

Tendril™ STS

Model 2088TC

Active-fixation

Bipolar

Steroid-eluting

Endocardial

Pacing leads

USER'S MANUAL



Unless otherwise noted, TM indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL and the nine-squares symbol are trademarks and service marks of St. Jude Medical, Inc. and its related companies.

Pat. <http://patents.sjm.com>

© 2017 St. Jude Medical, Inc. All Rights Reserved.

General Description

The Tendril™ STS Model 2088TC leads are bipolar, steroid-eluting, active fixation implantable pacing leads with Optim™ insulation.

Certain Tendril STS Model 2088TC lead lengths have been tested for use in the MRI environment and are designated MR Conditional. See MR Conditional Pacing System (page 2).

The Tendril STS Model 2088TC lead can be placed in either the right atrium or the right ventricle.

Features of the Tendril STS Model 2088TC leads include:

- Soft Tip Header — reduces lead tip pressure
- Optim™ insulation — a silicone-polyurethane copolymer
- Tantalum Marker Ring — to facilitate optimal lead positioning
- Active Fixation — features a rotating, extendable/retractable helix for secure anchoring
- 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

Tendril STS Model 2088TC low-polarization bipolar leads are compatible with the AutoCapture™ pacing system contained in St. Jude Medical devices.

Intended Use/Indications

The Tendril™ STS Model 2088TC lead is designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible devices.

Active leads such as Tendril STS Model 2088TC leads 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 Tendril STS Model 2088TC leads may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Table 1 lists accessories and their intended uses.

Table 1. Accessories and their intended uses

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

Contraindications

The Tendril™ STS Model 2088TC leads are 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.

MR Conditional Pacing System

The St. Jude Medical™ MR Conditional lead is part of the St. Jude Medical MR Conditional pacing system.

Patients with an implanted St. Jude Medical™ MR Conditional pacing system can have an MRI scan if the conditions for use, as described in the MRI Procedure Information document, are met.

The following lead lengths have been tested and determined to be MR Conditional when used according to the instructions in MRI Procedure Information document. Lead lengths marked "Untested" have not been tested and their use in an MR environment is not determined.

Table 2. MR Conditional lead lengths for Tendril STS leads

Lead Length (cm)	MR Status
34	Untested
40	Untested
46	MR Conditional
52	MR Conditional
58	MR Conditional
65	Untested
85	Untested
100	Untested

Warnings

- Implanted cardiac leads are subjected to a hostile environment within the body due to constant, complex flexural and torsional forces, interactions with leads and/or the pulse generator, or other forces associated with cardiac contractions and patient physical activity, posture, and anatomical influences. Cardiac leads' functional lifetimes can be affected by these and other factors.
- 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.
- Testing has demonstrated that the St. Jude Medical™ MR Conditional pacing system is conditionally safe for use in the MRI environment when used according to the instructions in the MRI Procedure Information document. The St. Jude Medical MR Conditional pacing system includes a St. Jude Medical MR Conditional pulse generator connected to one or

more St. Jude Medical MR Conditional leads.

- "Untested" indicates that the device has not been tested and its use in an MR environment is not determined. For more information, please consult the MRI Procedure Information document.

Precautions

- For single use only.
- Before opening the lead package, confirm that the lead is compatible with the pulse generator to be implanted.
- Carefully remove the tip retainer from the lead prior to implantation.

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, alcohol, 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 lead dislodgement or damage to the lead's insulation and/or conductor coil (see Securing the Lead (page 15)).
- The manipulation of any hardware in the vascular system should be performed only under continuous fluoroscopic monitoring.
- Pay close attention to the handling of the helix extension/retraction mechanism before and during implantation.

Potential Adverse Events

Potential complications associated with the use of Tendril™ STS Model 2088TC leads are the same as with the use of any lead and include:

Table 3. Potential adverse events

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. Cardiac tamponade.
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 sensing
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 valve.
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.

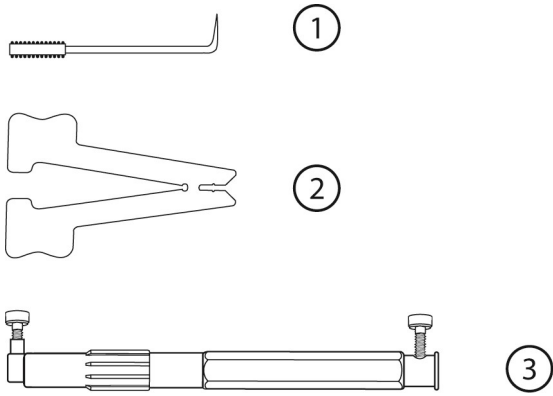
Packaging

Package Contents

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

- One lead
- One radiopaque suture sleeve attached to lead
- One vein lifter
- Two clip-on tools
- One tip retainer (to be removed prior to implant)
- Five stylets with knob colors designating degree of firmness:
 - Two extra soft, tapered ball-tipped stylets with light green knob and green button (0.35 mm diameter) (one installed in lead)
 - One soft, straight, tapered ball-tipped stylet with green knob with green button (0.35 mm diameter)
 - Two soft, J-shaped, tapered ball-tipped stylets with green knob with white button (0.35 mm diameter)
- One literature pouch

Figure 1. Tendril STS 2088TC Lead Accessories



1. Vein lifter
 2. Clip-on tool
 3. Fixation tool
-

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 a cardboard package. 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.

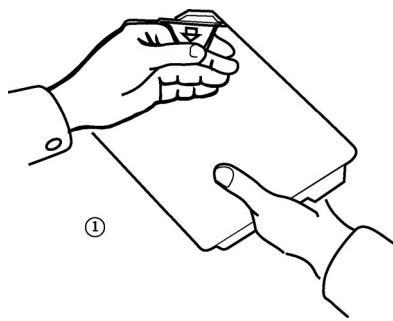
In order to preserve sterility, operating room procedures should be followed when opening the outer tray.

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.

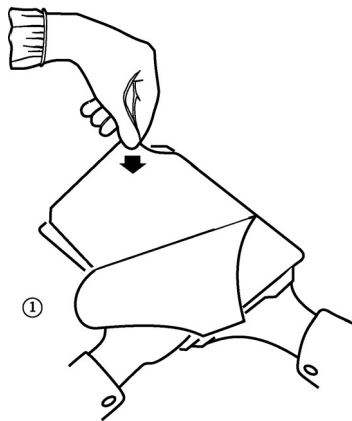
Tear the label off the tray to reveal the sealed inner tray. When ready, tear open the inner tray.

Figure 2. A person not prepared for the sterile field may open the outer tray



1. Unsterile field

Figure 3. Only a person prepared for the sterile field may open the inner tray



1. Inside sterile field

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.

Implanting the Tendril™ STS Lead

Pre-Implantation

Before implanting the lead:

- confirm compatibility between the device 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
- confirm the helix is completely retracted before implantation.

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, studies¹ indicate that the incidence of lead damage may be decreased with the lead placed by cephalic vein cutdown 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

Selected St. Jude Medical stylet kits² include 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's marker ring.

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. While holding the fixation tool in one hand, use the other hand to unscrew/screw the fixation tool to the connector pin.

Inserting and Removing the Stylet

The lead comes packaged with a straight stylet (light green knob) inserted into the lead.

Note

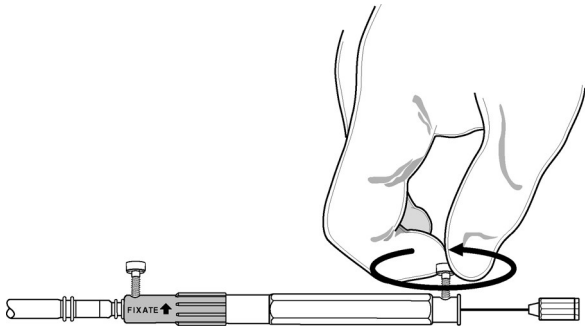
The stylet should be removed before testing the lead for mechanical stability or making intraoperative measurements.

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

¹ 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. 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.

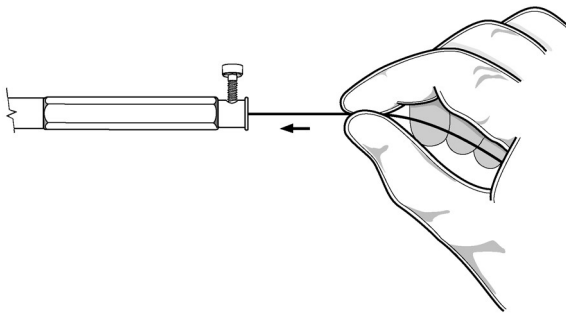
² For additional information, contact your St. Jude Medical Sales Representative.

Figure 4. Unscrew the proximal thumbscrew on the fixation tool before you withdraw the stylet



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

Figure 5. Insert the stylet into the fixation tool



Testing the Mechanical Operation of the Helix with the Fixation Tool

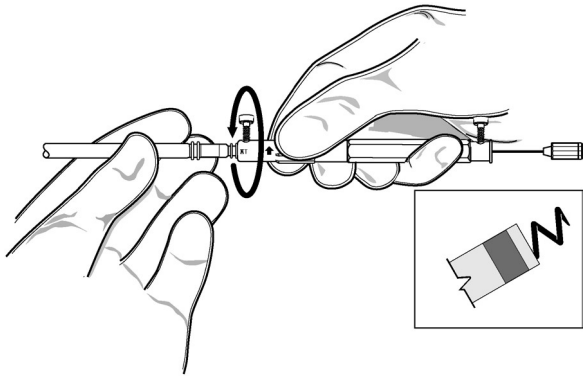
Before implanting the lead, the mechanical operation of the helix should be tested.

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

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").

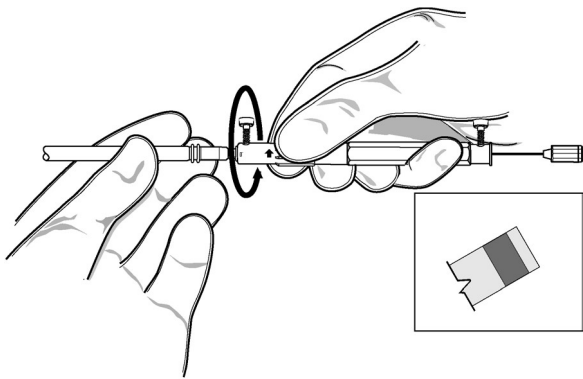
Check to see if the helix extends from the lead tip. The helix is considered fully extended when two turns are visible beyond the lead's marker ring.

Figure 6. 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 7. Retracting the helix by rotating the fixation tool counterclockwise



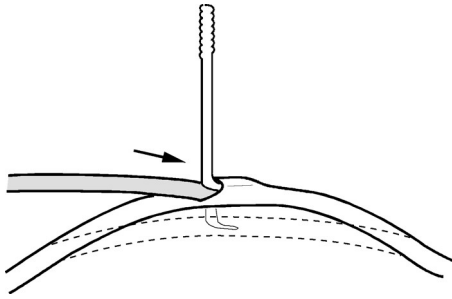
Testing the Mechanical Operation of the Helix with the Clip-On Tool

For information on using the clip-on tool, see Securing the Tip with the Clip-On Tool.

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 8. Vein lifter



Using the Lead Introducer

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

CAUTION

- If using a percutaneous lead introducer with a hemostasis valve, make sure the valve allows for appropriate passage of the lead without damaging the lead body.
- Be certain the vein lifter does not puncture the 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

Confirm that the helix is completely retracted before implantation. This will prevent the lead from being caught in the vein during lead introduction.

Note

If blood clogs the helix, repositioning may require a greater number of pin rotations to extend the helix. Repeated repositioning attempts may impair the helix extension mechanism.

Atrial Lead Placement

1. Using a straight (green or light 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 9. Atrial lead placement

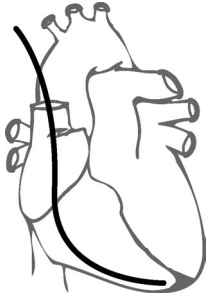


7. With the clip-on tool or the fixation tool, extend the helix so that the lead is fixed to the atrial wall (page 12).
8. Retract the entire stylet from the lead with a smooth and steady motion.
9. Check that the lead is properly anchored by introducing more of it into the heart until the loop that 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.
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 10. Ventricular lead placement

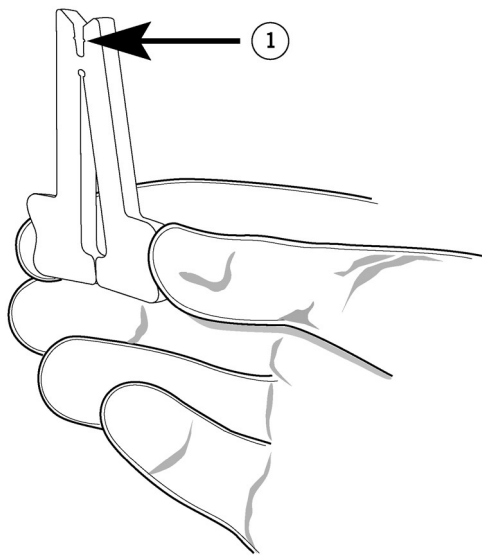


Securing the Tip with the Clip-On Tool

Tendril STS Model 2088TC leads are packaged with the clip-on tool only.

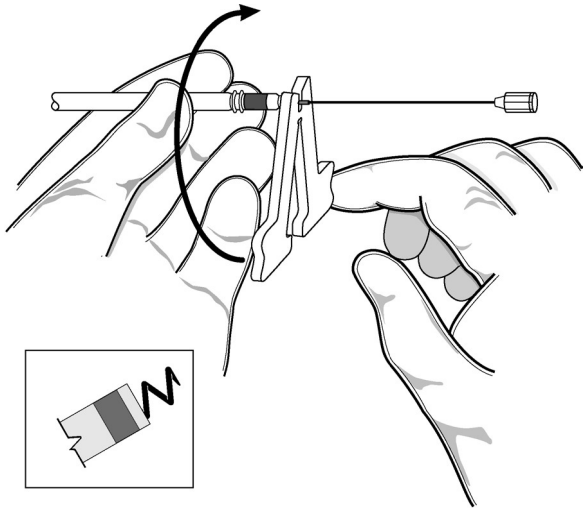
Insert the stylet into the lead and pinch open the clip-on tool. Place the lead terminal pin into the open notch of the clip-on tool so that the pin snaps into place and release the handles. Rotate the clip-on tool clockwise to extend the helix. To remove the clip-on tool, pinch it together and withdraw it from the lead connector.

Figure 11. Opening the clip-on tool



1. Insert lead into notch

Figure 12. Extending the helix by rotating the clip-on tool clockwise

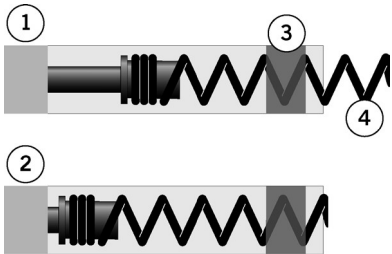


Securing the Tip with the Fixation Tool

As an alternative to the clip-on tool, the fixation tool may be used to extend or retract the helix. 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 marker ring.

When two turns of the helix extend past the marker ring, the helix is fully extended, as shown in 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



1. Helix fully extended
 2. Helix fully retracted
 3. Marker ring
 4. Electrically active 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.

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 the 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.

For more information, refer to the PSA manual.

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.

Recommended Values

Table 4. Recommended acute stimulation and sensing thresholds (0.4 ms pulse width, 500 Ω load)

Recommended values on implantation, measured with a PSA	Atrium	Ventricle
Acute Stimulation Threshold	<1.5 V <3.0 mA	1.0V <2.0 mA
Acute Sensing Threshold	>2.0 mV	>5.0 mV
Bipolar pacing impedance	250 — 2000 Ω	

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.

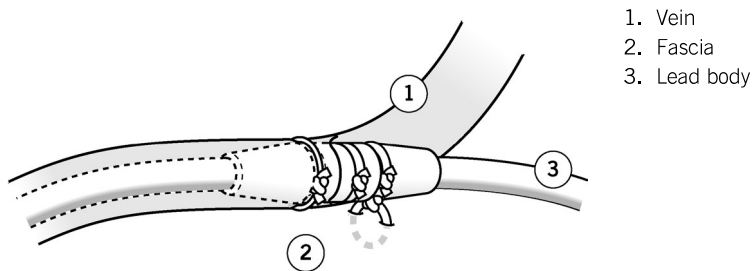
Securing the Lead

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, firmly 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. Tie sutures firmly around each available groove on the suture sleeve. The most distal groove may be used to tie off the vein over the suture sleeve.

Figure 14. Suturing the lead



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 Device

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

Grasp the lead connector as close as possible to the connector pin while inserting the lead connector straight into the pulse generator port. If necessary, regrip the lead and continue to insert the lead connector until it is fully seated in the pulse generator port.

CAUTION

Orient the excess lead length and the pulse generator to minimize the potential for insulation damage resulting from lead-to-lead or pulse generator-to-lead interaction. For example, minimize the potential for leads lying on top of each other under the pulse generator and ensure that there are no sharp bends in the lead. Lead insulation damage can create an alternate electrical current path which may result in compromised therapy delivery. Current practice indicates that a subcutaneous pocket is preferred over a subpectoral pocket^{3,4}.

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 implantable device system, particularly sepsis, may require the removal of both the device 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

St. Jude Medical maintains 24-hour phone lines for technical questions and support:

- 1 818 362 6822
- 1 800 722 3774 (toll-free within North America)
- + 46 8 474 4147 (Sweden)

For additional assistance, call your local St. Jude Medical representative.

³ Furman S, Hayes DL, Holmes DR. A Practice of Cardiac Pacing. 3rd ed. New York: Futura Publishing, Inc.; 1993:286-289.

⁴ Belott, PH, Reynolds, DW. Permanent Pacemaker and Implantable Cardioverter-Defibrillator Implantation. In: Ellenbogen KA, Kay GN, Wilkoff BL, eds. Clinical Cardiac Pacing and Defibrillation. 2nd ed. Philadelphia, Pa: WB Saunders; 1995:613-615.

Specifications

Table 5. Nominal Specifications

Length	34, 40, 46, 52, 58, 65, 85, 100 cm
Connector type	IS-1 ⁵ bipolar
Lead introducer (minimum recommended)	6F ⁶ (without retained guidewire)
Maximum diameter of lead body	1.9 mm
Fixation mechanism	active helix
Electrode configuration	
Tip	helix
Ring	cylindrical
Electrode spacing	
Tip to ring	10 mm
Electrode surface area	
Tip	6.9 mm ²
Ring	16 mm ²
Electrode length	
Tip (extended)	2 mm
Electrical resistance	
Tip to connector pin	34 cm: 10-16 Ω; 52 cm: 16-28Ω; 85 cm: 29-49Ω 40 cm: 12-20Ω; 58 cm: 19-31Ω; 100 cm: 34-58Ω 46 cm: 14-24Ω; 65 cm: 21-35Ω
Ring to connector ring	34 cm: 22-36 Ω; 52 cm: 33-55Ω; 85 cm: 54-90Ω 40 cm: 25-43Ω; 58 cm: 37-61Ω; 100 cm: 63-105Ω 46 cm: 29-49Ω; 65 cm: 41-69Ω
Materials	
Conductors	multifilar MP35N ⁷
Connectors	stainless steel
Lead body	Optim ^{TM8} insulation with exterior Fast-Pass TM coating
Suture sleeve	titanium nitride-coated platinum iridium alloy
Tip and ring electrodes	silicone rubber
Soft tip	silicone rubber with less than 1.0 mg dexamethasone
Steroid-eluting plug	sodium phosphate
Stylet	stainless steel
Typical number of rotations to extend helix for initial placement⁹	
Straight stylet	6-11 ¹⁰
J stylet	9-14 ¹¹

⁵ St. Jude Medical IS1 lead connectors are compatible with connector cavities that conform to the international connector standard ISO58413.

⁶ Compatible with introducers such as those manufactured by Daig and Pressure Products.

⁷ MP35N LT is a trademark of SPS Technologies.

⁸ Optim is a silicone-polyurethane copolymer.

⁹ Lead length, stylet configuration, and differences in anatomy may cause variations in the number of rotations required to extend the helix.

¹⁰ Not to exceed 35 rotations.

¹¹ Not to exceed 35 rotations.

Accessories

Table 6. Accessories

Stylet kit with Clip-On Tool
Stylet kit with Fixation Tool
Locator™ Steerable Stylet
Locator™ Plus Deflectable Stylet







Stylet Color Codes















Table 7. Stylet color codes

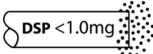







Knob Color	Description	Diameter
Green	Soft straight (20 mm taper)	0.014 in/0.35 mm
Light green	Extra-soft straight (40 mm taper)	0.014 in/0.35 mm
Yellow	Firm straight	0.015 in/0.38 mm
Red	Extra firm straight	0.016 in/0.41 mm
Green, white dot	Soft (20 mm taper)	0.014 in/0.35 mm

Symbols

The following symbols may be found on the product or product label:

Symbol	Description
	Sterilized using ethylene oxide
	Consult instructions for use
 <small>manuals-sjm.com</small>	Follow instructions for use on this website
	Date of Manufacture
	Manufacturer
	Country of manufacture; BE- Belgium, MY- Malaysia, US- United States

Symbol	Description
	Do not reuse
	Serial number
	Use by
	Temperature limitations
	Authorized EC Representative in the European Community
	Do not use if package is damaged
	Affixed 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.
	Device has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use.
	Reorder number
	Pacing lead
	Active fixation, Extendable/Retractable
	Steroid-eluting
IS-1 BI	Bipolar
	Endocardial
	Optim lead insulation overlay with Fast-Pass coating

Symbol	Description
	Contains less than 1.0 mg dexamethasone sodium phosphate
	Minimum introducer size
	Caution
	Not to be used when a single dose of 1.0 mg dexamethasone sodium phosphate is contraindicated
	Contents
	One lead
	Product literature
	Accessories
Made in USA	Made in USA

Manufacturer:
St. Jude Medical
Cardiac Rhythm
Management Division
15900 Valley View Court
Sylmar, CA 91342 USA
+1 818 362 6822

Manufacturing Site:
St. Jude Medical Puerto Rico LLC
Lot A Interior - #2 Rd Km. 67.5
Santana Industrial Park
Arecibo, PR 00612
USA

sjm.com

European Authorized Representative:
St. Jude Medical
Coordination Center BVBA
The Corporate Village
Da Vincilaan 11 Box F1
1935 Zaventem
Belgium
+32 2 774 68 11

Manufacturing Site:
St. Jude Medical Operations (M) Sdn. Bhd.
Plot 102, Lebuhraya Kampung Jawa,
Bayan Lepas Industrial Zone
11900 Penang
Malaysia

Australian Sponsor:
St. Jude Medical Australia Pty. Limited
17 Orion Road
Lane Cove NSW 2066
Australia



100155208

January 2017
ARTEN100155208A

CE
0123
2009