

**Physician's Manual**

**FLEXTEND®**

**Steroid-Eluting  
Extendable/Retractable Helix  
Pace/Sense Leads**

MODELS: 4086/4087/4088

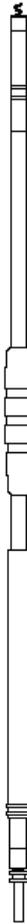
**GUIDANT**



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FLEXTEND® Leads



Models  
4086/4087/4088  
Bipolar leads

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## DEVICE DESCRIPTION

Guidant FLEXTEND® leads, Models 4086/4087/4088, are bipolar, steroid-eluting, transvenous pace/sense leads with an extendable/retractable active-fixation helix for permanent implantation in the atrium and/or ventricle. The lead is for use as an integral part of a pacing system with IS-1<sup>1</sup> ports.

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

## Indications

Guidant FLEXTEND leads, Models 4086/4087/4088, are intended for chronic pacing and sensing in the atrium and/or ventricle when used with a compatible pulse generator.

## Contraindications

Use of the FLEXTEND lead is contraindicated for the following patients:

- Patients with a hypersensitivity to a single dose of approximately 1.0 mg dexamethasone acetate.
- Patients with tricuspid valvular disease.
- Patients with mechanical tricuspid heart valves.

## 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 terminal pins must be insulated from any leakage currents that may arise from line-powered equipment.
- Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weakness, conductor discontinuity, or lead dislodgment (Page 10).

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

## FLEXTEND LEAD—DEVICE DESCRIPTION

### **Precautions**

- The FLEXTEND leads and 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 dexamethasone acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, 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 FLEXTEND 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**

A handling study was conducted on the FLEXTEND leads, Models 4086/4087/4088. The complications and observations are reported in Table 1 and Table 2.

DEVICE DESCRIPTION—FLEXTEND LEAD

**Table 1. FLEXTEND Lead, Models 4086/4087/4088, Atrial Morbidity<sup>a</sup>**

	# of pts. <sup>b</sup> (n = 30)	% of pts. (95% CI)	# of Leads	Adverse Events per Lead-Month
<b>Complications<sup>c</sup> (total)</b>	<b>0</b>	<b>-</b>	<b>0</b>	<b>0%</b>
<b>Observations<sup>d</sup> (total)</b>	<b>2</b>	<b>6.7 (1.2, 23.5)</b>	<b>2</b>	<b>3.14%</b>
Placement difficulty, lead damaged during implant	1	3.3 (0.2, 16.9)	1	1.57%
Lead caught in chordae	1	3.3 (0.2, 16.9)	1	1.57%

- a. Adverse event data is derived from 30 patients followed for 30 days.
- b. Patients and leads may have multiple adverse events.
- c. Complications are defined as adverse events requiring invasive measures to correct (eg, surgical intervention).
- d. Observations are defined as adverse events which are correctable by noninvasive measures (eg, reprogramming).

**Table 2. FLEXTEND Lead, Models 4086/4087/4088, Ventricular Morbidity<sup>a</sup>**

	# of pts. <sup>b</sup> (n = 30)	% of pts. (95% CI)	# of Leads	Adverse Events per Lead-Month
<b>Complications<sup>c</sup> (total)</b>	<b>1</b>	<b>3.3 (0.2, 16.9)</b>	<b>1</b>	<b>1.57%</b>
Lead dislodgement-right ventricle	1	3.3 (0.2, 16.9)	1	1.57%
<b>Observations<sup>d</sup> (total)</b>	<b>1</b>	<b>3.3 (0.2, 16.9)</b>	<b>1</b>	<b>1.57%</b>
Placement difficulty, lead damaged during implant	1	3.3 (0.2, 16.9)	1	1.57%

- a. Adverse event data is derived from 30 patients followed for 30 days.
- b. Patients and leads may have multiple adverse events.
- c. Complications are defined as adverse events requiring invasive measures to correct (eg, surgical intervention).
- d. Observations are defined as adverse events which are correctable by noninvasive measures (eg, reprogramming).

## *FLEXTEND LEAD—DEVICE DESCRIPTION*

### **Potential Adverse Events**

Based on the literature and lead implant experience, the possible physical effects from implantation of a FLEXTEND 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 lead 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
- Oversensing/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**

Clinical data supporting this lead comes from the FLEXTEND lead, Models 4086/4087/4088, handling study.

The handling study was an evaluation of the FLEXTEND lead, Models 4086/4087/4088, in 30 patients. The study provided reasonable assurance of safety and effectiveness. Lead safety was supported by a review of lead-related complications. In 60 implanted leads, a single lead-related complication was observed (a dislodgement at a two-week follow-up). Patient population characteristics and electrical performance are summarized in the tables below.

DEVICE DESCRIPTION—FLEXTEND LEAD

**Table 3. Patient Population Characteristics (N = 30 patients)**

Category	FLEXTEND lead, Models 4086/4087/4088
Number of Patients Implanted (N)	30
Age at Implant (years)	
N	30
Minimum	52.3
Maximum	100.0
Mean	78
Standard Deviation	9.3
Gender	
Male	15 (50%)
Female	15 (50%)

**Table 4. Mean Atrial Voltage Threshold at 0.5 ms by Follow-up Period (N = 30 patients)**

Follow-up	FLEXTEND lead, Models 4086/4087/4088		
	Number of Patients	Mean (V)	Standard Deviation
Pre-discharge	29	0.68	0.65
2 weeks	26	0.85	0.41
4 weeks	27	0.88	0.35
6 months	24	1.02	0.53

**Table 5. Mean Ventricular Voltage Threshold at 0.5 ms by Follow-up Period (N = 30 patients)**

Follow-up	FLEXTEND lead, Models 4086/4087/4088		
	Number of Patients	Mean (V)	Standard Deviation
Pre-discharge	30	0.57	0.17
2 weeks	27	1.06	0.82
4 weeks	28	0.95	0.62
6 months	23	1.08	0.55

FLEXTEND LEAD—DEVICE DESCRIPTION

**Table 6. Atrial Lead Impedance by Follow-up Period**

Follow-up	FLEXTEND lead, Models 4086/4087/4088		
	Number of Patients	Mean ( $\Omega$ )	Standard Deviation
Pre-discharge	30	535	111
2 weeks	26	511	79
4 weeks	29	528	96
6 months	26	575	100

**Table 7. Ventricular Lead Impedance by Follow-up Period**

Follow-up	FLEXTEND lead, Models 4086/4087/4088		
	Number of Patients	Mean ( $\Omega$ )	Standard Deviation
Pre-discharge	30	793	232
2 weeks	28	708	190
4 weeks	30	701	204
6 months	26	709	220

**Table 8. P-wave Sensing Amplitudes by Follow-up Period**

Follow-up	FLEXTEND lead, Models 4086/4087/4088		
	Number of Patients	Mean (mV)	Standard Deviation
Pre-discharge	26	2.52	0.91
2 weeks	26	2.83	1.17
4 weeks	28	2.85	1.24
6 months	22	2.77	1.18

**Table 9. R-wave Sensing Amplitudes by Follow-up Period**

Follow-up	FLEXTEND lead, Models 4086/4087/4088		
	Number of Patients	Mean (mV)	Standard Deviation
Pre-discharge	22	13.61	7.04
2 weeks	22	15.25	6.35
4 weeks	19	14.71	7.07
6 months	17	13.18	6.26

## Detailed Device Description

Guidant FLEXTEND leads, Models 4086/4087/4088, are bipolar, steroid-eluting, transvenous, silicone pace/sense leads with an extendable/retractable active-fixation helix. By rotating the IS-1 lead terminal pin with the fixation tool, the electrically active platinum-iridium helix can be extended or retracted to anchor the distal lead tip electrode to the endocardial surface without support of trabecular structures, and is intended for chronic pacing and sensing in the atrium and/or ventricle. Upon exposure to body fluids, the distal tip elutes a steroid, a single dose of approximately 1.0 mg dexamethasone acetate.

The thin lead body consists of a multistrand conductor coil-within-a-coil design that provides a conductive pathway and acts as a drive mechanism for extending or retracting the helix. Radiopaque markers in the lead tip are visual indicators for monitoring the helix extension during implantation. The conductors are each sheathed in a thin-walled tube of silicone rubber insulation. A color-coded mark on the terminal end of the lead allows for a quick visual reference of the lead length. The lead color matches the same length stylet cap color.

The FLEXTEND lead has a proprietary coating that makes the silicone lead surface more lubricious. The coating reduces both the static and dynamic coefficients of friction, making the lead surface feel like polyurethane.

## Warranty

See the enclosed Lead Information card for warranty and guarantee 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 only for informational purposes. Each physician must apply the information in these instructions according to professional medical training and experience.

## FLEXTEND LEAD—IMPLANT INFORMATION

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

### Included Items

The following items are packaged with the FLEXTEND lead:

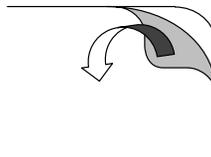
- Straight stylet, soft<sup>a</sup>
- Straight stylets, firm<sup>b</sup>
- J-shaped stylets, soft<sup>a</sup>
- Wide radius/long reach J-shaped stylets, soft<sup>a</sup>
- Fixation tools
- Stylet guide
- Vein pick
- Lead caps
- Literature

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

b. 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

Guidant sterilizes the lead and accessories with ethylene oxide gas (EO) before final packaging. When they are received, they are 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.

## Lead Accessories

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

### Fixation Tool

The fixation tool can be attached to the terminal pin and rotated clockwise or counterclockwise for extending or retracting the helix (Figure 1).

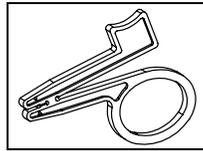


Figure 1. The fixation tool.

### Stylet Guide

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

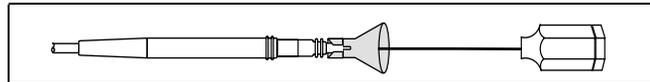


Figure 2. Using the stylet guide.

### Stylets

A stylet inserted in the lead aids in positioning the lead tip in the heart. Firm and soft straight stylets, soft J-shaped stylets, and soft wide radius/long reach J-shaped stylets are packaged with the FLEXTEND lead (Figure 3). Firm stylets have white knobs and soft stylets have green knobs. A straight stylet is preinserted in the packaged lead.

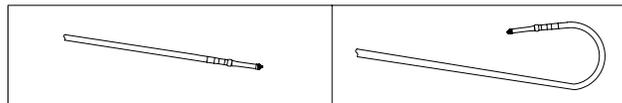
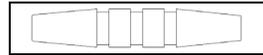


Figure 3. Lead with a straight stylet inserted. A straight lead with a J-shaped stylet inserted.

## FLEXTEND LEAD—IMPLANT INFORMATION

### Suture Sleeves

The suture sleeve is an adjustable, tubular reinforcement positioned over the outer lead insulation (Figure 4). 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.



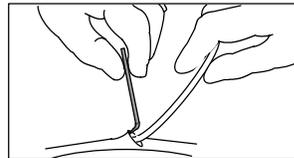
**Figure 4. The suture sleeve is symmetric.**

**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.

### 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.

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.



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

**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 when handling the lead:

**WARNING:** Although pliable, the lead is not designed to tolerate excessive flexing, bending, or tension. This could cause structural weaknesses, conductor discontinuity, or lead dislodgment.

#### **CAUTIONS:**

- Avoid holding or handling the distal tip of the lead.

## IMPLANTATION—FLEXTEND LEAD

- Do not wipe or immerse the electrode in fluid. Such treatment will reduce the amount of steroid available when the lead is implanted.
- Optimum threshold performance might not be achieved if the lead is chronically repositioned because the steroid can be depleted.
- The conductor insulation is silicone rubber, which can attract particulate matter and must always be protected from surface contamination.
- 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.
- Do not attempt to alter the electrodes. Do not apply pressure to the tip of the electrode.
- Mineral oil should never come in contact with a Guidant tip electrode. Mineral oil on the tip may inhibit tissue ingrowth and conduction.

**NOTE:** Guidant suggests using sterile water if a lubricant is needed when coupling the lead with the pulse generator.

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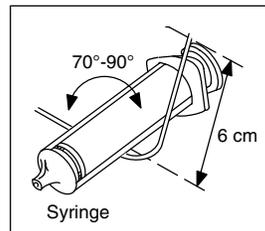
## IMPLANTATION

### Inserting the Stylet

Choose a stylet according to the function and to the firmness desired. Remove the preinserted stylet before inserting a different one. Make sure the stylet is fully inserted in the lead prior to inserting the lead into the vein.

Gently curve the preferred straight 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.

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



**Figure 6.** Curve the stylet.

## FLEXTEND LEAD—IMPLANTATION

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

### Handling the Fixation Helix

Before implanting the lead, verify the mechanical functioning of the lead by rotating the terminal pin and visually observing the helix extending and retracting. The helix can be extended or retracted by rotating the terminal pin clockwise to extend the helix or counterclockwise to retract it.

**NOTE:** Refer to the Lead Fixation section on Page 17 and to the Specifications section on page Page 24.

#### CAUTIONS:

- Do not overextend or overretract the helix. Exceeding the number of turns required to extend or retract the helix can damage the lead.
- If the helix cannot be extended or retracted, do not use the lead.
- Do not alter the electrodes or use a lead with a deformed helix or damaged helix fixation mechanism. **Do not attempt to straighten or realign the fixation helix.**

#### NOTES:

- Do not insert a lead into the vein if the helix is extended. Rotate the terminal pin counterclockwise to retract the helix into the distal lead tip prior to insertion into the vein.
- Any curves introduced into the stylet could increase the number of turns needed to extend or retract the helix.

### Inserting the Lead

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

#### **Via cutdown procedure 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 can 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.

## IMPLANTATION—FLEXTEND LEAD

**Percutaneously or via cutdown procedure 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.<sup>2</sup>

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.<sup>3</sup> Guidant recommends introducing the lead into the subclavian vein near the lateral border of the first rib.

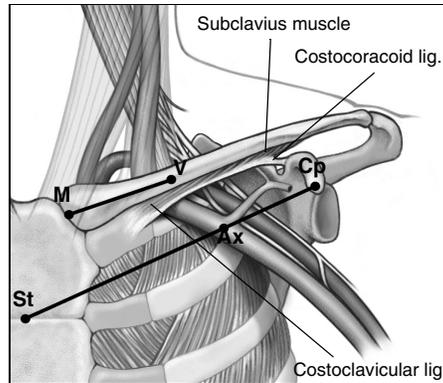
The syringe should be positioned directly above and parallel to the axillary vein to reduce the chance that the needle will contact the axillary or subclavian arteries or the brachial plexus. Use of fluoroscopy is helpful in locating the first rib and in guiding the needle. The steps below explain how 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).

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2. 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.
  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.

*FLEXTEND LEAD—IMPLANTATION*

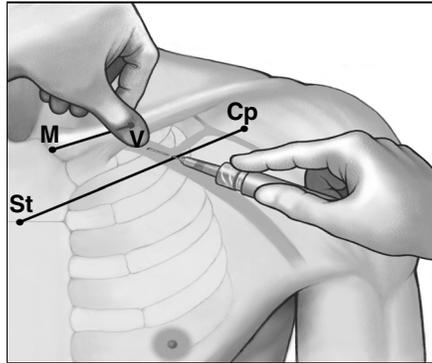
3. Place an index finger on the clavicle at the junction of the medial and middle thirds (point V), beneath which point the subclavian vein should be located.



**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 should be hypertrophied as well) (Figure 8).
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.

## IMPLANTATION—FLEXTEND LEAD



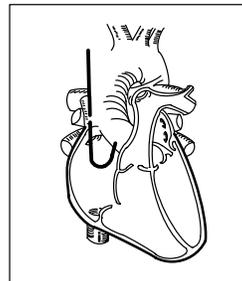
**Figure 8. Location of thumb and needle entry.**

**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.

### Positioning the Lead

#### Atrial Position.

1. Use a straight stylet to advance the lead into the right atrium.
2. With the lead low in the right atrium, insert the J-shaped or a curved straight stylet.
3. Gently pull the lead/stylet combination at the venous entry site to ensure contact between the lead tip and the endocardium (Figure 9).



**Figure 9. Atrial placement.**

Two different J-shape stylets are provided. One has a longer reach and may be suitable for most patient anatomies. The smaller stylet may be more suitable for a patient with a smaller atrium or a patient who has had previous cardiac surgery (ie, coronary artery bypass graft CABG).

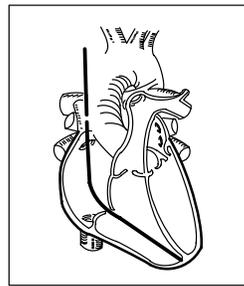
## FLEXTEND LEAD—IMPLANTATION

### NOTES:

- A satisfactory position has the lead tip situated against the endocardium in the atrial appendage.
- As viewed under fluoroscopy (A–P view), the lead tip should point medially forward towards the left atrium.
- After placing the lead, extend the helix as described in the “Lead Fixation” on page 17.

### Ventricular Position.

1. Advance the lead into the right atrium using a straight stylet.
2. Advance the lead through the tricuspid valve or place the lead tip against the lateral atrial wall and back the curved lead body through the tricuspid valve. A curved stylet may enhance maneuverability.
3. Use fluoroscopy (lateral position) to ensure that the lead is not lodged in the coronary sinus and is actually in the ventricle (Figure 10).
4. Insert a stylet into the lead and gently push the lead/stylet combination at the venous entry site to ensure contact between the lead tip and the endocardium.



**Figure 10. Ventricular placement.**

### CAUTIONS:

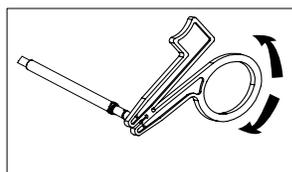
5. If the patient has a thin apical wall, another fixation site should be considered.
6. If a conscious patient feels a sharp pain, this may be an early indication of perforation.
7. To minimize the application of lead tip pressure, partially withdraw the stylet during lead positioning to minimize tip stiffness.
8. See “Lead Fixation” on page 17 to secure the lead.

## Lead Fixation

The FLEXTEND helix is electrically conductive to allow mapping of potential electrode positions. Mapping means pacing and sensing thresholds can be measured without extending the helix into the tissue, rather the distal tip of the lead can be placed against the tissue and measurements can be taken. If data is acceptable proceed with lead fixation. Mapping of the atrium or ventricle prior to lead fixation is recommended as it can reduce the potential need for multiple lead positionings.

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

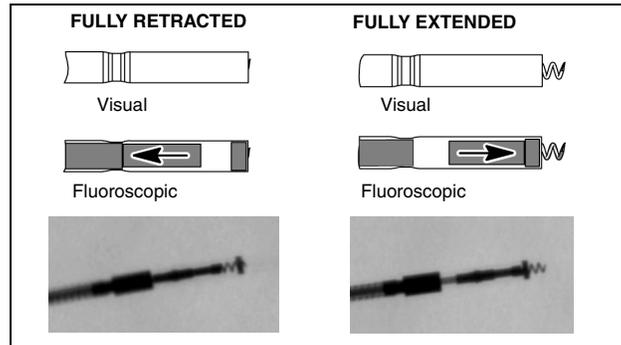
1. When the correct position has been achieved, attach the fixation tool to the terminal pin. Press the handles together and place the pin in the preformed groove. Release the tension on the handles to secure the terminal pin in the fixation tool (Figure 11).



**Figure 11. Attaching and rotating the fixation tool.**

2. Apply adequate pressure to seat the distal electrode against the desired fixation site and rotate the fixation tool *clockwise* to affix the distal electrode helix into the heart wall.
3. Use 6–8 turns, giving approximately 1 second for each turn to ensure helix penetration and transfer of torque.
4. Do not release the fixation tool—hold it stationary.
5. Verify under fluoroscopy that the radiopaque markers are joined and the fixation helix is extended outside the distal fluoroscopy markers (Figure 12).

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**Figure 12. Possible views of the helix electrode.**

6. If the markers are not joined, 1 to 2 additional turns may be necessary.

**CAUTION:** Minimize the number of turns. Excessive turns can cause damage to the lead, acute voltage thresholds to rise, lead dislodgement, and/or lead perforation.

7. Loosely hold the proximal end of the lead and release hold on the fixation tool.

**NOTE:** After following Step 7, minimal counter rotation in the terminal pin may be observed.

8. Remove the fixation tool from the terminal pin by pressing the handles of the tool together.
9. Carefully remove the stylet. Minimize manipulation of the lead to prevent dislodgement.
10. Ensure sufficient lead slack is present to prevent dislodgement.

If the helix mechanism fails to function properly during repositioning, the following caution must be carefully observed to avoid possible tissue snagging when removing the lead:

**CAUTION:** Do not use the lead if the helix cannot be retracted during implant. Continuous *counterclockwise* rotation of the lead body during lead removal is necessary to avoid inadvertent tissue trauma. Counterclockwise lead rotation helps to prevent accidental fixation and releases the electrode helix if tissue snagging has occurred.

## Checking for Lead Stability

After fixation, partially withdraw the stylet 8 to 10 cm. Check the stability of the lead using fluoroscopy. Do not tug on the lead. If possible, have the patient cough or take several deep breaths. When electrode position is satisfactory, completely withdraw the stylet.

**CAUTION:** Should dislodgment occur, immediate medical care is required to resolve the electrode position and minimize endocardial trauma.

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).

Ensure sufficient lead slack is present in the atrium. Lead slack helps prevent lead dislodgement. Sufficient slack is present if the lead assumes an L-shape as the patient inhales. Excessive slack is present if the lead drops near the tricuspid valve.

## Repositioning the Lead

If the lead needs repositioning, verify the stylet is fully inserted in the lead, reconnect the fixation tool, and rotate the tool counterclockwise to retract the helix. Excessive rotation can damage the lead. Fluoroscopy can help to verify that the helix is retracted and disengaged completely from the heart wall before attempting to reposition the lead. Reaffix the electrode using the handling, positioning, and checking for lead stability procedures previously discussed.

## Electrical Performance

Evaluate lead placement by determining P- or R-wave amplitude and pacing threshold. Reverify 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 terminal 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 terminal is the anode (+) conductor and should be

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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>a</sup>**

Atrial Data	Ventricular Data
Voltage threshold <sup>b</sup> $\leq 1.5$ V	Voltage threshold <sup>b</sup> $\leq 1.0$ V
Current threshold <sup>b</sup> $\leq 1.5$ mA	Current threshold <sup>b</sup> $\leq 1.5$ mA
P-wave amplitude $\geq 2.0$ mV	R-wave amplitude $\geq 5.0$ mV
Impedance 450-1800 $\Omega$	Impedance 450-1800 $\Omega$

a. Measured approximately 10 minutes after fixation.

b. 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.

### NOTES:

- *Low stimulation threshold readings indicate a desirable safety margin, since stimulation threshold may rise after implantation.*
- *Initial electrical measurements may deviate from recommendations because of acute cellular trauma. If this occurs, wait approximately 10 minutes and repeat testing. Values may be dependant on patient specific factors such as tissue condition, electrolyte balance and drug interactions.*
- *Overrotation of terminal pin may increase local tissue trauma and cause temporarily high voltage thresholds.*

## 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:

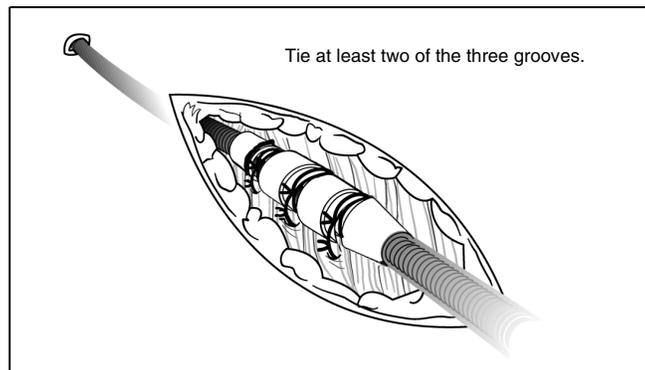
- Do not kink, twist, or braid the lead terminal with other leads as doing so could cause lead insulation abrasion damage.

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- 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.
- Ensure the suture sleeve remains proximal to the venous entry site.

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

1. Peel back the introducer sheath and slide the suture sleeve deep into the tissue (Figure 13).
2. Using the grooves, ligate the suture sleeve and the lead to the fascia. For additional stability, the sleeve may be secured to the lead first before securing the sleeve to the fascia.
3. The multiple grooves provide options for tie-down sites. At a minimum, two of the three grooves should be used for ligation.



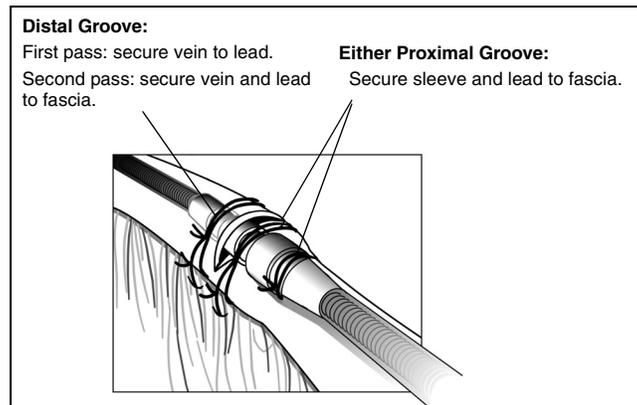
**Figure 13. Using the sleeve with the percutaneous implant technique.**

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.

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### **Venous Cutdown Technique**

1. Slide the suture sleeve into the vein past the most distal 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 14).



**Figure 14. Using the sleeve with the venous cutdown technique.**

2. Using one of the proximal grooves, secure the sleeve and the lead to the adjacent fascia. For additional stability, the sleeve may be secured to the lead first before securing the sleeve to the fascia. The other groove may be used as an additional tie-down site.
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.

## IMPLANTATION—FLEXTEND LEAD

### CAUTIONS:

- 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 terminal must be capped before closing the pocket incision. Place a suture around the lead cap to keep it in place.*

Giving consideration to patient anatomy and pulse generator size and motion, gently coil any excess lead and place adjacent to the pulse generator. It is important to place the lead into the pocket in a manner that minimizes lead tension, twisting, sharp angles, and/or pressure.

### 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 the phone number on the back of this manual for a Returned Product Kit.*

FLEXTEND LEAD—SPECIFICATIONS (NOMINAL)

**SPECIFICATIONS (Nominal)**

Model, length, color code	4086—45 cm, white 4087—52 cm, red 4088—59 cm, yellow Bipolar/Straight
Helix Extension Process (See “Lead Fixation” on page 17 for additional information.)	Verify mechanism performance prior to lead introduction. Apply 6–8 turns, 1 second per turn. Hold fixation tool. Verify fluoroscopic markers. Apply additional turns as necessary.
Compatibility	Guidant pulse generators that accept IS-1 connectors
Lead introducer: without guide wire with guide wire	8F 9.5F
Diameter: Lead body Proximal electrode Fixation helix (distal electrode)	2.4 mm 2.4 mm 1.3 mm
Active surface area: Fixation helix (distal electrode) Proximal electrode	5.7 mm <sup>2</sup> 35 mm <sup>2</sup>
Distance between electrodes	11 mm
Steroid	Approximately 1.0 mg dexamethasone acetate
Fixation helix penetration depth	1.9 mm
Number of coils in fixation helix	2 turns
Material: Electrode Conductor Insulation	Platinum iridium Tri- and quad-wound helical coils of MP35N Silicone rubber







**Guidant Corporation**

4100 Hamline Avenue North St. Paul, MN 55112-5798 USA

**24-Hour Consultation**

1-800-CARDIAC (227-3422)

Worldwide: +1.651.582.4000

[www.guidant.com](http://www.guidant.com)



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