Medtronic

SELECTSECURE™ 3830

Steroid eluting, bipolar, implantable, nonretractable screw-in, atrial/ventricular, catheter delivered, transvenous lead

Technical manual

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

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1 Device description

The Medtronic SelectSecure Model 3830 steroid eluting, bipolar, implantable, nonretractable screw-in, atrial/ventricular, catheter delivered, transvenous lead is designed for pacing and sensing in the atrium or ventricle.

The lead has a nonretractable helical electrode made of titanium nitride coated platinum alloy for active fixation in the endocardium by rotating the lead body in a clockwise direction. Active fixation leads are particularly beneficial for patients who have smooth or hypertrophic hearts where lead dislodgement may be a potential problem.

The lead also has a second, larger electrode made of titanium nitride coated platinum alloy proximal to the tip electrode and an IS-1[1] Bipolar (BI) connector. The lead features MP35N nickel alloy conductors, silicone inner insulation, and polyurethane outer insulation.

The distal tip contains a target dose of 17.9 µg beclomethasone dipropionate. Upon exposure to body fluids, the steroid elutes from the lead tip. Steroid is known to suppress the inflammatory response that is believed to cause threshold rises typically associated with implanted pacing electrodes.

Note: To implant the Model 3830, a compatible delivery system is required, such as a Medtronic delivery system. A compatible delivery system includes a guide catheter and an introducer valve which allows passage through or removal from an IS-1 connector. Contact your Medtronic representative for further information regarding compatible delivery systems.

1.1 Package contents

The lead and accessories are supplied sterile. Each package contains the following items.

- 1 lead with anchoring sleeve
- 1 vein lifter
- Product literature

[1] IS-1 BI refers to an International Connector Standard (ISO 5841-3) whereby pulse generators and leads so designated are assured of a basic mechanical fit.

1.2 Accessory descriptions

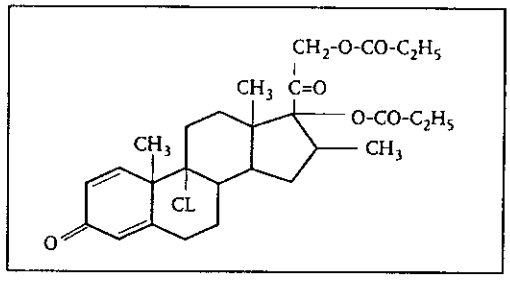
Anchoring sleeve – An anchoring sleeve secures the lead from moving and protects the lead insulation and conductors from damage caused by tight sutures.

Vein lifter – A vein lifter facilitates catheter or introducer insertion into a vessel.

2 Drug component description

The active ingredient in the Model 3830 lead is beclomethasone 17,21-dipropionate. The chemical name of beclomethasone dipropionate is 9-chloro-11β,17,21-trihydroxy-16β-methylpregna-1,4-diene-3, 20 dione 17,21-dipropionate. The structural formula for beclomethasone 17,21-dipropionate is shown below:

Figure 1. Structural formula for beclomethasone 17,21- dipropionate



Beclomethasone 17, 21-dipropionate is a diester of beclomethasone, a synthetic halogenated corticosteroid. Beclomethasone 17, 21-dipropionate is a white to creamy white, odorless powder with a molecular formula of $C_{28}H_{37}ClO_7$ and a molecular weight of 521.05. It is very slightly soluble in water, very soluble in chloroform, and freely soluble in acetone and alcohol.

The nominal dosage of beclomethasone 17, 21-dipropionate per Model 3830 lead is 17.9 µg.

3 Indications for use

The Model 3830 lead has application where implantable atrial or ventricular, single-chamber or dual-chamber pacing systems are indicated. The Model 3830 lead is intended for pacing and sensing in the atrium or ventricle.

4 Contraindications

The following are contraindications for use of Medtronic implantable, screw-in, catheter delivered, transvenous leads.

- Use of ventricular transvenous leads is contraindicated in patients with tricuspid valvular disease.
- Use of ventricular transvenous leads is contraindicated in patients with mechanical tricuspid heart valves.
- Use of steroid eluting transvenous leads is contraindicated in patients for whom a single dose of 40.0 µg beclomethasone dipropionate may be contraindicated.

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- Use of catheter-delivered transvenous leads is contraindicated in patients with obstructed or inadequate vasculature for intravenous catheterization.

5 Warnings and precautions

Line-powered and battery-powered equipment – An implanted lead forms a direct current path to the myocardium. During lead implant and testing, use only battery-powered equipment or line-powered equipment specifically designed for this purpose, to protect against fibrillation that may be caused by alternating currents. Line-powered equipment used in the vicinity of the patient must be properly grounded. Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.

Diathermy – People with metal implants such as pacemakers, implantable cardioverter defibrillators (ICDs), and accompanying leads should not receive diathermy treatment. The interaction between the implant and diathermy can cause tissue damage, fibrillation, or damage to the device components, which could result in serious injury, loss of therapy, and/or the need to reprogram or replace the device.

Vessel and tissue damage – Use care when positioning the lead.

- Consider another site for lead placement other than the apex of the right ventricle if there is reason to believe the patient has an unusually thin wall at the apex of the right ventricle.
- Avoid known infarcted or thin ventricular wall areas to minimize the occurrence of perforation and dissection.
- Avoid acute trauma to the endocardium, including possible perforation, caused by excessive torque, overrotation, and/or tip pressure. Acute trauma to the endocardium may result in temporarily high impedance or threshold values.

Single use – The lead is for single use only.

Inspecting the sterile package – Inspect the sterile package with care before opening it.

- Contact a Medtronic representative if the seal or package is damaged.
- Do not store this product above 40 °C.
- Do not use the product after its expiration date.

Sterilization – Medtronic has sterilized the package contents with ethylene oxide before shipment. This lead is for single use only and is not intended to be resterilized.

Drug interactions – No drug interactions with inhaled beclomethasone 17,21-dipropionate have been described. Drug interactions of beclomethasone 17,21-dipropionate with the Model 3830 lead have not been studied.

Use of multiple leads – Prior to implanting the Model 3830 lead, total patient exposure to beclomethasone 17,21-dipropionate should be considered when implanting multiple leads.

Handling the steroid tip – Avoid reducing the amount of steroid available prior to lead implantation. Reducing the available amount of steroid may adversely affect low-threshold performance.

- Do not allow the electrode surface to come in contact with surface contaminants.
- Do not wipe or immerse the electrode in fluid, except blood, at the time of implant.

Handling the lead – Handle the lead with care at all times.

- Do not implant the lead if it is damaged. Return the lead to your Medtronic representative.
- Do not attempt to straighten or realign the helix if the helix is deformed. Return the lead to your Medtronic representative.
- Protect the lead from materials that shed small particles such as lint and dust. Lead insulators attract these particles.
- Handle the lead with sterile surgical gloves that have been rinsed in sterile water or a comparable substance.
- Do not severely bend, kink, or stretch the lead.
- Do not apply pressure to the helix.
- Do not immerse the lead in mineral oil, silicone oil, or any other liquid, except blood, at the time of implant.
- Do not use surgical instruments to grasp the lead.
- Do not force the lead if resistance is encountered during lead passage. Resistance can be a result of guide catheter occlusion, i.e., kinking, folding, or thrombosis, or that the lead is in contact with cardiac tissue.
- Keep the helix within the guide catheter of the delivery system if passing through the tricuspid valve to prevent damage to the helix, valve, and/or endocardial tissue.

Necessary hospital equipment – Keep external defibrillation equipment nearby for immediate use during acute lead system testing, implant procedure, or whenever arrhythmias are possible or intentionally induced during post-implant testing.

Concurrent devices – Output pulses, especially from unipolar devices, may adversely affect device sensing capabilities. If a patient requires a separate stimulation device, either permanent or temporary, allow enough space between the leads of the separate systems to avoid interference in the sensing capabilities of the devices. Previously implanted pulse generators and implantable cardioverter defibrillators should generally be explanted.

Chronic repositioning or removal – Proceed with extreme caution if a lead must be removed or repositioned. Chronic repositioning or removal of screw-in transvenous leads may not be possible because the helix may become deformed and/or entangled as a result of manipulating the lead. In most clinical situations, it is preferable to abandon unused leads in place. Return all removed or unused leads, or lead sections, to Medtronic for analysis.

- Observe the helix via fluoroscopy or x-ray before attempting to reposition to determine if the helix shape is intact. If the helix appears deformed, removal may be difficult and is not recommended.
- Lead removal may result in avulsion of the endocardium, valve, or vein.
- Lead junctions may separate, leaving the lead tip and bare wire in the heart or vein.
- Chronic repositioning of a lead may adversely affect a steroid lead's low-threshold performance.
- Abandoned leads should be capped to avoid transmitting electrical signals.
- Severed leads should have the remaining lead end sealed and the lead body sutured to adjacent tissue.

6 Drug Information

6.1 Mechanism of action

Steroid suppresses the inflammatory response that is believed to cause threshold rises typically associated with implanted pacing electrodes. Beclomethasone dipropionate is a synthetic steroid of the glucocorticoid family. Glucocorticoid steroids have potent anti-inflammatory actions via direct and indirect effects on major inflammatory cells. While the mechanism of action of glucocorticoids is not fully understood, it is known that glucocorticosteroids bind to a cytoplasmic glucocorticoid receptor as well as to a membrane-bound receptor. Binding to the cytoplasmic receptor leads to receptor activation and translocation to the nucleus. The receptor interacts with specific DNA sequences (glucocorticoid responsive elements) within the regulatory regions of affected genes. Thus, glucocorticoids inhibit the production by multiple cells of factors that are critical in generating the inflammatory response, in particular via modulation of transcription factors.

6.2 Pharmacokinetics of the SelectSecure Model 3830 lead

Pharmacokinetics – The pharmacokinetics (local drug levels and systemic levels) of beclomethasone dipropionate and its metabolites following placement of the SelectSecure Model 3830 leads were not evaluated in the human clinical trials. A preclinical animal study using multiple leads and an assay with a limit of quantitation of 80 pcg/ml did not show any detectable levels of BDP, however, this study did not determine the levels of the active metabolite, beclomethasone-17-monopropionate.

Metabolism – Beclomethasone dipropionate (BDP) is a prodrug with weak glucocorticoid receptor binding affinity that is hydrolyzed via esterase enzymes to the active metabolite, beclomethasone-17-monopropionate (17-BMP). Minor inactive metabolites, beclomethasone-21-monopropionate (21-BMP) and beclomethasone (BOH) are also formed. The mean elimination half-life of 17-BMP is 2.8 hours. Irrespective of the route of administration (injection, oral, or inhalation), BDP and its metabolites are mainly excreted in the feces. Less than 10% of the drug and its metabolites are excreted in the urine.

6.3 Mutagenesis, carcinogenicity and reproductive toxicology

The mutagenesis, carcinogenicity, and reproductive toxicity of the Model 3830 lead have not been evaluated. However, the mutagenesis, carcinogenicity, and reproductive toxicity of beclomethasone dipropionate have previously been evaluated.

Mutagenesis – Beclomethasone dipropionate did not induce gene mutation in bacterial cells or mammalian Chinese Hamster ovary (CHO) cells in vitro or in the mouse micronucleus test in vivo.

Carcinogenticity – BDP was administered to rats for a total of 95 weeks (13 weeks inhalation: up to 0.4 mg/kg daily, 82 weeks oral administration: up to 2.4 mg/kg daily). Both of which represent approximately 40 times the maximum recommended human intranasal dosage on a mg/m^2 basis. There was no evidence of carcinogenic activity[1]. It is known that glucocorticoids are potent inhibitors of carcinogenesis[2]. Specifically, in a mouse model of benzypyrene-induced pulmonary adenoma formation, BDP inhalation reduced carcinoma formation by up to 60%[2].

Reproductive toxicity – Although there are no adequate and controlled studies that have been conducted to date in humans, subcutaneously administered BDP, at dosages that are approximately 1.2 times the maximum human intranasal dosage (on a mg/m^2 basis), have been shown to be teratogenic and embryocidal in rats and rabbits receiving 0.1 mg/kg and 0.025 mg/kg daily, respectively. Teratogenic effects in these animals include fetal resorption, cleft palate, agnathia, microstomia, aglossia, delayed ossification, and agenesis of the thymus gland. Teratogenic or embryocidal effects were not observed in rats following a combination of oral administration and inhalation of BDP at dosages of 10 and 0.1 mg/kg daily, respectively (approximately 250 times the maximum recommended human intranasal dosage (on a mg/m^2 basis)[3]).

6.4 Pregnancy

Pregnancy category C – Like other corticosteroids, beclomethasone dipropionate was teratogenic and embryocidal in the mouse and rabbit at a subcutaneous dose of 0.1 mg/kg in mice or 0.025 mg/kg in rabbits. There are no adequate and well-controlled studies in pregnant women of beclomethasone dipropionate or the Model 3830 lead. The Model 3830 lead should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

6.5 Lactation

Corticosteroids are secreted into human milk and there is a potential for serious adverse reactions. A decision should be made whether to nurse or to discontinue the drug, taking into

[1] AHFS Drug Information, 1999, ISBN 1-879907-91-7, pp 2420.
[2] Wattenberg, LW, et al., Chemoprevention of pulmonary carcinogenesis by brief exposures to aerosolized budesonide or beclomethasone dipropionate and by the combination of aerosolized budesonide and dieteray myo-inositol. Carcinogenesis 2000; 21 (2): 179-182.
[3] AHFS Drug Information, 1999, ISBN 1-879907-91-7, pp 2420

account the importance of the drug to the mother. These potential risks of corticosteroids should also be considered along with any other steroidal therapy being received by the patient.

7 Potential complications

The potential complications (listed in alphabetical order) related to the use of transvenous leads include, but are not limited to, the following patient-related conditions that can occur when the lead is being inserted and/or repositioned.

- Cardiac perforation
- Cardiac tamponade
- Fibrillation and other arrhythmias
- Heart wall or vein wall rupture
- Infection
- Muscle or nerve stimulation
- Pericardial rub
- Pneumothorax
- Thrombotic and air embolism
- Thrombosis
- Valve damage (particularly in fragile hearts)

Other potential complications related to the lead and the programmed parameters include, but are not limited to, the complications listed in the following table. Symptoms of the following potential complications include loss of capture or intermittent or continuous loss of capture or sensing[1]:

Complication	Corrective action to be considered
Lead dislodgement	Reposition the lead.
Lead conductor or helix fracture or insulation failure	Replace the lead. In some cases with a bipolar lead, the implantable device may be programmed to a unipolar configuration or the lead may be unipolarized.
Threshold elevation or exit block	Adjust the implantable device output. Replace or reposition the lead.

Potential acute/chronic complications associated with lead placement that may require lead replacement to correct include, but are not limited to, the following:

Implant technique	Potential complication
Forcing the lead through the guide catheter	Helix electrode and/or insulation damage
Use of too medial of an approach with the guide catheter resulting in clavicle & first rib binding	Conductor coil fracture, insulation damage
Puncturing the periosteum and/or tendon when using subclavian guide catheter approach	Conductor coil fracture, insulation damage

[1] Transient loss of capture or sensing may occur for a short time following surgery until lead stabilization takes place. If stabilization does not occur, lead dislodgement may be suspected.

8 Clinical trial

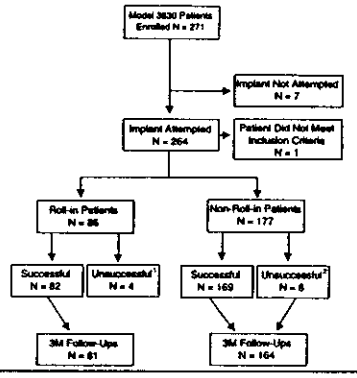
The following section describes the safety and effectiveness clinical trial of the Medtronic Model 3830 lead.

8.1 Summary

A multi-center, prospective, non-randomized control clinical study conducted at 26 investigational sites in the United States, 4 investigational sites in Canada, and 1 investigational site in Australia compared the Model 3830 steroid eluting lead using the Model 5076 steroid eluting lead as a historical control. The Model 3830 and Model 5076 leads are both active fixation leads.

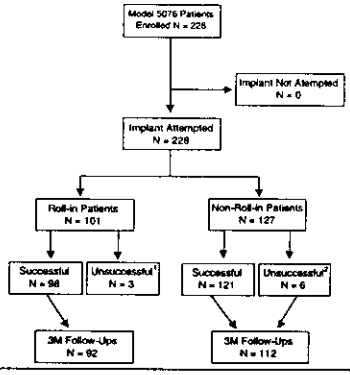
Data was collected for a total of 271 patients enrolled in the study. Of these patients, 264 patients underwent lead implant attempts (86 roll-in patients and 178 non-roll-in patients). One non-roll-in patient did not meet the inclusion/exclusion criteria and is not included in any of the data summaries. Follow-up was performed at pre-discharge (within 48 hours post-implant), 2 weeks, 1 month, and 3 months to meet study objectives. Patients continue to be followed at 6 months and every 6 months thereafter until study closure. See Figure 2 and Figure 3 for enrollment and follow-up of the Model 3830 lead and the Model 5076 lead.

Figure 2. Model 3830 enrollment and follow-up



[1] Four patients with unsuccessful implants in the roll-in group did not receive a Model 3830 lead in either chamber and did not continue to be followed past implant.
[2] Five of eight patients had at least one Model 3830 lead implanted and continued to be followed per the protocol.

Figure 3. Model 5076 enrollment and follow-up



[1] Three of three patients with unsuccessful implants in the roll-in group had at least one Model 5076 lead implanted and continued to be followed per the protocol.
[2] Five of six patients had at least one Model 5076 lead implanted and continued to be followed per the protocol.

Each implanting physician was required to enroll 2 roll-in patients that were followed for adverse events, but were not included in the analysis of the primary objectives.

8.2 Primary objectives

The following are the primary objectives of the Model 3830 clinical trial:

- Demonstrate the safety of the Model 3830 by comparing lead-related complications to those seen in the Model 5076.
- Demonstrate the safety of the Model 3830 by comparing lead related events to those seen in the Model 5076.
- Demonstrate the effectiveness of the Model 3830 by comparing pacing performance to the Model 5076.
- Demonstrate the effectiveness of the Model 3830 by comparing sensing performance to the Model 5076.

8.3 The following are the results of the Model 3830 clinical trial

8.3.1 Primary objective: lead-related adverse events

176 patient implant attempts with a Model 3830 lead in the atrium were analyzed per the statistical plan. There were a total of 15 atrial lead-related adverse events occurring in 14 patients. Of these 15 events, 5 are complications (2 of these complications were reported after the 3-month follow-up visit) and 10 are observations. See Table 1 for the types of atrial lead-related adverse events reported.

177 patient implant attempts with a Model 3830 lead in the ventricle were analyzed per the statistical plan. There were a total of 30 ventricular lead-related adverse events occurring in 28 patients. Of these 30 events, 12 (occurring in 12 patients) are complications and 18 are observations. See Table 2 for the types of ventricular lead-related adverse events reported.

Table 1. Atrial lead-related events

Event	Complications[a]/ Patients	Observations[b]/ Patients[c]	Total Events/ Patients[c]
Elevated pacing thresholds	0/0	4/4	4/4
Lead dislodgement	2/2	1/1	3/3
Muscle stimulation	0/0	2/1	2/1
Failure to sense/ undersensing	2/2	1/1	3/3
Venous occlusion	0/0	1/1	1/1
AFib/flutter	0/0	1/1	1/1
Pocket infection	1/1	0/0	1/1
Total	**5/5**	**10/9**	**15/14**

[a] A complication is defined as an event that is resolved invasively or that directly results in the death of, or serious injury to, the patient; the explant of the device; or the termination of significant device function regardless of other treatments. IV and IM drug therapies are considered invasive treatment.
[b] An observation is defined as an event that is resolved by non-invasive means such as medically or by reprogramming the device, or that is resolved spontaneously. Oral drugs are considered non-invasive treatment.
[c] Not mutually exclusive.

The atrial lead-related adverse event rate for the Model 3830 was found to be clinically equivalent to the Model 5076 at 3 months. The 95% upper confidence bound on the difference between rates of survival was 6.48%, which is less than the 10% bound criteria.

Table 2. Ventricular lead-related events

Event	Complications[a]/ Patients	Observations[b]/ Patients[c]	Total Events/ Patients[c]
Elevated pacing thresholds	2/2	12/12	14/14
Lead dislodgement	3/3	0/0	3/3
Failure to capture/loss of capture	1/1	1/1	2/2
Muscle stimulation	0/0	2/2	2/2
Pericardial effusion	3/3	1/1	4/4
Venous occlusion	0/0	1/1	1/1
Cardiac perforation	0/0	1/1	1/1
Cardiac tamponade	1/1	0/0	1/1
Pocket Infection	1/1	0/0	1/1
Chest pain/ angina pectoris	1/1	0/0	1/1
Total	**12/12**	**18/17**	**30/28**

[a] A complication is defined as an event that is resolved invasively or that directly results in the death of, or serious injury to, the patient; the explant of the device; or the termination of significant device function regardless of other treatments. IV and IM drug therapies are considered invasive treatment.

[b] An observation is defined as an event that is resolved by non-invasive means such as medically or by reprogramming the device, or that is resolved spontaneously. Oral drugs are considered non-invasive treatment.

[c] Not mutually exclusive.

The ventricular lead-related adverse event rate for the Model 3830 was found to be clinically equivalent to the lead Model 5076 at 3 months. The 95% upper confidence bound on the difference between rates of survival was 8.99%, which is less than the 10% bound criteria.

8.3.2 Primary objective: lead-related complications

The ventricular lead-related complication rate for the Model 3830 was not found to be clinically equivalent to the Model 5076 at 3 months. The 95% upper confidence bound on the difference between rates of survival was 7.10%, which is greater than the 6% bound criteria.

The atrial lead-related complication rate for the Model 3830 was found to be clinically equivalent to the Model 5076 at 3 months. The 95% upper confidence bound on the difference between rates of survival was 2.62%, which is less than the 6% bound criteria.

The ventricular lead related complication rate was continually evaluated during the clinical study. After the start of the implant phase, the sponsor held a meeting with the investigators to review the study adverse events and make implant technique recommendations. Prior to these recommendations, four ventricular lead related complications had occurred in the first 37 non-roll-in system implants (10.8% rate). After providing additional instruction on implant technique, an additional 140 patients were enrolled in the non-roll-in population, of which 6 additional ventricular lead related complications occurred (4.3% rate). The recommended techniques are summarized in Table 3:

Table 3. Recommended methods for minimizing Model 3830 lead implant difficulties.

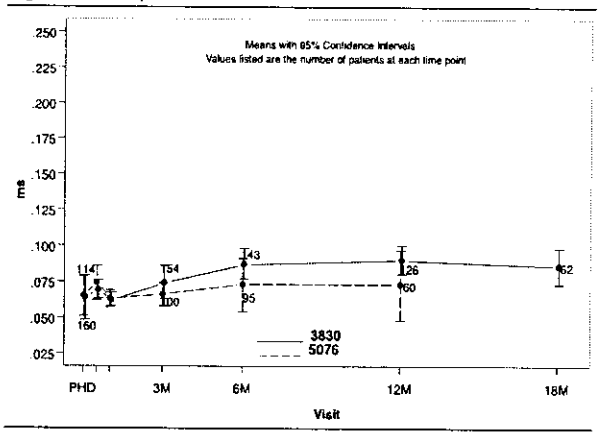
Potential difficulties	Recommendation
Catheter kinks, folds, or creases during lead implant, resulting in increased lead resistance during deployment.	Extend lead to distal tip of catheter prior to deflecting catheter.
Cardiac perforation from catheter during catheter positioning.	Track catheter over a guide wire to implant location.
Cardiac perforation from catheter during lead positioning	When distal tip of guide catheter is near desired location for lead placement, gently advance the lead through the guide catheter until the helix extends beyond the distal opening of the guide catheter. Avoid extending catheter up against wall.
Cardiac perforation during lead fixation	Avoid over-rotation of the lead; recommend 3-4 turns to affix the ventricular helix; 4-5 turns to affix the atrial helix.
Excessive force on lead during the slitting process results in lead dislodgement	Confirm helix fixation, gently advance lead and retract catheter to provide adequate lead slack. Slit off catheter, then establish final amount of slack on lead.

There were 4 catheter related adverse events which describe kinking of the catheter that occurred during the 3830 clinical study. These 4 events resulted in unsuccessful final lead placement of the 3830 investigational lead in 4 patients. All events were categorized as catheter-related observations involving 2 roll-in and 2 non-roll-in patients. All events were resolved on the date of occurrence.

8.3.3 Primary objective: pacing performance

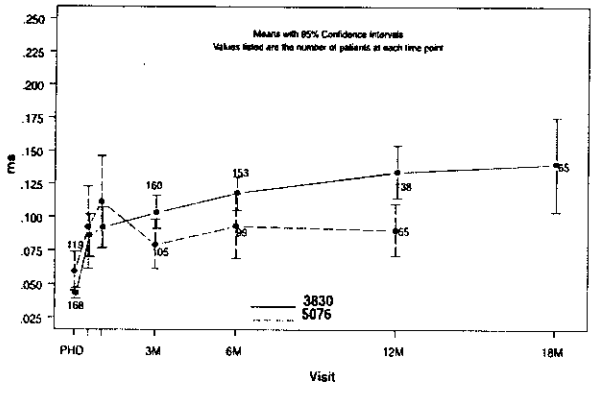
The atrial pulse width threshold for the Model 3830 was found to be clinically equivalent to the lead Model 5076 through the 3-month follow-up (patients unable to capture at 2.5 V were not included in the analysis). The 95% upper confidence bound on the difference was 0.026 ms, which is less than the 0.06 ms bound criteria. See Figure 4 for a comparison of Model 3830 and Model 5076 atrial pulse width thresholds.

Figure 4. Atrial pulse width thresholds



The ventricular pulse width threshold for the Model 3830 was found to be clinically equivalent to the lead Model 5076 through the 3-month follow-up (patients unable to capture at 2.5 V were not included in the analysis). The 95% upper confidence bound on the difference was 0.015 ms, which is less than the 0.06 ms bound criteria. See Figure 5 for a comparison of Model 3830 and Model 5076 ventricular pulse width thresholds.

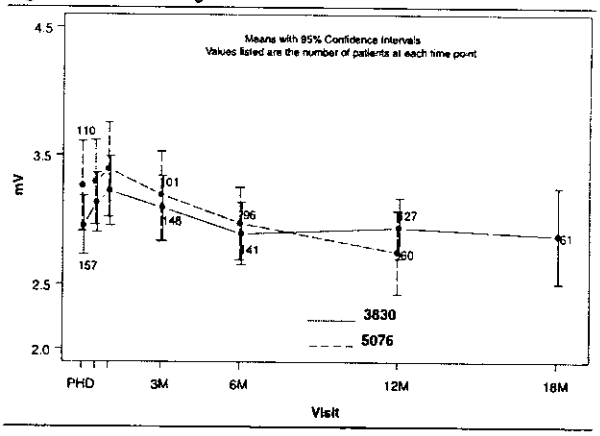
Figure 5. Ventricular pulse width thresholds



8.3.4 Primary objective: sensing data

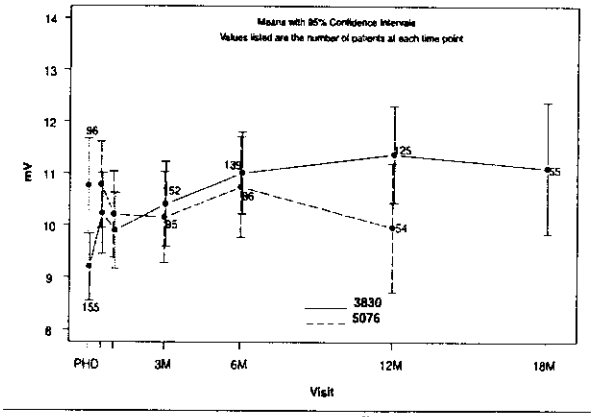
The P-wave amplitude for the Model 3830 was found to be clinically equivalent to the lead Model 5076 through the 3-month follow-up. The 95% upper confidence bound on the difference was 1.204 mV, which is less than the 1.5 mV bound criteria. See Figure 6 for a comparison of Model 3830 and Model 5076 P-wave sensing amplitudes.

Figure 6. Atrial sensing



The R-wave amplitude for the Model 3830 was found to be clinically equivalent to the lead Model 5076 through the 3-month follow-up. The 95% upper confidence bound on the difference was 1.578 mV, which is less than the 3.0 mV bound criteria. See Figure 7 for a comparison of Model 3830 and Model 5076 R-wave sensing amplitudes.

Figure 7. Ventricular sensing



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8.4 Conclusions

The Medtronic Model 3830 lead was engineered and designed to meet implanting physician's requirements for improvements over current pacing lead therapy. New data indicates an evolving clinical need to implant increased numbers of leads[1,2] and improve on long term pacing lead reliability.

The clinical study proves that the 3830 lead, the first lead without a stylet lumen, and first right-sided pacing lead delivered by a steerable catheter sheath:

- Achieved primary electrical endpoints as compared to the Model 5076 standard stylet lead through three months.
- Had an atrial and ventricular lead complication rate comparable to other currently marketed Medtronic leads (Models 5068 and 4068)[3]. (See Table 4). The atrial lead related complication rate achieved the primary safety end point compared to the 5076. The overall ventricular lead related complication rate exceeded the Model 5076 lead. Interim review of the data and modified implant technique recommendations were implemented with a corresponding decrease in ventricular lead related complications in alignment with current Medtronic marketed leads.
- Was implanted without an increase in lead related adverse events compared to currently marketed Medtronic stylet-delivered active fixation leads (see Table 4).
- At implant and follow-up had no unanticipated adverse device effects (UADE).
- Had a total lead related adverse event rate that is comparable to current published event rates of other Medtronic marketed leads.[4,5]

Table 4. Adverse event comparison through 3 months[a]

Lead	N	Atrial events	Ventricular events	Total events
Model 3830 (Includes roll-in pts)	262 atrial 263 ventricular	12 (in 12 pts) 12/262 = 4.6%	27 (in 26 pts) 27/263 = 10.3%	38 (in 36 pts) 38/525 = 7.2%[b]
Model 5076 (Includes roll-in pts)	229 atrial 228 ventricular	8 (in 8 pts) 8/229 **=3.5%**	15 (in 15 pts) 15/228 **=6.6%**	23 (in 23 pts) 23/457 **=5.0%**
Model 4068[c]	297 atrial 372 ventricular	32 32/297 **=10.8%**	31 31/372 **=8.3%**	63 63/669 **=9.4%**
Model 5068[c]	122 atrial 122 ventricular	6 (in 6 pts) 6/122=**4.9%**	13 (in 13 pts) 13/122 **=10.7%**	19 (in 16 pts) 19/244 **=7.8%**

[a] 3 months is defined as 135 days for all studies.
[b] In the 3830 study, one event (in one patient) was classified as both atrial and ventricular lead related.
[c] Information provided for comparison purposes only. This lead was not included in the Model 3830 clinical study.

No unanticipated adverse device effects were reported in this study and the lead performed effectively through three months with respect to lead-related adverse events, pacing performance, and sensing performance. Although the primary objective for ventricular lead–related complications was not met, the types of complications and the rate at which ventricular lead related complications occurred are comparable to other commercially available leads as reported in the literature.

9 Directions for use

Note: To implant the Model 3830, a compatible delivery system is required, such as a Medtronic delivery system. A compatible delivery system includes a guide catheter and an introducer valve which allows passage through or removal from an IS-1 connector. Contact your Medtronic representative for further information regarding compatible delivery systems.

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. Some implantation techniques vary according to physician preference and the patient's anatomy or physical condition. The implantation procedure generally includes the following steps.

- Recommended methods for minimizing Model 3830 lead implant difficulties
- Preparing the delivery system
- Selecting an insertion site
- Inserting the guide catheter assembly
- Positioning the guide catheter
- Inserting the lead into the guide catheter
- Positioning the lead
- Verifying helix electrode fixation

[1] Saksena S. The Role of Multisite Atrial Pacing in Rhythm Control in AF: Insights from Sub-analyses of the Dual Site Atrial Pacing for Prevention of Atrial Fibrillation Study. Pacing Clin Electrophysiol. 2003 Jul;26(7 Pt 1):1565.
[2] Saksena S. The Role of Multisite Atrial Pacing in Rhythm Control in AF: Insights from Sub-analyses of the Dual Site Atrial Pacing for Prevention of Atrial Fibrillation Study. Pacing Clin Electrophysiol. 2003 Jul;26(7 Pt 1):1565.
[3] Information provided for comparison purposes only. These leads were not included in the Model 3830 clinical study.
[4] Hill PE Complications of permanent transvenous cardiac pacing: a 14-year review of all transvenous pacemakers inserted at one community hospital. PACE 1987 May;(Pt 1):564-70.
[5] Crossley GH, Tonder L. et al. Active Fixation Permanent Pacemaker Leads Have More Perforations than Passive Fixation Leads and a Similar dislodgement Rate. Circ 94:I-677 Oct 15, 1996.

- Taking electrical measurements
- Repositioning or removing the lead
- Removing the guide catheter from the lead
- Anchoring the lead
- Connecting the lead
- Placing the implantable device and lead into the pocket

9.1 Recommended methods for minimizing Model 3830 lead implant difficulties

The potential difficulties associated with the Model 3830 lead implant can be minimized using the following recommended methods:

Potential difficulties	Recommendation
Catheter kinks, folds, or creases during lead implant, resulting in increased lead resistance during deployment.	Extend lead to distal tip of catheter prior to deflecting catheter.
Cardiac perforation from catheter during catheter positioning.	Track catheter over a guide wire to implant location.
Cardiac perforation from catheter during lead positioning	When distal tip of guide catheter is near desired location for lead placement, gently advance the lead through the guide catheter until the helix extends beyond the distal opening of the guide catheter. Avoid extending catheter up against wall.
Cardiac perforation during lead fixation	Avoid over-rotation of the lead; recommend 3-4 turns to affix the ventricular helix; 4-5 turns to affix the atrial helix.
Excessive force on lead during the slitting process results in lead dislodgement	Confirm helix fixation, gently advance lead and retract catheter to provide adequate lead slack. Slit off catheter, then establish final amount of slack on lead.

In the 3830 clinical study, the ventricular lead-related complication rate for the Model 3830 was not found to be clinically equivalent to the Model 5076 at 3 months. The 95% upper confidence bound on the difference between rates of survival was 7.10%, which is greater than the 6% bound criteria.

The atrial lead-related complication rate for the Model 3830 was found to be clinically equivalent to the Model 5076 at 3 months. The 95% upper confidence bound on the difference between rates of survival was 2.62%, which is less than the 6% bound criteria.

The ventricular lead related complication rate was continually evaluated during the clinical study. After the start of the implant phase, the sponsor held a meeting with the investigators to review the study adverse events and make implant technique recommendations. Prior to these recommendations, four ventricular lead related complications had occurred in the first 37 non-roll-in system implants (10.8% rate). After providing additional instruction on implant technique, an additional 140 patients were enrolled in the non-roll-in population, of which 6 additional ventricular lead related complications occurred (4.3% rate).

There were 4 catheter related adverse events which describe kinking of the catheter that occurred during the 3830 clinical study. These 4 events resulted in unsuccessful final lead placement of the 3830 investigational lead in 4 patients. All events were categorized as catheter-related observations involving 2 roll-in and 2 non-roll-in patients. All events were resolved on the date of occurrence.

9.2 Preparing the delivery system

Prepare the delivery system for lead implantation according to the instructions in the product literature packaged with the delivery system.

9.3 Selecting an insertion site

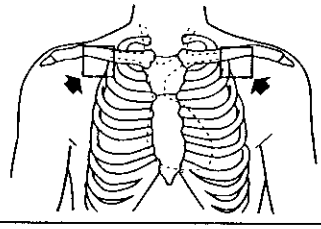
Caution: When using a subclavian approach for insertion, use a more lateral approach to minimize the risk of first rib clavicular crush. First rib clavicular crush may subsequently fracture the lead body.

Caution: Certain anatomical abnormalities, such as thoracic outlet syndrome, may pinch and subsequently fracture the lead body.

The guide catheter assembly may be inserted through several different venous routes, including the right or left cephalic vein or other subclavian branches.

Select an insertion site. See Figure 8 for the suggested insertion sites.

Figure 8.



9.4 Inserting the guide catheter assembly

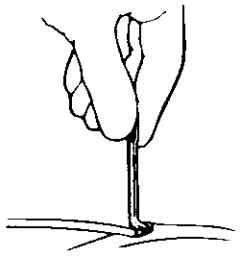
The guide catheter assembly may be inserted using either the vein lifter in the lead package or the method described in the delivery system product literature.

The guide catheter assembly may be inserted using venotomy through several venous routes, including the right or left cephalic vein or other subclavian branches. It is recommended to use a guide wire when inserting a guide catheter assembly. Advance the guide catheter over the guide wire to facilitate positioning of the guide catheter and to minimize the risk of tissue damage.

Insert the guide catheter assembly using the vein lifter:

1. Insert the tapered end of the vein lifter into the incised vein (Figure 9).

Figure 9.



2. Gently push the tip of the guide catheter assembly underneath the vein lifter and into the vein.

See the delivery system product literature for the recommended method of inserting the guide catheter assembly.

9.5 Positioning the guide catheter

See the delivery system product literature for details about positioning the guide catheter in the right atrium or right ventricle.

9.6 Inserting the lead into the guide catheter

Warning: For leads that will be placed in the right ventricle, keep the helix within the guide catheter when passing through the tricuspid valve to prevent damage to the helix, valve, and/or endocardial tissue.

Caution: If wiping the lead is necessary prior to insertion, avoid snagging the helix in gauze and ensure that the anchoring sleeve remains in position.

Insert the lead into the guide catheter. Pass the lead through the introducer valve to minimize the backflow of blood.

Note: Keep the helix within the catheter's distal tip.

9.7 Positioning the lead in the ventricle

Warning: To minimize the occurrence of perforation and dissection, avoid known infarcted or thin ventricular wall areas.

Warning: If there is reason to believe the patient has an unusually thin wall at the apex of the right ventricle, the implanter may wish to consider another site for placement of the lead.

Warning: Excessive torque or tip pressure may cause acute trauma to the endocardium, including possible perforation. The acute trauma may result in temporarily high impedance or threshold values.

Position the lead in the ventricle:

1. Position the distal tip of the guide catheter in the ventricle. See the delivery system product literature for details about positioning the guide catheter in the ventricle.
2. When the distal tip of the guide catheter is near the desired location for lead placement, gently advance the lead while retracting the guide catheter until the anode ring is extended approximately 2-3 cm beyond the distal opening of the guide catheter.
3. Use fluoroscopy to facilitate accurate lead placement.
4. Place one hand on the lead, by the valve, for stability; and, place the other hand on the lead connector sleeve (Figure 10). Using the hand on the lead connector sleeve, rotate the lead body clockwise to affix the helix in the endocardium. It is recommended that the implanter turn the lead body approximately 3 to 4 complete (360°) rotations so that the helix is fully imbedded in the endocardium.

   Note: Use either the lead serial number label or the anchoring sleeve to visually count the number of turns while using fluoroscopy.

   A possible indicator of helix fixation is when counterclockwise rotation of the lead body is observed when the hand on the connector sleeve is removed.

Accurate positioning of the electrode is essential for stable pacing and sensing. A satisfactory position is usually achieved when the above procedures are followed.

9.8 Positioning the lead in the atrium

Warning: Excessive torque or tip pressure may cause acute trauma to the endocardium, including possible perforation. The acute trauma may result in temporarily high impedance or threshold values.

Warning: If there is reason to believe the patient has an unusually thin wall at the appendage or lateral free wall of the right atrium, the implanter may wish to consider another site for placement of the lead.

Position the lead in the atrium:

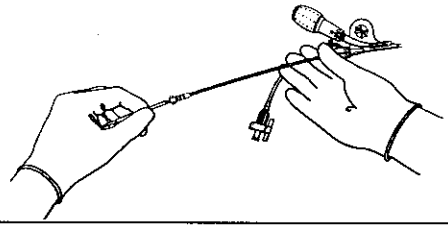
1. Position the distal tip of the guide catheter in the atrium. See the delivery system product literature for details about positioning the guide catheter in the atrium.
2. When the distal tip of the guide catheter is near the desired location for lead placement, gently push the lead through the guide catheter until the helix is outside the distal opening of the guide catheter.
3. Use fluoroscopy to facilitate accurate lead placement.
4. Place one hand on the lead, by the valve, for stability; and, place the other hand on the lead connector sleeve (Figure 10). Using the hand on the lead connector sleeve, rotate the lead body clockwise to affix the helix in the endocardium. It is recommended that the implanter turn the lead body approximately 4 to 5 complete (360°) rotations so that the helix is fully imbedded in the endocardium.

   Note: Use either the lead serial number label or the anchoring sleeve to visually count the number of turns while using fluoroscopy.

A possible indicator of helix fixation is when counterclockwise rotation of the lead body is observed when the hand on the connector sleeve is removed.

Accurate positioning of the electrode is essential for stable pacing and sensing. A satisfactory position is usually achieved when the above procedures are followed.

Figure 10.



9.9 Verifying helix electrode fixation

Verify helix electrode fixation:

1. Verify fixation using the proper technique depending on whether the lead was fixated in the ventricle or atrium:
   a. **For a ventricular lead:** Advance the lead to watch for slack to build up distal to the catheter to verify fixation. A properly fixated helix will remain in position. If the helix is not properly fixated, the lead tip will move into the right atrium or may become loose.
   b. **For an atrial lead:** Advance the lead to watch for slack to build up distal to the catheter to verify fixation. Use frontal fluoroscopy to check for lateral "to-and-fro" movement of the atrial tip, which reflects atrial and ventricular contractions. Poor fixation is suspected when lead tip movement seems random.
2. After confirmation of helix fixation, gently advance the lead to provide lead slack in the atrium or ventricle to prevent tip dislodgment. Enough slack is assumed present if, under fluoroscopy, an atrial lead assumes an "L" shape and a ventricular lead assumes an "S" shape or "U" shape, depending on the lead position, during deep inhalation. Avoid excessive slack buildup that may cause the loop of the atrial lead to drop near the tricuspid valve.
3. Obtain electrical measurements to verify satisfactory placement and electrode fixation. Refer to "Taking electrical measurements".
4. If a lead must be repositioned or removed, proceed with caution. Refer to "Repositioning or removing the lead".

9.10 Taking electrical measurements

Take electrical measurements:

1. Pull the guide catheter back to expose the ring electrode of the lead so the guide catheter does not interfere with electrical measurements.
2. Attach the clips of a surgical cable to the lead connector pin and connector ring.
3. Use an implant support instrument to obtain electrical measurements. Medtronic recommends using a pacing system analyzer. For information on the use of the implant support instrument, see the product literature for that device.

   Satisfactory lead placement is indicated by low stimulation thresholds and adequate sensing of intracardiac signal amplitudes.
   - A low stimulation threshold provides for a desirable safety margin, allowing for a possible rise in thresholds that may occur within 2 months following implantation.
   - Adequate sensing amplitudes ensure that the lead is properly sensing intrinsic cardiac signals. Minimum signal requirements depend on the implantable device's sensitivity capabilities. Acceptable acute signal amplitudes for the lead must be greater than the minimum implantable device sensing capabilities, including an adequate safety margin to account for lead maturity.

Table 5. Recommended measurements at implant

Measurement required	Ventricle	Atrium
Maximum acute stimulation thresholds[a]	1.0 V 3.0 mA	1.5 V 4.5 mA
Minimum acute sensing amplitudes	5.0 mV	2.0 mV

[a] At pulse duration setting of 0.5 ms.

4. If electrical measurements do not stabilize to acceptable levels, repositioning and repeating the testing procedure may be necessary. Refer to "Repositioning or removing the lead".

   Note: Initial electrical measurements may deviate from the recommendations because of acute cellular trauma. If this occurs, wait 5 to 15 minutes and repeat the testing procedure. Values may vary depending upon lead type, implantable device settings, cardiac tissue condition, and drug interactions.

9.10.1 Checking diaphragmatic stimulation

Diaphragmatic stimulation should also be checked by pacing at 10 V and observing on fluoroscopy whether the diaphragm contracts with each paced stimulus. If diaphragmatic pacing occurs, reduce the voltage until a diaphragmatic pacing threshold is determined. If the diaphragmatic threshold is less than the required programmed pacing output, the lead should be repositioned. Refer to "Repositioning or removing the lead".

9.10.2 Taking pacing impedance (resistance) measurements

Pacing impedance (or resistance) is used to assess implantable device function and lead integrity during routine implantable device patient follow-up and to assist in troubleshooting suspected lead failures. Additional troubleshooting procedures include ECG analysis, visual inspection, measurement of thresholds, and electrogram characteristics.

Pacing impedance values are affected by many factors including lead position, electrode size, conductor design and integrity, insulation integrity, and the patient's electrolyte balance. Apparent pacing impedance is also significantly affected by the measurement technique. Comparison of pacing impedance should be done using consistent methods of measurement and equipment.

An impedance higher or lower than the typical values is not necessarily a conclusive indication of a lead failure. Other causes must be considered as well. Before reaching a conclusive diagnosis, the full clinical picture must be considered. The full clinical picture includes pacing artifact size and morphology changes in 12-lead analog ECGs, muscle stimulation with bipolar leads, sensing and/or capture problems, patient symptoms, and implantable device characteristics.

Recommendations for clinically monitoring and evaluating leads in terms of impedance characteristics are listed below.

For implantable devices with telemetry readout of impedance:

- Routinely monitor and record impedance values, at implant and follow-ups, using consistent output settings.
  Note: Impedance values may be different at different programmable output settings (e.g., pulse width or pulse amplitude) of the implantable device or pacing system analyzer.
- Establish a baseline chronic impedance value once the impedance has stabilized, generally within 6 to12 months after implant.
- Monitor for significant impedance changes and abnormal values.
- Where impedance abnormalities occur, closely monitor the patient for indications of pacing and sensing problems. The output settings used for measuring impedance should be the same as that used for the original measurements.
- For patients at high risk, such as implantable device-dependent patients, physicians may want to consider further action such as increased frequency of monitoring, provocative maneuvers, and ambulatory ECG monitoring.

For implantable devices without telemetry:

- Record impedance value at implant. Also record the measurement device, its output settings, and the procedure used.
- At the time of implantable device replacement, if pacing analyzer system-measured impedance is abnormal, carefully evaluate lead integrity (including thresholds and physical appearance) and patient condition before electing to reuse the lead.
- Impedances below 250 Ω may result in excessive battery current drain, which may seriously compromise implantable device longevity, regardless of lead integrity.

For more information on obtaining electrical measurements, consult the product literature supplied with the testing device.

9.11 Repositioning or removing the lead

Warning: During the implant procedure, removal of the lead after fixation may result in avulsion of the endocardium. In addition, the lead junctions may separate leaving the helix or a portion of the lead in the heart or vein. In most clinical situations, it is preferable to abandon unused leads in place if this is a possibility.

Caution: If you determine that the lead requires repositioning, consider the possibility that the helix may become deformed and/or entangled as a result of manipulating the lead. Observe the helix via fluoroscopy or x-ray before attempting to reposition to determine if the helix shape is intact. If the helix appears deformed, removal may be difficult and is not recommended.

Use the following procedures for acute repositioning or removal of the lead as needed.

9.11.1 Acute repositioning of the lead

Reposition the lead:

1. Rotate the lead body counterclockwise to withdraw the helix from the implant site if the helix appears intact and repositioning is required.
   Note: The number of counterclockwise rotations needed to withdraw the helix from the implant site before applying traction may be greater than the number of revolutions required for fixation.
   Note: If the helix is still imbedded in the endocardium, additional turns on the lead body should be applied rather than applying a retraction force.
2. Counterclockwise rotation should be continued throughout the repositioning process to decrease the possibility of damage to the cardiovascular tissue.
3. Repeat the ventricular or atrial positioning procedure and the verifying helix electrode fixation procedure. Use the guide catheter to reposition the lead.

9.11.2 Acute removal of the lead

Remove the lead:

1. Rotate the lead body counterclockwise to withdraw the helix from the implant site if the helix appears intact and removal is required.
   Note: The number of counterclockwise rotations needed to withdraw the helix from the implant site before applying traction may be greater than the number of revolutions required for fixation.
   Note: If the helix is still imbedded in the endocardium, additional turns on the lead body should be applied rather than applying a retraction force.
2. Counterclockwise rotation should be continued throughout the removal process to decrease the possibility of damage to the cardiovascular tissue.
3. Remove the lead from the guide catheter while leaving the guide catheter in place.
4. Verify that the helix electrode is not damaged or deformed. Remove any tissue from the helix.

5. See "Inserting the lead into the guide catheter" to implant the lead. If the lead cannot be implanted, return the lead to Medtronic for analysis.

9.12 Removing the guide catheter from the lead

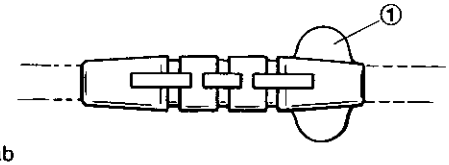
Once the lead is in the final position, verify that there is enough lead slack as recommended in step two of the "Verifying helix electrode fixation" section. Remove the guide catheter from the lead before surgical closure. See the delivery system product literature for details. Repeat electrical measurements, see the section "Taking electrical measurements".

9.13 Anchoring the lead

Cautions: Use care when anchoring the lead.

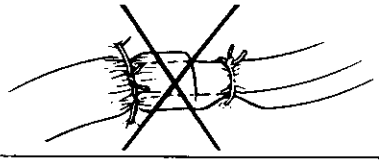
- Use an anchoring sleeve with all leads.
- Do not use absorbable sutures to anchor the lead.
- Do not secure the sutures so tightly that they damage the vein, lead, or anchoring sleeve.
- Do not use the anchoring sleeve tabs for suturing (Figure 11).
- Do not tie a suture directly to the lead body (Figure 12).
- Do not dislodge the lead tip.
- Do not attempt to remove or cut the anchoring sleeve.
- Do not remove the tabs on anchoring sleeves. Tabs are provided to minimize the possibility of the sleeve entering the vein.
- Do not allow passage of the anchoring sleeve into the guide catheter and/or the venous system.

Figure 11.



1 Tab

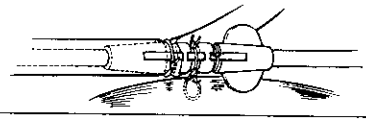
Figure 12.



Anchor the lead using all three grooves:

1. Position the anchoring sleeve against or near the vein.
2. Secure the anchoring sleeve to the lead body by tying a suture firmly in each of the three grooves (Figure 13).

Figure 13.



3. Use at least one additional suture in one of the grooves to secure the anchoring sleeve and lead body to the fascia.

9.14 Connecting the lead

Connect the lead to the implantable device according to the product literature packaged with the implantable device.

Connect the lead to the implantable device.

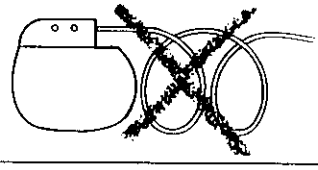
1. Obtain final electrical measurements.
2. Insert the lead connector into the connector block on the implantable device. For instructions on proper lead connections, see the product literature packaged with the implantable device.

9.15 Placing the implantable device and lead into the pocket

Cautions: Use care when placing the implantable device and lead into the pocket.

- Ensure that the lead does not leave the implantable device at an acute angle.
- Do not grip the lead or implantable device with surgical instruments.
- Do not coil the lead (Figure 14). Coiling the lead can twist the lead body and may result in lead dislodgement.

Figure 14.

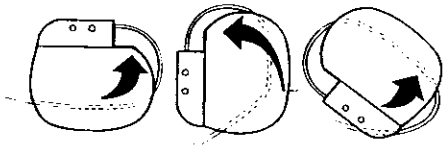


Caution: To prevent undesirable twisting of the lead body, wrap the excess lead length loosely under the implantable device and place both into the subcutaneous pocket.

Place the implantable device and lead into the pocket:

1. Rotate the implantable device to loosely wrap the excess lead length under the implantable device (Figure 15).

Figure 15.



2. Insert the implantable device and lead into the pocket.

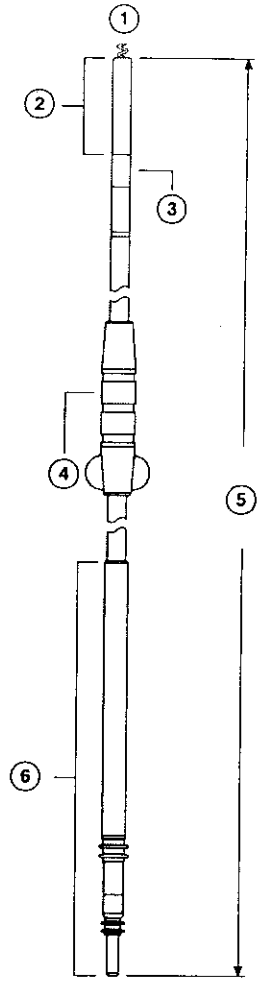
3. Suture the pocket closed.
4. Monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.

10 Detailed device description

10.1 Specifications (nominal)

Parameter		Model 3830
Type		Bipolar
Chamber		Atrium/Ventricle
Fixation		Nonretractable screw-in
Length		20-110 cm
Connector		IS-1 BI
Material	Conductors:	MP35N
	Connector pin:	Stainless steel
	Connector ring:	Stainless steel
	Inner insulator:	Silicone rubber/ETFE
	Outer insulator:	Polyurethane
Electrode material	Helix:	Titanium nitride coated platinum alloy
	Ring:	Titanium nitride coated platinum alloy
Electrode surface area	Helix:	3.6 mm^2
	Ring:	16.9 mm^2
Tip to ring spacing		9.0 mm
Lead body diameter		4.1 French (1.4 mm)
Catheter introduction size		9.0 French (3.0 mm)
Helix length (exposed)		1.8 mm
Resistance	Unipolar:	29 ± 6 Ω (69 cm)
	Bipolar:	99 ± 22 Ω (69 cm)
Steroid		Beclomethasone dipropionate
Amount of steroid (target dose)		17.9 µg

10.2 Specifications drawing (nominal)



1 Helix electrode surface area: 3.6 mm^2
2 Tip to ring spacing: 9.0 mm
3 Ring electrode surface area: 16.9 mm^2
4 Anchoring sleeve
5 Lead length: 20-110 cm
6 IS-1 BI connector

11 Medtronic warranty

For complete warranty information, see the accompanying warranty document.

12 Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise. For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

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