

**GUIDANT**

**Physician's Manual**

**SWEET PICOTIP™ Rx**

**Steroid-Eluting  
Positive-Fixation  
Porous Tip Pacing Leads**

**Models 4050/4051/4052  
4053/4054/4055**

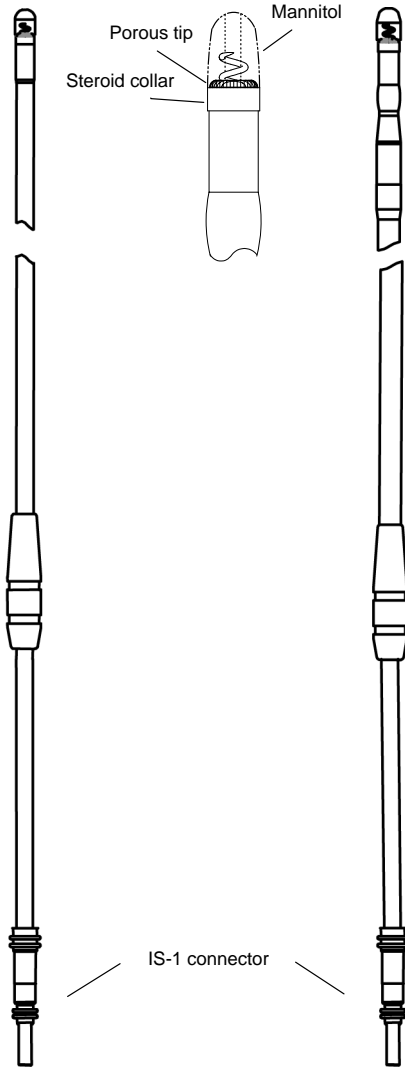
CARDIAC

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.

# SWEET PICOTIP Rx Leads



Model 4050/4051/4052  
Unipolar Lead

Model 4053/4054/4055  
Bipolar Lead

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## **DEVICE DESCRIPTION**

Guidant SWEET PICOTIP™ Rx steroid-eluting, porous tip, positive-fixation leads, unipolar Models 4050/4051/4052 and bipolar Models 4053/4054/4055, are IS-1\* screw-in leads designed for permanent implantation for either atrial and/or ventricular pacing applications. The lead features a small electrically 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**

SWEET PICOTIP Rx steroid-eluting, porous tip, positive-fixation leads, unipolar Models 4050/4051/4052 and bipolar Models 4053/4054/4055, are intended for chronic pacing and sensing of the atrium and/or ventricle when used with a compatible pulse generator.

## **Contraindications**

- Use of this lead is contraindicated in patients with a hypersensitivity to a single dose of 1.0 mg of dexamethasone acetate.
- Use of this lead is contraindicated in patients with an allergy to mannitol.
- Use of this lead is contraindicated in patients with tricuspid valvular disease.
- Use of this lead is contraindicated in patients with mechanical tricuspid heart valves.

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

## Warnings and Precautions

### Warnings

- The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that may 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 may arise from line-powered equipment.

### Precautions

- The SWEET PICOTIP Rx leads and accessories are intended for one-time use only. Do not reuse.
- Do not use unipolar leads having 3.2-mm connectors with pulse generators programmed to the bipolar mode. No output will result.
- 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 dexamethasone acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse events, refer to the *Physician's 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 SWEET PICOTIP Rx 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 and Table 2 report complications and observations for the SWEET PICOTIP Rx lead.

**Table 1. SWEET PICOTIP Rx Complications and Observations in the Atrium**

	# of pts (n=61)	% of pts [95% CI]	# of leads (n=61)	Adverse Events per Lead-Year
<b>Complications<sup>1</sup> (total)</b>	<b>1</b>	<b>1.6</b> <b>[0.0, 8.8]</b>	<b>1</b>	<b>0.042</b>
Brady capture— none or loss of capture	1	1.6 [0.0, 8.8]	1	0.042
<b>Observations<sup>2</sup> (total)</b>	<b>1</b>	<b>1.6</b> <b>[0.0, 8.8]</b>	<b>1</b>	<b>0.042</b>
Placement difficulty	1	1.6 [0.0, 8.8]	1	0.042

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

**Table 2. SWEET PICOTIP Rx Complications and Observations in the Ventricle**

	# of pts (n=61)	% of pts [95% CI]	# of leads (n=62)	Adverse Events per Lead-Year
<b>Complications<sup>1</sup> (total)</b>	<b>1</b>	<b>1.6</b> <b>[0.0, 8.8]</b>	<b>1</b>	<b>0.042</b>
Lead Dislodgment	1	1.6 [0.0, 8.8]	1	0.042
<b>Observations<sup>2</sup> (total)</b>	<b>5</b>	<b>8.1</b> <b>[3.0, 17.9]</b>	<b>5</b>	<b>0.209</b>
Placement difficulty	2	3.2 [0.1, 11.3]	2	0.083
Oversensing	2	3.2 [0.1, 11.3]	2	0.083
Impedance Related	1	1.6 [0.0, 8.8]	1	0.042

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

The study was a non-randomized historical control investigation comparing the performance of the SWEET PICOTIP Rx lead to that of the SWEET TIP lead. A total of sixty-two SWEET PICOTIP Rx leads were used in the atrium; sixty-one leads were implanted, one lead was attempted but not implanted. A total of sixty-four leads were used in the ventricle; sixty-two leads were

implanted with one lead replaced post implant, two leads were attempted but not implanted.

### **Potential Adverse Events**

Based on the literature and lead implant experience, the possible physical effects from implantation of a SWEET PICO-TIP Rx lead are listed below in alphabetical order:

- Air embolism
- Allergic reaction
- Bleeding
- Cardiac perforation
- Chronic nerve damage
- Displacement/dislodgment
- Erosion/extrusion
- Fibrotic tissue formation
- Hematoma
- Inappropriate therapy
- Incomplete connection with pulse generator
- Infection
- Keloid formation
- Lead abrasion
- Lead fracture, insulation break
- Lead tip deformation and/or breakage
- Local tissue reaction
- Low amplitude VF signals
- Myocardial injury
- Myocardial irritability
- Pneumothorax
- Post-shock rhythm disturbances
- Random component failures
- Shunting of current or insulation of myocardium during defibrillation with internal or external paddles
- Transvenous lead-related thrombosis
- Threshold elevation
- Venous occlusion
- Venous perforation

### **Clinical Studies**

The following is a summary of findings from the SWEET PICO-TIP Rx Lead Clinical Investigation.

Sixty-one patients were implanted with the SWEET PICOTIP Rx lead. The object of this investigation was to demonstrate higher pacing impedance and lower pacing threshold performance of the SWEET PICOTIP Rx lead compared to the historical control lead, SWEET TIP. The mean implant duration of the study population was 4.6 months with cumulative implant duration of 47.5 lead-years. No statistical differences were found in the baseline variables between the study patient group and the historical control group with respect to demographic profiles. Additional demographic information is presented in Table 3.

**Table 3. Description of the Study Population (n = 128 Patients)**

Demographics	SWEET PICOTIP Rx	Control
Number of Patients	61	67
Gender		
Male	39 (63.9%)	35 (52.2%)
Female	22 (36.1%)	32 (47.8%)
Age at Implant (years)		
Range	27–91	43–91
Mean $\pm$ Standard Deviation	70.5 $\pm$ 13.9	72.3 $\pm$ 11.4

The predominant pacing indications for the study population were sinus bradycardia 30% and third degree heart block 28%.

Results found in Table 4 through Table 9 demonstrate that the SWEET PICOTIP Rx lead was effective in reducing the typical post implant threshold rise normally associated with non-steroid leads and showed higher pacing impedance performance over standard pacing leads. The clinical study endpoint for pacing impedance intended to show a 30% increase in both the atrium and ventricular chambers over the control lead at all follow-up visits. Though a 30% increase was not maintained for each chamber at the 3-month visit, the average pacing impedance for both chambers throughout all visits was 32%. The increase in pacing impedance at all follow-ups was statistically significant as the mean pacing impedance in the atrium and ventricle remained above 900 and 1000 ohms respectively throughout the study.

**Table 4. Mean Atrial Voltage Threshold (V) at 0.5 ms by Follow-up Period**

Follow-up	SWEET PICOTIP Rx			Control (SWEET TIP)			Mean difference [95% CI]
	n	Mean (V) [95% CI]	STD	n	Mean (V) [95% CI]	STD	
Pre-discharge	59	0.61 [0.55, 0.67]	0.22	53	0.77 [0.63, 0.91]	0.53	-0.16 [-0.31, -0.01]
2 week	48	0.76* [0.66, 0.86]	0.34	57	1.25 [1.10, 1.40]	0.59	-0.49 [-0.68, -0.30]
6 week	52	0.75* [0.64, 0.86]	0.40	54	1.48 [1.18, 1.78]	1.14	-0.73 [-1.06, -0.40]
3 month	48	0.72* [0.63, 0.81]	0.33	51	1.29 [1.06, 1.52]	0.82	-0.57 [-0.82, -0.32]

\* Significantly different from the control (SWEET TIP) lead,  $p < 0.01$ , t-test.

**Table 5. Mean Ventricular Voltage Threshold (V) at 0.5 ms by Follow-up Period**

Follow-up	SWEET PICOTIP Rx			Control (SWEET TIP)			Mean difference [95% CI]
	n	Mean (V) [95% CI]	STD	n	Mean (V) [95% CI]	STD	
Pre-discharge	61	0.53 [0.50, 0.56]	0.10	54	0.59 [0.53, 0.65]	0.24	-0.06 [-0.13, -0.01]
2 week	56	0.78* [0.69, 0.87]	0.34	64	1.69 [1.48, 1.90]	0.86	-0.91 [-1.15, -0.67]
6 week	57	0.75* [0.67, 0.83]	0.31	61	1.68 [1.49, 1.87]	0.74	-0.93 [-1.14, -0.72]
3 month	55	0.71* [0.64, 0.78]	0.25	54	1.52 [1.38, 1.66]	0.52	-0.81 [-0.96, -0.66]

\* Significantly different from the control (SWEET TIP) lead,  $p < 0.01$ , t-test.

In the atrium, for a pulse width of 0.5 ms, mean voltage threshold for the SWEET PICOTIP Rx lead was 42.3% lower at 3 months post implant compared to the control lead. In the ventricle, for a pulse width of 0.5 ms, mean voltage threshold for the SWEET PICOTIP Rx lead was 53.3% lower at 3 months post implant compared to the control lead.

**Table 6. Atrial Lead Impedance ( $\Omega$ ) Recorded by Follow-Up Period**

Follow-up	SWEET PICOTIP Rx			Control (SWEET TIP)			Mean difference [95% CI]
	n	Mean (V) [95% CI]	STD	n	Mean (V) [95% CI]	STD	
Pre-discharge	61	957* [907, 1007]	200.6	66	668 [637, 699]	127.7	289 [230, 348]
2 week	56	919* [880, 958]	147.3	64	669 [643, 695]	107.9	250 [204, 296]
6 week	56	913* [883, 943]	113.3	60	709 [684, 734]	100.3	204 [165, 243]
3 month	55	923* [888, 958]	133.3	56	719 [690, 748]	108.9	204 [158, 250]

\* Significantly different from the control (SWEET TIP) lead,  $p < 0.01$ , t-test.

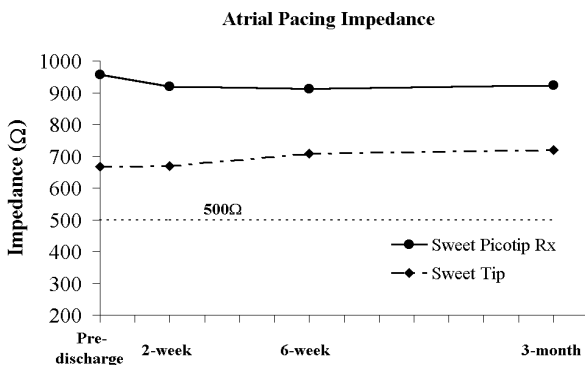
**Table 7. Ventricular Lead Impedance ( $\Omega$ ) Recorded by Follow-Up Period**

Follow-up	SWEET PICOTIP Rx			Control (SWEET TIP)			Mean difference [95% CI]
	n	Mean (V) [95% CI]	STD	n	Mean (V) [95% CI]	STD	
Pre-discharge	61	1221* [1151, 1291]	278.6	66	837 [801, 873]	147.6	384 [306, 462]
2 week	56	1031* [982, 1080]	185.3	63	804 [771, 837]	135.5	227 [169, 285]
6 week	57	1046* [997, 1095]	188.6	61	841 [805, 877]	142.6	205 [144, 266]
3 month	55	1025* [975, 1075]	187.8	54	839 [803, 875]	135.1	186 [124, 248]

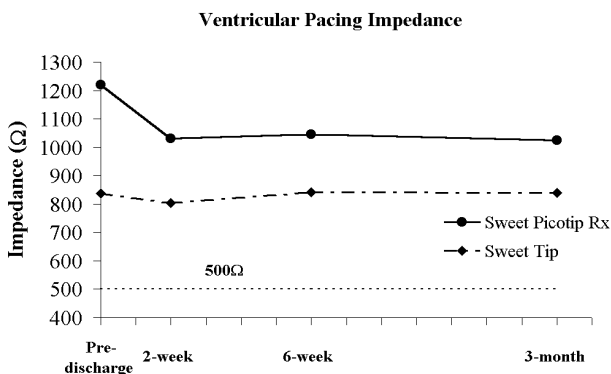
\* Significantly different from the control (SWEET TIP) lead,  $p < 0.01$ , t-test.

SWEET PICOTIP Rx lead impedance values were obtained from the pulse generator at pre-discharge, 2-week, 6-week, and 3-month follow-up visits. Results in Table 6 and Table 7 show statistically significant differences in impedance between the SWEET PICOTIP Rx lead and the control lead. Pacing impedance of the SWEET PICOTIP Rx lead remained consistently above the 900  $\Omega$  level in the atrium and above the 1000  $\Omega$  level in the ventricle throughout the 3-month follow-up period.

Figure 1 and Figure 2 show a graphical comparison of SWEET PICOTIP Rx lead, the control lead, and the nominal industry standard (500  $\Omega$ ) in terms of lead impedance for the atrium and ventricle respectively.



**Figure 1. SWEET PICOTIP Rx mean lead impedance in the atrium by follow-up period.**



**Figure 2. SWEET PICOTIP Rx mean lead impedance in the ventricle by follow-up period.**

SWEET PICOTIP Rx lead's P- and R-wave amplitude measurements were obtained using telemetered pacemaker diagnostics during follow-up. The P- and R-wave amplitude measurements were used to demonstrate appropriate electrical compatibility of the SWEET PICOTIP Rx lead with the pulse generator compared to the control lead. At each follow-up, the amplitude measured for the SWEET PICOTIP Rx lead was equivalent of the measurement obtained with the control lead as verified by equivalence test (Blackwelder, 1982) (Table 8 and Table 9).

**Table 8. P-wave Measurements Recorded by Follow-up Period**

Follow-up	SWEET PICOTIP Rx			Control (SWEET TIP)			Mean difference [95% CI]
	n	Mean (V) [95% CI]	STD	n	Mean (V) [95% CI]	STD	
Pre-discharge	60	2.28* [1.99, 2.57]	1.16	63	2.66 [2.35, 2.97]	1.27	-0.38 [-0.81, 0.05]
2 week	55	2.67* [2.28, 3.06]	1.47	61	2.60 [2.20, 3.00]	1.60	0.07 [-0.50, 0.64]
6 week	57	2.63* [2.27, 2.99]	1.37	57	2.78 [2.38, 3.18]	1.55	-0.15 [-0.69, 0.39]
3 month	52	2.32* [1.99, 2.65]	1.20	54	2.59 [2.21, 2.97]	1.44	-0.27 [-0.78, 0.24]

\* Statistical significance,  $p < 0.01$ , indicates equivalence: difference between means  $< 1.09$  mV.

**Table 9. R-wave Measurements Recorded by Follow-up Period**

Follow-up	SWEET PICOTIP Rx			Control (SWEET TIP)			Mean difference [95% CI]
	n	Mean (V) [95% CI]	STD	n	Mean (V) [95% CI]	STD	
Pre-discharge	49	8.19* [7.48, 8.90]	2.54	60	7.89 [7.13, 8.65]	2.99	0.3 [-0.77, 1.37]
2 week	50	8.05* [7.42, 8.68]	2.29	56	8.28 [7.67, 8.89]	2.33	-0.23 [-1.12, 0.66]
6 week	50	8.37* [7.79, 8.95]	2.10	54	7.94 [7.21, 8.67]	2.74	0.43 [-0.52, 1.38]
3 month	49	8.16* [7.58, 8.74]	2.07	52	8.13 [7.54, 8.81]	2.51	0.03 [-0.88, 0.94]

\* Statistical significance,  $p < 0.01$ , indicates equivalence: difference between means  $< 3.13$  mV.

There was no statistical difference in the number of patient deaths between the SWEET PICOTIP Rx lead and the control lead, and there were no lead related deaths reported in either group. There were two complications in the SWEET PICO-TIP Rx lead study. One complication in the atrium was due to loss of capture and was mitigated by repositioning the lead. There was one complication in the ventricle due to lead dislodgment.

SWEET PICOTIP Rx 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

The SWEET PICOTIP Rx steroid-eluting, positive-fixation, endocardial leads, unipolar Models 4050/4051/4052 and bipolar Models 4053/4054/4055, are atrial and ventricular transvenous pace/sense leads designed for use as an integral part of a pulse generator system with IS-1 ports. The lead uses a platinum-iridium porous-tip electrode with a polymer-coated fixation helix that provides a pacing and sensing surface by promoting fibrotic tissue ingrowth and physically stabilizing the tissue interface. The lead features a small electrically active surface area of the distal tip electrode that is designed to increase pacing impedance. The platinum-iridium helix anchors the pace/sense electrode to the endocardial surface without support of trabecular structures.

The tip electrode contains a nominal dose of 1.0 mg dexamethasone acetate contained in a silicone rubber collar.

The dissolvable mannitol capsule is designed to facilitate passage of the helix through the heart and blood vessels and to

protect the helix from damage. When the electrode tip is inserted into the vein, dissolution begins. The lead body consists of a multistrand conductor coil that provides a conductive pathway and is sheathed in a thin-walled tube of silicone rubber 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.

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## IMPLANT INFORMATION

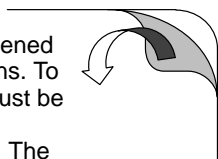
Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.

Items packaged with the SWEET PICOTIP Rx leads include the following:

- Soft straight and J-shaped stylets (0.014-in diameter [0.36-mm] green knobs)
- Firm straight and J-shaped stylets (0.016-in diameter [0.41-mm] white knobs)
- Stylet guide
- Vein pick
- Literature

## 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 leakage current when using electrical instrumentation.

## **Accessory Options**

### ***Pacemaker Accessory Kit***

Guidant has an operating room pacemaker accessory kit available that contains many of the tools, accessories, and adapters commonly used for lead implantation, repositioning, or both. Contact the nearest Guidant representative to order these accessories.

### ***Suture Sleeve***

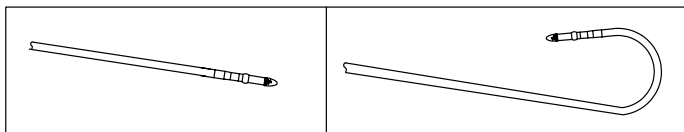
The suture sleeve is an adjustable, tubular reinforcement positioned over the outer lead insulation. It is designed to secure and protect the lead at the venous entry site after distal electrode fixation. Use of the suture sleeve helps to optimize device reliability and reduces the possibility of structural 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.

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

### ***Stylets***

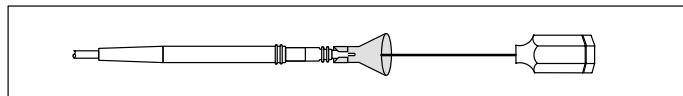
A stylet inserted in the lead aids in positioning the lead tip in the heart. Straight and J-shaped stylets are packaged with the SWEET PICOTIP Rx lead, providing firm and soft options (Figure 3): firm stylets have white knobs and soft stylets have green knobs. A soft straight stylet is preinserted in the packaged lead.



**Figure 3. Lead with straight stylet inserted. Lead with J-shaped stylet inserted.**

### **Stylet Guide**

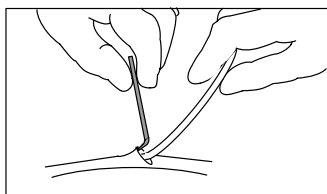
A stylet guide is packaged with the lead and is intended to ease insertion of a stylet into the lead (Figure 4).



**Figure 4. 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 5. Using the vein pick.**

To use the vein pick during a cutdown procedure, isolate and open the selected vein using an appropriate scalpel or scissors. Introduce the point of the vein pick via this incision into the lumen of the vein (Figure 5).

With the point of the vein pick facing in the direction of the

desired lead passage, gently raise and tilt the pick. 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. Be sure that the vein pick does not puncture the silicone rubber insulation of the lead. This might allow body fluids to seep into the lead and could prevent proper lead function.

## **Handling the Lead**

Observe the following cautions when handling SWEET PICO-TIP Rx leads:

### **CAUTIONS:**

- Do not wet the mannitol capsule at the tip of the lead before implantation. This will cause the capsule to begin

to dissolve and will shorten the time during which the helix is protected. This may also begin elution of the steroid and may reduce the amount of steroid available when the lead is implanted.

- The conductor insulation is silicone rubber, which can attract particulate matter and must always be protected from surface contamination.
- 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.
- Avoid bending the coil conductor; this may weaken the structure. Although pliable, a lead is designed to tolerate only normal flexing and tension.
- Do not apply pressure to the protective capsule over the electrode tip. If the capsule is damaged, the dissolving time may be shortened and/or the helix may be bent. If the helix is bent, the torsional fracture resistance of the helix may be reduced.
- Do not alter the electrodes or use a lead with a deformed helix. **Do not attempt to straighten or realign the fixation helix.**
- 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.

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## IMPLANTATION

### Inserting the Stylet

Choose a stylet according to the firmness desired. Remove the preinserted stylet before inserting a different one.

Gently curve the preferred stylet with any sterile, smooth-surfaced instrument (eg, 10- or 12-cc syringe barrel) (Figure 6) 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.

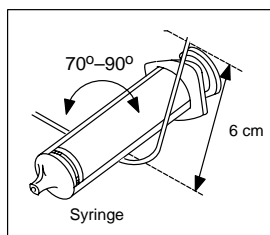


Figure 6. Curve the stylet.

**CAUTION:** Do not bend the lead with the stylet in place. Bending the lead may damage the conductor and insulation material.

**NOTE:** *To optimize stylet insertion into the lead, do not allow body fluids to come in contact with the stylet.*

## **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 (below the clavicle) 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.**

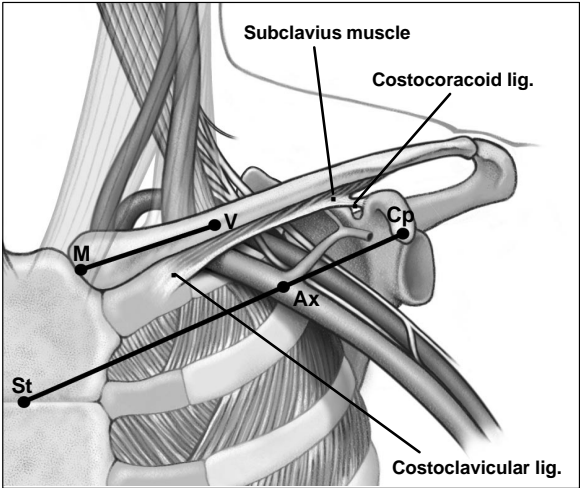
**CAUTION:** When attempting to implant the lead via a subclavian puncture, do not insert the lead under the medial one-third region of the clavicle. Damage to the lead is possible if the lead is implanted in this manner. If implantation via the subclavian vein is desired, the lead must enter the subclavian 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.

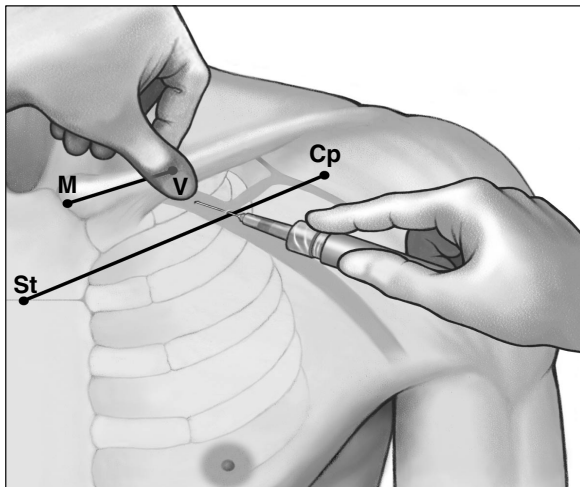
1. Referring to Figure 7, identify points St (sternal angle) and Cp (coracoid process).
2. Visually draw a line between St and Cp, and divide the segment into thirds. The needle should pierce the skin at the junction of the middle and lateral thirds, directly above the axillary vein (point Ax).
3. Place 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 7. 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 7).
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 8. 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.

## Handling the Fixation Helix

As soon as the capsule is inserted into the vein, the capsule begins to dissolve. The fixation helix remains encapsulated for approximately five minutes.

**NOTE:** *The mannitol capsule can have varying dissolution rates based on the patient's cardiac anatomy, lead placement, and various implant conditions.*

After approximately five minutes since the introduction of the lead, the fixation helix will be exposed. The following points must be carefully observed to avoid possible tissue snagging when inserting a lead having an exposed fixed helical coil:

### CAUTIONS:

- The method used to direct positive fixation leads through the veins to the heart is different from that used with other leads. To prevent entanglement, use the stylet to steer while rotating the lead body continuously

counterclockwise. Use of the lead body for steering may result in snagging and damaging the fixation helix.

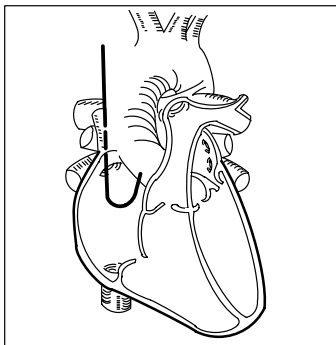
- Continuous *counterclockwise* rotation of the lead during maneuvering is necessary to avoid inadvertent tissue trauma.
- Do not rotate the lead *clockwise* until correct position has been achieved and fixation is intended.
- Should dislodgment occur, immediate medical care is required to resolve the electrode position and minimize endocardial trauma.

Advance the lead promptly to the appropriate heart chamber while directing the electrode with the appropriate stylet and rotating the lead body counterclockwise. Counterclockwise lead rotation helps to prevent accidental fixation and releases the electrode helix after fixation has occurred.

## Positioning the Lead

After immersion in blood, the SWEET PICOTIP Rx electrode is electrically conductive to allow mapping of potential electrode positions. Mapping of the atrium or ventricle prior to lead fixation is recommended as it can reduce the potential need for multiple lead positionings.

**Atrial Position.** With the straight stylet in the lead, advance the lead transvenously into the right atrium while guiding the electrode with the stylet. By replacing the straight stylet with a J-shaped stylet, the lead electrode can be directed upward into the atrial appendage (Figure 9).

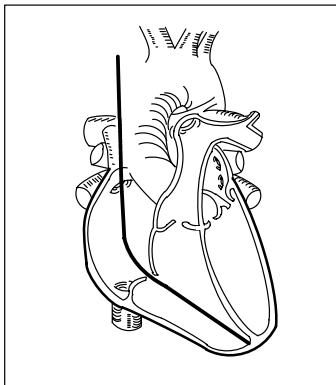


**Figure 9. Atrial placement.**

### NOTES:

- *When possible, the tip electrode should be positioned perpendicular to the heart wall prior to fixation. This will help reduce stress on the helix as the lead is affixed to the heart wall.*
- *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.*

**Ventricular Position.** With the gently curved stylet in the lead, advance the lead transvenously into the apex of the right ventricle where it can be affixed in the endocardium. If necessary, remove the curved stylet and use a straight stylet to advance the tip deeper into the trabeculae. Before affixing the distal electrode helix, use a fluoroscope to ensure that the lead is in the ventricle and not in the coronary sinus (Figure 10).



**Figure 10. Ventricular placement.**

## Lead Fixation

When the correct position has been achieved and five or more minutes have passed allowing the capsule to dissolve completely, affix the distal electrode helix into the heart wall.

**NOTE:** *The stylet must be fully inserted during fixation or repositioning.*

If implanting a **unipolar** SWEET PICOTIP Rx lead (Models 4050, 4051, 4052), affix the electrode helix into the heart wall by rotating the lead clockwise approximately 6 turns or until torsional resistance is felt.

If implanting a **bipolar** SWEET PICOTIP Rx lead (Models 4053, 4054, 4055), affix the electrode helix into the heart wall by rotating the lead clockwise approximately 3–5 turns, or until torsional resistance is felt.

## CAUTIONS:

- If the stylet begins to turn while fixing the lead, hold the stylet stationary while rotating the lead. Rotating the stylet during electrode fixation dislodges the electrode helix.
- Do not rotate the lead clockwise more than 10 turns when affixing the electrode helix to the heart wall. Excessive rotation may cause helix breakage.

After fixation, allow the lead to counterrotate passively, approximately 1.5 turns, to release excess torsional stress. Failure to observe counterrotation indicates incomplete fixation. Repeat clockwise rotations using the procedures previously discussed until torsional resistance is felt and counterrotation is observed

upon release. Check the stability of the electrode by having the patient cough or take a deep breath.

For atrial implantation, after the lead tip is affixed to the heart wall, check for proper lead movement: 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).

## Repositioning the Lead

If the lead needs repositioning, verify the stylet is in the lead and rotate the lead counterclockwise several turns to release the fixation helix. Fluoroscopy is recommended to verify the helix is disengaged completely from the heart wall before attempting to reposition the lead. Reaffix the electrode using the handling and positioning procedures previously discussed.

### CAUTIONS:

- Do not alter the electrodes or use a lead with a deformed helix. **Do not attempt to straighten or realign the fixation helix.**
- Chronic repositioning may adversely affect the lead's low-threshold performance because the steroid may be depleted.

## Electrical Performance

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

Evaluate lead placement by determining P- or R-wave amplitude and pacing threshold. Verify the 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 may 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 of the patient cable. TIP TO TIP and RING TO RING describes the lead conductor to lead electrode connections.

Sensing signals also may be measured with an ECG recorder or oscilloscope. Electrical performance should fall within the recommended values listed in Table 10.

**Table 10. Recommended threshold and sensing measurements<sup>1</sup>**

Atrial Data	Ventricular Data
Voltage threshold <sup>2</sup> $\leq 1.0$ V	Voltage threshold <sup>2</sup> $\leq 1.0$ V
Current threshold <sup>2</sup> $\leq 1.5$ mA	Current threshold <sup>2</sup> $\leq 1.5$ mA
P-wave amplitude $\geq 2.0$ mV	R-wave amplitude $\geq 5.0$ mV

1. Measured approximately 10 minutes after fixation.

2. Pulse width setting at 0.5 ms.

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

**NOTE:** *Low stimulation threshold readings indicate a desirable safety margin, since stimulation threshold may rise after implantation.*

## Securing the Lead

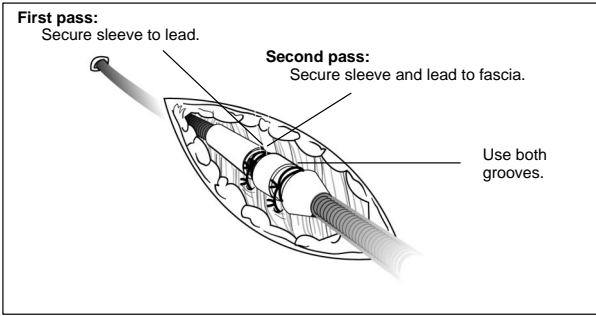
After the electrodes are satisfactorily positioned, secure the lead to the vein using the suture sleeves provided. Suture sleeve tie-down techniques can vary with the lead insertion technique used. Securing the lead will provide permanent hemostasis and lead stabilization.

### 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 can cause lead damage.

### ***Percutaneous Implant Technique***

1. Peel back the introducer sheath and slide the suture sleeve deep into the tissue (Figure 11).
2. Using both grooves, ligate the suture sleeve to the lead.
3. Next, secure the sleeve and lead to the fascia.



**Figure 11. 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 12).

#### **Distal Groove:**

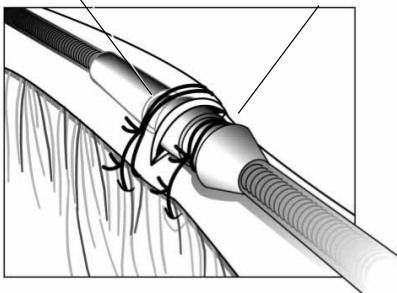
First pass: secure vein to lead.

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 12. 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.

### CAUTIONS:

- **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.**
- 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.

### 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 leads to Guidant. Examination of explanted leads may 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 1-800-CARDIAC or 612-638-4000 for a Returned Product Kit.*

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## 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	4050, 4051, 4052 Unipolar	4053, 4054, 4055 Bipolar
Length	4050 – 45 cm 4051 – 52 cm 4052 – 59 cm	4053 – 45 cm 4054 – 52 cm 4055 – 59 cm
Compatibility	Guidant pulse generators that accept 3.2-mm or IS-1 connectors	Guidant pulse generators that accept 3.2-mm or IS-1 connectors
Recommended lead introducer <sup>a</sup>	9 Fr	9 Fr
Diameter:		
Lead body	2.2 mm	2.2 mm
Distal electrode	2.0 mm	2.0 mm
Proximal electrode	NA	2.6 mm
Fixation helix	1.3 mm	1.3 mm
Active surface area:		
Distal electrode	3 mm <sup>2</sup>	3 mm <sup>2</sup>
Proximal electrode	NA	35 mm <sup>2</sup>
Distance between electrodes	NA	11 mm
Steroid	1.0 mg dexamethasone acetate	1.0 mg dexamethasone acetate
Fixation helix penetration depth	1.5 mm	1.5 mm
Number of coils in fixation helix	1.5 turns	1.5 turns
Conductors	Double-wound helical coil	Double- and quad-wound helical coils
Material:		
Helix coating	Parylene	Parylene
Electrode	Platinum iridium	Platinum iridium
Conductor	MP35N nickel	MP35N nickel
Insulation	Silicone rubber	Silicone rubber
Capsule	Mannitol	Mannitol

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







# GUIDANT

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