



Prospera Spinal Cord Stimulation System

ProMRI

Implantation Instructions for
Physicians

Technical Manual

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Distributor:

BIOTRONIK NRO, INC.
6024 Jean Road
Lake Oswego, OR, 97035
Tel (877) 246-1122 (24-hour)
Fax (866) 229-4744
www.biotronik.com

Manufacturer:

BIOTRONIK SE & Co. KG
Woermannkehre 1
12359 Berlin / Germany
Tel +49 (0) 30 68905-0
Fax +49 (0) 30 6852804
sales@biotronik.com
www.biotronik.com



Table of Contents

1	About This Technical Manual.....	3
	Objective	3
	Technical Manuals.....	3
	Conventions.....	3
2	Safety.....	7
	Warnings	7
	Precautions	7
	Risky Therapeutic and Diagnostic Procedures	9
	Transport and Storage.....	12
3	System Description.....	15
	Overview of the System Components.....	15
	Main Components.....	15
	Accessories	16
	Intended Medical Use	17
	Indications	18
	Contraindicated Patient Conditions	18
	Intended Users.....	18
4	Overview of the Implantation Procedure and Process	19
	Implantation Procedure.....	19
	Procedures Overview.....	19
5	First Steps	21
	Package Contents	21
	Unpacking	25
6	Implanting the Trial System	26
	Preparing the Implantation	26
	Inserting the Lead.....	27
	Performing Intraoperative Tests.....	28
	Connecting the Lead.....	29
	Attaching the External Stimulator to the Patient	30
	Programming the Stimulator	30
	Pairing the Patient Programmer with the External Stimulator.....	30
7	Replacing the Batteries of the External Stimulator during the Trial Phase	31
	Removing the External Stimulator from the Patient.....	31
	Replacing the Batteries of the External Stimulator	31
	Attaching the Header at the External Stimulator.....	31
	Testing the Stimulation	32
	Attaching the External Stimulator to the Patient	32
8	Removing the Trial System.....	33
	Removing the External Stimulator from the Patient.....	33
	Removing the Trial Leads.....	33

Collecting the Patient Programmer at the End of the Trial Phase	33
Cleaning, Disinfecting, and Storing the External Stimulator.....	33
9 Implanting the Permanent System.....	36
Preparing the Implantation	36
Inserting the Lead.....	36
Performing Intraoperative Tests.....	37
Anchoring the Lead.....	38
Shaping the Pocket for the Stimulator and Tunnel the Lead	39
Implanting the Stimulator and Connecting the Lead	41
Programming the Stimulator	42
Pairing the Patient Programmer with the Stimulator.....	42
10 Exchanging or Explanting the Permanent System	43
Exchanging the Stimulator	43
Explanting the Permanent System	44
11 Patient Education.....	45
Patient Implant Card	45
Risky Therapeutic and Diagnostic Procedures	45
12 Disposal	46
13 Appendix	47
Technical Data	47
Data Security.....	54
Open Source and Commercial Software	55
Order Numbers.....	55
Disclaimer, Warranty, and Warranty Conditions	56
Electromagnetic Compatibility.....	56
Country-Related Information	57
Symbols on the Implantable Stimulator	57
Symbols on the External Stimulator.....	58
Symbols on the Intraoperative Test Cable.....	58
Symbols on the Patient Affixation Pouch.....	59
Legend for the Label.....	59
14 Verification List (PFH-468-001_A).....	63
5. Implantable Pulse Generator	63
6. Trial Stimulator	83
7. Charger.....	102
10 Leads and Accessories	121
Index	147

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 (SCS) System for the trial phase and for permanent use.

- Implantation of percutaneous leads for trial and/or permanent use
- Connection of the leads for trial use to an external stimulator
- Implantation of an implantable stimulator
- Connection of the leads to an implantable stimulator
- Performance of intraoperative tests
- Explanation 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 storage 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 – Patient Guide for the Implanted System
- Prospera Spinal Cord Stimulation – Patient Guide for the Trial System
- Smartphone manufacturer's information on the patient programmer MyHomeStream
- Smartphone manufacturer's information on the patient programmer MyHomeStream TR
- HomeStreamCP – Clinical Programming of BIOTRONIK External and Implantable Spinal Cord Stimulators
- Tablet manufacturer's information on the HomeStreamCP

Conventions

Marking of Safety Messages

The following symbol indicates potential hazards:



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

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

Classification	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.
Caution	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	<p>The individual steps of an instruction are numbered. Prerequisites, intermediate results, and results may be specified.</p> <p>Prerequisite</p> <ul style="list-style-type: none"> This is a prerequisite. <ol style="list-style-type: none"> First step Second step <ul style="list-style-type: none"> ► Intermediate result Third step <p>Result</p> <p>This is the final result.</p>
Navigation paths	<p>The elements of a navigation path are shown in bold and separated by ">".</p> <p>Example: [Main menu] > [Sub-menu] > [Item]</p>
Cross references	<p>Cross references are indicated using "see" or "see also".</p>
Elements of the user interface	<p>Elements that are displayed on the user interface, such as buttons or menu items, are indicated by square brackets and bold font. Example: [Button].</p>
Emphasis	<p>Text that needs to be emphasized is shown in bold.</p>
Notes	<p>Useful information is indicated using the word Note.</p>

Figures

Figures that show the product or the user interface are used for illustration purposes only. The details shown in the figure may differ from that of the delivered product 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
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

Abbreviation	Meaning
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 Safety

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

Warnings

Please follow the listed safety messages when handling the external 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) from this device, this can result in a reduction in its performance. This applies even when using associated cables.

- When operating portable RF communication devices (including peripheral 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.

Precautions

Safety 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 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.

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

The improper cleaning and disinfecting of an external stimulator may lead to device malfunction and patient injury.

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

Safety 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 or Overheating 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, and to excessive heat development during the charging of the stimulator when 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 skin 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 or migrating.

Injury due to Heat Development during Charging when Using Metallic 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 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.

Safety Messages for Handling the Implant Accessories

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

Skin Injury if Tunneling Is too Shallow

If the tunneling of the implanted leads is too shallow, skin erosion 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.

Spinal Injury due to Puncturing with the Insertion Needle

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

- Dispense pressure in a suitable manner when inserting the insertion 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

Safety 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 stimulator and implanted trial leads:

lithotripsy, RF ablation, hyperbaric oxygen therapy, electrocautery, electrical therapy, high-power ultrasound, radiation therapy, MRI scan.

- Do not apply the above-listed procedures while the patient is undergoing 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 SCS system may interfere with the operation of implanted pacemakers or ICDs.
The effects of an implanted SCS system on other neurostimulators are unknown.



WARNING

Therapy Failure and Harm to the Patient due to External Defibrillation

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 External 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 SCS system. This may cause the stimulator to deliver too much or too little therapy.

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

Safety 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 stimulator or the leads.

- Avoid electrocautery if possible. If electrocautery is necessary, 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 electrocautery.



WARNING

Therapy Failure and Harm to the Patient due to External Defibrillation

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 SCS system may interfere with the operation of implanted pacemakers or ICDs. The effects of an implanted 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 serious patient injuries may occur in the area of the implanted stimulator 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 diathermy 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 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 High-Power Ultrasound Treatment**

Therapeutic and high-power ultrasound treatment exposes the SCS system to high doses of energy, which may lead to damage and function loss of the system and to therapy failure. Excessive heating may lead to tissue damage and patient injuries in the area of the implanted stimulator 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.

**Caution****Therapy Failure and Damage to the 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 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 lithotripsy.

**Caution****Therapy Failure and Damage to the 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.

**Caution****Therapy Failure Caused by Hyperbaric Ambient Conditions**

Therapy environments with increased ambient pressure can lead to insufficient or excessive stimulation 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.

**Caution****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 SCS system. This may cause the stimulator to deliver too much or too little therapy.

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

Sterility

Sterile Delivered Products

**Caution****Risk of Infection in case of Resterilization and Reuse**

The implanted 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 oxide. As a result, the inner blister is also sterile on the outside.

- 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

Storage Period

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

- Implantable stimulator
- Leads
- Active anchor
- Suture anchor
- Tunneling tool

- Spare accessories
- Long insertion needle
- Port plugs

3 System Description

Overview of the System Components

The SCS system consists of various components: the implantable stimulator, one or two percutaneous leads, the clinician programmer, the external stimulator, 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 wireless communication with the clinician programmer and the patient programmer.

Main Components

The 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 housing contains a rechargeable battery that can be charged transcutaneously. The header contains the connections 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 same 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 or 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 SCS system and are connected to the intraoperative test cable or to the implantable stimulator.

Clinician Programmer

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

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

Patient Programmer

The patient programmer is a phone which acts as the interface for 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 use programs transmitted by the physician.

Accessories

The 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.

Suture 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 space for lead insertion.

Clearing Wire

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

Stylet

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 as 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.

Charger

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 of the implantable stimulator.

Magnet

The magnet is used to pair the stimulators with the clinician programmer 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 (SCS) 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 accessories. The SCS system is intended to be implanted and managed by healthcare professionals familiar with the use of neurostimulation devices.

Indications

Spinal cord stimulation 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 FBSS or herniated disk
- Postlaminectomy pain
- Multiple back operations
- Unsuccessful disk surgery
- Degenerative Disk Disease (DDD)/herniated disk pain refractory to conservative and surgical therapies
- Peripheral causalgia
- Epidural fibrosis
- Arachnoiditis or lumbar adhesive arachnoiditis
- Complex Regional Pain Syndrome (CRPS), Reflex Sympathetic Dystrophy (RSD), or causalgia

Contraindicated Patient Conditions

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

- Are unable to operate the SCS system
- Have failed to receive effective pain relief during SCS trial stimulation
- 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.

Intended Users

Medical and Technical Users

The primary users of the SCS system for surgical and follow-up roles are physicians familiar with neurostimulator implantation, follow-up care, and risks associated 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 BIOTRONIK SCS 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 operation 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 out by a trained user of the clinician programmer. This includes pairing, intraoperative testing, programming, preparing the external stimulator for battery replacement, preparing the external stimulator for removal, resetting the patient programmer at the end of the trial phase, and deactivating a stimulator prior to explant.

Steps for Implanting and Removing the Trial System

	Procedure	Step
1	Prepare the implantation	
		Instructions before the Implantation [Page 26]
		Replacing the Batteries of the External Stimulator before each Implantation [Page 26]
2	Implant the trial lead	
		Inserting the Lead [Page 27]
		Performing Intraoperative Tests [Page 28]
		Connecting the Lead [Page 29]
3	Attach and program the external stimulator	
		Attaching the External Stimulator to the Patient [Page 30]
		Programming the Stimulator [Page 30]
		Pairing the Patient Programmer with the External Stimulator [Page 30]
4	Remove the trial system	
		Removing the External Stimulator from the Patient [Page 31]
		Removing the Trial Leads [Page 33]
		Cleaning, Disinfecting, and Storing the External Stimulator [Page 33]

Steps for Implanting the Permanent System

	Procedure	Step
1	Prepare the implantation	
		Instructions before the Implantation [Page 36]
2	Implant the permanent lead	
		Inserting the Lead [Page 36]
		Performing Intraoperative Tests [Page 37]
		Anchoring the Lead [Page 38]
		Shaping the Pocket for the Stimulator and Tunnel the Lead [Page 39]
3	Implant the implantable stimulator	
		Implanting the Stimulator and Connecting the Lead [Page 41]
4	Program the stimulator	
		Programming the Stimulator [Page 42]
		Pairing the Patient Programmer with the Stimulator [Page 42]

Steps for Exchanging or Explanting the Permanent System

	Procedure	Step
1	Exchange the implantable stimulator	
		Exchanging the Stimulator [Page 43]
2	Explant the permanent system	
		Explanting the Permanent System [Page 44]

5 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 55TR

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 55

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 programmer
- Charging cable
- Power plug adapter

MyHomeStream

The storage packaging includes the following:

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

SCS 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

SCS 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

SCS ND 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)

SCS 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 surfaces – unpacked 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.

Sterile 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 or 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.

Checking 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.

Checking 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 25].
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, see Cleaning, Disinfecting, and Storing the External Stimulator [Page 33].
6. Make sure that new batteries are always used for each patient, see Replacing the Batteries of the External Stimulator before each Implantation [Page 26]. If the batteries are not sufficiently charged, the intraoperative testing of the leads cannot be performed 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 use 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 leads.
1. Open the cover of the battery compartment.
 2. Replace the batteries with the provided batteries, see External Stimulator [Page 49]. 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



Caution

Spinal Injury due to Puncturing with the Insertion Needle

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

- Dispense pressure in a suitable manner when inserting the insertion 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 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 monitoring 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 of 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, see Implantable Stimulator [Page 47].
- 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 leads 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 test 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 leads from the intraoperative test cable. Make sure to lift, not pull, the leads off the connectors.

Connecting 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 addition, if the leads are not properly inserted at the header, the lead can be 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 tightening 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 stimulator, the leads of the trial system become non-sterile in the connection area and must be removed 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



Caution

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 under 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 stimulator 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 of the batteries.
 - ▶ If the batteries are inserted correctly, the LED lights up for 5 s and then turns off.
 4. Close the cover of the battery compartment.
 5. Check whether the external stimulator is still connected to the patient programmer.

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 stimulator.

Testing the Stimulation

Prerequisite

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



Caution

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 under 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 stimulator 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 affixation pouch.
7. Thoroughly clean and disinfect the external stimulator, see *Cleaning, Disinfecting, and Storing the External Stimulator* [Page 33].
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 33].
10. Dispose of all used components that are not intended for reuse 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 exits 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 wounds 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.

Collecting the Patient Programmer at the End of the Trial Phase

To prepare the patient programmer for the next use, do the following 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 stimulator.

Cleaning, Disinfecting, and Storing the External Stimulator



Caution

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

The improper cleaning and disinfecting of an external stimulator may lead to device malfunction and patient injury.

- Let the external stimulator be cleaned and disinfected by a BIOTRONIK representative after use 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 compromised 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 stimulation is turned off.

Cleaning 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 solution.
 3. Thoroughly dry the external stimulator.
 4. Check the external stimulator for dirt or visible damage after 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 disinfection.

Storing the External Stimulator **Caution****Risk of Infection or Damage to Stimulator when an External Stimulator Has Not Been Disinfected Correctly**

The improper cleaning and disinfecting of an external stimulator may lead to device malfunction and patient injury.

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

Removing the Trial System

Cleaning, Disinfecting, and Storing the External Stimulator

When the external stimulator has been cleaned and disinfected properly 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 stimulator to the clinician programmer and reset 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 49].

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 25].
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 temperature 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 use the clinician programmer or the patient programmer.

Inserting the Lead



Caution

Spinal Injury due to Puncturing with the Insertion Needle

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

- Dispense pressure in a suitable manner when inserting the insertion 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 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 monitoring 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 of 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, see Implantable Stimulator [Page 47].
- 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 leads 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 test 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 leads from the intraoperative test cable. Make sure to lift, not pull, the leads off the connectors.

Anchoring the Lead



Caution

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 during 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 of the anchor can cause lead conductor breakage. All this can lead to insufficient therapy or 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 supraspinous 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, or bend lead when anchoring to reduce 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 shifted when the insertion needle and the stylet were pulled out.
5. Continue as described below, depending on the chosen anchor.

Suture 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, securing 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 you hear a click.

Shaping the Pocket for the Stimulator and Tunnel the Lead**Caution****Skin Injury if Tunneling Is too Shallow**

If the tunneling of the implanted leads is too shallow, skin erosion 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.

**Caution****Skin Erosion or Overheating 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, and to excessive heat development during the charging of the stimulator when 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 skin 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 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 precautionary 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 incision 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 to the patient's anatomy if necessary.
12. Tunnel a suitable tunnel between the pocket for the stimulator 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 process.
16. Hold on to the tunneling sheath and insert the proximal end of the lead through the tunneling sheath 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 relief 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 stimulator or the leads.

- Avoid electrocautery if possible. If electrocautery is necessary, 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 electrocautery.



Caution

Injury due to Heat Development during Charging when Using Metallic 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 addition, if the leads are not properly inserted at the header, the lead can be 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 tightening 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 same 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 connector 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 37].
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 secure 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 stimulator is not delivering stimulation.
2. Surgically open the pocket of the stimulator. Make sure not to 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, temporarily 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 stimulator.
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 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.
12. If applicable, connect the second lead to the respective connector port of the stimulator in the same 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 37].
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 secure 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 stimulator 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 section 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



Caution

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 regulations; we recommend a suitable recycling method. Do not break 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-specific regulations, or else return it to BIOTRONIK. Dispose of 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

Category	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	12 months
Sterilization	Ethylene Oxide

Material in Contact with Human Tissue

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

Service Time

Category	Design
Service time	9 years

The service time has been calculated as follows:

- 3.0 mA, single electrode pair, 40 Hz, passive balance, 200 μ s 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 μ s pulse width, 750 Ω lead impedance, on 100% of the time, 7-day charge interval, no over discharge
- 1.7 mA, 3 cathode electrodes delivering a frequency of 600 Hz each, active balance, 300 μ s pulse width, 750 Ω lead impedance, on 100% of the time, 24 hr charge interval, no over discharge

Environmental Conditions

Category	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

Category	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

Category	Design
Frequency band	2.4 GHz ISM band
Operating frequency	2400 MHz ... 2483.5 MHz
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 BLOwand

Category	Design
Frequency band	9 kHz ... 315 kHz
Operating frequency	32 kHz ... 64 kHz
Data rate	64 kbit/s
Modulation	OOK

External Stimulator
General Characteristics

Category	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

Service Life

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

Material in Contact with Human Tissue

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

Environmental Conditions

Category	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

Category	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 μ s ... 1000 μ s
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

Category	Design
Frequency band	2.4 GHz ISM band
Operating frequency	2400 MHz ... 2483.5 MHz
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

Category	Design
Frequency band	9 kHz ... 315 kHz
Operating frequency	32 kHz ... 64 kHz
Data rate	64 kbit/s
Modulation	OOK

Lead
General and Physical Characteristics

Category	Design
Overall diameter	1,33 mm
Polarity	8 electrodes
Shelf life	12 months
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

Component	Material
Connector ring	MP35N
Insulation	Polyurethane
Anchor ring	MP35N

Conductor

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

Lead Body

Category	Design
Insulation	Polyurethane
Diameter	1,33 mm

Lead Tip

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

Electrode Ring

Category	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

Service Time

Category	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

Category	Design
Overall length	37.2 mm
Overall diameter	4.4 mm
Height	5 mm

Category	Design
Shelf life	12 months
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Material

Component	Material
Body	Silicone
	TiO ₂
Screw block	Titanium
Screw	Titanium
Mesh	Nitinol

Suture Anchor
General and Physical Characteristics

Category	Design
Overall length	30 mm
Overall diameter	4 mm
Shelf life	12 months
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Material in Contact with Human Tissue

Component	Material
Body	Silicone
	TiO ₂

Port Plug
General and Physical Characteristics

Category	Design
Overall length	16.6 mm
Overall diameter	5.7 mm
Pin length	12.2 mm

Category	Design
Shelf life	12 months
Sterilization	Ethylene Oxide
Storage temperature	+14 °F ... +131 °F (-10 °C ... +55 °C)

Material

Component	Material
Handle	Silicone
Pin	Titanium

Magnet**Dimensions**

Category	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

Category	Operation	Storage 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 stimulator:

- 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 stimulator.
- 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 require a password 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 over 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 security 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).

Open Source and Commercial Software

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

Order Numbers

Component	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

Component	Order Number
Prospera CHG	457862
Neuro M50	457863
Prospera IOC	457866

Disclaimer, Warranty, and Warranty Conditions

<https://www.biotronik.com/warranty-booklet-neuro/>

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 used in such an environment.

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

Section	Test	Test Level
7.1	CISPR 11 RF Radiated emission	<ul style="list-style-type: none"> Group 1 Class B
8.9 / 8.10	IEC 61000-4-2 Electrostatic discharge (ESD)	<ul style="list-style-type: none"> ± 8 kV contact discharge ± 2/4/8/15 kV air discharge
	IEC 61000-4-3 Radiated RF EM fields	<ul style="list-style-type: none"> 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	<ul style="list-style-type: none"> 3 Vrms 6 Vrms in ISM + Amateur Radio Bands 150 kHz ... 80 MHz
	IEC 61000-4-8 Power frequency magnetic fields	<ul style="list-style-type: none"> 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) from this device, this can result in a reduction in its performance. This applies even when using associated cables.

- When operating portable RF communication devices (including peripheral 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 other devices should be avoided, as this may lead to the external stimulator operating incorrectly.

- Where usage in such a manner is unavoidable, you should monitor 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.

Country-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 operation.

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




Symbols on the Implantable Stimulator

Symbol	Meaning
	Identification of port A and port B placement



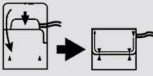
Symbols on the External Stimulator

Symbol	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)

Symbols on the Intraoperative Test Cable












Symbol	Meaning
	BIOTRONIK order number
	Do not reuse
	Lot number














Symbols on the Patient Affixation Pouch

Symbol	Meaning
	BIOTRONIK order number
	Do not reuse
IP 22	<ul style="list-style-type: none"> • 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:

Symbol	Meaning
	Medical device
	Manufacturing date
	BIOTRONIK order number
	Serial number
	Lot number
	Use by
	Unique device identifier
	Product identification number
	Temperature limit
	Humidity limit
	Acceptable atmospheric pressure range for storage

Symbol	Meaning
<p>manuals.biotronik.com</p> 	Follow the instructions for use!
	Contents
	Do not use if packaging is damaged and consult the technical manual
	Manufacturer
	Distributor
<p>R_x only</p>	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
	Device contains materials that must be correctly disposed of in accordance 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
	Do not reuse
	Single sterile barrier