Sentus ProMRI OTW QP L, S

ProMRI®

Quadripolar CS lead, suitable for 5 F catheters

Technical Manual

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1 Description

About this Technical Manual

Target Group

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

- The use of implantable triple-chamber pacemakers or ICDs and the respective leads
- 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 (https://manuals.biotronik.com/manuals/home).

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 a coil made up of several parallel wires.

The insulation is composed of silicone and has a coating to improve gliding properties.

Pacing and sensing

Sentus OTW QP features four electrodes in total (one tip and three ring). This allows for programming numerous sensing and pacing paths using one to two electrodes out of the four.

The contact surfaces of the tip and ring electrodes are equipped with a fractal iridium coating.

Lead connection

This lead is equipped with an IS4 connector.

This connection is designed as a quadripolar lead connector as per international standards ISO 27186 and is labeled "IS4-LLLL (LV)".

Lengths

Three lengths are available: 77 cm, 87 cm, and 97 cm.

Fixation

Two models are available for atraumatic fixation in a left ventricular coronary vessel:

- Model "QP S":
  - With a silicone thread between the tip electrode and the ring electrode, which wedges itself directly between the vessel walls
  - Suitable for coronary vessels with small internal diameters
- Model "QP L":
  - With a pre-shaped two-dimensional S-curve of the distal area
  - Suitable for coronary vessels with an internal diameter that is larger than the lead diameter.

Positioning

The lead can be guided into the target vein with a stylet or using the over-the-wire technique.

Seal for the guide wire

A seal at the lead tip prevents blood from penetrating the inner lumen of the lead.

The seal is designed so that the guide wire can be introduced from either the proximal or distal end of the lead.

Suitable stylets

Only the stylets provided with the lead and the stylets listed as suitable accessories within the lead's technical manual may be used for this process.

These stylets have the following features:

- Specially shaped distal end that ensures that the stylet reaches the lead tip in a defined manner
- Shaping near the handle to lock the stylet in the lead, which preserves the prestress between the stylet and the lead

Suitable implantation accessories

BIOTRONIK recommends that a combination of an inner and an outer Selectra guiding catheter be used for implantation of Sentus OTW QP.

The Selectra CS lead introducer system is a combination of implant accessories and various CS guiding catheters that was specifically designed for this lead.

Intended Use, Indications and Contraindications

Intended use and indications

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

- Permanent, transvenous implantation in the coronary venous system via the coronary sinus of the left side of the heart
- Permanent sensing and pacing of the left ventricle

Left ventricular pacing is indicated for patients who need ventricular resynchronization.

It can also be an alternative if the use of ventricular endocardial leads is contraindicated due to an artificial tricuspid valve.

The implanting surgeon is responsible for choosing the fixation and length variant.

Contraindications

Implantation of this lead is contraindicated in the following cases:

- Existing epicardial leads for left atrial pacing
- Coronary sinus anomalies
- Damage to tissue in the coronary sinus area resulting from infarction
- Venous anomalies that exclude transvenous implantation of leads
- Intolerance to dexamethasone acetate

Guidelines

For indications and contraindications of an ICD or pacemaker therapy, we also recommend following the respective current guidelines of the Heart Rhythm Society (HRS), the American College of Cardiology (ACC), the American Heart Association (AHA), and the German Cardiac Society (Deutsche Gesellschaft für Kardiologie, Herz- und Kreislaufforschung), 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 is intended for single use only. Reuse of leads can result in infections, embolisms and damage to the device. Resterilization and reuse are prohibited.

Storage

The following storage conditions must be maintained:

Storage temperature	Maximum storage duration
5 - 55 °C	2 years

CAUTION
Improper storage If the specified time periods and temperature ranges 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.

2 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
- 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 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 duration; 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 this lead implanted 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 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 given in the table.

Procedure	Type of danger	Recommendations for risk mitigation
Therapeutic ultra-sound	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 defibrilla-tion	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 (electro-cautery)	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 cham-bers).

- 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. 8).

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.

3 Handling and Implantation

Implantation: Basic Instructions and Safety Measures

Basic information

- Always monitor the implantation with X-ray equipment.
- 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.
- Under no circumstances is the inner lumen of the lead to be rinsed with irrigation fluid. The excess pressure inside the lead that results from this can damage the silicone insulation.
- 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 dislodgement and protect the lead body from possible damage from a ligature.
- When puncturing the subclavian vein: To prevent mechanical overstressing from causing failure of pacing/sensing functions, make sure that the lead does not become pinched between the clavicle and the first rib after implantation.

Information on the procedure with guide wire (over-the-wire)

- Use only a guide wire with a diameter of max. 0.36 mm (0.014 inches). Using a guide wire with a larger diameter can cause lead damage.
- Make sure that the guide wire is not kinked.
- When inserting the proximal end of the guide wire into the lead tip:
  - Take particular care to prevent damaging the seal inside the lead.
  - You can reduce the force that needs to be applied and reduce the risk of damaging the lead by keeping the distal pre-formed shape of the lead straight until the guide wire is in this area.
  - Despite the distal seal, a small amount of blood can enter the interior of the lead together with the guide wire. In this case, the inner lumen must not be rinsed, as the resulting excess pressure can damage the lead insulation.

Information on the procedure with stylet

- The stylet has a pre-shaped part near the handle, which can be used to lock the stylet within the lead and maintain a certain prestress.
  When inserting the stylet into the lead, be careful when exceeding the resistance with this locking mechanism.
- Coagulated blood may impair the maneuverability of the stylet inside the lead.
  Therefore, do not use a stylet that has come into contact with blood. A spare stylet is provided in the inner blister of the lead packaging.
  In this case, the inner lumen must not be rinsed, as the resulting excess pressure can damage the lead insulation.
- The use of unsuitable stylets or improper handling of the stylet can result in damage to the lead.
  This would result in a malfunction or failure of the lead.
  Moreover, the stylet could protrude from the lead tip and injure the patient.
  — Use only a suitable stylet for the respective lead (based on length and diameter). Additional information can be found in the Appendix.
  — 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.

Information on the steroid collar

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

The intended effect is the reduction of the inflammatory processes after implantation and the inflammation-related postoperative 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.

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

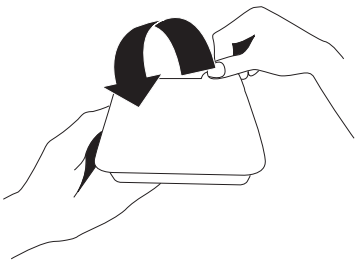
Packaging composition

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.

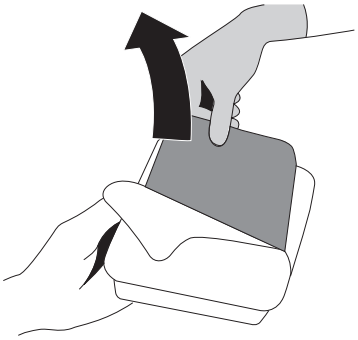
You can remove the inner blister by using a standard aseptic technique and place it in the sterile field.

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.

Accessing the Vein

Venous access - two methods

There are two options for inserting the lead or the CS guiding catheter into the vein:

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

Method A

Incision of 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	Guide the lead or the catheter of the CS lead introducer system through the opening into the vein.

Method B

Puncturing the subclavian vein:

- Use a suitable lead introducer set.
- Please consult the technical manual included with the lead introducer set.

After you have established access to the vein using a lead introducer set, insert the lead or the CS guiding catheter of the CS lead introducer system into the vein through the introducer sheath.

Probing the Ostium of the Coronary Sinus and Venogram

With a catheter of a CS lead introducer system

BIOTRONIK provides the Selectra CS lead introducer system for probing the ostium of the coronary sinus and positioning a CS lead in the coronary venous system.

A CS guiding catheter of these CS lead introducer systems can be guided directly via the vein opening (e.g. via the introducer sheath) through the vein to the coronary sinus.

Handling of the CS guiding catheter and the other implant accessories of these CS lead introducer systems is described in the accompanying technical manual.

With an additional EP catheter

The probing process can be simplified by using a suitable additional EP catheter.

For this purpose, the outer CS guiding catheter is advanced almost to the ostium of the coronary sinus, and a suitable EP catheter is advanced through the outer CS guiding catheter.

Once the entrance of the coronary sinus has been passed using the EP catheter, the CS guiding catheter can be inserted into the coronary sinus via the EP catheter and then the EP catheter can be removed.

Observe the technical manual accompanying the EP catheter.

Venogram

The preliminary creation of a venogram of the coronary vessels can facilitate the selection of a suitable coronary target vein and make subsequent lead positioning easier.

To do this, insert a suitable venogram balloon catheter through the CS guiding catheter into the coronary sinus.

Once the blood flow in the coronary vein has been temporarily blocked using the balloon catheter, a contrast medium can be introduced via the balloon catheter.

Observe the technical manuals for the balloon catheter and the CS lead introducer system.

Positioning the Lead in the Coronary Venous System

Two possible approaches

The CS leads can be positioned in the target vein using either of the following methods:

- With a guide wire (over-the-wire)
- With a stylet

CAUTION
Stylet or guide wire Either a guide wire or a stylet, but not both, can be placed in the lead at the same time. The chosen technique (over-the-wire or stylet) determines the tool.

CAUTION
Stylet technique The use of unsuitable stylets or improper handling of the stylet can result in damage to the lead. This would result in lead malfunction or failure. Moreover, the stylet could protrude from the lead tip and injure the patient.

Over-the-wire technique

To position the lead tip with the aid of a guide wire in the target vein, proceed as follows:

Step	Action
1	Insert the TVI (transvalvular insertion tool) provided into the proximal opening of the hemostatic valve of the CS guiding catheter. The TVI makes it easier to introduce the guide wire through the valve and into the CS guiding catheter.
2	Insert the guide wire through the TVI into the CS guiding catheter

Note: Use only guide wires with a diameter of max. 0.36 mm (0.014 inches). BIOTRONIK offers suitable guide wires in the Streamer product family with various levels of stiffness.

Step	Action
3	Position the guide wire in the desired target vein.
4	Remove the TVI.

Note: The included torque tool can be mounted onto the guide wire to achieve optimal maneuverability of the guide wire.
Guide the torque tool over the proximal end of the wire and tighten by turning it.
The torque tool must be removed before guiding the lead over the guide wire.

Step	Action
5	Guide the distal end of the lead over the proximal end of the guide wire and advance the lead to its target position.

Stylet technique

To position the lead tip with the aid of a stylet in the target vein, proceed as follows:

Step	Action
1	Use the stylet to apply mechanical tension to the lead.

Note: To maintain the mechanical prestress, you can anchor the pre-formed part near the handle of the stylet in the lead connector.
When the stylet has been anchored in the lead, rotations of the stylet handle are directly transmitted to the lead tip.

Note: A defined pre-formed lead tip is sometimes desirable to facilitate maneuvering of the lead in the coronary venous system.
To do this, shape the stylet appropriately prior to insertion, and then carefully insert the stylet into the lead.

Step	Action
2	Use X-ray monitoring to advance the lead through the CS guiding catheter into a position suitable for fixation in the coronary venous system.

Fixating the Lead in the Target Vein

Various procedures

The procedure for fixating the lead in the coronary vein differs depending on the type of distal anchoring.

Fixation with pre-shaped distal end

Proceed as follows to fixate a CS lead with a pre-shaped S-curve at the distal end in the target vein:

Step	Action
1	Withdraw the guide wire or stylet. After about 7 to 10 cm, the pre-shaped distal end unfolds two-dimensionally in the vessel and fixates the distal lead area.

Note: This procedure changes the position of the lead tip.
This means that the lead tip has reached its final position after fixation.

Step	Action
2	Gently pull on the lead to check that the fixation is secure.

Fixation with silicone thread

Proceed as follows to fixate a CS lead with a silicone thread in the target vein:

Step	Action
1	If there is a guide wire in the lead, it has to be replaced with a stylet.
2	The stylet must put the lead under mechanical prestress so that it can be advanced in the coronary vessel by applying the force required for this fixation method.
3	Advance the lead with the stylet until the threads of the lead lodge in the coronary vessel.

Note: Despite the shape of the silicone thread, no rotation of the lead in the vessel is required or intended.

Step	Action
4	Withdraw the stylet a little.
5	Gently pull on the lead to check that the fixation is secure.

Intraoperative Measurements and Tests

Purpose

For a qualitative evaluation of the lead position, it is necessary to measure pacing thresholds and intracardiac potentials.

Note: Use suitable patient cables and adapters when temporarily connecting the lead to an intraoperative test system. The stylet or guide wire must be removed prior to measurement.

Connecting the IS4 connector temporarily

Connecting an IS4 connector with an intraoperative test system requires the use of a suitable IS4 adapter. We recommend using a suitable adapter by BIOTRONIK.

The alligator clips of the patient cable are then clipped to the appropriate contact surfaces of the IS4 adapter.

Safety warnings

Please note the following when conducting intraoperative measurements and tests!

WARNING

Leakage currents can trigger ventricular fibrillation.

Only connect implanted leads to battery-operated 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.
All other line-powered devices connected to the patient must be properly grounded.

CAUTION

Risk of intermittent pacing

During intracardiac measurements, pacing will be temporarily interrupted.

Suitable measuring devices

BIOTRONIK provides measuring devices calibrated to the properties of the active devices for measuring pacing threshold, defibrillation threshold and intracardiac potentials.

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.

Please refer to the technical manuals of the respective testing and measuring devices for further details on performing measurements and tests.

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.

Measuring intracardiac signal amplitudes

The heart must not be paced externally while measuring the amplitudes of intrinsic cardiac events.

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:

Parameters for measurement in the coronary vein	Limit values
Pacing threshold [pulse width max. 0.5 ms]	Max. 3 V
Amplitude of the intracardiac signal	Min. 5 mV

Note: More details regarding electrophysiological measurements can be found in the technical manual of the measuring device.

Testing the complete device system

Note: The entire device system must pass a final performance test when the lead has been connected to the pacemaker or ICD and the active device has been implanted in a subsequent step.
To do so, communication with the test or programming devices is to be established via the programming head.

Removing the CS Guiding Catheter

Prerequisite for over-the-wire technique

Perform the following steps if a guide wire is still in the lead:

Step	Action
1	Completely remove the guide wire from the lead.
2	Insert a suitable stylet into the lead to stabilize the lead. The stylet tip should lie 7 to 10 cm from the front of the lead tip so as not to change the fixation of the lead tip.

Prerequisite for stylet technique

In this case, the stylet is already in the appropriate position inside the lead.

Removing the CS guiding catheter

To remove the guiding catheters, proceed as follows:

Step	Action
1	First remove the inner and then the outer CS guiding catheter with the aid of the slitter tool as described in the technical manual of the Selectra accessory kit.
2	Remove the stylet. While removing the stylet, hold the lead by its connector to stabilize the lead's position.
3	Now repeat the electrical measurements as described in the preceding section. This will help to verify that the lead is still positioned correctly after removal of the catheters.

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.

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

Prerequisites

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

Lead fixation sleeve

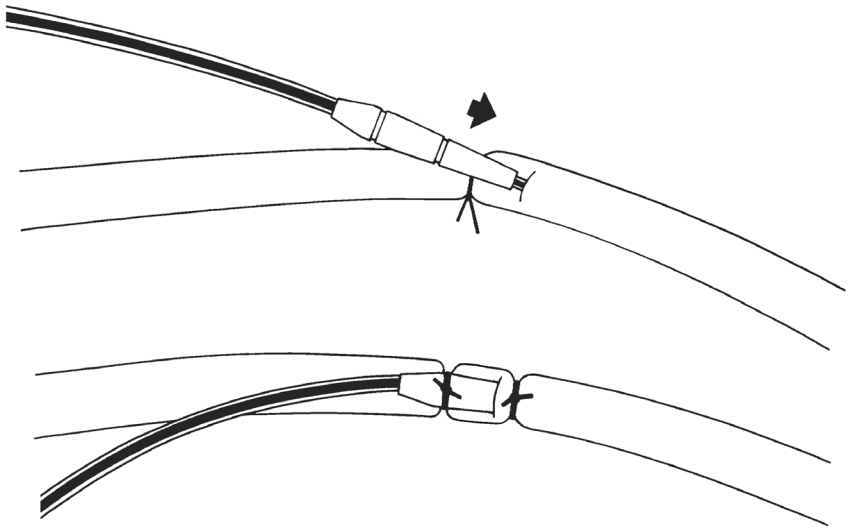
On delivery, the lead fixation sleeve with ligature grooves made of silicone is mounted on the lead.

Instructions for use

Move the lead fixation sleeve back to the puncture or incision site and fixate it with ligature sutures.

Both ligature grooves must be used in order to securely fixate the sleeve and the lead.

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



Connecting the Lead to the Active Device

Note Further information on the topic of connecting the lead to the active device's IS4 connection may be found in the designated device's technical manual.

Prerequisites Placement of the lead as well as the intracardiac tests and measurements have been performed successfully.

Position of the set screws In BIOTRONIK ICDs with an IS4 connection, the set screw of the IS4 port is accessible from the labeled side of the housing.

Safety warnings The following precautions are to be observed when connecting the lead to an active device.

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.

Note: Surgical instruments can cause damage to the lead connector. Make sure that the lead connector does not come into contact with surgical instruments during implantation.

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

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

Note: Ensure that connections are clean. • Clean the connector with a sterile cloth if it gets contaminated during the implantation.

Allocation for IS4 connectors All four contacts of the lead are suitable for left sided sensing and pacing. They are commonly connected via the four-pole IS4 connector.

The lead is connected based on the diagram on the housing of the active device.

The labels are allocated as follows:

Labeling of the lead connector	Labeling of the active device's connector port
IS4 LLLL (LV)	CS or LV

Connecting the IS4 connector

Proceed as follows:

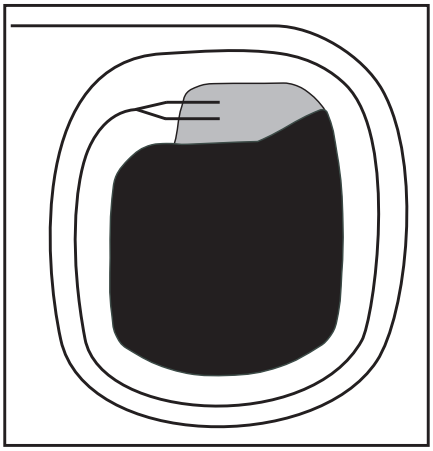
Step	Action
1	Remove, if present, the stylet or guide wire.
2	Using the screwdriver (provided with the active device), pierce the center of the silicone plug vertically, and insert the tip of the screwdriver into the respective set screw.
3	Rotate the set screw counterclockwise with the screwdriver until the connector port of the active device is completely clear.
4	Insert the lead connector into the port without bending the conductor or rotating the lead connector until the blue color mark of the DF4 connector becomes visible behind the set screw block.
5	If the lead connector cannot be easily pushed into the connector port, sterile water may be used for lubrication. Do not use any other lubricants.
6	If the lead connector cannot be inserted completely, the set screw may be protruding into the connector port of the set screw block. Carefully loosen the set screw without completely unscrewing it, so that it does not become tilted upon retightening.
7	Turn the set screw clockwise until the torque control starts (you will hear a clicking sound).
8	Carefully withdraw the screwdriver without retracting the set screw. • The other contacts of the IS4 port are designed as spring contacts. • When the screwdriver is withdrawn, the silicone plug automatically seals the lead connection safely.

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.

Pinching between clavicle and 1st rib

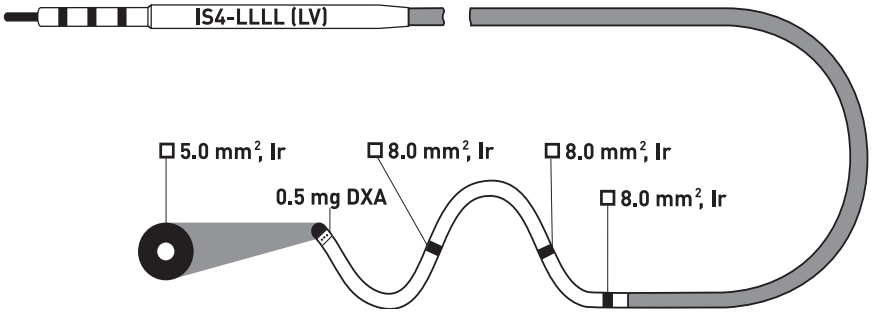
To prevent mechanical overstress from causing failure of the pacing/sensing function, make sure that the lead does not become pinched between the clavicula and the first rib after implantation.

4 Appendix

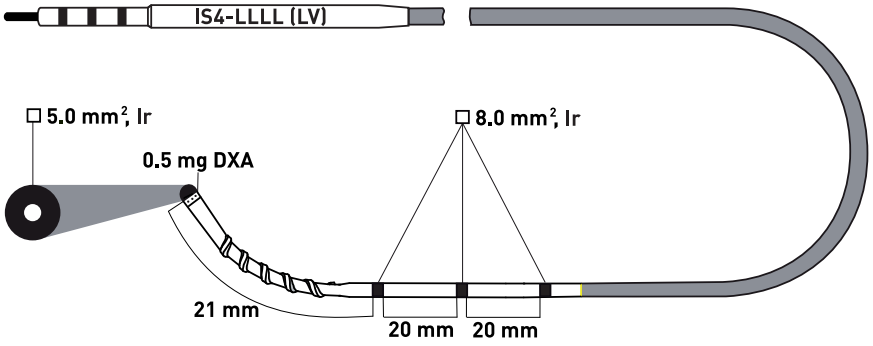
Technical Data

Diagrams: dimensions and schematic

Sentus ProMRI OTW QP L



Sentus ProMRI OTW QP S



Model versions

Model: Sentus ProMRI OTW	QP L-75	QP L-85	QP L-95
	QP S-75	QP S-85	QP S-95
Overall length	77 cm	87 cm	97 cm
Distance between the tip and the 1st ring electrode	21 mm		
Distance between 1st and 2nd ring electrode	20 mm		
Distance between 2nd and 3rd ring electrode	20 mm		

Lead connector

Design	IS4, quadripolar
Suitable for active devices with an IS4 connector	
Labeling	IS4-LLLL (LV)
Material of the connector pin	MP35N
Material of the contact rings	Platinum/iridium alloy

Fixation

Sentus OTW ProMRI QP L		
	Technique	Pre-shaped S-curve of the distal area
	Length of the pre-formed helix	Approx. 6 cm
Sentus OTW ProMRI QP S		
	Technique	Silicone thread between the tip and the ring electrodes

Tip electrode

Maximum diameter	1.6 mm (4.8 F)
Surface (size)	5 mm^2
Surface (material and structure)	Iridium, fractal

ring electrodes

Maximum diameter	1.6 mm (4.8 F)
Surface (size)	8 mm^2
Surface (material and structure)	Iridium, fractal

Steroid

Active agent	Dexamethasone acetate
Quantity	0.5 mg
Steroid bonding agent	Silicone rubber

Lead body

Material of insulation		Silicone
Anti-friction coating		
	Material	Polyurethane
	Thickness	0.1 mm
	Coated area	From 7.2 cm behind the tip to the connector
Maximum outer diameter		1.6 mm (4.8 F)
Conductor to tip electrode		Coil
	Architecture (structure)	Coradial coil made of 5 wires
		Each wire is electrically insulated.
	Number of wires per coil	5 parallel wires, coradial, insulated against each other
	Material of the wire	MP35N-DFT
	MP35N is a registered trademark for a particular cobalt-chrome-nickel alloy	
	Conductor resistance (wire)	0.08 Ω/cm
	Conductor to tip electrode	Two out of the five wires from the coil lead to the tip electrode.
	Conductor to the 3 ring electrodes	One of the five coil wires is connected to each ring electrode.

Pacing impedance

Pacing impedance according to EN 45502-2-1 or EN 45502-2-2	600 to 1200 Ω

Storage conditions

Permissible storage temperature range	5 - 55°C
Permissible storage period	2 years

Stylets

Accessories for:	Sentus ProMRI OTW QP L-75 and S-75	Sentus ProMRI OTW QP L-85 and S-85	Sentus ProMRI OTW QP L-95 and S-95
Usable length of the stylet	783 mm	883 mm	983 mm
Diameter at the stylet handle	3.5 mm		

Technical details for the stylets:

Designation	Diameter	Stiffness	Diameter of ball tip	Color coding (stylet handle)
S 75-K OTW S 85-K OTW S 95-K OTW	Max. 0.36 mm	Medium	0.48 mm	Green
S 75-G OTW S 85-G OTW S 95-G OTW	Max. 0.36 mm	Soft	0.48 mm	Purple

Guide wire

Guide wire	PTCA guide wire, max. diameter: 0.36 mm (0.014")
Recommended model	Streamer Polymer Wire ES/XT, Vision Wire

Recommended CS guiding catheters

Internal diameter	5 F
Recommended model	Selectra CS guiding catheter (inner and outer catheter)
Note: The Selectra accessory kit is required for proper use of the catheters.	

Scope of delivery

In the sterile container	1 pc.	Lead Sentus ProMRI OTW QP L-75, L-85 or L-95 or Sentus ProMRI OTW QP S-75, S-85 or S-95
	1 pc.	Type S XX-K OTW stylet, premounted in the lead
	2 pc.	Type S XX-K OTW stylet
	2 pc.	Type S XX-G OTW stylet
	1 pc.	Vein lifter
	1 pc.	Type EFH-20-5F lead fixation sleeve, unlacerated, made of silicone rubber, premounted on the lead
In box (non-sterile)	1 pc.	• Technical manual (printed) or • Supplement with information on how to download the technical manual as a PDF file from the Internet

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.

For example:

- 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
- Defense reactions 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 of 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.

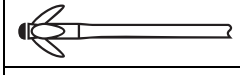
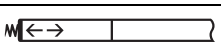
BIOTRONIK shall not be liable for any loss, damage, or injury of any nature, whether direct, indirect, or consequential, that may occur in connection with the leads and accessories or their use.

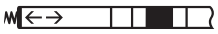
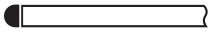
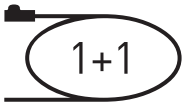
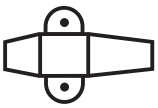
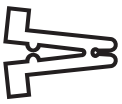
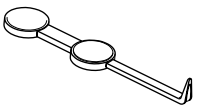
Specifically, BIOTRONIK shall not reimburse the customer or a third party for any costs incurred in connection with the use, malfunction, or failure of any lead or accessory, including physician's fees, hospital expenses, medication costs, subsidiary costs, and costs for consequential damages.

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 reuse!
	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 lead connector
	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

Symbol	Meaning
	Bipolar, endocardial active fixation lead with extendable and retractable screw
	Unipolar coronary sinus lead, fixation using preformed tip
	Bipolar coronary sinus lead, fixation using preformed tip
	Unipolar coronary sinus lead, fixation in vessel using silicone thread
	Bipolar coronary sinus lead; fixation using electrically passive, preshaped tip; two ring electrodes for left atrial application
	Quadripolar coronary sinus lead
	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
	Stylets included, here: 1 stylet in the lead, 1 additional stylet in the sterile packaging
	Lead suture sleeve, premounted on the lead inside the sterile packaging
	Fixation tool for active fixation lead
	Vein pick
	Torque tool for OTW guide wires
	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

Symbol	Meaning
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