Tendril™ SDX

Model 1688 T/TC

Endocardial
Steroid-eluting
Active fixation pacing leads

User's manual

St. Jude Medical™

General Description

The Tendril™ SDX Model 1688 is a bipolar, steroid-eluting, active fixation implantable pacing lead. The silicone-insulated lead can be placed either in the atrium or the ventricle.

Features of the Tendril SDX Model 1688 include:

- Electrically Active Collar — for mapping intracardiac signals to facilitate optimal lead positioning
- Active Fixation — features a rotating, extendable/retractable helix for secure anchoring
- Increased Helix Extension and Retraction Visibility — a marker aids visibility under fluoroscopy
- Steroid Elution — contains a monolithic controlled-release device (MCRD), located in the tip electrode of the lead, which is impregnated with dexamethasone sodium phosphate (DSP). The steroid (DSP) decreases the inflammatory reaction of the heart during the acute stage (0-3 months post implant) of patient recovery.
- Fast-Pass™ Coating — creates a highly lubricious surface for easy insertion

Note

The use of Tendril SDX Model 1688T/TC, a low-polarization bipolar lead, is compatible with the AutoCapture™ pacing system contained in St. Jude Medical pulse generators.

Intended Use/Indications

The Tendril SDX Model 1688 lead is designed for permanent sensing and pacing in either the atrium or the ventricle, in combination with a compatible pulse generator.

An active lead such as the Model 1688 may be indicated for patients where permanent fixation of passive leads is suspected to be unstable.

In atrial applications, the use of a screw-in lead such as the Model 1688 may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Table 1 lists accessories and their intended uses.

Accessories	Intended Use
Fixation tool	Insert and secure the stylet in the lead to allow extension and retraction of the helix.
Stylet	Stiffen and support the lead to facilitate placement.
Clip-on tool	Extend and retract the helix of an active-fixation lead.

Table 1. Accessories and their intended uses

Contraindications

The Tendril SDX Model 1688 lead is contraindicated:

- in the presence of tricuspid atresia
- for patients with mechanical tricuspid valves
- in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Packaging

Package Contents

The contents of the package are sterile. Each package contains:

- One lead
- One radiopaque suture sleeve attached to lead
- One vein lifter
- One (1688T) or two (1688TC) clip-on tools
- One fixation tool[1]
- Four stylets
  - Three soft, straight, tapered ball-tipped stylets with green knob with green button (0.35 mm diameter) (one installed in lead)
  - One soft, J-shaped, tapered ball-tipped stylet with green knob with white button (0.35 mm diameter)
- One literature pouch

1. Not included with Model 1688TC.

Packages may also contain:

- One additional soft, J-shaped, tapered ball-tipped stylet with green knob with white button (0.35 mm diameter)

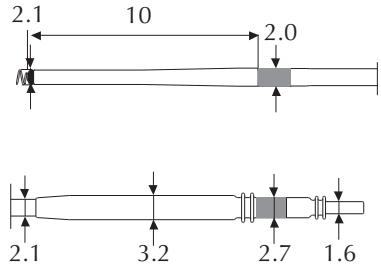

Figure 1. Tendril SDX Model 1688T/TC Lead Dimensions (in mm)

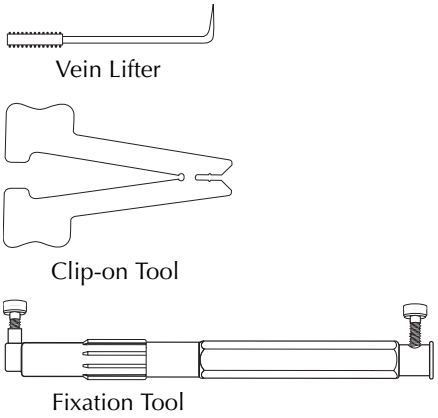

Figure 2. Tendril SDX Lead Accessories
(NOTE: The fixation tool is not included with the Model 1688TC)

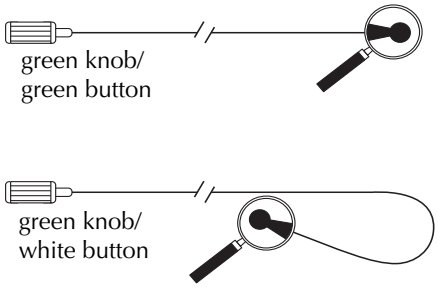

Figure 3. Tendril SDX Stylets

Storage

The lead should be stored at room temperature. Permitted storage temperatures are between -5° C (23° F) and +50° C (122° F).

Outer Package

The lead is delivered in an outer cardboard package sealed in plastic film. The package label contains valuable descriptive information, including model designation, serial number, and the "Use Before" date for implantation.

Before opening, verify: (1) the package has not been damaged, punctured or otherwise compromised, (2) the lead contained is suitable for your application. Do not implant if the "Use Before" date has expired.

Note

The lead and its accessories should be kept inside their sterile package until implantation.

Inner Package

Inside the cardboard box is an outer tray containing a sterilized inner tray. The inner tray contains the lead and its accessories. In order to preserve sterility, operating room procedures should be followed when opening the outer tray.

> **CAUTION**
>
> Only a person prepared for the sterile field may handle the sterile inner tray.
>
> Use only powderless, sterile surgical gloves when handling the lead.

Tear the label off the tray to reveal the sealed inner tray (Figure 4). When ready, tear open the inner tray (Figure 5).

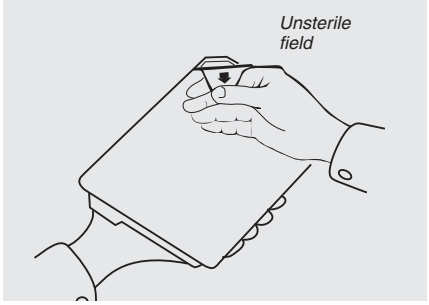

Figure 4. Opening the outer tray may be done by a person not prepared for the sterile field

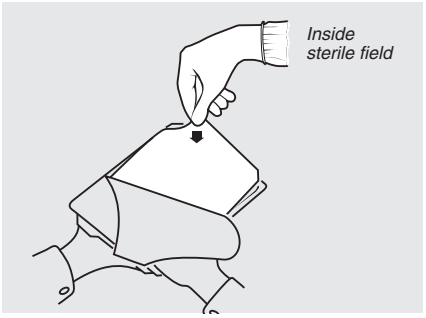

Figure 5. Only a person prepared for the sterile field may open the inner tray

Sterilization

- The package contents have been sterilized with ethylene oxide before shipment. This lead is for single use only and is not intended to be resterilized.
- If the sterile package has been compromised, contact St. Jude Medical.

Warnings

- Exercise extreme caution when testing leads.
- Use only battery-powered equipment during lead implantation and testing to protect against fibrillation which may be induced by alternating current.
- Use only properly grounded line-powered equipment in the vicinity of the patient during the implant procedure.
- Insulate lead connector pins from any leakage currents that may arise from line-powered equipment.
- Avoid diathermy, even if the device is programmed off, as it may damage tissue around the implanted electrodes or may permanently damage the pulse generator.

Precautions

- Before opening the lead package, confirm that it is compatible with the pulse generator to be implanted.

Handling

- The lead conductor and its insulating sheath may be damaged if subjected to extreme mechanical stress.
- Do not stretch, crush, kink, or bend the lead as leads may be damaged by improper handling before and during implant or by excessive mechanical stress post-implantation.
- Do not bring the lead into contact with sharp objects which could puncture or otherwise compromise the insulation.
- Avoid handling the lead with any surgical tools such as hemostats, clamps, or forceps.
- Avoid touching or handling the lead tip electrode.
- Do not immerse the lead body in mineral oil, silicone oil, or any liquid other than sterile saline or injectable fluid.
- Do not immerse the tip electrode in any fluid prior to implantation; immersion of the electrode may cause a small amount of steroid to be prematurely eluted.

Implantation

- Lead implantation should be performed only when proper emergency facilities for cardioversion and/or defibrillation are available.
- Do not slide the suture sleeve over the electrode ring(s), as this could cause damage to the lead.
- If subclavian venipuncture is used for lead introduction, it is important to insert the lead as lateral as possible when gaining entry of the lead into the vein.
- Perforation of the atrial or ventricular wall may cause phrenic nerve stimulation, diaphragmatic stimulation, or in some instances, cardiac tamponade. Phrenic nerve or diaphragmatic stimulation may also be a result of lead position.
- Failure to use the suture sleeve to anchor the lead may result in damage to the lead's insulation, conductor coil, or both (see "Securing the Lead", page 10).
- The manipulation of any hardware in the vascular system should be performed only under continuous fluoroscopic monitoring.

Potential Adverse Events

Potential complications associated with the use of the Tendril SDX Model 1688 lead are the same as with the use of any lead and include:

Complication	Possible effects
Perforation of the myocardium	Rupture of the heart muscle wall, "heart block", temporary or permanent loss of stimulation and/or sensitivity, stimulation of muscles or nerves, pericardial rub.
Stimulation of the phrenic nerve	The lead may need to be moved from the side wall
Dislodgement of the electrode tip or a break in the electrical conductor	Temporary or permanent loss of stimulation and/or sensitivity
Irritation of the heart muscle	Fibrillation
Transvenous introduction	Air embolism
Increased threshold level	Loss of stimulation
Infection	It may become necessary to perform surgical intervention to remove the lead.
Valve damage	It may become necessary to perform surgical intervention to repair the damaged vessel.
Tissue necrosis	It may become necessary to perform surgical intervention to remove the lead.
Damage to vessels	It may become necessary to perform surgical intervention to remove the lead and/or repair the damaged vessel.

Table 2. Potential Adverse Events

Implanting the Tendril™ SDX

The following sections describe various stages of lead implantation. Procedures included in these sections are only recommendations. Actual implant procedures are left to the discretion of the implanting physician.

It is best to keep the lead and its accessories inside the sterile package until they are to be used.

CAUTION

Pacing leads should only be implanted in conjunction with continuous fluoroscopic monitoring.

Pre-Implantation

Before implanting the lead:

- confirm compatibility between the pulse generator and the lead and review the implantation instructions
- select an appropriate venous route
- select and install an appropriate stylet
- test the mechanical function of the helix.

Selecting and Accessing a Vein

The suggested entry site is the left cephalic vein entered via a venous cutdown. Alternatively, the lead may be implanted percutaneously via the left subclavian vein. However, studies[2,3] indicate that the incidence of lead damage may be decreased with the lead placed by cephalic vein cut-down or, if a percutaneous subclavian entry is chosen, with a puncture site as lateral as possible (in the area under the lateral two-thirds of the clavicle, lateral to the subclavius muscle). The right subclavian vein and the internal jugular vein may also be used.

The Fixation Tool (Model 1688T only)

The Tendril SDX Model T is packaged with a simple fixation tool designed to insert and secure the stylet in the lead and to allow extension and retraction of the helix.

The tool is made up of two linked pieces. The proximal (white) portion contains a thumbscrew which holds the stylet in place. The distal (gray) portion contains a thumbscrew which secures the fixation tool to the lead collar.

To use the fixation tool, attach the terminal lead pin into the distal (gray) portion of the tool, then insert the stylet through the proximal (white) portion.

Inserting and Removing the Stylet

The Tendril SDX lead comes packaged with a straight stylet (green knob) inserted into the lead and secured into the fixation tool.

Note

The stylet should be removed before testing the lead for mechanical stability or making intraoperative measurements.

To remove the stylet from the fixation tool, unscrew the proximal thumbscrew on the tool by turning it counterclockwise and withdrawing the stylet (Figure 6).

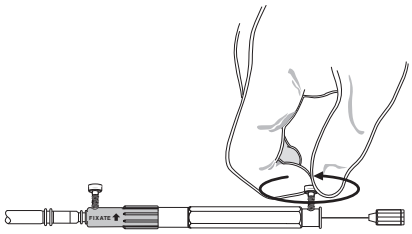

Figure 6. Unscrewing the proximal thumbscrew on the fixation tool before withdrawing the stylet

To replace the stylet, insert it into the fixation tool and tighten the proximal thumbscrew (Figure 7). The stylet should be inserted into the lead before the lead is inserted into the vein.

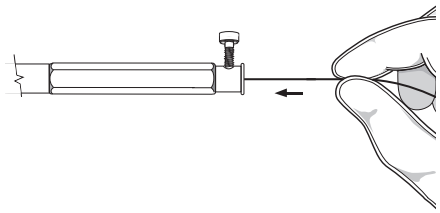

Figure 7. Inserting the stylet into the fixation tool

2. Magney, J.E., Flynn, D.M. Parsons, J.A., et al.: Anatomical Mechanisms Explaining Damage to Pacemaker Leads, Defibrillator Leads, and Failure of Central Venous Catheters Adjacent to the Sternoclavicular Joint. PACE 16 (I): 445-457, 1993.
3. Jacobs, D.M., Fink, A.S., Miller, R.P., et al.: Anatomical and Morphological Evaluation of Pacemaker Lead Compression. PACE 16 (I): 434-444, 1993.

Testing the Mechanical Operation of the Helix

Before implanting the lead, the mechanical operation of the helix should be tested.

With both thumbscrews secured and with the fixation tool in one hand, hold the lead stationary with the other hand (Figure 8).

Use the thumb and forefinger to rotate only the gray portion of the tool clockwise (in the direction of the arrow on the tool marked "FIXATE").

Check to see if the helix extends from the lead tip. The helix is considered fully extended when two turns are visible beyond the lead's collar. (Figure 8).

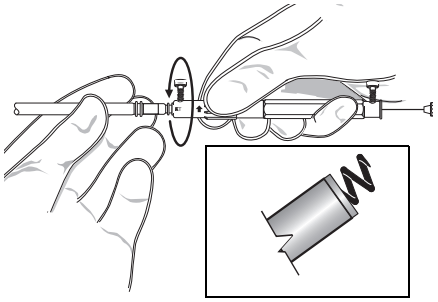

Figure 8. Extending the helix by rotating the fixation tool clockwise

Retract the helix by holding the lead body stationary in one hand and turning only the gray portion of the tool counterclockwise (opposite the direction indicated by the arrow "FIXATE"; Figure 9).

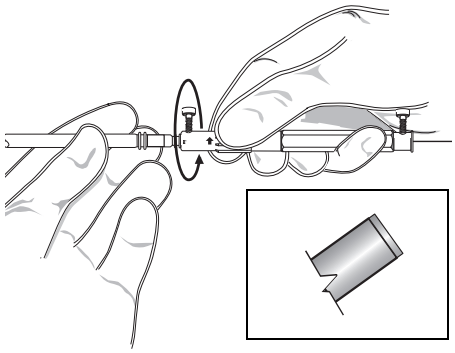

Figure 9. Retracting the helix by rotating the fixation tool counterclockwise

Using the Vein Lifter

A vein lifter is supplied to facilitate the introduction of the lead into a free-standing vein. Insert the tip of the vein lifter into the vein incision and gently lift it while introducing the lead underneath, into the vein.

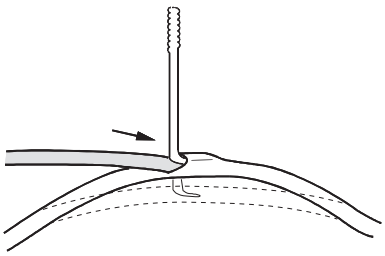

Figure 10. Vein lifter

Using the Lead Introducer

If a lead introducer is used, follow the instructions provided with the introducer.

CAUTION

Be certain the vein lifter does not puncture the silicone rubber insulation of the lead. This could prevent proper lead function.

Do not use excessive force while inserting the stylet.

When subclavian venipuncture is used for lead introduction, it is important to insert the lead as lateral as possible during entry of the lead into the vein.

Avoid positioning the lead so that it becomes sharply bent or subjected to tension.

Do not grip the lead with surgical instruments.

Do not leave a lead unconnected in a patient unless the lead is capped.

Positioning the Lead

Before the lead is inserted, be sure that the helix is completely retracted to prevent the lead from being caught in the vein during lead introduction.

Atrial Lead Placement

1. Using a straight (green knob) stylet, introduce the lead into the atrium so that it rests on the floor of the atrial chamber.
2. Replace the straight stylet with a J-shaped (green knob) stylet, or withdraw the existing stylet, bend it into a soft J-shape, and reinsert the curved stylet into the lead.
3. As the stylet approaches the electrode tip, introduce more lead to ensure that the tip remains in the atrium as the lead takes its "J" shape.
4. Retract the lead as necessary to ensure that the electrode tip slides into the atrial appendage. Observe the fluoroscopy monitor to verify that the "J" is straightening.
5. When the lead tip is past the appendage and in the chamber, feed more lead into the heart so that it regains its "J" shape.
6. Take a firm grip on the stylet, then introduce more of the lead so that the electrode tip goes as far as possible into the atrium. On fluoroscopy, the electrode tip will "tilt over" as proof that it can go no further.

Figure 11. Atrial lead placement

7. With the clip-on tool or the fixation tool, extend the helix so that the lead is fixed to the atrial wall (page 8-11).
8. Retract the entire stylet from the lead with a smooth and steady motion.
9. Check that the lead is properly anchored by introducing more of it into the heart until the loop that forms either lies on the bottom of the atrium, or is about to enter the inferior vena cava or the right ventricle. Retract any excess lead until it acquires the correct "J" shape (Figure 11).
10. Ask the patient to breathe deeply and check that the lead keeps its "J" shape.
11. Ask the patient to cough to ensure that the electrode is securely anchored.

Ventricular Lead Placement

1. Advance the lead into the atrium.
2. Pull the stylet back a few centimeters to reduce the risk of the lead damaging the valves or penetrating the heart muscle when it continues down into the ventricle.
3. Continue to advance the lead. When the tip reaches the apex, retract the stylet an additional ten or more centimeters.
4. With the clip-on tool or the fixation tool, extend the helix to fix the lead tip to the ventricular wall. If the tip is correctly secured, the lead will be felt to jerk slightly.
5. Remove the stylet completely. Adjust the lead so that it lies in the desired position in the ventricle (Figure 12).

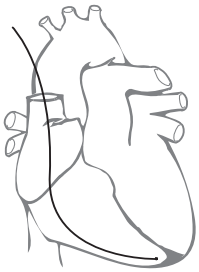

Figure 12. Ventricular lead placement

Securing the Tip with the Fixation Tool

After the fixation site has been selected, hold the lead body stationary in one hand and turn the distal (gray) section of the fixation tool clockwise (in the direction marked "FIXATE"). See the enclosed specification sheet for the approximate number of turns required for each lead length. On the fluoroscopic image, the helix will be extended beyond the mapping collar.

When two turns of the helix extend past the mapping collar, the helix is fully extended (Figure 13). Since the lead design allows for a versatile fixation site, it may be necessary to reposition the fluoroscopy camera or to advance the lead body in order to see the entire helix.

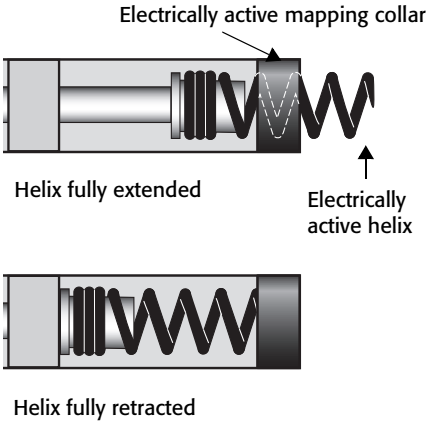

Figure 13. Extension and retraction of the helix

Once fixation is verified, loosen the proximal thumbscrew on the fixation tool and carefully withdraw the stylet under fluoroscopic observation. The lead tip should remain in position. Exercise caution during stylet retraction to avoid dislodging the lead.

Retraction of the J-shaped stylet may be more difficult than retraction of a straight stylet. A recommended method for retracting a J-shaped stylet is to loosen the proximal thumbscrew and hold the stylet handle manually; then gently advance the lead body into the atrium while simultaneously, but more slowly, advancing the stylet. Advance about twice as much lead as stylet; in this way, the J shape widens and the stylet can be more readily removed.

Securing the Tip with the Clip-On Tool

As an alternative to the fixation tool, the clip-on tool may be used to extend or retract the helix. It is included with all models. The Model 1688 TC is packaged with the clip-on tool only.

If using the clip-on tool with the Model T, remove the fixation tool and stylet. Insert the stylet into the lead and pinch open the clip-on tool (Figure 14). Place the lead terminal pin into the open notch of the clip-on tool so that the pin snaps into place and release the handles. Rotate the clip-on tool clockwise to extend the helix (Figure 15). To remove the clip-on tool, pinch it together and withdraw it from the lead connector.

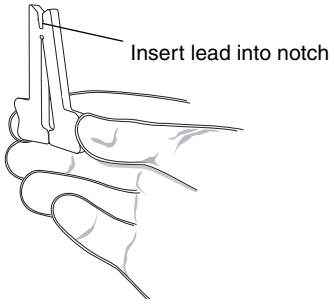

Figure 14. Opening the clip-on tool

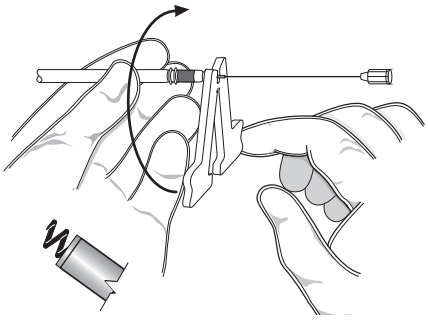

Figure 15. Extending the helix by rotating the clip-on tool clockwise

Intraoperative Measurements

During implantation, the stimulation threshold and the intracardiac signal should be measured using a pacing system analyzer (PSA). A low threshold value and high intracardiac signals are signs that the lead has been positioned satisfactorily.

WARNING

A pacing lead inserted into the heart presents a direct, low-impedance pathway for current flow to the myocardium. Use only battery-powered test equipment for electrical measurements.

Connection to Pacing System Analyzer

Make sure that the percutaneous lead introducer and stylet are removed from the lead and that the lead is fixated in what is believed to be a suitable location.

Use the PSA cables to connect the terminal pin of the implanted pacing lead to the PSA. It is recommended that the PSA be programmed OFF or passive while connections are being made.

Connect the positive (red) PSA cable to the lead connector's terminal ring (associated with the anode ring electrode) and connect the negative (black) PSA cable to the lead connector pin (cathode).

CAUTION

Carefully apply alligator clips to the lead's connector pin to avoid damaging the insulation between terminals.

Do not use an alligator clip as an indifferent electrode by connecting it directly to tissue. This can result in tissue trauma and cause inaccurate voltage thresholds and impedance measurements.

For more information, refer to the PSA manual.

Recommended Values

Recommended values on implantation, measured with a PSA	Ventricle	Atrium
Maximum stimulation threshold value	0.5 V (1 mA)	1.0 V (2 mA)
Minimum intracardiac amplitude	5 mV	2 mV
Lead impedance typical	500–2000 Ω	

Table 3. Recommended values on implantation, measured with a PSA

If the initial measurements are different from those recommended above, it is best to wait a while and then repeat the measurements. If the values do not stabilize at an acceptable level it may be necessary to alter the position of the electrode tip.

Securing the Lead

A suture sleeve is used to secure the lead to the vein or underlying fascia and to prevent damage to the insulation of the conductor which otherwise might be caused by the ligature.

When the positioning and measurements are complete, secure the lead with the suture sleeve to prevent the lead from sliding along the vein and rotating.

The ligature around the sleeve should be tight enough to hold the lead still, but not so tight as to damage the insulation or the conductor. Sew the suture sleeve to the tissue.

CAUTION

Do not slide suture sleeve over the electrode ring.

Suture sleeve sticking can occur. If this occurs, carefully twist the sleeve off the ring toward the connector pin; pulling the suture sleeve when it is positioned over the electrode ring may cause a tear in the lead body near the electrode ring.

Do not apply the ligature directly to the lead body, as this can damage the lead's insulation or conductor coil.

Do not tie the suture around the suture sleeve and lead too tightly, as this may result in excessive stress applied to the lead body.

Use the suture sleeve to distribute the tension created by the suture. Failure to use the suture sleeve may result in damage to the lead's insulation or conductor coil.

Connection to the Pulse Generator

Once the lead is anchored, connect the lead to the pulse generator following the instructions in the pulse generator manual.

CAUTION

Do not allow lead to become twisted. Instead, after connecting the lead, roll up surplus lead by rotating the pulse generator. Place the loops that this makes under the pulse generator.

Lead Extraction

Infection of the pacemaker system, particularly sepsis, may require the removal of both the pulse generator and the lead. Multiple abandoned leads and limitations to venous access are other common reasons to recommend lead extraction.

If it is necessary to abandon an indwelling pacing lead, cap its connector pin. Never cut an indwelling pacing lead. Cutting an indwelling pacing lead may cause the insulation to separate from the conductor coil and leave an exposed wire in the body.

If a lead must be removed due to infection or other serious reason, exercise great care, as lead extraction carries with it clinical risk.

Note

A pacing lead explanted for any reason should never be implanted in another patient.

It is generally recommended that a chronically implanted endocardial pacing lead not be repositioned except in special circumstances.

Explantation

If the lead or any portion of it is extracted, handle it according to local regulations. Clean the explanted device with disinfectant and return it to St. Jude Medical for investigation and safe disposal. For safety reasons, we recommend that all used leads be enclosed in a protective cover.

Please complete an Out of Service/Explant/Patient Death form and return it to St. Jude Medical with the explanted device. Whenever possible, send along a printout of the programmed settings of the pulse generator.

Technical Service

Members of the Technical Services Department are available to provide technical consultation 24 hours every day for any questions about the pacing system:

- In Sweden: +46 8-474 4147
  FAX: +46 8-760 5126 (during business hours only)

- In North America: +1-818-362-6822 or (toll-free) +1-800-722-3774
  FAX: +1-818-362-7182

Your local sales representative can also provide assistance.

Symbols

The following symbols are used on the lead labels.

	Method of sterilization using ethylene oxide
	Caution, Consult Accompanying Documents
	Date of Manufacture
	Country of manufacture; BE- Belgium, MY- Malaysia, US- United States
	Do Not Reuse
SN	Serial Number
	Use By
CE 0123	Affixed to this device in accordance with European Council Directive 90/385/EEC and 1999/5/EC. Hereby, St. Jude Medical declares that this device is in compliance with the essential requirements and other relevant provisions of these Directives.

Cardiac Rhythm Management Division

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