Myopore®

Bipolar Porous Tip Sutureless
Myocardial Pacing Lead

Instructions for Use (en) 2

Greatbatch™
Medical

DEVICE DESCRIPTION/GENERAL INFORMATION

The Greatbatch Medical Myopore® Bipolar Sutureless Myocardial Pacing Lead is designed for long term ventricular pacing and sensing. The FasTac® Introducer aids attachment of the lead to the epicardial surface of the heart. The lead is packaged pre-loaded onto the FasTac Introducer, ready to use. Reloading of the lead can be accomplished in a few seconds. The lead may be detached from the introducer FasTac Introducer using only one hand. The FasTac Introducer allows for re-grasping the lead using only one hand. Multiple leads may be implanted to meet varied patient systems requirements. The lead and accessories are sterile packaged.

STERILE TRAY CONTENTS

1 Lead
1 FasTac Introducer
1 Tunneler
1 Bi-directional Tunneler Tip
1 Connector Pin Cap

SPECIFICATIONS

The provided lead specifications are based on nominal conditions.

Models	511210 (25 cm)	511211 (35 cm)	511212 (54 cm)
Electrode surface area -cathode -anode	10 mm^2 62 mm^2	10 mm^2 62 mm^2	10 mm^2 62 mm^2
Helix penetration depth	3.5 mm	3.5 mm	3.5 mm
Number of helix turns	2.25	2.25	2.25
Lead Resistance -cathode -anode	20 Ohms 38 Ohms	27 Ohms 46 Ohms	41 Ohms 75 Ohms
Lead length	25 cm	35 cm	54 cm
FasTac Introducer length	27 cm	27 cm	27 cm
Tunneler Length	27 cm	27 cm	27 cm
Connector type	IS-1 BI*	IS-1 BI*	IS-1 BI*
Electrode material -helix -anode plate	Platinum/Iridium Titanium	Platinum/Iridium Titanium	Platinum/Iridium Titanium
Conductor material	MP35N (Mulitifilar coil)	MP35N Multifilar coil)	MP35N (Multifilar coil)
Insulation material	Silicone Rubber (Medical Grade)	Silicone Rubber (Medical Grade)	Silicone Rubber (Medical Grade)
Connector pin material	316L Stainless Steel	316L Stainless Steel	316L Stainless Steel

*Connector conforms to the IS-1 standard, ISO 5841

INDICATIONS FOR USE

The Myopore Bipolar Sutureless Myocardial Pacing Lead is indicated for use when ventricular epicardial attachment is required, or when a transvenous lead cannot provide effective pacing. This type of lead is useful in situations where it is required that the potential for lead dislodgement be diminished, or that pacing and/or sensing will be established subsequent to open heart surgery.

CONTRAINDICATIONS

The Myopore Bipolar Sutureless Myocardial Pacing Lead is contraindicated for:

- Patients in which the ventricular myocardium is thin walled, suffused with fat or fibrotic tissue, or is heavily infarcted.
- Atrial implantation due to helix length (3.56 mm) being longer than the average atrial wall thickness (0.5 - 3.55 mm).

WARNINGS AND PRECAUTIONS

General

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- The surgical approach must provide adequate clearance for the FasTac Introducer to completely open when the FasTac Introducer is held at the implant position (see Figure 5).
- The Myopore Lead and accessories are intended for single use only. Do not reuse.
- Reuse of single-use devices creates a potential risk of patient or user infections. Contamination of the device may lead to injury, illness or death of the patient.
- Cleaning, disinfection and sterilization may compromise essential material and design characteristics leading to device failure.
- Confirm compatibility with the implantable pulse generator before opening the lead package. Consult implantable pulse generator's instructions for use.
- Use only battery-powered equipment during lead implantation and testing to protect against fibrillation that may be caused by alternating current.
- Only line-powered equipment that is properly grounded should be used in the vicinity of the patient during the implant procedure.
- Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.
- 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.

- The patient should be isolated from hazardous leakage current when using electrical instrumentation.
- Patients with metal implants such as implantable cardiac leads should not receive diathermy treatment, MRI, or Lithotripsy.
- 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.
- Patients should be warned to seek medical advice before entering environmental areas that could adversely affect the operation of the implantable pulse generator. See the device manufacturer's instructions for use with EMI, and environmental warnings and precautions.
- 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 Greatbatch Medical.
- Lead extraction presents clinical risks to the patient. Great care should be exercised.
- The electrode helix should not be altered or manipulated in any manner, since reshaping it may cause weakening or damage.

Storage and Handling

- Although the lead is quite flexible, care should be taken to apply only normal flexing pressure.
- Do not bring sharp objects in contact with the lead as they can compromise the leads insulation.
- Handle the lead with sterile gloves.
- Avoid handling the lead with excessive force or surgical tools.
- Do not wipe or immerse lead head in any fluid prior to implantation.
- The silicone rubber insulation of the lead has a strong affinity for dust, lint and foreign material. The lead should not be handled around items shedding these materials.

Lead Implantation

- Do not suture directly to the lead body.
- After initial penetration of the helix tip into epicardium, 2.25 turns are required.
- Cardiac strangulation is a known rare complication of epicardial lead placement. Signs and symptoms reported to be associated with strangulation include, but are not limited to, chest pain, general fatigue, syncope, symptoms of myocardial infarction, heart failure and new cardiac murmer. 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.
- 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.

POTENTIAL ADVERSE EVENTS

Potential adverse events associated with the implantation and use of epicardial leads include:

- Cardiac perforation
- Cardiac tamponade
- Exit Block, elevated thresholds
- Loss of pacing and/or sensing due to dislodgement or mechanical malfunction of the pacing lead
- Hematoma/Seroma
- Complications due to general surgical procedures such as infection or foreign body reaction
- Muscle or nerve stimulation
- Pocket stimulation
- Excessive fibrotic tissue
- Myocardial injury or irritation
- Induced ventricular arrhythmias
- Pneumothorax
- Thrombosis
- Death
- Breakage of the lead insulation, conductor, or helix
- Poor connection to the implantable pulse generator

STERILIZATION

- Single use only.
- The Myopore Lead has been sterilized using a 100% Ethylene Oxide sterilization method.
- The package and its contents should not be exposed to Autoclave, Flash Autoclave or any other alternative methods of sterilization.
- Do not resterilize lead or package contents; if sterility is compromised return to Greatbatch Medical.

STORAGE AND HANDLING

- The lead should be stored at temperatures between -37°C (-35°F) and 66°C (150°F) and kept dry.
- The lead package has been sterilized with Ethylene Oxide for direct introduction of the inner tray into the sterile field.
- Care should be taken in handling the package. Do not store under heavy objects, or store or handle around sharp objects.

OPENING INSTRUCTIONS

- Check the "Use By" date on the label before opening the lead. Do notimplant the lead if the "Use By" date has expired.
- Before the package is opened, inspect it visually for any damage that mayhave compromised sterility. Locate the corner on the package label lid andcarefully peel back the lid.

Note: The serial number label for the lead is located on the connector and should be documented on the Medical Device Registration Form (82131).

- If the container, the package, or the lead appears to be damaged do not use the lead and return it to Greatbatch Medical.

(See Figures 1 and 2)

Figure 1

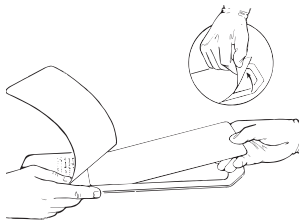

Figure 2

CLINICAL SUMMARY

The safety, effectiveness and survivability of the Myopore Leads were evaluated through two different approaches. The results from each support the safety, effectiveness and long term performance of the Myopore Lead, when used in a manner consistent with the labeling and intended use. A presentation of the evaluation methods and results follows:

Clinical Literature Search

An extensive clinical literature search was conducted to identify peer-reviewed articles that reported information regarding epicardial lead safety, effectiveness and survivability. These articles were filtered by using systematic keywords for epicardial leads and reviewed using objective criteria.

The results of the relevant articles (n=76), spanning 3 decades from 1982 to 2012, were synthesized, summarizing the safety, effectiveness, electrical performance and survivability of epicardial leads.

Meta-Analysis

A detailed meta-analysis of the relevant clinical articles was conducted to derive safety, effectiveness and survivability information of epicardial leads in a quantitative and pooled fashion. Data abstraction for the meta-analysis used standard abstraction forms defined a priori. The analysis dataset combined the data extracted from 76 articles, contributing a total of 123 unique cohorts of subjects (78,776 patients), using at least 10,648 leads. Of the 123 unique cohorts, 85 summarized results for subjects who had received epicardial leads (4,814 patients). The pooled lead data covered 4,814 patients implanted with at least 5220 leads. The patients included in the analysis were from across the globe and represented a maximum follow-up of 38 years.

Data Analysis Methods

For all information extracted from the publications, values that were not reported remained missing in the analysis dataset. That is, if a publication did not mention any occurrences of a particular outcome, that outcome remained missing for all analyses (e.g. it was not assumed that there were zero occurrences of that event).

After the fixed effect model was executed, statistical heterogeneity across cohorts was assessed using the Q-statistic. The Q-statistic follows the chi-square distribution, and the corresponding p-value was reported for each calculation; a value ≤ 0.05 was considered statistically significant, and indicated significant heterogeneity of event rates across the published study cohorts.

In view of the differences expected between studies and in order to be conservative, a random effects model was used to determine pooled estimates. The methods of DerSimonian and Laird[1] were applied to calculate the pooled event rates.

Meta-Analysis Limitations

The meta-analysis has methodological limitations that should be noted. As with most meta-analyses, there is inherent publication bias. That is, only studies that were published are included in the meta-analysis. Often, unsuccessful studies are not published, resulting in a potential bias in the results of a meta-analysis.

A potential weakness of this meta-analysis is the variability in study design among the included studies. While most studies were either prospective or retrospective cohort studies at a single center, the study population and timing of the studies varied and contributed to some heterogeneity.

It should also be noted that the publications covered a wide range of duration of follow-up, and loss-to-follow-up was rarely reported. Therefore, the estimated outcome rates and corresponding confidence intervals may carry some mis-estimation error that would be difficult to quantify.

[1] DerSimonian R, Laird N. (1986). Meta-Analysis in Clinical Trials. *Controlled Clinical Trials* 7:177-188.

Nonetheless, the meta-analysis spans a large time period of clinical investigations, performed independently in multiple geographies for a variety of clinical uses and using different adjunct pacing systems and implant procedures. Therefore, it is reasonable to conclude that the results of the meta-analysis adequately represent the pooled clinical experience with epicardial leads.

Summary of Meta-Analysis Results

Estimated occurrence rates of relevant safety and effectiveness outcomes were derived for the overall patient cohort, which was also analyzed in subgroups covering different cohorts.

a. Overall patient cohort outcomes

Table 1 shows the overall estimates for fixed and random effects models for all epicardial leads.

Table 1: Meta-Analysis of Outcome Rates

			Fixed Effect		Test Of Homogeneity		Random Effect	
Study Group	**Cohorts**	**Subjects**	**Estimate (%)**	**95% CI**	**Q**	**P-value**	**Estimate (%)**	**95% CI**
All-Cause Death	46	2,401	9.18	(7.99, 10.37)	183.09	>0.99	9.26	(6.72, 11.81)
Infection	33	2,275	2.88	(2.13, 3.64)	21.427	0.08	2.88	(2.13, 3.64)
Any Reintervention	23	1,874	12.04	(10.31, 13.76)	-451.7	.	12.04	(10.31, 13.76)
Any Complication	20	1,159	22.90	(19.81, 25.98)	31.860	0.97	8.37	(5.05, 11.7)
Lead Failure	59	3,337	9.76	(8.73, 10.78)	-270.1	.	9.76	(8.73, 10.78)
Lead Fracture	36	2,575	4.24	(3.5, 4.98)	106.15	1.00	4.79	(3.36, 6.22)
Lead Threshold Issue	38	2,138	6.66	(5.72, 7.6)	312.87	>0.99	10.70	(7.67, 13.73)
Lead Sensing Issue	22	940	3.10	(1.95, 4.25)	32.353	0.95	1.89	(0.63, 3.15)
Exit Block	19	1,034	7.80	(6.16, 9.43)	120.33	>0.99	9.48	(4.72, 14.25)
Extracardiac Stimulation	11	540	0.54	(0, 1.08)	11.148	0.65	0.14	(0, 0.52)
Insulation Issue	1	184	0.54	(0, 1.61)	--	--	0.54	(0, 1.61)

The summary of the analysis highlights a pooled estimate of occurrence of all-cause death at 9.18% or 9.26% depending on the effects models used (Fixed or Random). Similarly, infection rates are estimated at 2.88%/2.88%. Any complications related to the implant of the lead and any medical reintervention to address complications are estimated at 22.90%/8.37% and 12.04%/12.04%, respectively. Focusing on lead-related issues, the pooled data suggest a lead failure rate of 9.76%/9.76%, lead fracture rate 4.24%/4.79%. Other electrical performance issues are assessed with estimates ranging from 0.54%/0.54% for extracardiac (phrenic or diaphragmatic nerve) stimulation to 7.80%/9.48% for exit block. The results of the homogeneity tests suggests that, overall, the two effects models are not significantly different. The outcomes rate presented support acceptable levels of safety and effectiveness for the use of epicardial leads, regardless if evaluated using a fixed or a random effects model.

Since the results of the Q statistic from the two effects models in this meta-analysis across all patient cohorts suggest there is no statistical evidence of differences between the two models, the following sub-analyses will be presented using only the Random Effects model.

b. Different settings: acute and chronic using a 30 day cut-off

The surgical placement of the epicardial lead, though potentially minimally-invasive, may cause the patient to experience adverse events in the acute setting or the chronic setting, defined by a 30-day cut-off for acute and greater than 30 days for chronic events. These adverse events may be related to the implant procedure itself, dependent of the lead performance or independent of both and due to patient disease characteristics.

Table 2: Meta-Analysis of Acute and Chronic Outcome Rates

	Acute		Acute		Chronic		Chronic	
Study Group	**Cohorts**	**Subjects**	**Estimate (%)**	**95% CI**	**Cohorts**	**Subjects**	**Estimate (%)**	**95% CI**
All-Cause Death	28	1,553	3.80	(2.64, 4.96)	28	1,553	4.30	(1.94, 6.66)
Renal Issues	5	150	4.89	(0, 100)	5	150	40.00	(15.21, 64.79)
Infection	8	328	0.14	(0, 0.91)	33	2,275	2.83	(2.07, 3.58)
Complication	13	499	8.66	(0.78, 16.55)	20	1,159	7.91	(3.99, 11.84)
Lead Failure	12	479	4.14	(1.36, 6.92)	59	3,337	12.37	(9.69, 15.04)

The results do not raise any safety issues that would be unique to the acute or chronic settings. All-cause mortality and complications in both settings are

comparable (3.80%/4.30% and 8.66%/7.91%, respectively). As would be expected, lead failure does increase in the chronic setting (4.14% to 12.37%). The estimated chronic renal failure is notably higher, however, the direct role an epicardial lead implant plays in the occurrence or exacerbation of chronic renal failure cannot be readily explained. It is notable that many patients referred to epicardial lead placement could have failed transvenous lead placement after a prolonged attempt (which is associated with significant contrast dye usage)[2] or have an underlying disease with kidney dysfunction (common in heart failure patients). Aside from the considerations relative to renal complications, the data does support an acceptable level of safety in the acute and chronic settings.

c. Different study follow-up duration: short and long follow-up using a two-year cut-off

The clinical literature reviewed had varied levels of follow-up for patients with epicardial leads. In order to elucidate any potential impact that the follow-up period may play in the overall estimates for product safety and performance characteristics, an analysis was conducted to compare two cohorts dichotomized over a follow-up cut-off of 2 years.

Table 3. Meta-Analysis of Outcome Rates

	Short Duration (≤2 Yrs)		Short Duration Random Effect		Long Duration (>2 Yrs)		Long Random Effect	
Study Group	**Cohorts**	**Subjects**	**Estimate (%)**	**95% CI**	**Cohorts**	**Subjects**	**Estimate (%)**	**95% CI**
All-Cause Death	22	776	8.14	(5.01, 11.27)	24	1,625	9.67	(5.97, 13.38)
Infection	13	832	2.42	(1.22, 3.61)	20	1,443	3.19	(2.22, 4.17)
Any Reintervention	9	487	10.13	(2.86, 17.41)	14	1,387	13.52	(11.26, 15.78)
Any Complication	12	760	13.21	(7.68, 18.74)	8	399	30.26	(21.61, 38.9)
Lead Failure	27	1,209	14.10	(10.75, 17.45)	32	2,128	8.44	(7.19, 9.68)
Lead Fracture	12	829	2.54	(0.75, 4.33)	24	1,746	6.30	(4.24, 8.36)
Lead Threshold Issue	15	763	10.15	(5.72, 14.58)	23	1,375	10.72	(6.88, 14.56)
Lead Sensing Issue	7	190	5.93	(0, 12.47)	15	750	3.40	(1.44, 5.37)
Exit Block	12	418	4.03	(0.15, 7.9)	7	616	15.91	(6.3, 25.53)
Extracardiac Stimulation	8	362	0.30	(0, 1.32)	3	178	1.45	(0, 3.08)
Insulation Issue	--	--	--	--	1	184	0.54	(0, 1.61)

The meta-analysis results suggest that most safety and effectiveness measures are not affected by the mean study follow-up duration. Some estimates did change however; any complication increased (13.21% to 30.26%), lead failures decreased (14.10% to 8.44%) and lead fracture increased (2.54% to 6.30%). This finding is not surprising since some parameters would be expected to develop and increase (like lead fracture) over time. Lead failure decreases over time, largely due to the early contribution of acute lead failures that resolves with longer follow-up durations.

Aside from time-based changes, the data do not reveal any unexpected or previously unknown outcome concerns related to follow-up durations. Overall, the data supports an acceptable level of safety and performance for the use of epicardial leads with short mean follow-up durations that is maintained over longer follow-up durations.

d. Survivability: a weighted average survivability of epicardial leads

Epicardial leads have been in clinical use with tenure of several decades. Therefore, the survivability analysis assessed from the reported literature would represent a real-world experience with epicardial leads. To represent the industry-wide epicardial lead survivability, an analysis was performed to derive a pseudo-survivability curve as a weighted average of actual reported epicardial lead survivability data from the clinical literature. This analysis included lead survival, freedom from failure, adjusted survivability and freedom from reintervention for lead replacement, explants or abandonment. Figure A shows the average lead survival of the Myopore Lead over a ten year period.

2 AilawadiG et al. Surgically placed left ventricular leads provide similar outcomes to percutaneous leads in patients with failed coronary sinus lead placement. Heart Rhythm 2010; 7: 619-625.

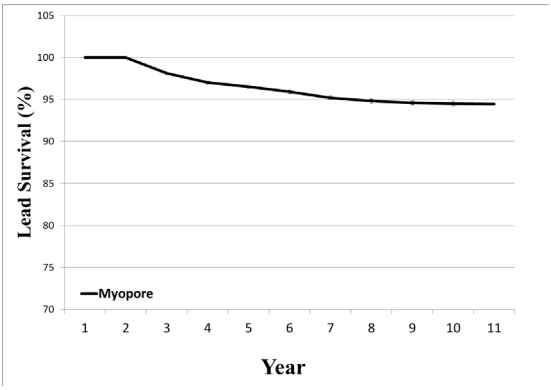

Figure A: Average Survivability Plot for the Myopore Lead

The weighted average survival reported in the literature typically accounts for combined acute and chronic events for the duration of follow-up / retrospective review. In addition, it assesses the survivability at discrete time points based on the literature reporting survivability for the epicardial lead cohorts. The contribution of the cohorts was weighted to the size of the study and the sample size at study onset. Without the actual censored events, it is difficult to assess the actual cohort sample size contributing to the individual points.

These data are derived from studies conducted in the US as well as other countries. It is also derived from clinical literature using multiple epicardial lead manufacturers, across a long period of time, over multiple age cohorts, multiple disease cohorts, multiple follow-up periods and multiple implant techniques. Although the survivability analysis could not adjust for potential confounding variables, it is believed that when taking the scope, scale and long clinical tenure included in this analysis, the weighted average survival analysis would homogenize any peculiarities or nuances inherent to each clinical article when examined individually. In summary, the survivability data derived from this analysis suggests that epicardial leads have an acceptable level of device longevity under real-world conditions.

In conclusion, the results of the meta-analysis support a safe and effective product with acceptable adverse event and complication occurrence rates in the cohorts analyzed. It also indicates epicardial leads have an acceptable survivability profile over a period of 15 years.

IMPLANT INFORMATION

Physician Training

Physicians should be familiar with sterile implant procedure and follow-up evaluation. The following sections describe various stages of lead implantation. Procedures included in these sections are only recommendations. Actual implant procedures are left to the discretion of the implanting physician.

WARNING: PACING LEADS PROVIDE A LOW RESISTANCE PATH DIRECTLY TO THE HEART. BATTERY POWERED OR PROPERLY GROUNDED DEFIBRILLATION/PACING EQUIPMENT SHOULD BE READILY AVAILABLE FOR USE IF NEEDED. A BATTERY POWERED OR PROPERLY GROUNDED PACING SYSTEM ANALYZER SHOULD BE USED TO MEASURE BOTH PACING THRESHOLD AND R-WAVE AMPLITUDE AFTER ATTACHMENT OF THE LEAD TO THE HEART.

Surgical Preparation

- The following instrumentation should be available during the surgical procedure: Heart monitoring, imaging (Fluoroscopy), external defibrillation, and pacing threshold sensitivity measurement equipment such as a pacing system analyzer (PSA).
- The patient should be isolated from hazardous leakage current when using electrical instrumentation.
- Compatibility of the lead with the implantable pulse generator should be confirmed prior to implantation of the pacing system.
- The implanting physician must completely understand the mechanical operation of this lead and the FasTac Introducer prior to surgery.

Lead Placement

The lead may be implanted via a subxyphoid, limited thoracotomy, median sternotomy, or other similar surgical approach. The surgical approach must provide adequate clearance for the FasTac Introducer to completely open when the FasTac Introducer is held at the implant position (see Figure 5).

An area of the ventricle, free of fat, vessels, and infarcted tissue should be chosen for placement of the lead. The left ventricle is the preferable pacing site. Prior to lead insertion, mapping may be useful for selecting the most appropriate site for final implantation. One or more leads may be used. If more than one lead is placed, a minimum distance of 2.5 cm between leads is recommended.

Note: Complete and mail the Medical Device Registration Form (82131).

Lead Introduction

Hold the lead and FasTac Introducer perpendicular to and above the selected implant site. Gently, but firmly advance the electrode into contact with the epicardium and rotate the FasTac Introducer and lead 2.25 turns in a clockwise direction.

(See Figures 3 and 4)

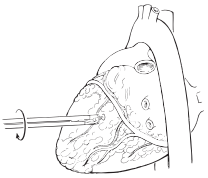

Figure 3

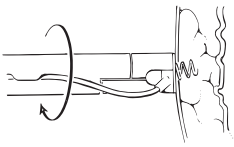

Figure 4

CAUTION: Gentle pressure is all that is required.

To release the lead from the FasTac Introducer, squeeze the FasTac Introducer firmly on the dots located between two arrows on either side of the FasTac Introducer and quickly release to allow the FasTac Introducer to open (as illustrated in Figure 5). Specifically, the dots are located directly over the latching mechanism 3½ inches from the proximal end of the FasTac Introducer. The lead body and head will detach from the FasTac Introducer. Ensure that the FasTac Introducer opens fully (as illustrated in Figure 5) before attempting to separate the FasTac Introducer from the lead head.

(See Figure 5)

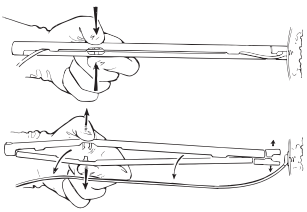

Figure 5

Visually confirm that the lead head is seated against the epicardium. If there is space between the lead head and the epicardium regrasp the lead and continue to turn the lead head clockwise until the anode plate (base of lead head) is fully seated.

CAUTION: Rotation past the point of anode plate and epicardium contact, should be avoided.

(See Figures 6 and 7)

Figure 6

Figure 7

Lead Repositioning

The lead may be easily repositioned following these steps:

- Ensure the FasTac Introducer is unlatched.
- Carefully align the FasTac Introducer with the lead head. Rotate the FasTac Introducer such that one of the slots at the tip aligns with the body of the lead where it exits from the side of the lead head (see Figure 8).
- Gently push the FasTac Introducer over the lead head. Grasp the lead head by gently squeezing over the dots until a single click is heard indicating that the FasTac Introducer is latched. If two clicks are felt and the FasTac Introducer opens when pressure is released attempt to grasp again by squeezing with lighter pressure.
- Unscrew the lead counterclockwise (see Figure 9) until the helix is completely removed from the heart tissue.
- Before repositioning on the heart, check to assure that the lead head is seated firmly and squarely in the FasTac Introducer. Press the body of the lead into the slots at both ends of the FasTac Introducer.

Note: The lead body will be firmly seated only at both ends of the FasTac Introducer. It will remain loose along the central portion of the FasTac Introducer groove.

The lead may now be positioned on the heart again, following the "Lead Introduction" instructions.

(See Figures 8 and 9)

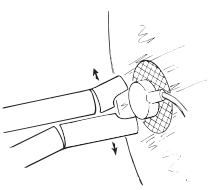

Figure 8

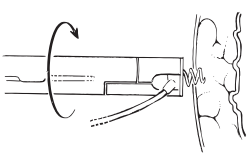

Figure 9

Electrical Performance

WARNING: PACING LEADS PROVIDE A LOW RESISTANCE PATH DIRECTLY TO THE HEART. BATTERY POWERED OR PROPERLY GROUNDED DEFIBRILLATION/ PACING EQUIPMENT SHOULD BE READILY AVAILABLE FOR USE IF NEEDED. A BATTERY POWERED OR PROPERLY GROUNDED PACING SYSTEM ANALYZER SHOULD BE USED TO MEASURE BOTH PACING THRESHOLD AND R-WAVE AMPLITUDE AFTER ATTACHMENT OF THE LEAD TO THE HEART.

Prior to permanent implantation of the lead, the stimulation threshold and sensing capability should be verified. A device such as a pacing system analyzer (PSA) is recommended for obtaining these measurements.

Using PSA cables, attach the lead connector "pin" (cathode) to the negative conductor of the PSA and attach the lead connector "ring" (anode) to the positive conductor of the PSA.

Stimulation threshold and R-wave amplitude measurements should now be made using the pacing system analyzer and the pacemaker manufacturer's recommendations. If the values measured are not satisfactory, refer to the section entitled "Lead Repositioning". If the original measurements are different than those recommended in Table 4, it is best to wait a while (15-20 minutes) and repeat the measurements. If the values do not stabilize at an acceptable level it may be necessary to reposition the lead.

Table 4: Recommended Implantation Values

	Implant Data
Acute Stimulation	Threshold ≤ 3 V at 0.5 msec.
Acute Sensing	Threshold ≥ 5 mV
Acute Impedance	≥ 300 and ≤ 1500 Ω

Tunneling

After electrode stability and satisfactory stimulation thresholds have been attained, the lead may be passed to the pacemaker pocket using the tunneler.

Prior to tunneling the lead, the lead body should be looped in a clockwise direction around the lead head to create enough slack so tension is not applied directly to the lead/tissue interface.

Note: Do not loop the lead in a counterclockwise direction as this may cause the lead to partially unscrew.

Standard Tunneling

If the tunneler is to be passed from the lead implantation site to the pocket, use the tunneler as provided in the sterile tray. After the tip of the tunneler has entered the pocket, firmly seat the lead terminal pin into the slotted hole at the blunt end of the tunneler and draw the lead through to the pocket. When seating or removing the connector pin from the tunneler, care must be used to avoid damaging the connector. A loop of the lead should be left within the pericardial sac area to lessen tension on the helix electrode.

Reverse Tunneling

If the tunneler is to be passed from the pacemaker pocket to the lead implant site, attach the bi-directional tip included in the tray to the tunneler by firmly seating the pin into the slotted hole at the blunt end of the tunneler. After the bi-directional tip has entered the implant site, detach the tip from the tunneler, firmly seat the lead terminal pin into the slotted hole in the tunneler and draw the lead through to the pocket. When seating and removing the connector pin from the tunneler, care must be used to avoid damaging the connector. A loop of the lead should be left within the pericardial sac area to lessen tension on the helix electrode.

CAUTION: Reverse tunneling using the reversible tip should not be performed if the pacemaker implantation site is in the pectoral region.

CAUTION: Cardiac strangulation is a known rare complication of epicardial 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 murmer. 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.

Connection to Implantable Pulse Generator

When the lead is secured, connect the lead to the compatible implantable pulse generator following the procedure in the applicable implantable pulse generator's physician's manual.

CAUTION: To prevent undesirable twisting of the lead body, wrap the excess lead length loosely under the implantable pulse generator and place both into the subcutaneous pocket (see Figure 10).

CAUTION: When placing the implantable pulse generator and leads into the subcutaneous pocket:

- **Do not coil the lead. Coiling the lead can twist the lead body and may result in lead dislodgement (see Figure 11).**
- **Do not grip the lead or implantable pulse generator with surgical instruments.**

(See Figures 10 and 11)

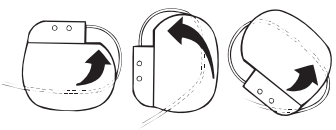

Figure 10

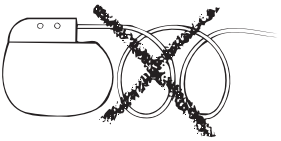

Figure 11

After implantation, monitor the patient's electrocardiogram continuously. If a lead dislodges, it usually occurs during the immediate post-operative period.

Connector Pin Cap
The Connector Pin Cap may be used to seal off the connector pin if the lead is being reserved for implantable pulse generator connection at a future date or if the lead has been abandoned (i.e. any lead not explanted, but not connected to the implantable pulse generator).

Place the cap over the lead connector 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 pin cap's groove.

CAUTION: Do not secure the ligature so tightly that it damages the connector pin cap or the lead.

Lead Extraction
Explantation of this lead is not recommended and should only be performed when the lead or implantable pulse generator presents a risk to the patient.

CAUTION:
- **Lead extraction presents clinical risks to the patient. Great care should be exercised.**
- **An explanted lead should never be reused.**

Note: If it is necessary to explant the lead, all portions of the explanted lead should be returned to Greatbatch Medical for analysis with the Explant Form (82132).

Note: Transportation and disposal of explanted devices is subject to local, state, and federal regulations.

FORMS

The following forms should be completed and sent to Greatbatch Medical as needed:
- Medical Device Registration Form (82131)
- Explant Form (82132)

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Greatbatch Medical hereby warrants that if the Greatbatch Medical product fails to perform within Greatbatch Medical's normal tolerance due to defects in materials or workmanship, Greatbatch Medical in its sole discretion will either provide, at no charge, a replacement to the failed product or a refund of the purchase price.
This Limited Warranty applies only if:
1. Greatbatch Medical packaged and labeled the product;
2. The product was used before the applicable "Use By" date;
3. The failed product is returned to Greatbatch Medical;
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5. The product has not been mishandled, reprocessed, altered or damaged.

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SYMBOL KEY:

MODEL
Greatbatch Medical Model Number

SN
Serial Number


Length (cm)


Use by date

Bipolar Connector (IS-1)
Bipolar connector


Date of manufacture


Distributed by


Temperature limitation


Do not use if package is damaged

STERILE EO
Sterilized using Ethylene Oxide

AUSTRALIAN PRODUCT SPONSOR
Australian Product Sponsor

Do not re-use

Caution, consult accompanying documents

Keep away from sunlight, including UV light

Keep dry

Do not resterilize

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

Manufactured by

Authorized European Representative

Instructions for Use

Greatbatch™
Medical

Greatbatch Medical
2300 Berkshire Lane North
Minneapolis, MN 55441 USA
tel 763-951-8181
fax 763-559-0148

www.greatbatchmedical.com

EC REP

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

CE
0123

Made in the USA

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