

GUIDANT

Physician's Manual

SELUTE® PICOTIP™

**Steroid-Eluting
Endocardial
Atrial-J Leads**

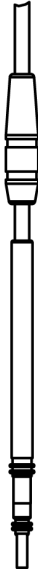
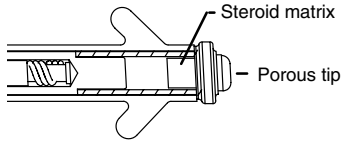
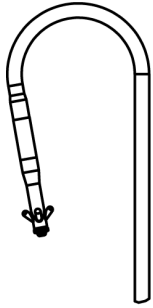
Models 4063/4064

CARDIAC

RHYTHM

MANAGEMENT

RESTRICTED DEVICE: Federal law (USA) restricts the sale, distribution, or use of this device to, by, or on the lawful order of a physician.



Model 4063/4064
Bipolar Lead

IS-1 connector

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DEVICE DESCRIPTION

SELUTE[®] PICOTIP[™] steroid-eluting endocardial atrial-J leads, Models 4063/4064, are tined atrial transvenous bipolar pace/sense leads designed for use as an integral part of a pulse generator system with IS-1¹ ports. The lead features a small active surface area of the distal tip electrode that is designed to increase pacing impedance.

Instructions in this manual should be used in conjunction with other resource material, including the applicable pulse generator physician's manual.

Indications

SELUTE PICOTIP steroid-eluting endocardial atrial-J leads, Models 4063/4064, are intended for chronic pacing and sensing of the atrium when used with a compatible pulse generator.

Contraindications

Use of this lead is contraindicated in patients with a hypersensitivity to a single dose of approximately 1.0 mg of dexamethasone sodium phosphate.

Warnings and Precautions

Warnings

- The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that might be caused by alternating currents.
- Line-powered equipment used in the vicinity of the patient must be properly grounded.
- Lead connector pins must be insulated from any leakage currents that could arise from line-powered equipment.

Precautions

- The lead and its accessories are intended for one-time use only. Do not reuse.
- Prior to the implantation of this lead, confirm lead/pulse generator compatibility with Guidant technical services.
- It has not been determined whether the warnings, precautions, or complications usually associated with injectable

1. IS-1 refers to the international standard ISO 5841.3:1992.

dexamethasone sodium phosphate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse events, refer to the *Physicians' Desk Reference*.

- Defibrillating equipment should be kept nearby for immediate use during the implantation procedure.
- Lead fracture, dislodgment, abrasion and/or an incomplete connection can cause periodic or continual loss of pacing and/or sensing.

Refer to the Implant Information and Implantation sections of this manual for cautions specific to handling, implanting, and testing the SELUTE PICOTIP atrial-J lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage, and/or harm to the patient.

Adverse Events

Observed Adverse Events

Table 1 reports lead-related complications and observations for the SELUTE PICOTIP atrial-J lead.

Table 1. SELUTE PICOTIP Atrial-J Lead-Related Complications and Observations

| | # of pts (n=78) | % of pts [95% CI] | # of Leads (n=78) |
|---|--------------------|---------------------------|----------------------|
| Complications¹ (Type I) | 5 | 6.4 [2.4, 14.5] | 5 |
| Brady capture— none or loss of capture | 1 | 1.3 [0.1, 7.1] | 1 |
| Placement difficulty | 3 | 3.8 [1.0, 11.0] | 3 |
| Pneumothorax | 1 | 1.3 [0.1, 7.1] | 1 |
| Observations² (Type I) | 6 | 7.7 [3.2, 16.1] | 6 |
| Brady capture— none or loss of capture | 2 | 2.6 [0.4, 9.1] | 2 |
| Placement difficulty | 2 | 2.6 [0.4, 9.1] | 2 |
| Threshold difficulty | 2 | 2.6 [0.4, 9.1] | 2 |

1. Complications are defined as adverse events requiring invasive measures to correct (eg, surgical intervention).
2. Observations are defined as adverse events that are correctable by noninvasive measures (eg, reprogramming).

The clinical study used historical and randomized concurrent controls comparing the performance of the SELUTE PICOTIP atrial-J lead to that of the commercially available atrial-J control lead. A total of seventy-eight SELUTE PICOTIP atrial-J leads were used in the atrium; seventy-five leads were successfully implanted, three leads were attempted but not implanted.

Potential Adverse Events

Based on the literature and lead implant experience, the possible physical events from implantation of a SELUTE PICOTIP atrial-J lead are listed below in alphabetical order:

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac perforation/
tamponade
- Chronic nerve damage
- Death
- Elevated pacing
thresholds
- Erosion/extrusion
- Excessive fibrotic tissue
growth
- Formation of hematomas
or cysts
- Inappropriate therapy
- Incomplete connection
with pulse generator
- Infection
- Keloid formation
- Lead abrasion
- Lead displacement/
dislodgment
- Lead fracture, insulation
break
- Lead tip deformation
and/or breakage
- Local tissue reaction
- Myocardial injury
- Myocardial irritability
- Over/undersensing
- Pneumothorax
- Random component
failures
- Shunting current or
insulating myocardium
during defibrillation with
internal or external
paddles
- Thromboemboli
- Transvenous lead-related
thrombosis
- Venous occlusion
- Venous perforation/
erosion

Clinical Study

The following is a summary of findings from the SELUTE PICOTIP Atrial-J Lead Clinical Investigation.

Seventy-five patients were implanted with the SELUTE PICOTIP atrial-J lead. The object of this investigation was to demonstrate higher pacing impedance and lower pacing threshold performance of the SELUTE PICOTIP atrial-J lead compared to the commercially available atrial-J control lead. The mean implant duration of the study population was 13.1 months with cumulative implant duration of 984.7 months. No statistical differences

were found in the baseline variables between the study patient group and the control group with respect to demographic profiles. Additional demographic information is presented in Table 2.

Table 2. Description of the Study Population (n=163 Patients)

| Demographics | SELUTE PICOTIP atrial-J lead | Control (atrial-J) |
|-------------------------|------------------------------|--------------------|
| Number of Patients | 78 | 85 |
| Gender (patients, %) | | |
| Male | 42 (53.8%) | 44 (51.8%) |
| Female | 36 (46.2%) | 41 (48.2%) |
| Age at Implant (years) | | |
| Range | 25.1–90.3 | 31.3–92.7 |
| Mean±Standard Deviation | 71.7±12.6 | 70.9±12.9 |

The predominant pacing indications for the study population were sinus bradycardia and third degree heart block, typical of dual chamber pacemaker implants.

Table 3 and Table 4 provide the results from the clinical study.

Table 3. Mean Atrial Voltage Threshold (V) at 0.5 ms by Follow-up Period

| Follow-up | SELUTE PICOTIP atrial-J lead | | | Control (atrial-J) | | |
|---------------|------------------------------|-------------------|------|--------------------|-------------------|------|
| | n | Mean (V) [95% CI] | STD | n | Mean (V) [95% CI] | STD |
| Pre-discharge | 71 | 0.68 [0.58, 0.78] | 0.41 | 78 | 0.65 [0.61, 0.69] | 0.19 |
| 2 week | 62 | 0.82 [0.61, 1.03] | 0.85 | 71 | 1.17 [1.04, 1.30] | 0.54 |
| 6 week | 59 | 0.86 [0.59, 1.13] | 1.04 | 66 | 1.20 [1.04, 1.36] | 0.66 |
| 3 month | 57 | 0.81 [0.60, 1.02] | 0.79 | 67 | 1.05 [0.93, 1.17] | 0.52 |

* Significantly different from the control (atrial-J) lead, p<0.05, t-test.

Table 4. Atrial Lead Impedance (Ω) Recorded by Follow-Up Period

| Follow-up | SELUTE PICOTIP atrial-J lead | | | Control (atrial-J) | | |
|---------------|------------------------------|----------------------|-----|--------------------|----------------------|-----|
| | n | Mean (V) [95% CI] | STD | n | Mean (V) [95% CI] | STD |
| Pre-discharge | 73 | 850 [815, 884] | 149 | 80 | 546 [522, 570] | 108 |
| 2 week | 64 | 869 [839, 898] | 120 | 74 | 551 [531, 571] | 88 |
| 6 week | 60 | 886 [856, 916] | 117 | 69 | 607 [584, 630] | 97 |
| 3 month | 58 | 887 [857, 917] | 117 | 72 | 642 [619, 665] | 99 |

* Statistical significance $p < 0.001$, t-test.

Figure 1 shows a graphical comparison of the SELUTE PICOTIP atrial-J lead, the commercially available atrial-J control lead, and the nominal industry standard in terms of lead impedance.

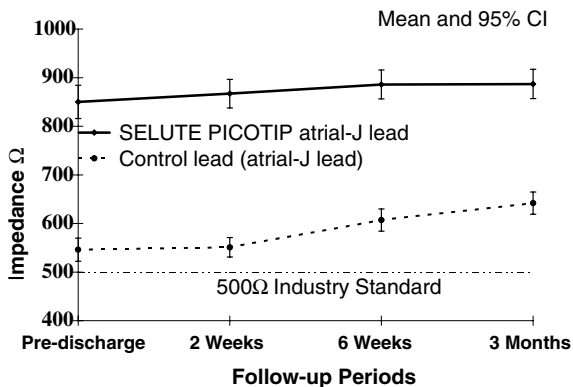


Figure 1. SELUTE PICOTIP atrial-J lead impedance by follow-up period.

SELUTE PICOTIP atrial-J lead's higher impedance values and low pacing thresholds combine to reduce pacing system energy requirements—potentially improving pacing system longevity. For specific pacing system longevity values, refer to the applicable pulse generator physician's manual.

Detailed Device Description

SELUTE PICOTIP steroid-eluting endocardial atrial-J leads, Models 4063/4064, are tined atrial transvenous bipolar pace/sense leads designed for use as an integral part of a pulse generator system with IS-1 ports. The lead features a small active

surface area of the distal tip electrode that is designed to increase pacing impedance.

The lead uses a platinum-iridium porous-tip electrode that provides a pacing and sensing surface. In addition, the tip electrode contains a single dose of approximately 1.0 mg dexamethasone sodium phosphate contained in silicone.

The lead body consists of a multistrand conductor coil that provides a conductive pathway and is sheathed in a thin-walled tube of silicone insulation. The IS-1 connector provides a pulse generator connection.

Warranty

Guidant Corporation does not warrant or guarantee its leads. Please see the enclosed Lead Information card for further information. For additional copies, please contact Guidant Corporation at the address on the back cover.

Refer to the Contraindications, Warnings and Precautions, and Adverse Events sections of this manual for information concerning the performance of this device.

IMPLANT INFORMATION

Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.

The SELUTE PICOTIP lead is not designed, sold, or intended for use except as indicated.

Items Included

The following items packaged with the SELUTE PICOTIP leads:

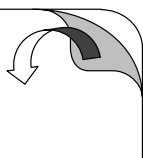
- Straight stylets, soft²
- Firm straight stylets³
- Stylet guide
- Vein pick
- Literature

2. Green knobs, 0.014-in (0.36-mm) diameter

3. White knobs, 0.016-in (0.41-mm) diameter

Opening Instructions

The outer package and sterile tray may be opened by authorized personnel under clean conditions. To ensure sterility, the sealed inner sterile tray must be opened using accepted aseptic technique by scrubbed, masked, sterile-gowned personnel. The sterile tray is opened by peeling back the cover.



Sterilization

The lead and accessories are packaged sterile and ready for use. If the container is wet, damaged, punctured, or if the seal is broken, return the lead to the nearest Guidant representative. Never attempt to resterilize the lead. Instead, return the lead to Guidant.

Surgical Preparation

Instrumentation for heart monitoring, imaging (fluoroscopy), external defibrillation, and pacing threshold and sensitivity measurements should be available during implantation. Sterile duplicates of all implantable items also should be available for use if accidental damage or contamination occurs. Always isolate the patient from potentially hazardous current leakage when using electrical instrumentation.

Accessory Options

Pacing Accessory Kit

Several pacing accessories are available for use in implanting or repositioning the lead. Contact the nearest Guidant representative to order these accessories.

The following items are packaged with the lead and are also available from Guidant as accessory items:

Suture Sleeve

The suture sleeve is an adjustable, tubular reinforcement positioned over the outer lead insulation. It is designed to secure and protect the lead at the venous entry site after lead placement. Using a suture sleeve reduces the possibility of structural damage caused by suturing directly over the lead body.

If a suture sleeve supplied on the lead becomes damaged, a lead anchor should be used in its place. It is available from Guidant as an accessory item.

CAUTION: Do not suture directly over the lead body, as this may cause structural damage. Use the suture sleeve to secure the lead lateral to the venous entry site.

Stylets

A stylet inserted in the lead aids in positioning the lead tip in the heart. Stylets are packaged with the lead, providing firm and soft options: firm stylets have white knobs and soft stylets have green knobs. A soft stylet is preinserted in the packaged lead.

Stylet Guide

A stylet guide is packaged with the lead, and is intended to ease insertion of the stylet into the lead. (Figure 2)

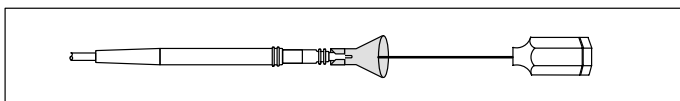


Figure 2. Using the stylet guide.

Vein Pick

The vein pick is a sterile, disposable, nontoxic, nonpyrogenic plastic device designed to assist the physician during entry of the lead's electrode tip into the vein.

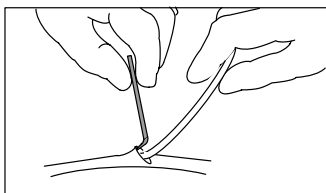


Figure 3. Using the vein pick.

Isolate and open the vein selected for transvenous insertion using an appropriate scalpel or scissors. Introduce the point of the vein pick via the incision into the lumen of the vein (Figure 3). With the point of the vein pick facing in the direction of desired lead passage,

gently raise and tilt the pick away from the lead electrode entering the vein. Pass the lead under the vein pick and into the vein.

CAUTION: The vein pick is not intended either for puncturing the vein or for dissecting tissue during a cutdown procedure.

Handling the Lead

Observe the following cautions when handling the leads:

CAUTIONS:

- **Do not wipe or immerse the electrode in fluid.** Such treatment will reduce the amount of steroid available when the lead is implanted.
- Do not allow the electrode surface to come in contact with surface contaminants.
- To prevent damage to the lead or potential lead dislodgment, do not use excessive force or surgical instruments

- in handling. Use a suture sleeve to avoid placing the lead under extreme tension.
- Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted.
 - Do not apply pressure to the electrode tip.
 - The conductor insulation is silicone rubber, which can attract particulate matter and must always be protected from surface contamination.
 - Avoid bending the coil conductor, this may weaken the structure. Although pliable, a lead is designed to tolerate only normal flexing and tension.
 - Mineral oil should never come in contact with a Guidant porous-tipped lead electrode. Mineral oil on the porous tip may inhibit tissue ingrowth and conduction.

IMPLANTATION

Inserting the Stylet

The stylets packaged with the leads provide two stiffness options. Choose a stylet according to the firmness desired. Remove the preinserted stylet before inserting a different one.

If necessary, gently curve the preferred stylet with any sterile, smooth-surfaced instrument (eg, 10- or 12-cc syringe barrel) and carefully insert the stylet through the lumen of the conductor. A sharp bend in the stylet may straighten as it passes through the lumen of the terminal pin. A gentle curve is less likely to straighten.

CAUTION: Do not bend the lead with the stylet in place.

Bending the lead may damage the conductor and insulation material.

Inserting the Lead

The lead may be inserted using one of the following methods:

Via cutdown through the left or right cephalic vein.

Only one incision over the deltopectoral groove is required to insert the lead through the cephalic vein. The endocardial lead is inserted into the right or left cephalic vein in the deltopectoral groove.

The vein pick packaged with this lead may be used during a cutdown procedure to aid insertion of the lead into the vein.

Before inserting the lead see “Accessory Options” for instructions on using the vein pick.

Percutaneously or via cutdown through the subclavian vein or internal jugular vein—typically the left subclavian or right internal jugular vein.

CAUTION: When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage to the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian vein near the lateral border of the first rib and must avoid penetrating the subclavius muscle. It is important to observe these implant precautions in order to avoid clavicle/first rib damage to the lead. It has been established in the literature that lead fracture can be caused by lead entrapment in such soft tissue structures as the subclavius muscle, costocoracoid ligament, or the costoclavicular ligament. Excessive lead compression has also been reported in patients with anatomical abnormalities between the clavicle and first rib.

Leads placed by percutaneous subclavian venipuncture should enter the subclavian vein where it passes over the first rib (rather than more medially) to avoid entrapment by the subclavius muscle or ligamentous structures associated with the narrow costoclavicular region. Guidant suggests introducing the lead into the subclavian vein near the lateral border of the first rib.

The syringe should be positioned directly above and parallel to the axillary vein to reduce the chance that the needle will contact the axillary or subclavian arteries or the brachial plexus. Use of fluoroscopy is helpful in locating the first rib and in guiding the needle. The steps below explain how to identify the skin entry point and define the course of the needle toward the subclavian vein where it crosses the first rib.

1. Referring to Figure 4, identify points St (sternal angle) and Cp (coracoid process).
2. Visually draw a line between St and Cp, and divide the segment into thirds. The needle should pierce the skin at the junction of the middle and lateral thirds, directly above the axillary vein (point Ax).
3. Place an index finger on the clavicle at the junction of the medial and middle thirds (point V), beneath which point the subclavian vein should be located.

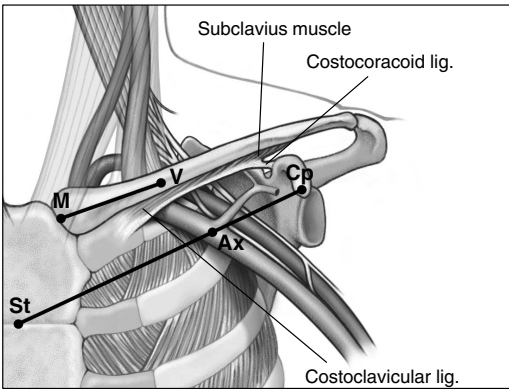


Figure 4. Landmarks identify the entry point for a percutaneous subclavian venipuncture.

4. Press a thumb against the index finger and project one or two centimeters below the clavicle to shield the subclavius muscle from the needle (when hypertrophy of the pectoralis muscle is apparent, the thumb should project about two centimeters below the clavicle because the subclavius muscle could be hypertrophied as well) (Figure 5).
5. Feel with the thumb the pressure from the passage of the needle through the superficial fascia; direct the needle deep into the tissues toward the subclavian vein and the underlying first rib. Fluoroscopic guidance will reduce the chance that the needle would pass below the first rib and into the lung.

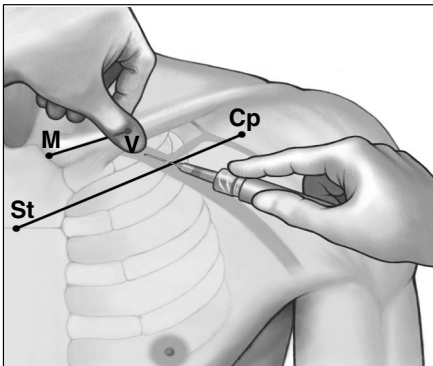


Figure 5. Location of thumb and needle entry.

CAUTION: When implanting the lead via a subclavian puncture, allow slack in the lead between the distal suture sleeve and

the venous entry site. This will help minimize flexing at the suture sleeve and interaction with the clavicle/first rib region.

Lead Positioning

With the straight stylet in the lead, advance the lead transvenously into the right atrium (Figure 6). Withdraw the stylet far enough to determine the direction of the J curve. Rotate the lead until the electrode tip is directed anteriorly and medially.

When properly directed, and by further withdrawing the stylet, the J shape will continue to form while the electrode tip moves upward into position in the atrial appendage.

Check the stability of the electrode using fluoroscopy.

NOTE: When the distal electrode is positioned correctly, lead movement is from side to side during each atrial contraction (anteroposterior view). In the absence of spontaneous atrial contraction, pace the atrium through the lead and check tip movement.

After the distal electrode is in the proper position, withdraw the stylet 8 to 10 cm and verify the electrical performance of the lead.

Electrical Performance

Verify electrical performance of the lead *before* attaching the lead to the pulse generator and *after* allowing sufficient time for the effect of local tissue trauma to subside (approximately 10 minutes). Threshold and sensing data can be measured directly from the lead using a pacing system analyzer.

For bipolar leads, the lead connector pin is the cathode (–) conductor and should be connected to the negative conductor of the pacing system analyzer's patient cable. The ring of the lead connector is the anode (+) conductor and should be connected to the positive conductor on the patient cable. TIP to TIP and RING to RING describes conductor to lead electrode connections.

Sensing signals also can be measured with an ECG recorder or oscilloscope. Electrical performance should fall within the recommended values listed in Table 5.

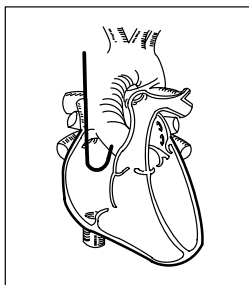


Figure 6. Atrial placement.

Table 5. Recommended threshold and sensing measurements¹

| Atrial Data |
|--|
| Voltage threshold ² ≤ 1.0 V |
| Current threshold ² ≤ 1.5 mA |
| P-wave amplitude ≥ 2.0 mV |

1. Measured approximately 10 minutes after fixation.
2. Pulse width setting is 0.5 ms.

If the measurements do not conform to these values, reinsert the stylet and reposition the electrode using the positioning procedures previously discussed. Verify that measurements fall within the recommended values.

After the lead tip is satisfactorily positioned, check for proper tension. As the patient exhales, the lead's J shape should appear secure in the atrial appendage. As the patient inhales, the lead's J shape straightens (forms an L shape).

Securing the Lead

After the electrodes are satisfactorily positioned, secure the lead to the vein using the suture sleeves provided. Suture sleeve tie-down techniques can vary with the lead insertion technique used. Securing the lead will provide permanent hemostasis and lead stabilization.

CAUTIONS:

- Do not kink, twist, or braid the lead terminal with other leads as doing so could cause lead insulation abrasion damage.
- When ligating the vein, avoid too tight a stricture. A tight stricture might damage the silicone rubber insulation or sever the vein. Avoid dislodging the electrode tip during the anchoring procedure.
- Do not remove or cut the suture sleeve from the lead as it may cause lead damage.

Percutaneous Implant Technique

1. Peel back the introducer sheath and slide the suture sleeve deep into the tissue (Figure 7).
2. Using both grooves, ligate the suture sleeve to the lead.
3. Next, secure the sleeve and lead to the fascia.

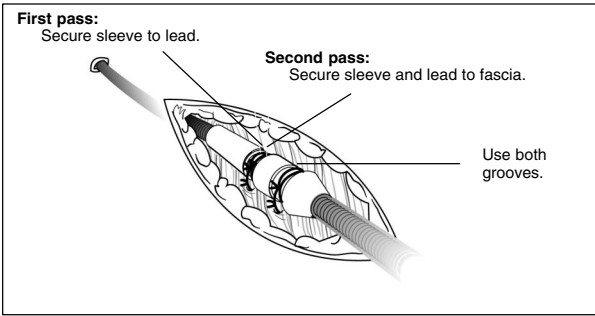


Figure 7. Using the sleeve with the percutaneous implant technique.

4. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

Venous Cut-Down Technique

1. Slide the suture sleeve into the vein past the distal pre-formed groove. Ligate the vein around the suture sleeve to obtain hemostasis. Next, using the same groove, secure the lead and vein to the adjacent fascia (Figure 8).

Distal Groove:

First pass: secure vein to lead.
Second pass: secure vein and lead to fascia.

Proximal Groove:

First pass: secure sleeve to lead.
Second pass: secure sleeve and lead to fascia.

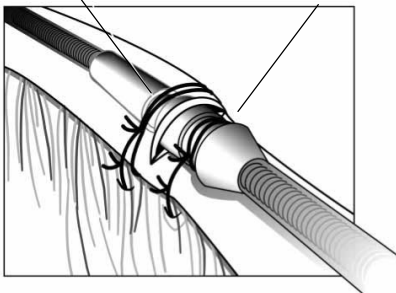


Figure 8. Using the sleeve with the venous cutdown technique.

2. Using the proximal pre-formed groove, secure the sleeve to the lead. Using the same groove, secure the sleeve and lead to the adjacent fascia.

3. Check the suture sleeve after tie-down to demonstrate stability and lack of slippage by grasping the suture sleeve with fingers and trying to move the lead in either direction.

NOTE: *If venous entry is made using a Guidant lead introducer, ligate the lead to the adjacent fascia using the suture sleeve to prevent lead movement.*

Connection to a Pulse Generator

When the lead is secured at the venous entry site, reverify threshold measurements and connect the lead to the pulse generator using the procedure described in the applicable pulse generator physician's manual.

- Remove the stylet and the stylet guide before connecting the lead to the pulse generator. Under no circumstances should the stylet be left in the lead. Leaving the stylet in the lead could cause (1) lead perforation, (2) myocardial perforation, or (3) inability to remove the stylet and reposition the lead.
- Insert the IS-1 lead terminal straight into the lead port. Do not bend the lead near the lead-header interface. Improper insertion can cause insulation damage near the terminal ring that could result in lead damage.

NOTES:

- *If necessary, lubricate the lead terminal sparingly with sterile water to make insertion easier.*
- *If the lead terminal pin will not be connected to a pulse generator at the time of lead implantation, the lead connector must be capped before closing the pocket incision. Place a suture around the lead cap to keep it in place.*

Gently coil the excess lead wires and place them in a separate pocket above or to the side of (not behind) the pulse generator, giving consideration to lead tension and device motion. It is important to place the lead into the pocket in a manner that minimizes pressure and reduces lead-on-lead and/or lead-on-pulse generator contact.

Explantation

Return all explanted leads to Guidant. Examination of explanted leads can provide information for continued improvement in system reliability. Use a Guidant Returned Product Kit to properly package the lead and complete an Observation/Complication/Out-of-Service Report form. Send the form and kit to Guidant at the address on the back of this manual.

NOTE: Disposal of explanted devices is subject to local, state, and federal regulations. Contact your Guidant representative or call Guidant at the phone number on the back of this manual for a Returned Product Kit.

REFERENCES

1. Magney JE, et al. Anatomical mechanisms explaining damage to pacemaker leads, defibrillator leads, and failure of central venous catheters adjacent to the sternoclavicular joint. *PACE*. 1993;16:445–457.
2. Suzuki Y, Fujimori S, Sakai M, et al. A case of pacemaker lead fracture associated with thoracic outlet syndrome. *PACE*. 1988;11:326–330.
3. Magney JE, et al. A new approach to percutaneous subclavian venipuncture to avoid lead fracture or central venous catheter occlusion. *PACE*. 1993;16:2133–2142.

SPECIFICATIONS (Nominal)

| | |
|--|--|
| Model | 4063/4064 Bipolar |
| Length | 4063 – 45 cm 4064 – 52 cm |
| Compatibility | Bipolar pulse generators that accept IS-1 connectors |
| Recommended lead introducer ^a | Size 10 Fr |
| Lead body diameter | 2.2 mm (6.6 Fr) |
| Lead insulation material | Silicone rubber |
| Conductors: | |
| Conductor type | Triple- and quad-wound helical coils |
| Conductor material | MP35N |
| Electrodes: | |
| Distal electrode surface area | 2.0 mm ² |
| Proximal electrode surface area | 50 mm ² |
| Distance between electrodes | 11 mm |
| Electrode material | Platinum iridium |
| Steroid | Approximately 1.0 mg dexame- thasone sodium phosphate |
| Tines: | |
| Angle of tine projection | 45 degrees |
| Tine material | Silicone rubber |

a. Implants using the retained guidewire technique may require larger introducers.

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