IMPULSE DYNAMICS

ODOCOR II Cardiac Contractility Modulation Lead

INSTRUCTIONS FOR USE

Part No.: 23-290-001-EU Rev. 03

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Please read the complete documentation provided before you use the device.

CE 0344

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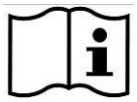
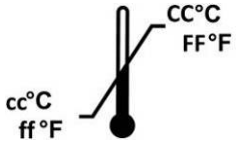
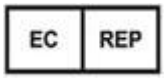
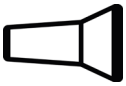
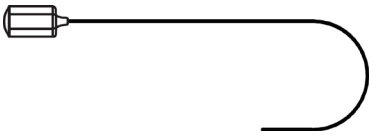
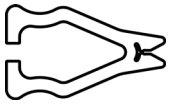
EXPLANATION OF SYMBOLS ON LABELS

SYMBOL	DESCRIPTION
	Part Number
	Serial Number
	Use By
	Date of Manufacture
	Lot Number
	Conformité Européenne 0344 = Notified Body Number
	Do Not Reuse
	Do Not Use if Package is Damaged
	Consult instructions for use.
	Sterilized with Ethylene Oxide
	Transport Temperature Limits
	European Representative
	Manufacturer
	Open Here
	Lead
	Funnel
	Suture Sleeve
	Vein Lifter

SYMBOL	DESCRIPTION
	Straight Stylet
	Curved Stylet
	Holding Tool

1. THE ODOCOR II SYSTEM: AN OVERVIEW

The ODOCOR II system is comprised of the following components:

- ODOCOR II Cardiac Contractility Modulation (CCM) Lead (1)
- Holding Tools (2)
- Vein Lifter (1)
- Funnel (1)
- Suture Sleeve (1)
- Stylet Hoops (2)
- Ball Tip Stylets (4)

1.1 Description of the ODOCOR II CCM Lead

The ODOCOR II CCM Lead is a bipolar, active fixation lead with a retractable screw-in helix for ventricular fixation. The electrically active fixation helix is permanently attached to the inner three-filar coil, which is connected to the moveable pin of the IS-1 connector.

To extend or retract the fixation helix, a fixation tool ("holding tool") must first be attached to the IS-1 connector pin. When the attached holding tool is then turned clockwise or counter-clockwise, the conductor coil rotates, resulting in the extension or retraction of the fixation helix, respectively.

The lead comes with two red-handle and two green-handle stylets. One of these green-handle stylets is packaged with the lead.

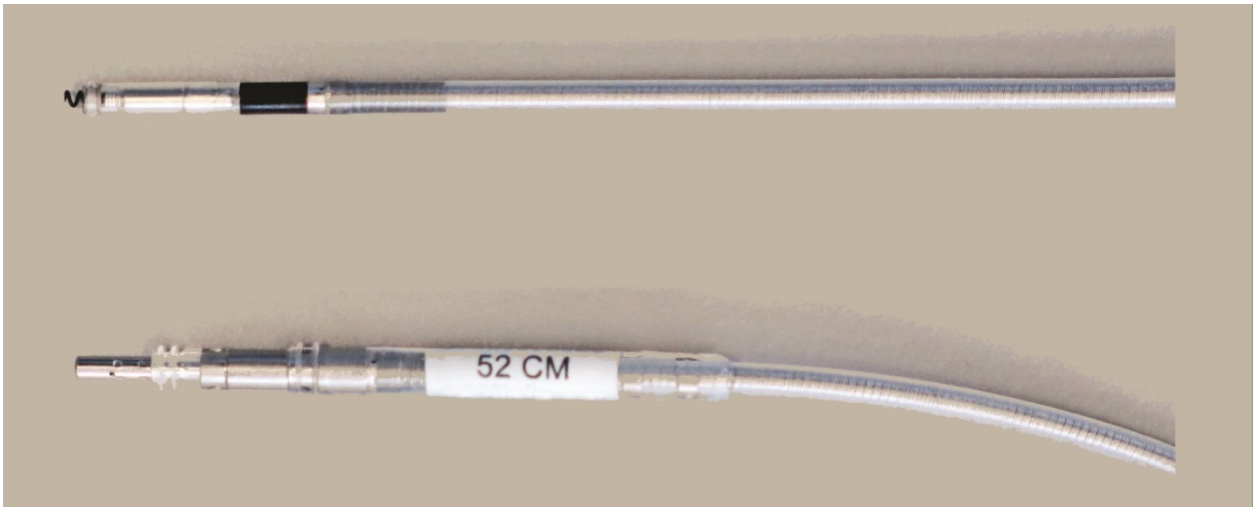


Figure 1: Example of ODOCOR II CCM Lead (52 cm Lead Shown)

1.2 ODOCOR II CCM Lead Physical Characteristics

Lead Diameter (Fr)	6.5
Introducer Size	7 Fr and 9 Fr with 0.89 mm guidewire
Length (cm)	52 and 58
Connector	IS-1 Bipolar
Fixation	Extendible/Retractable Screw-in Helix
Extend / Retract	IS-1 Pin Driven
Electrically Active Helix	Yes
Electrically-Active Electrode Surface Area (mm^2)	Tip: 6.9 Ring: 31.0
Electrode Spacing (mm)	10.5
Electrode Material	Tip and Ring: PtIr
Electrode Coating	Tip and Ring: TiN
Helix Extension (mm)	2.1 ± 0.18
Distal Rigid Section - nominal length (mm)	17.7
Distal Shape	Straight
Maximum Stylet Diameter (mm)	0.40
Inner and Outer Insulation	Silicone

1.3 ODOCOR II CCM Lead Length and Resistance

Conductor	52 cm Lead	58 cm Lead
Inner	52 Ω NOM	58 Ω NOM
Outer	82 Ω NOM	92 Ω NOM

2. INDICATIONS

The ODOCOR II CCM Lead is indicated for use with an Impulse Dynamics OPTIMIZER Implantable Pulse Generator (IPG) to deliver CCM signals to the right ventricle. The ODOCOR II CCM Lead is NOT intended to be used to deliver cardiac pacing signals to the heart.

The ODOCOR II CCM Lead is intended for prescription use only, by the implanting physician in a procedure or operating room equipped for sterile implantation of the IPG and leads.

The ODOCOR II CCM Lead is meant to be permanently implantable and is expected to withstand long-term (up to 10 years) exposure to the environment typically found inside the upper torso of the human body.

3. CONTRAINDICATIONS AND PRECAUTIONS

Use of the ODOCOR II CCM Lead is **contraindicated** in the presence of certain heart abnormalities such as:

1. Patients with mechanical tricuspid valve
2. Tricuspid Atresia
3. Ebstein's Malformation
4. Patients in whom vascular access for implantation of the leads cannot be obtained because of atrial or ventricular transposition.

4. WARNINGS

4.1 Potential Complications of Lead Implantation

With the use of endocardial leads, complications might occur during implantation, explantation, or at any time postoperatively, and may require non-invasive or invasive techniques for management, as determined by the clinical judgment of the physician. Intermittent or continuous loss of CCM signal delivery or sensing can be caused by a displacement of the electrode, unsatisfactory electrode position, breakage of the conductor or its insulation, an increase in thresholds, or poor electrical connection to the pulse generator. After implantation, the patient should be monitored for electrode displacement, and the lead should be repositioned if necessary. Active fixation leads, passed transvenously, present the possibility of inadvertent engagement between the lead tip and intracardiac structures such as the tricuspid valve or chordae tendineae. Perforation of the ventricle wall may cause diaphragmatic muscle stimulation as well as cardiac tamponade. When explanting a lead whose connector is cut off, it is recommended to cap the proximal portion off to prevent exposed conductor parts in the vein whenever the lead will be left in the heart.

4.2 Atrial and Ventricular Arrhythmias Potentially Caused by Lead Implantation

The use of transvenous leads may lead to arrhythmias, some of which may be life-threatening such as ventricular fibrillation and ventricular tachycardia. The use of screw-in leads such as those used for CCM signal delivery also have the potential of causing conduction disturbances such as bundle branch block. These can be minimized by performing the implant with the use of fluoroscopic guidance, ensuring that the leads are in appropriate position prior to fixation and by limiting the number of lead manipulations. Please read and follow all directions to minimize adverse events connected to lead implantation.

4.3 MRI Compatibility

The ODOCOR II CCM Lead is NOT compatible with MRI. Patients with this lead implanted should not undergo MRI procedures.

4.4 Handling

Read the label on the product package before opening to ensure you have the right product. The package contents are sterile. Inspect the package carefully to ensure it is intact. Do not use a damaged or opened package. Introduce the contents into a sterile field: (1) Peel the Tyvek lid from the outer tray, (2) use a sterile handling technique to put the inner tray into sterile field, (3) peel the Tyvek lid from inner tray to expose the contents.

The insulating materials are body compatible, but they are nevertheless prone to attract foreign particles. Avoid any contamination before introduction of the lead into the body. Do not wipe or immerse the lead in fluid. Damaged packages need to be returned to Impulse Dynamics.

4.5 Storage

The recommended storage temperature range for the ODOCOR II CCM Lead is 15°C to 25°C. Atmospheric pressure and relative humidity have no impact on the ODOCOR II CCM Lead.

4.6 Packaging Information

The ODOCOR II CCM Lead is supplied in a shelf box containing the sterile package. The sterile pack has been sterilized with ethylene oxide gas and comprises an outer TYVEK/PET blister pack containing an inner TYVEK/PET blister.

The following items are included in the shelf box:

- Insert Card
- Peel-off labels for use with implantation documents
- Sterile pack

The inner blister pack contains:

- ODOCOR II Cardiac Contractility Modulation (CCM) Lead (1)
- Holding Tools (2)
- Vein Lifter (1)
- Funnel (1)
- Suture Sleeve (1)
- Stylet Hoops (2)
- Ball Tip Stylets (4)

Before opening the sterile package, check for any signs of damage suggesting that the sterility of the package or its contents might have been compromised. Damaged packages need to be returned to Impulse Dynamics. Do not attempt to resterilize the contents of the sterile package that has been damaged or in any way compromised.

4.7 Resterilization and Reuse

Do not resterilize any component of the ODOCOR II system. An ODOCOR II CCM Lead that has been explanted for any reason may not be reimplanted in another patient.

5. CAUTIONS

The following discussion on potential hazards focuses on maintaining the utmost patient safety.

- Device is supplied sterile. Do not use if package has been previously opened or damaged.
- Prior to use, read all package inserts, warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.
- Procedure must be performed by trained medical personnel well versed in anatomical landmarks, safe technique, and potential complications.
- The product is designed for single use only.
- Do not resterilize or reuse. Do not alter the lead in any way.

6. POTENTIAL ADVERSE EFFECTS

Examples of adverse effects that may occur as the result of the surgical procedure are listed below in the order of their clinical severity:

1. Death
2. Arrhythmias (brady- or tachyarrhythmias including fibrillation)
3. Stroke or TIA ("transient ischemic attack")
4. Respiratory/ventilatory failure
5. RV perforation
6. Hemorrhage
7. Infection
8. Pleura or pericardial effusion
9. Pneumothorax

7. DEVICE IMPLANTATION

Physicians implanting the Optimizer Smart with ODOCOR II leads must undergo the manufacturer's prescribed training prior to treatment of any patient with the devices.

7.1 General Considerations

The use of the subclavian venipuncture technique for lead introduction may be associated with conductor fractures. If the physician elects to use the subclavian venipuncture, a more lateral puncture site should be considered to avoid the subclavian muscle and costoclavicular ligament, or at least its densest part. The procedure is suggested to be done under fluoroscopic guidance. After placement, the lead should be checked by multiview cineradiography during movements of the ipsilateral upper extremity to ensure that the lead(s) have not been entrapped. The posteroanterior chest x-ray can also be used to confirm that the lead(s) are not entrapped. Clinical evidence suggests that certain upper extremity activities are contraindicated for persons with implantable pulse generators because they require movements that can cause damage to the leads and possible failure of the leads. Active people, particularly those who perform repetitive upper extremity exercise at work or play, should be cautioned that they could subject leads to damaging stress. Be sure to leave sufficient slack in the lead to compensate for body movements.

Subclavian venous access is preferred over access via the axillary or cephalic vein, because two (or optionally 3) intracardiac leads have to be inserted. Two right ventricular leads are placed for CCM signal delivery, one of these preferably in an anterior septal and the other in a posterior septal location, approximately half way between base and apex. Placing both leads in an anterior or posterior septal location is an acceptable alternative, provided the leads are separated by at least 2 cm. In patients who carry an ICD, one needs to ensure that there is adequate separation between CCM leads and ICD lead.

Warning: Avoid Subclavian crush by proper lead placement. Patients need to be monitored closely after the implantation procedure.

Warning: Exercise care while placing the leads to avoid formation of a blood clot, which could prevent retraction of the corkscrew.

Warning: It is important to avoid prolonged manipulation of the leads and catheters in the venous system, which could lead to venous thrombosis.

Warning: During implantation, leads and catheters need to be manipulated with extra caution in order to avoid perforation of the right ventricular wall. Obtain X-rays, perform echocardiography, and device interrogation after implantation to detect perforations even in the absence of corresponding symptoms.

Warning: In order to prevent vascular injury and hemorrhage, be extremely cautious when introducing catheters and leads into arteries and veins.

7.2 Opening the Lead Sterile Package(s)

Visually inspect the lead packages before opening them for implantation. Proceed as follows with each sterile package:

- Open the shelf box outside the sterile field and remove the TYVEK/PET molded tray.
- Using the provided tab, peel back the TYVEK from the outer PET molded tray, taking care not to touch the inner sterile package.
- Using strict sterile technique, open the inner sterile blister pack and make it accessible to the scrub nurse. At the recess adjacent to the molded tab, the inner TYVEK/PET container can be removed from the outer tray with a pair of forceps.
- Peel back the inner cover starting at the provided peel tab.
- Remove the lead from the inner package and place it on a sterile and lint-free surface.

7.3 Safety Precautions

An implanted lead constitutes a direct, low resistance current path to the heart. During operative, connective, and testing procedures, only battery-powered devices and instruments should be used with the lead system to protect against ventricular fibrillation induced by alternating currents. Extreme caution should be taken to properly ground all line-powered equipment used in the vicinity of the patient. The terminal of the implanted lead must be insulated from any leaking currents, which can arise from using line-powered equipment.

7.4 Suggested Implantation Procedure

Although these instructions are based on user's experience, the physician may wish to vary the implantation procedure with their clinical judgment.

7.4.1 Testing the Screw-In Mechanism Before Use (must be performed)

Before implantation, the screw-in helix mechanism must be tested. This is accomplished by fully extending and retracting the lead helix.

Caution: When checking the extension and retraction of the helix (dry run), do not continue to turn the IS-1 connector pin once the helix is extended. Likewise, do not continue to turn the IS-1 connector pin after the helix is retracted. In order to avoid damage to the lead, do not turn the IS-1 connector pin more than required.

Caution: The recommended number of turns of the IS-1 connector pin for complete extension and retraction are 8-12 turns. The number of turns can vary depending on the shape of the stylet used as well as the length of the lead. Do not make more than 28 turns clockwise or counterclockwise. The number of turns needed to extend and retract the helix may not be equal. Do not repeat this test more than is necessary.

Caution: Verify that the lead helix is fully retracted before implantation. The helix is fully retracted when its pointed tip is slightly visible.

7.4.2 Rotation of the Suture Sleeve Before Use (must be performed)

Before implantation, the suture sleeve must be conditioned to ensure that it able to slide along the lead. This is accomplished by holding the suture sleeve between the thumb and forefinger of one hand, holding the lead body adjacent to the suture sleeve with the other hand, and lightly rotating and sliding the suture sleeve over the lead body.

7.4.3 Lead Introduction, Vein Lifter, Introducer Size

Use the already inserted stylet for introduction and positioning. To facilitate introduction of the lead in case of a cut-down procedure, a disposable vein lifter is provided in the package. Make an incision at the venous site and carefully insert the tapered end of the lifter in it. Hold the lifter in position and gently push the lead tip into the vein. Remove the lifter and advance the lead into the heart.

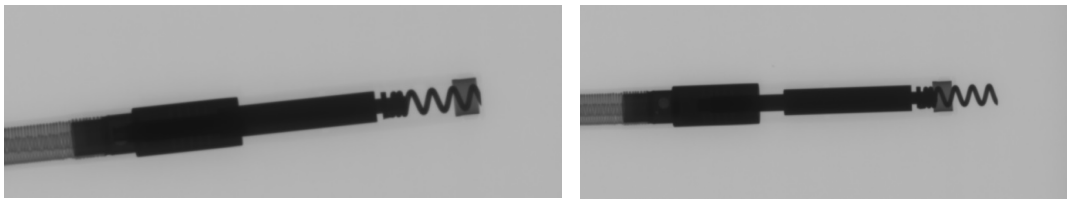
Note: Vein lifter is not intended to puncture the vein or dissect a tissue.

If a lead introducer set is used, follow the Instructions for Use enclosed with an Introducer set package. Refer to package labeling for suggested introducer size without retained guidewire. When introducing the lead, some blood may enter the conductor coil. This is typical of retractable screw-in leads and will not impair the function of the lead. Impulse Dynamics Inc. considers the ingression of body fluid into the lead a cosmetic event only.

Caution: Always use a new clean stylet during any stylet exchange.

7.4.4 Ventricular Lead Positioning and Fixation, Use of Stylet

Under fluoroscopic observation, maneuver the lead body with the green-handle stylet inside until the lead distal tip is in the desired position in the ventricle. Care should be exercised to avoid perforating the heart wall. If advancement is resisted, withdraw the lead a short distance and with the stylet fully inserted, attempt to advance the lead again. Repeat as required. The stylet may be bent or shaped to position the tip appropriately. To extend the helix (screw), attach the holding tool to the IS-1 connector pin, hold the lead connector firmly so that the lead does not rotate, and turn the holding tool clockwise for the recommended number (see Section 7.4.1) of complete turns. Always confirm radiographically, while performing helix advancement and at the end of the procedure, that the helix (screw) is extended by observing for helix extension past the screw extension marker. **See Figure 2.**



Retracted screw *Extended screw*

Figure 2: Radiographic Views of the Lead Helix

Once the desired fixation is achieved and the screw tip is in the myocardium, turn the entire lead assembly (the lead body, its connector and the holding tool) one complete clockwise rotation. This movement will create a more desirable interface between the tip and the endocardium. Once the lead has been positioned, slowly withdraw the stylet, detach the holding tool from the IS-1 connector pin, and then discard the stylet and holding tool.

7.5 Lead anchoring, Ligature (suture) sleeve

Each lead contains a ligature sleeve on the lead body. Impulse Dynamics recommends using the ligature sleeve at all times.

Note: The silicone ligature sleeve on silicone lead may slightly stick to the lead body. To release the pressure, turn and pull the sleeve body slightly back and forth. To prevent damage to the lead insulation and coil, the suture at the vein exit should not be too tight. After final fixation of the lead in the heart, secure the ligature sleeve with non-absorbable sutures to the CCM lead. Slide the ligature sleeve into the vein, near the point where the CCM lead enters the vein, and secure the lead to subcutaneous tissue.

Caution: Do not tie a suture directly to the lead body. Be sure to leave sufficient slack in the lead to compensate for body movements.

7.6 Connecting the Implanted Leads to the OPTIMIZER Smart IPG

Important considerations:

- When tightening or loosening the set screws, always insert the tip of the torque wrench fully and in line with the set screw. Do not insert the wrench into the set screw at an angle.

- Prior to inserting the IS-1-BI lead connectors, verify visually that none of the set screws protrude into any of the IPG header ports. Back off any set screw found protruding beyond the wall into the header cavity by turning it back with the Allen wrench in a counter-clockwise direction. Turn the set screw just enough so that its tip is no longer inside the header cavity. Do not back the set screws completely out of the terminal block.

Note: Provided the connectors are correctly installed, the connector retention force in the terminals is at least 10 N.

Clean the lead plugs with sterile distilled water (if using saline, wipe the plugs dry with a surgical sponge afterwards) and fully insert each plug into the respective connector terminal at the IPG. Observe that the male ends of the lead plugs are inserted beyond the respective lead tip terminals. Tighten the set screws using the sterile #2 Allen torque wrench included in the IPG package. Turn the torque wrench clockwise until there is a distinct clicking sound/feel. This feature prevents over-tightening of the set screw. Carefully apply traction on the strain relief of each lead to make sure that the leads are securely anchored in the terminal. Finally, tighten the set screws securing the contact between the rings of the plugs and the corresponding parts of the terminal block.

8. STERILIZATION

The leads are supplied sterile. A sterilization method is indicated on the product label. The sterility is compromised when the package is opened or damaged. Impulse Dynamics does not assume any liability or responsibility for sterilization by a third party.

9. LEAD EXPLANTATION / REPLACEMENT

Using a torque wrench, loosen the set screw of the lead terminal whose lead is to be disconnected from the IPG. While holding the IPG in one hand, grasp the silicone lead connector between thumb and forefinger. Pull the lead connector from the terminal by cautious application of constant traction. Grasping the plug with a sterile pad can help improve traction. Never apply traction to the actual lead body, which could damage the lead and cause lead failure.

Note: When tightening or loosening a set screw, always insert the tip of the torque wrench fully into and in line with the set screw. Do not insert the torque wrench into the set screw at an angle.

Note: Prior to inserting the IS-1-BI lead connectors, verify visually that none of the set screws protrudes into any of the IPG header cavities. Back off any set screw found protruding beyond the wall into the header cavity by turning it back in a counter-clockwise direction with the Allen wrench. Turn the set screw just enough so that its tip is no longer inside the header cavity. Do not back the set screw completely out of the terminal block.

When removing a lead from the patient, it is recommended not to cut off the proximal end. If the proximal end is cut off, however, firmly grasp both the conductor coil and outer tubing before applying tension to the lead.

Note: A traction removal of chronic screw-in leads is not recommended due to ingrown fibrotic tissue in and around the helix.

Warning: Implantable parts are not to be reused if they have previously been implanted in another patient.

10. PRODUCT AWARENESS

The CCM leads are implanted in the extremely hostile environment of the human body. Because the leads are very small in diameter and must be very flexible, it inevitably reduces their potential performance and longevity. Leads may fail to function for a variety of causes, including medical complications, body rejection phenomenon, allergic reaction, fibrotic tissue problem, or a failure of lead by damage, fracture, or by breach of their insulation. Despite of all due care in design, component quality, manufacture, and testing prior to sale, leads may be damaged by improper handling, use, placement, or other intervening facts.

Users are encouraged to report any suspected or actual device related incidents or adverse events to Impulse Dynamics and Hospital Authorities.

No representation or warranty is made that (1) the failure or cessation of lead function will not occur, or (2) the body will not react adversely to the implantation, or (3) medical complications will not follow the implantation, or (4) the lead will in all cases restore adequate cardiac function.

APPENDIX I

As a convenience to the user, the following overview provides a brief and succinct summary of the characteristics of the ODOCOR II CCM Lead.

Physical Characteristics

Lead Diameter (Fr)	6.5
Introducer Size	7 Fr and 9 Fr with 0.89 mm guidewire
Length (cm)	52 and 58
Connector	IS-1 Bipolar
Fixation	Extendible/Retractable Screw-in Helix
Extend / Retract	IS-1 Pin Driven
Electrically Active Helix	Yes
Electrically-Active Electrode Surface Area (mm^2)	Tip: 6.9 Ring: 31.0
Electrode Spacing (mm)	10.5
Electrode Material	Tip and Ring: PtIr
Electrode Coating	Tip and Ring: TiN
Helix Extension (mm)	2.1 ± 0.18
Distal Rigid Section - nominal length (mm)	17.7
Distal Shape	Straight
Maximum Stylet Diameter (mm)	0.40
Inner and Outer Insulation	Silicone

Lead Length and Resistance

CONDUCTOR	**52 cm Lead**	**58 cm Lead**
Inner	52 Ω NOM	58 Ω NOM
Outer	82 Ω NOM	92 Ω NOM