# Tendril™ STS

Pacing leads
Model 2088TC

# User's Manual

St. Jude Medical

# 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 device.

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.

For indications for use for the pacing system, please refer to the applicable pulse generator manual.

Table 1 lists the lead 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. |

NOTE: Some accessories are not necessarily packaged with the lead and may be ordered separately. For more information, contact your local St. Jude Medical representative.

# 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.

For contraindications for the pacing system, please refer to the applicable pulse generator manual.

# 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-Ready Systems Manual, are met.

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 | MR Status |
|---|---|
| 34 cm | Untested |
| 40 cm | Untested |
| 46 cm | MR Conditional |
| 52 cm | MR Conditional |
| 58 cm | MR Conditional |
| 65 cm | Untested |
| 85 cm | Untested |
| 100 cm | 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-Ready Systems manual. 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-Ready Systems manual.

# 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 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 Effects

The following table lists potential adverse effects and their categories as applicable when using a Tendril™ STS lead.

Table 3. Potential Adverse Effects

| Adverse Effect | Categories |
|---|---|
| Arrhythmia | • Induced atrial ectopy or arrhythmias<br>• Induced atrioventricular or bundle branch block<br>• Induced ventricular ectopy or arrhythmias<br>• Lead dysfunction (sensing/threshold Issue) |
| Cardiac perforation | • Cardiac tamponade<br>• Perforation of the myocardium<br>• Pericardial effusion<br>• Pericarditis |
| Death | — |
| Embolism | • Air embolus<br>• Intravascular foreign body<br>• Dislodgement of intracardiac thrombus |
| Extra-cardiac stimulation | — |
| Heart failure | • Right ventricular decompensation<br>• Tricuspid valve dysfunction |
| Hypersensitivity | • Allergic reaction |
| Infection | • Endocarditis<br>• Pericarditis |
| Lead revision or reprogramming | • Electrical malfunction of the lead<br>• Lead dislodgement<br>• Lead dysfunction (sensing/threshold Issue)<br>• Mechanical malfunction of the lead |
| Pleural perforation | • Hemothorax<br>• Pneumothorax |
| Prolonged exposure to fluoroscopic radiation | — |
| Tricuspid value perforation | — |
| Vascular perforation | • Arteriovenous fistula<br>• Arterial perforation<br>• Coronary sinus or coronary vein perforation<br>• Hematoma<br>• Venous perforation |
| Vascular thrombosis | — |

# Packaging

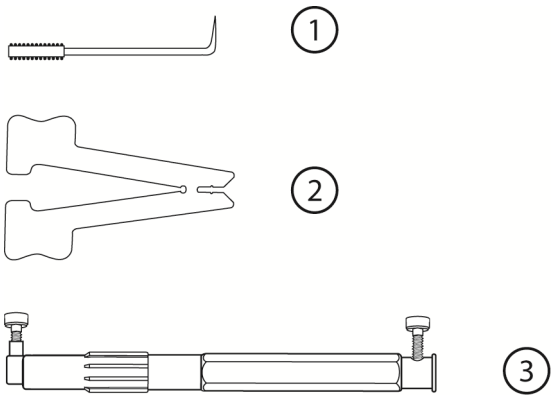
## Package Contents

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)
- Stainless steel stylets with knob colors designating degree of firmness. See Stylet Color Codes (page 19).
- One literature pouch

Figure 1. Tendril™ STS 2088TC Lead Accessories




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

## Storage

Store the lead at temperatures 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.

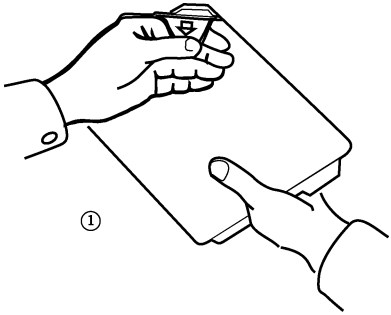
In order to preserve sterility, operating room procedures should be followed when opening the outer tray.

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.**

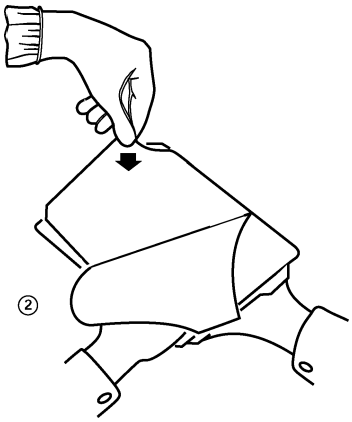
Tear the label off the tray to reveal the sealed inner tray. When ready, tear open the inner tray.

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




2. 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 lead may be implanted via a cephalic vein cutdown, or percutaneously, via the axillary, subclavian, or internal jugular veins. Either the left or right side may be used.

## The Fixation Tool

Selected St. Jude Medical stylet kits[1] 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

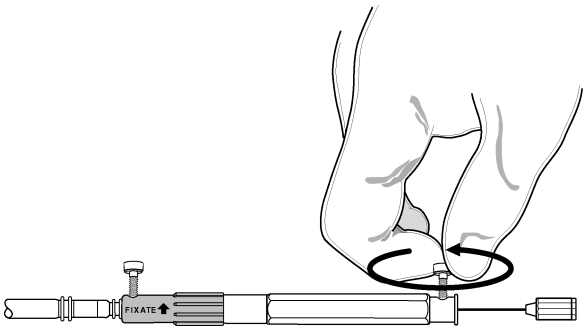
The lead comes packaged with a straight stylet (light green knob) inserted into the lead.

> 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.

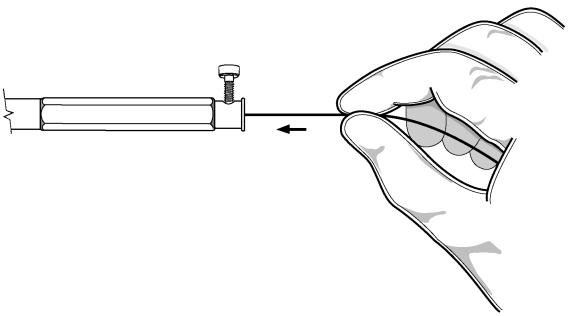
[1] For additional information, contact your St. Jude Medical Sales Representative.

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

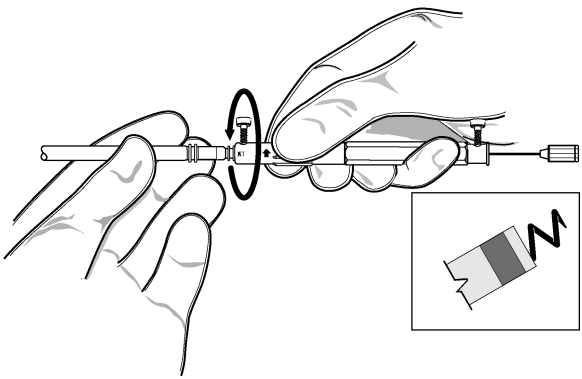
Before implanting the lead, the mechanical operation of the helix should be tested.

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").

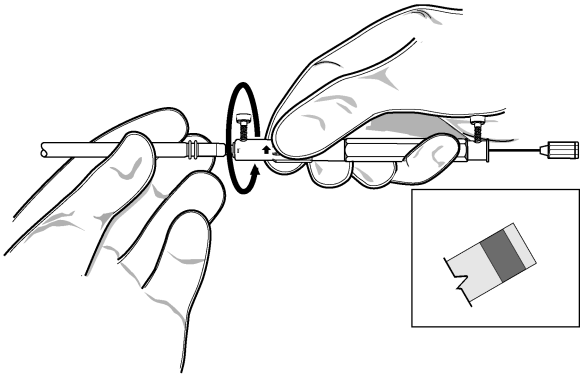
Check to see if the helix extends from the lead tip. The helix is considered fully extended when two turns are visible beyond the lead's marker ring.

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



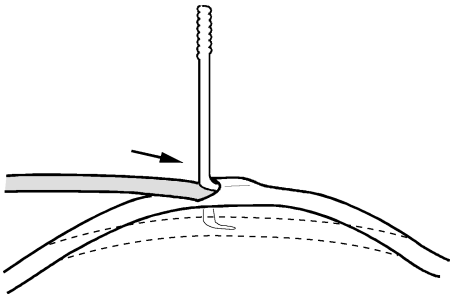
## Testing the Mechanical Operation of the Helix with the Clip-On Tool

For information on using the clip-on tool, see Securing the Tip with the Clip-On Tool (page 12).

## 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 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

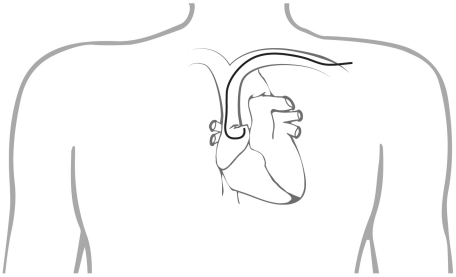
Confirm that the helix is completely retracted before implantation. This will prevent the lead from being caught in the vein during lead introduction.

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 so that the electrode tip of the lead is placed into the center of the right atrium.
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 right atrium as the lead takes its "J" shape.
4. Retract the lead as necessary to ensure that the electrode tip slides into the right 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, then gently advance the 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 right atrium. On fluoroscopy, the electrode tip will "tilt over" as proof that it can go no further.

Figure 9. Atrial lead placement

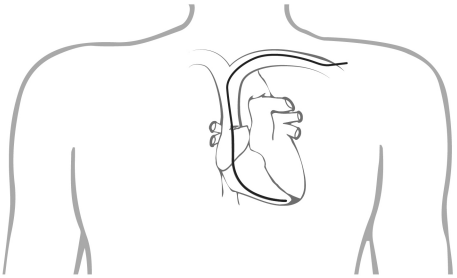


7. With the clip-on tool or the fixation tool, extend the helix so that the lead is fixed to the right atrial appendage.
8. Retract the entire stylet from the lead with a smooth and steady motion.
9. Check that the lead is properly anchored by introducing more of it into the heart until the loop that 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 right 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 electrode tip reaches the right ventricular apex, retract the stylet an additional ten centimeters or more.
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 right ventricle.

Figure 10. Ventricular lead placement

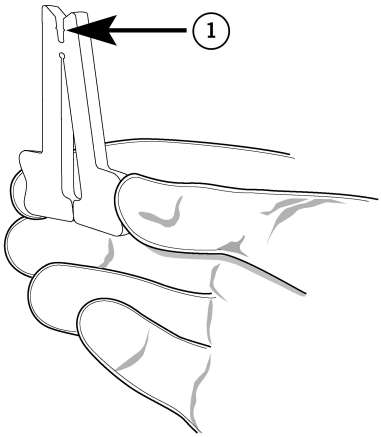


## Securing the Tip with the Clip-On Tool

The lead is packaged with the clip-on tool only.

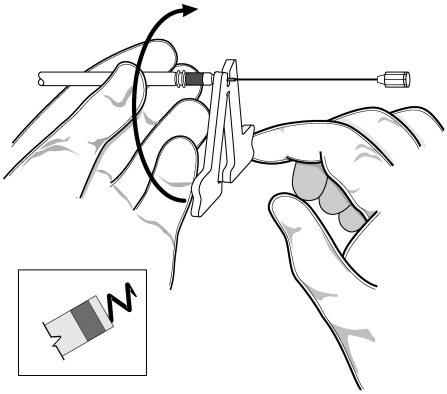
Insert the stylet into the lead and pinch open the clip-on tool. Place the lead terminal pin into the open notch of the clip-on tool so that the pin snaps into place and release the handles. Rotate the clip-on tool clockwise to extend the helix. To remove the clip-on tool, pinch it together and withdraw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

Figure 11. Open the clip-on tool




1. Insert lead into notch

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



## Securing the Tip with the Fixation Tool

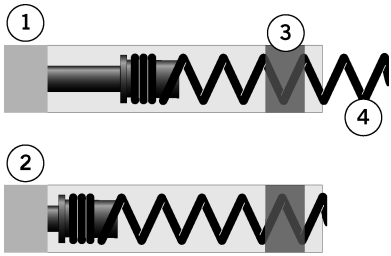
As an alternative to the clip-on tool, the fixation tool may be used to extend or retract the helix.

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

the following figure. 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.**

The following table contains recommended acute stimulation and sensing thresholds as measured with a PSA (0.4 ms pulse width, 500 Ω load).

Table 4. Recommended values measured with a PSA

| Measurement | Atrium | Ventricle |
|---|---|---|
| Acute Stimulation Threshold | <1.5 V<br><3 mA | 1.0 V<br><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.

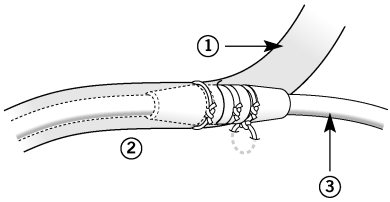
# Securing the Lead

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




1. Vein
2. Fascia
3. Lead body

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.

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[2,3].**

**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.

Percutaneous extraction, when indicated, may be performed using a stepwise approach using standard documented techniques and equipment for extracting transvenous pacemaker leads[4]. The specific steps to be used for extraction may vary from patient to patient depending on the clinical circumstances and encountered anatomy. In general, the following steps may be used, but are not limited to, to extracting the Tendril™ STS lead (Model 2088TC):

1. After opening the device pocket detach the pacing lead from the pulse generator and completely dissect the lead free from any tissue and sutures all the way to the venous insertion site.

2. Insert a stylet to the distal end of the lead and retract the fixation helix from the heart tissue using the clip-on tool.

3. Attempt to remove the lead from the heart and venous system using manual traction under fluoroscopic guidance. If the lead cannot be easily removed, then utilize standardized extraction tools such as a locking stylet and specialized sheaths.

4. Manual traction with a locking stylet may be used initially. If the lead cannot be extracted with manual traction alone, then extraction with a specialized sheath such as a mechanical sheath, laser sheath, electrosurgical sheath, or telescoping sheath may be used. Consult with the instructions for use provided by the manufacture of the locking stylet and specialized sheath for further specific instructions.

5. If extraction of the lead is not possible, then it may be necessary to consider using an additional venous approach (e.g., femoral vein) for completing the extraction procedure, or

[2] Furman S, Hayes DL, Holmes DR. A Practice of Cardiac Pacing. 3rd ed. New York: Futura Publishing, Inc.; 1993:286-289.
[3] 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.
[4] Wilkoff BL, Love CJ, Byrd CL, et al. Transvenous lead extraction: Heart Rhythm Society Expert Consensus on Facilities, Training, Indications, and Patient Management. Heart Rhythm 6(7):1085-104, 2009; Smith MC, Love CJ. Extraction of Transvenous Pacing and ICD Leads. Pacing and Clinical Electrophysiology 31(6):736-752; 2008.

consideration should be given to abandoning the pacing lead, or referring the patient for extraction using an open cardiac surgery approach.

**WARNING: Extraction of a pacing lead has the potential to result in serious complications secondary to cardiovascular injury, including the potential for death, and should only be performed by individuals that are experienced and trained to perform such a procedure.**

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.

**WARNING: 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 Support

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)
- + 61 2 9936 1200 (Australia)
- manuals.sjm.com

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

# Technical Specifications

Table 5. Technical 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<br>40 cm: 12-20 Ω<br>46 cm: 14-24 Ω | 52 cm: 16-28 Ω<br>58 cm: 19-31 Ω<br>65 cm: 21-35 Ω | 85 cm: 29-49 Ω<br>100 cm: 34-58 Ω |
| Ring to connector ring | 34 cm: 22-36 Ω<br>40 cm: 25-43 Ω<br>46 cm: 29-49 Ω | 52 cm: 35-55 Ω<br>58 cm: 37-61 Ω<br>65 cm: 41-69 Ω | 85 cm: 54-90 Ω<br>100 cm: 63-105 Ω |
| **Materials** | | | |
| Conductors | multifilar MP35N[7] | | |
| Connectors | stainless steel | | |
| Lead body | Optim™[8] insulation with exterior Fast-Pass™ coating | | |
| Suture sleeve | silicone rubber | | |
| Tip and ring electrodes | titanium nitride-coated platinum iridium alloy | | |
| Soft tip | silicone rubber | | |
| Steroid-eluting plug | silicone rubber with less than 1.0 mg dexamethasone sodium phosphate | | |
| Stylet | stainless steel | | |

[5] St. Jude Medical IS1 lead connectors are compatible with connector cavities that conform to the international connector standard ISO 58413.
[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.

Table 5. Technical Specifications

| | |
|---|---|
| **Typical number of rotations to extend helix for initial placement[9]** | |
| Straight stylet | 6-11[10] |
| J stylet | 9-14[11] |

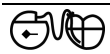
# Stylet Color Codes

Table 6. Stylet color codes

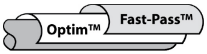
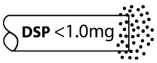
| Knob Color | Description | Diameter |
|---|---|---|
| Green | Soft straight (20 mm taper) | 0.014 in/0.35 mm |
| Light green | Extra-soft straight (40 mm taper) | 0.014 in/0.35 mm |
| Yellow | Firm straight | 0.015 in/0.38 mm |
| Red | Extra firm straight | 0.016 in/0.41 mm |
| Green, white dot | Soft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

# Symbols

The symbols below and harmonized symbols may be found on the product or product label. For harmonized symbols, refer to the Universal Symbols Glossary at https://manuals.sjm.com.

| Symbol | Description |
|---|---|
|   | Follow instructions for use on this website |
|  | Manufacturing Facility |
| CE 0123 | 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. |
|  | Pacing lead |
|  | Active fixation, Extendable/Retractable |

[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.

| Symbol | Description |
|---|---|
|  | Steroid-eluting |
| IS1-BI | Bipolar |
|  | Endocardial |
|  | Optim lead insulation overlay with Fast-Pass coating |
|  | 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 |

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