



P960013

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Mark J. Faillace  
Director, Regulatory Affairs  
Pacesetter, Incorporated  
15900 Valley View Court  
P.O. Box 9221  
Sylmar, California 91392-9221

JUN 20 1997

Re: P960013  
Tendril® DX Models 1388T/K Endocardial, Steroid Eluting,  
Screw-In Pacing Leads  
Ventricitex Assure™ AFS Models 7010T/K Endocardial, Steroid  
Eluting Screw-In Pacing Leads  
Filed: May 10, 1996  
Amended: July 18 and 25, and December 16, 1996 and  
April 7 and 11, and June 3, 1997

Dear Mr. Faillace:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Tendril® DX Models 1388T/K Endocardial, Steroid Eluting, Screw-In Pacing Leads and Ventricitex Assure™ AFS Models 7010T/K Endocardial, Steroid Eluting Screw-In Pacing Leads. These devices are indicated for use in combination with a compatible pulse generator to provide permanent pacing and sensing in either the atrium or ventricle. We are pleased to inform you that the PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that to ensure the safe and effective use of the device that the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q)

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In addition to the postapproval requirements in the enclosure, the postapproval reports must include the results of fatigue testing conducted out to 400 million cycles on the Tendril® DX leads within one month of test completion.

Expiration dating for this device has been established and approved at two years.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)  
Center for Devices and Radiological Health  
Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

In addition under section 522(a) of the act, manufacturers of certain types of devices identified by the act or designated by FDA are required to conduct postmarket surveillance studies. FDA has identified under section 522(a)(1)(A) the above noted device as requiring postmarket surveillance.

Upon approval and within thirty (30) days of first introduction or delivery for introduction of this device into interstate commerce you will be required to submit to FDA certification of the date of introduction into interstate commerce, a detailed protocol which describes the postmarket surveillance study, and a detailed profile of the study's principal investigator that clearly establishes the

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qualifications and experience of the individual to conduct the proposed study. For your information, general guidance on preparing a protocol for a postmarket surveillance study is enclosed. In addition, a copy of the "Guidance to Sponsors on the Development of a Discretionary Postmarket Surveillance Study for Permanent Implantable Cardiac Pacemaker Electrodes (Leads)" has been enclosed.

At that time you should submit five (5) copies to:

Postmarket Studies Document Center  
1350 Piccard Drive (HFZ-544)  
Rockville, Maryland 20850

Within sixty (60) days of receipt of your protocol, FDA will either approve or disapprove it and notify you of the Agency's action in writing. Do not undertake a postmarket surveillance study without an FDA approved protocol.

Failure to certify accurately the date of initial introduction of your device into interstate commerce, to submit timely an acceptable protocol, or to undertake and complete an FDA approved postmarket surveillance study consistent with the protocol, will be considered violations of section 522.

In accordance with the Medical Device Amendments of 1992, failure of a manufacturer to meet its obligations under section 522 is a prohibited act under section 301(q)(1)(C) of the act (21 U.S.C. 331(q)(1)(C)). Further, under section 502(t)(3) of the act (21 U.S.C. 352(t)(3)), a device is misbranded if there is a failure or refusal to comply with any requirement under section 522 of the act. Violations of sections 301 or 502 may lead to regulatory actions including seizure of your product, injunction, prosecution, or civil money penalties or other FDA enforcement actions including (but not limited to) withdrawal of your PMA.

If you have any questions concerning postmarket surveillance study requirements, contact the Postmarket Surveillance Studies Branch, at (301) 594-0639.

Under section 519(e) of the act (as amended by the Safe Medical Devices Act in 1990), manufacturers of certain devices must track their products to the final user or patient so that devices can be located quickly if serious problems are occurring with the products. The tracking requirements apply to (1) permanent implants the failure of which would be reasonably likely to have serious adverse health consequences; (2) life sustaining or life supporting devices that are used outside of device user facilities the failure of which would be

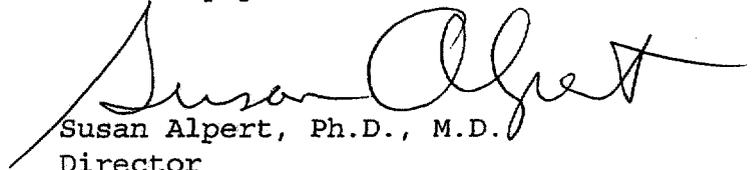
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reasonably likely to have serious adverse health consequences; and (3) other devices that FDA has designated as requiring tracking. Under section 519(e), FDA believes that your device is a device that is subject to tracking because it is a permanent implant whose failure would be reasonably likely to have serious adverse consequences.

FDA's tracking regulations, published in the FEDERAL REGISTER on August 16, 1993, appear at 21 CFR Part 821. These regulations set out what you must do to track a device. In addition, the regulations list example permanent implant and life sustaining or life supporting devices that FDA believes must be tracked at 21 CFR § 821.20(b) and the devices that FDA has designated for tracking at 21 CFR § 821.20(c). FDA's rationale for identifying these devices is set out in the FEDERAL REGISTER (57 FR 10705-10709 (March 27, 1991), 57 FR 22973-22975 (May 29, 1992), and 58 FR 43451-43455 (August 16, 1993)).

If you have questions concerning this approval order, please contact Lynette Gabriel at (301) 443-8243.

Sincerely yours,



Susan Alpert, Ph.D., M.D.  
Director  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosures

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CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the applicant or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.

All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

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A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the addition of, but not the replacement of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgment by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgment is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

- (1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).
- (2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:
  - (a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

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- (b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

- (1) A mixup of the device or its labeling with another article.
- (2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and
  - (a) has not been addressed by the device's labeling or
  - (b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.
- (3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

- (1) may have caused or contributed to a death or serious injury or
- (2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-531)  
Center for Devices and Radiological Health  
Food and Drug Administration  
1350 Piccard Drive, Room 240  
Rockville, Maryland 20850  
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the address below or by telephoning 1-800-638-2041.

Division of Small Manufacturers Assistance (HFZ-220)  
Center for Devices and Radiological Health  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857

# Tendril® DX Endocardial, Steroid Eluting, Screw-in Pacing Leads, Models 1388T and 1388K.

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# SUMMARY OF SAFETY AND EFFECTIVENESS

## I. GENERAL INFORMATION

Device Generic Name: Implantable, transvenous, endocardial, bipolar, steroid eluting, atrial/ventricular pacing lead

Device Trade Names: Tendril® DX Endocardial, Steroid Eluting, Screw-in Pacing Leads, Models 1388T and 1388K.

Applicant's Name and Address: Pacesetter, Inc.  
A St. Jude Medical Company  
15900 Valley View Court  
P.O. Box 9221  
Sylmar, CA 91392-9221

PMA Number: P960013

Date of Notice of Approval to Applicant: June 20, 1997

## II. INDICATIONS FOR USE

The Tendril DX model 1388T and 1388K pacing leads are intended for use in combination with compatible pulse generators to provide permanent pacing and sensing in either the atrium or ventricle.

## III. DEVICE DESCRIPTION

The Tendril DX model 1388T (model 1388T) and Tendril DX model 1388K (model 1388K) are transvenous, endocardial, steroid eluting, screw-in pacing leads with a microporous titanium nitride (TiN) coated helix electrode

The distal electrodes of these leads include between 200 and 1000 micrograms of dexamethasone sodium phosphate (a steroid) in a silicone rubber matrix, housed in the helix assembly. This combination of medical adhesive and steroid is referred to as a monolithic controlled release device (MCRD).

The model 1388T lead has two multifilar, MP35N conductor coils, one terminating at the tip helix and the other at the ring electrode. The ring electrode consists of platinum iridium (Pt-Ir) with a microporous TiN coating. The fixation helix is also TiN-coated Pt-Ir. The Pt-Ir collar surrounding the distal electrode is electrically inactive. Silicone rubber tubing is used to insulate both the inner and outer conductor coils. The outer insulation is coated with a thin layer of polyvinyl pyrrolidone (PVP) to increase the lubricity of the lead during implant.

The model 1388K lead is a unipolar version of the model 1388T lead. Since the model 1388K is unipolar, it has only one conductor coil and does not include a proximal electrode.

## IV. CONTRAINDICATIONS

The use of the model 1388T or 1388K leads is contraindicated:

- in the presence of tricuspid atresia and in patients with mechanical tricuspid valves
- in patients with tricuspid valvular disease
- in patients who are expected to be hypersensitive to a single dose of 1.0 milligram of dexamethasone sodium phosphate

## V. WARNINGS

- Only battery powered equipment should be used during lead implantation and testing to protect against fibrillation which may be induced by alternating currents.
- Any line-powered equipment used in the vicinity of the patient during the implant procedure should be properly grounded.
- Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.
- The Tendril DX lead and its accessories are intended for one time use only. Do not reuse.

## VI. PRECAUTIONS

### General

- Do not sterilize the lead using an autoclave, gamma radiation or ultrasonics.
- The manipulation of any and all hardware while in the vascular system should only be performed under continuous fluoroscopic monitoring.
- Prior to opening the lead package, confirm that the lead is compatible with the pulse generator to be implanted.

### Handling and Storage

- Cardiac pacing leads can be damaged by improper handling before and during implant or by excessive mechanical stress post-implantation.
- The lead conductor, its insulating sheath, and the helix mechanism may be damaged if subjected to extreme mechanical stress.
- Do not stretch, crush, kink, or bend the lead.
- Avoid bringing the lead in contact with any sharp objects which could puncture or otherwise compromise the insulation.
- Do not handle the lead except with powderless, sterile surgical gloves.
- Avoid handling the lead with any surgical tools, e.g. hemostats, clamps, forceps.

- Leads have an electrostatic affinity for particulate matter; do not expose them to lint, dust or other such material.
- The lead is supplied with the helix in its fully retracted position. Avoid touching or handling the helix itself.
- Do not immerse the lead body in mineral oil, silicone oil or any liquid other than sterile saline or injectable fluid.
- Do not immerse the tip electrode in any fluid prior to implantation. Immersion of the electrode may cause a small amount of steroid to be prematurely eluted from the helix housing.
- The lead should be stored at temperatures between -5 °C (23 °F) and 55 °C (131 °F).

#### Implantation

- Lead implantation should only be performed when proper emergency facilities for cardioversion and/or defibrillation are available.
- If subclavian venipuncture is used for lead introduction, it is important to avoid extremely medial entry of the lead into the vein, which may contribute to lead conductor fracture or other lead damage.
- Electrode dislodgement or displacement may produce erratic, intermittent or total loss of pacing or sensing. It may also induce atrial or ventricular ectopy.
- Perforation of the atrial or ventricular wall may cause phrenic nerve stimulation, diaphragmatic stimulation or, in some instances, cardiac tamponade. Phrenic nerve or diaphragmatic stimulation may also result from lead position.
- Use the anchoring sleeve to distribute the tension created by the suture used to secure the lead at or near the venous entry site. Failure to use the anchoring sleeve may result in damage to the lead's insulation or conductor coil or both.

## VII. ALTERNATIVE PRACTICES AND PROCEDURES

Other marketed implantable cardiac pacing leads with or without steroid may meet the needs of patients for whom the model 1388T and 1388K leads are intended.

## VIII. MARKETING HISTORY

Approximately 180 model 1388T leads have been distributed in Western Europe through May 1996. Commercial distribution of the model 1388K lead has not yet been initiated. The Tendril DX model 1388T leads have not been withdrawn from marketing for any reason relating to the safety and effectiveness of the device.

## IX. POTENTIAL ADVERSE EFFECTS OF THE DEVICES ON HEALTH

The Tendril DX model 1388T clinical trial involved 521 devices (398 model 1388T leads, 123 model 1188T leads) implanted in 303 patients. Cumulative duration for atrial implantation of the model 1388T lead was 19,477 days (mean implant duration 108.8 days, range 5 to 205 days). Cumulative implant duration for model 1388T leads positioned in the ventricle was 24,155 days (mean implant duration 110.3 days, range 0 to 205 days). A total of 10 patients died during the course of the clinical trial. None of these deaths were deemed lead related.

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Adverse event (AEs) observed during the clinical trial are summarized in Tables 1 and 2. In addition to the adverse events reported during the course of the clinical trial, other possible adverse events which may occur based on historical experience with this type of device include:

- embolism
- excessive bleeding
- thrombosis
- infection
- induced atrial or ventricular ectopy
- phrenic nerve stimulation
- diaphragmatic stimulation
- cardiac tamponade
- loss of pacing and or sensing due to dislodgement or mechanical malfunction of the pacing lead

**Table 1: Tendril DX Model 1388T, Atrial Leads**

Device-Related Complications	Number of Patients (n=179)	% of Patients	Number of Leads	Adverse Events per Lead-Month
Loss of sensing	1	0.6	1	0.00313*
Loss of capture or elevated thresholds	2	1.1	2	0.00313
Lead dislodgement	2	1.1	2	0.00313
Difficulty with lead placement	1	0.6	1	0.00156
Cardiac perforation	0	0.0	0	0.0
High lead impedance	0	0.0	0	0.0
Low lead impedance	1	0.6	1	0.00156
Cardiac Tamponade	1	0.6	1	0.00156
Coil Damage	1	0.6	1	0.00156
Device-Related Observations	Number of Patients (n=179)	% of Patients	Number of Leads	Adverse Events per Lead-Month
Low lead impedance	1	0.6	1	0.00156
<b>Total (any adverse event)</b>	<b>10</b>	<b>5.6</b>	<b>10</b>	<b>0.01718</b>

Device Related Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require physician intervention.

Device related observations are defined as symptomatic or asymptomatic device related clinical events which do not require physician intervention.

\*One lead experienced loss of atrial sensing on two separate occasions.

**Table 2: Tendril DX Model 1388T, Ventricular Leads**

Device-Related Complications	Number of Patients (n=219)	% of Patients	Number of Leads	Adverse Events per Lead-Month
Loss of sensing	1	0.5	1	0.00126
Loss of capture or elevated thresholds	5	2.3	5	0.00630
Lead dislodgement	1	0.5	1	0.00126
Difficulty with lead placement	0	0.0	0	0.0
Cardiac perforation	1	0.5	1	0.00126
High lead impedance	0	0.0	0	0.0
Low lead impedance	1	0.5	1	0.00126
Cardiac Tamponade	1	0.5	1	0.00126
Coil Damage	0	0.0	0	0.0
Device-Related Observations	Number of Patients (n=219)	% of Patients	Number of Leads	Adverse Events per Lead-Month
none	0	0.0	0	0.0
<b>Total (any adverse event)</b>	<b>10</b>	<b>4.6</b>	<b>10</b>	<b>0.01259</b>

Device Related Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require physician intervention.

Device related observations are defined as symptomatic or asymptomatic device related clinical events which do not require physician intervention.

## X. SUMMARY OF STUDIES

### A. *Qualification Of Assembled Leads*

A series of in vitro (laboratory) tests were performed on the model 1188T, 1188K, 1388T and 1388K pacing leads to verify that these devices meet all requirements of their respective design specifications. The model 1188T and 1188K leads are identical to the model 1388T and 1388K leads except for the following characteristics:

- The helix of the model 1388T and 1388K leads (and the proximal electrode of the 1388T) is coated with TiN whereas the electrodes of the model 1188T and 1188K leads are not coated.
- The model 1388T and 1388K leads include a MCRD positioned in the helix. The MCRD releases dexamethasone sodium phosphate to the tissue surrounding the helix after implant. The model 1188T and 1188K leads do not include a MCRD.

Because of the similarity between the model 1188T/1188K and the model 1388T/1388K pacing leads, testing performed for the 1188T and 1188K leads is applicable to the 1388T/1388K leads and therefore was not repeated during the 1388T/1388K qualification. Qualification tests performed for the model 1188T lead included the following:

#### 1. **Multiple Sterilization**

Thirty packaged leads were subjected to five complete EtO sterilization cycles. Following completion of the fifth cycle, the packaging was inspected to verify that the lead and components were properly positioned and that there was no fogging, contamination, cracking or separation of the sterile seal. All leads utilized for the qualification underwent these multiple sterilizations prior to subsequent test to confirm that multiple sterilization cycles do not adversely affect the leads' mechanical integrity. All leads successfully passed this test.

#### 2. **Visual Examination**

Thirty leads were subjected to visual examination at 7X magnification. All leads met the established acceptance criteria which requires an absence of any damage such as tears, cuts or fractures in the tubing; kinks, fractures, contamination, unevenness or separation of the conductor coil or any damage or contamination of the electrodes and connector.

#### 3. **Lead Resistance**

The resistances of the conductor paths from the lead connector to the distal and proximal electrodes were measured for thirty leads (six leads for each of the five available lead lengths). All resistances were within the specified limits.

#### 4. **Insulation Hypot Test**

Thirty leads were tested by applying a potential of 1000 VDC to the distal and proximal conductors for a minimum of five seconds while monitoring for any measurable leakage current. All leads passed the specified requirement of no measurable leakage current during the testing.

#### 5. **Helix Extension/Retraction**

The maximum number of connector pin revolutions required to fully extend and retract the helix was measured for a total of 30 leads. All leads meet the specified requirements

except for one model 1188T lead which exceeded the maximum allowed number of connector pin revolutions for helix retraction by one revolution after multiple sterilization testing and subsequent helix extension and retraction testing. Failure analysis revealed that this condition was a result of an operator error during the manufacture of this unit. Modifications were made to the production manufacturing and inspection instructions to prevent this condition from reoccurring.

**6. Lead Connector Dimensional Evaluation**

Five lead connectors were measured using an electronic toolmakers microscope to confirm compliance with the dimensional requirements of the IS-1 pacing lead connector standard. One of the connectors did not meet the requirement for the length of the connector pin. Four connectors did not comply with the IS-1 requirements for the diameter of the connector body beyond the seal rings. In both cases, modifications to the manufacturing instructions were made to address these areas of noncompliance. Additional leads were produced subsequent to these modifications and were verified to conform to the IS-1 dimensional requirements.

**7. Temperature Cycling**

Ten leads were subjected five continuous temperature cycles between -10°C and +55°C. Following the temperature cycling, the leads were visually inspected and subjected to DC resistance and helix extension and retraction testing. All leads met the specified requirements except for one lead which did not meet the acceptance criteria for maximum number of turns to extend the helix. As previously described in Section 5 (Helix Extension/Retraction), failure analysis revealed that this condition was a result of an operator error during the manufacture of this unit. Modifications were made to the production manufacturing and inspection instructions to prevent this condition from reoccurring.

**8. Lead Connector Insertion/Extraction**

Ten leads underwent testing to measure the dry and wet insertion and extraction forces using a calibrated IS-1 connector go gage. All leads except for two met the acceptance criteria of less than 2.0 pounds insertion and extraction force. Two model 1188T leads were found to require greater than the specified 2.0 pounds for insertion into the IS-1 go-gage. This condition was determined to be related to the oversized connector body diameter discussed in Section 6 (Lead Connector Dimensional Evaluation). The modification to manufacturing instructions which corrected the dimensional discrepancies also corrected the insertion force discrepancy. Leads built and tested following the manufacturing modifications all exhibited insertion/extraction forces less than the specified 2.0 pound maximum.

**9. Joint Bond High Stress Flexing**

Twenty leads were tested by subjecting each rubber bond to five 90 degree bends over a five millimeter diameter mandrel. All bonds were visually inspected after bending and showed no evidence of bond separation, cracking, tearing or contamination.

**10. Composite Lead Durability**

Twenty leads were pulled to a force of 1.5 pounds and then visually inspected, measured for length and subjected to helix extension/retraction testing. All leads met the visual criteria and exhibited less than the specified 5% maximum change in length. All leads met the helix extension/retraction requirement except the one lead previously discussed in Section 5 (Helix Extension/Retraction).

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- 11. Suture Sleeve Performance Test**

Five leads were subjected to a suture sleeve performance test by measuring the force required to move the sleeve both with and without a suture in place. Testing was performed with the lead both wet and dry. All leads met the acceptance criteria of less than 0.4 pounds force without a suture and greater than 4.0 pounds force with the suture in place.
- 12. Insulation Leakage Resistance**

Five leads were subjected to insulation leakage testing by immersing the leads in body temperature (37°C) saline solution for ten days. Insulation resistance was measured by applying a 2.8 volt AC (100 Hz) signal between the conductors and each conductor and the solution while monitoring the leakage current. In all cases, the insulation resistance significantly exceed the 50,000 ohm acceptance criteria.

The leads were also subjected to a helix extension/retraction test after the ten day soak. All leads met the specified acceptance criteria except for the one lead previously described in Section 5 (Helix Extension/Retraction).
- 13. Composite Lead Tensile Strength**

Fifteen leads were pulled to a force of 2.0 pounds, held at 2.0 pounds for 60 seconds and then pulled to failure. All leads met the acceptance criteria of withstanding a force of 2.0 pounds without any separation or damage and withstanding a force of 3.5 pounds without separation or damage to the connector.
- 14. Temperature Shock**

Ten leads were subjected to five continuous temperature shock cycles at temperatures of -55°C and +65°C with a maximum transition time of one minute between temperatures. Leads were visually inspected and underwent measurement of DC resistance and helix extension/retraction testing following the shock exposure. All leads met all specified acceptance criteria.
- 15. Polarization**

Ten leads underwent measurement of electrode polarization potential with the helix extended. All leads exhibited polarization values less than the specified maximum allowable value of 700 millivolts.
- 16. Helix Over-Torque Evaluation**

Ten leads were subjected to a helix over-torque evaluation by rotating the connector pin 20 turns, which exceeds the recommended number of turns required for helix extension. Appropriate helix extension and retraction was verified after helix over-torquing. All leads tested demonstrated appropriate helix extension/retraction within the specified maximum number of connector pin rotations after exposure to over-torquing.
- 17. IS-1 Setscrew Deformation**

Five leads were placed in a setscrew deformation test fixture and the setscrew was tightened to a force of 21 inch-ounces. Force was applied to the lead connector prior to retracting the setscrew and the force required to remove the lead connector after the setscrew was retracted was measured. All leads meet the requirement that the insertion and withdrawal forces not exceed 2.0 pounds after the setscrew deformation testing.

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**18. IS-1 Electrical Isolation Test**

Five leads were inserted into a test fixture and immersed in body temperature saline for a minimum of ten days. The impedance between the tip electrode and solution, the ring electrode and solution and the tip and ring electrodes was then measured using a 250 millivolt RMS sine wave with a frequency of 100 Hz. A helix extension/retraction test was also performed after the saline soak.

All leads met the acceptance criteria of greater than 50 kilohms leakage impedance and passed the helix extension/retraction test.

**19. Temperature Storage**

Ten leads were subjected to storage at +65°C for 96 hours followed by storage at -25°C for 96 hours. All leads were subjected to both visual inspection and measurement of impedance after storage at high and low temperature. Leads also underwent helix extension/retraction testing following the low temperature storage.

All leads tested met all applicable acceptance criteria.

**20. Multiple Helix Activation**

Ten leads were subjected to a total of 20 helix extensions and retractions. The leads were then tested to confirm that the helix would extend and retract within the maximum specified number of connector pin rotations.

All leads met the specified requirements.

**21. Stylet Insertion**

Ten leads were tested by measuring the force required to insert and withdraw both a 0.015 inch diameter ball tipped straight stylet and a 0.014 inch diameter balled tipped J stylet. In all cases, the insertion and extraction forces were less than the specified maximum acceptable value of 0.4 pounds.

**22. Lead Introducer Test**

Ten leads were tested by monitoring the force required to pass the lead through an 8 French lead introducer. All leads passed through the introducer without binding and without damage to the lead electrode or insulation.

**23. Tip Stiffness Test**

Five leads were evaluated for tip stiffness using a test fixture which determines the maximum pressure that will be exerted against the heart wall by the lead tip during contractions of the heart. All leads exhibited a maximum force less than the specified maximum acceptable value of 25 PSI.

**24. Flex Test**

Five leads were inserted into pacer connector tops, immersed in body temperature saline and flexed for greater than one million cycles. Leakage impedance was measured using a 2.8 volt RMS sine wave with a frequency of 100 Hz. Helix extension/retraction testing was also performed following the flexing.

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All leads met the acceptance criteria of greater than 50 kilohms leakage impedance and passed the helix extension/retraction test.

**25. Vibration Test**

Five leads were packaged and vibrated at frequencies between five and 500 Hz in each of three mutually perpendicular axes. All leads and packaging were visually inspected following the vibration testing and confirmed to be free of any damage such as breaks, tears, cracking or seal separation.

**26. UPS Shipping Test**

Five packaged leads were subjected to a standard UPS shipping test to verify that the product will withstand the stresses experienced during normal shipping and handling. All leads and packages were inspected and confirmed to be free of any damage such as breaks, tears, cracking or seal separation after the shipping test.

**27. Spin Fatigue Test**

Five sections of both the inner and outer conductors coils were spun at a rate of 400 rpm and a radius of 0.5 inches for greater than one million spin cycles. All samples were visually examined and resistance was measured prior to and upon completion of the spin testing. All samples were free of any evidence of damage or electrical discontinuity at the completion of the testing.

**28. Crimp Joint Pull**

All crimp joints of twenty lead subassemblies were subjected to destructive pull testing to verify the strength of these joints. All joints exhibited pull strengths which significantly exceeded the minimum specified strength of 3.0 pounds.

**29. Rubber To Metal Bond Strength**

All rubber to metal bonds of twenty leads were pulled tested to failure to determine the yield strength of these bonds. All bonds exhibited pull strength which significantly exceeded the specified minimum strength of 1.0 pounds.

**30. Laser Weld Strength**

All laser welds of twenty leads were pulled to failure to determine the yield strength of these joints. All laser welds exhibited pull strengths which significantly exceeded the specified minimum value of 2.5 pounds.

Extensive qualification was also performed for the model 1188K and 1388T pacing leads using similar procedures to those described in the preceding section on the qualification of the model 1188T pacing lead. An overview of the testing performed for these leads and the results of this testing is provided in the tables which follow.

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**Table 3: Summary of 1188K Qualification**

Test	Number Tested	Results	Comments
multiple sterilization	51	passed	
lead resistance	36	passed	
helix extension/retraction	36	passed	
temperature shock	36	passed	
temperature storage	36	passed	
multiple helix activation	36	passed	
helix over-torque	36	passed	
joint bond flexing	36	passed	
stylet performance	36	passed	
composite durability	36	passed	
introducer test	36	passed	
tip stiffness	36	passed	
connector dimensional	12	failed	One dimension was oversized - a new mold was created which produced a connector which met all requirements
connector insertion/extraction	12	passed	
setscrew deformation	12	passed	
suture sleeve performance	12	passed	
composite strength	12	passed	
polarization	12	passed	
IS-1 electrical isolation	12	passed	
insulation leakage resistance	12	passed	
flex test	12	passed	
vibration test	15	passed	
UPS shipping test	15	passed	

**Table 4: Summary of 1388T Qualification Testing**

Test	Number Tested	Results	Comments
multiple sterilization	12	passed	
UPS shipping	12	passed	
vibration	12	passed	
visual examination	12	failed	Two leads failed visual inspection with TiN debris noticed on the steroid plug surface. An insertion tooling change was implemented to prevent this condition from occurring and production inspection procedures were enhanced to ensure that leads with this condition would be identified and rejected during the manufacturing process.
temperature shock	12	passed	
temperature storage	12	passed	
polarization	12	passed	
lead soak	12	passed	
helix extension/retraction	12	failed	Two leads showed higher extension and retraction values after exposure to a three hour saline soak. One lead was identified as having a post within the header with rounded edges. The header was replaced, retested and passed the extension and retraction test. The production documentation was modified by reducing the allowable radius for the post in question. The second lead had a post which was damaged. Corrective action in this case was expansion of the production inspection procedure to require examination for post damage after insertion of the MCRD.
lead resistance	12	passed	

**B. Bell Mouth Flex Test**

A total of 12 model 1388T leads were subjected to "Bell Mouth" flex testing of both the lead body and the lead connector. This testing is based on the recommendation of the Lead Test Task Force of the CEN/CENELEC Joint Working Group on Active Implantable Medical Devices (prEN 45502-#). This testing is intended to simulate worst case in vivo loading conditions and to demonstrate that the lead will not be adversely affected by its intended long term implant environment.

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The lead body and lead connector portion were subjected to 47,000 and 164,000 flex cycles respectively. All samples were examined visually and tested electrically and the absence of any electrical or mechanical damage was confirmed. Since the model 1388K has similar mechanical construction to the 1388T, but without the outer conductor coil and proximal electrodes and connector rings, this test also indicates that the 1388K body and connector will demonstrate acceptable fatigue resistance under implant conditions.

**C. *Distal Tip Fatigue Test***

Distal tip fatigue testing was performed on the distal portion of a total of 20 model 1388T pacing leads. Ten samples were subjected to flexing representative of that experience by the distal portion of the lead during atrial placement. The remaining ten samples were subjected to flexing representative of that experienced by the distal portion of the lead during ventricular placement. This testing is intended to evaluate the integrity and reliability of the transition areas between the distal tip electrode and the surrounding portions of the lead and is designed to simulate the maximum stress that the distal portion of the lead experiences during both atrial and ventricular implant applications. All samples were examined visually and tested electrically after 150 million flex cycles and the absence of any electrical or mechanical damage was confirmed. Since the model 1388K has similar mechanical construction to the 1388T, but without the outer conductor coil and proximal electrodes and connector rings, this test also indicates that the distal portion of the model 1388K will demonstrate acceptable fatigue resistance under implant conditions.

The distal tip fatigue test is ongoing at the time of FDA approval of the Tendril DX leads. This in vitro testing will continue until the samples have reached 400 million cycles. A final report will be provided to FDA upon completion of this testing.

**D. *In Vitro Pacing Test for TiN-Coated Electrodes***

The electrical, chemical and physical stability of the TiN coating after exposure to the electrical currents associated with cardiac pacing was evaluated by subjecting six Pacesetter model 1242T pacing leads to an in vitro pacing test. The model 1242T is a bipolar endocardial pacing lead with TiN coated distal and proximal pacing electrodes. Although this testing was not performed using the model 1388T and 1388K pacing leads, the TiN coating and electrode base material are the same as those used in the electrodes of Tendril DX leads, and therefore this testing is applicable to the model 1388T and 1388K series leads.

During the test, the six leads were immersed in body temperature (37°) pseudo extracellular fluid and paced at a high rate (110 pulses per minute) and high output (6 volts and 1.5 millisecond pulse width) for a total of six months. At the conclusion of this test, the TiN coating was examined utilizing scanning electron microscopy and confirmed to exhibit no evidence of corrosion or structural changes. Additionally, the pseudo extracellular fluid utilized during the testing was analyzed for corrosion products using inductively coupled plasma discharge, graphite furnace atomic absorption spectroscopy and cold vapor absorption spectroscopy. This analysis confirmed the absence of any metallic components which would suggest corrosion of any components of the pacing leads.

**E. *Swell Testing of the MCRD***

Testing was performed to evaluate the extent of MCRD swelling and the possible effect of this swelling on the operation of the helix. When exposed to pseudo extracellular fluid, the maximum number of turns to extend the helix does not exceed 11 during the first three hours of soaking.



## F. Testing of the MCRD

### 1. Evaluation Of Drug Elution Rate

The rate of elution of dexamethasone sodium phosphate from the MCRD used in the model 1388T and 1388K leads was evaluated by placing multiple release devices into water and then determining the concentration of dexamethasone sodium phosphate in the solution at regular intervals using ultraviolet spectrophotometry. This evaluation indicates that in water, the steroid is eluted rapidly at first, with approximately 50% of the total amount released into the solution within 2 days. A representative elution profile for the testing performed in water is provided in Figure 1. The in vivo elution rate is expected to be slower due to more complex interactions with blood and tissue.

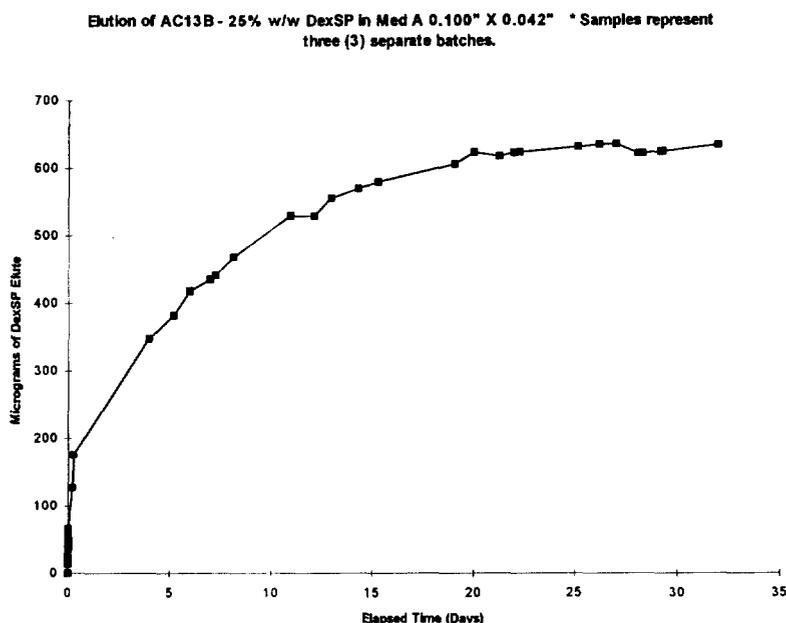


Figure 1: Representative Elution Profile

### 2. Evaluation of Drug Stability/Shelf Life

The stability (over time) of the MCRD used in the model 1388T and 1388K leads was evaluated by subjecting multiple samples to EtO sterilization and storing the samples at room temperature, 37°C and 50°C. Samples were evaluated at regular intervals by extraction into deionized water and analysis of the extraction solution using high pressure liquid chromatography (HPLC). This study revealed that there is measurable conversion of the dexamethasone sodium phosphate to dexamethasone at higher storage temperatures. Additionally, there was no evidence of conversion of the dexamethasone sodium phosphate to any species other than dexamethasone. Based on the results from this study, it is estimated that at room temperature, 13.1% of the dexamethasone sodium phosphate will be converted to dexamethasone after 14.5 months.

Since both dexamethasone sodium phosphate and dexamethasone are effective anti-inflammatory agents, the results of this study indicate that the efficacy of the MCRD used in the model 1388T and 1388K leads is not affected by long term storage at elevated temperatures.

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Labeling will state that the lead should be stored at temperatures between -5°C (23°F) and 55°C (131°F) and that expiration dating for the lead will be two years.

### 3. **Evaluation of Multiple Sterilization on Drug Stability**

Testing was performed to determine if multiple EtO sterilizations of the MCRD used in the model 1388T and 1388K pacing lead caused any undesirable chemical changes to the dexamethasone sodium phosphate. A total of 32 MCRD samples were subjected to five sequential sterilizations in EtO. An additional 32 samples were subjected to a single sterilization cycles as a control. Following sterilization, the samples were sectioned and placed in deionized water to extract any soluble contents of the MCRD. The extraction solution was analyzed using HPLC to identify the contents of the solution. The chromatographs for the samples subjected to the multiple sterilizations were compared to those of the control samples to allow identification of any changes due to exposure to multiple EtO sterilization cycles.

This evaluation revealed a small, but measurable increase in the conversion of dexamethasone sodium phosphate to dexamethasone in the samples subjected to five (rather than one) sterilization cycles. This increase was not statistically significant. Additionally, there was no evidence of any additional species in the extraction solution for either group.

Since both dexamethasone sodium phosphate and dexamethasone are effective anti-inflammatory agents, the results of this study indicate that the efficacy of the MCRD is not affected by multiple EtO sterilization cycles.

### G. **Evaluation of Biocompatibility**

The following materials used in the model 1388T and 1388K pacing leads come in contact with the patient's blood and/or tissue while the lead is implanted in the body:

- ETR silicone, 65 durometer (Q7-4765) and 80 durometer (Q7-4780)
- Pellethane 75D
- Pt-Ir
- TiN
- Dow Corning medical adhesive A
- Dexamethasone sodium phosphate
- MDX silicone (4516)
- Polyvinyl Pyrolidone

All blood/tissue contact materials used in the model 1388T and 1388K leads (except for the TiN electrode coating, medical adhesive A and dexamethasone sodium phosphate) have a long history of successful use in long term implants and are identical to those used in the Pacemaker model 1188T and 1188K pacing leads.

In addition to the extensive implant experience with these materials, standard biocompatibility testing (cytotoxicity, intracutaneous toxicity, acute systemic toxicity, intramuscular implants, hemolysis and USP pyrogen) have been performed for all blood/tissue contact materials, except for Pt-Ir. Biocompatibility testing for Pt-Ir was not deemed necessary due to its history of over 20 years of successful use as an electrode material for cardiac pacing leads.

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In addition to standard biocompatibility testing, more extensive testing, including chronic toxicity, guinea pig maximization (sensitization) and *Salmonella* reverse mutation assay (Ames) tests were performed for TiN. The dexamethasone sodium phosphate used in the MCRD is a marketed drug and therefore testing beyond that performed by the drug manufacturer and described in the approved NDA was not deemed necessary.

The results of biocompatibility testing performed for the blood/tissue contact materials of the model 1388T and 1388K leads, in addition to extensive clinical experience with these materials in long term cardiovascular implant applications, indicate that all materials used are biocompatible and therefore are safe for the intended application.

#### **H. Preclinical Animal Testing**

An animal evaluation of the model 1388T lead was performed prior to the initiation of human clinical trials. This study involved the implant of two model 1388T leads into each of a total of eight adult mongrel canines. Each test subject had the electrode of one lead positioned at or near the apex of the right ventricle. The electrode of the second lead was positioned in or near the right atrial appendage. The connectors of both leads were inserted into a specially designed subcutaneous epoxy block to allow percutaneous measurement of lead electrical characteristics post implant. Measurements were made using a Pacing System Analyzer at implant and at 7( $\pm$ 1), 14( $\pm$ 2), 21( $\pm$ 2), 28( $\pm$ 2), 35( $\pm$ 2), 42( $\pm$ 2), 60( $\pm$ 5) days post implant. Measurements were made on a monthly basis ( $\pm$ 5 days) following the 60 day post implant measurements.

The maximum mean capture threshold (at a pulse width of 0.5 milliseconds) through 630 days post implant was 1.05 volts for atrial leads and 1.24 volts for ventricular leads. These values are significantly less than the maximum mean threshold values of values of 2.37 volts (atrial) and 2.01 volts (ventricular) observed during a prior canine evaluation of the non-steroid model 1188T lead. In addition, the endocardial signal amplitudes obtained with the model 1388T leads were significantly larger than those observed during the previous evaluation of the model 1188T lead. There were no significant differences observed between the pacing impedances for the model 1388T and model 1188T leads.

#### **I. CLINICAL STUDIES**

##### **1. Introduction**

A clinical investigation of the model 1388T lead was conducted in the United States under Investigational Device Exemption G950081. The design of the study was to demonstrate a decreased pacing threshold of the model 1388T through three months post implant compared to that of a commercially available nonsteroid active fixation lead (1188T). The study used a prospective, randomized, controlled design with a three to one (1388T to 1188T) randomization ratio.

Patients of any age and either sex who required either initial or replacement implant of a cardiac pacing system were considered for inclusion in this study. Upon entry into the study, patients were randomly assigned to receive either the 1388T or the control lead in the atrium and/or ventricle. Lead electrical characteristics (capture thresholds, sensing thresholds and impedances) were measured in both the bipolar and unipolar configurations at implant, 14 days ( $\pm$ 4 days), 30 days ( $\pm$ 7 days), 90 days ( $\pm$  14 days) and 180 days ( $\pm$ 30 days) post implant.

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An analysis of all clinical data received by Pacesetter from the initiation of the trial on August 23, 1995 through March 15, 1996 was performed. This analysis includes a total of 521 leads (398 model 1388T and 123 model 1188T) implanted in 303 patients at a total of 35 centers. Two hundred (66.0%) of the 303 patients were males and 103 (34.0%) were females. The average age at implant was 70 years. The youngest patient enrolled in the study was 9 years at the time of implant whereas the oldest was 103 years. Only one patient was reported as lost to follow-up. Several attempts were made to contact this patient for his three month follow-up visit with no success.

The total number of investigational and control lead follow-ups performed as of March 15, 1996 and included in the clinical data analysis is indicated in Table 5:

**Table 5: Implant and Follow-Up Data Received**

lead model	implant	two weeks	one month	three months	six months
1388T	398	371	369	205	8
1188T	123	118	119	63	3
total	521	489	488	268	11

**2. Gender Bias Analysis**

Overall, 34.0% of the patients included in the clinical trial were female. This is comparable to the percentage of women in the general population who undergo pacemaker implantation (Sgarbossa et al, 1994; Shen et al, 1994; Tung et al, 1994) indicating that both sexes are appropriately represented in the study population.

**3. Comparison of Experimental and Control Populations**

The Fisher's exact test was applied to compare gender distribution for the control and experimental leads (for both the atrial and the ventricular leads). Similar tests were done for physiologic conditions affecting pacing thresholds and drugs affecting pacing thresholds, both at the time of implant. Student's t test was applied (two-tailed at the 0.05 significance level) to patient age at implant. The results are presented in Table 6.

With only a single exception, all p-values are larger than 0.05, indicating that statistically significant differences were not detected. The exception was found in comparing the populations who received ventricular leads and pertained to a significant difference in the proportion of patients with sick sinus syndrome as their primary indication for pacing ( $p=.034$ ). This difference would not be expected to bias lead performance, as sick sinus syndrome is a condition that affects the SA node and should therefore not have any physiological impact on these patients' ventricles, especially with regard to the types of analyses performed in this clinical trial.

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**Table 6: Comparison of Experimental and Control Populations**

Variables	ATRIAL			VENTRICLE		
	1188T	1388T	Statistics	1188T	1388T	Statistics
<b>Gender</b>						
Male	45 (69.2%)	112 (62.6%)	Fisher's Exact Test p = 0.367	36 (62.1%)	144 (65.8%)	Fisher's Exact Test p = 0.643
Female	20 (30.8%)	67 (37.4%)		22 (37.9%)	75 (34.3%)	
<b>Age (years):</b>						
Range	20.0 - 95.1	8.9 - 102.8	t = 0.4957 d.f. 145.8 p = 0.621	42.7 - 91.7	15.0 - 102.8	t = 0.9372 d.f. 126.8 p = 0.350
Mean	70.6	69.7		72.7	71.2	
STD	12.0	15.4		9.3	13.4	
<b>Primary Indication</b>						
<b>Sick Sinus:</b>						
Reported	28 (43.1%)	72 (40.2%)	Fisher's Exact Test p = 0.769	30 (51.7%)	78 (35.6%)	Fisher's Exact Test p = 0.034
Normal *	37 (56.9%)	107 (59.8%)		28 (48.3%)	141 (64.4%)	
<b>Sinus Bradycardia:</b>						
Reported	7 (10.8%)	25 (14.0%)	Fisher's Exact Test p = 0.669	5 (8.6%)	30 (13.7%)	Fisher's Exact Test p = 0.378
Normal *	58 (89.2%)	154 (86.0%)		53 (91.4%)	189 (86.3%)	
<b>Heart Block:</b>						
Reported	32 (49.2%)	78 (43.6%)	Fisher's Exact Test p = 0.469	20 (34.5%)	96 (43.8%)	Fisher's Exact Test p = 0.232
Normal *	33 (50.8%)	101(56.4%)		38 (65.5%)	123 (56.2%)	
<b>PCAPT:</b>						
Condition(s)	12 (18.5%)	36 (20.2%)	Fisher's Exact Test p = 0.857	13 (22.4%)	43 (19.7%)	Fisher's Exact Test p = 0.714
None	53 (81.5%)	142 (79.8%)		45 (77.6%)	175 (80.3%)	
Not Reported **	0	1	0	1		
<b>MAPT:</b>						
Not reported at Implant	41 (63.1%)	129 (72.1%)	Fisher's Exact Test p = 0.208	35 (60.3%)	141 (64.4%)	Fisher's Exact Test p = 0.646
Reported at Implant	24 (36.9%)	50 (27.9%)		23 (39.7%)	78 (35.6%)	
<b>Total Patients w/in Lead Group</b>	<b>65</b>	<b>179</b>		<b>58</b>	<b>219</b>	

\* Normal Function, relative to the corresponding Primary Indication  
 \*\* Not included in statistical analysis  
 PCAPT = Physiological Conditions Affecting Pacing Thresholds  
 MAPT = Medications Affecting Pacing Thresholds

**4. Effectiveness Data**

Both unipolar and bipolar capture threshold data were analyzed separately for atrial and ventricular lead placement. A summary of this data is provided in Tables 7 and 8.

**Table 7: Atrial Capture Thresholds (V) at 0.4 ms Pulse Width**

follow-up	unipolar: mean±SD (N)			bipolar: mean±SD (N)		
	1188T	1388T	P value†	1188T	1388T	P value†
implant	1.1±0.4 (59)	0.9±0.4 (160)	0.0002	1.1±0.4 (61)	0.8±0.4 (162)	0.0001
two week	2.2±1.0 (56)	0.9±0.4 (153)	0.0001	2.6±1.3 (59)	1.0±0.5 (154)	0.0001
one month	2.1±0.7 (57)	0.9±0.4 (151)	0.0001	2.4±0.9 (59)	1.0±0.3 (154)	0.0001
three month	2.0±0.8 (28)	0.9±0.3 (89)	0.0001	2.1±0.9 (29)	1.0±0.4 (89)	0.0001
six month	1.5±0.7 (2)	0.8±0.3 (3)		2.0±0.7 (2)	0.8±0.3 (3)	

† Wilcoxon Rank Sum Test

**Table 8: Ventricular Capture Thresholds (V) At 0.4 MS Pulse Width**

follow-up	unipolar: mean±SD (N)			bipolar: mean±SD (N)		
	1188T	1388T	P value†	1188T	1388T	P value†
implant	0.9±0.5 (55)	0.7±0.3 (208)	0.0001	0.9±0.3 (54)	0.8±0.3 (212)	0.0001
two week	2.4±1.3 (57)	1.0±0.4 (193)	0.0001	2.8±1.4 (56)	1.0±0.4 (197)	0.0001
one month	2.3±1.3 (55)	1.0±0.4 (195)	0.0001	2.5±1.1 (54)	1.0±0.4 (196)	0.0001
three month	2.0±0.9 (28)	1.0±0.5 (106)	0.0001	2.3±0.9 (33)	1.0±0.6 (109)	0.0001
six month	2.0 (1)	0.8±0.3 (5)		2.0 (1)	1.0±0.0 (5)	

† Wilcoxon Rank Sum Test

In all cases, both the unipolar and bipolar mean capture thresholds for the model 1388T lead were lower than those of the model 1188T control lead. The difference between the mean threshold values at implant were relatively small. The difference between the means at all post implant follow-up were large, with the mean capture threshold for the 1388T being less than half that of the model 1188T leads.

The difference in capture thresholds at implant, two weeks post implant, one month post implant and three months post implant were statistically significant with P values equal to or less than 0.0002 (Wilcoxon Rank Sum Test). The samples size at six months post implant was too small to demonstrate statistical significance.

In addition to the previously described statistical analysis which demonstrated a statistically significant difference in the mean thresholds of the investigational and control leads, a statistical method known as bootstrapping was applied to the data. This analysis allowed determination of 95% confidence intervals for the difference between the mean capture thresholds for the 1388T and 1188T leads at the two week, one month and three month follow-up intervals. In all cases (atrial or ventricular placement, unipolar or bipolar pacing configuration), the lower limit of the confidence interval exceeded the predetermined minimum clinically significant difference of 0.5 volts. In other words, there is a greater than 95% probability that the true mean capture threshold (through three months post) of the model 1388T is at least 0.5 volt lower than that of the model 1188T control lead.

Analysis of sensing thresholds and lead impedance at all follow-up intervals was also performed. In all cases, the mean sensing thresholds for the model 1388T leads were superior to (greater than) the control lead. The mean lead impedances for the 1388T lead were lower than those for the model 1188T.

## 5. Safety Data

A total of ten patients (3.3%) out of the population of 303 patients were reported to have expired during the study. In all cases, there was no indication that the patient death was related to either the investigational or control lead(s) implanted in the patient.

One or more lead related complications or adverse events were reported for 9 (5.0%) of the 179 model 1388T leads positioned in the atrium and 9 (4.1%) of the 219 model 1388T leads positioned in the ventricle. The percentages of the model 1188T control leads with reported complications were 1.5% and 5.1% respectively for leads positioned

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in the atrium or ventricle. Complications/adverse effects reported for the model 1388T lead included loss of sensing (2), loss of capture or elevated thresholds (7), lead dislodgement (3), difficulty with lead placement (1), cardiac perforation (1), low lead impedance (2), cardiac tamponade (2) and coil damage (1).

The number and rate of complications for 1188T and 1388T leads in the atrial and ventricular positions, respectively are provided in Tables 9 and 10. No statistically significant differences were detected in the rate of individual complications or in the total cumulative rate of lead related complications between the two lead models in the atrial position (p=0.297, Fisher's Exact Test, 2-Tailed) or in the ventricular position (p=0.738, Fisher's Exact Test, 2-Tailed).

**Table 9: Complication/Adverse Event Rates For Atrial Leads**

type of event	1188T		1388T		statistical comparison*
	number of events	rate (events/lead/month)	number of events	rate (events/lead/month)	
loss of sensing	0	0	1	0.0015	p=1.0
loss of capture or elevated thresholds	0	0	2	0.0031	p=1.0
lead dislodgement	0	0	2	0.0031	p=1.0
difficult placement	1	0.0042	1	0.0015	p=0.46
cardiac perforation	0	0	0	0	p=1.0
high lead impedance	0	0	0	0	p=1.0
low lead impedance	0	0	2	0.0031	p=1.0
cardiac tamponade	0	0	1	0.0015	p=1.0
coil damage	0	0	1	0.0015	p=1.0
<b>total</b>	<b>1</b>	<b>0.0042</b>	<b>10</b>	<b>0.0154</b>	<b>p=0.30</b>

\* p values determined using Fisher's Exact Test, 2-Tailed

**Table 10: Complication/Adverse Event Rates for Ventricular Leads**

type of event	1188T		1388T		statistical comparison*
	number of events	rate (events/lead/month)	number of events	rate (events/lead/month)	
loss of sensing	0	0	1	0.0012	p=1.0
loss of capture or elevated thresholds	2	0.0093	5	0.0062	p=0.64
lead dislodgement	1	0.0046	1	0.0012	p=1.0
difficult placement	0	0	0	0	p=1.0
cardiac perforation	0	0	1	0.0012	p=1.0
high lead impedance	0	0	0	0	p=1.0
low lead impedance	0	0	1	0.0012	p=1.0
cardiac tamponade	0	0	1	0.0012	p=1.0
coil damage	0	0	0	0	p=1.0
<b>total</b>	<b>3</b>	<b>0.0139</b>	<b>10</b>	<b>0.0124</b>	<b>p=0.74</b>

\* p values determined using Fisher's Exact Test, 2-Tailed

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## 6. Clinical Event Analysis

Kaplan-Meier Survival Curves (Figures 2 and 3) were generated for lead related events (complications and adverse events). The Wilcoxon test was used to compare the curves for the atrial control lead versus the atrial experimental lead and for the ventricular control lead versus the ventricular experimental lead. The tests showed that no statistically significant differences at the .05 significance level. The p-value for the Wilcoxon test is 0.1076 for the atrial lead comparison and 0.7328 for the ventricular lead comparison.

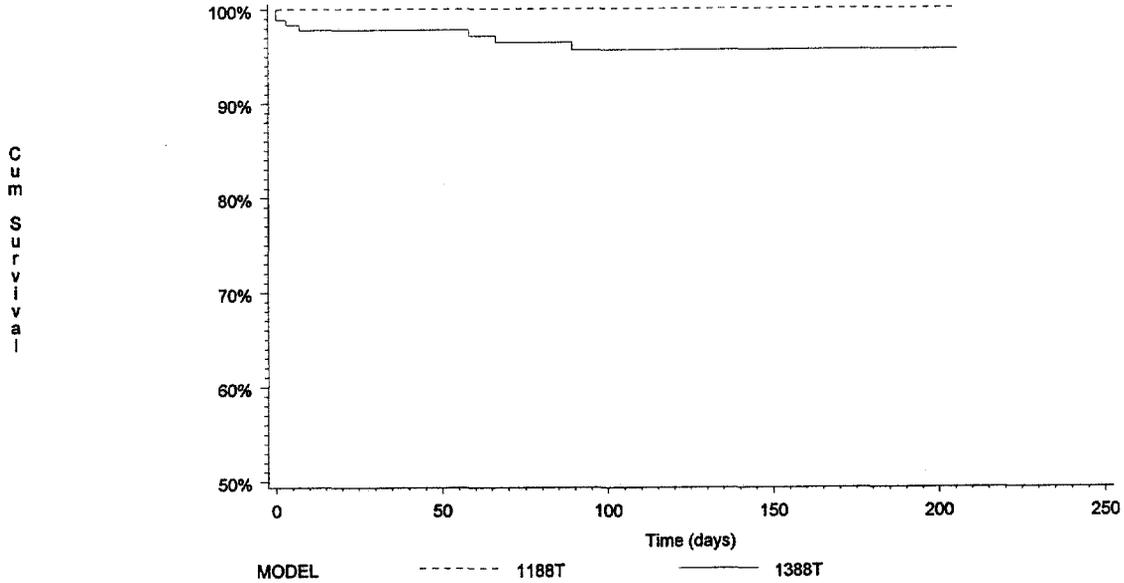


Figure 2: Survival Curves for Atrial Lead Related Clinical Events

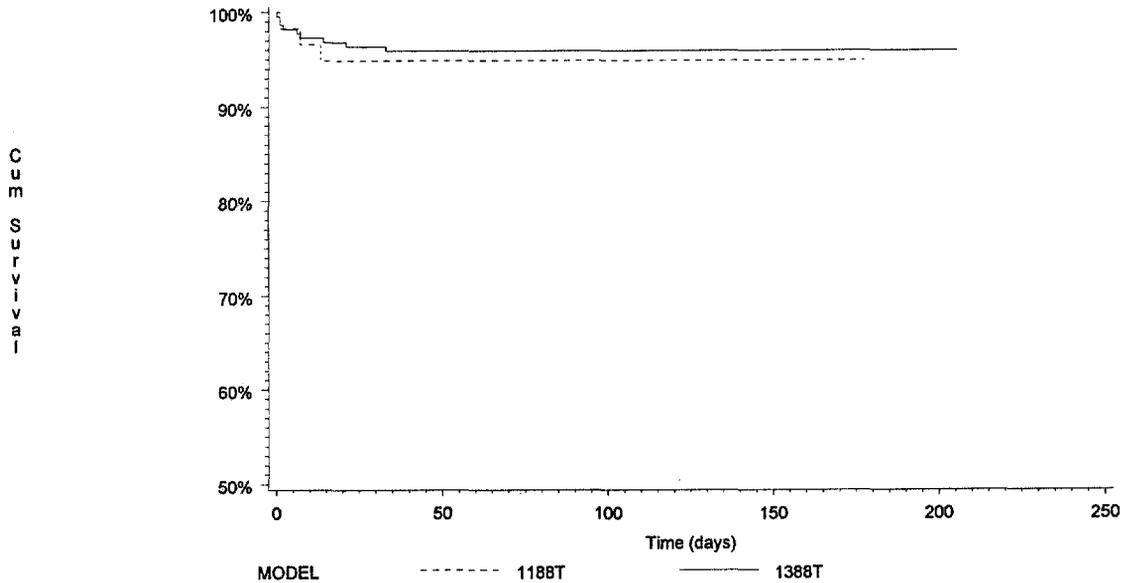


Figure 3: Survival Curves for Ventricular Lead Related Clinical Events

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## **XI. CONCLUSION DRAWN FROM THE STUDIES**

A series of *in vitro* qualification tests performed for the model 1388T and 1388K leads (as well as tests performed for the similar model 1188T and 1188K leads) has demonstrated the mechanical integrity of the Tendril DX pacing leads and their ability to withstand stresses encountered during normal use. Additional bench testing performed on the model 1388T/K leads included the following: bell mouth flex testing of the lead body and connector, distal tip fatigue testing, MCRD swell testing, evaluation of drug elution rate, evaluation of drug shelf life and evaluation of multiple sterilizations on the MCRD. The results of these tests provide further confirmation of the ability of the leads to perform effectively during long term implant in the human body.

Clinical trials conducted with the model 1388T leads have demonstrated that the presence of the MCRD in the fixation helix results in a significant reduction in capture thresholds through three months post implant relative to a nearly identical lead without a steroid release mechanism. Clinical trials were not conducted for the model 1388K lead. However, since the distal electrode portion of the 1388K is identical to that of the model 1388T, the clinical study results for the 1388T are applicable to the 1388K and confirm that this lead will also demonstrate the desired reduction in subacute capture thresholds.

In conclusion, the results of extensive *in vivo* and *in vitro* testing provide reasonable assurance that the model 1388T and 1388K Tendril DX pacing leads are safe and effective for their intended use when utilized in accordance with the product labeling. Additionally, clinical trials have confirmed that the Tendril DX leads provide clinically significant lower capture thresholds during the first three months post implant than a non-steroid control lead.

## **XII. PANEL RECOMMENDATIONS**

Pursuant to section 515(f)(2) of the act as amended by the Safe Medical Devices Act of 1990, this PMA was not referred to the Circulatory System Devices Panel for review and recommendations because the information in the PMA substantially duplicated information previously review by this panel.

## **XIII. FDA DECISION**

FDA recommends approval of the application with the condition that the manufacturer submit a final report for the results of distal tip flex testing when testing through 400 million cycles has been completed.

## **XIV. APPROVAL SPECIFICATION**

Directions for use: See labeling

Hazards to Health from use of Device: See Indications, Contraindications, Warnings, Precautions, and Adverse Events sections in the labeling

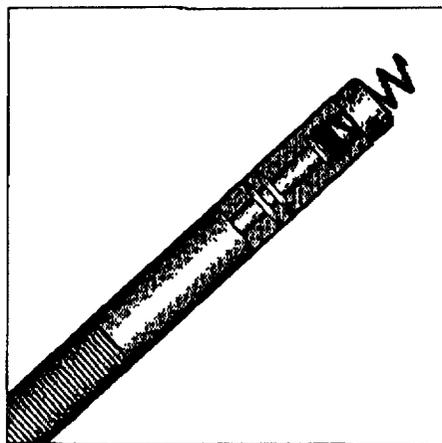
Post Approval Requirements and Restrictions: See approval order



# Assure™ AFS

Models 7010T/K

Endocardial Steroid-Eluting Screw-in Pacing Leads



Copyright 1997

Ventritex  
a St. Jude Medical Company  
15900 Valley View Court  
Sylmar, CA 91342 USA  
(800) 777-2257 (818) 362-6822

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

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## Device Description

Assure™ AFS leads are silicone insulated, steroid-eluting, Titanium Nitride (TiN) coated, endocardial pacing leads, which may be either unipolar (model 7010K), or bipolar (model 7010T). Assure AFS leads are suitable for either atrial or ventricular placement and feature active fixation, via a rotating extendible/retractable helix.

Assure AFS leads have a monolithic controlled-release device (MCRD), located in the tip electrode of the lead. The MCRD is a molded plug of silicone medical adhesive A impregnated with less than one milligram of dexamethasone sodium phosphate (DSP). The steroid (DSP) decreases the inflammatory reaction of the heart during the acute stage (0-3 months post implant) of patient recovery.

## Indications for Use

The Assure AFS lead is designed for use in combination with a compatible pulse generator to provide permanent pacing and sensing in either the atrium or ventricle.

## Contraindications

The use of this endocardial lead is contraindicated:

- in the presence of tricuspid atresia and in patients with mechanical tricuspid valves<sup>1</sup>
- in patients with tricuspid valvular disease
- in patients who are expected to be hypersensitive to a single dose of 1.0 milligrams of dexamethasone sodium phosphate.

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## Warnings

- Only battery powered equipment should be used during lead implantation and testing to protect against fibrillation which may be induced by alternating currents.
- Any line-powered equipment used in the vicinity of the patient during the implant procedure should be properly grounded.
- Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.
- The Assure AFS lead and its accessories are intended for one time use only. Do not reuse.

## Precautions

### General

- Prior to opening the lead package, confirm that it is compatible with the pulse generator to be implanted.
- Do not sterilize this lead using an autoclave, gamma radiation or ultrasonics.
- The manipulation of any and all hardware while in the vascular system should only be performed under continuous fluoroscopic monitoring.

### Handling and Storage

- Cardiac pacing leads can be damaged by improper handling before and during implant or by excessive mechanical stress post-implantation.
- The lead conductor, its insulating sheath, and the helix mechanism may be damaged if subjected to extreme mechanical stress.
- Do not stretch, crush, kink, or bend the lead.
- Avoid bringing the lead in contact with any sharp objects which could puncture or otherwise compromise the insulation.
- Do not handle the lead except with powderless, sterile surgical gloves.



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- Avoid handling the lead with any surgical tools, e.g. hemostats, clamps, forceps.
- Leads have an electrostatic affinity for particulate matter; do not expose them to lint, dust or other such materials.
- The lead is supplied with the helix in its fully retracted position. Avoid touching or handling the helix itself.
- Do not immerse the lead body in mineral oil, silicone oil or any liquid other than sterile saline or injectable fluid.
- Do not immerse the tip electrode in any fluid prior to implantation. Immersion of the electrode may cause a small amount of steroid to be prematurely eluted from the helix housing.
- The lead should be stored at temperatures between -5 °C (23 °F) and 55 °C (131 °F).

### Implantation

- Lead implantation should only be performed when proper emergency facilities for cardioversion and/or defibrillation are available.
- If subclavian venipuncture is used for lead introduction, it is important to avoid extremely medial entry of the lead into the vein, which may contribute to lead conductor fracture or other lead damage.<sup>2</sup>
- Electrode dislodgment or displacement may produce erratic, intermittent or total loss of pacing or sensing. It may also induce atrial or ventricular ectopy.
- Perforation of the atrial or ventricular wall may cause phrenic nerve stimulation, diaphragmatic stimulation or, in some instances, cardiac tamponade.<sup>3</sup> Phrenic nerve or diaphragmatic stimulation may also result from lead position.
- Use the anchoring sleeve to distribute the tension created by the suture used to secure the lead at or near the venous entry site. Failure to use the anchoring sleeve may result in damage to the lead's insulation or conductor coil or both.

## Adverse Events

The Assure AFS model 7010T clinical trials involved 521 devices [398 model 7010T leads, 123 Pacesetter model 1188T leads] implanted in 303 patients. Cumulative duration for atrial implantation of model 7010T was 19,477 days (mean implant duration 108.8 days, range 5 to 205 days). Cumulative implant duration for model 7010T leads positioned in the ventricle was 24,155 days (mean implant duration 110.3 days, range 0 to 205 days). Adverse events (AEs) are listed in Table 1 and Table 2.

A total of 10 patients died during the course of this clinical trial. None of these deaths were deemed lead related.

In addition to the adverse events reported during the course of the clinical trial, other possible adverse events may occur based on historical experience include:

- embolism
- excessive bleeding
- thrombosis
- infection
- induced atrial or ventricular ectopy
- phrenic nerve stimulation
- diaphragmatic stimulation
- cardiac tamponade
- loss of pacing and or sensing due to dislodgment or mechanical malfunction of the pacing lead.

Table 1. Tendril DX Model 1388T, Atrial Leads

Device-Related Complications	Number of Patients (n=179)	% of Patients	Number of Leads	Adverse Events per Lead-Month
Loss of sensing	1	0.6	1	0.00313*
Loss of Capture or Elevated Thresholds	2	1.1	2	0.00313
Lead Dislodgment	2	1.1	2	0.00313
Difficulty with Lead Placement	1	0.6	1	0.00156
Cardiac Perforation	0	0.0	0	0.0
High Lead Impedance	0	0.0	0	0.0
Low Lead Impedance	1	0.6	1	0.00156
Cardiac Tamponade	1	0.6	1	0.00156
Coil Damage	1	0.6	1	0.00156
Device-Related Observations	Number of Patients (n=179)	% of Patients	Number of Leads	Adverse Events per Lead-Month
Low Lead Impedance	1	0.6	1	0.00156
<b>Total (any adverse event)</b>	<b>10</b>	<b>5.6</b>	<b>10</b>	<b>0.01718</b>

Device Related Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require physician intervention.

Device Related Observations are defined as symptomatic or asymptomatic device related clinical events which do not require physician intervention.

\* One lead experienced loss of atrial sensing on two separate occasions.

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Table 2. Tendril DX Model 1388T, Ventricular Leads

Device-Related Complications	Number of Patients (n=219)	% of Patients	Number of Leads	Adverse Events per Lead-Month
Loss of sensing	1	0.5	1	0.00126
Loss of Capture or Elevated Thresholds	5	2.3	5	0.00630
Lead Dislodgment	1	0.5	1	0.00126
Difficulty with Lead Placement	0	0.0	0	0.0
Cardiac Perforation	1	0.5	1	0.00126
High Lead Impedance	0	0.0	0	0.0
Low Lead Impedance	1	0.5	1	0.00126
Cardiac Tamponade	1	0.5	1	0.00126
Coil Damage	0	0.0	0	0.0
Device-Related Observations	Number of Patients (n=219)	% of Patients	Number of Leads	Adverse Events per Lead-Month
None	0	0	0	0
<b>Total (any adverse event)</b>	<b>10</b>	<b>4.6</b>	<b>10</b>	<b>0.01259</b>

Device Related Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require physician intervention.

Device Related Observations are defined as symptomatic or asymptomatic device related clinical events which do not require physician intervention.

## Clinical Trials

### NOTE

The Ventritex Assure AFS models 7010T/K leads are identical to the Pacemaker Tendril DX models 1388T/K leads. Therefore, the clinical performance information collected during the Tendril DX clinical trials and discussed in the following sections is also applicable to the Ventritex Assure AFS models 7010T/K leads.

A multicenter, prospective, randomized control clinical trial was conducted to compare the capture thresholds of the model 1388T lead through three months post implant to those of a commercially available, non-steroid active-fixation lead (model 1188T). Patients were randomized to receive either a model 1388T or 1188T lead in the atrium and/or ventricle using a 3:1 randomization ratio (three model 1388T leads to each model 1188T lead).

Lead electrical performance characteristic, including capture thresholds and sensing thresholds, were evaluated at implant and at 14 days ( $\pm 4$  days), 30 days ( $\pm 7$  days), 90 days ( $\pm 14$  days), and 180 days ( $\pm 30$  days) post implant.

A total of 521 devices were implanted (398 model 1388T leads and 123 model 1188T leads) as of March 15, 1996. The average patient age at implant was 70 years with 66% male and 34% female patients, respectively. Statistical comparison of the patient populations receiving the model 1388T and 1188T leads (Table 3) indicate no statistically significant differences in patient demographics (age and sex), physiologic conditions which could affect pacing thresholds or medications which could affect pacing thresholds.

The only statistically significant difference between the populations involved the percentage of patients with sick sinus syndrome as the primary indication for implant. For patients receiving ventricular leads, 51.7% receiving the control lead had sick sinus syndrome as a primary indication whereas the proportion was 35.6% for patients receiving the investigational lead. Since sick sinus syndrome is a disorder affecting the sinus node (located in the atrium), this difference would not impact ventricular lead performance and therefore would not bias study results.

Analysis of the clinical data collected as of March 15, 1996 demonstrated that the presence of the MCRD in the fixation helix results in a significant reduction in capture thresholds through three months post implant relative to an active-fixation lead without a steroid release mechanism (Table 4 and Table 5).

Although the addition of a steroid release device to the model 138BT lead has been shown to reduce capture thresholds relative to a non-steroid control lead, the Tendril DX clinical trial did not specifically address whether or not the addition of the MCRD also reduces the incidence of exit block. Therefore, at present, there is no objective clinical evidence that the incidence of exit block for Tendril DX leads will be less than that observed with non-steroid active-fixation leads.

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Table 3. Comparison of patients Receiving 1388T and 1188T Leads

Variables	Atrial			Ventricular		
	1188T	1388T	Statistics	1188T	1388T	Statistics
Gender						
Male	45 (69.2%)	112 (62.6%)	Fisher's Exact Test p = 0.367	36 (62.1%)	144 (65.8%)	Fisher's Exact Test p = 0.643
Female	20 (30.8%)	67 (37.4%)		22 (37.9%)	75 (34.3%)	
Age(years):						
Range	20.0 - 95.1	8.9 - 102.8	t = 0.4957 d.f. 145.8 p = 0.621	42.7 - 91.7	15.0 - 102.8	t = 0.9372 d.f. 126.8 p = 0.350
Mean	70.6	69.7		72.7	71.2	
STD	12.0	15.4		9.3	13.4	
Primary Indication						
Sick Sinus:			Fisher's Exact Test p = 0.769			Fisher's Exact Test p = 0.034
Reported	28 (43.1%)	72 (40.2%)		30 (51.7%)	78 (35.6%)	
Normal *	37 (56.9%)	107 (59.8%)		28 (48.3%)	141 (64.4%)	
Sinus Bradycardia:			Fisher's Exact Test p = 0.669			Fisher's Exact Test p = 0.378
Reported	7 (10.8%)	25 (14.0%)		5 (8.6%)	30 (13.7%)	
Normal *	58 (89.2%)	154 (86.0%)		53 (91.4%)	189 (86.3%)	
Heart Block:			Fisher's Exact Test p = 0.469			Fisher's Exact Test p = 0.232
Reported	32 (49.2%)	78 (43.6%)		20 (34.5%)	96 (43.8%)	
Normal *	33 (50.8%)	101 (56.4%)		38 (65.5%)	123 (56.2%)	
PCAPT:			Fisher's Exact Test p = 0.857			Fisher's Exact Test p = 0.714
Condition(s)	12 (18.5%)	36 (20.2%)		13 (22.4%)	43 (19.7%)	
None	53 (81.5%)	142 (79.8%)		45 (77.6%)	175 (80.3%)	
Not Reported**	0	1		0	1	
MAPT:			Fisher's Exact Test p = 0.208			Fisher's Exact Test p = 0.646
Not reported at Implant	41 (63.1%)	129 (72.1%)		35 (60.3%)	141 (64.4%)	
Reported at Implant	24 (36.9%)	50 (27.9%)		23 (39.7%)	78 (35.6%)	
Total Patients within Lead Group	65	179		58	219	

\* Normal Function, relative to the corresponding Primary Indication

\*\* Not included in statistical analysis

PCAPT = Physiological Conditions Affecting Pacing Thresholds

MAPT = Medications Affecting Pacing Thresholds

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Table 4. Atrial Capture Thresholds (V) at 0.4 ms Pulse Width

Follow-Up	Unipolar: mean $\pm$ SD <sup>1</sup> (N) <sup>2</sup>			Bipolar: mean $\pm$ SD <sup>1</sup> (N) <sup>2</sup>		
	1188T	1388T	P value <sup>3</sup>	1188T	1388T	P value <sup>3</sup>
implant	1.1 $\pm$ 0.4 (59)	0.9 $\pm$ 0.4 (160)	0.0002	1.1 $\pm$ 0.4 (61)	0.8 $\pm$ 0.4 (162)	0.0001
two week	2.2 $\pm$ 1.0 (56)	0.9 $\pm$ 0.4 (153)	0.0001	2.6 $\pm$ 1.3 (59)	1.0 $\pm$ 0.5 (154)	0.0001
one month	2.1 $\pm$ 0.7 (57)	0.9 $\pm$ 0.4 (151)	0.0001	2.4 $\pm$ 0.9 (59)	1.0 $\pm$ 0.3 (154)	0.0001
three month	2.0 $\pm$ 0.8 (28)	0.9 $\pm$ 0.3 (89)	0.0001	2.1 $\pm$ 0.9 (29)	1.0 $\pm$ 0.4 (89)	0.0001
six month	1.5 $\pm$ 0.7 (2)	0.8 $\pm$ 0.3 (3)	*	2.0 $\pm$ 0.7 (2)	0.8 $\pm$ 0.3 (3)	*

1. SD = standard deviation

2. N = sample size

3. Wilcoxon Rank Sum Test

\* Sample size too small to perform statistical analysis.

Table 5. Ventricular Capture Thresholds (V) at 0.4 ms Pulse Width

Follow-Up	Unipolar: mean $\pm$ SD <sup>1</sup> (N) <sup>2</sup>			Bipolar: mean $\pm$ SD <sup>1</sup> (N) <sup>2</sup>		
	1188T	1388T	P value <sup>3</sup>	1188T	1388T	P value <sup>3</sup>
implant	0.9 $\pm$ 0.5 (55)	0.7 $\pm$ 0.3 (208)	0.0001	0.9 $\pm$ 0.3 (54)	0.8 $\pm$ 0.3 (212)	0.0001
two week	2.4 $\pm$ 1.3 (57)	1.0 $\pm$ 0.4 (193)	0.0001	2.8 $\pm$ 1.4 (56)	1.0 $\pm$ 0.4 (197)	0.0001
one month	2.3 $\pm$ 1.3 (55)	1.0 $\pm$ 0.4 (195)	0.0001	2.5 $\pm$ 1.1 (54)	1.0 $\pm$ 0.4 (196)	0.0001
three month	2.0 $\pm$ 0.9 (33)	1.0 $\pm$ 0.5 (106)	0.0001	2.3 $\pm$ 0.9 (33)	1.0 $\pm$ 0.6 (109)	0.0001
six month	2.0 (1)	0.8 $\pm$ 0.3 (5)	*	2.0 (1)	1.0 $\pm$ 0.0 (5)	*

1. SD = standard deviation

2. N = sample size

3. Wilcoxon Rank Sum Test

\* Sample size too small to perform statistical analysis.

## Detailed Device Description

The implantable endocardial screw-in pacing leads from Ventritex are designed for use with implantable pulse generators for long-term cardiac pacing. They are passed transvenously to the heart and attached to the endocardium. Once properly fixated, the pacing lead is connected to the pulse generator.

Steroid will be slowly released through the helix housing upon contact with body fluid. The drug promotes low acute-to-chronic pacing threshold by suppressing the inflammation response to a foreign body.

The lead conducts stimulating pulses from the pulse generator to the heart and, in demand pacing modes, delivers electrical information on the intrinsic cardiac activity to the sense amplifiers of the pulse generator.

The endocardial screw-in leads are available in both unipolar and bipolar models. Model 7010K unipolar leads have one conductor that terminates at the tip helix. Model 7010T bipolar leads have two conductors: one terminating at the tip helix (cathode) and the other at the larger, microporous titanium nitride-coated ring electrode (anode) approximately 10 millimeters from the tip.

Endocardial screw-in leads comply with IS-1 connector standard ISO 5841-3.

Assure AFS implantable pacing leads from Ventritex are made of biocompatible materials.

### NOTE

**A pacing lead explanted for any reason should never be implanted in another patient.**

### Contents of Package

The contents of the package are sterile. Each package contains:

- one screw-in pacing lead with anchoring sleeve attached
- one fixation tool
- one vein lifter
- stainless steel stylets
- two clip-on tools.

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## Operating Instructions

### Lead Selection

There are many factors to take into account when choosing a pacing lead. The first is compatibility with the pulse generator, which may be verified by consulting with your Ventritex representative and, if applicable, the pulse generator manufacturer. Compatibility includes the size, connector configuration and polarity (unipolar or bipolar).

#### NOTE

**Because of the numerous available 3.2 mm configurations, e.g. the IS-1 and VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer[s] prior to implantation of a pacing system.**

Many pulse generators offer programmable polarity, meaning that pacing and/or sensing may be programmed to function in a unipolar or bipolar configuration. The bipolar, steroid eluting screw-in lead may function in either a unipolar or bipolar configuration, depending on how the pulse generator is programmed.

Some pulse generators offer independently programmable polarity for both pacing and sensing. Unipolar pacing produces a relatively large pacing artifact that is easily recognizable on a surface ECG. However, unipolar pacing may cause skeletal muscle stimulation in the pocket area. Unipolar sensing may be more sensitive to extracardiac signals than bipolar sensing.

Bipolar pacing is much less likely to cause muscle stimulation than unipolar pacing. However, the bipolar pacing spike is usually very small and may be difficult to discern on a surface ECG. Bipolar sensing is known to be much less affected by myopotentials and external interference than unipolar sensing.<sup>4</sup>

## Implantation

The goal of any lead implantation is to minimize mechanical stresses on the pacing lead while simultaneously maximizing the lead's electrical contact with cardiac tissue. Pacing leads should only be implanted in conjunction with simultaneous fluoroscopic verification of lead position.

---

### Caution

*The manipulation of any and all hardware while in the vascular system should only be performed under continuous fluoroscopic monitoring.*

*Lead implantation should only be performed when proper emergency facilities for cardioversion and/or defibrillation are available. An adequate number of trained personnel should be present during the procedure.*

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## Sterilization

The package and its contents have been sterilized with ethylene oxide for direct introduction into the surgical field. Before the package is opened, inspect it visually for any damage that may have compromised sterility.

If resterilization is necessary, place the lead and accessories in a gas-permeable package and resterilize in ethylene oxide. The sterilizer temperature should not exceed 52°C (125°F). After sterilization, allow the lead to aerate at 52°C (125°F) for at least 12 hours to allow dissipation of ethylene oxide residuals prior to implantation. Use biological controls to verify the effectiveness of the resterilization.

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### Caution

*Do not sterilize this lead using an autoclave, gamma radiation or ultrasonics.*

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## NOTES

The lead may be resterilized only once.

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## Lead Preparation

It is important that the implanting physician completely understand the mechanical operation of this lead before surgery.

The lead comes preloaded with the stylet in the fixation tool (Figure 1). The lead is held securely in the fixation tool by the distal thumbscrew.

If a different stylet is desired, loosen the proximal thumbscrew by turning it counterclockwise. Then remove the preinserted stylet, insert the new stylet into the lumen of the fixation tool, and advance it through the lead.

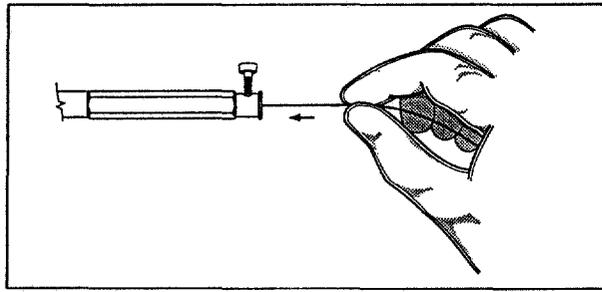


Figure 1

*The stylet is secured with the proximal thumbscrew.*

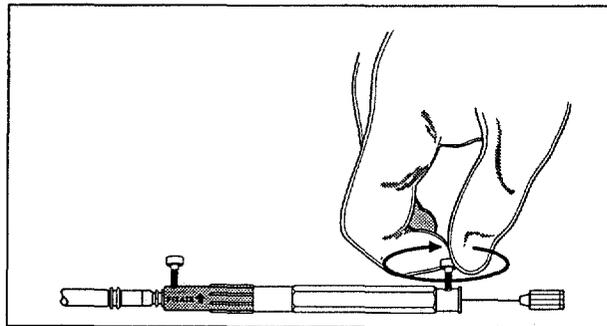


Figure 2

*Fully advance the stylet. Then hold it in place by tightening the proximal thumbscrew clockwise.*



Remove the lead with fixation tool from the tray. Place it on a clean, lint-free, sterile field.

Test the operation of the extendable/retractable helix before implantation. Secure the stylet by turning the proximal thumbscrew clockwise (Figure 2). With the fixation tool in one hand, hold the lead body itself stationary with the other hand. Rotate the grooved gray section of the tool clockwise (as indicated by the arrow on the tool marked "FIXATE") and observe the helix extend from the lead tip. The helix is considered fully extended when two full turns are visible beyond the lead's inactive platinum collar, which serves as a radiopaque indicator. (See Figure 3.)

The helix may be retracted by holding the lead body stationary in one hand and turning the grooved gray portion of the tool counterclockwise (opposite the direction indicated by the arrow "FIXATE"). (See Figure 4.)

Verify proper mechanical operation before proceeding with implantation.



WJ

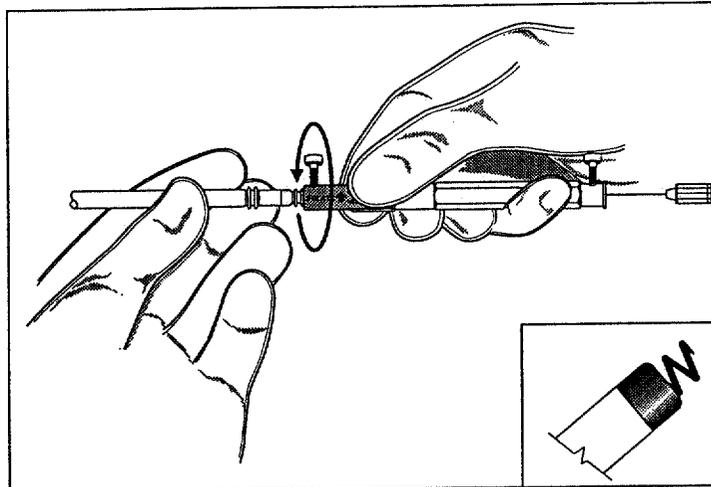


Figure 3

Extend the helix by holding the lead body stationary in one hand and turning the gray grooved portion of the tool clockwise (in the direction indicated by the arrow "FIXATE").

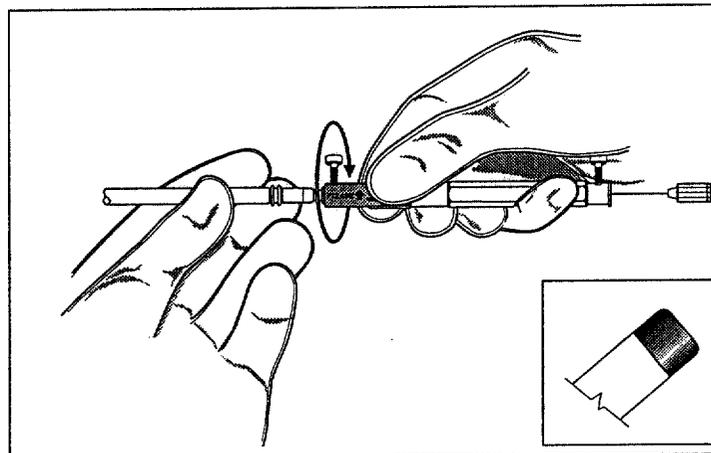


Figure 4

Retract the helix by holding the lead body stationary in one hand and turning the gray grooved portion of the tool counterclockwise (in the opposite direction indicated by the arrow "FIXATE").

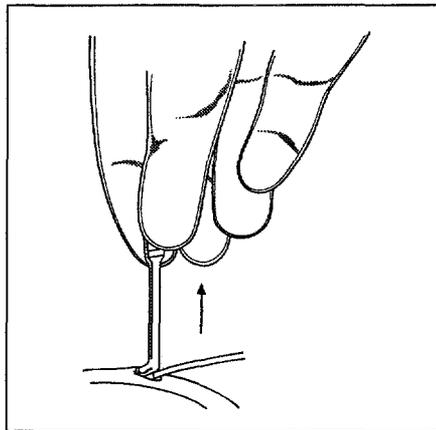
## Venous Routes

There are several venous routes for passing the endocardial pacing lead, including either the right or left cephalic, subclavian, axillary, or internal or external jugular veins. Veins may be accessed using the cut-down or venipuncture method.

### Cut-down method

Any of the above veins may be used for the cut-down technique. In the cut-down technique, the desired vein is identified and a small incision is made for lead insertion. The vein lifter tool, included in this package, can be used to hold open and dilate the vein, facilitating lead insertion.

A vein lifter facilitates lead introduction into an exposed vein. Insert its tapered end into the incised vein and gently push the lead tip underneath the exposed wall and into the vein. Then gently lift to create an opening through which the lead may be inserted. (See Figure 5.)



*Figure 5. When using the cut-down technique, the vein lifter facilitates lead introduction. Insert its tapered end into the vein and gently lift.*

### Subclavian puncture method

The subclavian puncture method requires the use of a percutaneous lead introducer kit. Use the needle in the introducer kit to puncture the vein. Take the guide wire and advance the J straightener over the J-shaped tip to facilitate placement of the guide wire into the needle and thus into the vein. Remove the needle, leaving the guide wire in place. The J configuration to the tip minimizes trauma to the vessel and facilitates passage.

When the guide wire is in the right atrium, advance the dilator and sheath with a rotating motion over the guide wire and into the vein. To remove the dilator, hold the T handle of the sheath and rotate the dilator counterclockwise. [These instructions assume the use of a peel-away introducer. If another type of introducer is used, follow the manufacturer's directions.] Retract the guide wire and dilator, leaving the sheath in position. Introduce the pacing lead with inserted stylet into the sheath and advance the lead into position.

When the lead is properly positioned, remove the sheath by using the tabs on either side to tear the sheath down and away. For more information on the subclavian puncture method using the percutaneous introducer kit, please consult the introducer manual.

---

*Caution*

*To reduce the potential for conductor fracture or other lead damage when using the subclavian puncture method, avoid extremely medial placement of the point of entry of the endocardial lead through the infraclavicular space.<sup>5</sup>*

---

**NOTES**

The normal status of the subclavian vein often renders it difficult to puncture unless it is distended by raising the patient's legs to a 45° angle or by using the Trendelenburg position. The vein will be much easier to locate if the patient is well hydrated.<sup>6</sup>

When retracting the guide wire and dilator in the subclavian puncture technique, manually compress or cover the opening of the introducer sheath to avoid inadvertent air aspiration.

**Dual-Chamber Pacemakers**

Dual-chamber pacemakers require the implantation of two leads, one in the atrium and the other in the ventricle. Two leads may be implanted by making two venipunctures, by making one puncture and using an introducer sufficiently large to accommodate both leads or by using a variation of the retained guide wire technique. The retained guide wire technique, the most commonly used method, involves using the introducer in one venipuncture but removing the guide wire and dilator together before the lead is inserted into the

sheath. For the second lead, the guide wire is reinserted down the first sheath; the first sheath is then removed and the second sheath placed over the guide wire. The guide wire is then removed and the second lead is inserted through the second sheath.<sup>7</sup>

Fast Pass® molecular coating is designed to facilitate the passage and the positioning of two silicone leads by creating a highly lubricious lead surface. This is of particular importance when using the retained guide wire technique, or a single large sheath where two leads are introduced into the same puncture site.

### Stylets

The Assure AFS lead comes supplied with stylets. When inserted into the pacing lead through the lumen of the fixation tool, the stylet gives the lead sufficient rigidity to be manipulated easily through the vein and into the heart. The stylet should be inserted into the lead before the lead is inserted into the vein. The stylet should be removed before testing the lead for mechanical stability or making intraoperative measurements.

A straight stylet may be curved by running it firmly over a blunt, sterile instrument.

Straight stylets are indicated by a red cap; J stylets are indicated by a bone white cap.

### Ventricular Lead Placement

Make sure that the helix is in the fully retracted position before attempting to insert the lead.

#### NOTES

Ensure that there is a stylet inserted in the lead before attempting to introduce the lead. Always remove the stylet before checking mechanical stability or intraoperative measurements.

Take care to avoid contaminating the stylet with blood. Blood introduced into the core of the lead via the stylet may cause the stylet to bind, so that it cannot be advanced or manipulated. If this problem occurs, remove the lead and replace it with a new one.

Secure the stylet in place by turning the proximal thumbscrew on the fixation tool clockwise. Advance the lead cautiously under fluoroscopic observation into the right atrium. Remove the straight stylet by loosening the thumbscrew (counterclockwise) and then withdrawing the stylet. Take a new stylet, curve it gently and insert it into the lumen of the fixation tool, holding it in place with the proximal thumbscrew. This curve helps the lead negotiate its way across the tricuspid valve as it is gently manipulated into the right ventricle. Once the lead is in the right ventricle, loosen the thumbscrew, retract the stylet slightly (to minimize the chance of perforation of the cardiac wall) and again tighten the thumbscrew to secure the stylet for lead positioning.

An alternative method involves using the straight stylet with the lead in the right atrium. Retract the straight stylet a few centimeters so that the lead tip is floppy. (Loosen the proximal thumbscrew, retract the stylet, then tighten the thumbscrew again to accommodate the new position.) Gently advance sufficient lead within the right atrium so that a loose loop forms. Under fluoroscopic observation, allow this loop to flip or prolapse through the tricuspid valve so that the loop passes through the valve first, drawing the tip through afterward.

Once the lead is in the right ventricle, advance it cautiously toward the right ventricular apex. To avoid the inadvertent placement of the lead in the coronary sinus, it may be useful to advance the lead through the right ventricle and into the pulmonary artery. At this point, replace the curved stylet with a straight stylet (if necessary) and gently withdraw the lead into the right ventricle.

Once the lead is in a potentially suitable location, the lead should then be fixated to the ventricular wall using the method described in the section on Electrode Fixation [page 23].

#### NOTE

If the stylet is partially retracted to increase the flexibility of the lead tip, be sure to readvance the stylet before fixating the lead to the endocardium. It is not possible to fixate the lead unless the stylet is fully inserted.

CU

### Atrial Lead Placement

Make sure that the helix is in the fully retracted position before attempting to insert the lead.

Using fluoroscopy, advance the lead cautiously into the atrium. If resistance is encountered, pull the lead back a short distance and readvance it, repeating this procedure as often as necessary. If this technique is ineffective, withdraw the stylet 2 to 4 cm, allowing the tip to become floppy.

Advance the lead; once past the obstruction, cautiously readvance the stylet.

Guide the lead into the right atrium and into the inferior vena cava. Loosen the proximal thumbscrew and remove the straight stylet, replacing it with a J-shaped stylet and securing it in place by tightening the proximal thumbscrew. Once the J-shaped stylet is fully inserted, the lead will take on a J shape.

If one or more tight bends are induced in the lead as a result of placement in the patient's vascular system, additional force may be required to advance the stylet (particularly a J-shaped stylet) through the lead body. If resistance is encountered, prior to using additional force to advance the stylet, advance the entire lead body past the point of tortuosity until the stylet can again be advanced easily and without resistance. If resistance is still encountered, use gentle force on the stylet to attempt to advance the stylet. When this force is applied to the stylet near the end of the fixation tool, the stylet may tend to bow up or become kinked, making advancement even more difficult.

Follow the procedures illustrated in Figures 6 and 7 to reduce any chance of the stylet kinking during implant.

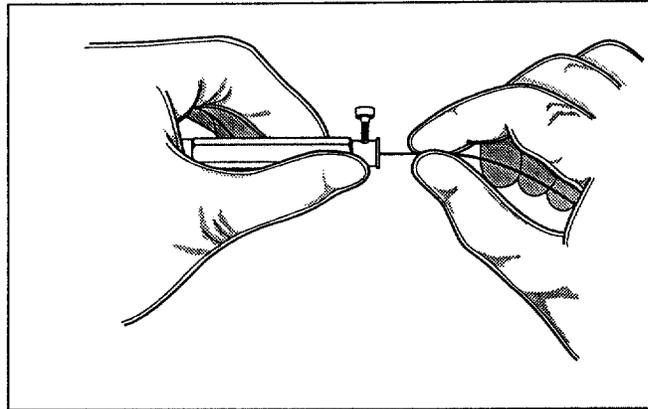


Figure 6

*To prevent inadvertent bending or kinking of the stylet, advance it slowly. Moving the body of the pacing lead backward and forward slightly while advancing the stylet may also help to reduce the insertion force required.*

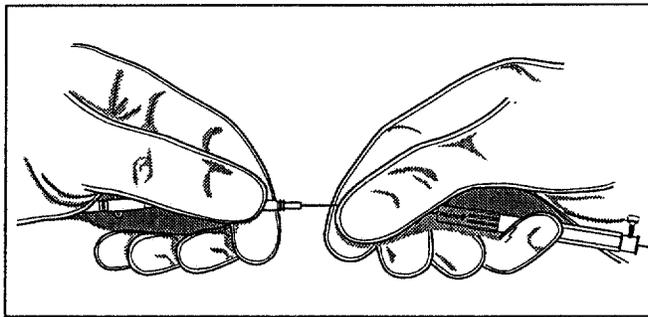


Figure 7

*If advancement of the stylet is still difficult, loosen the thumbscrew and remove the fixation tool from the connector pin of the pacing lead. Then, grasp the stylet and push it just beyond the point where it enters the connector pin as shown. Once the stylet is fully advanced, reattach the tool to the connector pin of the lead to allow helix extension and fixation.*

---

**Caution**

*Do not advance or manipulate the stylet or lead without the aid of direct fluoroscopic observation.*

---

### Electrode Fixation

Locate the desired fixation site. Hold the lead body stationary in one hand and turn the grooved section of the fixation tool approximately eight turns (for 58 cm lead) clockwise (in the direction marked "FIXATE"). (See Figure 8.) On the fluoroscopic image, the helix will be seen to extend beyond the platinum cap. The helix is fully extended when two full turns extend past the cap. (See Figure 9.) Use fluoroscopy to verify helix extension. Since the lead design allows for a versatile fixation site, it may be necessary to rotate the C-arm or to advance the lead body in order to see the entire helix.

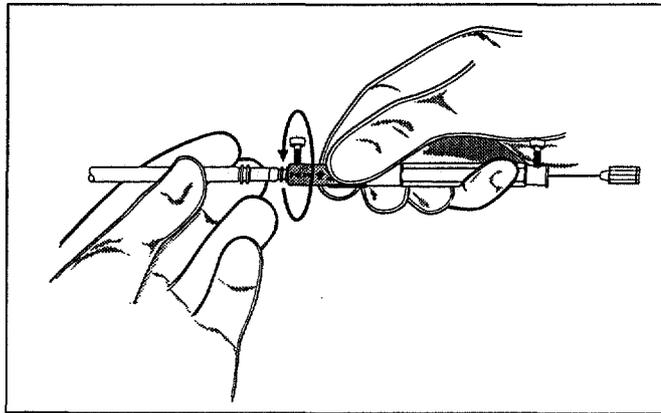
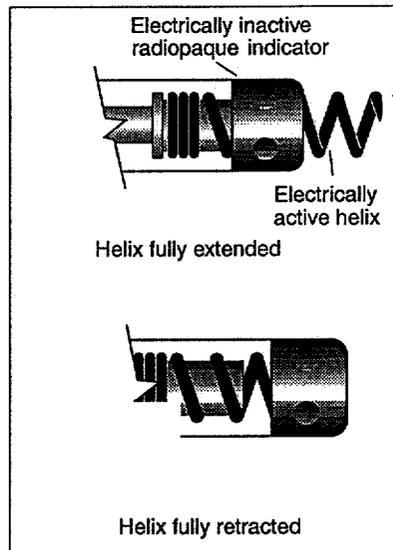


Figure 8

*Hold the lead body stationary in one hand and the fixation tool in the other. Rotate the grooved portion of the tool in the direction of the arrow shown at "FIXATE." The helix extends.*

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*Figure 9. When the helix is fully extended, two full turns will be visible beyond the platinum cap when the lead tip is viewed under fluoroscopy.*

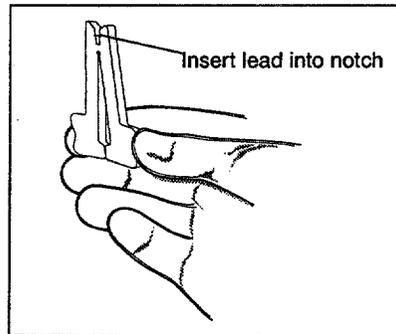
Once fixation is verified, loosen the proximal thumbscrew and carefully withdraw the stylet under fluoroscopic observation. The lead tip should remain in position. Exercise caution during stylet retraction to avoid dislodging the lead.

Retraction of the J-shaped stylet may be more difficult than retraction of a straight stylet. A recommended method for retracting a J-shaped stylet is to loosen the proximal thumbscrew and hold the stylet handle manually; then gently advance the lead body into the atrium while simultaneously, but more slowly, advancing the stylet. Advance about twice as much lead as stylet; in this way, the J shape widens and the stylet can be more readily removed.

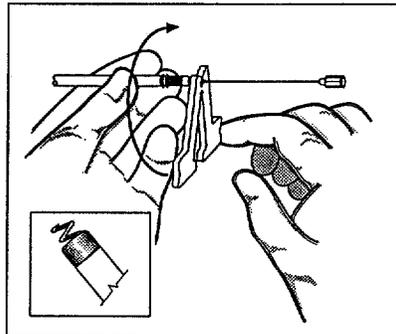
CS

### Optional Clip-On Tool

Included in the package are two optional clip-on tools which may be used to extend or retract the helix. To use the clip-on tool, remove the preassembled fixation tool and stylet. Reinsert the stylet into the lead, pinch open the clip-on tool (Figure 10) and insert the lead terminal pin so that it fits snugly in the notch in the clip-on tool. Release the handles so that the clip-on tool firmly grasps the lead connector. Rotate the clip-on tool clockwise to extend the helix (Figure 11). To remove the clip-on tool, pinch it together and withdraw it from the lead connector.



*Figure 10. Pinch open the clip-on tool and insert the lead into the notch.*



*Figure 11. Rotate the clip-on tool clockwise to extend the helix*

#### NOTE

Do not push the lead connector to the back portion of the clip-on tool. This action might cause the terminal pin to bend. Insert the connector only as far as the notch.

### **Intraoperative Measurements**

Once the lead is fixated, it is very important to verify stimulation threshold and sensing capability during implantation. A measuring device, such as a pacing system analyzer (PSA) is recommended for these electrical measurements.

While initial threshold measurements may be taken with the fixation tool attached, it is recommended that the stylet be removed for taking final threshold measurements.

#### **NOTE**

**When withdrawing the stylet, look for any signs of residual torque (looping, figure-8 twists in the lead body, etc.). It is important to relieve this tension by turning the fixation tool counterclockwise until the tension dissipates.**

#### **NOTE**

**Threshold measurements must always be obtained after fixation. Pre-fixation threshold values are guideline values only.**

---

#### **WARNING**

**A pacing lead inserted into the heart presents a direct, low-impedance pathway for current flow to the myocardium. Use only battery-powered test equipment for electrical measurements.**

---

### **Connection to the PSA**

Make sure that the percutaneous lead introducer and stylet are removed from the lead and that the lead is fixated in what is believed to be a suitable location.

Use the PSA cables to connect the terminal pin of the implanted pacing lead to the PSA. It is recommended that the PSA be programmed OFF or to a passive setting while connections are being made.

For bipolar leads, connect the positive PSA cable (red) to the lead connector's terminal ring (associated with the anode ring electrode) and connect the negative PSA cable (black) to the lead connector pin (cathode).

**NOTE**

**Alligator clips should be carefully applied to the in-line bipolar terminal pin to avoid damaging the insulation between terminal pins.**

For unipolar leads, connect the positive PSA cable (red) to an indifferent electrode or large metal instrument placed into the pocket and connect the negative PSA cable (black) to the lead connector pin (cathode).

**NOTE**

**Do not use an alligator clip as an indifferent electrode by connecting it directly to tissue. This causes tissue trauma and provides a very small surface area, giving inaccurate voltage thresholds and impedance measurements.**

For more information on the use of the PSA, please refer to the PSA manual.

**Stimulation Threshold**

As a general rule, the stimulation threshold (i.e. the output values needed to reliably and consistently capture the heart) is lowest in the acute phase. The stimulation threshold can be expected to increase during the next several weeks after implant and then remain at the new value or decrease slightly to stabilize, typically at one to three months post-implantation.

In selecting output parameter values for the pulse generator (pulse amplitude and pulse width) every effort should be made to obtain the lowest possible settings and provide an adequate safety margin. An adequate safety margin assures that capture will occur even if the patient's threshold increases over time. Once lead maturation has occurred, an adequate safety margin can be maintained with lower output settings as the threshold is no longer likely to change markedly.

Reducing the output can increase pulse generator longevity. The stimulation threshold provides the necessary data so that the lowest possible output parameters may be selected while, at the same time, preserving a safety margin that reliably assures capture. A safety margin of two to three times the voltage stimulation threshold is generally considered adequate.

**NOTE**

Thresholds are measured using either pulse amplitude (voltage) or pulse width (milliseconds). Doubling the pulse amplitude quadruples the energy output of the pulse generator, while doubling the pulse width doubles the energy output.

*Table 6  
Recommended Acute Stimulation Thresholds  
(0.4 ms pulse width, 500  $\Omega$  lead impedance)*

Atrial	Ventricular
< 1.5 V	< 1.0 V
< 3.0 mA	< 2.0 mA

Using a 0.4 ms pulse width and assuming a 500 ohm load, it should be possible to obtain an acute atrial stimulation threshold of less than 1.5 V or 3.0 mA. For a ventricular lead, it should be possible to obtain an acute ventricular stimulation threshold of less than 1.0 V or 2.0 mA. (See Table 6.) If the threshold values are greater than the recommended values, the lead should be repositioned; see the section on Acute Repositioning (page 30).

Initial intraoperative measurements may deviate from the recommended values because of acute cellular trauma. Should this occur, wait five to ten minutes and repeat the testing procedure. Values may vary depending on lead type, pulse generator settings, cardiac tissue condition and drug interactions.

**Sensing Threshold**

For pulse generators with demand mode capabilities, the sensing threshold should be verified at implant. The sensing threshold describes the largest stable endocardial signal that can be detected by the pulse generator's sensing circuitry. The sensing threshold is stated as the lowest sensitivity setting of the pulse generator's sensing circuitry that can appropriately sense the intrinsic endocardial signal. The sensing threshold is often defined by the pulse generator's sensitivity parameter (mV setting). Note that an intrinsic signal measuring 5.5 mV will be sensed when pulse generator sensitivity is programmed to 5.0 mV, but will not be sensed when sensitivity is set at 6.0 mV.

**NOTE**

**A higher mV setting decreases sensitivity, while a lower mV setting increases sensitivity.**

*Table 7  
Recommended Acute Sensing Thresholds*

Atrial	Ventricular
> 2.0 mV	> 5.0 mV

For an atrial lead, the sensing threshold should be greater than 2.0 mV. For a ventricular lead, the sensing threshold should be greater than 5.0 mV. If the acute sensing threshold falls below these recommended values, the lead should be repositioned. [See Table 7.]

When trying to determine an appropriate sensing signal, it is possible that an optimal signal cannot be found. This could lead to either undersensing (failure to sense an appropriate signal) or oversensing (sensing an inappropriate signal) if sensitivity is reprogrammed to a different mV setting. For bipolar programmable pulse generators, it may be useful to examine the intracardiac electrogram for unipolar and bipolar configurations to evaluate whether one signal is better than the other. If both signals are poor, a bipolar sensing configuration is generally preferable since it minimizes oversensing at a more sensitive setting.

**Lead Impedance**

Impedance values should also be verified at this time and entered on the patient chart. Impedance values are not related to stimulation and sensing thresholds. In general, lead impedance values should be between 300 and 1500 ohms. An impedance value lower than this range may be indicative of a problem with the lead insulation<sup>8</sup> while an impedance value higher than this range can indicate conductor fracture or poor lead connection to the pulse generator.

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## Acute Repositioning

If repositioning is required, hold the lead body stationary in one hand while rotating the grooved portion of the tool or the entire clip-on tool counterclockwise. Verify with fluoroscopy that the helix is completely retracted before attempting to withdraw the lead to reposition. Repeat the electrode fixation procedure at the new location.

## Anchoring the Lead

Before anchoring the lead, loosen both thumbscrews on the fixation tool and remove it from the lead connector. [See Figure 12.]

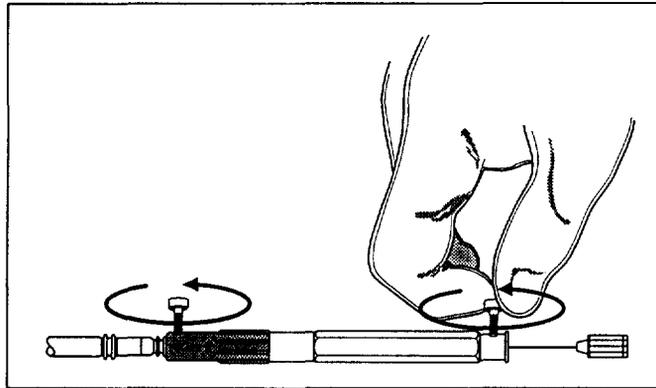


Figure 12

*Before anchoring the lead, remove the stylet (if not already done) and the fixation tool.*

*To remove the stylet, loosen the proximal thumbscrew (counterclockwise) and withdraw the stylet.*

*To remove the fixation tool from the lead connector, loosen the distal thumbscrew (counterclockwise) several turns. Do not attempt to remove the fixation tool without first loosening the distal thumbscrew; this might damage the connector pin.*

Once the lead has achieved a stable mechanical position and good thresholds have been obtained, the lead should be securely anchored at or near the venous entry site using the anchoring sleeve and a nonabsorbable synthetic suture. First secure the anchoring sleeve to the underlying tissue, then recheck lead position visually and under fluoroscopy (to prevent twisting of the lead and to identify inadvertent

retraction or advancement of the lead) before securing the ligature around the anchoring sleeve to secure the lead in place. Do not apply the ligature directly to the lead body, as this can damage the lead conductor, insulation or both. The suture around the anchoring sleeve and lead should not be tied too tightly, as this may also result in excessive stress applied to the lead body.

Once the lead is anchored, connect the lead to the pulse generator following the instructions in the pulse generator manual.

#### NOTES

**Use the anchoring sleeve to distribute the tension caused by the suture. Failure to use the anchoring sleeve may result in damage to the lead's insulation, conductor coil, or both. Care must be taken to prevent the anchoring sleeve from passing into the vein.**

**Ligature tied too tightly may result in excessive stress applied to the lead body.**

#### Chronic Repositioning

It is generally recommended that a chronically implanted endocardial pacing lead not be repositioned except in special circumstances. Should it be necessary to abandon an indwelling pacing lead, its connector pin should be removed from the pulse generator and capped, using the standard cap of the lead manufacturer. Never cut an indwelling pacing lead; this may cause the insulation to separate from the conductor coil and leave an exposed wire in the body. The extraction of any lead carries a clinical risk<sup>9</sup> and should only be undertaken with extreme caution. If the lead or any portion of it is extracted, it should be returned to Ventritex.

Should it be necessary to explant a chronically implanted lead, expose the lead entry site and remove the ligatures from around the anchoring sleeve with extreme caution so as not to damage the lead insulation or the anchoring sleeve itself.

After disconnecting the lead from the pulse generator, attach the fixation tool to the lead connector pin. Insert the appropriate stylet, contained in the model 4018 or 4019 repositioning kit, through the lumen in the back of the fixation tool. With extreme caution, advance the stylet fully into the lead. If using the clip-on tool, insert the stylet into the lead and attach the clip-on tool to the lead pin. Holding the lead body

stationary in one hand, rotate the grooved portion of the fixation tool (or the entire clip-on tool) counterclockwise and use fluoroscopy to observe helix retraction. Blood, fibrosis, or expansion of the MCRD within the helix may make it impossible to withdraw the helix with this method; if this occurs, rotate the lead body itself counterclockwise several turns. Note that blood, tissue ingrowth, and MCRD expansion which may occur with a chronically implanted lead impairs the extendable/retractable helix mechanism and thus can make it impossible for that same lead to be repositioned. If this is the case, replace it with a new lead.

Infection of the pacemaker system, particularly sepsis, generally requires the removal of both the pulse generator and lead(s).<sup>10</sup> Multiple abandoned leads and limitations to venous access are other common reasons to recommend lead extraction.

#### NOTES

**If a pacing lead is to be abandoned, it is recommended that it be capped and left in place rather than cut or removed.**

**If a pacing lead must be removed because of infection or for another serious reason, great care should be exercised, as lead extraction involves a clinical risk**

**Use a new lead if significant traction is required to disengage the chronic lead.**

#### Service

Members of Ventritex Technical Services Department are available to provide technical consultation 24 hours every day. This service can be obtained by dialing 1 800 722 3774. Additionally, highly trained sales and service professionals are located worldwide to assist you.

## References

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- 10 Belott PH, Byrd CL *op cit*, p. 121.



Manufactured by:

**ST. JUDE MEDICAL**  
CARDIAC RHYTHM MANAGEMENT DIVISION

15900 Valley View Ct.  
Sylmar, CA 91342  
(800) 777-2237  
(818) 362-6822

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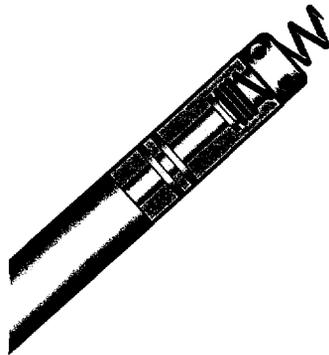
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*TENDRIL® DX*

Models 1388T/K  
Endocardial Steroid Eluting  
Screw-In Pacing Leads



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15900 Valley View Court  
Sylmar, CA 91342 USA  
800/777-2237 818/362-6822

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

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## Device Description

Tendril DX leads are silicone insulated, steroid-eluting, Titanium Nitride (TiN) coated, endocardial pacing leads, which may be either unipolar (Tendril DX 1388K), or bipolar (Tendril DX 1388T). Tendril DX leads are suitable for either atrial or ventricular placement. Tendril DX features active fixation, via a rotating extendible/retractable helix.

Tendril DX leads have a monolithic controlled-release device (MCRD), located in the tip electrode of the lead. The MCRD is a molded plug of silicone medical adhesive impregnated with less than one milligram of dexamethasone sodium phosphate (DSP). The steroid (DSP) decreases the inflammatory reaction of the heart during the acute stage (0-3 months post implant) of patient recovery.

## Indications for Use

The Tendril DX lead is designed for use in combination with a compatible pulse generator to provide permanent pacing and sensing in either the atrium or ventricle.

## Contraindications

The use of this endocardial lead is contraindicated:

- in the presence of tricuspid atresia and in patients with mechanical tricuspid valves<sup>1</sup>
- in patients with tricuspid valvular disease

- in patients who are expected to be hypersensitive to a single dose of 1.0 milligram of dexamethasone sodium phosphate.

## Warnings

- *Only battery powered equipment should be used during lead implantation and testing to protect against fibrillation which may be induced by alternating currents.*
- *Any line-powered equipment used in the vicinity of the patient during the implant procedure should be properly grounded.*
- *Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.*
- *The Tendril DX lead and its accessories are intended for one time use only. Do not reuse.*

## Precautions

### General

- Do not sterilize this lead using an autoclave, gamma radiation or ultrasonics.
- The manipulation of any and all hardware while in the vascular system should only be performed under continuous fluoroscopic monitoring.
- Prior to opening the lead package, confirm that it is compatible with the pulse generator to be implanted.

## Handling and Storage

- Cardiac pacing leads can be damaged by improper handling before and during implant or by excessive mechanical stress post-implantation.
- The lead conductor, its insulating sheath, and the helix mechanism may be damaged if subjected to extreme mechanical stress.
- Do not stretch, crush, kink, or bend the lead.
- Avoid bringing the lead in contact with any sharp objects which could puncture or otherwise compromise the insulation.
- Do not handle the lead except with powderless, sterile surgical gloves.
- Avoid handling the lead with any surgical tools, e.g. hemostats, clamps, forceps.
- Leads have an electrostatic affinity for particulate matter; do not expose them to lint, dust or other such materials.
- The lead is supplied with the helix in its fully retracted position. Avoid touching or handling the helix itself.
- Do not immerse the lead body in mineral oil, silicone oil or any liquid other than sterile saline or injectable fluid.
- Do not immerse the tip electrode in any fluid prior to implantation. Immersion of the electrode may cause a small amount of steroid to be prematurely eluted from the helix housing.
- The lead should be stored at temperatures between -5°C (23°F) and 55°C (131°F).

## Implantation

- Lead implantation should only be performed when proper emergency facilities for cardioversion and/or defibrillation are available.
- If subclavian venipuncture is used for lead introduction, it is important to avoid extremely medial entry of the lead into the vein, which may contribute to lead conductor fracture or other lead damage.<sup>2</sup>
- Electrode dislodgment or displacement may produce erratic, intermittent or total loss of pacing or sensing. It may also induce atrial or ventricular ectopy.
- Perforation of the atrial or ventricular wall may cause phrenic nerve stimulation, diaphragmatic stimulation or, in some instances, cardiac tamponade.<sup>3</sup> Phrenic nerve or diaphragmatic stimulation may also result from lead position.
- Use the anchoring sleeve to distribute the tension created by the suture used to secure the lead at or near the venous entry site. Failure to use the anchoring sleeve may result in damage to the lead's insulation or conductor coil or both.

## Adverse Events

The Tendril DX model 1388T clinical trials involved 521 devices (398 model 1388T leads, 123 model 1188T leads) implanted in 303 patients. Cumulative duration for atrial implantation of model 1388T is 19,477 days (mean implant duration 108.8 days, range 5 to 205 days). Cumulative implant duration for model 1388T leads positioned in the ventricle was 24,155 days (mean implant duration 110.3 days, range 0 to 205 days). Adverse events (AEs) are listed in Table 1 and Table 2.

A total of 10 patients died during the course of this clinical trial. None of these deaths were deemed lead related.

In addition to the adverse events reported during the course of the clinical trial, other possible adverse events which may occur based on historical experience with this type of device include:

- embolism
- excessive bleeding
- thrombosis
- infection
- induced atrial or ventricular ectopy
- phrenic nerve stimulation
- diaphragmatic stimulation
- cardiac tamponade
- loss of pacing and or sensing due to dislodgment or mechanical malfunction of the pacing lead.

Table 1. Tendril DX Model 1388T, Atrial Leads

Device-Related Complications	Number of Patients (n=179)	% of Patients	Number of Leads	Adverse Events per Lead-Month
Loss of sensing	1	0.6	1	0.00313*
Loss of Capture or Elevated Thresholds	2	1.1	2	0.00313
Lead Dislodgment	2	1.1	2	0.00313
Difficulty with Lead Placement	1	0.6	1	0.00156
Cardiac Perforation	0	0.0	0	0.0
High Lead Impedance	0	0.0	0	0.0
Low Lead Impedance	1	0.6	1	0.00156
Cardiac Tamponade	1	0.6	1	0.00156
Coil Damage	1	0.6	1	0.00156
Device-Related Observations	Number of Patients (n=179)	% of Patients	Number of Leads	Adverse Events per Lead-Month
Low Lead Impedance	1	0.6	1	0.00156
<b>Total (any adverse event)</b>	<b>10</b>	<b>5.6</b>	<b>10</b>	<b>0.01718</b>

Device Related Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require physician intervention.

Device Related Observations are defined as symptomatic or asymptomatic device related clinical events which do not require physician intervention.

\* One lead experienced loss of atrial sensing on two separate occasions.

Table 2. Tendril DX Model 1388T, Ventricular Leads

Device-Related Complications	Number of Patients (n=219)	% of Patients	Number of Leads	Adverse Events per Lead-Month
Loss of sensing	1	0.5	1	0.00126
Loss of Capture or Elevated Thresholds	5	2.3	5	0.00630
Lead Dislodgment	1	0.5	1	0.00126
Difficulty with Lead Placement	0	0.0	0	0.0
Cardiac Perforation	1	0.5	1	0.00126
High Lead Impedance	0	0.0	0	0.0
Low Lead Impedance	1	0.5	1	0.00126
Cardiac Tamponade	1	0.5	1	0.00126
Coil Damage	0	0.0	0	0.0
Device-Related Observations	Number of Patients (n=219)	% of Patients	Number of Leads	Adverse Events per Lead-Month
None	0	0	0	0
<b>Total (any adverse event)</b>	<b>10</b>	<b>4.6</b>	<b>10</b>	<b>0.01259</b>

Device Related Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require physician intervention.

Device Related Observations are defined as symptomatic or asymptomatic device related clinical events which do not require physician intervention.

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## Clinical Trials

A multicenter, prospective, randomized control clinical trial was conducted to compare the capture thresholds of the model 1388T lead through three months post implant to those of a commercially available, non-steroid active-fixation lead (model 1188T). Patients were randomized to receive either a model 1388T or 1188T lead in the atrium and/or ventricle using a 3:1 randomization ratio (three model 1388T leads to each model 1188T lead).

Lead electrical performance characteristic, including capture thresholds and sensing thresholds, were evaluated at implant and at 14 days ( $\pm 4$  days), 30 days ( $\pm 7$  days), 90 days ( $\pm 14$  days), and 180 days ( $\pm 30$  days) post implant.

A total of 521 devices were implanted (398 model 1388T leads and 123 model 1188T leads) as of March 15, 1996. The average patient age at implant was 70 years with 66% male and 34% female patients, respectively. Statistical comparison of the patient populations receiving the model 1388T and 1188T leads (Table 3) indicate no statistically significant differences in patient demographics (age and sex), physiologic conditions which could affect pacing thresholds or medications which could affect pacing thresholds.

The only statistically significant difference between the populations involved the percentage of patients with sick sinus syndrome as the primary indication for implant. For patients receiving ventricular leads, 51.7% receiving the control lead had sick sinus

syndrome as a primary indication whereas the proportion was 35.6% for patients receiving the investigational lead. Since sick sinus syndrome is a disorder affecting the sinus node (located in the atrium), this difference would not impact ventricular lead performance and therefore would not bias study results.

Analysis of the clinical data collected as of March 15, 1996 demonstrated that the presence of the MCRD in the fixation helix results in a significant reduction in capture thresholds through three months post implant relative to an active-fixation lead without a steroid release mechanism (Table 4 and Table 5).

Although the addition of a steroid release device to the model 1388T lead has been shown to reduce capture thresholds relative to a non-steroid control lead, the Tendril DX clinical trial did not specifically address whether or not the addition of the MCRD also reduces the incidence of exit block. Therefore, at present, there is no objective clinical evidence that the incidence of exit block for Tendril DX leads will be less than that observed with non-steroid active-fixation leads.

Table 3. Comparison of patients Receiving 1388T and 1188T Leads

Variables	Atrial			Ventricular		
	1188T	1388T	Statistics	1188T	1388T	Statistics
Gender						
Male	45 (69.2%)	112 (62.6%)	Fisher's Exact Test $p = 0.367$	36 (62.1%)	144 (65.8%)	Fisher's Exact Test $p = 0.643$
Female	20 (30.8%)	67 (37.4%)		22 (37.9%)	75 (34.3%)	
Age(years):						
Range	20.0 - 95.1	8.9 - 102.8	$t = 0.4957$ d.f. 145.8 $p = 0.621$	42.7 - 91.7	15.0 - 102.8	$t = 0.9372$ d.f. 126.8 $p = 0.350$
Mean	70.6	69.7		72.7	71.2	
STD	12.0	15.4		9.3	13.4	
Primary Indication						
Sick Sinus:			Fisher's Exact Test $p = 0.769$			Fisher's Exact Test $p = 0.034$
Reported	28 (43.1%)	72 (40.2%)		30 (51.7%)	78 (35.6%)	
Normal *	37 (56.9%)	107 (59.8%)		28 (48.3%)	141 (64.4%)	
Sinus Bradycardia:			Fisher's Exact Test $p = 0.669$			Fisher's Exact Test $p = 0.378$
Reported	7 (10.8%)	25 (14.0%)		5 (8.6%)	30 (13.7%)	
Normal *	58 (89.2%)	154 (86.0%)		53 (91.4%)	189 (86.3%)	
Heart Block:			Fisher's Exact Test $p = 0.469$			Fisher's Exact Test $p = 0.232$
Reported	32 (49.2%)	78 (43.6%)		20 (34.5%)	96 (43.8%)	
Normal *	33 (50.8%)	101 (56.4%)		38 (65.5%)	123 (56.2%)	
PCAPT:			Fisher's Exact Test $p = 0.857$			Fisher's Exact Test $p = 0.714$
Condition(s)	12 (18.5%)	36 (20.2%)		13 (22.4%)	43 (19.7%)	
None	53 (81.5%)	142 (79.8%)		45 (77.6%)	175 (80.3%)	
Not Reported**	0	1		0	1	
MAPT:			Fisher's Exact Test $p = 0.208$			Fisher's Exact Test $p = 0.646$
Not reported at Implant	41 (63.1%)	129 (72.1%)		35 (60.3%)	141 (64.4%)	
Reported at Implant	24 (36.9%)	50 (27.9%)		23 (39.7%)	78 (35.6%)	
<b>Total Patients within Lead Group</b>	<b>65</b>	<b>179</b>		<b>58</b>	<b>219</b>	

\* Normal Function, relative to the corresponding Primary Indication

\*\* Not included in statistical analysis

PCAPT = Physiological Conditions Affecting Pacing Thresholds

MAPT = Medications Affecting Pacing Thresholds

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Table 4. Atrial Capture Thresholds (V) at 0.4 ms Pulse Width

Follow-Up	Unipolar: mean ± SD <sup>1</sup> (N) <sup>2</sup>			Bipolar: mean ± SD <sup>1</sup> (N) <sup>2</sup>		
	1188T	1388T	P value <sup>3</sup>	1188T	1388T	P value <sup>3</sup>
implant	1.1±0.4 (59)	0.9±0.4 (160)	0.0002	1.1±0.4 (61)	0.8±0.4 (162)	0.0001
two week	2.2±1.0 (56)	0.9±0.4 (153)	0.0001	2.6±1.3 (59)	1.0±0.5 (154)	0.0001
one month	2.1±0.7 (57)	0.9±0.4 (151)	0.0001	2.4±0.9 (59)	1.0±0.3 (154)	0.0001
three month	2.0±0.8 (28)	0.9±0.3 (89)	0.0001	2.1±0.9 (29)	1.0±0.4 (89)	0.0001
six month	1.5±0.7 (2)	0.8±0.3 (3)	*	2.0±0.7 (2)	0.8±0.3 (3)	*

1. SD = standard deviation
  2. N = sample size
  3. Wilcoxon Rank Sum Test
- \* Sample size too small to perform statistical analysis.

Table 5. Ventricular Capture Thresholds (V) at 0.4 ms Pulse Width

Follow-Up	Unipolar: mean ± SD <sup>1</sup> (N) <sup>2</sup>			Bipolar: mean ± SD <sup>1</sup> (N) <sup>2</sup>		
	1188T	1388T	P value <sup>3</sup>	1188T	1388T	P value <sup>3</sup>
implant	0.9±0.5 (55)	0.7±0.3 (208)	0.0001	0.9±0.3 (54)	0.8±0.3 (212)	0.0001
two week	2.4±1.3 (57)	1.0±0.4 (193)	0.0001	2.8±1.4 (56)	1.0±0.4 (197)	0.0001
one month	2.3±1.3 (55)	1.0±0.4 (195)	0.0001	2.5±1.1 (54)	1.0±0.4 (196)	0.0001
three month	2.0±0.9 (33)	1.0±0.5 (106)	0.0001	2.3±0.9 (33)	1.0±0.6 (109)	0.0001
six month	2.0 (1)	0.8±0.3 (5)	*	2.0 (1)	1.0±0.0 (5)	*

1. SD = standard deviation
  2. N = sample size
  3. Wilcoxon Rank Sum Test
- \* Sample size too small to perform statistical analysis.

## Detailed Device Description

The implantable endocardial screw-in pacing leads from Pacesetter are designed for use with implantable pulse generators for long-term cardiac pacing. They are passed transvenously to the heart and attached to the endocardium. Once properly fixated, the pacing lead is connected to the pulse generator.

Steroid will be slowly released through the helix housing upon contact with body fluid. The drug promotes low acute to chronic pacing threshold by suppressing the inflammation response to a foreign body.

The lead conducts stimulating pulses from the pulse generator to the heart and, in demand pacing modes, delivers electrical information on the intrinsic cardiac activity to the sense amplifiers of the pulse generator.

The endocardial screw-in leads are available in both unipolar and bipolar models. 1388K unipolar leads have one conductor that terminates at the tip helix. 1388T bipolar leads have two conductors: one terminating at the tip helix (cathode) and the other at the larger, microporous titanium nitride-coated ring electrode (anode) approximately 10 millimeters from the tip.

Endocardial screw-in leads comply with IS-1 connector standard ISO 5841-3.

All implantable pacing leads from Pacesetter are made of biocompatible materials.

### NOTE

A pacing lead explanted for any reason should never be implanted in another patient.

### NOTE

Because of the numerous available 3.2 mm configurations, e.g. the IS-1 and VS-1 standards, lead/pulse generator compatibility should be confirmed with the pulse generator and/or lead manufacturer(s) prior to implantation of a pacing system.

### Contents of Package

The contents of the package are sterile. Each package contains:

- One screw-in pacing lead with anchoring sleeve attached
- One fixation tool
- One vein lifter
- Stainless steel stylets
- Two clip-on tools

## Operating Instructions

### Lead Selection

There are many factors to take into account when choosing a pacing lead. The first is compatibility with the pulse generator, which may be verified by consulting with your Pacesetter representative and, if applicable, the pulse generator manufacturer. Compatibility includes the size, connector configuration and polarity (unipolar or bipolar).

Many pulse generators offer programmable polarity, meaning that pacing and/or sensing may be

programmed to function in a unipolar or bipolar configuration. The bipolar, steroid eluting screw-in lead may function in either a unipolar or bipolar configuration, depending on how the pulse generator is programmed.

Some pulse generators offer independently programmable polarity for both pacing and sensing. Unipolar pacing produces a relatively large pacing artifact that is easily recognizable on a surface ECG. However, unipolar pacing may cause skeletal muscle stimulation in the pocket area. Unipolar sensing may be more sensitive to extracardiac signals than bipolar sensing.

Bipolar pacing is much less likely to cause muscle stimulation than unipolar pacing. However, the bipolar pacing spike is usually very small and may be difficult to discern on a surface ECG. Bipolar sensing is known to be much less affected by myopotentials and external interference than unipolar sensing.<sup>4</sup>

## Implantation

The goal of any lead implantation is to minimize mechanical stresses on the pacing lead while simultaneously maximizing the lead's electrical contact with cardiac tissue. Pacing leads should only be implanted in conjunction with simultaneous fluoroscopic verification of lead position.

### CAUTION

*The manipulation of any and all hardware while in the vascular system should only be performed under continuous fluoroscopic monitoring.*

### CAUTION

*Lead implantation should only be performed when proper emergency facilities for cardioversion and/or defibrillation are available. An adequate number of trained personnel should be present during the procedure.*

## Sterilization

The package and its contents have been sterilized with ethylene oxide for direct introduction into the surgical field. Before the package is opened, inspect it visually for any damage that may have compromised sterility.

If resterilization is necessary, place the lead and accessories in a gas-permeable package and resterilize in ethylene oxide. The sterilizer temperature should not exceed 52°C (125°F). After sterilization, allow the lead to aerate at 52°C (125°F) for at least 12 hours to allow dissipation of ethylene oxide residuals prior to implantation. Use biological controls to verify the effectiveness of the resterilization.

### CAUTION

*Do not sterilize this lead using an autoclave, gamma radiation or ultrasonics.*

### NOTES

**The lead may be resterilized only once.**

## Lead Preparation

It is important that the implanting physician completely understand the mechanical operation of this lead before surgery.

The lead comes preloaded with the stylet in the fixation tool (Figure 1). The lead is held securely in the fixation tool by the distal thumbscrew.

If a different stylet is desired, loosen the proximal thumbscrew by turning it counterclockwise. Then remove the preinserted stylet, insert the new stylet into the lumen of the fixation tool, and advance it through the lead.

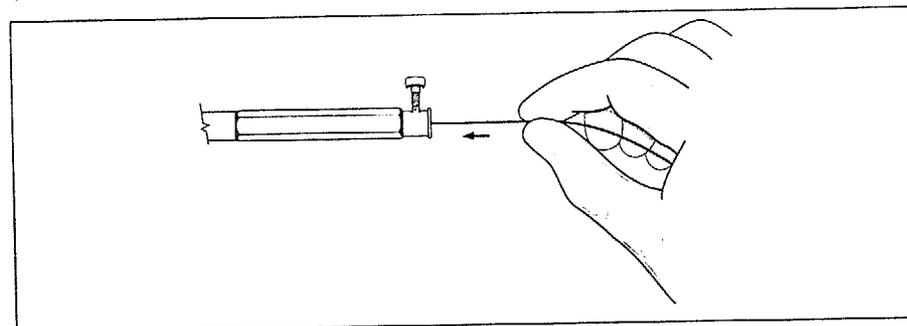


Figure 1

*The stylet is secured with the proximal thumbscrew.*

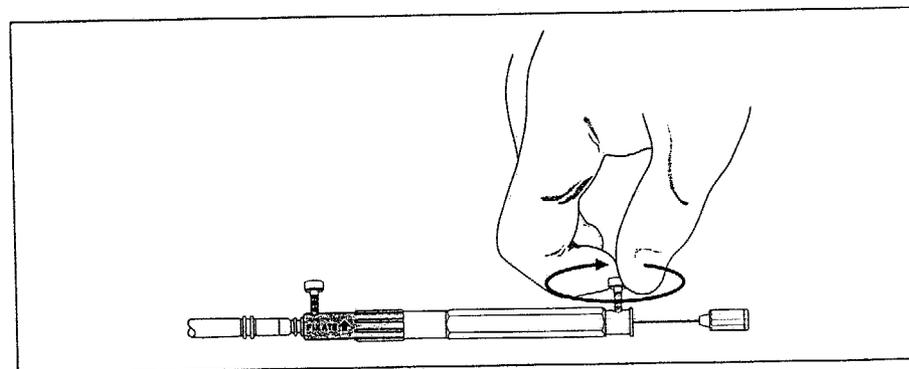


Figure 2

*Fully advance the stylet. Then hold it in place by tightening the proximal thumbscrew clockwise.*

Remove the lead with fixation tool from the tray. Place it on a clean, lint-free, sterile field.

Test the operation of the extendable/retractable helix before implantation. Secure the stylet by turning the proximal thumbscrew clockwise (Figure 2). With the fixation tool in one hand, hold the lead body itself stationary with the other hand. Rotate the grooved gray section of the tool clockwise (as indicated by the arrow on the tool marked "FIXATE") and observe the helix extend from the lead tip. The helix is considered fully extended when two full turns are visible beyond the lead's inactive platinum collar, which serves as a radiopaque indicator. (See Figure 3.)

The helix may be retracted by holding the lead body stationary in one hand and turning the grooved gray portion of the tool counterclockwise (opposite the direction indicated by the arrow "FIXATE"). (See Figure 4.)

Verify proper mechanical operation before proceeding with implantation.

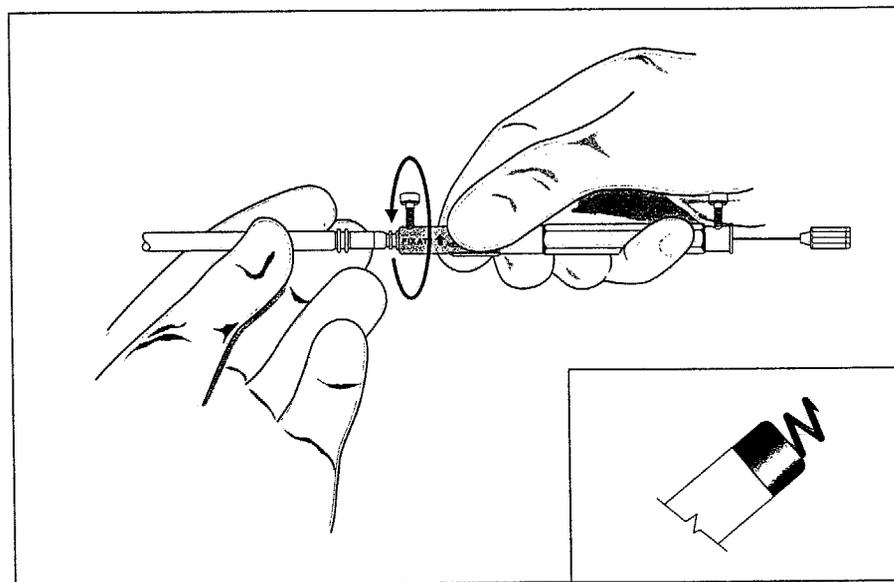


Figure 3

Extend the helix by holding the lead body stationary in one hand and turning the gray grooved portion of the tool clockwise (in the direction indicated by the arrow "FIXATE").

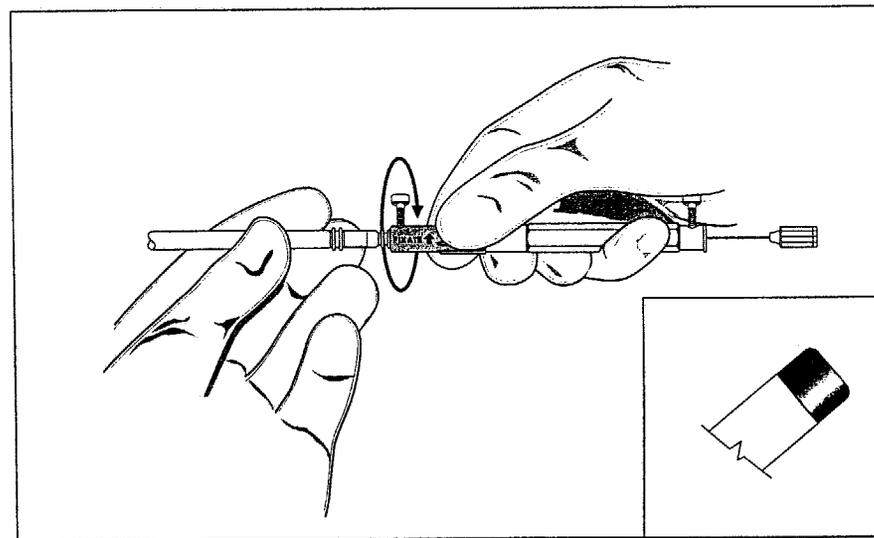


Figure 4

Retract the helix by holding the lead body stationary in one hand and turning the gray grooved portion of the tool counterclockwise (in the opposite direction indicated by the arrow "FIXATE").

## Venous Routes

There are several venous routes for passing the endocardial pacing lead, including either the right or left cephalic, subclavian, axillary or internal or external jugular veins. Veins may be accessed using the cut-down or venipuncture method.

Any of the above veins may be used for the cut-down technique. In the cut-down technique, the desired vein is identified and a small incision is made for lead insertion. The vein lifter tool, included in this package, can be used to hold open and dilate the vein, facilitating lead insertion.

A vein lifter facilitates lead introduction into an exposed vein. Insert its tapered end into the incised vein and gently push the lead tip underneath the exposed wall and into the vein. Then gently lift to create an opening through which the lead may be inserted. (See Figure 5.)

The subclavian puncture method requires the use of a percutaneous lead introducer kit. Use the needle in the introducer kit to puncture the vein. Take the guide wire and advance the J straightener over the J-shaped tip to facilitate placement of the guide wire into the needle and thus into the vein. Remove the needle, leaving the guide wire in place. The J configuration to the tip minimizes trauma to the vessel and facilitates passage.

When the guide wire is in the right atrium, advance the dilator and sheath

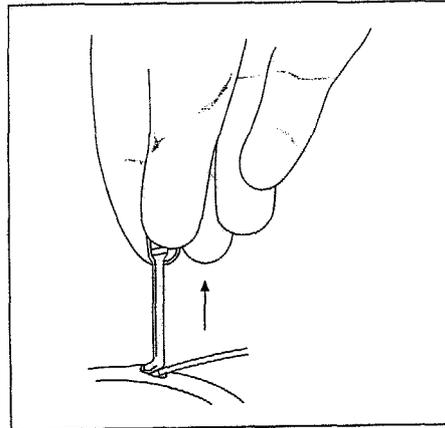


Figure 5

*When using the cut-down technique, the vein lifter facilitates lead introduction. Insert its tapered end into the vein and gently lift.*

with a rotating motion over the guide wire and into the vein. To remove the dilator, hold the T handle of the sheath and rotate the dilator counterclockwise. (These instructions assume the use of a Pacesetter introducer. If another type of introducer is used, follow the manufacturer's directions.) Retract the guide wire and dilator, leaving the sheath in position. Introduce the pacing lead with inserted stylet into the sheath and advance the lead into position.

When the lead is properly positioned, remove the sheath by using the tabs on either side to tear the sheath down and away. For more information on the subclavian puncture method using the percutaneous introducer kit, please consult the introducer manual.

## CAUTION

*To reduce the potential for conductor fracture or other lead damage when using the subclavian puncture method, avoid extremely medial placement of the point of entry of the endocardial lead through the infraclavicular space.<sup>5</sup>*

## NOTE

**The normal status of the subclavian vein often renders it difficult to puncture unless it is distended by raising the patient's legs to a 45° angle or by using the Trendelenburg position. The vein will be much easier to locate if the patient is well hydrated.<sup>6</sup>**

## NOTE

**When retracting the guide wire and dilator in the subclavian puncture technique, manually compress or cover the opening of the introducer sheath to avoid inadvertent air aspiration.**

## Dual-Chamber Pacemakers

Dual-chamber pacemakers require the implantation of two leads, one in the atrium and the other in the ventricle. Two leads may be implanted by making two venipunctures, by making one puncture and using an introducer sufficiently large to accommodate both leads or by using a variation of the retained guide wire technique. The retained guide wire technique, the most commonly used method, involves using

the introducer in one venipuncture but removing the guide wire and dilator together before the lead is inserted into the sheath. For the second lead, the guide wire is reinserted down the first sheath; the first sheath is then removed and the second sheath placed over the guide wire. The guide wire is then removed and the second lead is inserted through the second sheath.<sup>7</sup>

Fast Pass® molecular coating is designed to facilitate the passage and the positioning of two silicone leads by creating a highly lubricious lead surface. This is of particular importance when using the retained guide wire technique, or a single large sheath where two leads are introduced into the same puncture site.

## Stylets

Every Pacesetter lead comes supplied with stylets. When inserted into the pacing lead through the lumen of the fixation tool, the stylet gives the lead sufficient rigidity to be manipulated easily through the vein and into the heart. The stylet should be inserted into the lead before the lead is inserted into the vein. The stylet should be removed before testing the lead for mechanical stability or making intraoperative measurements.

A straight stylet may be curved by running it firmly over a blunt, sterile instrument.

Straight stylets are indicated by a red cap; J stylets are indicated by a bone white cap.

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## Ventricular Lead Placement

Make sure that the helix is in the fully retracted position before attempting to insert the lead.

### NOTE

Ensure that there is a stylet inserted in the lead before attempting to introduce the lead. Always remove the stylet before checking mechanical stability or intraoperative measurements.

### NOTE

Take care to avoid contaminating the stylet with blood. Blood introduced into the core of the lead via the stylet may cause the stylet to bind, so that it cannot be advanced or manipulated. If this problem occurs, remove the lead and replace it with a new one.

Secure the stylet in place by gently tightening the proximal thumbscrew on the fixation tool clockwise. Advance the lead cautiously under fluoroscopic observation into the right atrium. Remove the straight stylet by loosening the thumbscrew (counterclockwise) and then withdrawing the stylet. Take a new stylet, curve it gently and insert it into the lumen of the fixation tool, holding it in place with the proximal thumbscrew. This curve helps the lead negotiate its way across the tricuspid valve as it is gently manipulated into the right ventricle. Once the lead is in the right ventricle, loosen the thumbscrew, retract the stylet slightly (to minimize the chance of perforation of the cardiac wall) and again tighten the thumbscrew to secure the stylet for lead positioning.

An alternative method involves using the straight stylet with the lead in the right atrium. Retract the straight stylet a few centimeters so that the lead tip is floppy. (Loosen the proximal thumbscrew, retract the stylet, then tighten the thumbscrew again to accommodate the new position.) Gently advance sufficient lead within the right atrium so that a loose loop forms. Under fluoroscopic observation, allow this loop to flip or prolapse through the tricuspid valve so that the loop passes through the valve first, drawing the tip through afterward.

Once the lead is in the right ventricle, advance it cautiously toward the right ventricular apex. To avoid the inadvertent placement of the lead in the coronary sinus, it may be useful to advance the lead through the right ventricle and into the pulmonary artery. At this point, replace the curved stylet with a straight stylet (if necessary) and gently withdraw the lead into the right ventricle.

Once the lead is in a potentially suitable location, the lead should then be fixated to the ventricular wall using the method described in the section on Electrode Fixation (page 18).

### NOTE

If the stylet is partially retracted to increase the flexibility of the lead tip, be sure to readvance the stylet before fixating the lead to the endocardium. It is not possible to fixate the lead unless the stylet is fully inserted.

## Atrial Lead Placement

Make sure that the helix is in the fully retracted position before attempting to insert the lead.

Using fluoroscopy, advance the lead cautiously into the atrium. If resistance is encountered, pull the lead back a short

distance and readvance it, repeating this procedure as often as necessary. If this technique is ineffective, withdraw the stylet 2 to 4 cm, allowing the tip to become floppy.

Advance the lead; once past the obstruction, cautiously readvance the stylet.

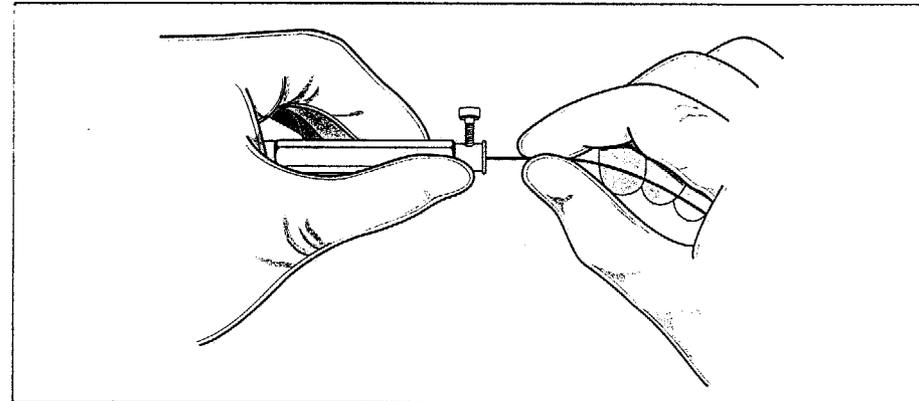


Figure 6

To prevent inadvertent bending or kinking of the stylet, advance it slowly. Moving the body of the pacing lead backward and forward slightly while advancing the stylet may also help to reduce the insertion force required.

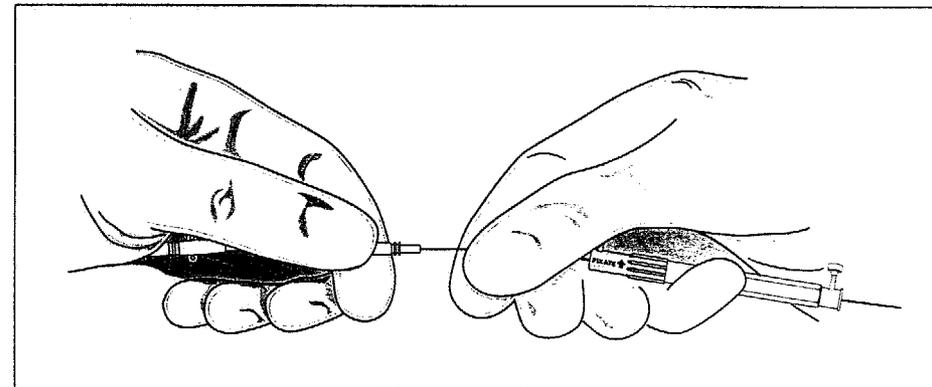


Figure 7

If advancement of the stylet is still difficult, loosen the thumbscrew and remove the fixation tool from the connector pin of the pacing lead. Then, grasp the stylet and push it just beyond the point where it enters the connector pin as shown. Once the stylet is fully advanced, reattach the tool to the connector pin of the lead to allow helix extension and fixation.

Guide the lead into the right atrium and into the inferior vena cava. Loosen the proximal thumbscrew and remove the straight stylet, replacing it with a J-shaped stylet and securing it in place by tightening the proximal thumbscrew. Once the J-shaped stylet is fully inserted, the lead will take on a J shape.

If one or more tight bends are induced in the lead as a result of placement in the patient's vascular system, additional force may be required to advance the stylet (particularly a J-shaped stylet) through the lead body. If resistance is encountered, prior to using additional force to advance the stylet, advance the entire lead body past the point of tortuosity until the stylet can again be advanced easily and without resistance. If resistance is still encountered, use gentle force on the stylet to attempt to advance the stylet. When this force is applied to the stylet near the end of the fixation tool, the stylet may tend to bow up or become kinked, making advancement even more difficult.

Follow the procedures illustrated in Figures 6 and 7 to reduce any chance of the stylet kinking during implant.

#### CAUTION

*Do not advance or manipulate the stylet or lead without the aid of direct fluoroscopic observation.*

#### Electrode Fixation

Locate the desired fixation site. Hold the lead body stationary in one hand and turn the grooved section of the fixation tool approximately 8 turns (for 58 cm lead) clockwise (in the direction marked "FIXATE"). (See Figure 8.) On the fluoroscopic image, the helix will be seen to extend beyond the platinum cap. The helix is fully extended when two full turns extend past the cap. (See Figure 9.) Use fluoroscopy to verify helix extension. Since the lead design allows for a versatile fixation site, it may be necessary to rotate the C-arm or to advance the lead body in order to see the entire helix.

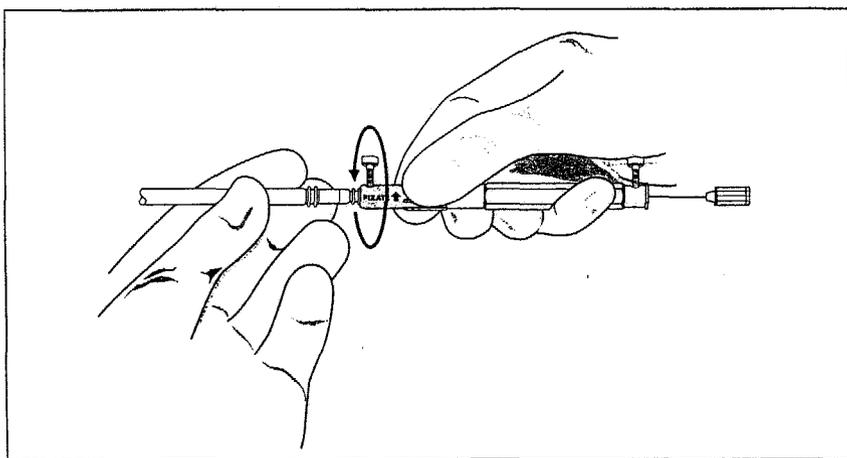


Figure 8

*Hold the lead body stationary in one hand and the fixation tool in the other. Rotate the grooved portion of the tool in the direction of the arrow shown at "FIXATE." The helix extends.*

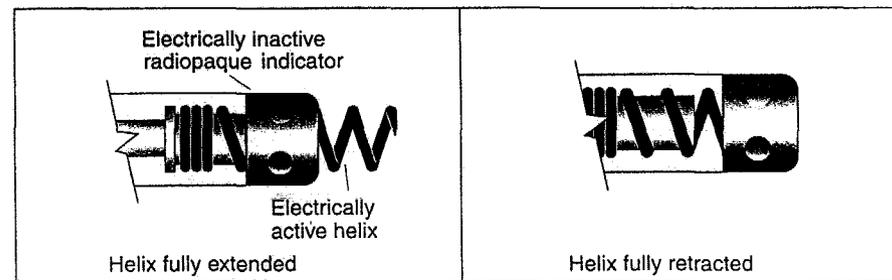


Figure 9

*When the helix is fully extended, two full turns will be visible beyond the platinum cap when the lead tip is viewed under fluoroscopy.*

Once fixation is verified, loosen the proximal thumbscrew and carefully withdraw the stylet under fluoroscopic observation. The lead tip should remain in position. Exercise caution during stylet retraction to avoid dislodging the lead.

Retraction of the J-shaped stylet may be more difficult than retraction of a straight stylet. A recommended method for retracting a J-shaped stylet is to loosen the proximal thumbscrew and hold the stylet handle manually; then gently advance the lead body into the atrium while simultaneously, but more slowly, advancing the stylet. Advance about twice as much lead as stylet; in this way, the J shape widens and the stylet can be more readily removed.

#### Optional Clip-On Tool

Included in the package are two optional clip-on tools which may be used to extend or retract the helix. To use the clip-on tool, remove the preassembled fixation tool and stylet. Reinsert the stylet into the lead, pinch open the clip-on tool (Figure 10) and insert the lead terminal pin so that it fits snugly in the notch in the clip-on tool. Release the handles so that the clip-on

tool firmly grasps the lead connector. Rotate the clip-on tool clockwise to extend the helix (Figure 11). To remove the clip-on tool, pinch it together and withdraw it from the lead connector.

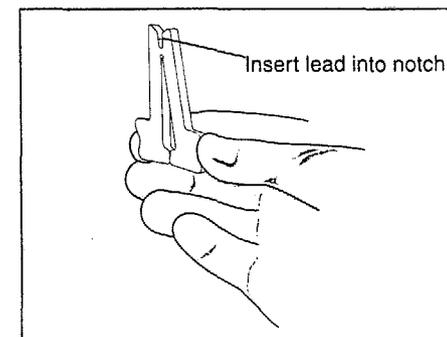


Figure 10

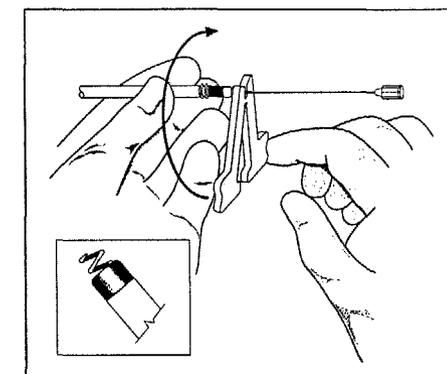


Figure 11

10

## NOTE

Do not push the lead connector to the back portion of the clip-on tool (Figure 10). This action might cause the terminal pin to bend. Insert the connector only as far as the notch.

## Intraoperative Measurements

Once the lead is fixated, it is very important to verify stimulation threshold and sensing capability during implantation. A measuring device, such as a pacing system analyzer (PSA) is recommended for these electrical measurements.

While initial threshold measurements may be taken with the fixation tool attached, it is recommended that the stylet be removed for taking final threshold measurements.

## NOTE

When withdrawing the stylet, look for any signs of residual torque (looping, figure-8 twists in the lead body, etc.). It is important to relieve this tension by turning the fixation tool counterclockwise until the tension dissipates.

## NOTE

Threshold measurements must always be obtained after fixation. Pre-fixation threshold values are guideline values only.

## WARNING

A pacing lead inserted into the heart presents a direct, low-impedance pathway for current flow to the myocardium. Use only battery-powered test equipment for electrical measurements.

## Connection to Pacing System Analyzer

Make sure that the percutaneous lead introducer and stylet are removed from the lead and that the lead is fixated in what is believed to be a suitable location.

Use the PSA cables to connect the terminal pin of the implanted pacing lead to the PSA. It is recommended that the PSA be programmed OFF or to a passive setting while connections are being made.

For bipolar leads, connect the positive PSA cable (red) to the lead connector's terminal ring (associated with the anode ring electrode) and connect the negative PSA cable (black) to the lead connector pin (cathode).

## NOTE

Alligator clips should be carefully applied to the in-line bipolar terminal pin to avoid damaging the insulation between terminal pins.

For unipolar leads, connect the positive PSA cable (red) to an indifferent electrode or large metal instrument placed into the pocket and connect the negative PSA cable (black) to the lead connector pin (cathode).

## NOTE

Do not use an alligator clip as an indifferent electrode by connecting it directly to tissue. This causes tissue trauma and provides a very small surface area, giving inaccurate voltage thresholds and impedance measurements.

For more information on the use of the PSA, please refer to the PSA manual.

## Stimulation Threshold

As a general rule, the stimulation threshold (i.e. the output values needed to reliably and consistently capture the heart) is lowest in the acute phase. The stimulation threshold can be expected to increase during the next several weeks after implant and then remain at the new value or decrease slightly to stabilize, typically at one to three months post-implantation.

In selecting output parameter values for the pulse generator (pulse amplitude and pulse width) every effort should be made to obtain the lowest possible settings and provide an adequate safety margin. An adequate safety margin assures that capture will occur even if the patient's threshold increases over time. Once lead maturation has occurred, an adequate safety margin can be maintained with lower output settings as the threshold is no longer likely to change markedly.

Reducing the output can increase pulse generator longevity. The stimulation threshold provides the necessary data so that the lowest possible output parameters may be selected while, at the same time, preserving a safety margin that reliably assures capture. A safety margin of two to three times the voltage stimulation threshold is generally considered adequate.

## NOTE

Thresholds are measured using either pulse amplitude (voltage) or pulse width (milliseconds). Doubling the pulse amplitude quadruples the energy output of the pulse generator, while doubling the pulse width doubles the energy output.

Table 6  
Recommended Acute Stimulation Thresholds  
(0.4 ms pulse width, 500  $\Omega$  lead impedance)

Atrial	Ventricular
< 1.5 V	< 1.0 V
< 3.0 mA	< 2.0 mA

Using a 0.4 ms pulse width and assuming a 500 ohm load, it should be possible to obtain an acute atrial stimulation threshold of less than 1.5 V or 3.0 mA. For a ventricular lead, it should be possible to obtain an acute ventricular stimulation threshold of less than 1.0 V or 2.0 mA. (See Table 6.) If the threshold values are greater than the recommended values, the lead should be repositioned; see the section on Acute Repositioning (page 22).

Initial intraoperative measurements may deviate from the recommended values because of acute cellular trauma. Should this occur, wait five to ten minutes and repeat the testing procedure. Values may vary depending on lead type, pulse generator settings, cardiac tissue condition and drug interactions.

### Sensing Threshold

For pulse generators with demand mode capabilities, the sensing threshold should be verified at implant. The sensing threshold describes the largest stable endocardial signal that can be detected by the pulse generator's sensing circuitry. The sensing threshold is stated as the lowest sensitivity setting of the pulse generator's sensing circuitry that can appropriately sense the intrinsic endocardial signal. The sensing threshold is often defined by the pulse generator's sensitivity parameter (mV setting). Note that an intrinsic signal measuring 5.5 mV will be sensed when pulse generator sensitivity is programmed to 5.0 mV, but will not be sensed when sensitivity is set at 6.0 mV.

**NOTE**  
A higher mV setting *decreases* sensitivity, while a lower mV setting *increases* sensitivity.

Table 7  
Recommended Acute Sensing Thresholds

Atrial	Ventricular
> 2.0 mV	> 5.0 mV

For an atrial lead, the sensing threshold should be greater than 2.0 mV. For a ventricular lead, the sensing threshold should be greater than 5.0 mV. If the acute sensing threshold falls below these recommended values, the lead should be repositioned. (See Table 7.)

When trying to determine an appropriate sensing signal, it is possible that an optimal signal cannot be found. This could lead to either undersensing (failure to sense an appropriate signal)

or oversensing (sensing an inappropriate signal) if sensitivity is reprogrammed to a different mV setting. For bipolar programmable pulse generators, it may be useful to examine the intracardiac electrogram for unipolar and bipolar configurations to evaluate whether one signal is better than the other. If both signals are poor, a bipolar sensing configuration is generally preferable since it minimizes oversensing at a more sensitive setting.

### Lead Impedance

Impedance values should also be verified at this time and entered on the patient chart. Impedance values are not related to stimulation and sensing thresholds. In general, lead impedance values should be between 300 and 1500 ohms. An impedance value lower than this range may be indicative of a problem with the lead insulation<sup>8</sup> while an impedance value higher than this range can indicate conductor fracture or poor lead connection to the pulse generator.

### Acute Repositioning

If repositioning is required, hold the lead body stationary in one hand while rotating the grooved portion of the tool or the entire clip-on tool counterclockwise. Verify with fluoroscopy that the helix is completely retracted before attempting to withdraw the lead to reposition. Repeat the electrode fixation procedure at the new location.

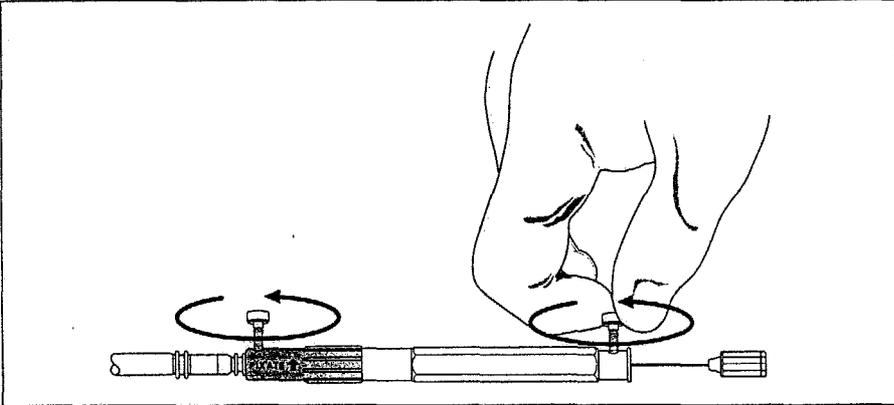


Figure 12

Before anchoring the lead, remove the stylet (if not already done) and the fixation tool.  
To remove the stylet, loosen the proximal thumbscrew (counterclockwise) and withdraw the stylet.  
To remove the fixation tool from the lead connector, loosen the distal thumbscrew (counterclockwise) several turns. Do not attempt to remove the fixation tool without first loosening the distal thumbscrew; this might damage the connector pin.

### Anchoring the Lead

Before anchoring the lead, loosen both thumbscrews on the fixation tool and remove it from the lead connector. (See Figure 12.) Once the lead has achieved a stable mechanical position and good thresholds have been obtained, the lead should be securely anchored at or near the venous entry site using the anchoring sleeve and a nonabsorbable synthetic suture. First secure the anchoring sleeve to the underlying tissue, then recheck lead position visually and under fluoroscopy (to prevent twisting of the lead and to identify inadvertent retraction or advancement of the lead) before securing the ligature around the anchoring sleeve to secure the lead in place. Do not apply the ligature directly to the lead body, as this can damage the lead conductor, insulation or both. The suture around the anchoring sleeve

and lead should not be tied too tightly, as this may also result in excessive stress applied to the lead body.

Once the lead is anchored, connect the lead to the pulse generator following the instructions in the pulse generator manual.

**NOTE**  
Use the anchoring sleeve to distribute the tension caused by the suture. Failure to use the anchoring sleeve may result in damage to the lead's insulation, conductor coil, or both. Care must be taken to prevent the anchoring sleeve from passing into the vein.

**NOTE**  
Ligature tied too tightly may result in excessive stress applied to the lead body.

## Chronic Repositioning

It is generally recommended that a chronically implanted endocardial pacing lead not be repositioned except in special circumstances. Should it be necessary to abandon an indwelling pacing lead, its connector pin should be removed from the pulse generator and capped, using the standard cap of the lead manufacturer. Never cut an indwelling pacing lead; this may cause the insulation to separate from the conductor coil and leave an exposed wire in the body. The extraction of any lead carries a clinical risk<sup>9</sup> and should only be undertaken with extreme caution. If the lead or any portion of it is extracted, it should be returned to Pacesetter.

Should it be necessary to explant a chronically implanted lead, expose the lead entry site and remove the ligatures from around the anchoring sleeve with extreme caution so as not to damage the lead insulation or the anchoring sleeve itself.

After disconnecting the lead from the pulse generator, attach the fixation tool to the lead connector pin. Insert the appropriate stylet, contained in the model 4018 or 4019 repositioning kit, through the lumen in the back of the fixation tool. With extreme caution, advance the stylet fully into the lead. If using the clip-on tool, insert the stylet into the lead and attach the clip-on tool to the lead pin. Holding the lead body stationary in one hand, rotate the grooved portion of the fixation tool (or the entire clip-on tool) counterclockwise and use fluoroscopy to observe helix retraction. Blood, fibrosis, or expansion of the MCRD within the helix may make it impossible to withdraw the helix with

this method; if this occurs, rotate the lead body itself counterclockwise several turns. Note that blood, tissue ingrowth, and MCRD expansion which may occur with a chronically implanted lead impairs the extendable/retractable helix mechanism and thus can make it impossible for that same lead to be repositioned. If this is the case, replace it with a new lead.

Infection of the pacemaker system, particularly sepsis, generally requires the removal of both the pulse generator and lead(s).<sup>10</sup> Multiple abandoned leads and limitations to venous access are other common reasons to recommend lead extraction.

### NOTE

**If a pacing lead is to be abandoned, it is recommended that it be capped and left in place rather than cut or removed.**

### NOTE

**If a pacing lead must be removed because of infection or for another serious reason, great care should be exercised, as lead extraction involves a clinical risk.**

### NOTE

**Use a new lead if significant traction is required to disengage the chronic lead.**

## Service

Members of Pacesetter Technical Services Department are available to provide technical consultation 24 hours every day. This service can be obtained by dialing 1 800 722 3774. Additionally, highly trained sales and service professionals are located worldwide to assist you.

## References

- 1 Furman S, Hayes DL, Holmes DR Jr. *A Practice of Cardiac Pacing, 2d ed.* Mount Kisco, Futura Publishing Company, Inc., 1989, p. 272.
- 2 Belott PH, Byrd CL. Recent developments in pacemaker implantation and lead retrieval. In Barold SS, Mugica J, (eds.): *New Perspectives In Cardiac Pacing.* Mount Kisco, Futura Publishing Company, Inc., 1991, p. 107.
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- 4 Moses HW, Taylor GJ, Schneider JA, Dove JT. *A Practical Guide to Cardiac Pacing.* Boston, Little, Brown and Company, 1987, pp. 30-36.
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- 6 Belott PH, Byrd CL. *op cit*, p. 109.
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- 8 Furman S et al. *op cit*, p. 107.
- 9 Byrd CL, Schwartz SJ, Hedin N. Intravascular techniques for extraction of permanent pacemaker leads. *J Thorac Cardiovasc Surg* 1991; 101:989-991.
- 10 Belott PH, Byrd CL *op cit*, p. 121.