Setrox S

ProMRI®

Bipolar, steroid-eluting endocardial lead with extendable and retractable screw

Technical manual

407053

Revision: G (2016-05-31)

© BIOTRONIK SE & Co. KG
All rights reserved.
Specifications subject to modification, revision and improvement.

® All product names in use may be trademarks or registered trademarks held by BIOTRONIK or the respective owner.

CE 0123 (2005)
90/385/EEC

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

BIOTRONIK
excellence for life

Table of Contents

1 Version Comparison

Change History

Document The changes relate to the following document:

Title	Setrox S
Order number	407053
Revision status, old	F
Revision status, new	G

Changes The following changes relate to the document:

#	Change	In section
1	Description adjusted	Target group, p. 4
2	Note added	Medical complications, p. 8
3	Modification to available accessories	Available accessories, p. 27

2 Description

About this Technical Manual

Target group

This technical manual is targeted at medical personnel, cardiologists, cardiac surgeons and electrophysiologists who are familiar with the following topics:

- The use of implantable pacemakers and / or ICDs and the respective leads, bradycardia therapy and / or tachycardia therapy
- The implantation methods required for this as well as the associated risks and possible complications

This technical manual

This technical manual is either included in hard copy form in the product packaging or can be downloaded as a file from the Internet. In the latter case, the package will include an insert with the URL instead of the technical manual in hard copy form.

Note: Keep this technical manual for later use.

Observe other manuals

Please also observe the technical manuals and accompanying documents for devices combined with this lead (ICD, pacemaker, additional leads) and for devices and accessories used during implantation.

Design and Properties of the Lead

Lead body

The lead body consists of two coaxial coils, each of which is made up of several parallel wires.

The coils make up the conduction paths to the tip and ring electrodes. They are insulated from each other and from the outside environment using silicone.

Electrical properties

Pacing and sensing occurs between the distal pole and the ring electrode.

The fixation screw is electrically active and forms the distal pole (tip electrode) of the lead.

Fixation

The lead tip has an extendable/retractable screw for fixating the lead in the myocardium.

The screw-in mechanism of the fixation screw is operated by rotating the connector pin of the lead connector. This rotates the inner coil inside the lead body.

For improved handling, a fixation tool is provided for the connector pin of the lead connector.

Steroid collar

The lead tip has a steroid collar in the form of a rubber silicone ring that contains dexamethasone acetate.

Lead connection

The lead connector is a bipolar connector as per international standards ISO 5841-3 and EN 50077. It is labeled "IS-1 BI".

Note: Pacemakers and ICDs with connectors that do not correspond to the above-mentioned standards may only be connected to this lead using a suitable adapter. Further information about the compatibility of the lead connectors can be obtained from BIOTRONIK or the manufacturer of the active device.

Overview of key features

The main advantages of the lead are as follows:

- Electrically active fixation screw
- Small distance (10 mm) between the tip and the ring electrode
- Active fixation with screw-in mechanism
- A rotating inner conductor enables extension and retraction of the fixation screw without turning the entire lead.
- Steroid reduces inflammatory processes and threshold increase after implantation
- Electrocardiac measurements possible when fixation screw (tip electrode) is not extended

Intended Use, Indications and Contraindications

Intended use and indications

In combination with a compatible implantable pacemaker or ICD, this lead is indicated for the following:

- Permanent sensing and pacing in the right ventricle or atrium

This lead meets all the above-mentioned clinical requirements.

Note: With its active fixation screw, this lead is especially suited for positioning in the atrium and for patients with deteriorating ventricular trabeculae for whom passive fixation with silicone tines is not possible.

Contraindications

Implantation of this lead is contraindicated in the following cases:

- If the lead is to be guided into the ventricle: Patients with mechanical tricuspid valve prosthesises or severe tricuspid valve diseases
- Patients with an intolerance against dexamethasone acetate

Together with an active device (ICD or pacemaker), this lead constitutes a device system. The indications and contraindications for the lead are similar to those of the respective ICD or pacemaker.

Guidelines

For the indications of an ICD or pacemaker therapy, we recommend following the respective current guidelines of the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), the European Society of Cardiology (ESC), and the German Cardiac Society (DGK), as well as those of other national cardiology associations.

Packaging, Sterility, Storage, and Disposal

Box and label

The lead is delivered in a box bearing a quality control seal and a product information label.

The label contains the following information about the lead:

- Model type
- Technical properties and data
- Serial number
- Use by date
- Details on sterility
- Storage information

Sterility

The lead and its accessories are sealed in two blisters, one within the other, and sterilized with ethylene oxide. As a result, the inner blister is also sterile on the outside.

CAUTION
Risk to sterility due to damaged blister To ensure sterility, the container should be checked for damage prior to opening. Do not use a lead if you are unsure of its sterility.

CAUTION
Resterilization and reuse This lead and the provided accessories are intended for single use exclusively. Reuse of leads or accessories can result in infections, embolisms and damage to the product. Resterilization and reuse are prohibited.

Storage

The following storage conditions must be maintained:

	Storage temperature	Maximum storage duration
Normal conditions	5 - 25 °C	2 years
Short-term exception	5 - 50 C	1 month

CAUTION
Improper storage If the specified time period and temperature range for storage are exceeded, then the documented properties of the lead can no longer be guaranteed. Technical malfunctions - as well as decreased effectiveness of the steroid in the case of steroid-eluting leads - may result.

Disposal

An explanted lead must be disposed of as medical waste in an environmentally friendly and proper manner.

The lead does not contain any materials which require any further provisions.

3 Safety

Medical and Technical Complications

Medical complications

Potential medical complications of using implantable pacemakers or ICDs include the following:

- Formation of fibrotic tissue
- Thrombosis, embolism
- Elevated pacing thresholds
- Foreign body rejection phenomena
- Lead erosion
- Pericardial tamponade
- Valvular damage
- Damage of vessels, nerves or the lung during the placement of the venal access by puncture.
- Muscle and nerve stimulation
- Infection
- Pacemaker-induced arrhythmias (some forms of which can be life-threatening)

Technical complications

The following could result in technical malfunctions of the device system, which consists of pacemaker or ICD and leads:

- Incorrect lead implantation
- Lead dislodgement
- Lead fracture
- Insulation defect
- Battery depletion or component failure of the active device

Potential adverse events and corrective measures

Some of the potential adverse events and corrective measures are listed in the table below.

Problem	Possible cause	Corrective measure
Loss of pacing or sensing	Improper connection between lead and the active device	Properly connect the lead to the active device.
	Lead dislodgement	Reposition lead.
	Lead fracture	Replace lead.
	Insulation defect	Replace lead.
Significant worsening of the threshold	Excessive fibrotic tissue formation	Adjust pulse amplitude and pulse width; reposition or replace the lead.

Risky Therapeutic and Diagnostic Procedures and Environmental Influences

Improper procedures

The procedures listed in the following table must be avoided for patients with an implanted lead or a device system (pacemaker or ICD).

Procedure	Type of danger
Diathermy	• Tissue damage due to excessive heating of the lead • Induction of ventricular fibrillation
Magnetic resonance imaging (Please read the explanation at the end of this section.)	• Tissue damage due to excessive heating of the lead • Change of position of the lead (lead dislodgement) or the active device • Pulse inhibition, asynchronous and/or triggered pulse delivery by the active device
Hyperbaric oxygen therapy	• Penetration of bodily fluids into the lead or device
Transcutaneous electrical nerve stimulation (TENS), stimulation current	• Induction of ventricular fibrillation

Note: Tissue damage due to excessive heating usually causes change or loss of the sensing and pacing function of the implanted lead.

Magnetic resonance imaging

Magnetic resonance imaging is contraindicated due to the associated high frequency fields and magnetic flux density.

- Patients with an implanted lead of this type may be examined using magnetic resonance imaging only when specific measures have been taken to ensure the safety of the patient and device.
- Please contact the responsible authorities or BIOTRONIK beforehand to determine whether these products are actually certified "MR conditional" in your country or region.

ProMRI®	• You can find detailed information about the requirements, conditions and measures for safely conducting an MRI scan in our manual "ProMRI®, MR conditional device systems." You can download this manual as a PDF file from www.biotronik.com/manuals/manualselection or https://manuals.biotronik.com or order a printed copy from BIOTRONIK.

Risky procedures

The table below provides an overview of procedures that present a risk to patients with an implanted lead or a device system. Take appropriate precautionary measures and observe the specific instructions listed in the table.

Procedure	Type of danger	Recommendations for risk mitigation
Therapeutic ultrasound	Tissue damage due to excessive heating of the lead	Do not direct the energy focus onto the lead or the device. Afterwards: perfom a full follow-up.
External defibrillation	Tissue damage due to excessive heating of the lead	Afterwards: perfom a full follow-up.
Electrophysiological ablation	Tissue damage due to excessive heating of the lead Induction of ventricular fibrillation Damage to the lead	Switch off the active device beforehand. Keep as much distance as possible between the ablator and the lead. Following ablation and prior to restarting the active device: perfom a full follow-up.
HF surgery (electrocautery)	Tissue damage due to excessive heating of the lead Induction of ventricular fibrillation	Do not direct the energy focus onto the lead or the device. Afterwards: perfom a full follow-up.
Lithotripsy	Mechanical effect on or damage to the lead	Keep energy focus from the lead. Afterwards: perfom a full follow-up.

Note: Tissue damage due to excessive heating usually causes change or loss of the sensing and pacing function of the implanted lead.

Problematic environmental influences

- Increased ambient pressure:
  The leads are manufactured under standard atmospheric pressure and are not designed to withstand increased ambient pressure.
  Stress resulting from excess pressure may damage the leads.

CAUTION

Damage and failure of the device system

Patients with device systems must avoid situations or environments in which they would be exposed to high ambient pressures (such as diving or pressure chambers).

- Electromagnetic interference:
  Electromagnetic fields may negatively affect patients with device systems as the intensity and duration of exposure increase. This can have the following consequences:
  — Temporary or permanent effect on or damage to the device system
  — Induction of tachycardias, up to and including ventricular fibrillation (in rare cases)
  — Thermal tissue damage (in severe cases)
  The patient should be properly informed and instructed on behaviors to avoid situations with especially risky electromagnetic effects.
  Perform a follow-up for clarification if electromagnetic interference is suspected to have impaired the function of the device system.
  In most cases, the problem can be solved by reprogramming the device.

Electrical and Electromagnetic Safety

Electrical safety

Implanted leads are a direct electrical connection to the myocardium.

Therefore, it is important for the safety of the patient that no electrical energy - other than the pulses from the active device - is conducted to the lead, neither by direct contact nor indirectly due to electromagnetic conduction.

WARNING
Risk of death due to induction of ventricular fibrillation
Ensure that the contact surfaces of the lead connectors of implanted leads never touch any electrically conducting or wet surfaces, including human hands or skin.

Electromagnetic induction

A lead can receive electromagnetic energy as an antenna would and cause electrical voltages at the lead tip and connector.

This can induce ventricular fibrillation in some cases, as well as damage or otherwise affect the active device and, if the energy dose is high enough, even damage the myocardium.

Note: For information about therapy or diagnostic procedures that pose a potential risk, refer to the appropriate section of this manual (see Risky Therapeutic and Diagnostic Procedures and Environmental Influences, p. 9).

Additional information

For further information about this topic and possibilities of risk mitigation, refer to the manuals for BIOTRONIK active devices.

Preventing leakage currents

Leakage currents to the active device, the lead or directly to the myocardium must be prevented, as they can trigger lethal arrhythmias.

Line-powered devices operated in the patient's vicinity must always be grounded according to regulations. Otherwise, there is a danger of leakage currents caused by such devices being conducted to the myocardium via the lead.

Only connect the lead to battery-powered measurement and pacing devices or to devices that are classified as type CF (Cardiac Floating) applied parts complying with EN 60601, and follow the instructions in the respective technical manuals.

4 Handling and Implantation

Basic Advice and Precautionary Measures for the Implantation

- Always implant the lead using X-ray monitoring.
- Monitor the ECG carefully during implantation and keep external defibrillation equipment and a pacing system analyzer on standby.
- Handle the lead with care. Any strong application of force, such as bending, stretching and kinking, can permanently damage the lead.
- Do not perforate or damage the lead's insulation or coils when working with the stylet, tweezers, or other surgical instruments.
- To prevent mechanical overstressing from causing failure of the pacing/sensing function, make sure that the lead does not become pinched between the clavicle and the first rib after implantation.
- Ensure that the lead fixation sleeve is close to the connector, so that insertion and positioning of the lead is not hindered.
- Always use the supplied lead fixation sleeve when implanting the lead. This will reduce the risk of lead dislodgment and protect the lead body from possible damage from a ligature.
- Move active fixation leads intracorporally only when the screw is fully retracted because an extended screw could tear the vascular wall or perforate the myocardium.
- Coagulated blood can affect the maneuverability of the stylet in the lead and inhibit or block the screw mechanism.
  - — Ensure that no blood reaches the interior of the lead on, or with, the stylet.
  - — As far as possible, prevent blood from entering the lead from other pathways.
  - — If needed, use a spare stylet or, when the screw mechanism is affected, replace the lead with a new one.
- The use of unsuitable stylets or improper handling of the stylet can result in damage to the lead (such as detachment of the silicone insulation at the ring electrode or separation of the contact ring from the lead connector).

  This would result in malfunction or failure of the lead.
  - — Use only a suitable stylet for the respective lead (based on length and diameter). Refer to the Technical Data section for further information.
  - — Never use extremely curved or bent stylets.

Note: Suitable spare stylets are included in sterile packaging with the lead. They can also be ordered individually as accessories.

The use of active fixation leads is associated with an increased risk of perforation and rupture.

- The lead should be implanted in such a way that the fixation screw is not tensed during contraction and relaxation movements of the heart or other movements made by the patient.
- Fixate the lead at the incision point of the vein so that there is no tension and so that the action of the tricuspid valve is not impeded.

Information on the Steroid Collar

Intended medical use

The lead tip has a steroid collar in the form of a silicone rubber ring that contains dexamethasone acetate.

The intended effect is the reduction of the inflammatory processes after implantation and the inflammation-related post-operative threshold increase (lead maturation behavior).

CAUTION
Premature elution of the steroid Do not wipe the lead or immerse the lead in liquids any more than absolutely necessary.

Long-term performance of the steroid eluant

The greater the elapsed time since the implantation, the more the original amount of steroid is eluted.

Over time, the maturation behavior of the lead begins to resemble that of the same type of lead without steroid-eluting properties. This aspect must be considered if a lead is to be repositioned.

Opening the Package

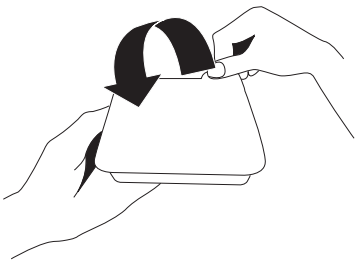
Packaging composition

The lead and its accessories are sealed in two blisters, one within the other, and sterilized with ethylene oxide. As a result, the inner blister is also sterile on the outside.

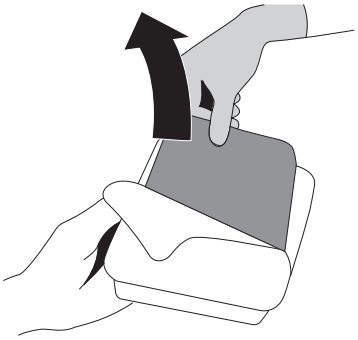
You can remove the inner blister by using a standard aseptic technique and place it in the sterile field.

How to open the package

To open, proceed as follows:

Step	Figure	Action
1		In the non-sterile area: open the outer blister by peeling off the paper seal in the direction of the arrow.

CAUTION
Risk to sterility The inner blister must not come into contact with non-sterile instruments or be touched by persons who are not wearing sterile gloves.

Step	Figure	Action
2		In the sterile area: • Remove the sterile inner blister by using the gripping tab. • Open the inner blister by peeling off the paper seal in the direction of the arrow.

Checking the Function of the Fixation Screw before Implantation

Function

Use the enclosed fixation tool to extend the fixation screw (turn right, clockwise) and retract it (turn left, counterclockwise).

When fully extended, the fixation screw protrudes a maximum of 1.8 mm from the lead body.

Number of rotations

The maximum number of rotations permissible for the complete extension of the fixation screw and the maximum number of rotations required to do so are listed in the "Technical Data" section of this technical manual.

The exact number of rotations required depends on several factors:

- Lead length
- Precise position and curves of the lead
- Residual torque in either direction resulting from previous rotational movements
- Increased static friction with first use of the screw mechanism after long storage

CAUTION
Damage to the lead caused by turning the screw mechanism too far
Do not exceed the maximum number of rotations to extend or retract the fixation screw as specified in the Technical Data section.

Checking the screw mechanism before implantation

Before starting the implantation process, test proper functionality of the screw mechanism by fully extending and retracting the fixation screw.

CAUTION
Damage to the lead when using the screw mechanism
Please take the following precautions into account to prevent damage to the lead: • Only use the lead with a stylet inserted, even if you only want to check the screw mechanism. • The stylet must not be kinked or overbent. • Only use the provided fixation tool clamped to the connector's contact pin to extend or retract the fixation screw. Do not use any other tools or accessories.

CAUTION
Leads with a defective screw mechanism are not suitable for implantation
Do not implant the lead if it fails the function test. Instead, use a replacement lead that has passed the same test.

Step	Action
1	Remove the stylet guide from the lead connector. It will remain on the part of the stylet that is protruding from the lead. The stylet remains entirely in the lead.
2	Clamp the enclosed fixation tool on to the connector pin of the lead connector. Alternative: Clamp the connector's contact pin into the groove of the fixation tool.
3	Turn the fixation tool in a clockwise direction until the fixation screw is fully extended.
4	Turn the fixation tool in a counterclockwise direction until the fixation screw is fully retracted.
5	Remove the fixation tool from the connector pin and place the stylet guide back on the lead connector.
6	Do not implant the lead if it fails the function test. Instead, use a replacement lead that has passed the same test.

Accessing the Vein and Inserting the Lead

Preparing the lead

After all implantation preparations have been made, proceed as follows:

Step	Action
1	Ensure that the fixation screw is completely retracted.
2	Move the premounted lead fixation sleeve close to the lead connector.
3	Ensure that a straight stylet is completely inserted into the lead.

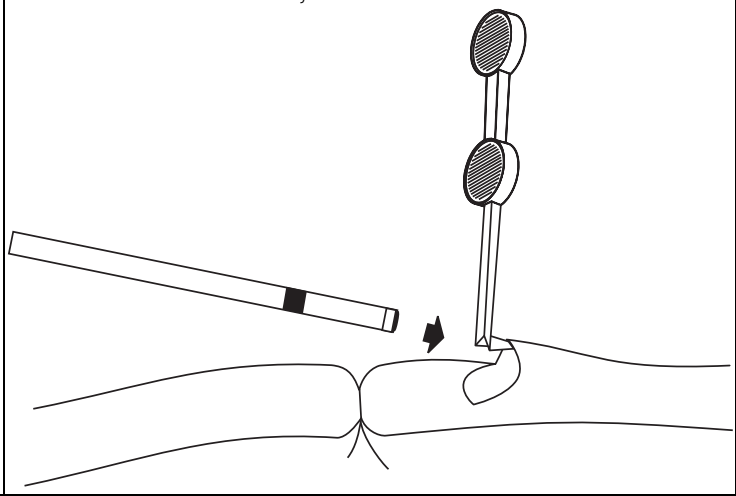
Two methods of accessing the vein

There are 2 options for inserting the lead into the vein:

Either	Method A	Incision of the cephalic vein
Or	Method B	Puncturing the subclavian vein

Method A

Through the cephalic vein:

Step	Action
1	Prepare the cephalic vein.
2	Open the vein.
3	Carefully insert the tip of the vein lifter provided into the lumen of the vein.
4	Raise the vein lifter carefully. 
5	Insert the lead into the vein through the opening.

Method B

Through the subclavian vein:

- Use a suitable lead introducer set.

  Stop the procedure if the lead cannot be easily inserted into the introducer sheath and check whether the lead introducer set is appropriate for the lead.
- Please consult the technical manual included with the lead introducer set.

After having established access to the vein using the lead introducer set, insert the lead into the vein through the introducer sheath.

Positioning and Fixating the Lead

Prerequisite

Access to the vein has been obtained through incision of the cephalic vein or puncture of the subclavian vein, and the lead tip has been inserted.

Atrium or ventricle

The subsequent procedure varies according to where the lead is to be positioned and fixated:

Either	In the atrium
Or	In the ventricle

Positioning the lead in the atrium

Positioning the lead in the atrium:

Step	Action
1	Advance the lead tip into the right atrium.
2	Remove the straight stylet from the lead and replace it with a J-shaped or curved stylet.
3	Find a suitable position for the lead tip: • If possible, perpendicular to the myocardium

Positioning the lead in the ventricle

Positioning the lead in the ventricle:

Step	Action
1	Carefully advance the lead tip through the tricuspid valve into the right ventricle.
2	Find a suitable position for the lead tip: • Close to or on the ventricular apex. • If possible, perpendicular to the myocardium

Test measurement to assess the lead position

The electrically active tip of the fixation screw can also contact the myocardium when the screw is retracted.

Thus, the position of the lead tip can be assessed prior to fixation using electrocardiac measurements without injuring the tissue.

Fixating the lead tip

When the lead tip has been placed in a suitable position in the atrium or the ventricle, the fixation screw is screwed into the myocardium in order to fixate the lead tip.

Step	Action
1	Remove the stylet guide from the lead connector. It is now on the end of the stylet that is protruding from the lead. The stylet remains entirely in the lead.
2	Clamp one of the included fixation tools onto the contact pin of the lead connector.
3	Anchor the lead tip in the myocardium by rotating the fixation tool to the right.

Note: The position of the fixation screw can be clearly seen on the X-ray image when the lead is X-rayed from the lateral view (see figure).

X-ray image of the lead with retracted fixation screw:

X-ray image of the lead with extended fixation screw:

WARNING

The myocardium can be damaged if the fixation screw is over-rotated!

Only rotate the fixation screw as many times as are necessary for complete extension.
Observe the position of the fixation screw on the X-ray.

CAUTION

Damage to the lead

The following circumstances may damage the lead to the point of uselessness:

- The screw mechanism has become sticky due to coagulated blood or bodily fluids.
- The screw mechanism has been substantially overwound during retraction or extension.

CAUTION

Avoid excessive pressure on the lead

Temporary or sustained excessive pressure exerted by the lead tip on the myocardium can cause short-term or long-term lead failure, pressure necroses, myocardial perforations, irritation to the tricuspid valve or other unwanted complications.

- Apply pressure carefully when fixating the lead tip.
- Consider the following two aspects when elongating between the distal and proximal fixations of the lead:
  - The patient's own movement and heart contractions should not exert tensile force on the fixation.
  - The constant pressure applied to the myocardium by the lead tip should remain as low as possible.

4	If, due to repeated extension and retraction of the fixation screw (repositioning of the lead tip), the mechanism becomes stiff or tight, you have the following options: • No longer use the screw mechanism. • Replace the lead with a new one. • Rotate the entire lead with inserted stylet counterclockwise in order to unscrew the lead from the myocardium without using the screw mechanism.
5	If the stylet can only be moved in the lead using excessive force, the following measures are recommended: • Do not continue to reposition the lead. • Replace the lead with a new one.

Measuring Pacing Threshold and Intracardiac Signals

Temporary contact with the lead

To obtain short-term measurements of pacing thresholds and the intracardiac potential, clamp an alligator clip to the connector pin through the opening in the stylet guide.

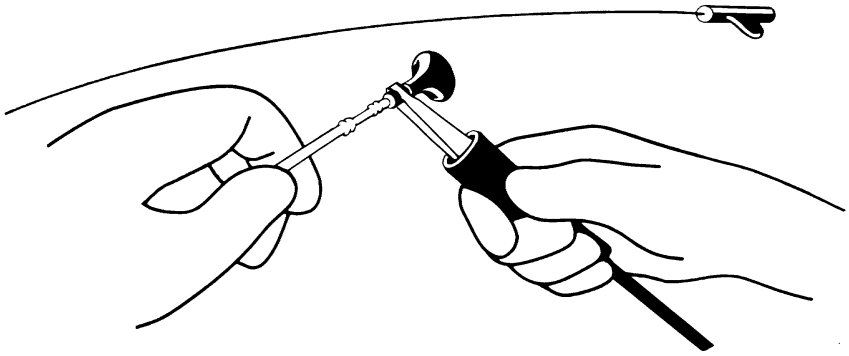
The contact ring of the bipolar lead connector is directly accessible for an additional alligator clip.

CAUTION

Damaging the seal

Ensure that the sealing rings of the lead connector are not damaged by the alligator clips.
This applies especially when connecting an alligator clip to the contact ring of the lead connector.

Clamping an alligator clip to the connector pin:



Safety warnings

Observe the following when measuring the thresholds and the intracardiac potentials!

WARNING

Leakage currents can trigger ventricular fibrillation

Only conduct electrophysiological measurements or temporary pacing through implanted leads with devices that are classified as type CF (Cardiac Floating) applied parts complying with EN 60601 or with battery-powered measuring and pacing devices.
All other line-powered devices connected to the patient must be properly grounded.

Suitable measuring devices

Measuring devices that are adapted to the properties of active devices are provided to measure the threshold and determine the intracardiac potential.

The input filter characteristics of the measuring device must be as close as possible to those of the active device, especially when evaluating the intracardiac signal amplitude.

Measuring the threshold

In order to measure the pacing threshold, the pacing rate of the measuring device should be set slightly higher than the patient's intrinsic rate (if present).

The threshold is the lowest pulse amplitude at which the heart can still be paced.

CAUTION

Risk of interrupted pacing

During intracardiac measurements, any conceivable pacing will be temporarily interrupted.

Target values

Generally, the lead position is considered acceptable if the pacing threshold does not exceed the maximum values shown below, and the intracardiac signal amplitudes do not fall below the minimum values shown below:

	Atrium	Ventricle	Measurement condition
Pacing threshold	Max. 1.5 V	Max. 1.0 V	Pulse width: 0.5 ms
Intracardiac signal	Min. 1.5 mV	Min. 5 mV	--

Note: A recently implanted lead can irritate the myocardium.
This can result in a temporary change in the measured values.
Wait until the measured values have become sufficiently stabilized. In general, this occurs 5 to 10 minutes after fixation.

Fixating the Lead at the Lead Incision Point

Purpose Fixating the lead at the incision point in the vein or in the muscle minimizes the risk of dislodgment.

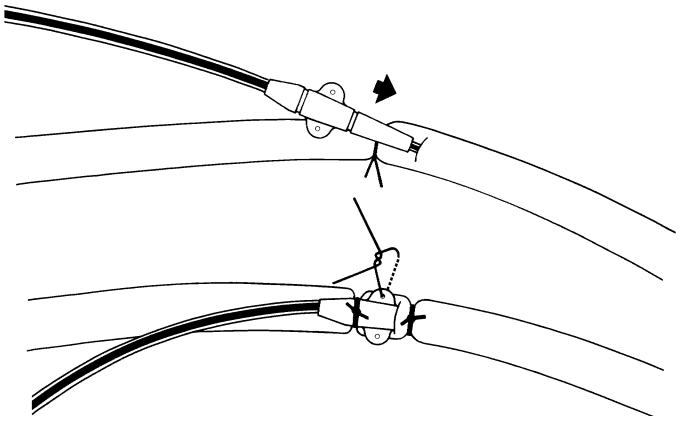
Prerequisites Placement of the lead and measurement of the threshold and the intracardiac signals were successful.

CAUTION
Tensile force on the endocardial fixation or impediment of the heart valve
The distance between the fixations at the tip and at the entry site of the lead must be dimensioned in such a way that the following conditions are met: • Contraction of the heart and other movement of the patient should not put tension on the fixation. • The tricuspid valve's function must not be hindered by the lead.

Lead fixation sleeve The lead comes with a lead fixation sleeve which has ligature grooves and ligature tabs.

The lead fixation sleeve enables secure and smooth fixation of the lead at its entry site and decreases the risk of damaging the insulation or coil during fixation.

Example: Fixate the lead at the incision site of the vein using the fixation sleeve.



Connecting the Lead to the Active Device's IS-1 Connector

Note Further information on connecting the lead to the active device's IS-1 connector may be found in the technical manual of the designated pacemaker or ICD.

Prerequisites The placement of the lead and the measurement of the threshold and the intracardiac signals were successful.

Procedure Proceed as follows to connect the lead to an IS-1 connector:

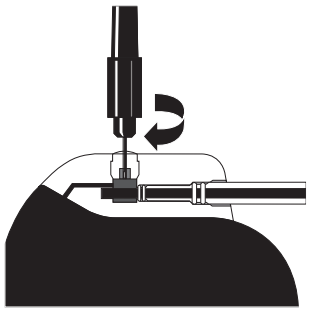
Step	Action
1	Remove the stylet and the stylet guide from the lead.
2	Using the screwdriver (included with the active device), pierce the center of the silicone plug vertically and insert the tip of the screwdriver into the set screw located on the header of the active device.
3	Using the screwdriver, rotate the set screw(s) counterclockwise until the connector port of the active device is completely clear.

CAUTION
Damage to the lead connector
Ensure that the set screw(s) in the connector ports of the active device do not impede the smooth insertion of the connector into the port.

CAUTION
Damage to the thread
To avoid cross threading, never fully remove the set screw(s) from their threaded holes.

Step	Action
4	Insert the lead connector into the connector port of the active device. Please consult the technical manual provided with the device for this procedure.
5	Tighten the set screw(s) by turning the screwdriver in the clockwise direction.

CAUTION
Damage to the thread
Use a screwdriver with torque control! The screwdriver provided with the active device ensures optimal torque for securing the connector without damaging the thread.

Step	Action
6	Check that the connector has been correctly inserted (that it has been placed deep enough). The tip of the connector should visibly extrude from the other side of the header as illustrated in the following figure: 
7	Carefully withdraw the screwdriver without retracting the set screw. When you withdraw the screwdriver, the silicone plug automatically seals the lead connector port safely.
8	• If the bipolar IS-1 connector port has only one set screw, the connection to the contact ring is already established via a spring contact in the port while introducing the connector. • If the bipolar IS-1 port has two set screws, proceed with the second set screw in the same way as with the first set screw.
9	Do a final visual and mechanical check by pulling on the connection carefully.

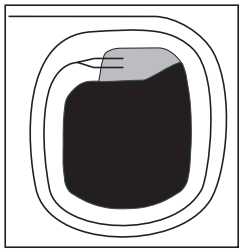
Note: For active devices that require a separate silicone plug to be inserted into the screw hole, proceed as indicated in the technical manual provided with the respective device.

Lead Placement

Depending on the implantation site and patient's anatomy, the lead may be longer than required to connect the active device and position the lead in the heart.

In this case, we recommend placing the excess lead length around the active device in loose loops.

Schematic diagram: Placing the lead around the active device



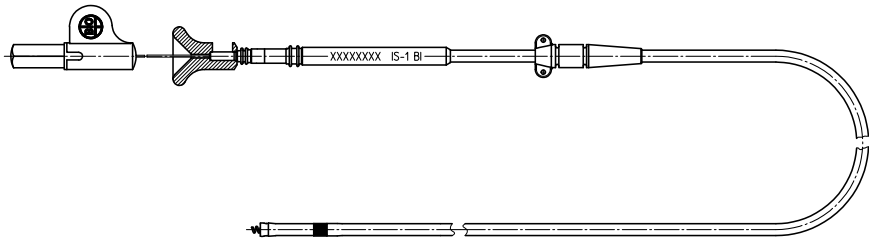
CAUTION
Damage to the lead as a result of mechanical overstress
When positioning the lead, make sure it is not knotted, twisted or bent.

CAUTION
Damage to the lead as a result of mechanical overstress
If the active device is implanted underneath the pectoral muscle, ensure that no parts of the lead lie between the housing of the device and the ribs. Otherwise local pressure and abrasion can damage the lead insulation.

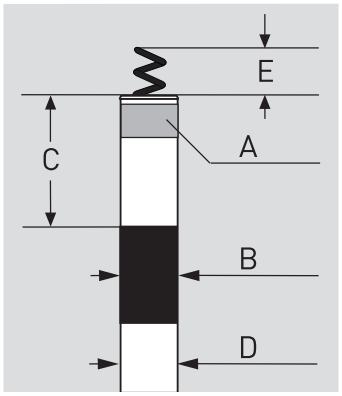
5 Appendix

Technical Data

Lead Schematic diagram:



Lead tip

Diagram: details and dimensions	Legend	
	A	Steroid collar
	B	Diameter: 2.23 mm (6.7 F)
	C	10 mm
	D	Diameter: 2.2 mm (6.6 F)
	E	Max. 1.8 mm

IS-1 connector

Design	IS-1, bipolar
Suitable for active devices with an IS-1 connector	
Labeling	IS-1 BI
Material of contacts (connector pin and contact ring)	Stainless steel
Material of insulation	Silicone

Fixation screw

Properties		Extendable/retractable, electrically active
Penetration depth (extended length)		Maximum 1.8 mm
Electrically active surface (size)		4.5 mm^2
Material		Platinum/iridium alloy
Surface, structure		Iridium, fractal
Typical number of rotations for extension or retraction		6 to 9 rotations
Maximum number of rotations for extension or retraction		
	Setrox S 45	19 rotations
	Setrox S 53	20 rotations
	Setrox S 60	21 rotations

Ring electrode

Outer diameter	2.23 mm (6.7 F)
Surface (size)	17.5 mm^2
Material	Platinum/iridium alloy
Surface, structure	Iridium, fractal
Distance to tip electrode	10 mm

Lead body

Material of insulation		Silicone	
Material of wire (conductor)		MP35N	
MP35N is a registered trademark for special cobalt-chrome-nickel alloys.			
Outer diameter		2.2 mm (6.6 F)	
Lead length	Model	Length	
	Setrox S 45	45 cm	
	Setrox S 53	53 cm	
	Setrox S 60	60 cm	
Number of wires per coil		4	
Resistance conductor to tip electrode		0.65 ± 0.13 Ω/cm	
Resistance conductor to ring electrode		2.04 ± 0.35 Ω/cm	

Steroid

Active ingredient	Dexamethasone acetate
Quantity	0.75 mg
Steroid carrier	Silicone

Storage conditions

Permissible storage temperature range	5-25°C (50°C; max. 1 month)
Permissible storage period	2 years

Package contents

In the sterile packaging:

- Lead with premounted stylet
- Lead fixation sleeve made of silicone rubber, premounted on the lead
- Vein lifter
- Stylet guide
- Fixation tools
- Additional stylets

In box (non-sterile):

- Technical manual (printed)

  or

  Supplement with information on how to download the technical manual as a PDF file from the Internet

Available accessories

Recommended product	Name / specification	Order number
Lead introducer set	LI-7 plus	352722
Stylets for Setrox S 45 lead	S 45 K S 45 F S 45 J S 45 JL	113588 130091 113395 353385
Stylets for Setrox S 53 lead	S 53 K S 53 F S 53 J S 53 JL	107235 130093 107237 353234
Stylets for Setrox S 60 lead	S 60 K S 60 F	106162 124697
Vein lifter	--	--
Lead fixation sleeve	7 F	--
Fixation tool for active fixation	Suitable for IS-1 connector	--

Note on lead introducer set

Note: Prior to using an introducer sheath with hemostatic valve, check whether the lead can be guided through the valve without difficulty.
If necessary, select a larger diameter than recommended in the table above in order to minimize the risk of damage to the lead.

Disclaimer

Conditions of use and requirements

Implantable BIOTRONIK leads (called "leads" in the following) are sophisticated, precision mechanical medical products.

They should be as thin and flexible as possible.

After implantation, they are subjected to great stress due to the mobilization of the immune defense of the human organism.

Although they are designed to function reliably for many years under the given conditions, their resilience and durability are limited.

Risks and possible complications

Problems or failures that occur during or after lead implantation can have many causes, including the following:

- Medical complications
- Foreign body rejection phenomena
- Fibrosis
- Lead dislodgement
- Erosion
- Migration through body tissue
- Insulation defect

Risk of damage

Despite meticulous care in development, material selection, production, and final inspection prior to delivery, leads can be easily damaged in the event of improper handling or use.

Limitation of liability

BIOTRONIK does not guarantee that the following events will not occur:

- Lead malfunctions or failures
- Immune response of the body against lead implantation
- Medical complications (including myocardial perforation) during lead implantation or as a consequence of implanting the lead

The same applies to implantation and lead accessories by BIOTRONIK.

Burden of proof for defective goods

The state of the product at the time of sale is critical for any product returns.

No liability is assumed for any defects not immediately detected upon receipt of the goods.

Responsibility for complications and consequential damage

The buyer/user bears the entire risk associated with the use of the lead.

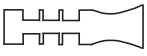
BIOTRONIK shall not be liable for any loss, damage, or injury of any nature, whether direct, indirect, or consequential, that may occur in connection with the leads and accessories or their use.

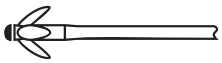
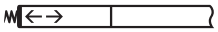
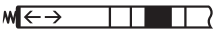
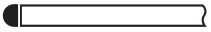
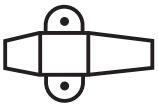
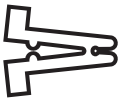
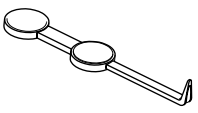
BIOTRONIK shall not reimburse the customer or a third party for any costs incurred in connection with the use, malfunction, or failure of any lead or accessory, including physician's fees, hospital expenses, medication costs, subsidiary costs, and costs for consequential damages.

Final clause

No one is authorized to hold BIOTRONIK liable for any statement or warranty deviating from the above.

Legend for the Label

Symbol	Meaning
	Manufacturing date
	Use by
	Storage temperature
	BIOTRONIK order number
	Serial number
	Lot number
	Sterilized with ethylene oxide
	Do not resterilize
	Single use only. Do not re-use!
	Non-sterile
	Follow the instructions for use!
	Contents
	Do not use if packaging is damaged
	CE mark
	Unipolar IS-1 connector
	Bipolar IS-1 connector
	Unipolar DF-1 connector
	DF4 connector for ICD leads with one shock coil
	DF4 connector for ICD leads with two shock coils
	IS4 connector for quadripolar LV lead
	Adapter for IS4 and DF4 connectors

Symbol	Meaning
	Unipolar endocardial lead with tines for passive fixation
	Bipolar endocardial lead with tines for passive fixation
	Unipolar, endocardial active fixation lead with extendable and retractable screw
	Bipolar, endocardial active fixation lead with extendable and retractable screw
	Unipolar LV lead, fixation using preformed tip
	Bipolar LV lead, fixation using preformed tip
	Unipolar LV lead, fixation in vessel using silicone thread
	Bipolar LV lead, fixation using electrically passive, preshaped tip; two ring electrodes for left atrial application
	Outer diameter
	Maximum outer diameter
	Minimum internal diameter
	Maximum permissible guide wire diameter
	Total length
	Surface and material of the indicated lead
	Recommended size of the lead introducer set
	Additional stylets
	Lead fixation sleeve, premounted on the lead inside the sterile packaging
	Fixation tool for active fixation leads
	Vein lifter
	Torque tool for OTW guide wires

Symbol	Meaning
	Teflon cannula for the hemostatic valve
	MR conditional Patients with a device system having implanted devices labeled with this symbol on the packaging can be examined using an MRI scan under precisely defined conditions.
A	Atrium
V	Ventricle
LA	Positioning the lead in the coronary venous system for left atrial pacing
LV	Positioning the lead in the coronary venous system for left ventricular pacing
CS	Coronary sinus
Pace	Pacing
Sense	Sensing
Shock	Shock
DXA	Dexamethasone acetate as steroid eluant