Durata™

Model 7120Q
Model 7121Q
Model 7122Q

Quadpole connector
Active-fixation
True bipolar
Dual-coil/Single coil
Steroid-eluting
Endocardial
Defibrillation leads

User's Manual

ST. JUDE MEDICAL

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

WARNING: This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defects or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Description

Durata™ Models 7120Q, 7121Q, and 7122Q transvenous tachyarrhythmia leads are steroid-eluting, active fixation leads, and are designed for long-term attachment to an implantable cardioverter defibrillator (ICD). The Models 7120Q and 7121Q leads have two defibrillation electrodes. The Model 7122Q lead has one defibrillation electrode. The leads provide true bipolar rate-sensing, pacing, and delivery of cardioversion/defibrillation shocks.

Models 7120Q, 7121Q, and 7122Q are designed for implantation with the distal tip positioned in the right ventricle. The tip incorporates an extendable/retractable helix for fixation in the ventricle. The low profile, flat-wire defibrillation electrodes with silicone rubber backfilling are intended to preclude tissue ingrowth.

Models 7120Q and 7121Q are quadripolar leads. Model 7122Q is a tripolar lead. The true bipolar leads have an electrically active, titanium nitride (TiN) coated, platinum iridium helix electrode and ring electrode for pacing and sensing. The design of the tip aids visibility under fluoroscopy. The retracted helix allows the electrical testing of possible lead positions prior to advancement of the fixation helix. A 5 cm long distal defibrillation electrode coil is located 17 mm from the distal tip of the lead. An 8 cm long proximal defibrillation electrode is located 17 cm (Model 7120Q) or 21 cm (Model 7121Q) from the distal tip of the lead.

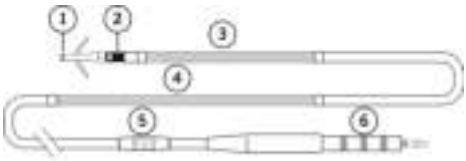
A single DF4 (quadpole, four electrical terminal) lead connector connects the electrodes to the pulse generator for delivery of high voltage cardioversion/defibrillation and pacing/sensing therapies. The DF4 lead connector is compatible with device headers with a DF4-LLHH lead receptacle designation. The DF4 lead connector connects the lead to the pulse generator for bipolar sensing and pacing using the pacing tip as the cathode (-) and a small-surface ring electrode as the anode (+). The DF4 lead terminal pin has an opening to accept the positioning stylet and rotates to extend and retract the helical tip. SJ4-LLHH is equivalent to DF4-LLHH. SJ4 and DF4 connectors comply with ISO27186:2010(E).

Portions of the lead body have an Optim™ (silicone polyurethane copolymer) insulation overlay. The lead body insulation tubing is Optim insulation and silicone rubber for long-term biocompatibility and biostability. The lead body is treated with Fast-Pass™ coating to provide lubricity during lead implant. The minimum introducer size recommended is 7 French. The silicone distal header is collapsible and is compatible with a 7 French introducer.

After contact with body fluid, the helix electrode elutes dexamethasone sodium phosphate (DSP), a steroid. This minimizes tissue inflammation, which, in turn, is believed to reduce both acute and chronic pacing thresholds. The target dose of dexamethasone sodium phosphate (DSP) in the monolithic controlled release device (MCRD) is 491 micrograms.

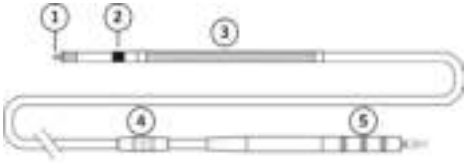
For information on the specifications of any lead model, refer to the Technical Specifications sheet.

Figure 1. Durata Model 7120Q/7121Q lead



1. Tip Electode (Cathode)
2. Ring Electrode (Anode)
3. Distal Defibrillation Electrode
4. Proximal Defibrillation Electrode
5. Suture Sleeve
6. DF4 Connector

Figure 2. Durata Model 7122Q lead



1. Tip Electrode (Cathode)
2. Ring Electrode (Anode)
3. Defibrillation Electrode
4. Suture Sleeve
5. DF4 Connector

Indications

The Durata™ Models 7120Q, 7121Q, and 7122Q leads are 7 French, transvenous, steroid eluting, bipolar, DF4 compatible (single connector with four electrical terminals), active fixation leads intended for permanent sensing and pacing of the right ventricle and the delivery of cardioversion/defibrillation therapy when used with a compatible St. Jude Medical™ pulse generator with a DF4-LLHH lead receptacle designation.

Contraindications

Durata™ Models 7120Q, 7121Q, and 7122Q leads are contraindicated in the following:

- Patients with tricuspid valvular disease or a mechanical tricuspid valve.
- Patients with ventricular tachyarrhythmias resulting from transient or correctable factors such as drug toxicity, electrolyte imbalance, or acute myocardial infarction.
- Patients for whom a single dose of 1.0 mg of dexamethasone sodium phosphate is contraindicated.
- For use with extra firm (red color knob) stylets.

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.
- Use only battery-powered equipment when implanting and testing the lead to avoid fibrillation caused by alternating current.

- Ground all line-powered equipment used near the patient to avoid fibrillation caused by alternating current.
- Insulate lead connector pins from potential leakage currents from line-powered equipment to avoid fibrillation caused by the leakage current.

Precautions

- Do not tie a ligature directly to the lead body, tie it too tightly on the suture sleeve, or otherwise create excessive strain at the insertion site as this may damage the lead.
- Do not grip the lead with surgical instruments as this may damage the lead.
- Use the same polarity evaluated during testing when connecting the lead to the pulse generator to ensure defibrillation efficacy.
- If a thoracotomy is required to place epicardial patches, it should be done during a separate procedure to reduce the risk of morbidity and mortality.
- If countershock is unsuccessful using external paddles, adjust the external paddle position, for example, anterior-lateral to anterior-posterior.
- Do not severely bend or kink stylets or leads as this may damage the lead.
- Keep the stylets clean and free from blood, tissue, or other debris to reduce any potential for the stylet sticking or binding within the lead body.
- Do not use excessive force or surgical instruments to insert a stylet into a lead as this may damage the lead.
- Withdraw the stylet after placing the lead to prevent potential malfunction of the lead.
- Use only St. Jude Medical™ suture sleeves to immobilize and protect the lead against damage from ligatures.
- Do not place the lead near another implanted lead to ensure sensing and defibrillation efficacy.
- Do not rotate the connector pin after the helix is fully extended or retracted as doing so may damage the lead.
- To avoid distortion of the Durata™ lead tip, do not use a St. Jude Medical™ Seal-Away™ hemostasis valve.

Adverse Events in the Riata™ Models 1580 and 1581 Leads

The Durata™ Models 7120Q and 7121Q leads are functionally and physically identical to the Riata Models 1580 and 1581 leads except for the Durata leads' reduced diameter, Optim® insulation overlay, and a single DF4 (quadpole, four electrical terminal) lead connector. The Durata Model 7122Q lead is the single coil version of the Durata Models 7120Q and 7121Q leads. Therefore, no additional clinical evaluation was performed on the Durata Models 7120Q, 7121Q, and 7122Q leads. The clinical data presented in this document were collected on the Riata 1580 and 1581 lead models. The purpose of the clinical study on the Riata 1580 and 1581 lead models was to evaluate the safety and effectiveness of the Riata transvenous defibrillation lead system (Models 1580 and 1581).

The Riata transvenous defibrillation lead system clinical trial involved 85 patients with implanted systems and 14,864 cumulative implant days (40.7 years). The mean implant duration was 175 days (ranging from <1 day to 240 days). The clinical trial involved the Model 1580 and 1581 leads, which are the active-fixation versions of the Riata family of leads.

Two patients expired during the course of the clinical study. An independent Events Committee felt that neither of the deaths was attributable to the Riata lead. One death was classified as cardiac-arrhythmic/sudden (intraoperative) and the second death was classified as unknown/unknown.

Five additional patients were withdrawn from the study. Two patients were withdrawn from the study following lead revisions. The three other patients were withdrawn when their ICD's were either turned off or explanted for end-stage disease or for management of incessant supraventricular arrhythmias.

Observed Adverse Events

The Table below lists the observations and complications reported from this clinical trial. For the purposes of this discussion, a complication is defined as a clinical event with potential adverse effects that requires invasive intervention to treat or resolve. Observations are those clinical events with potential adverse effects that do not require invasive intervention. A total of 7 complications and 38 observations were reported in 28 patients during the Riata lead system clinical investigation. The three-month complication-free survival for the Riata lead population was 92.9%.

Table 1. Observed Adverse Events

	# Pts with AEs (n = 85)	% of Pts with AEs	# of AEs	AE/pt-years (n = 40.7 yrs)
Complications (total)	7	8.2%	7	0.172
Migration	2	2.4%	2	0.049
Migration after LVAD implantation	1	1.2%	1	0.025
Decreased R-wave amplitude	1	1.2%	1	0.025
Elevated ventricular pacing threshold	1	1.2%	1	0.025
Incorrect lead connection	1	1.2%	1	0.025
Loose set screw	1	1.2%	1	0.025
Observations (total)	24	28.2%	38	0.934
Inappropriate device mode switching due to Far-R sensing	8	9.4%	10	0.246
Helix retraction difficulties	6	7.0%	7	0.172
Inappropriate therapy for supraventricular tachycardia or atrial flutter	5	5.9%	7	0.172
Elevated atrial pacing threshold	3	3.5%	3	0.074
T-wave sensing resulting in therapy delivered	2	2.4%	2	0.049
Migration	1	1.2%	1	0.025
Decreased R-wave amplitude	1	1.2%	1	0.025
Diaphragmatic stimulation	1	1.2%	1	0.025

Table 1. Observed Adverse Events

	# Pts with AEs (n = 85)	% of Pts with AEs	# of AEs	AE/pt-years (n = 40.7 yrs)
Decreased pacing lead impedance	1	1.2%	1	0.025
Bent connector pin at implant	1	1.2%	1	0.025
Bleeding/hematoma	1	1.2%	1	0.025
Sensing external noise, resulting in therapy delivered	1	1.2%	1	0.025
Atrial lead undersensing	1	1.2%	1	0.025
Suspected generator malfunction	1	1.2%	1	0.025

Potential Adverse Events

Possible adverse events associated with the use of transvenous lead systems include, but are not limited to, those summarized in the Table below.

Refer to the appropriate pulse generator manual for additional complications and precautions specific to the pulse generator.

Table 2. Potential Adverse Events

Event	Possible Effects
Dislodgement, breaching of the lead insulation, connector fracture, poor connection to the pulse generator, electrode fracture, or conductor discontinuity.	Intermittent or continuous loss of sensing, possibly resulting in nondetection of arrhythmia; oversensing of artifact, possibly causing inappropriate delivery of therapy from the pulse generator; intermittent or continuous loss of defibrillation, cardioversion, or pacing therapy; possible muscle or nerve stimulation in the pocket area; intermittent or continuous loss of cardioversion/defibrillation therapy, sensing, or pacing therapies.
Cardiac perforation	Intermittent or continuous loss of sensing, cardiac tamponade, hemorrhage, pneumothorax, or loss of contractility
Venous perforation	Acute hemorrhage (may not be readily apparent), hemothorax, pneumothorax, or cardiac tamponade
Myocardial irritability	Premature ventricular contractions, supraventricular and ventricular tachyarrhythmias, postoperative heart failure
Transvenous implantation procedure	Air embolism
Chronic (> 3 months) implantation	Venous thrombosis and/or obstruction, tissue necrosis, skin erosion, tricuspid valve dysfunction, chronic mechanical stimulation of the heart

Table 2. Potential Adverse Events

Event	Possible Effects
Contamination	Infection requiring removal of lead system, pulse generator, or both
Post-shock rhythm disturbances	Post-shock bradycardia or supraventricular arrhythmias, conduction disturbances
Threshold elevation or exit block	Loss of efficacy of defibrillation, cardioversion, or pacing therapy
Shunting or insulating of current during defibrillation with internal or external paddles	Increased external defibrillation energy and/or repositioning of paddles required

Clinical Studies in the Riata™ Models 1580 and 1581 Leads

The Durata™ Models 7120Q and 7121Q leads are functionally and physically identical to the Riata Models 1580 and 1581 leads except for the Durata leads' reduced diameter, Optim™ insulation overlay, and a single DF4 (quadpole, four electrical terminal) lead connector. The Durata Model 7122Q lead is the single coil version of the Durata Models 7120Q and 7121Q leads. Therefore, no additional clinical evaluation was performed on the Durata Models 7120Q, 7121Q, and 7122Q leads. The clinical data presented in this document were collected on the Riata 1580 and 1581 lead models. The purpose of the clinical study on the Riata 1580 and 1581 lead models was to evaluate the safety and effectiveness of the Riata transvenous defibrillation lead system (Models 1580 and 1581).

Patients Studied

Eighty-five (85) patients were implanted with the Riata lead system and 78 followed through three months. (See below.) The study was conducted from May 16, 2001 through January 11, 2002. The population was predominantly male (72.9%) with a mean age of 68.7 years. The arrhythmia diagnosis was ventricular fibrillation (VF) in 15.3% of patients, ventricular tachycardia (VT) in 60% of patients, and both VT and VF in 24.7% of patients. Coronary artery disease was the primary disease process in 74.1% of patients, and the mean ejection fraction was 33.9%.

Table 3. Patient enrollment

Follow-Ups	Number of Patients
Implant	85
One month	82
Three months	78
Six months	34

Methods

The primary objective of the study was to determine whether there was a clinically important difference between the study group and a recent historical control group consisting of patients implanted with the SPL™ lead in the Photon™ DR device clinical investigation (PMA File Number P910023/S47, approved October 27, 2000). The primary endpoints were implant defibrillation thresholds and the time to detect and redetect ventricular fibrillation. Defibrillation thresholds were determined by step-down testing to failure, with a maximum of 100 V or 5 J step-size. Stored electrograms were used to calculate detection and redetection times to within one-tenth of a second.

The following data were also compared between the study group and the historical control group: complication and observation rates, complication-free survival, chronic induction efficacy. In addition, ventricular pacing threshold, pacing lead impedance and defibrillation lead impedance at implant were compared. The following data were also summarized: ventricular pacing threshold, pacing lead impedance, defibrillation lead impedance, and R-wave measurements at implant and scheduled follow-up visits, R-wave measurements with the mapping collar prior to and after extending the helix, and lead handling characteristics during implant.

Results

A comparison of demographic information for the 85 patients in the Riata lead study group and the 90 patients in the Photon DR/SPL device historical control group indicated that the Riata lead study group was not statistically significantly different from the control group in any respect. The study hypothesis was that there was a clinically important difference between the study group and the historical control group for implant defibrillation thresholds and time to detect and redetect ventricular fibrillation. For implant defibrillation thresholds, a difference in means of 4.5 J was chosen as the clinically important difference to detect. For detection and redetection times, a difference in medians of 0.6 seconds was chosen as the clinically important difference to detect. The results are summarized in Table 4. The mean implant defibrillation thresholds and median detection and redetection times were equivalent between the Riata lead study group and the Photon DR/SPL device group.

Table 4. Implant defibrillation thresholds and detection and Redetection times

	Riata lead	Control
Defibrillation Threshold		
No of patients	84	90
Mean ± SD	9.5 ± 5 J	10.1 ± 5.2 J
Range	1 to 22.5 J	2.7 to 24.8 J
Detection Time		
No. of episodes	340	323
Mean ± SD	2.8 ± 0.5 sec	2.8 ± 0.5 sec
Median	2.8 sec	2.8 sec
Range	1.3 to 4.6 sec	1.7 to 6 sec
Redetection Time		

Table 4. Implant defibrillation thresholds and detection and Redetection times

	Riata lead	Control
No. of episodes	106	106
Mean ± SD	1.5 ± 0.4 sec	1.3 ± 0.3 sec
Median	1.4 sec	1.3 sec
Range	0.8 to 3.2 sec	0.8 to 2.4 sec

The overall adverse event rates for the Riata lead group and the Photon DR/SPL device group were 1.11 and 1.81 per patient year, respectively. The adverse event rate among the Riata lead group was statistically significantly better than that in the Photon DR/SPL device group ($p = 0.04$). The most common Riata lead-related observation was helix-retraction difficulties. As a result, the helix deployment/retraction mechanism was slightly modified, and on bench testing demonstrated a greater than 25% reduction in the number of turns required to retract the helix. The complication-free survival for the Riata lead group and the Photon DR/SPL device group were estimated as 92.9% and 92.7%, respectively. There was no statistically significant difference in the complication-free survival curves between the two groups. There was no statistically significant difference in the chronic induction efficacy between the two groups. The average max R-wave amplitude measured by PSA prior to extending the helix was 15.1 ± 6.2 mV (range 6 to 30 mV). The average R-wave amplitude measured by PSA after extending the helix was 14 ± 5.8 mV (range 5 to 31 mV). Table 5 summarizes the ventricular pacing threshold, ventricular pacing lead impedance, defibrillation lead impedance, and R-wave Amplitude at implant, discharge, one-month, three-month and six-month visits.

The implanting physicians rated Riata lead handling characteristics at least as good as the SPL lead in 84 out of 85 (98.8%) of the implant procedures.

Table 5. Summary of pace/sense measurements at Implant, Discharge, 1 month, 3 month and 6 month visits

Visit Type	Ventricular Pacing Threshold	Ventricular Pacing Lead Impedance	Defibrillation Lead Impedance	R-wave Amplitude[1]
Implant				
n = 85				
Mean ± SD	0.53 ± 0.2 V	463 ± 111 Ω	39.3 ± 5.7 Ω	10.1 ± 2.2 mV
Range	0.25 to 1.25 V	265 to 850 Ω	27 to 59 Ω	5.3 to 12.0 mV
Discharge				
n = 84				
Mean ± SD	0.5 ± 0.3 V	393 ± 76 Ω	40.3 ± 6.6 Ω	10.0 ± 2.5 mV
Range	0.25 to 2.75 V	255 to 630 Ω	30 to 57 Ω	3.5 to 12.0 mV

[1] Note: The device reports any R-wave amplitude greater than 12mV as ">12 mV".

Table 5. Summary of pace/sense measurements at Implant, Discharge, 1 month, 3 month and 6 month visits

Visit Type	Ventricular Pacing Threshold	Ventricular Pacing Lead Impedance	Defibrillation Lead Impedance	R-wave Amplitude[1]
1 month				
N = 82				
Mean ± SD	0.64 ± 0.4 V	367 ± 95 Ω	39.2 ± 3.4 Ω	10 ± 2.8 mV
Range	0.25 to 3.0 V	215 to 730 Ω	33 to 49 Ω	2.8 to 12.0 mV
3 month				
n = 78				
Mean ± SD	0.68 ± 0.4 V	367 ± 100 Ω	40.6 ± 5.5 Ω	10.5 ± 2.4 mV
Range	0.25 to 3.25 V	225 to 770 Ω	31 to 54 Ω	3.5 to 12.0 mV
6 month				
n = 34				
Mean ± SD	0.65 ± 0.3 V	371 ± 124 Ω	46.6 ± 6.8 Ω	10.8 ± 2.0 mV
Range	0.5 to 2.25 V	260 to 750 Ω	36 to 55 Ω	3.7 to 12.0 mV

Instructions for Use

Personnel Training

Because of the nature of the lead implantation procedure, physicians should be familiar with all components of the system and the contents of this manual before beginning the procedure. St. Jude Medical provides physicians with comprehensive, on-site training and support. Topics include:

- Lead handling
- Lead configurations
- Lead positioning
- Lead testing
- Lead suturing and fixation

Required Equipment

Equipment for cardiac monitoring, fluoroscopic imaging, external defibrillation, and measuring lead signals should be available for immediate use during lead implantation and tachyarrhythmia induction testing. Additional quantities of all sterile implantable devices should be available in case of accidental contamination or damage.

Package Inspection

St. Jude Medical packages all leads under clean conditions and sterilizes them using ethylene oxide gas before shipment. Inspect the package carefully before opening and check the "Use Before" date on the product label. If the lead package and seal are intact, the lead and accompanying components are ready to use. Do not use the lead if there appears to be damage to the package or the lead. If the package is wet, damaged, or punctured, or if the seal is broken,

contact St. Jude Medical.

Verify that the sterility indicator on the inner package is not purple. Purple indicates that the package has not been sterilized.

St. Jude Medical does not recommend use of the product after its expiration date. If the lead package has been breached outside a sterile field or the expiration date has passed, contact St. Jude Medical.

Package Contents

The lead is packaged separately and supplied sterile. Packages contain:

- 1 lead with stylet and suture sleeve in place
- 1 vein pick
- 2 clip-on tools
- Stylets of varying firmness
- Product documentation
- IS4/DF4 Connector Sleeve

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.

Handling the Lead

Use caution when handling the lead. It is designed to be pliable, but will not tolerate excessive bending or stretching.

> **CAUTION: Permanent damage to the lead may result from severe bending, kinking, or stretching, or from excessive manipulation with surgical instruments. Never apply pressure to the lead with a surgical instrument, such as a hemostat.**
>
> **Do not try to alter electrodes or apply pressure to the tips of electrodes. Avoid contact of the electrode with a hard surface, and guard against contaminating the lead tip with insulating materials such as lubricants or medical adhesive.**

Use powderless surgical gloves when handling the lead, or remove talc from surgical gloves before handling the lead. Because lead insulation attracts particulate matter such as lint and dust, minimize contamination by protecting the lead from materials that shed such particles.

> NOTE: Do not immerse the tip electrode in liquid or wipe it with any liquid as this may reduce the amount of DSP eluted after implantation.

Implantation Procedure

Implantation of a transvenous lead generally involves:

- Selecting, isolating, and opening the desired vein.
- Inserting the lead using the vein pick and stylets.
- Positioning and securing the lead.
- Testing the sensing, pacing, and cardioversion/defibrillation functions of the lead.
- Suturing the lead in place.

- Connecting the lead to the pulse generator

Techniques for implantation vary among physicians and depend on the patient's anatomy and physical condition. The following description presents a typical technique; other methods may also be applicable.

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.
- To avoid distortion of the Durata™ lead tip, do not use a St. Jude Medical™ Seal-Away™ hemostasis valve.

Using the Stylets

CAUTION:

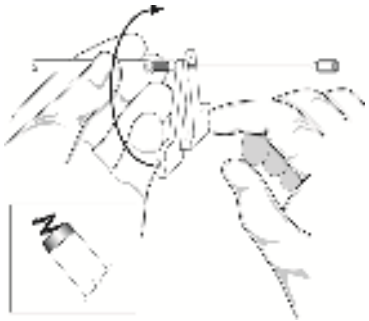
- To avoid damaging the lead or body tissue, do not use excessive force or surgical instruments to insert a stylet into a lead.
- When handling a stylet, avoid severe bending, kinking, or blood contact. Accumulated blood or other debris on the stylet may hinder its passage into or removal from the lead and make future insertion of stylets impossible.
- Try to keep the lead straight when inserting a stylet; do not insert a stylet into a severely bent lead.
- While removing a stylet, hold the lead at the connector end with the lead straight to avoid stress on the lead body.

Preparing the Lead

Test the extension and retraction of the helix before implanting the lead.

1. Insert a stylet into the lead, if necessary. Verify that the stylet is fully inserted.
2. Straighten the lead on a flat surface.
3. Pinch the clip-on tool open and insert the DF4 connector pin into the first notch. Place the clip-on tool on the larger diameter surface of the connector pin. Make sure the clip-on tool remains in this position on the connector pin when you rotate the clip-on tool to extend the helix. Release the handles of the tool so that it grasps the DF4 connector pin firmly.

Figure 3. Using the clip-on tool



4. While keeping the lead as straight as possible, grasp the DF4 connector boot with one hand and with the other hand, rotate the clip-on tool clockwise to extend the helix. (Refer to the Technical Specifications sheet for the number of rotations required to extend the helix.) The helix is fully extended when at least 2 turns are visible beyond the lead tip.

   CAUTION:

   - **While extending or retracting the helix, keep the lead as straight as possible. Bending or kinking the lead body may interfere with the helix movement or cause damage to the lead.**
   - **Do not grasp the lead body. Doing so may interfere with the helix movement or cause damage to the lead.**

5. Rotate the clip-on tool counter-clockwise to retract the helix.

   CAUTION: Do not further rotate the connector pin after the helix is fully extended or retracted. Doing so may damage the helix mechanism.

6. To remove the clip-on tool, pinch the handles and withdraw the DF4 connector pin from the tool.

Selecting and Opening a Vein

The suggested entry site is the left cephalic vein entered through a venous cutdown. Alternatively, the lead may be implanted percutaneously through the left subclavian vein. However, studies[2] 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 can also be used.

Inserting the Lead

A vein pick is included in the package to aid in inserting the lead into the vein. Its use is optional and depends on the implantation technique chosen.

To use the vein pick:

1. Isolate and open the selected vein with scissors or a scalpel.
2. Orient the point of the vein pick in the direction the lead will be passed and insert the point through the incision into the vessel lumen.
3. Raise and tilt the vein pick gently, and pass the lead tip under the pick into the vein lumen.

   CAUTION: Do not use the vein pick for puncturing the vein, dissecting tissue during cutdown, or manipulating the lead.

Positioning the Lead

Confirm that the helix is completely retracted before implantation. When the helix is completely retracted, the helix tip might extend slightly beyond the lead tip.

[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.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.

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.

1. Under fluoroscopic guidance and with the helix retracted, advance the lead into the right atrium.
2. To aid in passing the lead through the tricuspid valve and into the right ventricle:
   - remove the stylet from the lead.
   - shape the distal end of the stylet into a gentle curve.
   - carefully reinsert the stylet into the lead.

   The flexibility of the lead's distal defibrillation coil allows the distal end of the lead to conform to the shape of the stylet.

   CAUTION: To avoid damage to the stylet and lead, do not attempt to curve the stylet while it is inserted in the lead. Do not use a sharp object to curve the distal end of the stylet.
3. Under close fluoroscopic monitoring, advance the curved lead/stylet through the tricuspid valve and into the ventricular chamber.
4. 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.
5. Continue to advance the lead. When the tip reaches position in the right ventricle, retract the stylet an additional ten centimeters or more.

   Accurate electrode positioning is vital for stable sensing and pacing. Verify that the lead tip is not placed in the coronary sinus or in a retrograde position, and that the entire distal coil is below the tricuspid valve.
6. If desired, evaluate one or more potential fixation sites using the helix tip prior to extending the helix.

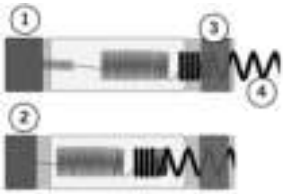
   Refer to the appropriate pulse generator manual for the recommended procedures and values for determining the sensed R-wave amplitude.

   CAUTION: Do not place the lead near another implanted lead. Such close proximity could result in the electrodes making contact with each other and cause electrical interference.
7. Once the desired fixation site has been located, hold the lead body stationary in one hand and attach the clip-on tool to the DF4 connector pin.

   For instructions on using the clip-on tool, see Preparing the Lead (page 11).
8. While keeping the lead as straight as possible, grasp the DF4 connector boot with one hand and with the other hand, rotate the clip-on tool clockwise to extend the helix. (Refer to the Technical Specifications sheet for the number of rotations required to extend the helix.)

   When viewed on the fluoroscope, the helix is fully extended when at least 2 turns are visible beyond the lead tip (shown below).
   For instructions on using the clip-on tool, see Preparing the Lead (page 11).

Figure 4. Helix retraction and extension



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

CAUTION: Do not further rotate the connector pin after the helix is fully extended or retracted. Doing so may damage the helix mechanism.

9. Under fluoroscopy, verify that the helix is extended, then carefully withdraw the stylet while observing the lead's position.

   CAUTION: The stylet must be withdrawn before defibrillation testing to prevent potential malfunction of the lead. However, the sensing and pacing functions of the lead can be evaluated with the stylet still in place.

10. Verify that the helix is fixed by pulling gently on the lead and checking for resistance.

    If the lead is properly fixed, resistance will be felt and the lead will remain in place. A poorly affixed lead will come loose easily and must then be repositioned.
    Allow enough slack in the lead so that it is not under tension as the heart contracts, or the patient breathes deeply or stretches. At the same time for dual-coil leads, ensure that there is not an excess of slack which may allow the proximal electrode to contact the tricuspid valve.

11. Verify proper lead placement by measuring the sensed R-wave amplitude and determining the pacing threshold.

    Refer to the appropriate pulse generator manual for recommended procedures and acceptable values.

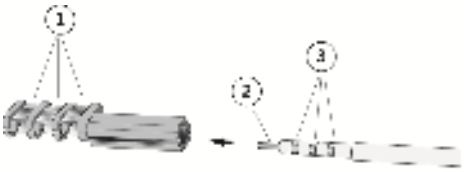
    NOTE: For DF4 leads, use a sterile patient cable with a plunger clip (such as Models 4160 or 4161) or the IS4/DF4 connector sleeve (Model EX3151). The use of alligator clips directly on the lead is not recommended because they may damage the lead.

IS4/DF4 Connector Sleeve

The IS4/DF4 connector sleeve is designed for use with an IS4 or a DF4 lead. It provides a safe and secure connection and disconnection to the lead connector.

1. Insert the IS4 or the DF4 lead into the IS4/DF4 connector sleeve until the lead cannot be inserted any further.
2. Verify the connector ring electrodes are visible in each of the contact clip windows.
3. Attach all alligator clips to the appropriate connector ring electrodes.

Figure 5. Inserting the lead into the connector sleeve



1. Contact clips
2. Lead connector pin
3. Connector ring electrodes

Figure 6. Connector ring electrodes displayed in the contact clip windows

Figure 7. Attaching the alligator clips

NOTE: Remove alligator clips prior to removing the connector sleeve from the lead.

Testing Defibrillation Efficacy

Once acceptable sensing and pacing performance has been verified, defibrillation lead testing should be performed to determine the voltage/energy requirements for reliable defibrillation, and to ensure that those requirements are well within the output capabilities of the pulse generator.

Refer to the appropriate pulse generator manual for recommended test procedures and acceptable values for defibrillation voltage and high-voltage lead impedance.

Ensure that the stylet has been withdrawn from the implanted lead. When appropriate, induce and terminate ventricular tachycardia using antitachycardia pacing or cardioversion.

If the tested configuration does not provide effective defibrillation, reposition the lead or choose another lead or shock vector configuration and repeat the test. In some patients, however, no lead configuration may provide reliable defibrillation, and the use of an alternative lead system should be considered.

CAUTION: If a thoracotomy is required, it should be done during a separate procedure.

After successful defibrillation testing, suture the lead in place and connect it to the pulse generator.

Suturing the Lead

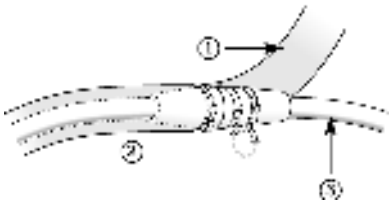
After verifying acceptable lead performance, use the suture sleeve to secure the lead to prevent dislodgement or migration. The suture sleeve protects the lead insulation and conductor coil against damage from ligatures.

The suture sleeve is on the lead, located near the lead body connector boot.

1. Position the suture sleeve distally to place it near, against, or just inside the vein.
2. Ensure that excess slack in the lead body is removed before suturing by viewing the position of the lead under fluoroscopy.

   Allow enough slack in the lead so that it is not under tension as the heart contracts, or the patient breathes deeply or stretches.
3. Using heavy, nonabsorbable suture on the distal groove, secure the suture sleeve to the vein. Tie all sutures firmly but gently to avoid damaging the lead (shown below).

Figure 8. Suturing the lead



1. Vein
2. Fascia
3. Lead body

4. Loop heavy, nonabsorbable suture through the fascia underneath the proximal groove and tie a knot to create a base. 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.

   CAUTION:

   - **Damage to the lead insulation, damage to the coil, and impairment of lead function may result from failure to use suture sleeves, tying the ligatures too tightly, or otherwise creating excessive strain at the insertion site. Never tie a ligature directly to the lead body. Be careful not to dislodge the lead tip during suturing. Always use heavy, nonabsorbable suture (shown above).**
   - **If an accessory suture sleeve is used, it should be used as a replacement to the existing suture sleeve on the lead and should not be used in conjunction with the existing suture sleeve. The use of multiple suture sleeves to secure the lead is not recommended as it may result in damage to the lead.**

If an accessory suture sleeve is utilized:

1. Carefully open the slit in the sleeve and position the sleeve on the lead body.
2. Follow the procedure above to suture and secure the sleeve.

Connecting the Lead to the Pulse Generator

CAUTION:

- To prevent damage to the lead, do not use excessive force on the lead body or connectors. To avoid dislodgement or potential fracture, do not put the lead under extreme tension or flexion. Do not apply pressure to the lead with a surgical instrument.
- Grasp the lead as close as possible to the connector 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.
- Before the lead is connected to the pulse generator, the lead's position should be reviewed under fluoroscopy and the R-wave amplitude and pacing threshold measurements should be repeated to verify that it has not become dislodged or damaged.
- 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 result in electrical current arcing to the pulse generator, thereby damaging the high-voltage circuitry, or creating 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]

Refer to the appropriate pulse generator manual for the configuration of the ports on each model and for the use of setscrews, receptacle plugs (if needed), and accompanying tools.

1. Connect the lead, carefully pushing the connector all the way into the pulse generator port.
2. Verify visually through the clear top of the pulse generator that the lead connector pin has been pushed in completely and can be seen protruding behind the port connector.
3. Tighten the lead connector setscrew. Gently tug on the lead to verify that the lead is securely connected to the pulse generator.
4. To avoid twisting the lead body, loosely roll excess lead length under the pulse generator before placing the excess lead and the generator in the subcutaneous pocket.

   CAUTION:

   - To avoid stressing the lead conductors and insulation, do not implant the pulse generator with the lead attached to the ports at a sharp angle.
   - Do not grip the lead or the pulse generator with surgical instruments. Use of excessive force or improper instruments on the lead body or connector during pulse generator placement can cause damage affecting the long-term reliability of the connector and can impair its function.
5. After connecting the lead to the pulse generator, test the function of the lead with the pulse generator to ensure sensing, pacing, and cardioversion/defibrillation efficacy.

[3] Furman S, Hayes DL, Holmes DR: A Practice of Cardiac Pacing. 3rd ed. New York: Futura Publishing, Inc.; 1993:286-289.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; 1955:613-615.

Post-Implantation Follow-Up

St. Jude Medical strongly recommends pre-discharge and chronic follow-up electrophysiology studies, including induction of ventricular fibrillation, in order to verify the long-term performance of the lead system. Follow-up chest x-rays to verify the position of the lead are also recommended. Testing should be repeated if the patient's clinical status or antiarrhythmic drug therapy has changed.

CAUTION: The energy required to cardiovert/defibrillate with transthoracic paddles may be increased by the presence of epicardial or subcutaneous defibrillation patch electrodes. If countershock is unsuccessful, adjust the external paddle position, for example, anterior-lateral to anterior-posterior, and be sure that the external paddle is not positioned over a patch electrode (if present).

Removing Chronically Implanted Leads

Use extreme caution when removing chronically implanted leads, which may be anchored by fibrotic tissue. If a lead must be removed, carefully inspect it for insulation, electrode, and conductor coil damage. Return all removed leads, whether intact or not, and all unused leads, to St. Jude Medical for investigation. It is not recommended that chronically implanted leads be re-used after removal.

Cap any abandoned lead and secure the lead caps with sutures to prevent unwanted transmission of electrical signals from the electrode to the heart. Seal the remaining open end of any severed lead with medical adhesive and a lead cap. Suture the remnant to adjacent tissue using heavy, nonabsorbable suture to prevent migration of the lead fragment into the heart.

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)

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

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