Medtronic

5071

Sutureless, unipolar, myocardial, screw-in pacing lead

Technical Manual

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

Contents

1 Description/Intended Use

The Medtronic Model 5071 sutureless, unipolar, myocardial, screw-in lead is designed for ventricular pacing and sensing. The lead has application where permanent ventricular or dual-chamber pacing systems are indicated. Two leads may be used for bipolar pacing.

The lead's screw-in electrode is designed to be secured to the myocardium with two clockwise turns. A polyester mesh allows fibrous ingrowth for additional fixation.

The lead requires no stab wounds or sutures for electrode placement and fixation. Tissue damage from electrode insertion may be compared to the insertion of a 15-gauge needle.

The lead also features a MP35N nickel alloy conductor, silicone rubber insulation and a unipolar connector (IS-1 UNI).[1]

1.1 Package contents

Leads and accessories are supplied sterile. Each package contains the following items:

- 1 lead
- 1 lead handle
- 1 tunneler
- 1 lead end cap
- product literature

2 Contraindications

The lead should not be used on a patient with a thin-walled, heavily infarcted, or fibrotic myocardium. It is also contraindicated for the patient whose myocardium is suffused with fat.

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

3 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 treatment (including therapeutic ultrasound) – Diathermy is a treatment that involves the therapeutic heating of body tissues. Diathermy treatments include high frequency, short wave, microwave, and therapeutic ultrasound. Except for therapeutic ultrasound, do not use diathermy treatments on cardiac device patients. Diathermy treatments may result in serious injury or permanent damage to an implanted device and leads. Therapeutic ultrasound (including physiotherapy, high intensity therapeutic ultrasound, and high intensity focused ultrasound), is the use of ultrasound at higher energies than diagnostic ultrasound to bring heat or agitation into the body. Therapeutic ultrasound is acceptable if treatment is performed with a minimum separation distance of 15 cm (6 in) between the applicator and the implanted device and leads, as long as the ultrasonic beam is pointing away from the device and leads.

Magnetic resonance imaging (MRI) – An MRI is a type of medical imaging that uses magnetic fields to create an internal view of the body. Do not conduct MRI scans on patients who have this device or lead implanted. MRI scans may result in serious injury, induction of tachyarrhythmias, or implanted system malfunction or damage.

Single use – The lead and accessories are 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 (104 °F).
- 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.

Handling a screw-in lead – Handle the lead with care at all times.

- Do not implant the lead if it is damaged. Return the lead to a 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.
- Dry the electrode head and handle before remounting if the lead is removed during surgery.
- 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.

- Form a loop immediately behind the electrode to ensure proper stability on the handle.
- Do not force the lead if resistance is encountered during lead passage.

Necessary hospital equipment – Keep external defibrillation equipment nearby for immediate use during acute lead system testing, the 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 of a screw-in lead – Chronic repositioning or removal of the lead after it has been implanted in the patient is not recommended. If removal is unavoidable, return the lead to Medtronic.

If a lead is abandoned, it should be capped to avoid transmitting electrical signals from the pin to the heart. A lead that has been cut off should have the remaining lead end sealed and it should be sutured to adjacent tissue to avoid migration.

4 Summary of clinical performance of the Model 5071 lead

4.1 Clinical study

The Medtronic Model 5071 lead is studied within the Medtronic System Longevity Study (SLS). The SLS is a prospective, non-randomized, multi-center study of implanted commercially available cardiac therapy products. This study is currently being conducted in the United States (US), Canada, and EMEA (Europe, Middle East and Africa).

As of the January 31, 2013 cutoff date, a total of 290 Model 5071 leads in 212 subjects have been enrolled in the Medtronic System Longevity Study (SLS). The first 5071 implant occurred on February 17, 1994. There have been 21(in 17 subjects) reported Model 5071 lead-related complications, and a total of 146 exits (including 37 deaths). The observed survival rate of freedom from Model 5071 lead-related complications at 5 years was 85.4%, with a 2-sided 95% confidence interval of (76.8%, 91.1%).

4.2 Clinical inclusion and exclusion criteria

Subjects who meet the following inclusion criteria and do not meet any of the following exclusion criteria are eligible for enrollment as subjects in the SLS.

4.2.1 Inclusion criteria

- Subjects or appropriate legal guardians provide written informed consent and/or authorization for access to and use of health information, as required by an institution's IRB/MEC/REB.

AND one of the following (a or b) must also apply:

a. Subjects indicated for implant or within six months post-implant of a Medtronic market-released lead connected to a market-released IPG, ICD, or CRT Device. The Medtronic lead must be used for a pacing, sensing or defibrillation application.

b. Subjects who participated in a qualifying study of a Medtronic cardiac therapy product and for whom:

- product is market-released
- complete implant and follow-up data, including product-related adverse events, are available
- subject or appropriate legal guardian authorizes release of subject study data to SLS

4.2.2 Exclusion criteria

- Subjects receiving an implant of a Medtronic lead at a non-participating center and the implant data and current status cannot be confirmed within 30 days after implant
- Subjects who are, or will be inaccessible for follow-up at a SLS center
- Subjects implanted with a Medtronic cardiac therapy device whose predetermined enrollment limit for that specific product has been exceeded
- Subjects with exclusion criteria required by local law (Europe, Middle East and Africa)

Data included in this clinical Safety and Efficacy Summary is a subset of the SLS dataset. The subset criteria are:

- A subject who is implanted with at least 1 Model 5071 lead with valid implant date and product serial number
- A subject is enrolled in a verifiable study center

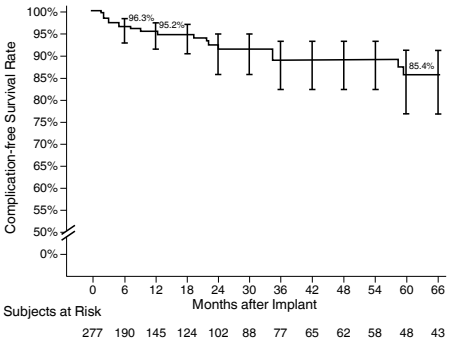
4.3 Clinical study results

As of the cut-off date, 212 subjects have been enrolled in the study with a Model 5071 lead, 91 (42.9%) subjects are female and 121 (57.1%) are male. The average age was 53.4 years with 32 (15.1%) subjects younger than 19 and 94 (44.3%) subjects older than 65 years of age.

4.3.1 Lead survival probability

As of the data cut-off date, 21 Model 5071 lead related complications were observed in 21 Model 5071 leads. The survival curve is presented in Figure 1. All enrolled Model 5071 leads were included in this analysis. Subjects who exited the study due to a non-model 5071 lead related reason were censored at the date of study exit. The observed survival rate of freedom from Model 5071 lead-related complications at 5 years was 85.4%, with a 2-sided 95% confidence interval of (76.8%, 91.1%).

Figure 1. Kaplan-Meier Estimate of Model 5701 Complication Free Survival Probability



4.3.2 Adverse effects that occurred in the clinical study

As of the data cut-off date, there have been 21 (in 21 implanted Model 5071 lead, in 17 subjects) reported Model 5071 lead related chronic complications. Table 1 is a summary of Model 5071 related complications (or failure modes).

Table 1. Summary of complication rates

Complication	Number of leads (in # subjects)	Complication rate (N=290)	95% Confidence interval[b]
Abnormal impedance	1(1)	0.003	(0.0001, 0.0191)
Elevated Thresholds	3 (2)	0.010	(0.0021, 0.0299)
Failure to Capture	12 (10)	0.041	(0.0216, 0.0712)
Oversensing	2(1)	0.007	(0.0008, 0.0247)
Undersensing	1(1)	0.003	(0.0001, 0.0191)
Other[a]	2(2)	0.007	(0.0008, 0.0247)
Overall	21(17)	0.072	(0.0454, 0.1086)

[a] The cause of two lead revisions was not reported. These two events were conservatively counted as lead related complications.
[b] 2-sided 95% Confidence Intervals are calculated using the Exact binomial method.

4.3.3 Subgroup analyses

Additional ad-hoc analyses were carried out to further present Model 5071 lead safety performance in different age, gender and geographic groups. It was observed that Model 5071 leads implanted in patients in the age group of 19-65 years experienced better complication free survival (93.9% at 5 years), comparing to either younger or older patient group (75.5% and 79.0% at 5 years, respectively).

4.4 Effectiveness analysis

The study of Model 5071 lead within the System Longevity Study Protocol did not intensively examine the efficacy performance of the lead, i.e. there were no specific requirements regarding lead electrical testing done at each follow-up visit. Model 5071 lead efficacy performance data are summarized based on data collected from (de-identified) patients who are implanted with Model 5071 leads and Medtronic generators, and are registered in the Medtronic CareLink remote monitoring system.

The effectiveness analysis was conducted utilizing device data (n=3794) collected via Medtronic CareLink system. The Model 5071 lead observed mean LV pacing thresholds (weekly max) of 2.39±1.05V at implant and 2.33 ± 0.98V at 5 years. The electrical performance was stable over time and was within expected values, with 23.9-35.1% > 3V through 5 years post implant.

4.5 Summary of supplemental clinical information

Most of the studied Model 5071 leads were enrolled in the SLS after their successful implant procedure. Therefore, the clinical study does not provide sufficient data to provide an unbiased evaluation of implant tools, implant success rates and implanter experiences. Nonetheless, Model 5071 leads were researched and published in several peer reviewed Journals.

Implanting technique and experience for cardiac epicardial leads, including Model 5071 leads, was discussed in the Mair[2] paper which was published in The Heart Surgery Forum (2003). The paper studied three epicardial lead implantation techniques: (1) left lateral mini-thoracotomy; (2) a video-assisted thoracoscopy approach using lead implantation tools; and (3) a robotically enhanced telemanipulation system. In a total of 80 patients, the study observed that intended lead location on the LV was achieved in all patients. Acute and 3-month LV lead thresholds were satisfactory in 79 patients (99%). The paper detailed the thoracoscopic approach using the Medtronic 10626 epicardial lead implant tool for the Medtronic 5071 epicardial pacing lead and concluded that the thoracoscopic approaches with further improvements in the leads and implantation devices were at least equivalent or possibly better treatment options than the coronary sinus approach for BiV pacing.

[2] Helmut Mair, Jean-Luc Jansens, Omar M. Lattouf, Bruno Reichart, Epicardial Lead Implantation Techniques for Biventricular Pacing via Left Lateral Mini-Thoracotomy, Video-Assisted Thoracoscopy, and Robotic Approach, The Heart Surgery Forum Volume 6 (5), 2003

Screw-in epicardial lead implant techniques were also discussed in the Navia[3] paper published in The Annuals of Thoracic Surgery (2005). This study enrolled patients for undergoing surgical epicardial implantation after transvenous implantation failure. Surgical approach was either endoscopic (video-assisted thoracoscopic surgery or robotic) or by means of minithoracotomy. The paper compared safety and efficacy of these two approaches and concluded that both procedures were safe, with short procedure times, no implant failure, no mortality, and minimal morbidity. Heart failure conditions were improved in most patients.

Doll[4] reported 7 cases of Model 5071 implant procedure using Medtronic Model 10626 epicardial lead placement tool in The Annals of Thoracic Surgery (2003). In 5 patients, the procedure was performed at the same time as biventricular defibrillator implantation. Two patients underwent isolated epicardial lead placement 1 day and 10 days after failed transvenous LV lead placement. The paper concluded that the implanting tool was safe and efficient.

Lead placement technique and CRT response after Model 5071 lead implantation were studied in the Edgerton[5] paper published in The Annals of Thoracic Surgery (2007). A total of 29 patients with heart failure class III or IV and had failed transvenous LV lead placement were included in this study. All patients were prepared for thoracoscopic placement of a Medtronic 5071 lead. A follow-up telephone survey was carried out to measure change in the patients' quality of life. The Model 5071 lead placements were 100% successful. The study reported that Quality of Life scores improved in 90.9% of patients with mapped lead placement and in 66.6% of the patients without mapped lead placement.

In summary, this peer-reviewed clinical evidence demonstrates that Model 5071 implanting tools are acceptable and that the implanting technique is mature. Patient clinical outcome after receiving a Model 5071 lead is acceptable.

5 Potential complications

The potential complications related to the use of myocardial leads include, but are not limited to, the following patient-related conditions that can occur when the lead is being inserted or repositioned:

- cardiac tamponade
- fibrillation and other arrhythmias
- heart wall damage
- infection
- muscle or nerve stimulation
- pericardial rub

[3] Navia Jose L, Fernando A, Grimm Richard, et. al. Minimally Invasive Left Ventricular Epicardial Lead Placement: Surgical Techniques for Heart Failure Resynchronization Therapy, The Annals of The Thoracic Surgery 2005; 79:1536-1544

[4] Nicolas Doll, Ulrich T, et. al. Facilitated Minimally Invasive left Ventricular Epicardial Lead Placement, The Annals of Thoracic Surgery 2005;79:1023–5

[5] James R Edgerton, Zachary Edgerton, et. al. Ventricular Epicardial Lead Placement for Resynchronization by Determination of Paced Depolarization Intervals: Technique and Rationale, The Annals of Thoracic Surgery 2007; 83:89-92

Other potential complications related to the screw-in lead and the programmed parameters include, but are not limited to, the complications listed in the following table.

Complication	Symptom	Corrective action to be considered
Cardiac strangulation	Chest pain, general fatigue, syncope, symptoms of myocardial infarction, heart failure, new cardiac murmur.	Reposition or replace the lead.
Lead dislodgement	Intermittent or continuous loss of capture or sensing[a]	Reposition the lead.
Lead conductor or helix fracture or insulation failure	Intermittent or continuous loss of capture or sensing[a]	Replace the lead.
Threshold elevation or exit block[a]	Loss of capture[a]	Adjust the implantable device output. Replace or reposition the lead.
Bipolar pacing indicated (use two leads)	Increased risk of inducing tachyarrhythmia due to equal surface area or anodal and cathodal electrodes	If the paced stimuli are observed to be falling on the T-Wave, it may help to unipolarize the system.

[a] 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.

The potential complications listed above may occur at a higher rate with the use of these leads in pediatric patients.

6 Implant procedure

Proper surgical procedures and sterile techniques are the responsibility of the medical professional. Some implant techniques vary according to physician preference and the patient's anatomy or physical condition.

6.1 Surgical approaches

A variety of surgical approaches can be used to implant this lead, including limited thoracotomy, subxiphoid, transxiphoid, and transmediastinal. In many cases, local anesthesia can be used.

6.2 Mounting the lead

Before implant, ensure that the lead is properly mounted on the handle. If it is necessary to remount the lead, follow the instructions hereafter.

1. Insert the electrode head in the groove at the handle's tip (Figure 2). Insert the pointed tip of the tunneler into the handle cavity. Slide it through the cavity until the tunneler's slight projections are in line with the notches on the handle. Then, rotate the tunneler counterclockwise and pull it back until the projections rest snugly within the two notches (Figure 3).

Figure 2. Electrode head in the groove of the handle

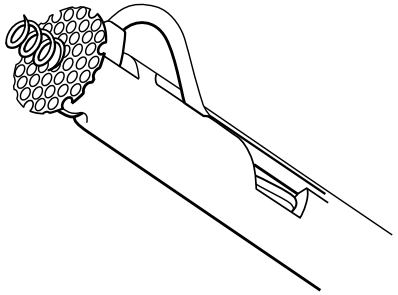
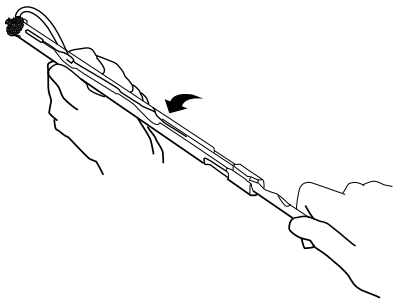
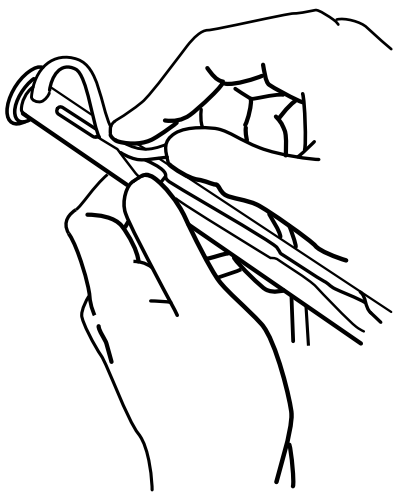


Figure 3. Fitting tunneler in the handle



2. Insert the lead body into the handle grooves while leaving a small loop near the electrode head (Figure 4).

Figure 4. Loop near the electrode head



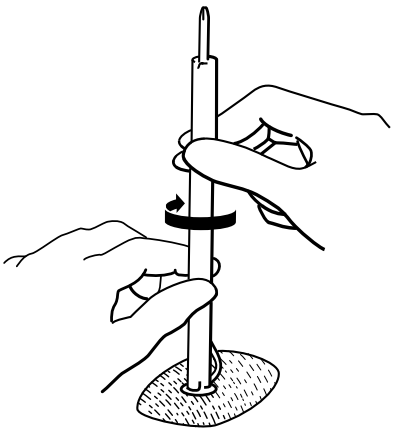
6.3 Lead fixation

The implant site should be an avascular area free of infarcts, fat, or fibrosis. If bipolar pacing is indicated, a separate electrode may be installed adjacent to the first with a minimum of 2.5 cm (0.98 in) space between them (unless a different spacing is required for a particular pulse generator).[6]

To fixate the lead:

1. Place the mounted electrode tip in the desired position. Affix the electrode to the myocardium with two clockwise turns. Each turn is to be made during systole. Use only light pressure (Figure 5).

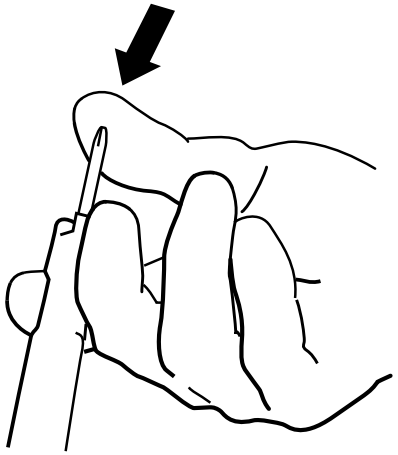
   Figure 5. Affixing the lead

2. Electrical measurements should be taken before unloading the lead from the handle. Initial electrical measurements may be unsatisfactory because of acute cellular trauma. If this occurs, wait five to ten minutes and repeat measurement procedures. If electrical measurements remain unacceptable, another implantation site should be selected.
3. Release the electrode and lead body by gripping the handle between two fingers and gently pushing the tunneler in a syringe-type action (Figure 6).

[6] Refer to the Potential complications section of this manual.

Figure 6. Releasing the electrode and lead body



Caution: Heavy pressure on the electrode may force the electrode through the myocardial wall. Make sure the electrode is completely detached from the handle before removing the handle from the operative site.

4. If a separate pocket is created for the pulse generator, the lead should be passed within muscle layers to the pocket while avoiding sharp angle bends of the lead body. Attach the lead connector pin to the tunneler and pass the tunneler to the pocket incision. When removing the lead from the tunneler, hold the lead connector tightly near the pin and gently pull and twist off.

6.4 Acute lead repositioning

If lead repositioning is necessary and the lead has not been detached from the handle, rotate the lead and handle assembly counterclockwise two turns to achieve safe, acute lead removal. However, if the lead has been detached from the handle, follow the procedure below:

1. Remove the tunneler from the handle.
2. Carefully fit the handle's curved groove over the electrode head.
3. Rotate the electrode head counterclockwise two to three turns to achieve removal.

6.5 Taking electrical measurements

Low stimulation thresholds and adequate sensing of intra-cardiac signal amplitudes indicate satisfactory lead placement. Medtronic recommends using a voltage source such as a pacing system analyzer for obtaining electrical measurements.

A low stimulation threshold provides for a desirable safety margin, allowing for a possible rise in thresholds that may occur within two months following implantation.

Adequate sensing amplitudes ensure that the lead is properly sensing intrinsic cardiac signals. Minimum signal requirements depend on the pulse generator's sensitivity capabilities. Acceptable acute sensing amplitudes for the lead must be greater than the minimum pulse generator sensing capabilities including an adequate safety margin to account for lead maturity.

Table 2. Recommended measurements at implant when using a pacing system analyzer

Measurement required	
Maximum acute stimulation thresholds[a]	1.0 V
Minimum acute sensing amplitudes	4.0 mV

[a] At pulse duration setting of 0.5 ms.

These measurements assume a 500 Ω pacing resistance.

Initial electrical measurements may deviate from the recommendations because of acute cellular trauma. If this occurs, wait five to fifteen minutes and repeat the testing procedure.

Values may vary depending upon lead type, pulse generator settings, cardiac tissue condition, and drug interactions.

If electrical measurements do not stabilize to acceptable levels, it may be necessary to reposition the lead and to repeat the testing procedure.

For more information on obtaining electrical measurements, consult the technical manual supplied with the testing device.

6.6 Connecting the lead

Connect the lead to the pulse generator according to the instructions in the pulse generator manual.

The connector on the Model 5071 is a unipolar connector (IS-1 UNI).

IS-1 UNI and IS-1 BI leads always have the label identification "IS-1 UNI" or "IS-1 BI" on the connector. IS-1 UNI leads may sometimes be further identified by a blue ring located distal to the connector pin.

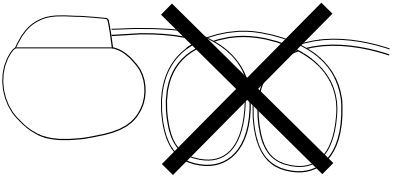
1. Obtain final electrical measurements.
2. Insert the lead connector into the connector block on the device. For instructions on proper lead connections, see the product literature supplied with the device.

6.7 Placing the device and lead into the pocket

Cautions:

- Use care when placing the device and lead into the pocket.
- Ensure that the lead does not leave the device at an acute angle.
- Do not grip the lead or device with surgical instruments.
- Do not coil the lead (Figure 7). Coiling the lead can twist the lead body and may result in lead dislodgment.

Figure 7. Do not coil the lead body

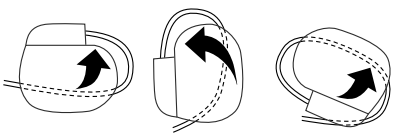


Caution: To prevent undesirable twisting of the lead body, wrap the excess lead length loosely under the device and place both the device and the lead into the subcutaneous pocket.

Place the device and lead into the pocket:

1. Rotate the device to loosely wrap the excess lead length under the device (Figure 8).
   Caution: Cardiac strangulation is a known rare complication of myocardial lead placement. Signs and symptoms reported to be associated with strangulation can include, but are not limited to, chest pain, general fatigue, syncope, symptoms of myocardial infarction, heart failure, and new cardiac murmur. Particular attention should be taken for the appropriate placement and routing of the lead to the pacemaker in order to reduce the risk of cardiac strangulation.

   Figure 8. While rotating the pulse generator, loosely wrap the excess lead length and place it under the pulse generator



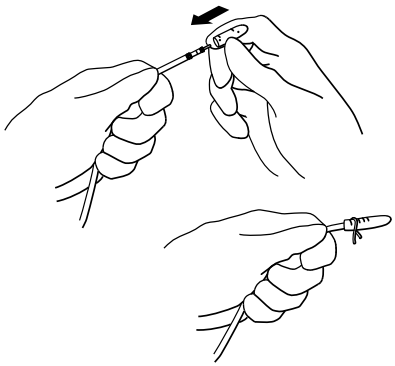
2. Insert the device and lead into the pocket.
3. Suture the pocket closed.
4. Monitor the patient's electrocardiogram until the patient is discharged. If a lead dislodges, it usually occurs during the immediate postoperative period.

6.8 Using the lead end cap

Use a lead end cap to seal off the connector pin (Figure 9) if the lead is being reserved for pulse generator connection at a future date or if the lead has been abandoned (i.e. any leads not explanted, but not connected to the pulse generator).

Insert the end cap over the lead connector pin so that the sealing rings on the lead are fully covered. Sterile water may be used to facilitate this application. No adhesives are necessary. Tie a nonabsorbable, synthetic ligature in the end cap's groove.

Figure 9. Using the lead end cap



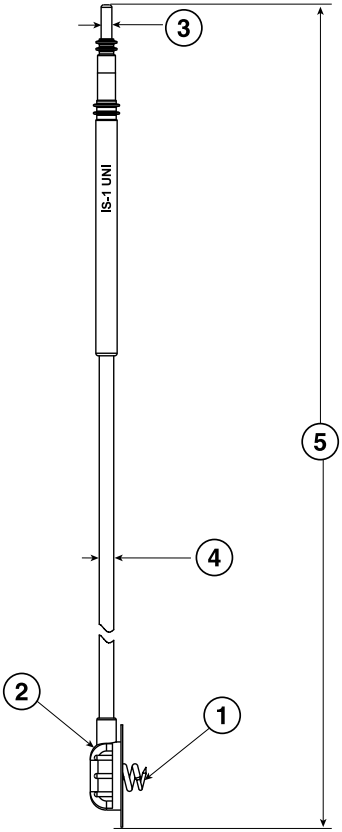
Caution: Do not secure the ligature so tightly that it damages the end cap and the lead.

The end cap can be removed at a later date without damaging the lead.

7 Specifications (nominal)

Parameter		**Model 5071**
Type		Unipolar
Chamber		Ventricle
Fixation		Screw-in
Length		15–110 cm (5.9–43.3 in)
Connector		IS-1 UNI
Material	Conductor:	MP35N
	Connector pin:	Stainless steel
	Insulator:	Treated silicone rubber
	Helix electrode:	Platinum alloy
Diameter	Lead body:	2.2 mm (0.09 in)
Electrode surface area	Helix:	6.6 mm^2 (0.26 in^2)
Helix length (fully extended)		3.5 mm (0.14 in) (2 turns)
Unipolar resistance		39 Ω (35 cm) (13.78 in)
		59 Ω (53 cm) (20.87 in)

Figure 10. Model 5071 lead components



1 Electrode surface area: 6.6 mm^2 (0.26 in^2)
2 Electrode head
3 Connector pin diameter: 1.6 mm (0.06 in)
4 Lead body diameter: 2.2 mm (0.09 in)
5 Lead length:15–110 cm (5.9–43.3 in)

8 Medtronic warranty

For complete warranty information, see the accompanying warranty document.

9 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 more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate telephone number or address listed on the back cover.

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