1	0.6% (1/166)
Cardiac perforation/tamponade	6	3.0% (5/166)
Cardiogenic shock	2	1.2% (2/166)
Chordae entrapment requiring surgical intervention	0	0.0% (0/166)
Complete heart block	0	0.0% (0/166)
Damage or movement of ICD leads requiring revision	0	0.0% (0/166)
Death from any cause	2	1.2% (2/166)
New incessant VT/VF	2	1.2% (2/166)
Phrenic nerve injury which does not resolve in 7 days	0	0.0% (0/166)
Pulmonary embolism documented by imaging and requiring intervention	0	0.0% (0/166)
Stroke	1	0.6% (1/166)
TIA	0	0.0% (0/166)
Valve injury requiring surgical intervention	1	0.6% (1/166)
Vascular access complications requiring surgical intervention or >2 units of blood transfusion	2	1.2% (2/166)
Other	20	9.0% (15/166)
Arrhythmia New	1	0.6% (1/166)
Bleeding/Anemia	1	0.6% (1/166)
Hypotension	5	3.0% (5/166)
Infection	2	1.2% (2/166)
Myocardial Infarction	1	0.6% (1/166)
Pericardial Bleed	1	0.6% (1/166)
Pericardial Effusion	1	0.6% (1/166)
Pericarditis	3	1.8% (3/166)

Table 15. Primary Safety Endpoint Events (SAF Population)

		PSAE within 7 Days of Index Procedure (N=166)
Primary Safety Endpoint Event Criteria	Number of Events	Number of Subjects
Respiratory Failure / Depression / Compromise	1	0.6% (1/166)
Vascular Access Site Complications	2	1.2% (2/166)
Ventricular Arrhythmia with Significant Deterioration	1	0.6% (1/166)
Visceral Structure or Organ Damage Including Bleed/Hematoma	1	0.6% (1/166)
Total	37	16.3% (27/166)

Note: Some subjects may have experienced more than one type of event. Therefore, the total number of subjects may be less than the sum of the numbers of subjects who experienced each type of event.

PSAE denotes primary safety adverse event, VT/VF ventricular tachycardia/ventricular fibrillation, TIA transient ischemic attack, and ICD implantable cardioverter-defibrillator or cardiac resynchronization therapy-defibrillator.

Table 16. Primary Effectiveness Endpoint Analysis (EFF Population)[2]

Primary Effectiveness Endpoint			
Population	Number of Subjects	95% One-Sided Confidence Interval Lower Bound	Performance Goal
Effectiveness Population[4]	58.2% (85/146)	51.1%	> 40.2%

[4]The analysis population for the primary effectiveness endpoint includes treated subjects who have completed a 6- or 12-month visit with ICD interrogation or experienced a primary effectiveness endpoint failure.

Table 17. Freedom from Primary Effectiveness Endpoint Failure Modes (EFF Population[5])

Effectiveness Definition	Number of Subjects
Freedom from Repeat Ablation	95.2% (139/146)
Freedom from Recurrent Sustained MMVT	80.1% (117/146)
Freedom from New or Increased Class I/III AAD	69.2% (101/146)

[5]The analysis population for the primary effectiveness endpoint includes treated subjects who have completed a 6- or 12-Month visit with ICD interrogation or experienced a primary effectiveness endpoint failure.

Sensitivity Analyses

All subjects in the CIN population completed 7 days of follow-up and there were no missing data for the primary safety endpoint. Therefore, sensitivity analyses for the primary safety endpoint to account for missing data (i.e., Best Case, Worst Case, Tipping Point, and Multiple Imputation) were not performed.

There were 19 subjects in the TRT population that were discontinued prior to 6 months or otherwise did not complete a 6- or 12-month visit with ICD interrogation, and who did not experience a primary effectiveness endpoint failure. These were considered missing data for the primary effectiveness endpoint. The best- and worst-case analyses were performed on the primary effectiveness endpoint (Best Case Analysis for the Primary Effectiveness Endpoint (TRT Population) table and Worst Case Analysis for the Primary Effectiveness Endpoint (TRT Population) table). In the best-case analysis, subjects with missing primary effectiveness endpoint data were treated as successes (best case), and the primary effectiveness endpoint rate was 63.0% (104/165) with the 95% one-sided confidence interval lower bound of 56.4%. In the worst-case analysis, subjects with missing primary effectiveness endpoint data were treated as failures (worst case), and the primary effectiveness endpoint rate was 51.5% (85/165) with the 95% one-sided confidence interval lower bound of 44.8%. Even with the worst-case analysis, the lower bound of the primary endpoint remains higher than the performance goal of 40.2%. Since the performance goal was achieved under the worst-case scenario, a tipping point analysis result is not presented.

Table 18.

Population	Number of Subjects	95% One-Sided Confidence Interval Lower Bound	Performance Goal
Treated Subjects	63.0% (104/165)	56.4%	>40.2%

Best case sensitivity analysis was done by including treated subjects that were removed from the primary effectiveness endpoint analysis as successes.

Table 19. Worst Case Analysis for the Primary Effectiveness Endpoint (TRT Population)

Population	Number of Subjects	95% One-Sided Confidence Interval Lower Bound	Performance Goal
Treated Subjects	51.5% (85/165)	44.8%	>40.2%

Worst case sensitivity analysis was done by including treated subjects that were removed from the primary effectiveness endpoint analysis as failures.

Procedural Results

A total of 165 subjects underwent an index procedure where the study catheter was inserted and RF energy was delivered. Of these 165 subjects, 9 subjects (5.5%) also underwent one staged procedure each.

Table 20. Index and Staged Procedures

Index and Staged Procedures	(N=165)
Procedures	
Index Procedure	100.0% (165/165)
Index plus Staged Procedure	5.5% (9/165)
Reason for Staged Procedure	
Planned prior to discharge from EP lab	2.4% (4/165)
Recurrence of arrhythmia	3.0% (5/165)

Table 21. Procedural Details

Procedural Detail	Index Procedure (N=165)	Staged Procedure (N=9)	Aggregate Index plus Staged Procedure (N=165)
Anesthesia			
Conscious Sedation	7.9% (13/165)	22.2% (2/9)	NA[6]
General	83.6% (138/165)	66.7% (6/9)	NA[6]
Monitored Anesthesia Care	8.5% (14/165)	11.1% (1/9)	NA6
Hemodynamic Support			
Balloon Pump	0.6% (1/165)	11.1% (1/9)	1.2% (2/165)
Impella	0.6% (1/165)	22.2% (2/9)	1.8% (3/165)
Other	0.6% (1/165)	0.0% (0/9)	0.6% (1/165)
Not Used	98.2% (162/165)	66.7% (6/9)	96.4% (159/165)

[6]Parameter is specific to individual procedures and is not aggregated

Table 22. Procedure Metrics

Procedure Metric	Index Procedure (N=165)	Staged Procedure (N=9)	Aggregate Index plus Staged Procedure (N=165)
Irrigation Fluid Input from Pump (ml)			
Mean ± StdDev (n)	746.3 ± 433.4 (160)	1056.4 ± 545.4 (9)	805.7 ± 580.3 (160)
Median (Q1, Q3)	676.0 (402.5, 1000.0)	1000.0 (853.0, 1358.0)	681.5 (402.5, 1000.0)
(Min, Max)	(0, 2222)	(100, 2000)	(0, 4000)
Cardioversion Performed	66.1% (109/165)	88.9% (8/9)	66.7% (110/165)
Number Performed			
Mean ± StdDev (n)	3.1 ± 2.5 (109)	3.5 ± 2.1 (8)	3.3 ± 2.8 (110)
Median (Q1, Q3)	2.0 (1.0, 4.0)	3.0 (2.0, 5.0)	2.0 (1.0, 4.0)
(Min, Max)	(1, 13)	(1, 7)	(1, 7)
Ventricular Ablation Abandoned	4.8% (8/165)	22.2% (2/9)	NA[6]

[6]Parameter is specific to individual procedures and is not aggregated

Other Safety Results

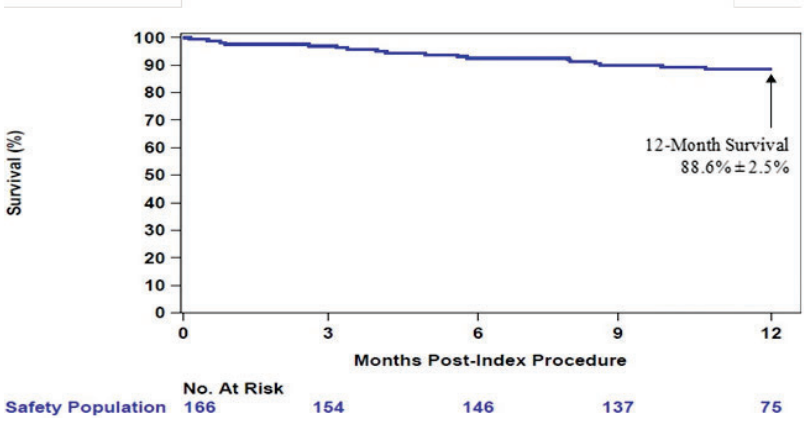
Table 23. Serious Adverse Events Related to the Procedure or Device (CIN Population)

			CEC Assessment	
Adverse Event	Events	Subject % (n/N)	Device Related	Procedure Related
Abnormal labs (e.g. Cpk, Creatinine, Troponin)	1	0.6% (1/166)	0	1
Arrythmia new (atrial arrythmia)	1	0.6% (1/166)	0	1
Bleeding / anemia	2	1.2% (2/166)	0	2
Cardiac arrest	2	1.2% (2/166)	0	2
Cardiac perforation	3	1.8% (3/166)	0	3
Cardiac tamponade	2	1.2% (2/166)	2	2
Chest pain / angina	1	0.6% (1/166)	0	1
Heart failure	4	2.4% (4/166)	4	4
Hemothorax	1	0.6% (1/166)	0	1
Hypotension	4	2.4% (4/166)	0	4

Table 23. Serious Adverse Events Related to the Procedure or Device (CIN Population)

			CEC Assessment	
Adverse Event	Events	Subject % (n/N)	Device Related	Procedure Related
Infection	3	1.8% (3/166)	0	3
Myocardial infarction	1	0.6% (1/166)	0	1
Pericardial bleed	1	0.6% (1/166)	0	1
Pericardial effusion	3	1.8% (3/166)	1	3
Pericarditis	4	2.4% (4/166)	3	4
Peripheral thrombus	2	0.6% (1/166)	0	2
Pleural effusion	1	0.6% (1/166)	0	1
Pulmonary embolism	1	0.6% (1/166)	0	1
Respiratory failure / depression / compromise	1	0.6% (1/166)	0	1
Shock	2	0.6% (1/166)	0	2
Stroke / CVA / embolic event	1	0.6% (1/166)	0	1
Valve damage / insufficiency / regurgitation	2	1.2% (2/166)	2	2
Vascular access site complications	4	2.4% (4/166)	0	4
Ventricular arrythmia with significant deterioration	4	2.4% (4/166)	1	4
Visceral structure or organ damage (NG tube related gastric ulcer)	1	0.6% (1/166)	0	1
Total	52	21.1% (35/166)	13	52

Figure 2. Kaplan Meier Estimate of Survival at 12 Months



The table below summarizes the adverse events that led to death. The primary cause of death was classified by the CEC as cardiovascular in all 18 subjects. Two (2) events leading to death were adjudicated as procedure related, and none (0) were adjudicated as device related. One subject (1/166, 0.6%) died within 7 days of the index procedure. Another subject had an adverse event within 7 days of the index procedure that led to death on day 15.

Table 24. Summary of Causes of Deaths

		CEC Adjudication	
Adjudicated AE Event Leading to Death	Days from Procedure to Death	Procedure Related	Device Related
0-7 Days			
Cardiac Perforation	During staged procedure	Yes	No
8-30 Days			
Ischemic leg, septic shock	15	Yes	No
Respiratory failure	23	No	No
Ventricular arrhythmia with significant deterioration	26	No	No
1-3 Months			
Shock	78	No	No
3-6 Months			
Unknown (sudden death)	95	No	No
Unknown (loss to follow-up)	102	No	No
Ventricular arrhythmia with significant deterioration	120	No	No

Table 24. Summary of Causes of Deaths

		CEC Adjudication	
Adjudicated AE Event Leading to Death	Days from Procedure to Death	Procedure Related	Device Related
Unknown	126	No	No
Shock	150	No	No
Heart failure	170	No	No
Ventricular arrhythmia with significant deterioration	176	No	No
Heart failure	239	No	No
Heart failure	240	No	No
Ventricular arrhythmia with significant deterioration	256	No	No
Ventricular arrhythmia with significant deterioration	259	No	No
Cancer	297	No	No
Shock (after repeat VT ablation procedure)	324	No	No

Study Conclusions

The LESS-VT IDE study NICM cohort results demonstrate that the FlexAbility™ SE catheter is safe and effective for endocardial or epicardial mapping, stimulation and ablation for the treatment of recurrent, drug-refractory, sustained MMVT in patients with non-ischemic structural heart disease, when used in conjunction with a compatible RF generator and a compatible cardiac mapping system.

Directions

1. Verify the generator and related accessories are set up per the diagram in the RF generator Operator's Manual. Do not connect the Sensor Enabled™ Ablation Connection Cable until after the catheter is connected and prepared, as indicated in step 7. Use care to isolate any unused connector pins of the 4 Lead EGM Cable if it is used with a mapping or recording system. This will reduce the chances of developing accidental current pathways to the heart.
2. Inspect the catheter package prior to use. Do not use if the package is open, damaged, or expired.
3. Remove the catheter from its package. Inspect the electrodes and catheter carefully for integrity and overall condition.
4. Connect a sterile luer lock syringe filled with saline mix to the luer connection of the catheter. Push the contents of the syringe into the catheter to confirm all irrigation ports are open.
5. Connect the catheter to the irrigation system using standard luer fittings. The pump must be able to operate at a minimum injection pressure of 15 psi.
6. Make sure to purge the tubing and catheter of air bubbles before insertion. Flush the catheter using a high flow pump setting. Add heparin to the saline infusion medium according to the patient's anticoagulant condition.
7. Connect the Sensor Enabled™ Ablation Connection Cable to the catheter. Observe connector polarity; do not force connectors or pin damage can occur. Then connect the cable to the socket labeled Catheter Extension Connector on the generator front panel. Refer to the cable's instructions for use for information regarding connecting to compatible visualization and navigation systems.
8. Power ON the generator and initialize the pump. Refer to the Operational Sequence Section of the RF generator Operator's Manual for a complete description of generator and pump set-up and communication between the two instruments.

Table 25. Settings During Ablation Procedure

Pump Settings		
Irrigation flow rate during ablation		800 ml/hr (13 ml/min)
Minimum continuous flow rate		120 ml/hr (2 ml/min)
RF Generator Settings		
Power	Initial Setting	20 W
	Maximum Setting	50 W
Temperature	Initial Setting	40°C
	Maximum Setting	45°C
Maximum continuous ablation time at a single site		60 Seconds
Default Mode		Temperature Control

NOTE: Irrigated ablation systems have been shown to create larger lesions than standard RF ablation catheters. Care should be taken when ablating near electrically vulnerable, thin-walled or other arterial structures.

NOTE: There is a possibility of higher incidences of steam pops at power levels exceeding 40W and increased collateral damage when maximum power settings (50W) are used. Power should be increase to these levels only if lower energies do not achieve the intended result.

9. Prior to entering ablation parameters in the generator, ensure the indifferent electrode is appropriately placed on the patient's body.
10. Ensure the initial power level is set to 20 watts.

11. Ensure the initial temperature is set to 40°C.

    NOTE: Temperature represents the tip electrode temperature only and does not reflect tissue temperature.

12. Make sure the catheter is in the neutral (straight) position before insertion. An 8.5 F minimum introducer sheath may be used to aid in insertion. To avoid occlusion of the irrigation conduits, the catheter must be continuously irrigated when within the vasculature. Irrigation should only be stopped after removal of the catheter from the body.

13. Connect the catheter to the compatible visualization and navigation system using the appropriate cable. For instructions regarding the use of the visualization and navigation system with this device, refer to the appropriate system's instructions for use.

14. The catheter should be passed from a peripheral vessel to the desired endocardiac position with the aid of fluoroscopy.

15. To adjust the curve of the distal tip on the uni-directional catheter, push or pull the thumb control located on the handle. To adjust the curve of the distal tip on the bi-directional catheter, use the actuator to deflect the catheter in either direction. Do not pull on the saline luer or connector.

    NOTE: The bi-directional handle has an adjustable tension control knob that allows the operator to use the actuator and deflectable section in an unlocked state or adjust the tension to where the actuator and deflectable section are locked in place. The amount of friction increases as the knob is rotated clockwise until it reaches the fully plus (+) position.
    NOTE: The uni-directional handle has an adjustable tension control knob that allows the operator to use the actuator and deflectable section in an unlocked state or adjust the tension to where the actuator and deflectable section are locked in place. Out of the package, the knob will be in the locked position. If necessary, the tension control knob may be rotated to increase or decrease the tension.

16. Monitor the impedance display on the RF generator, before, during, and after RF power delivery. If a sudden rise in impedance is noted during RF delivery that does not exceed the preset limit, manually discontinue the power delivery. Clinically assess the situation. If necessary, remove the catheter and clean the distal tip to eliminate any coagulum if present.

17. Press the RF Energy Delivery Button on the generator to begin RF therapy (ablation). The pump will automatically increase from basal flow rate to high flow rate.

18. If creating a drag lesion, move the catheter in a linear fashion remaining at one site for no more than 60 seconds.

19. From the initial power setting (20 watts), power may be increased as needed to the maximum setting (50 watts) to create an effective lesion. Intracardiac electrograms and impedance should be assessed prior to changing the power setting. Because there is a possibility of higher incidences of steam pops at power levels of 40 watts and higher, power should be increased to these levels only if lower energies do not achieve the intended results.

    NOTE: Irrigated ablation systems have been shown to create larger lesions than standard RF ablation catheters. Initial power settings should be used when ablating near electronically vulnerable, thin-walled or other arterial structures.

20. If initial temperature (40°C) is reached but the preset power output is not, it is permissible to increase the temperature setting to the maximum setting (45°C). Intracardiac electrograms and impedance should be assessed prior to changing the temperature settings.

21. In case of a steam pop, discontinue RF.

22. In case of a steam pop or automatic shut off, remove the catheter for visual inspection and check for coagulum, charring, or other catheter defects. Flush the ports prior to reinsertion in the patient. If the catheter has defects, exchange it for a new one. Relocate the catheter and attempt another RF application.

23. If the pump alarms and stops the irrigation, immediately remove the catheter from the patient and inspect and re-flush the catheter (see Generator Operator's Manual and Pump Operator's Manual). At the end of each ablation period, the pump will automatically return to the baseline flow rate based on programmed delay.

24. When the procedure is finished, be sure to bring the catheter to its neutral position (straight) before removing the catheter from the patient.

Connecting Other Equipment

This device may be connected to a commercially available EP recording system using a connection cable with connectors in the pin configuration corresponding to this catheter. The use of cables with shrouded pins is recommended and is required in some countries such as the United States. Such equipment must be "patient isolated," or have an isolated patient cable. Current leakage from the connected EP recording system must not exceed 10 microamps for intracardiac electrodes.

Packaging and Shelf-Life

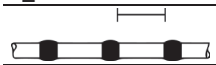
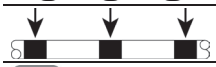
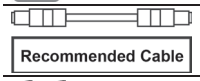
The catheter packaging is designed to prevent crushing of the product, to minimize product exposure to the atmosphere, and to provide for aseptic product transfer. It is recommended that the product remain in the unopened package until time of use. Contents are sterile if the package is unopened and undamaged. Do not resterilize. Do not use the device if the packaging sterile barrier is open or damaged. The expiration date is marked on the outside of the package. The product must be stored in a cool, dry location. The instructions for use are recyclable. Dispose of product and packaging according to standard solid biohazard waste procedures.

Warranty

Abbott Medical warrants that its products shall be free from defects in materials and workmanship under normal use. This warranty does not exceed the "Expiration" date stated on any product labeling. The authorized uses and approved methods of use of each of our products are set forth in the related "Instructions for Use" that accompany each product. Abbott Medical disclaims any responsibility and liability for the use of its products in a manner that has not been authorized or approved. Abbott Medical's liability under this warranty is limited to replacing its products. The foregoing warranty excludes and is in lieu of all other warranties whether expressed or implied including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Abbott Medical disclaims any liability for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this product, other than as expressly provided by specific law. Abbott Medical neither assumes nor authorizes any other person to assume for it any other or additional liability for loss, damage, or expense in connection with this product. For more details please review complete Abbott Medical warranty policy available from Abbott Medical or on the back of an Abbott Medical invoice.

Symbols

Symbol	Description

Symbol	Description
	Caution, consult accompanying documents
	Sterilized using ethylene oxide
	Consult instructions for use
	Follow instructions for use on this website
	Do not use if package is damaged
	Do not reuse
	Batch code
	Unique Device Identification
	Use by
	Ablation catheter
	Reorder number
	Non-pyrogenic
	Manufacturer
	Usable Length
	Keep away from sunlight
	Spacing
	Electrodes
	Number of electrodes
	Recommended cable
	Conformité Européenne (European Conformity). Affixed in accordance with European Council Directive 93/42/EEC (NB 2797) and 2011/65/EU. Hereby, Abbott Medical declares that this device is in compliance with the essential requirements and other relevant provisions of this directive.
	Date of Manufacture
	Quantity
	Authorized European representative
	Do not resterilize
	Outer Diameter
	Manufacturing Facility
	CAUTION: Federal law (U.S.) restricts this device to sale by or on the order of a physician.
	Keep dry

Symbol	Description
	Temperature limitations
	Humidity limitation

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