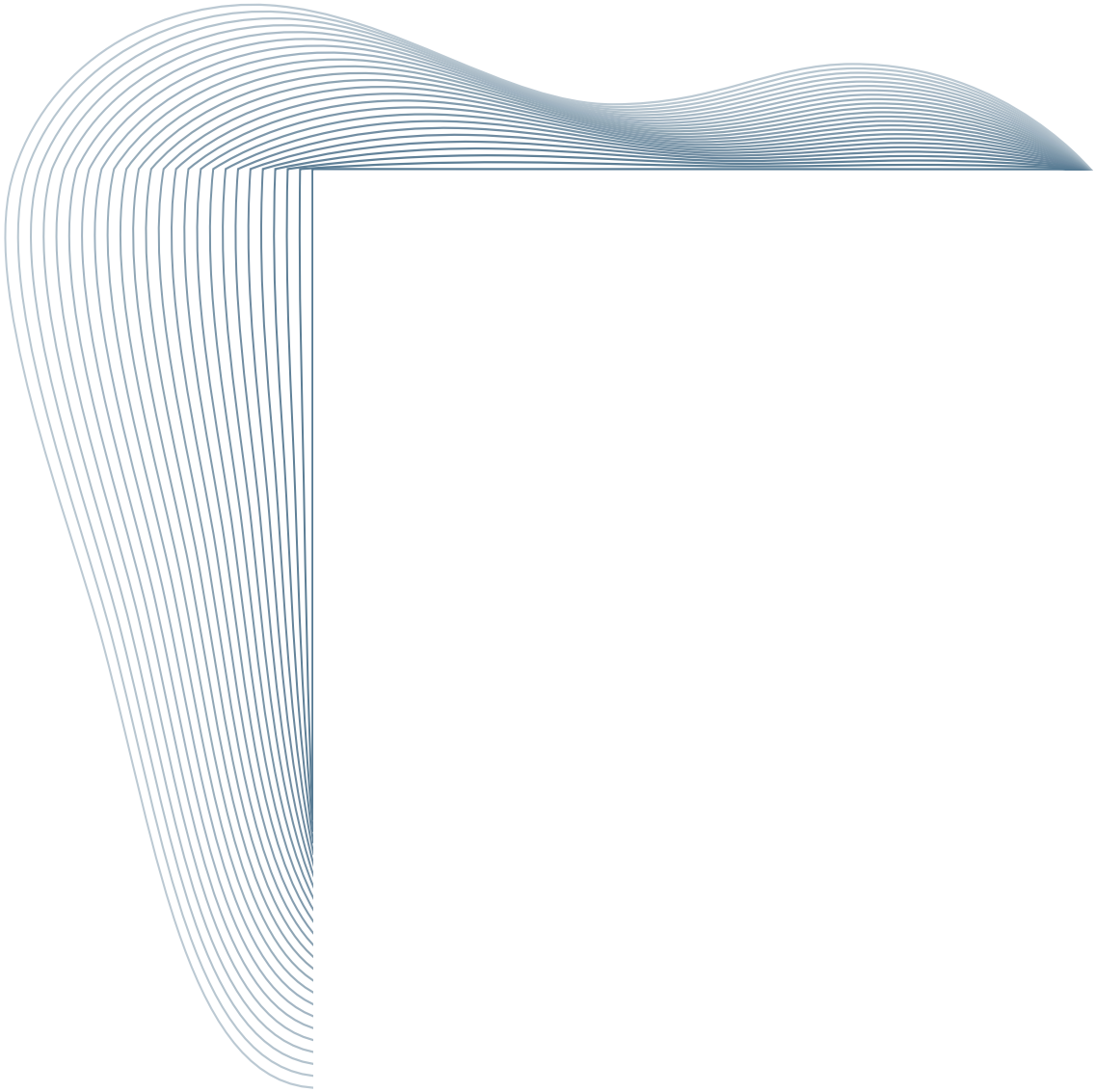

ProMRI

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1 About This Technical Manual

Objective

This technical manual contains information for physicians, trained users of the clinician programmer, and medical personnel regarding the implantation, setup, and follow-up of the Prospera Spinal Cord Stimulation System, in the following called Prospera SCS System, for the trial phase and for permanent e.

- Implantation of percutaneous leads for trial and/or permanent e
- Connection of the leads for trial use to an external stimulato
- Implantation of an implantable stimulator
- Connection of the leads to an implantable stimulator
- Performance of intraoperative tests
- Explantation of leads and stimulators

All activities performed with the clinician programmer are carried out by a trained user of the clinician programmer. A detailed description for trained users of the clinician programmer on the handling of the clinician programmer can be found in HomeStreamCP – Clinical Programming of BIOTRONIK External and Implantable Spinal Cord Stimulators.

Technical Manuals

Technical manuals are either included in hard copy form in the torage package or available in digital form on the internet: https://manuals.biotronik.com.

1. Consult all relevant technical manuals.
2. Keep the technical manuals for future reference.

To ensure safe operation, in addition to this technical manual, please also consult the following technical manuals:

- Prospera Spinal Cord Stimulation System – MRI Guidelines
- Prospera Spinal Cord Stimulation System – Patient Guide for the Implanted System
- Prospera Spinal Cord Stimulation System – Patient Guide for the Trial System
- Smartphone manufacturer's information on the patient programme MyHomeStream
- Smartphone manufacturer's information on the patient programme MyHomeStream TR
- HomeStreamCP – Clinical Programming of Prospera SCS System Stimulators
- Tablet manufacturer's information on the HomeStreamCP

onventions

Marking of Safety Messages

The following symbol indicates potential hazards:

Follow all safety messages indicated by this symbol to avoid se ious or even fatal injury or damage to the system.

Safety messages are also indicated by a classification to indicate severity.

assification	Meaning
Danger	Non-compliance **may immediately lead to severe injury or death.**
Warning	Non-compliance leads to a potentially dangerous situation that **can cause severe injuries or death.**
aution	Non-compliance leads to a potentially dangerous situation that **can cause moderate injuries.**
Attention	Non-compliance leads to a potentially dangerous situation that **can cause minor injuries or material damage.**

Typographical Conventions

The following typographical conventions are used in this technical manual:

Elements	Description and Appearance
Instructions	The individual steps of an instruction are numbered. Prerequisites, intermediate results, and results may be specified. **Prerequisite** • This is a prerequisite. 1. First step 2. Second step ▶ Intermediate result 3. Third step **Result** This is the final result.
Navigation paths	The elements of a navigation path are shown in bold and separated by ">". Example: **[Main menu]** > **[Sub-menu]** > **[Item]**
Cross references	Cross references are indicated using "see" or "see also".
Elements of the user interface	Elements that are displayed on the user interface, such as butt ns or menu items, are indicated by square brackets and bold font. Example: **[Button]**.
Emphasis	Text that needs to be emphasized is shown in **bold**.
Notes	Useful information is indicated using the word **Note**.

Figures

Figures that show the product or the user interface are used fo illustration purposes only. The details hown in the figure may differ from that of the delivered produ ct or your software version.

Abbreviations

The following abbreviations are used in this technical manual.

Abbreviation	Meaning
ABS	Acrylnitril/Butadien/Styrol
CISPR	Comité International Spécial des Perturbations Radioélectriques
CRPS	Complex Regional Pain Syndrom
DDD	Degenerative Disk Disease
EIRP	Equivalent Isotropically Radiated Power
EM fields	Electromagnetic fields
ESD	Electrostatic Discharge
FBS	Failed Back Syndrom
FCC	Federal Communications Comission

Abbreviation	Meaning
GFSK	Gaussian Frequency Shift Keying
HIPAA	Health Insurance Portability and Accountability Act
ICD	Implantable Cardioverter-Defibrillator
Patient ID card	Patient Identification card
IEC	International Electrotechnical Commission
ISM band	Industrial, Scientific and Medical band
IT	Information Technology
LED	Light-Emitting Diode
MRI	Magnetic Resonance Imaging
OOK	On-Off Keying
OOS form	Out Of Service form
RF ablation	Radio Frequency ablation
RSD	Reflex Sympathetic Dystrophy
SCS	Spinal Cord Stimulation
TENS	Transcutaneous Electrical Nerve Stimulation
UDI	Unique Device Identifier
USB	Universal Serial Bus
WEEE 2	European guideline 2012/19/EU on waste electrical and electronic equipment
WiFi	Wireless Fidelity
WPA2	WIFI Protected Access, Version 2

Gender

Personal designations are used in the male or female form in order to facilitate the flow of reading. This form is intended to include all gender identities.

2 afety

This chapter contains safety messages referring to the handling f the Prospera SCS System, therapeutic and diagnostic procedures and transport and storage f the system components.

Warnings

Please follow the listed safety messages when handling the exte nal stimulator:

Risk of Electromagnetic Interference through the Use of Portable RF Communication Equipment

If portable RF communication devices (including peripheral devices such as antenna cables and external antennae) are operated closer than 30 cm (12 inches) f m this device, this can result in a eduction in its performance. This applies even when using asso ciated cables.

- When operating portable RF communication devices (including pe ipheral devices such as antenna cables and external antennae), keep such devices at a distance f at least 30 cm (12 inches) from the external stimulator and the charger.

Precautions

afety Messages for Handling the Trial System

Please follow the listed safety messages when handling any of the system components:

Electrode Corrosion and Loss of Therapy due to an Improperly Sealed or Affixed Pouch

If the pouch is not affixed properly, water may enter the pouch, as a result the electrodes may corrode and the therapy may fail. Furthermore, an improperly attached p ch may move, which could lead to therapy failure.

- Orient and affix the pouch properly in a way that no liquids can enter the pouch.
- Make sure that the pouch is completely sealed around all edges and corners and also around the leads.
- If necessary, use additional adhesive strips to secure the pouch.

Risk of Infection or Damage to Stimulator when an External Stimulator Has Not Been Disinfected orrectly

The improper cleaning and disinfecting of an external stimulato may lead to device malfuntion and patient injury.

- Let the external stimulator be cleaned and disinfected by a BIOTRONIK representative after use by each patient.

afety Messages for Handling the Implantable Stimulator

Please follow the listed safety messages when handling the implantable stimulator:

Product Damage and Risk of Injuries due to Modification of the Medical Device

Unauthorized modification to the medical device is prohibited. System integrity could be compromised and patient harm or injury may occur if the medical devices are modified without authorization.

- Do not modify the medical device.

Risk of Infection if an Explanted Stimulator Is Not Properly Disposed of

An explanted stimulator must not be reused due to the risk of infection, and it must be properly disposed of.

- Dispose of the explanted stimulator as medical waste in an environmentally sound and proper manner.
- Do not cremate the stimulator. Explant the stimulator to cremation of a deceased patient.
- Return the explanted stimulator to BIOTRONIK for an environmentally sound disposal.

Skin Erosion, Overheating, or Charging Difficulties due to an Improper Pocket Depth and Location

An improperly placed device pocket may lead to skin erosions if placed too close to the surface. It may lead to charging difficulties or to excessive heat devel pment during the charging of the timulator, if placed too deep.

- Please follow the instructions for the creation of a device pocket.
- If necessary, use the pocket template to shape the device pocket properly.
- Implant the stimulator no more than 2 cm (0.78 inch) below the kin surface with the labeled side facing the skin, so that the charging coil is close to the patient surface.
- Lay sutures through the eyelets at the stimulator header to prevent the stimulator from inverting migrating.

Injury due to Heat Development during Charging when Using Metal c Clamps

When charging the implanted stimulator, surgical staples made of metal that are situated in the vicinity of the implanted stimulator may heat up and damage the patient's tissue in this area.

- Do not use surgical staples made of metal in the vicinity of the implanted stimulator.

Risk of Infection in case of Resterilization and Reuse

The implanted Prospera SCS System is designed for single use only. Resterilization and reuse of previously used implantable stimulators, leads or accessories can result in infections, embolisms, and damage to the components.

- Resterilization and reuse are prohibited.
- Please note the single-use label on the components.

afety Messages for Handling the Implant Accessories

Please follow the listed safety messages when handling the implantation accessories:

kin Injury if Tunneling Is too Shallow

If the tunneling of the implanted leads is too shallow, skin er ion and exposure of the implanted leads may occur.

- Please tunnel the leads deep enough to prevent skin erosion and exposure of the implanted leads.
- If very long tunneling is required, it is recommended to lead the lead out of the skin and create a econd tunnel.

pinal Injury due to Puncturing with the Insertion Needle

Spinal injury may occur if excessive pressure is used when acce ing the epidural space. Furthermore, teep insertion angles may inhibit ability to subsequently inse t the lead and/or may result in ndesired injury of spinal tissues.

- Dispense pressure in a suitable manner when inserting the inse tion needle into the epidural space.
- Carefully insert the insertion needle at a shallow insertion angle.
- As appropriate, consider the use of fluoroscopic visualization to aid in needle and lead insertion.

Risky Therapeutic and Diagnostic Procedures

afety Messages for Handling the Trial System

Please follow the listed safety messages when handling the trial system:

WARNING

Adverse Interactions and Damage of the Trial System due to Medical Procedures

The following medical procedures may lead to adverse interactions and to damage to the external timulator and implanted trial leads:
lithotripsy, RF ablation, hyperbaric oxygen therapy, electrocautery, diathermy, high-power ltrasound, radiation therapy, MRI scan.

- Do not apply the above-listed procedures while the patient is ndergoing an SCS trial phase.
- Turn off the external stimulator and remove the external stimulator and implanted trial leads before using one of the above-listed procedures for this patient.

WARNING

Interference with the Operation of Implanted Pacemakers or ICDs

The Prospera SCS System may interfere with the operation of implanted pacemakers or ICDs. The effects of an implanted Prospera SCS System on other neurostimulators are unknown.

WARNING

Therapy Failure and Harm to the Patient due to External Defibri ation

External defibrillation may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage in the area of the implanted leads may occur due to excessive heat development at the lead tip.

- Turn the stimulation off temporarily.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the defibrillation.

Attention

Disruption of the Therapy of the External Stimulator by Externa Defibrillation

External defibrillation may lead to damage and function loss of the external stimulator.

- Replace an external stimulator that was worn during an external defibrillation of a patient with a new external stimulator.
- Return the external stimulator that was worn during an external defibrillation of a patient to BIOTRONIK.

Attention

Undesirable Therapy Possible with TENS Use

When using transcutaneous electrical nerve stimulation (TENS), the output power may affect the Prospera SCS System. This may cause the stimulator to deliver t much or too little therapy.

- Use the TENS unit only in locations that do not pass current through the implanted parts of the Prospera SCS System.

afety Messages for Handling the Permanent System

Please follow the listed safety messages when handling the permanent system:

⚠ **WARNING**

Therapy Failure and Harm to the Patient due to Electrocautery

Electrocautery may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage and serious patient injuries may occur in the area of the implanted timulator or the leads.

- Avoid electrocautery if possible. If electrocautery is necessa y, pay attention to the following:
- Turn the stimulation off temporarily.
- Use bipolar electrocautery.
- Do not apply unipolar electrocautery.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the electr cautery.

⚠ **WARNING**

Therapy Failure and Harm to the Patient due to External Defibri ation

External defibrillation may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage in the area of the implanted leads may occur due to excessive heat development at the lead tip.

- Turn the stimulation off temporarily.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the defibrillation.

⚠ **WARNING**

Interference with the Operation of Implanted Pacemakers or ICDs

The Prospera SCS System may interfere with the operation of implanted pacemakers or ICDs. The effects of an implanted Prospera SCS System on other neurostimulators are unknown.

⚠ **WARNING**

Therapy Failure and Harm to the Patient due to Diathermy Therapy, including Shortwave, Microwave, and Therapeutic Ultrasound Therapies

Diathermy therapy, including shortwave, microwave, and therapeutic ultrasound therapy, may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage and erious patient injuries may occur in the area of the implanted timulator or the leads.

- Avoid diathermy therapy if possible. If diathermy therapy is necessary, pay attention to the following:
- Turn the stimulation off temporarily.
- Do not apply the diathermy therapy in the immediate vicinity of the implanted stimulator or the leads.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the diathe my therapy.

⚠ WARNING

Therapy Failure and Harm to the Patient due to the Use of Magnetic Resonance Imaging (MRI)

The use of magnetic resonance imaging outside of the specified conditions may damage the Prospera SCS System due to strong magnetic interactions. In addition, the patient may come to harm due to excessive heating of the body tissue in the area of the implanted system.

- Please inform yourself on the safe performance of an MRI scan. Refer to Prospera Spinal Cord Stimulation System – MRI Guidelines.
- You can download the MRI Guidelines on the internet: https://manuals.biotronik.com.
- A printed copy can be ordered from BIOTRONIK.

⚠ WARNING

Therapy Failure and Harm to the Patient due to Therapeutic or H gh-Power Ultrasound Treatment

Therapeutic and high-power ultrasound treatment exposes the Pro pera SCS System to high doses f energy, which may lead to damage and function loss of the sy tem and to therapy failure. Excessive heating may lead to tissue damage and patient injurie in the area of the implanted timulator or the leads.

- Avoid therapeutic or high-power ultrasound treatments if possible. If these treatments are necessary, pay attention to the following:
- Turn the stimulation off temporarily.
- Do not apply the ultrasound treatment in the immediate vicinity of the implanted stimulator or the leads.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the electrical therapy.

⚠ aution

Therapy Failure and Damage to the Prospera SCS System due to Lithotripsy

Lithotripsy may lead to damage and function loss of the system and to therapy failure.

- Turn the stimulation off temporarily.
- Keep the focal point of the lithotripsy at least 2.5 cm from the implanted Prospera SCS System.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the lithot ipsy.

⚠ aution

Therapy Failure and Damage to the Prospera SCS System due to RF Ablation

RF ablation may lead to damage and function loss of the system and to therapy failure.

- Turn the stimulation off temporarily.
- Avoid direct contact between the ablation catheter and the implanted system.
- Position the grounding plate in such a way that the current path does not run through or in the vicinity of the implanted stimulator and the leads.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the RF ablation.

⚠ aution

Therapy Failure Caused by Hyperbaric Ambient Conditions

Therapy environments with increased ambient pressure can lead t insufficient or excessive timulation and the associated adverse stimulation side effects .

- Turn the stimulation off temporarily.
- Apply hyperbaric oxygen therapy only under ambient conditions listed as permissible in this technical manual (e.g., maximum pressure).
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the hyperbaric oxygen therapy.

⚠ aution

Therapy Failure and Damage to the Stimulator due to Radiation Therapy

Radiation therapy may lead to damage and function loss of the stimulator and to therapy failure.

- Turn the stimulation off temporarily.
- Place a lead shield above the area of the stimulator.
- Note that damage might not be obvious and may lead to a malfunction of the stimulator.
- Perform a complete system follow-up after finishing the radiation therapy.

⚠ Attention

Undesirable Therapy Possible with TENS Use

When using transcutaneous electrical nerve stimulation (TENS), the output power may affect the Prospera SCS System. This may cause the stimulator to deliver t much or too little therapy.

- Use the TENS unit only in locations that do not pass current through the implanted parts of the Prospera SCS System.

Transport and Storage

⚠ Attention

Damage to the System due to Noncompliance with the Conditions for Transport and Storage

If the conditions for transport and storage stated in this technical manual are not met, the system may be damaged. The system function may be permanently compromi ed by this.

- Please follow the conditions for transport and storage listed in this technical manual.
- Do not use system components that were not transported or stored correctly.

terility

⚠ Sterile Delivered Products

⚠ aution

Risk of Infection in case of Resterilization and Reuse

The implanted Prospera SCS System is designed for single use only. Resterilization and reuse of previously used implantable stimulators, leads or accessories can result in infections, embolisms, and damage to the components.

- Resterilization and reuse are prohibited.
- Please note the single-use label on the components.

The following components are sealed in 2 blisters, one within the other, and sterilized with ethylene xide. As a result, the inner blister is also sterile on the ou tside.

- Implantable stimulator, torque wrench and pocket template
- Leads and accessories
- Active anchors
- Suture anchors
- Port plugs

The following components are sealed in a blister and sterilized with ethylene oxide.

- Intraoperative test cable
- Spare accessories
- Tunneling tool
- Insertion needle

⚠ Non-Sterile Delivered Products

The following products are delivered non-sterile:

- External stimulator
- Trial Kit
- Magnet
- Charger

Temperature during Transport and Storage

Store the following components at an ambient temperature of -4 °F to +140 °F (-20 °C to +60 °C):

- Magnet

Store the following components at an ambient temperature of +14 °F to +113 °F (-10 °C to +45 °C):

- External stimulator
- Charger
- Intraoperative test cable
- Trial kit

Store the following components at an ambient temperature of +14 °F to +131 °F (-10 °C to +55 °C):

- Implantable stimulator
- Leads
- Active anchor
- Suture anchor
- Port plugs
- Spare accessories
- Tunneling tool
- Long insertion needle

torage Period

Store the following components for a storage period of 12 month :

- Implantable stimulator
- Leads
- Active anchor
- Suture anchor
- Tunneling tool
- Spare accessories
- Long insertion needle
- Port plugs

3 ystem Description

Overview of the System Components

The Prospera SCS System consists of various components: the implantable stimulator, one or two percutaneous leads, the clinician programmer, the external stim lator, the patient programmer, and the charger. There are also additional accessories that are implanted or used during or after the implantation.

First, trial leads are implanted and connected to an external stimulator. This system can be used to check the effectiveness of the therapy during a trial phase.

If the trial phase was successful, the patient is implanted with permanent leads and an implantable stimulator. The implantable stimulator is charged by the patient with a charger.

Both the external and the implantable stimulator are in wireles communication with the clinician programmer and the patient programmer.

Main Components

The Prospera SCS System consists of the following main components:

Implantable Stimulator

The implantable stimulator is a device for the electrical stimulation of nerves in the spinal cord.

The stimulator is made up of the housing and the header. The ho ing contains a rechargeable battery that can be charged transcutaneously. The header contains the c nnections for up to two leads that are attached with set screws and the charging coil for recharging the battery.

The implantable stimulator communicates wirelessly with other system components, such as the patient programmer, the clinician programmer, and the charger. With the help of the patient programmer and the clinician programmer, the therapy delivered by the implantable stimulator can be adapted to the needs of the patient. The implantable stimulator can also store data that can be read with the help of the clinician programmer.

External Stimulator

The external stimulator is a device that is able to deliver the ame therapies as the implantable stimulator.

The external stimulator is made up of a housing and a header. The housing contains the batteries. In addition, the housing has a connection point where the header o the intraoperative test cable can be attached. The header has lead connections, to which the proximal ends of the trial leads are connected. The leads are held in place with a cover at the contacts of the lead connections.
The external stimulator is used during implantation to perform intraoperative tests. To this end, the implanted leads are connected to the external stimulator via the intraoperative test cable.

At the start of the trial phase, the external stimulator is connected to the trial leads and attached to the patient's body with an affixation pouch. The effectiveness of the delivered therapies can be assessed during the trial phase.

The external stimulator can communicate wirelessly with the patient programmer and the clinician programmer.

Leads

The leads have the purpose to deliver stimulation to the spinal cord. The leads are implanted in the epidural space.

The lead connector has 8 contacts that are connected to the header of the external stimulator, the implantable stimulator, or the intraoperative test cable. At the distal end of the lead, there are 8 ring electrodes, through which therapy is delivered.

The system comprises both trial and permanent leads. The trial leads are used during the trial phase and are connected to the intraoperative test cable or to the external stimulator. The permanent leads are used during the permanent implantation of an Prospera SCS System and are connected to the intraoperative test cable or to the implantable stimulator.

cian Programmer

The clinician programmer is a tablet able to communicate wirele ly with the implantable and the external stimulator. With the clinician programmer, a trained u er of the clinician programmer can perform the following tasks:

- Pairing
- Intraoperative tests
- Programming parameter adjustments
- Preparing the external stimulator for battery replacement and emoval
- Preparing the implantable stimulator for removal

Patient Programmer

The patient programmer is a phone which acts as the interface f communication with the external and the implantable stimulator. With the patient programmer, the patient can turn the stimulation on and off, adjust the intensity of the therapy, and receive and u e programs transmitted by the physician.

Accessories

The Prospera SCS System also contains the following accessories that are implanted or used during or after the implantation:

Port Plug

The port plug is an implantable accessory. The port plug is used to close off an unused lead connection at the header of the implantable stimulator if only one lead is implanted.

Active Anchor

The active anchor is an implantable accessory. The lead is attached at the lead epidural exit site with the anchor.
The active anchor is pushed onto the lead and secured to the lead with a screw mechanism.
The anchor has eyelets for suturing it to the tissue.

uture Anchor

The suture anchor is an implantable accessory. The lead is attached at the lead epidural exit site with the suture anchor in the same manner as the active anchor.
The suture anchor is secured to the lead by tying a suture around a ligature groove.

Insertion Needle

The insertion needle is used to provide access to the epidural pace for lead insertion.

earing Wire

The clearing wire can be used during the implantation to predefine the insertion path of the lead into the epidural space.

tylet

With the help of the stylet, the lead can be positioned at the desired implantation site during the implantation. Stylets are available in two configurations: straight and curved.

Tunneling Tool

The tunneling tool is used to tunnel subcutaneously from the lead implantation site to the device pocket during the implantation, to guide the lead from the implantation site to the device pocket.

Torque Wrench

The torque wrench is used during the implantation of the implantable stimulator to secure the leads to the header of the device with the set screws. In addition, the torque wrench is used to secure the active anchor to the lead via a set screw.

The torque wrench is available in two lengths, which can be selected depending on the anatomy of the patient.

Pocket Template

The pocket template is used before or during the implantation a template to shape the device pocket. The pocket template has the same shape and size as the implantable stimulator.

Intraoperative Test Cable

The intraoperative test cable connects the leads to the external stimulator during implantation for intraoperative testing.

The intraoperative test cable consists of the lead connection and the header, which are connected to a cable. The lead connection contains the lead contacts, to which the leads are attached. The header can be connected to the external stimulator that is used to perform the intraoperative tests.

harger

The charger is used for transcutaneous charging of the implanted stimulator by the patient. The charger contains a rechargeable battery that is charged before charging the implantable stimulator. To charge the stimulator, the charger is placed over the header f the implantable stimulator.

Magnet

The magnet is used to pair the stimulators with the clinician p grammer or the patient programmer. When the magnet is placed on the stimulator, the stimulator enters a mode that enables the communication. When the magnet is placed on the stimulator for longer than 60 s, the stimulation therapy is suspended.

Intended Medical Use

The Prospera Spinal Cord Stimulation System is designed to manage chronic pain by delivering electrical impulses to nerve structures in and around the spinal cord. The implantable stimulator is intended to be used with compatible leads and associated access ies. The Prospera SCS System is intended to be implanted and managed by healthcare professional familiar with the use of neurostimulation devices.

Indications

The Prospera SCS System is indicated as an aid in the management of chronic, intractable pain in the trunk and/or limbs, which may include unilateral or bilateral pain, resulting from any of the following:

- Failed Back Syndrome (FBS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBS surgery or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical interventions
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dyst phy (RSD), or causalgia

ontraindicated Patient Conditions

Implantation of a spinal cord stimulator may be contraindicated in patients with the following characteristics:

- Are unable to operate the Prospera SCS System
- Have failed to receive effective pain relief during SCS trial timulation
- Are poor candidates for surgery

Note

The safety and effectiveness of spinal cord stimulation has not been established in pediatric patients or pregnant or nursing patients.

Adverse Effects

Below is a list of the potential adverse effects (e.g., complications) associated with the use of SCS ystems. The Prospera SCS System is similar to other legally ma keted SCS systems in intended use, target patient population, technology, device design, and output characteristics. Therefore, as there is no published data on the use of the Prospera SCS System, the following list of potential adverse effects have been identified from peer-reviewed published literature of tudies and device labeling of other legally marketed fully implantable SCS systems similar to the P pera SCS System. [1,2,3,4,5] The adverse effects include, in order of increasing specificity: (1) those associated with any surgical procedure, (2) those associated with the SCS system placement procedures, and (3) those associated with having an implanted SCS system to treat pain, including the Prospera SCS System. In addition to the risks listed below, there is the risk that the SCS therapy may not be effective in relieving symptoms or may cause worsening of symptoms. Additional intervention may be required to correct some of the adverse effects.

- Risks associated with any surgical procedure: abscess; cellulitis; excessive fibrotic tissue; wound dehiscence; wound, local or systemic infection; wound necrosis; edema; inflammation; foreign body reaction; hematoma; seroma; thrombosis; ischemia; embolism; thromboembolism; hemorrhage; thrombophlebitis; adverse reactions to anesthesia; hypertension; pulmonary complications; organ, nerve or muscular damage; gastrointestinal or genitourinary compromise; eizure, convulsion, or changes to mental status; complications f pregnancy including miscarriage and fetal birth defects; inability to resume activities of daily living; and death.
- Risks associated with SCS system placement procedures: tempora y pain at the implant site, infection, cerebrospinal fluid (CSF) leakage, CSF fistula, epid al hemorrhage, bacterial meningitis, eroma, hematoma, and paralysis. Patient use of anticoagulation therapies may increase the risk f procedure-related complications such as hematomas, which cou ld produce paralysis.
- Risks associated with the use of an SCS system: lead migration; stimulator migration; allergic response or tissue reaction to the implanted system material; hematoma or seroma at the implant ite; skin erosion at the implant site; persistent pain at the timulator, extension, or lead site; adicular chest wall stimulation; disturbed urination; dysesthe ia; decubitus; premature battery depletion; loss of assistance in managing pain over time; and uncomfortable stimulation or ineffective pain management caused by random failure of the system components or battery, changes in lead position, loose electrical connections, lead or extension insulation breaches or fractures.

Summaries of specific adverse events and device-related complications identified in a systematic eview and meta-analysis of published clinical studies used to evaluate the safety of the Prospera SCS System, are provided in the section: Summary of Clinical Evaluation [Page 66]

[1]Algostim, LLC. Summary of Safety and Effectiveness Data: Algovita™ Spinal Cord Stimulation (SCS) System. 2015. P130028.
[2]Advanced Bionics Corporation. Summary of Safety and Effectivene Data: PRECISION ™ Spinal Cord Stimulator (SCS) System. 2004. P030017.
[3]Advanced Neuromodulation Systems (ANS), Inc. Summary of Safety and Effectiveness Data: Genesis Neurostimulation (IPG) System. 2001. P010032.
[4]Boston Scientific Neuromodulation Corporation. Summary of Safety and Effectiveness Data: Precision™ and Spectra WaveWriter™ Spinal Cord Stimulation (SCS) Systems. 2017. P030017/S275.
[5]Nevro Corp. Summary of Safety and Effectiveness Data: Senza Spinal Cord Stimulation (SCS) System. 2017. P130022.

Intended Users

Medical and Technical Users

The primary users of the Prospera SCS System for surgical and f llow-up roles are physicians familiar with neurostimulator implantation, follow-up care, and risks as ciated with neurostimulation systems. Qualified BIOTRONIK representatives and other hospital staff will provide support for the needs of these primary users.

Users of the clinician programmer are personnel who are trained in Prospera SCS System technical settings for therapy and other options in the patient's stimulator.

Patient User

The primary user of the Prospera SCS System for the role of ope ation of the patient programmer and the charger is the patient who receives the stimulator.

4 Overview of the Implantation Procedure and Process

Implantation Procedure

The implantation is divided into two phases. First, a trial system is implanted, and the effectiveness of the therapy is tested. If the effectiveness has been confirmed, the permanent system is implanted.

During the implantation of the trial system, up to two leads are temporarily implanted in the patient, the proximal ends exit the patient's body and are connected to an external stimulator with a header. The external stimulator is attached to the patient with an affixation pouch. After testing the effectiveness, the trial leads are removed.

If it was shown that the use of a stimulator is suitable, the permanent system with up to two leads and the implantable stimulator is implanted.

Procedures Overview

The steps performed with the clinician programmer are carried o t by a trained user of the clinician programmer. This includes pairing, intraoperative testing, prog amming, preparing the external timulator for battery replacement, preparing the external stim lator for removal, resetting the patient programmer at the end of the trial phase, and deactivating a stimulator prior to explant.

teps for Implanting and Removing the Trial System

	Procedure	tep
1	Prepare the implantation	
		Instructions before the Implantation [Page 28]
		Replacing the Batteries of the External Stimulator before each Implantation [Page 28]
2	Implant the trial lead	
		Inserting the Lead [Page 29]
		Performing Intraoperative Tests [Page 30]
		Connecting the Lead [Page 31]
3	Attach and program the external stimulator	
		Attaching the External Stimulator to the Patient [Page 32]
		Programming the Stimulator [Page 32]
		Pairing the Patient Programmer with the External Stimulator [Page 32]
4	Remove the trial system	
		Removing the External Stimulator from the Patient [Page 33]
		Removing the Trial Leads [Page 35]
		Cleaning, Disinfecting, and Storing the External Stimulator [Page 36]

teps for Implanting the Permanent System

	Procedure	tep
1	Prepare the implantation	
		Instructions before the Implantation [Page 38]
2	Implant the permanent lead	
		Inserting the Lead [Page 38]
		Performing Intraoperative Tests [Page 40]
		Anchoring the Lead [Page 41]
		Shaping the Pocket for the Stimulator and Tunnel the Lead [Page 42]
3	Implant the implantable stimulator	
		Implanting the Stimulator and Connecting the Lead [Page 44]
4	Program the stimulator	
		Programming the Stimulator [Page 45]
		Pairing the Patient Programmer with the Stimulator [Page 45]

teps for Exchanging or Explanting the Permanent System

	Procedure	tep
1	Exchange the implantable stimulator	
		Exchanging the Stimulator [Page 46]
2	Explant the permanent system	
		Explanting the Permanent System [Page 46]

First Steps

Package Contents

Prospera IPG

The storage package includes the following:

- Sterile packaging with device and accessories
- Medical device registration form
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Implantable stimulator
- Torque wrench
- Pocket template

Resilience 5 TR

The storage package includes the following:

- Sterile packaging with lead and accessories
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Lead with inserted curved stylet (55 cm)
- Straight stylet (55 cm)
- 2 suture anchors
- Clearing wire
- Straight insertion needle

Resilience 75TR

The storage package includes the following:

- Sterile packaging with lead and accessories
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Lead with inserted curved stylet (75 cm)
- Straight stylet (75 cm)
- 2 suture anchors
- Clearing wire
- Straight insertion needle

Prospera EPG

The storage package includes the following:

- External stimulator
- External stimulator cap

Prospera Trial Acc

The storage package includes the following:

- Header of the external stimulator
- External stimulator cap
- 2 patient affixation pouches
- 3 batteries, type AAA
- Prospera Spinal Cord Stimulation – Patient Guide for the Trial System

Resilience 5

The storage package includes the following:

- Sterile packaging with lead and accessories
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Lead with inserted curved stylet (55 cm)
- Straight stylet (55 cm)
- 2 suture anchors
- Clearing wire
- Straight insertion needle

Resilience 75

The storage package includes the following:

- Sterile packaging with lead and accessories
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- Lead Resilience 75 with inserted curved stylet (75 cm)
- Straight stylet (75 cm)
- 2 suture anchors
- Clearing wire
- Straight insertion needle

HomeStreamCP

The storage package includes the following:

- Tablet
- Tablet manufacturer's information on the clinician programmer
- Charging cable and power plug adapter

MyHomeStream TR

The storage packaging includes the following:

- Smartphone with installed application
- Smartphone manufacturer's information on the patient programme
- Charging cable
- Power plug adapter

MyHomeStream

The storage packaging includes the following:

- Smartphone with installed application
- Smartphone manufacturer's information on the patient programme
- Charging cable
- Power plug adapter

PP

The storage package includes the following:

- Sterile packaging with port plugs
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- 2 port plugs

Anchor

The storage package includes the following:

- Sterile packaging with active anchors
- Patient ID card
- Patient record stickers
- OOS form

The sterile packaging includes the following:

- 2 active anchors

NDL L

The storage package includes the following:

- Sterile packaging with insertion needle

The sterile packaging includes the following:

- Long insertion needle

Tunneler

The storage package includes the following:

- Sterile packaging with tunneling tool and accessories

The sterile packaging includes the following:

- Tunneling tool
- Tunneling shaft (premounted)
- Sharp tip
- Blunt tip

Prospera IOC

The storage package includes the following:

- Sterile packaging with intraoperative test cable

The sterile packaging includes the following:

- Intraoperative test cable (2.0 m)

Resilience Acc

The storage package includes the following:

- Sterile packaging with spare parts

The sterile packaging includes the following:

- Curved stylet
  - 55 cm
  - 75 cm
- Straight stylet
  - 55 cm
  - 75 cm
- Straight insertion needle
- Long torque wrench (43 mm)

Prospera CHG

The storage packaging includes the following:

- Charger
- 2 charger belts of different lengths
- Wall adapter with USB connector and power plug adapters
- Prospera Spinal Cord Stimulation – Patient Guide for the Implanted System

Neuro M50

The storage package includes the following:

- Magnet

Unpacking

⚠ Attention

Functional Impairment due to External Damage

Mechanical impact, for example, dropping a component on hard su faces – unpackaged already from a dropping height of just 5 cm – can permanently impair the function.

- Do not use the component.
- Return the component to BIOTRONIK.
- Exchange the dropped component against a new one.

terile Packaging

Please proceed as follows when unpacking the components from the sterile packaging.

Unpacking

1. Check whether the packaging is damaged.
   ▶ Do not use parts from damaged packaging.
   ▶ Have spares of sterile parts available.
2. Peel off the sealing paper of the outer blister in the direction indicated by the arrow.
   ▶ The inner blister must not come into contact with persons who have not sterilized their hands gloves, or with non-sterile instruments!
3. Hold the inner blister at the gripping tab and lift it out of the outer blister.
4. Peel the sealing paper off of the sterile inner blister at the marked position in the direction indicated by the arrow.

hecking Parts

1. Check that all parts are contained in the package contents.
2. Check whether parts are damaged.
   Exchange damaged parts.

Non-Sterile Packaging

Please proceed as follows when unpacking parts from non-sterile packaging.

Unpacking

1. Check whether the packaging is damaged.
   ▶ Do not use parts from damaged packaging.
2. Unpack all parts from the package contents.

hecking Parts

1. Check that all parts are contained in the package contents.
2. Check whether parts are damaged.
   Exchange damaged parts.

6 Implanting the Trial System

Preparing the Implantation

Instructions before the Implantation

1. Please follow the unpacking instructions and make sure that the sterility is ensured, see Unpacking [Page 27].
2. Check all needed components for damage and only use undamaged components.
3. Check the required components for, e.g., length and type and make sure that all required components match and are suited for the implantation and the patient.
4. Make sure that the intended location for the pouch that attaches the external stimulator to the patient is adequately prepared, for example by shaving.
5. Make sure that an already used external stimulator has been thoroughly cleaned and disinfected, ee Cleaning, Disinfecting, and Storing the External Stimulator [Page 36].
6. Make sure that new batteries are always used for each patient, see Replacing the Batteries of the External Stimulator before each Implantation [Page 28]. If the batteries are not sufficiently charged, the intraoperative testing of the leads cannot be perf med and delays in the implantation procedure will occur.
7. Pair the clinician programmer with the stimulator.
8. Make sure that no therapy program is programmed and active on the stimulator. For this, you can e the clinician programmer or the patient programmer.

Replacing the Batteries of the External Stimulator before each Implantation

⚠ Attention

Product Damage and Risk of Injuries due to Modification of External Stimulator

Any modification of the external stimulator might lead to a device malfunction and result in injuries.

- Do not modify the external stimulator.

Prerequisite

- Stimulation is turned off, and it is not connected to the lead .

1. Open the cover of the battery compartment.
2. Replace the batteries with the provided batteries, see External Stimulator [Page 51]. Ensure proper polarity alignment.
   ▶ If the batteries are inserted correctly, the LED lights up for 5 s and then turns off.
3. Close the cover of the battery compartment. Ensure the cover is secure and properly snapped into place.
4. Check the battery status with the patient programmer or the clinician programmer.

Inserting the Lead

⚠ aution

pinal Injury due to Puncturing with the Insertion Needle

Spinal injury may occur if excessive pressure is used when acce ing the epidural space. Furthermore, steep insertion angles may inhibit ability to subsequently insert the lead and/or may esult in undesired injury of spinal tissues.

- Dispense pressure in a suitable manner when inserting the inse tion needle into the epidural space.
- Carefully insert the insertion needle at a shallow insertion angle.
- As appropriate, consider the use of fluoroscopic visualization to aid in needle and lead insertion.

⚠ Attention

Prolongation of the Implantation Procedure due to Damage at an Already Existing Lead during Implantation of a Second Lead

Additional intervention or prolonged procedure may result if an inserted lead is damaged when inserting a second lead.

- Handle the introduction of a second lead into an area where a lead is already implanted with care and attentiveness.
- If inserting a second lead, do not remove needles until both leads are implanted. The first needle protects the lead from the second needle.

Improper or careless handling of the system may damage the system and permanently impair the function.

- Handle the Prospera SCS System with care.
- Follow the instructions in this technical manual.
- Exchange damaged components.

Note

If the lead is handled excessively, it can be damaged.

- Handle the lead carefully.
- Avoid excessive bending, stretching, kinking etc. of the lead.

1. Prepare the patient's skin at suitable sites.
2. Cover the patient while following the customary precautionary measures.
3. If preoperative antibiotic prophylaxis had been judged to be necessary, make sure that it has been performed.
4. Inject a local anesthetic at the suitable insertion site for the insertion needle.
5. Check that the stylet is inserted in the insertion needle.
6. Carefully insert the insertion needle under fluoroscopy monit ing into the posterior ligament complex of the suited section of the spine. Make sure that the insertion angle is not too steep.
7. Remove the stylet from the insertion needle.
8. Check the position of the insertion needle by fluoroscopy monitoring.
9. Check the entry into the epidural space with a standard method, e.g., loss of resistance or using the provided clearing wire.
   If you use the clearing wire provided, handle it carefully and push it carefully through the insertion needle to prevent injury to spinal tissues.
10. Select an appropriate length lead to accommodate patient anatomy and strain relief loops.
11. Make sure the suitable stylet has been completely inserted into the lead and is extended to the tip f the lead.
12. Make sure that the insertion needle is not occluded.
13. Slowly push the lead with the stylet through the insertion needle into the epidural space.
14. Use the stylet to steer the lead under fluoroscopy monitoring to the respective section of the spine.
15. Proceed in the same manner when inserting a second lead. Make sure to insert the second insertion needle in such a way that the first lead is not damaged. Do not remove the needle of the first lead until both leads are implanted. The first needle protects the lead from the second needle.

Performing Intraoperative Tests

⚠ Attention

False Measurement Results due to Temperature Differences

Temperature differences between the stimulator and body or room temperature can lead to false results when measuring the lead impedance. If a false measurement is su pected, proceed as follows:

- Acclimate the temperature of the stimulator to room or body temperature before starting the implantation and the programming session.
- Pay attention to the conditions for operating the stimulator, ee Implantable Stimulator [Page 49].
- Perform the lead impedance measurement again.

Once the lead position has been verified under fluoroscopy monitoring, perform an intraoperative test to check correct placement.

Throughout the intraoperative tests, be sure to handle the lead carefully.

1. If two leads were placed, mark them with a sterile surgical marker to be able to differentiate them.
2. Make sure during all handling steps that the position of the leads is not changed.
3. Slightly retract the stylet, ensuring that it remains in the lead but is not in the tip of the lead.
4. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
5. Make sure that the lead connection of the intraoperative test cable is only used in a sterile area, and the header for the external stimulator at the intraoperative te t cable only in a non-sterile area.
6. In the sterile area, open the cover of the lead connection of the intraoperative test cable.
7. Align the lead contacts with the contacts of the lead connection and press them carefully and gently into the lead connection.
8. If applicable, continue in the same manner with the second lead.
9. Close the lead connection cover of the intraoperative test cable.
10. Make sure that the stimulation is turned off and the external stimulator cap has been removed.
11. In the non-sterile area, plug the header of the intraoperative test cable into the external stimulator. While doing so, align the guide tabs of the header with the notches of the external stimulator.
12. Close the latch on the header to lock it to the external stimulator.
13. Turn on the external stimulator and use the clinician programmer to perform all necessary intraoperative tests to verify the lead position.
14. When you have performed all necessary intraoperative tests, turn off the external stimulator.
15. Unlock the header tab and detach it from the external stimulator.
16. Open the lead connection cover and carefully detach the lead from the intraoperative test cable. Make sure to lift, not pull, the leads off the connectors.

onnecting the Lead

⚠ Attention

Incorrect Measurement Results, and Insufficient Therapy May Occur due to Improper Connection of the Leads

If the leads are not properly connected at the header, the connection between the leads and the stimulator may be poor or even non-existent. This can lead to incorrect results of the impedance measurement. The stimulation therapy can then not be optimally configured and performed.
In additional, if the leads are not properly inserted at the header, the lead can damaged by the screw.

- Follow the instructions for connecting the leads to the header in this technical manual.
- Make sure that the lead connector is completely inserted into the connector port.
- Before tighten the screw of the connector port, perform an impedance test and check the measurement values for plausibility.
- If the impedances are out of range, check the connection of the leads.

Note

The external stimulator cannot be sterilized. To prevent infection, do not connect any leads to the external stimulator that will be fully implanted in the body. By connecting them to the external timulator, the leads of the trial system become non-sterile in the connection area and must be emoved before implanting the permanent system.

- Connect only trial leads that will not be fully implanted in the body to the external stimulator.

1. Hold on to the lead while removing the stylet and insertion needle carefully and with minimal force. If the stylet is stuck and cannot be pulled out, remove the lead. Insert a new lead and perform the necessary intraoperative tests as described above.
2. Apply a suitable sterile bandage at the site at which the lead exits the body.
3. Form a strain relief loop.
4. Fixate the part of the lead that exits the body with suitable adhesive tape to the patient's skin.
5. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
6. Open the cover of the header for the external stimulator.
7. Align the lead contacts with the contacts of the lead connection and press them carefully and gently into the lead connection.
8. If applicable, continue in the same manner with the second lead.
9. Close the header cover.
10. Make sure that the stimulation is turned off and the external stimulator cap has been removed.
11. Plug the header into the external stimulator. While doing so, align the guide tabs at the header along the notches at the external stimulator.
12. Close the latch on the header to lock it to the external stimulator.

Attaching the External Stimulator to the Patient

⚠ aution

Electrode Corrosion and Loss of Therapy due to an Improperly Sealed or Affixed Pouch

If the pouch is not affixed properly, water may enter the pouch, as a result the electrodes may corrode and the therapy may fail. Furthermore, an improperly attached pouch may move, which could lead to therapy failure.

- Orient and affix the pouch properly in a way that no liquids can enter the pouch.
- Make sure that the pouch is completely sealed around all edges and corners and also around the leads.
- If necessary, use additional adhesive strips to secure the pouch.

1. Thoroughly clean the skin in the planned area of the patient affixation pouch.
2. Put the external stimulator into a patient affixation pouch.
3. Remove the adhesive film on the closure of the patient affixation pouch.
4. Close the closure of the patient affixation pouch. Align the arrow markings on the pouch then press down. Ensure all edges and corners are properly sealed and there are no visible gaps.
5. Pull off the protective film at the backside of the patient affixation pouch to expose the adhesive face.
6. Firmly press the patient affixation pouch against the patient's skin. Take care that the leads are not nder tensile stress.
7. To additionally secure the patient affixation pouch, use bandaging material or medical adhesive tape as needed.

Programming the Stimulator

Use the clinician programmer to program the stimulator.

Pairing the Patient Programmer with the External Stimulator

Pairing the patient programmer with the stimulator is done by a trained user of the clinician programmer.

7 Replacing the Batteries of the External Stimulator during the Trial Phase

If the batteries become weak or die during the trial phase, you need to replace the batteries of the external stimulator. The battery status is shown on the clinician programmer and the patient programmer.

Removing the External Stimulator from the Patient

1. If the stimulation is turned on, turn it off with the clinician programmer or the patient programmer.
2. Carefully cut open the patient affixation pouch and remove the external stimulator. Take care not to damage the connected leads in the process.
3. Open the header latch.
4. Remove the header from the external stimulator and remove the timulator from the patient.
5. Carefully detach the patient affixation pouch from the patient's skin.
6. Thoroughly clean the skin in the planned area of the patient affixation pouch.
7. Dispose of all used components that are not intended for reuse in an environmentally sound manner and according to the applicable country-specific directives.

Replacing the Batteries of the External Stimulator

Prerequisite

- The stimulation is turned off.
- The leads are not connected to the external stimulator.
- The external stimulator is not attached to the patient.

1. Connect the external stimulator to the clinician programmer and use the clinician programmer to prepare the battery swap for the external stimulator.
2. Wait 30 s and then open the cover of the battery compartment.
3. Replace the batteries. Pay attention to the correct polarity f the batteries.
   ► If the batteries are inserted correctly, the LED lights up for 10 s and then turns off.
4. Close the cover of the battery compartment.
5. On the patient programmer select **[Connect]**. Ensure the external stimulator is still connected to the patient programmer.
   Note that it takes a while for the external stimulator to connect to the patient programmer after battery replacement.

Attaching the Header at the External Stimulator

Prerequisite

- The stimulation is turned off.

1. Plug the header into the external stimulator. While doing so, align the guide tabs at the header along the notches at the external stimulator.
2. Close the latch on the header to lock it to the external stim lator.

Testing the Stimulation

Prerequisite

- The leads are connected at the header of the external stimulat .
- The external stimulator is connected to the patient programmer the clinician programmer.

1. Turn on the stimulation with the clinician programmer or the patient programmer.
2. Select a suitable stimulation program.
3. With the assistance of the patient, check whether the stimulation is appropriate.

Attaching the External Stimulator to the Patient

⚠ aution

Electrode Corrosion and Loss of Therapy due to an Improperly Sealed or Affixed Pouch

If the pouch is not affixed properly, water may enter the pouch, as a result the electrodes may corrode and the therapy may fail. Furthermore, an improperly attached pouch may move, which could lead to therapy failure.

- Orient and affix the pouch properly in a way that no liquids can enter the pouch.
- Make sure that the pouch is completely sealed around all edges and corners and also around the leads.
- If necessary, use additional adhesive strips to secure the pouch.

1. Thoroughly clean the skin in the planned area of the patient affixation pouch.
2. Put the external stimulator into a patient affixation pouch.
3. Remove the adhesive film on the closure of the patient affixation pouch.
4. Close the closure of the patient affixation pouch. Align the arrow markings on the pouch then press down. Ensure all edges and corners are properly sealed and there are no visible gaps.
5. Pull off the protective film at the backside of the patient affixation pouch to expose the adhesive surface.
6. Firmly press the patient affixation pouch against the patient's skin. Take care that the leads are not nder tensile stress.
7. To additionally secure the patient affixation pouch, use bandaging material or medical adhesive tape as needed.

8 Removing the Trial System

Removing the External Stimulator from the Patient

1. If the stimulation is turned on, turn it off with the clinician programmer or the patient programmer.
2. Carefully cut open the patient affixation pouch and remove the external stimulator. Take care not to damage the connected leads in the process.
3. Open the header latch.
4. Remove the header from the external stimulator and remove the timulator from the patient.
5. Carefully detach the patient affixation pouch from the patient's skin.
6. Thoroughly clean the skin in the area of the patient affixati n pouch.
7. Thoroughly clean and disinfect the external stimulator, see Cleaning, Disinfecting, and Storing the External Stimulator [Page 36].
8. Use the clinician programmer to reset the external stimulator and delete all patient data to be able to use it for the next patient.
9. Store the external stimulator for the next patient, see Cleaning, Disinfecting, and Storing the External Stimulator [Page 36].
10. Dispose of all used components that are not intended for reu e in an environmentally sound manner and according to the applicable country-specific directives.

Removing the Trial Leads

1. Remove the sterile bandage at the site at which the lead exit the body.
2. Carefully pull the lead out of the patient.
3. Proceed in the same manner when removing a second lead.
4. If no further implantation steps are planned, close all wound and provide them with bandage material in the usual surgical manner.
5. Dispose of all used components in an environmentally sound manner and according to the applicable country-specific directives.

ollecting the Patient Programmer at the End of the Trial Phase

To prepare the patient programmer for the next use, do the foll wing at the end of the trial phase:

- Ensure the external stimulator has been reset via the clinician programmer. This will clear all patient information from the external stimulator.
- Reset the patient programmer so it is no longer paired with the external stimualtor.

eaning, Disinfecting, and Storing the External Stimulator

⚠ aution

Risk of Infection or Damage to Stimulator when an External Stimulator Has Not Been Disinfected orrectly

The improper cleaning and disinfecting of an external stimulato may lead to device malfuntion and patient injury.

- Let the external stimulator be cleaned and disinfected by a BIOTRONIK representative after e by each patient.

⚠ Attention

Damage to the System due to Noncompliance with the Conditions for Transport and Storage

If the conditions for transport and storage stated in this technical manual are not met, the system may be damaged. The system function may be permanently compromi ed by this.

- Please follow the conditions for transport and storage listed in this technical manual.
- Do not use system components that were not transported or stored correctly.

The external stimulator is intended for reuse. After you have removed the trial system, you must thoroughly clean the external stimulator, disinfect it sufficiently, and store it for the next patient.

Note

Avoid bringing the external stimulator into direct contact with water or solvents.

Prerequisites for Cleaning, Disinfection, and Storage

- The external stimulator is not attached to the patient, is not connected to the leads, and the timulation is turned off.

eaning the External Stimulator

Use the following products for cleaning the external stimulator:

- A clean, soft lint-free cloth
- A mild soap solution

1. Place cap over the connector pins.
2. Clean the external stimulator with a damp cloth and mild soap lution.
3. Thoroughly dry the external stimulator.
4. Check the external stimulator for dirt or visible damage afte the cleaning.

Disinfecting the External Stimulator

Use the following products for disinfecting the external stimulator:

- A quaternary ammonium agent (e.g. PDI Sani-cloth)

1. Place cap over connector pins.
2. Disinfect the external stimulator per disinfecting wipe manufacturer's instructions.
3. Allow the external stimulator to dry thoroughly, until all the residues of the disinfectant have completely evaporated.
4. Check the external stimulator for visible damage after the di infection.

toring the External Stimulator

⚠ aution

Risk of Infection or Damage to Stimulator when an External Stimulator Has Not Been Disinfected orrectly

The improper cleaning and disinfecting of an external stimulato may lead to device malfuntion and patient injury.

- Let the external stimulator be cleaned and disinfected by a BIOTRONIK representative after e by each patient.

When the external stimulator has been cleaned and disinfected p perly and shows no damage, store the external stimulator for the next patient.

1. Carefully put the external stimulator cap on the contact surface of the external stimulator to protect it. Take care not to damage the contact surfaces in the process.
2. Use the clinician programmer to connect the external stimulat to the clinician programmer and eset the external stimulator to delete its settings.
3. Store the external stimulator at a suitable and protected location. Pay attention to the storage temperatures, see External Stimulator [Page 51].

9 Implanting the Permanent System

Preparing the Implantation

Instructions before the Implantation

1. Please follow the unpacking instructions and make sure that the sterility is ensured, see Unpacking [Page 27].
2. Check all needed components for damage and only use undamaged components.
3. Check the required components for, e.g., length and type and make sure that all required components match and are suited for the implantation and the patient.
4. Acclimate the temperature of the stimulator to room temperatu e in the blister or package. The stimulator will not charge if the temperature is lower than +64.4 °F (+18 °C). Avoid charging in cold environments such as operating rooms.
5. Check the charging status of the stimulator and make sure it is sufficient for complete planned communication and testing. If necessary, charge the stimulator. For this, proceed as described in Prospera Spinal Cord Stimulation – Patient Guide for the Implanted System.
6. Pair the clinician programmer with the stimulator.
7. Make sure that no therapy program is programmed and active on the stimulator. For this, you can e the clinician programmer or the patient programmer.

Inserting the Lead

⚠ aution

pinal Injury due to Puncturing with the Insertion Needle

Spinal injury may occur if excessive pressure is used when acce ing the epidural space. Furthermore, steep insertion angles may inhibit ability to subsequently insert the lead and/or may esult in undesired injury of spinal tissues.

- Dispense pressure in a suitable manner when inserting the inse tion needle into the epidural pace.
- Carefully insert the insertion needle at a shallow insertion angle.
- As appropriate, consider the use of fluoroscopic visualization to aid in needle and lead insertion.

⚠ Attention

Prolongation of the Implantation Procedure due to Damage at an Already Existing Lead during Implantation of a Second Lead

Additional intervention or prolonged procedure may result if an inserted lead is damaged when inserting a second lead.

- Handle the introduction of a second lead into an area where a lead is already implanted with care and attentiveness.
- If inserting a second lead, do not remove needles until both leads are implanted. The first needle protects the lead from the second needle.

Improper or careless handling of the system may damage the system and permanently impair the function.

- Handle the Prospera SCS System with care.
- Follow the instructions in this technical manual.
- Exchange damaged components.

Note

If the lead is handled excessively, it can be damaged.

- Handle the lead carefully.
- Avoid excessive bending, stretching, kinking etc. of the lead.

1. Prepare the patient's skin at suitable sites.
2. Cover the patient while following the customary precautionary measures.
3. If preoperative antibiotic prophylaxis had been judged to be necessary, make sure that it has been performed.
4. Inject a local anesthetic at the suitable insertion site for the insertion needle.
5. Check that the stylet is inserted in the insertion needle.
6. Carefully insert the insertion needle under fluoroscopy monit ing into the posterior ligament complex of the suited section of the spine. Make sure that the insertion angle is not too steep.
7. Remove the stylet from the insertion needle.
8. Check the position of the insertion needle by fluoroscopy monitoring.
9. Check the entry into the epidural space with a standard method, e.g., loss of resistance or using the provided clearing wire.
   If you use the clearing wire provided, handle it carefully and push it carefully through the insertion needle to prevent injury to spinal tissues.
10. Select an appropriate length lead to accommodate patient anatomy and strain relief loops.
11. Make sure the suitable stylet has been completely inserted into the lead and is extended to the tip f the lead.
12. Make sure that the insertion needle is not occluded.
13. Slowly push the lead with the stylet through the insertion needle into the epidural space.
14. Use the stylet to steer the lead under fluoroscopy monitoring to the respective section of the spine.
15. Proceed in the same manner when inserting a second lead. Make sure to insert the second insertion needle in such a way that the first lead is not damaged. Do not remove the needle of the first lead until both leads are implanted. The first needle protects the lead from the second needle.

Performing Intraoperative Tests

⚠ Attention

False Measurement Results due to Temperature Differences

Temperature differences between the stimulator and body or room temperature can lead to false results when measuring the lead impedance. If a false measurement is suspected, proceed as follows:

- Acclimate the temperature of the stimulator to room or body temperature before starting the implantation and the programming session.
- Pay attention to the conditions for operating the stimulator, ee Implantable Stimulator [Page 49].
- Perform the lead impedance measurement again.

Once the lead position has been verified under fluoroscopy monitoring, perform an intraoperative test to check correct placement.

Throughout the intraoperative tests, be sure to handle the lead carefully.

1. If two leads were placed, mark them with a sterile surgical marker to be able to differentiate them.
2. Make sure during all handling steps that the position of the leads is not changed.
3. Slightly retract the stylet, ensuring that it remains in the lead but is not in the tip of the lead.
4. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
5. Make sure that the lead connection of the intraoperative test cable is only used in a sterile area, and the header for the external stimulator at the intraoperative te t cable only in a non-sterile area.
6. In the sterile area, open the cover of the lead connection of the intraoperative test cable.
7. Align the lead contacts with the contacts of the lead connection and press them carefully and gently into the lead connection.
8. If applicable, continue in the same manner with the second lead.
9. Close the lead connection cover of the intraoperative test cable.
10. Make sure that the stimulation is turned off and the external stimulator cap has been removed.
11. In the non-sterile area, plug the header of the intraoperative test cable into the external stimulator. While doing so, align the guide tabs of the header with the notches of the external stimulator.
12. Close the latch on the header to lock it to the external stimulator.
13. Turn on the external stimulator and use the clinician programmer to perform all necessary intraoperative tests to verify the lead position.
14. When you have performed all necessary intraoperative tests, turn off the external stimulator.
15. Unlock the header tab and detach it from the external stimulator.
16. Open the lead connection cover and carefully detach the lead from the intraoperative test cable. Make sure to lift, not pull, the leads off the connectors.

Anchoring the Lead

⚠ aution

Product Damage and Risk of Injuries due to Modification of the Medical Device

Unauthorized modification to the medical device is prohibited. System integrity could be compromised and patient harm or injury may occur if the medical devices are modified without authorization.

- Do not modify the medical device.

⚠ Attention

Insufficient or Missing Therapy due to Improper Fixation of the Implanted Leads

If the anchors supplied as part of the shipment are not used du ing the implantation of the leads, the fixation of the leads at the supraspinous ligament might not be stable and the leads may shift from their intended position. Furthermore lead damage can occur from needle puncture or excessively tight sutures. In addition, an inappropriate angle f the anchor can cause lead conductor breakage. All this can lead to insufficient therapy o to a complete loss of therapy.

- Use only the anchor supplied as part of the shipment to fixate the leads safely and stably at the praspinous ligament.
- If you use the active anchor, tighten the anchor set screw with the supplied torque wrench only to ensure lead is properly anchored.
- Handle the needle to attach the anchor to the lead with care and attentiveness.
- Anchor lead in neutral angle, do not excessively twist, tug, o bend lead when anchoring to educe risk lead conductor breakage.

1. Make an incision around the insertion needle.
2. Gain access to the supraspinous ligament by sharp and blunt dissection.
3. Hold on to the lead while removing the stylet and insertion needle carefully and with minimal force. If the stylet is stuck and cannot be pulled out, remove the lead. Insert a new lead and perform the necessary intraoperative tests as described above.
4. Check the correct position of the lead by fluoroscopy monitoring and make sure the lead has not hifted when the insertion needle and the stylet were pulled ou t.
5. Continue as described below, depending on the chosen anchor.

uture Anchor

1. Slide the anchor over the lead to the supraspinous ligament.
2. Secure the anchor to the lead with at least two suture loops. To prevent slippage and lead migration, use the ligature grooves to place two suture loops and tie the thread around the anchor, ecuring it to the lead body.
   Use non-resorbable suture material.
3. Use the eyelets or grooves of the anchor to suture the anchor to the supraspinous ligament or deep connective tissue.
   Use non-resorbable suture material.
4. Ensure that the suture seam is sufficiently tight.

Active Anchor

1. Slide the anchor over the lead to the supraspinous ligament.
2. Attach the anchor to the supraspinous ligament or deep in the connective tissue.
   Use non-resorbable suture material.
   Use the eyelets or grooves in the anchor to tie the suture to the anchor.
3. Ensure that the suture seam is sufficiently tight.
4. Tighten the set screw with the supplied torque wrench to attach the active anchor at the lead.
   To this end, turn the supplied torque wrench clockwise until yo hear a click.

haping the Pocket for the Stimulator and Tunnel the Lead

⚠ aution

kin Injury if Tunneling Is too Shallow

If the tunneling of the implanted leads is too shallow, skin er ion and exposure of the implanted leads may occur.

- Please tunnel the leads deep enough to prevent skin erosion and exposure of the implanted leads.
- If very long tunneling is required, it is recommended to lead the lead out of the skin and create a second tunnel.

⚠ aution

Skin Erosion, Overheating, or Charging Difficulties due to an Improper Pocket Depth and Location

An improperly placed device pocket may lead to skin erosions if placed too close to the surface. It may lead to charging difficulties or to excessive heat devel pment during the charging of the timulator, if placed too deep.

- Please follow the instructions for the creation of a device pocket.
- If necessary, use the pocket template to shape the device pocket properly.
- Implant the stimulator no more than 2 cm (0.78 inch) below the kin surface with the labeled ide facing the skin, so that the charging coil is close to the patient surface.
- Lay sutures through the eyelets at the stimulator header to prevent the stimulator from inverting or migrating.

⚠ Attention

Prolongation of the Implantation Procedure due to Damage at an Already Existing Lead during Implantation of a Second Lead

Additional intervention or prolonged procedure may result if an inserted lead is damaged when inserting a second lead.

- Handle the introduction of a second lead into an area where a lead is already implanted with care and attentiveness.
- If inserting a second lead, do not remove needles until both leads are implanted. The first needle protects the lead from the second needle.

1. Prepare the patient's skin at suitable sites.
2. Cover the patient while following the customary sterile preca tionary measures.
3. Identify a suitable implantation site. Take into account infection control and patient comfort. If the placement is too close to the surface, skin erosions may result, and if the placement is deeper than 2 cm (0.78 inch), excessive heat development may occur during the charging of the stimulator.
4. Anesthetize the implantation site for the pocket of the stimulator.
5. Mark the implantation site and make a sufficiently large inci ion that allows the insertion of the stimulator. Use the pocket template of the stimulator to correctly choose the size and position of the incision.
6. Form a subcutaneous pocket for the stimulator by blunt dissection. Keep in mind that the pocket may not be deeper than 2 cm (0.78 inch) below the skin and not be larger than the stimulator, to allow optimal charging of the stimulator.
7. Select a suitable tunneling tool tip.
8. Remove the protective cap and screw the tip onto the shaft of the tunneling tool.
9. Mark a suitable tunneling path.
10. Inject a local anesthetic along the tunneling path.
11. By careful bending, adjust the shaft of the tunneling tool t the patient's anatomy if necessary.
12. Tunnel a suitable tunnel between the pocket for the stimulat and the site of the lead anchor with the tunneling tool. Tunnel deep enough to prevent skin erosion and exposure of the implanted leads. Make sure to insert the tunneling tool far enough that the beginning of the tunneling sheath exits.
13. Have a sufficiently strong hold on the shaft and the tunneling tool tip.
14. Unscrew the tunneling tool tip and remove it. Make sure not to drop the tip.
15. Hold on to the tunneling sheath and carefully pull out the shaft of the tunneling tool. Make sure that the tunneling sheath does not change its position in the p cess.
16. Hold on to the tunneling sheath and insert the proximal end f the lead through the tunneling heath to the implantation site of the stimulator.
17. Carefully pull the desired length of lead out of the tunneling sheath for both leads. Take stress elief loop into account when determining the amount of lead to pull.
18. Hold on to the leads at the site of the anchor and carefully pull out the tunneling sheath. Make sure that the leads don't change position in the process.

Implanting the Stimulator and Connecting the Lead

⚠ **WARNING**

Therapy Failure and Harm to the Patient due to Electrocautery

Electrocautery may lead to damage and function loss of the system and to therapy failure. In addition, tissue damage and serious patient injuries may occur in the area of the implanted timulator or the leads.

- Avoid electrocautery if possible. If electrocautery is necessa y, pay attention to the following:
- Turn the stimulation off temporarily.
- Use bipolar electrocautery.
- Do not apply unipolar electrocautery.
- Note that damage might not be obvious and may lead to a malfunction of the system.
- Perform a complete system follow-up after finishing the electr cautery.

⚠ **aution**

Injury due to Heat Development during Charging when Using Metal c Clamps

When charging the implanted stimulator, surgical staples made of metal that are situated in the vicinity of the implanted stimulator may heat up and damage the patient's tissue in this area.

- Do not use surgical staples made of metal in the vicinity of the implanted stimulator.

⚠ **Attention**

Incorrect Measurement Results, and Insufficient Therapy May Occur due to Improper Connection of the Leads

If the leads are not properly connected at the header, the connection between the leads and the stimulator may be poor or even non-existent. This can lead to incorrect results of the impedance measurement. The stimulation therapy can then not be optimally configured and performed. In additional, if the leads are not properly inserted at the heade , the lead can damaged by the screw.

- Follow the instructions for connecting the leads to the header in this technical manual.
- Make sure that the lead connector is completely inserted into the connector port.
- Before tighten the screw of the connector port, perform an impedance test and check the measurement values for plausibility.
- If the impedances are out of range, check the connection of the leads.

1. Make sure that no hemostasis is required.
2. Avoid electrocautery if possible. If electrocautery is necessary, temporarily turn off the stimulation and apply only bipolar electrocautery.
3. If two leads were placed, mark them with a sterile surgical marker to be able to differentiate them.
4. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
5. Carefully connect the lead to the respective connector port of the stimulator. Make sure that the lead connector is completely inserted into the connector port.
   If the lead connector cannot be completely inserted, check whether the set screw at the stimulator is not blocking access to the port. To this end, use the supplied torque wrench to loosen the screw by turning the screw counterclockwise.
6. If applicable, connect the second lead to the respective connector port of the stimulator in the ame manner.
7. Make sure that the information of which lead is connected to which connector port will be available at a later time.
8. If only one lead was placed and connected, close the unused c nnector port of the stimulator with a port plug. Make sure that the port plug is completely inserted into the connector port.
9. Perform all necessary intraoperative tests, see Performing Intraoperative Tests [Page 40].
10. If the intraoperative tests were successful, use the supplied torque wrench to tighten the screw for the leads or the port plug of the respective connector port to the appropriate torque by turning clockwise until it clicks.
11. Wrap excessive parts of the lead behind the implanted stimulator in loosely coiled loops.
12. Place the stimulator in the subcutaneous pocket and align the stimulator with the labeled side facing the skin during the implantation.
13. Lay sutures through the eyelets at the stimulator and use non-resorbable suture material to ecure the stimulator to the pocket.
14. Check the communication between the stimulator and the patient programmer.
15. Close all wounds and provide them with bandage material in the usual surgical manner. Do not use surgical staples made of metal for this because they heat up when the implanted stimulator is charged and may damage the patient's tissue in this area.

Programming the Stimulator

Use the clinician programmer to program the stimulator.

Pairing the Patient Programmer with the Stimulator

Pairing the patient programmer with the stimulator is done by a trained user of the clinician programmer.

10 Exchanging or Explanting the Permanent System

Exchanging the Stimulator

1. Connect the stimulator to the clinician programmer and deactivate all programs. Check that the timulator is not delivering stimulation.
2. Surgically open the pocket of the stimulator. Make sure not t damage the leads in the process.
3. Avoid electrocautery, if possible, before the stimulator has been removed from the patient, and the leads from the stimulator. If electrocautery is necessary, temp arily turn off the stimulation and apply only bipolar electrocautery.
4. Take out the stimulator. Make sure that the position of the lead does not change in the process.
5. If two leads were placed, mark them with a sterile surgical marker to be able to differentiate them.
6. Use the supplied torque wrench to loosen the set screws securing the leads by turning counterclockwise. Make sure that the set screw is not removed in the process.
7. Carefully remove the lead from the stimulator. Make sure that the position of the lead does not change in the process.
8. If a second lead had been implanted, proceed in the same manner and remove it from the timulator.
9. Dispose of the explanted stimulator and all used components in an environmentally sound manner and according to the applicable country-specific directives.
10. Wipe off fluids and debris (e.g., blood) from the lead connector at the proximal end of the lead.
11. Carefully connect the lead to the respective connector port f the stimulator. Make sure that the lead connector is completely inserted into the connector port.
    If the lead connector cannot be completely inserted, check whether the set screw at the stimulator is not blocking access to the port. To this end, use the supplied torque wrench to loosen the screw by turning the screw counterclockwise.
12. If applicable, connect the second lead to the respective connector port of the stimulator in the ame manner.
13. Make sure that the information of which lead is connected to which connector port will be available at a later time.
14. If only one lead was placed and connected, close the unused connector port of the stimulator with a port plug. Make sure that the port plug is completely inserted into the connector port.
15. Perform all necessary intraoperative tests, see Performing Intraoperative Tests [Page 40].
16. If the intraoperative tests were successful, use the supplied torque wrench to tighten the screw for the leads or the port plug of the respective connector port to the appropriate torque by turning clockwise until it clicks.
17. Wrap excessive parts of the lead behind the implanted stimulator in loosely coiled loops.
18. Place the stimulator in the subcutaneous pocket and align the stimulator with the labeled side facing the skin during the implantation.
19. Lay sutures through the eyelets at the stimulator and use non-resorbable suture material to ecure the stimulator to the pocket.
20. Check the communication between the stimulator and the patient programmer.
21. Close all wounds and provide them with bandage material in the usual surgical manner. Do not use surgical staples made of metal for this because they heat up when the implanted stimulator is charged and may damage the patient's tissue in this area.

Explanting the Permanent System

1. Connect the stimulator to the clinician programmer and deactivate all programs. Check that the timulator is not delivering stimulation.
2. Surgically remove the implanted stimulator and the leads.

11 Patient Education

Patient Implant Card

The system is provided with a patient ID card.

1. Fill in the patient ID card.
2. Hand over the patient ID card to the patient after the implantation.

Risky Therapeutic and Diagnostic Procedures

The therapeutic and diagnostic procedures listed in the Safety ection must not be used at all or only under the listed conditions. See Risky Therapeutic and Diagnostic Procedures [Page 9].

Make your patient aware of this.

12 Disposal

⚠ aution

Risk of Infection if an Explanted Stimulator Is Not Properly Disposed of

An explanted stimulator must not be reused due to the risk of infection, and it must be properly disposed of.

- Dispose of the explanted stimulator as medical waste in an environmentally sound and proper manner.
- Do not cremate the stimulator. Explant the stimulator to cremation of a deceased patient.
- Return the explanted stimulator to BIOTRONIK for an environmentally sound disposal.

Dispose of the packaging in an environmentally sound manner in accordance with to the applicable country-specific regulations.

Dispose of implantation accessories and implantation tools and explanted leads as medical waste in an environmentally sound manner.

The batteries of the external stimulator must not enter the environment uncontrolled. They must be disposed of in an environmentally sound manner according to the applicable country-specific egulations; we recommend a suitable recycling method. Do not b eak or damage the batteries before disposal.

If the external stimulator is no longer used and can't be reused, return it to BIOTRONIK.

If the patient has returned the charger or the patient programmer or its associated wall adapter and if the item can't be reused, dispose of it as electronic waste in accordance with the applicable country-pecific regulations, or else return it to BIOTRONIK. Dispose o f the charger belt in the general trash.

BIOTRONIK ensures disposal in accordance with the national versions of the European guideline 2012/19/EU on waste electrical and electronic equipment (WEEE 2).

13 Appendix

Technical Data

Implantable Stimulator

General and Physical Characteristics

ategory	Design
Dimensions (W x D x H)	59 mm x 11 mm x 44 mm
Radiopaque ID code	
Polarity	Multi-Cathode with Multi-Anode Return (Traditional Therapy) Interleaved Pulses
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide

Material in Contact with Human Tissue

omponent	Material
Housing	Titanium
Header	Epoxy
Strain relief	Silicone
Silicone plugs	Silicone

ervice Time

ategory	Design
Service time	9 years

The service time has been calculated as follows:

- 3.0 mA, single electrode pair, 40 Hz, passive balance, 200 µs pulse width, 750 Ω lead impedance, on 100% of the time, 14-day charge interval, no over discharge
- 6.5 mA, single electrode pair, 70 Hz, passive balance, 230 µs pulse width, 750 Ω lead impedance, on 100% of the time, 7-day charge interval, no over discharge
- 1.7 mA, 3 electrodes delivering interleaved pulses at a frequency of 600 Hz each, active balance, 300 µs pulse width, 750 Ω lead impedance, on 100% of the time, 24 hr charge interval, no over discharge

Environmental Conditions

ategory	Design
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)
Atmospheric pressure	700 hPa ... 1060 hPa
Operation at altitudes	Up to 3000 m (9843 ft)
Relative humidity	15% ... 90%, non-condensing

Functional Parameters and Limit Values

ategory	Value
Electrode configuration (traditional therapy)	Maximum 4 cathodes, 4 anodes electrodes
Electrode configuration (interleaved pulses)	Maximum of 4 electrodes
Number of programs	Up to 12 programs (additionally, up to 4 sub-programs for traditional therapy)
Amplitude range	0.1 mA ... 20.0 mA
Pulse width range	30 µs ... 1000 µs
Frequency (rate) range	2 Hz ... 1400 Hz
Frequency (rate) range Traditional therapy	2 Hz ... 1400 Hz
Frequency (rate) range Interleaved pulses therapy	2 Hz ... 1400 Hz
Soft Start/Stop duration	2 s ramp up, starting at 50% of final amplitude
Cycling	Continuous

RF Parameters for Communication with the Patient Programmer and the Clinician Programmer

ategory	Design
Frequency band	2.4 GHz ISM band
Operating frequency	2400 MHz ... 2483.5 MHz
Operating range	0 - 2 m
Number of channels	40
Bandwidth	2 MHz / channel
Max. transmission power (EIRP)	Class 1: 8 dBm (6.3 mW)
Modulation	GFSK
Robustness	Frequency Hopping

RF Parameters for Communication with the BIOwand

ategory	Design
Operating frequency	32 kHz ... 64 kHz
Operating distance	< 10 cm
Bandwidth	17 kHz
Modulation	OOK

External Stimulator

General Characteristics

ategory	Design
Dimensions (W x D x H)	77 mm x 86 mm x 20 mm
Battery life	7 days (with 3 disposable LiFeS2 AAA batteries)
Polarity	Multi-Cathode with Multi-Anode Return (Traditional Therapy) Interleaved Pulses
Sterilization	Non-sterile

ervice Life

ategory	Design
Service life of the external stimulator	2 years
Service life of the affixation pouch	7 days

Material in Contact with Human Tissue

ategory	Design
Housing	Polycarbonate ABS blend
Affixation pouch	Tyvek and 3M 4075 adhesive

Environmental Conditions

ategory	Operation	Transport and Storage
Temperature	+59 °F ... +99 °F (+15 °C ... +37 °C)	+14 °F ... +113 °F (-10 °C ... +45 °C)
Atmospheric pressure	700 hPa ... 1060 hPa	
Relative humidity	15% ... 90%, non-condensing	
Operation at altitudes	Up to 3000 m (9843 ft)	

Functional Parameters and Limit Values

ategory	Value
Electrode configuration (traditional therapy)	Maximum 4 cathodes, 4 anodes electrodes
Electrode configuration (interleaved pulses)	Maximum of 4 electrodes
Number of programs	Up to 12 programs (additionally, up to 4 sub-programs for traditional therapy)
Amplitude range	0.1 mA ... 20.0 mA
Pulse width range	30 µs ... 1000 µs
Frequency (rate) range	2 Hz ... 1400 Hz
Frequency (rate) range Traditional therapy	2 Hz ... 1400 Hz
Frequency (rate) range Interleaved pulses therapy	2 Hz ... 1400 Hz
Soft Start/Stop duration	2 s ramp up, starting at 50% of final amplitude
Cycling	Continuous

RF Parameters for Communication with the Patient Programmer and the Clinician Programmer

ategory	Design
Frequency band	2.4 GHz ISM band
Operating frequency	2400 MHz ... 2483.5 MHz
Operating range	0 - 2 m
Number of channels	40
Bandwidth	2 MHz / channel
Max. transmission power (EIRP)	Class 1: 8 dBm (6.3 mW)
Modulation	GFSK
Robustness	Frequency Hopping

RF Parameters for Communication with the BIOwand

ategory	Design
Operating frequency	32 kHz ... 64 kHz
Operating distance	< 10 cm
Bandwidth	17 kHz
Modulation	OOK

Lead

General and Physical Characteristics

ategory	Design
Overall diameter	1.33 mm
Polarity	8 electrodes
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Lead Length

Model	Length
Resilience 55	55 cm
Resilience 55TR	55 cm
Resilience 75	75 cm
Resilience 75TR	75 cm

Lead Connector

omponent	Material
Connector ring	MP35N
Insulation	Polyurethane
Anchor ring	MP35N

onductor

ategory	Design
Construction	Multi-stranded cable with insulative coating
Conductor material	MP35N jacket with silver core
Coating material	Fluoropolymer
Resistance	Max. 20 Ω

Lead Body

ategory	Design
Insulation	Polyurethane
Diameter	1.33 mm

Lead Tip

ategory	Design
Material	Polyurethane
Metal stopper material	MP35N
Length beyond first electrode	2.5 mm

Electrode Ring

ategory	Design
Material	Platinum/iridium alloy (90% / 10%)
Surface area	12.5 mm^2
Ring width	3 mm
Electrode spacing	4 mm
Insulation material between electrodes	Polyurethane

ervice Time

ategory	Design
Service time	10 years

The service time can be influenced by several factors which are not attributable to the lead design such as but not limited to:

- Abnormal or special anatomy
- Implantation approach
- Experience of the implanting physician
- Excessive degree of physical activity
- Device location
- Number of implanted leads
- Lead fixation (active, passive)
- Location of the lead fixation
- Path of leads
- Lead slack
- Number of windings in the device pocket

Active Anchor

General and Physical Characteristics

ategory	Design
Overall length	37.2 mm
Overall diameter	4.4 mm
Height	5 mm
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Material

omponent	Material
Body	Silicone
	TiO_2
Screw block	Titanium
Screw	Titanium
Mesh	Nitinol

uture Anchor

General and Physical Characteristics

ategory	Design
Overall length	30 mm
Overall diameter	4 mm
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Material in Contact with Human Tissue

omponent	Material
Body	Silicone
	TiO_2

Port Plug

General and Physical Characteristics

ategory	Design
Overall length	16.6 mm
Overall diameter	5.7 mm
Pin length	12.2 mm
Shelf life	See use-by date on the device label
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Material

omponent	Material
Handle	Silicone
Pin	Titanium

Magnet

Dimensions

ategory	Design
Dimensions (W x D x H)	61 mm x 17 mm x 28.2 mm (2.4'' x 0.67'' x 1.1'')
Weight	0.192 kg (0.42 lbs)
Magnetic flux density minimum at a distance of 20 mm longitudinal	≥ 12.5 mT
Sterilization	Non-sterile
Longevity	8 years

Ambient Conditions

ategory	Operation	torage and Shipping
Temperature	+23 °F ... +104 °F (-5 °C ... +40 °C)	-4 °F ... +140 °F (-20 °C ... +60 °C)
Relative humidity	20% ... 75%, non-condensing	
Atmospheric pressure	700 hPa ... 1060 hPa	

Data Security

Please note the following information on data security for the timulator:

- Wireless communication between the clinician programmer, the stimulator, the patient programmer, and the BIOTRONIK server includes multiple levels of encryption to protect patient and clinician data.
- Only authorized BIOTRONIK devices, such as the clinician programmer and the patient programmer, are able to pair and communicate with the stimulato .
- Only attempt to pair the stimulator with authorized BIOTRONIK devices, such as the clinician programmer and the patient programmer.
- Use only wireless access points (WiFi) that are secure and req ire a password to join (at least WPA2 security standard).
- The stimulator is capable of inductive communication with the BIOwand which is connected to the clinician programmer.
- Patient information and stimulator data are protected by the close proximity which is required for inductive communication.
- Only allow authorized BIOTRONIK representatives to attempt to communicate with the stimulator ver the inductive link.
- Keep the external stimulator safe and protect it from unauthorized access. Only allow authorized personnel to touch or manipulate the external stimulator.
- If you have any questions or concerns regarding the security of the stimulator, contact your IT ecurity department or BIOTRONIK.

Note

Ensure the patient's consent to electronic processing of patient data to be compliant with the Health Insurance Portability and Accountability Act (HIPAA).

Quality of Service for Wireless Technology

2.4 GHz GFSK wireless technology is used for the communication between the stimulator and the clinician programmer or the patient programmer.

The quality of wireless communication will vary depending on the operating environment such as tdoors, home, operating room, or a recover room. The quality f service should be sufficient to transfer more than 8 kbps with latency depending on the type of transaction. Interrogation of 32 kB of data may take up to 20 s whereas 2 kB of data will require less than 5 s.

In the case of interference, the system will retry communication to ensure reliable data transfer resulting in longer durations for user transactions. In very high interference cases, you could lose the connection to the device.

To resolve communication issues, do the following:

1. Move the clinician programmer or the patient programmer close to the stimulator.
2. Ensure there is a direct line of sight between the clinician programmer or the patient programmer and the stimulator.
3. Turn off or move away from other devices that may be operating in the 2.4 GHz band. Such devices include wireless home networks, mobile phones, wireless consume devices, etc. For information n wireless security, see above, Data Security.

Near-field coil telemetry is used for communication between the timulator and BIOwand as a technical support tool used only by trained personnel. The quality of service will depend on the perating environment and how close the wand is in proximity to the stimulator.

The quality of service should be 90% with regard to successful interrogation and download of software to the stimulator. In the case of interference, ensure a minimum distance of 30 cm from potential interference sources and ensure the stimulator and BIOwand are in close proximity. For information on wireless security, see above, Data Security.

Open Source and Commercial Software

A list of hardware and software components used is available up n request.

Order Numbers

omponent	Order Number
Prospera IPG	457849
Resilience 55TR	457850
Resilience 75TR	457851
Resilience 55	457852
Resilience 75	457853
SCS PP	457854
Tunneler	457855
SCS NDL L	457857
SCS Anchor	457858
SCS Resilience Acc	457860
Prospera Trial Acc	457865
HomeStreamCP	459231
MyHomeStream	459232
MyHomeStream TR	459233
Prospera EPG	457861
Prospera CHG	457862
Neuro M50	457863
Prospera IOC	457866

Disclaimer, Warranty, and Warranty Conditions

For warranty questions or a copy of the warranty, contact BIOTRONIK.

Electromagnetic Compatibility

The external stimulator is suitable for use in all home care and professional healthcare establishments, including those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. The external stimulator maintains safe levels of stimulation in the presence of electromagnetic interference. The devices are intended for use in the electromagnetic environment specified in the following tables. The user should ensure that they are ed in such an environment.

The following tests were performed according to IEC 60601-1-2: 2014:

ection	Test	Test Level
7.1	CISPR 11 RF Radiated emission	• Group 1 • Class B
8.9 / 8.10	IEC 61000-4-2 Electrostatic discharge (ESD)	• ± 8 kV contact discharge • ± 2/4/8/15 kV air discharge
	IEC 61000-4-3 Radiated RF EM fields	• Modulation 1 kHz • 10 V/m, 80 MHz ... 2.7 GHz • Limits for RF communication equipment per Table 9 in IEC 60601-1-2 (9 V/m ... 28 V/m)
8.9	IEC 61000-4-6 Conducted disturbances induced by RF fields	• 3 Vrms • 6 Vrms in ISM + Amateur Radio Bands • 150 kHz ... 80 MHz
	IEC 61000-4-8 Power frequency magnetic fields	• 30 A/m • 50/60 Hz

WARNING

Risk of Electromagnetic Interference through the Use of Portable RF Communication Equipment

If portable RF communication devices (including peripheral devices such as antenna cables and external antennae) are operated closer than 30 cm (12 inches) f m this device, this can result in a eduction in its performance. This applies even when using asso ciated cables.

- When operating portable RF communication devices (including pe ipheral devices such as antenna cables and external antennae), keep such devices at a distance of at least 30 cm (12 inches) from the external stimulator and the charger.

Attention

Risk of Electromagnetic Interference

The use of the external stimulator adjacent to or stacked with ther devices should be avoided, as this may lead to the external stimulator operating incorrectly.

- Where usage in such a manner is unavoidable, you should monito the external stimulator and the other device(s) being used with it in order to ensure that they are all working correctly.

⚠ Attention

Risk of Electromagnetic Interference through the Use of Unauthorized Accessories

The use of accessories, transducers or cables not listed by BIOTRONIK or of accessories other than those specified by BIOTRONIK, can produce elevated electromagnetic emissions or cause degradation in the device's resistance to electromagnetic interference. Such effects can lead to the faulty operation of the device.

- Only use accessories authorized by BIOTRONIK.

ountry-Related Information

International Radio Certification

Telemetry Information for Australia

This device is in compliance with the Australian "Radiocommunications Act 1992" and, therefore, it is labeled according to the "Radiocommunications (Compliance labeling – Devices) Notice".

Telemetry Information for the USA

The stimulator will be registered with the Federal Communications Commission under the following number:

- External stimulator:

  FCC ID: QRI-SCSTS
- Implantable stimulator:

  FCC ID: QRI-SCSIPG

This device complies with part 15 of the FCC Rules.
Operation is subject to the following two conditions:

1. This device may not cause harmful interference, and
2. this device must accept any interference received, including interference that may cause undesired peration.

Changes or modifications not expressly approved by the party re ponsible for compliance could void the er's authority to operate the equipment.

ymbols on the Implantable Stimulator

ymbol	Meaning
	Identification of port A and port B placement

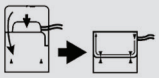
ymbols on the External Stimulator

ymbol	Meaning
	Manufacturer
	Manufacturing date
	BIOTRONIK order number
	Serial number
	Observe the technical manual
	Store in a dry place
	Type BF applied part
	MR Unsafe
GTIN	Global Trade Item Number
	Regulatory compliance mark (for Australia)

ymbols on the Intraoperative Test Cable

ymbol	Meaning
	BIOTRONIK order number
	Do not reuse
	Lot number

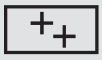
ymbols on the Patient Affixation Pouch

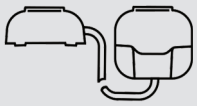
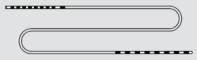
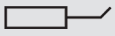
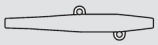
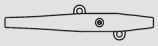
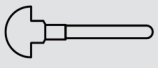
ymbol	Meaning
REF	BIOTRONIK order number
	Do not reuse
IP22	• Protection against the ingress of solid foreign bodies with a ≥ 12 mm diameter • Protection against dripping water falling at an angle up to 15°
	Storage instructions for the external stimulator

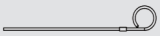
Legend for the Label

The label icons symbolize the following:

ymbol	Meaning
MD	Medical device
	Manufacturing date
REF	BIOTRONIK order number
SN	Serial number
LOT	Lot number
	Use by
UDI	Unique device identification
PID	Product identification number
	Temperature limit
	Humidity limit
	Acceptable atmospheric pressure range for storage

ymbol	Meaning
manuals.biotronik.com 	Consult the technical manual
	Contents
	Do not use if packaging is damaged and consult the technical manual
	Manufacturer
	Distributor
	Caution: Federal law (USA) restricts this device to sale by or n the order f a physician.
	Device contains materials that must be correctly disposed of in acco dance with environmental protection regulations. The European Directive 2012/19/EU on waste electrical and electronic equipment (WEEE 2) applies. Return devices that are no longer used to BIOTRONIK.
	Quantity (in the package)
	MR Conditional
	Non-sterile
	Sterilized with ethylene oxide
	Do not resterilize
	Single use only. Do not reuse!
	Single sterile barrier system
	Single sterile barrier system with protective packaging inside
	Outer diameter

ymbol	Meaning
	Internal diameter
	Total length
	Implantable stimulator
	Pocket template of the implantable stimulator
	Identification of port A and port B placement
	External stimulator without external stimulator cap
	External stimulator cap
	Header for the external stimulator
	Intraoperative test cable
	Battery
	Affixation pouch
	Lead
	Stylet
	Straight Stylet Handle (gray)
	Curved Stylet Handle (white)
	Insertion needle
	Clearing wire
	Suture anchor
	Active anchor
	Port plug

ymbol	Meaning
	Tunneling tool
	Tunneling sheath (premounted)
	Blunt tip for tunneling tool
	Sharp tip for tunneling tool
	Torque wrench
	Magnet Neuro M50
	Magnetic field
	Patient with stimulator
	Compatible with BIOTRONIK products only.

ummary of Clinical Evaluation

The safety and effectiveness of the Prospera SCS System were ba ed on a systematic review and meta-analysis (for safety outcomes) of published clinical studies that evaluated the safety and/or effectiveness of similar commercially available, fully implantable SCS systems in treating chronic intractable pain of the trunk and/or limbs, which may include unilateral or bilateral pain. The Prospera SCS System is similar in design, technology, performance, intended use, and patient population to the SCS systems evaluated in these studies. Therefore, the clinical data obtained from the published literature described below represents evidence supporting the safety and effectiveness of the Prospera SCS System for the treatment of chronic intractable pain in the trunk and/or limbs, which may include nilateral or bilateral pain. The literature review strategy wa conducted according to the guidelines outlined in the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) Statement.[6]

A total of 19 studies (23 articles) were identified for inclusi n in the systematic review (see references). A total of 13 studies (16 articles) representing a total of 626 patients were identified for inclusion in the safety analysis. A total of 18 studies (22 articles) representing a total of 864 patients were identified for inclusion in the effectiveness analysis.

The Prospera SCS System is similar to the SCS systems reported in the published literature in intended use, target patient population, device design and output characteristics. Based on these similarities the primary objective of the literature search was to provide clinical evidence of the safety and effectiveness of the Prospera device, for the relief of chronic, intractable pain in the trunk and/or limbs (unilateral or bilateral pain) resulting from any of the following:

- Failed Back Surgery Syndrome (FBSS) or low back syndrome or failed back
- Radicular pain syndrome or radiculopathies resulting in pain secondary to FBSS or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD) / herniated disk pain refracto y to conservative and surgical therapies
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dyst phy (RSD), or causalgia

[6]Page MJ, McKenzie JE, Bossuyt PM, et al. The PRISMA 2020 statement: an updated guideline for eporting systematic reviews. BMJ. 2021;372:n71.

Objectives of Systematic Review and Meta-Analysis

Effectiveness was demonstrated by the following:

- A reduction of pain as demonstrated by a clinically significant reduction in a validated patient- eported assessment of pain (e.g., visual analog scale [VAS], n meric rating scale [NRS], patient-reported pain relief [PRP])
- A 50% reduction in pain using a validated patient-reported assessment of pain (e.g., VAS, NRS, PRP) in at least 30% of patients included in the study
- A clinically significant difference in pain reduction as measu ed by a validated patient-reported assessment of pain (e.g., VAS, NRS, PRP) when compared to a control group

Safety of the Prospera SCS System was established using literat e articles by examining the incidence of complications of the SCS systems used in each study. The articles report data for patient populations implanted with SCS systems to treat chronic, intractable pain in the trunk and/or limbs (unilateral or bilateral pain) resulting from any of the indications listed ab ve.

ummary of Literature Search Strategy

The literature search was conducted on October 25, 2021 utilizing two databases:

- PubMed, which is the online version of Index Medicus produced by the US National Library of Medicine (NLM). It provides (among other resources) free access to MEDLINE, NLM's database of citations and abstracts in the fields of biomedicine and life sciences.
- To ensure the literature search was thorough and extensive, a econd well-established database was searched: EMBASE, a comprehensive biomedical research database

The PubMed and EMBASE searches were designed to identify publications providing evidence of the afety and effectiveness of SCS systems that are similar to the Prospera SCS System.

Terms were searched as keywords within all fields (not only titles) and explored where possible in both PubMed and EMBASE. The PubMed database was searched first, and bsequently the EMBASE database search was carried out, including a secondary step to eliminate potential duplication of ecords obtained from the PubMed search.

The initial search of the two databases resulted in a total of 1713 records (Embase: 607, PubMed: 1106). After removal of duplicate records (N=23), 1690 records remained. Following the execution of the initial database searches and removal of duplicates, detailed screening f the 1690 articles against the protocol eligibility criteria was carried out in the following teps:

- Screening of the article information from the 1690 records yielded by the PubMed and EMBASE earches (e.g., information present in titles, abstracts, etc.) against the eligibility criteria was carried out independently by the two reviewing authors. Results from the independent classification were reviewed, and any differences between reviewers was resolved through discussion. Full publications were sought for all articles that appeared to meet the eligibility criteria or where there was any uncertainty, and one of these reports could not be obtained (N=207/1690 records selected).
- Clinical review for inclusion of the remaining publications wa carried out independently by the two reviewing authors for the full text reports to further assess whether the article satisfied all pre-defined protocol eligibility criteria. The results of this independent classification were reviewed, and any differences were resolved through discussion.
- Final appraisal and selection of eligible articles by the two independent clinical reviewers and a tatistical reviewer (N= 23/207 reports selected).
- Determination of studies meeting all protocol eligibility criteria including reporting of safety data/ endpoints appropriate to evaluate the safety of the Prospera SCS System (N= 16 reports)
- Determination of studies meeting all eligibility criteria incl ding reporting of effectiveness tcomes data/endpoints appropriate to evaluate the effectivene f the Prospera SCS System (N= 22 reports).

afety Results

The evaluation of safety is based on the incidence of adverse events (AE)s, device-related complications and/or surgical interventions reported from a total of 13 study populations representing a total of 626 patients implanted with SCS systems of similar design to the Pr pera SCS System. The median ample size was 42 (range, 15 to 97) patients, and 386 (61.7%) f the patients were female. The median average age was 52 (range, 39.0 to 56.3) years. The median foll w-up time was 12.1 (range, 3.0 to 60.0) months. The studies were published between 1999 and 2020, and 4/13 (30.8%) studies were conducted in the United States, representing 225 (35.9%) of the patients in the safety analysis. The primary treated pain diagnoses were FBSS: N=427 (68.2%), CRPS: N=153 (24.4%), radiculopathy/radicular pain syndrome: N=69 (11.0%) and DDD: N=49 (7.8%). These characteristics are consistent with the patient population for which the Prospera SCS System is indicated.

The safety profile was based on adverse events (AEs) device-related complications, and surgical interventions reported for patient populations with characteristics that are consistent with the Prospera SCS System indications, following treatment with a totally implantable SCS system of similar design to the Prospera SCS System.

Adverse Events, Device-related Complications, and Surgical Interventions

Standard summary statistics are provided for each adverse event type and surgical intervention. In cases where data for a particular event was reported in at least 4 studies, a andom-effects model was used to estimate a pooled rate. Two models stratified by follow up time post-implant (⩾3 and < 12 months, ⩾12 months) were conducted for adverse event and complications eported in at least 4 studies for their respective time periods. If the numbe f events was reported in the article rather than the number of participants experiencing an event, it was assumed that each event was experienced by a unique participant.

Ten adverse event/complication types/surgical interventions rep ted in at least four studies were formally meta-analyzed: pain at the implant site (e.g., stimulator, lead), infection, hematoma, cerebrospinal fluid leak, ineffective pain control (permanent implant), device malfunction (e.g., mechanical or technical failure of stimulator, lead, etc.), uncomfortable stimulation (target or non-target area), lead migration, lead fracture/failure, and su gical intervention (e.g., revision, explant, eplacement).

Table 1 provides a summary of all meta-analyzed adverse events, device-related complications and surgical interventions.Table 1: Summary of Meta-analyzed Events: Adverse Events, Device-related Complications, Surgical Interventions

Event Type	N Studies (N Patients)*	Median (Range) Follow-up (months)	Pooled Rate (95% CI)	Median Rate (IQR) [Range]
Adverse Events				
Pain at the implant site (e.g. timulator, lead)	8 (479)	11.5 (3.0 to 32.0)	3.9% (1.7-6.2)	3.7% (2.7 to 7.8) [2.2 to 16.7]
Infection	9 (469)	12.1 (3.0 to 32.0)	2.7% (0.8-4.7)	4.8% (2.2 to 6.7) [1.0 to 10.0]
Hematoma	4 (261)	9.8 (3.0 to 32.0)	2.3% (0-5.2) †	2.1% (2.1 to 5.4) [2.1 to 8.7]
Cerebrospinal Fluid (CSF) Leak	5 (345)	10.9 (3.0 to 12.1)	1.7 % (0.1-3.4) †	2.4% (2.1 to 4.2) [1.1 to 4.6]
Device-related complications				
Ineffective pain control (permanent implant)	6 (320)	13.3 (8.6 to 32.0)	12.6% (0-27.5)	7.4% (3.2 to 22.0) [0.2 to 53.3]
Device malfunction (e.g. mechanical or technical failure of stimulator, lead, etc.)	7 (322)	12.1 (3.0 to 32.0)	8.2 % (3.1-13.3)	8.7% (4.8 to 14.6) [1.1 to 16.7]
Uncomfortable stimulation, target or non-target area	5 (339)	10.9 (3.0 to 24.0)	7.9% (0.6-15.3)	9.2% (8.3 to 11.3) [1.1 to 14.6]
Lead Migration	9 (510)	12.0 (8.6 to 32.0	7.4% (4.7-10.0) †	7.1% (6.4 to 13.0) [5.2 to 16.7]
Lead Fracture/Failure	4 (130)	22.7 (12.1 to 32.0)	3.5% (0-8.6)	4.2% (3.2 to 5.5) [2.4 to 6.7]
urgical intervention				
Surgical intervention (e.g. evision, explant, replace-ment)	12 (578)	12.1 (8.6 to 60.0)	31.4% (16.6-46.2)	27.1% (13.1 to 44.7) [5.3 to 75.0]

Tab. 1: **Summary of Meta-analyzed Events: Adverse Events, Device-related Complications, Surgical Interventions**

*Refers to the number of study populations and patients for which each outcome measure was assessed.
†To permit estimation, the variance matrix was forced to allow negative values in the restricted maximum likelihood (REML).

All other adverse event and device-related complications were reported in fewer than 4 studies and were not meta-analyzed. Table 2 provides an overall summary of non-meta-analyzed events, including mmary statistics.

Event Type	N studies (N patients)	Median (Range) Follow-up (months)	Median Rate (Range)
Adverse Events			
Inflammation at implant site	2 (90)	7.6 (3.0-12.1)	11.2% (10.4 to 11.9)
Spinal tap	1 (36)	24.0	8.3%
Death (non-device related)	2 (126)	23.3 (11.0-35.6)	7.4% (1.0 to 13.8)
Recurrent rejection ascribed to SCS ystem	1 (24)	60.0	4.2%
Seroma	2 (107)	21.6 (12.1-31.0)	3.9% (3.1 to 4.8)
herpes zoster	1 (29)	12.0	3.5%
Ulcerative colitis	2 (60)	42 (24.0-60.0)	3.5% (2.8 to 4.2)
Implant site irritation (e.g. dermatitis, rash, pruritus)	3 (210)	7.0 (3.0-11.0)	3.1% (1.5 to 8.3)
Pain	3 (210)	10.9 (3.0-11.0)	3.1% (1.0 to 16.7)
Other postoperative pain	2 (139)	11.5 (11.0-12.1)	2.9% (1.0 to 4.8)
Cellulitis	1 (48)	3.0	2.1%
Hypoesthesia	1 (48)	3.0	2.1%
Muscle spasms	2 (97)	7.0 (3.0-11.0)	2.1% (2.1 to 2.1)
Nausea	1 (65)	11.0	1.5%
Abstinence syndrome	1 (65)	10.9	1.5%
Headache	3 (198)	11.0 (10.9-24)	1.5% (1.0 to 2.8)
Seizure	1 (65)	10.9	1.5%
Skin erosion	1 (93)	8.6	1.1%
Micturition urgency	1 (97)	11.0	1.0%
Anxiety	1 (97)	11.0	1.0%
Arrhythmia	1 (97)	11.0	1.0%
Cardiac arrest	1 (97)	11.0	1.0%

Event Type	N studies (N patients)	Median (Range) Follow-up (months)	Median Rate (Range)
Extradural abscess	1 (97)	11.0	1.0%
Implant site effusion	1 (97)	11.0	1.0%
Stitch abscess	1 (97)	11.0	1.0%
Tinnitus	1 (97)	11.0	1.0%
Urinary retention	1 (97)	11.0	1.0%
Dehiscence	1 (97)	11.0	0.0%
Impaired healing at implant site	1 (97)	11.0	0.0%
Motor dysfunction	1 (97)	11.0	0.0%
Other wound complication at implant site	1 (97)	11.0	0.0%
Paresis	1 (97)	11.0	0.0%
Suture removal	1 (97)	11.0	0.0%
Device-related complications			
SCS system explant (cessation of treatment)	1 (36)	24.0	11.1%
Over/under-stimulation	3 (107)	24.0 (12.1-35.6)	9.5% (2.8 to 20.7)
Recharging issue	2 (90)	7.6 (3-12.1)	7.6% (4.8 to 10.4)
Stimulator/lead heating	1 (15)	31.0	6.7%
Device connection issue (e.g. lead, lead connection)	2 (65)	22.1 (12.1-32.0)	5.7% (4.4 to 7.1)
Inability to place lead	1 (42)	12.1	4.8%
Damage to device	2 (135)	10.4 (8.6-12.1)	3.3% (2.4 to 13.8)
Device use error	2 (90)	7.6 (3.0-12.1)	3.3% (2.4 to 4.2)
Other stimulation issue	3 (181)	11.0 (3.0-24.0)	2.8% (1.0 to 4.2)
Technical procedure problems during the implantation	1 (36)	24.0	2.8%
Premature generator battery depletion	3 (219)	11.0 (8.6-35.6)	1.6% (1.0 to 2.2)
Stimulation-related neurologic deficit	2 (126)	11.5 (11.0-12.0)	0.0%

Tab. 2: Summary of Non-meta-analyzed Events: Adverse Events, Device-related Complications

Manufacturer and User Facility Device Experience (MAUDE) Database Search Results for SCS ystems used in Publications Selected to Evaluate the Safety an d Effectiveness of the Prospera SCS ystem

To supplement the evaluation of safety in the systematic review, an analysis of MAUDE database event information was carried out for the similar commercial SCS systems implanted in the patient populations for all 19 selected studies. The MAUDE search included the overall time period from 1988 (date of approval of the earliest similar device PMA) through J ne 30, 2021. Search criteria included the product code: LGW (Stimulator, Spinal-Cord, Totally Implanted F Pain Relief), and the stimulator and lead model information obtained from the selected studies. The earch identified a total of 117888 MDRs reporting a total of 128950 patient problems and 190562 device problems. Table 3 and Table 4 provide summaries of the reported patient problems and device p blems.

Patient Problems	N Events (% Total Events)
Inadequate Pain Relief	21545 (16.708%)
Pain	19931 (15.456%)
Therapeutic Effects, Unexpected	18501 (14.347%)
Therapeutic Response, Decreased	7647 (5.930%)
Discomfort	7299 (5.660%)
Electric Shock	5152 (3.995%)
Complaint, Ill-Defined	5077 (3.937%)
Undesired Nerve Stimulation	4492 (3.484%)
Burning Sensation	4066 (3.153%)
Unspecified Infection	3803 (2.949%)
Device Overstimulation of Tissue	2808 (2.178%)
Ambulation Difficulties	1516 (1.176%)
Swelling	1322 (1.025%)
Fall	1256 (0.974%)
Bacterial Infection	926 (0.718%)
Post Operative Wound Infection	837 (0.649%)
Numbness	824 (0.639%)
Tingling	767 (0.595%)
Scar Tissue	661 (0.513%)
Muscle Spasm(s)	633 (0.491%)
Fluid Discharge	628 (0.487%)
Headache	626 (0.485%)

Patient Problems	N Events (% Total Events)
Erythema	597 (0.463%)
Wound Dehiscence	590 (0.458%)
Staphylococcus Aureus	572 (0.444%)
Weight Changes	521 (0.404%)
Sleep Dysfunction	518 (0.402%)
Erosion	513 (0.398%)
Fever	480 (0.372%)
Irritation	424 (0.329%)
Impaired Healing	401 (0.311%)
Cerebrospinal Fluid Leakage	388 (0.301%)
Burn(s)	328 (0.254%)
Purulent Discharge	307 (0.238%)
Nausea	306 (0.237%)
Inflammation	305 (0.237%)
Pocket Erosion	297 (0.230%)
Bruise/Contusion	287 (0.223%)
Seroma	287 (0.223%)
Muscle Weakness	285 (0.221%)
Hematoma	279 (0.216%)
Discharge	278 (0.216%)
Alteration In Body Temperature	257 (0.199%)
Hypersensitivity/Allergic reaction	252 (0.195%)
Malaise	245 (0.190%)
Weakness	245 (0.190%)
Skin Erosion	237 (0.184%)
Seizures	231 (0.179%)
Paralysis	212 (0.164%)
Cramp(s)	201 (0.156%)
Itching Sensation	199 (0.154%)
Device Embedded In Tissue or Plaque	197 (0.153%)

Patient Problems	N Events (% Total Events)
Shaking/Tremors	197 (0.153%)
Death	194 (0.150%)
Anxiety	185 (0.143%)
Muscular Rigidity	181 (0.140%)
Distress	174 (0.135%)
Neuropathy	174 (0.135%)
Shock	171 (0.133%)
Neck Pain	165 (0.128%)
Abdominal Pain	160 (0.124%)
Cognitive Changes	156 (0.121%)
Vomiting	155 (0.120%)
Neurological Deficit/Dysfunction	153 (0.119%)
Skin Irritation	149 (0.116%)
Rash	145 (0.112%)
Failure of Implant	144 (0.112%)
Incontinence	138 (0.107%)
Nerve Damage	135 (0.105%)
Foreign Body Reaction	134 (0.104%)
Other events (313 event types with individual incidence <0.1%)	5484 (4.253%)
Total	**128950 (100.0%)**

Tab. 3: MAUDE Database: Reported Patient Problems

Device Problem	N Events (% Total Events)
Device Operates Differently Than Expected	14742 (7.736%)
High impedance	11695 (6.137%)
Charging Problem	11514 (6.042%)
Failure to Deliver Energy	9417 (4.942%)
Battery Problem	8185 (4.295%)
Charging issue	6740 (3.537%)
Migration	5782 (3.034%)
Improper or Incorrect Procedure or Method	5261 (2.761%)
Unintended Collision	4893 (2.568%)
Therapeutic or Diagnostic Output Failure	4802 (2.520%)
Inappropriate Shock	4718 (2.476%)
Communication or transmission issue	4563 (2.394%)
Failure to Interrogate	4423 (2.321%)
Communication or Transmission Problem	4375 (2.296%)
Migration of device or device component	4133 (2.169%)
Migration or Expulsion of Device	3964 (2.080%)
Energy Output Problem	3714 (1.949%)
Intermittent Continuity	3513 (1.843%)
Device displays error message	3472 (1.822%)
Unexpected Therapeutic Results	3401 (1.785%)
Low Battery	3372 (1.770%)
Delayed Charge Time	3202 (1.680%)
Battery issue	3189 (1.673%)
Therapy Delivered to Incorrect Body Area	2892 (1.518%)
No Device Output	2531 (1.328%)
Use of Device Problem	2197 (1.153%)
Malposition of Device	1991 (1.045%)
Inappropriate/Inadequate Shock/Stimulation	1987 (1.043%)
Premature Discharge of Battery	1832 (0.961%)
Fracture	1829 (0.960%)

Device Problem	N Events (% Total Events)
Device Displays Incorrect Message	1824 (0.957%)
Patient Device Interaction Problem	1803 (0.946%)
Overheating of Device	1687 (0.885%)
Break	1664 (0.873%)
Impedance Problem	1640 (0.861%)
Use of Device Issue	1515 (0.795%)
Failure to Charge	1430 (0.750%)
Positioning Issue	1351 (0.709%)
Wireless Communication Problem	1329 (0.697%)
Low impedance	1254 (0.658%)
Device Inoperable	1222 (0.641%)
Unstable	1108 (0.581%)
Impedance issue	1105 (0.580%)
Electromagnetic Compatibility Problem	1066 (0.559%)
Connection Problem	975 (0.512%)
Temperature issue	931 (0.489%)
Connection issue	840 (0.441%)
Overheating of device or device component	793 (0.416%)
Electromagnetic Interference	708 (0.372%)
Electro-magnetic interference (EMI)	691 (0.363%)
Positioning Problem	681 (0.357%)
Electromagnetic compatibility issue	677 (0.355%)
Replace	661 (0.347%)
Explanted	630 (0.331%)
Material Integrity Problem	615 (0.323%)
Material integrity issue	597 (0.313%)
Display or Visual Feedback Problem	542 (0.284%)
Device remains implanted	510 (0.268%)

Device Problem	N Events (% Total Events)
Energy Output To Patient Tissue Incorrect	495 (0.260%)
Data Problem	473 (0.248%)
Implant, reprogramming of	450 (0.236%)
Disconnection	446 (0.234%)
Defective Device	398 (0.209%)
Pocket Stimulation	396 (0.208%)
Unknown (for use when the device problem is not known)	376 (0.197%)
Device Or Device Fragments Location Unknown	361 (0.189%)
Device Stops Intermittently	325 (0.171%)
Improper Device Output	303 (0.159%)
Patient-Device Incompatibility	285 (0.150%)
Electronic property issue	248 (0.130%)
Unintended Movement	248 (0.130%)
Device Remains Activated	219 (0.115%)
Material Deformation	212 (0.111%)
Loss of Data	209 (0.110%)
Incorrect display	194 (0.102%)
Other events (323 event types with individual incidence <0.1%)	6746 (3.540%)
Total	**190562 (100.0%)**

Tab. 4: MAUDE Database: Reported Device Problems

Effectiveness Results

The evaluation of effectiveness is based on data reported from a total of 18 studies (22 articles) epresenting a total of 864 patients implanted with SCS systems f similar design to the Prospera SCS System. The median sample size was 37 (range, 8 to 117) patient , and 600 (69.4%) of the patients were female. The median average age was 53.3 (range, 40.0 to 63.5) years. The median follow-up time was 12.0 (range, 3.0 to 60.0) months. The studies were published between 2000 and 2021, and 6/18 (33.3%) studies were conducted in the United States, representing 338 (39.1%) of the patients in the effectiveness analysis. The primary treated pain diagnoses were FBSS: N=638 (73.8%), CRPS: N=222 (25.7%), radiculopathy/radicular pain syndrome: N=137 (15.9%) and DDD: N=63 (7.3%). These characteristics are consistent with the patient population for which the Prospera SCS System is indicated.

A summary of effectiveness results in the selected studies is p vided in Error! Reference source not found.. The number of patients with demographic data and pain diagnoses/etiologies reported in the publications is provided, as well as the total number of patients included in the effectiveness analysis. Reasons for differences between the total number of patients analyzed for effectiveness outcomes and the total number of patients with demographic/pain diagnoses include:

- For some articles, not all patients reported in the demographic summaries were assessed for the effectiveness outcomes at the respective time intervals (e.g., demographic data was reported for all enrolled patients, and not all enrolled patients were implanted and/or completed the respective follow-up).
- For some articles where sufficient outcomes data was reported eparately for different SCS system types, treatments, pain etiologies, etc., the sub-set of patients meeting all systematic review protocol eligibility criteria were sub-selected for analysis (e.g., excluding patients not meeting all ystematic review eligibility criteria)

Success percentages (e.g., responder rates) were determined by dividing the number of patients meeting one or more definitions of effectiveness listed above by the total number of patients that were evaluated for each respective time interval. The specific succe criterion and time point for which the criteria was assessed are provided. If outcomes were reported f pecific pain locations (e.g., overall, back, leg) and/or pain etiologies (e.g., FBSS, CRPS, etc.), outcomes results are provided for the respective pain areas and etiologies. For articles where a clinically significant change in the pain outcome measure was reported, summary statistics for the outcome measure at the assessed time points, along with the number of participants assessed and results of any statistical tests are provided.

Publication	tudy Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: uccess % (N of Patients) or clinically significant change in primary outcome measure
Villavicencio et al. 2000	Retrospective, non-randomized, single-center study	27 (implanted): 44.4% female Cylindrical percutaneous leads (used for analysis): 15/27, mean age (range): 53 (24-74) years	FBSS: 60%, N=9 Causalgia I and II: 13%, N=2 Neuropathic pain: 7%, N=1 Other: 20%, N=3	Follow-up duration (percutaneous): mean: 10.3 months Follow-up time points: all patients followed at least 6 months	Responder rate % (Criterion: PRP ⩾ 50%): Mean follow-up: 10.3 months: 80% (12/15)
Forouzanfa et al. 2004	Prospective, non-randomized, single-center study	36 (implanted): mean age (± SD): 40 (± 10.1) years, ange: 26-59 years; 66.7% female	CRPS I: 100%, N=36	Follow-up duration: Median (range): 24 months (12 to 24 months) Follow-up time points (n patients completing): baseline (36/36), 6 months (36/36), 12 months (36/36), 24 months (31/36) post implantation	Responder rate % (Criterion: ⩾ 50% eduction in VAS): 6 months: 63.9% (23/36) 12 months: 61.1% (22/36) 24 months: 45.2% (14/31)
Harke et al. 2005	Prospective, non-randomized, single-center study	29 (implanted): mean age (± SD): 49.8 (± 14.5) years, ange: 27-86 years; 55.2% female	CRPS I: 100%, N=29	Follow-up duration: mean: 35.6 ± 21 months. Follow-up time points: all patients followed at least 12 months	Responder rate % (Criterion: ⩾ 50% eduction in VAS): 12 months: Deep pain: 96.6% (28/29) Allodynia: 100.0% (22/22) Last follow-up: 35.6 ± 21 months Deep pain: 100.0% (29/29) Allodynia: 100.0% (22/22)

Publication	tudy Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: uccess % (N of Patients) or clinically significant change in primary outcome measure
Oakley et al. 2007 Supplemental articles: Krames et al. 2008	Prospective, non-randomized, multicenter study	65 (trialed): mean age (range): 52.0 (28-84) years; 40.0% female	FBSS: 61.5%, N=40 CRPS: 13.9%, N=9 Radiculopathy/ neuropathy: 6.2%, N=4 Other: 4.6%, N=3 Unknown: 13.9%, N=9	Follow-up duration: mean: 10.9 months Follow-up time points: baseline, 2 weeks, 3 months, 6 months, and every six months thereafter until tudy closure	Responder rate % (Criterion: ⩾ 50% VAS eduction, stim ON vs. Off): 3 months: 63% (24/38) 6 months: 55% (18/33)
Kemler et al. 2008 Supplemental articles: Kemler et al. 2000, 2004	Prospective, ingle-center, RCT (2:1)	36 (trialed): mean age (± SD): 40 (± 12) years; 61.1% female	CRPS I: 100%, N=24	Follow-up duration: Median: 60 months Follow-up time points (n patients completing): baseline, 3, 6, 12, 24 (24/24), 36, 48, 60 months (20/24)	Criterion: significant eduction in mean VAS 24 months: mean reduction in VAS (SCS+PT group): 3.0 cm (N=24) mean reduction in VAS (PT alone): 0.0 cm (N=16) p=0.001 60 months: mean reduction in VAS (SCS+PT group): 2.5 cm (N=20) mean reduction in VAS (PT alone): 1.0 cm (N=13) p=0.06
Van Buyten et al. 2008	Prospective, non-randomized, multicenter study	45 (trialed): mean age: 51.3 years, range: 31.1 to 69.4 years; 66.7% female	Post-operative back or leg pain: 55%, N=25 Radicular pain: 27%, N=12 CRPS I: 7%, N=3 CRPS II: 7%, N=3 Other: 4%, N=2	Follow-up duration: mean (range) 12 months (8 to 13 months) Follow-up time points: baseline, 6, 12 months post-implant	Responder rate % (Criterion: PRP ⩾ 50%): 12 Months: 80.5% (33/41)

Publication	tudy Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: uccess % (N of Patients) or clinically significant change in primary outcome measure
Moriyama et al. 2012	Prospective, non-randomized, multi-center study	34 (implanted): mean age (± SD): 53.5 (± 16.9) years; 52.9% female	FBSS: 50.0%, N=17 CRPS: 41.2%, N=14 Other: 8.8%, N=3	Follow-up duration: median: 6 months Follow-up time points (n patients completing): baseline, 1, 6 months (29/34)	Responder rate % (Criterion: ⩾ 50% eduction in VAS): 6 Months: Total Population: 65.5% (19/29), CRPS: 83.3% (10/12), FBSS: 46.7% (7/15), Other: 100% (2/2)
Kinfe et al. 2014	Prospective, non-randomized, single-center study	100 (trialed): mean age (range): 56.3 (27-89) years; 57.0% female Cylindrical percutaneous leads (used for analysis): N=50	FBSS: 100%, N=100	Follow-up duration: mean 1.2 ± 0.3 years (range: 0.4-2.0 years): Follow-up time points: all patients followed at least 4 months	Responder rate % (Criterion: ⩾ 50% eduction in VAS): 1.2 ± 0.3 years (range: 0.4-2.0 years): 70% (35/50) (cylindrical percutaneous leads) Percentage pain elief (SD): 69.6% (11.2%)(cylindrical percutaneous leads)
Kapural et al. 2016 (primary ce for effectiveness analysis) Supplemental articles: Kapural et al. 2015 (primary ce for afety analysis)	Prospective, multi-center RCT	87 (per protocol population): mean age (± SD): 55.2 (± 13.4) years, range: 19.2 to 82.3 years; 58.6% female	FBSS: 74.7%, N=65 Radiculopathy: 60.9%, N=53 Degenerative disc disease: 57.5%, N=49 Spondylosis: 36.8%, N=32 Mild/moderate pinal stenosis: 19.5%, N=17 Sacroiliac dysfunction: 16.1%, N=14 Lumbar facet-mediated pain: 16.1%, N=14 Spondylolis thesis: 2.3%, N=2 Other chronic pain: 20.7%,	Follow-up duration: median: 24 months Follow-up time points (n patients completing): baseline, 3, 6, 12 (80/81), 18, and 24 (71/81) months	Responder rate % (Criterion: ⩾ 50% eduction in VAS): Leg pain 12 months: 50.0% (40/80) 24 months: 49.3% (35/71) Back pain 12 months: 51.3% (41/80) 24 months: 49.3% (35/71)

Publication	tudy Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: uccess % (N of Patients) or clinically significant change in primary outcome measure
			N=18 Other neu pathic pain: 12.6%, N=11		
Denisova et al. 2016	Prospective, non-randomized, single-center study	75 (implanted): median age (range): 51.6 (26 to 83) years; 62.7% female	FBSS: 70.7%, N=53 CRPS II: 12.0%, N=9 Other: 17.3%, N=13	Follow-up duration: Range: 6-18 months Follow-up timepoints: baseline, 3, 6, 12 months	Criterion: significant eduction in mean VAS N=75 Baseline (mean (range) VAS): 6.5 (5-10) cm 3 months (mean VAS): 3.1 cm, Difference in means: -3.4 cm 6 months (mean VAS): 3.1 cm, Difference in means: -3.4 cm 12 months (mean VAS): 3.6 cm, Difference in means: -2.9 cm
De Andres et al. 2017	Prospective, andomized, ingle-blinded (evaluators collecting pain atings), single-center study	29 (implanted): mean age: 53.8 years; 62.1% female	FBSS: 100%, N=29	Follow-up duration: 12 months (all implanted participants) Follow-up time points (n patients completing): baseline (29/29), 3 (29/29), 6 (29/29), 12 months (29/29) post-implant	Criterion: significant eduction in mean NRS Conventional frequency group (excluding HF10) (N=29): 6 months: mean of the difference (SD): -1.67 (2.69), P.000 12 months: mean of the difference (SD) -1.44 (2.28), P.000
Deer et al. 2017	Prospective, multi-center, RCT	76 (trialed): mean age (± SD): 52.5 (± 11.5) years; 51.3% female	CRPS: 56.6%, N=43 Causalgia: 43.4%, N=33	Follow-up duration: median (implanted): 12 months (range: 3-12 months)	Responder rate % (Criterion: ⩾ 50% eduction in VAS in the primary area of pain with no incidence of stimulation-

Publication	tudy Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: uccess % (N of Patients) or clinically significant change in primary outcome measure
				Follow-up time points (n patients completing): baseline, 3 (54/54), 6 (52/54), 12 months (50/54)	induced neurological deficits): SCS arm: 3 months: 55.7% (39/70)* 6 months: 60.3% (41/68)* 12 months: 53.0% (35/66)* *Randomized bjects who did not proceed to permanent implant were considered treatment failures for this endpoint at each tudy visit.
Gatzinsky et al. 2017	Prospective, non-randomized, multicenter study	93 (trialed): mean age (± SD): 52 (± 12) years; 52.7% female	FBSS: 100.0%, N=93	Follow-up duration: median: 12 months Follow-up time points (n patients completing): baseline, 6 (68/81), 12 months (65/81) post implant	Responder rate % (Criterion: ⩾ 50% eduction in VAS): 6 months: Leg pain: 63.3% (38/60) Back pain: 34.0% (22/65) 12 months: Leg pain: 63.1% (41/65) Back pain: 40.3% (25/62)
Tanei et al. 2018	Retrospective, non-randomized, single-center study	8 (implanted): mean age (± SD): 63.5 (± 15.1) years, ange: 40-78 years; 44.4% female	FBSS: 62.5%, N=5 Peripheral neuropathy: 25.0%, N=2 CRPS I: 12.5%, N=1	Follow-up duration: mean (± SD): 29.5 (± 16.8) months, ange: 12-63 months Follow-up time points: baseline, 1, 6, 12 months, last follow-up	Responder rate % (Criterion: ⩾ 50% eduction in VAS): 6 Months: Total population: 50.0% (4/8), FBSS: 40.0% (2/5), CRPS I: 100.0% (1/1), PNP: 50.0% (1/2) 12 Months: Total

Publication	tudy Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: uccess % (N of Patients) or clinically significant change in primary outcome measure
					population: 50.0% (4/8), FBSS: 40.0% (2/5), CRPS I: 100.0% (1/1), PNP: 50.0% (1/2) Last Follow-up (mean: 29.5 months): Total population: 50.0% (4/8), FBSS: 40.0% (2/5), CRPS I: 100.0% (1/1), PNP: 50.0% (1/2)
Benyamin et al. 2020	Prospective, non-randomized, multi-center study	32 (implanted): mean age (± SD): 56.0 (± 11.9) years; 59.4% female	FBSS: 100.0%, N=32	Follow-up duration: median: 3 months Follow-up time points (n patients completing): baseline, 1, 2, and 3 months (29/32) post-implant	Responder rate % (Criterion: ⩾ 3 point eduction in NRS) Overall pain 3 months: 69.0% (22/32), mean reduction of 3.7 points from baseline (P < 0.01)
Graziano et al. 2020	Prospective, non-randomized, single-center	23 (implanted): mean age (± SD): 61.6 (± 11.5) years, ange: 38-79 years; 47.8% female	FBSS: 100.0%, N=23	Follow-up duration: mean (±SD): 12.9 (± 8.2) months, ange: 1-25 months Follow-up time points: all patients followed at least 1 month.	Responder rate % (Criterion: VAS ⩽ 3): 12.9 months (range: 1 to 25 months)*: 87.0% (20/23) *Patients meeting ccess criteria in the publication but with < 3 months follow-up are excluded from the analysis. Patients not meeting success criteria are included independent of follow-up time and counted as failures.
Hatheway et al. 2021	Prospective, non-randomized, single-arm, multi-center tudy	103 (implanted): mean age (range) 60.8 (29-93) years; 54.4% female	FBSS: 44.7%, N=46 Radicular pain yndrome: 27.2%, N=28	Follow-up duration: median: 12 months Follow-up time	Responder rate % (95% CI) (Criterion: ⩾ 50% reduction in VAS): Overall pain, Low back pain, Leg

Publication	tudy Design	Demographic Data (N patients, age, gender)	Diagnoses (Etiology, Condition, Implant Indications)	Timeframe	Effectiveness Outcomes Endpoint Duration: uccess % (N of Patients) or clinically significant change in primary outcome measure
			Degenerative disc disease: 13.6%, N=14 CRPS I: 1.0%, N=1 Other: 13.6%, N=14	points (n patients completing): baseline, 3 months (98/103), 6 months (96/103), 12 months (91/103) post-activation	pain 3 months (N=103): 68.3% (59.0–77.5%) 59.8% (49.9–69.7%) 77.4% (69.1–85.7%) 6 months (N=103): 66.2% (56.9–75.5%) 58.4% (48.8–68.1%) 72.2% (63.1–81.3%) 12 months (N=103): 59.1% (49.0–69.2%) 57.1% (47.1–67.1%) 67.9% (58.5–77.2%)
Kallewaard et al. 2021	Retrospective, multi-center bservational cohort study	188 (implanted): mean age (± SD): 60.0 (± 12.3) years; 53.7% female	FBSS: 64%, N=120 Lumbosacral adiculopathy: 21%, N=40 Compressive myelopathy from pinal stenosis: 9%, N=17 Other: 6%, N=11	Follow-up duration: mean (± SD): 9.73 (±6.81) months Follow-up time points: baseline, 3 months, 12 months.	Responder rate % (Criterion: ⩾ 50% eduction in NRS for verall pain): 3 mo: 68.4% (80/117) 12 mo: 70.0% (63/90)

onclusions

The clinical evidence provided to support the safety of the Pro pera SCS System includes:

- A systematic literature review, safety summary results and meta-analysis of study populations implanted with SCS systems of similar design to the Prospera SCS System.
- Analysis of Manufacturer and User Facility Device Experience (MAUDE) Database search results for the SCS systems utilized in the studies selected in the systematic review.

Summary information for the adverse events, device-related complications and surgical interventions eported in the 13 study populations:

- A total of 135 AEs were reported in the safety population of 626 patients. Pain at the implant site was the most frequently occurring individual AE reported (30 events [5.9%]), followed by infection (19 events [3.2%]), pain (12 events [5.7%]) and inflammation at implant site (10 events [5.3%]).
- A total of 211 device-related complications were reported in the safety population of 626 patients. Lead migration was the most frequently occurring device-related complication (49 events [9.6%]), followed by ineffective pain control (31 events [9.7%], uncomfo table stimulation (30 events [8.8%), device malfunction (28 events [8.7%), premature generator batte y depletion (19 events [8.7%] and ver/under-stimulation (17 events [15.9%]).
- A total of 205 surgical interventions (e.g., stimulator/lead revision, explant, replacement) were eported in the safety population of 626 patients, resulting in an overall rate of 32.7%.

Summary information for the meta-analyzed events reported in at least 4 studies, including estimated pooled rates of occurrence:

- Four adverse event types: pain at the implant site (3.9%) infection (2.7%), hematoma (2.3%) and CSF leak (1.7%)
- Five device-related complication event types: ineffective pain control (permanent implant) (12.6%), device malfunction (8.2%), uncomfortable stimulation (7.9%), lead migration (7.4%), and lead fracture/failure (3.5%)
- Surgical intervention: any device-related intervention (e.g., timulator/lead revision, explant, eplacement) (31.4%)

The reported event rates including the estimated pooled rates of occurrence of these events that were appropriate for meta-analysis are consistent with trends reported in the literature and in other imilarly designed evaluations of SCS system safety based on la ge-scale systematic reviews. [1,2,3,4,5] Additionally, the results reported for non-meta-analyzed event types, and the results of the MAUDE Database analysis of patient and device problems are consistent with the results above, and indicate relatively stable reporting of well-known, previously identified risks associated with SCS.

The results of the systematic literature review support the safety of SCS therapy (delivered by legally marketed, fully implantable SCS systems with similar designs to the Prospera SCS System) in treating patients who suffer from chronic, intractable pain in the trunk and/or limbs which may include nilateral or bilateral pain.

The evaluation of effectiveness is based on data reported from a total of 18 studies (22 articles) epresenting a total of 864 patients implanted with SCS systems f similar design to the Prospera SCS System. The median sample size was 37 (range, 8 to 117) patient , and 600 (69.4%) of the patients were female. The median average age was 53.3 (range, 40.0 to 63.5) years. The median follow-up time was 12.0 (range, 3.0 to 60.0) months. The studies were published between 2000 and 2021, and 6/18 (33.3%) studies were conducted in the United States, representing 338 (39.1%) of the patients in the effectiveness analysis. The primary treated pain diagnoses were FBSS: N=638 (73.8%), CRPS: N=222 (25.7%), radiculopathy/radicular pain syndrome: N=137 (15.9%) and DDD: N=63 (7.3%). These characteristics are consistent with the patient population for which the Prospera SCS System is indicated. SCS treatment with SCS systems of similar design to theProspera SCS System was demonstrated to be effective in all 18 patient populations desc ibed in the articles.

The improvement in pain across all conditions/etiologies/pain l cations for the 15/18 studies with esponse rates reported ranged from:

- 34% to 100%, with 10/15 studies reporting success rates ⩾ 50%, and 7/15 studies reporting success ates ⩾ 68% (all follow-up durations)
- 40% to 100%, with 8/11 studies reporting success rates ⩾ 50%, and 5/11 studies reporting success ates ⩾ 70% (follow-up ⩾ 12 months)

The results of the systematic literature review support the effectiveness of SCS therapy (delivered by legally marketed, fully implantable SCS systems of similar design to the Prospera SCS System) in treating patients who suffer from chronic, intractable pain in the trunk and/or limbs which may include nilateral or bilateral pain.

The results of the systematic review provide clinical evidence to support the safety and effectiveness of the Prospera SCS System, when used in accordance with the propo ed indications for use, including pport for its long-term performance. The clinical evidence su pporting the safety and effectiveness of the Prospera SCS System is based on a foundation of 22 years of clinical research and experience as reported in the published studies of patient populations (with characteristics that are consistent with the Prospera SCS System indications) implanted with SCS systems f similar design to the Prospera SCS System. The presented analysis of clinical evidence also supports a favorable benefit-risk determination.

[1]Algostim, LLC. Summary of Safety and Effectiveness Data: Algovita™ Spinal Cord Stimulation (SCS) System. 2015. P130028.
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Note on Limitations of the Data

The data used to support the effectiveness of the Prospera device was based on literature studies. Some studies were open label, in that patients knew they were receiving stimulation. Open label studies may cause an overestimation of the treatment effect in investigator and subject ratings. Also, open label studies do not assess the magnitude of the placebo respon e, regression to the mean, the effect f changes in medications or other treatments to alleviate pain changes in the underlying severity of the pain disorder.

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