

FINELINE™ II STEROX EZ

Models 4469/4470/4471/4472/4473/4474

Guidant® Implantable Pacing Lead

CAUTION: Federal Law restricts this device to sale by or on the order of a physician trained or experienced in device implant and follow-up procedures.

Boston Scientific Corporation acquired Guidant Corporation in April 2006. During our transition period, you may see both the Boston Scientific and Guidant names on product and patient materials. As we work through the transition, we will continue to offer doctors and their patients technologically advanced and high quality medical devices and therapies.

DESCRIPTION

The FINELINE¹ II Sterox EZ models 4469, 4470, 4471, 4472, 4473, and 4474 bipolar endocardial pacing leads are designed for atrial or ventricular use with implantable pulse generators for long-term cardiac pacing. A silicone rubber collar at the distal tip contains less than 1.0 mg of dexamethasone acetate. Each lead is composed of two individually coated conduction wires coradially wound together to form a single conductor coil. The lead includes silicone rubber (models 4472, 4473, and 4474) or polyurethane (models 4469, 4470, and 4471) outer insulation, iridium oxide-coated (IROX™) titanium tip electrode and a platinum iridium anode. The cork-screw tip is coated with mannitol. The lead is compatible with pulse generators having IS-1² connectors.

Pacing and sensing impedance values, determined according to European Standard prEN45502-2

(September 1996, paragraphs 6.2.1.4 and 6.2.2.2) are nominally 980 Ω and 400 Ω, respectively, in the silicone model, and 670 Ω and 330 Ω, respectively, in the polyurethane model². Note that these values are derived from *in vitro* testing, and are not representative of clinically measured lead impedance.

This device is intended for single-use only.

INDICATIONS

The lead is intended for chronic pacing and sensing of the atrium or ventricle when used with a compatible pulse generator.

CONTRAINDICATIONS

Do not use this lead in patients with:

- tricuspid valvular disease
- mechanical heart valve
- likelihood of an adverse reaction to a single dose of 1.0 mg of dexamethasone acetate
- an allergy to mannitol

1. FINELINE is a registered trademark of Guidant Corporation, St. Paul Minnesota. U.S.A.
2. International Standard ISO 5841-3: 1992

WARNINGS

- The use of battery-powered equipment is recommended during lead implantation and testing to protect against fibrillation that may be caused by alternating currents.
- Line-powered equipment used in the vicinity of the patient must be properly grounded.
- Lead connector pins must be insulated from any leakage currents that may arise from line-powered equipment.
- MRI exposure. Do not expose a patient to the MRI environment. Strong electromagnetic fields in the MRI environment may interfere with the pulse generator and lead system and cause injury to the patient.
- Diathermy exposure. Patients with implanted leads should not receive diathermy treatment. Shortwave or microwave diathermy can cause tissue damage and injure the patient.

PRECAUTIONS

General

- The lead and its accessories are intended for one-time use only. Do not reuse.
- Inspect sterile packaging prior to opening. Do not use if damaged. (See "Sterilization" on page 7.)
- Prior to the implantation of this lead, confirm lead/pulse generator compatibility by contacting Guidant customer service.
- Defibrillating equipment should be kept nearby for immediate

use during the implantation procedure.

- It has not been determined whether the warnings, precautions, or precautions usually associated with injectable dexamethasone acetate apply to the use of this lead. Refer to a current *Physician's Desk Reference* for potential adverse effects.

Handling

- Avoid the use of excessive force or surgical instruments, as damage to the insulation could cause leakage and/or prevent proper lead function.
- Do not wipe or immerse the electrode in fluid.
- Use the suture sleeve when securing the lead to avoid placing the lead under extreme tension.
- Avoid bending the conductor coil, since attempts to restore the original shape may weaken the structure.

Implanting

- The subclavian venipuncture technique for lead introduction may be associated with an increased risk of conductor failure due to compressive forces generated in the medial angle between the clavicle and the first rib; thus, an extremely medial introduction site should be avoided.
- Remove the stylet and funnel/cap before connecting the lead to the pulse generator. Leaving the stylet in the lead could cause coil fracture and/or heart perforation.

- Do not suture directly to the insulation. Always use the suture sleeve to anchor the lead.

Potential Adverse Events

Adverse events associated with pacing leads based on historical implant experience include:

- cardiac perforation
- cardiac tamponade
- transvenous lead-related thrombosis
- elevated thresholds
- body rejection phenomena
- hematoma/seroma
- nerve and muscle stimulation
- myopotential sensing
- local tissue reaction
- fibrotic tissue formation
- oversensing
- dislodgment
- lead abrasion
- lead fracture, insulation break
- physician elected explants
- pulse generator erosion
- pocket infection
- pocket hematoma
- ventricular ectopy

ADVERSE EVENTS

Notes:

- Clinical investigation was conducted on the Intermedics models 438-35S and 438-25S leads, which are identical to the FINELINE II models 4469/4470/4471 and 4472/4473/4474 leads, respectively.
- In clinical application, dexamethasone sodium phosphate is functionally equivalent to dexamethasone

acetate. The dexamethasone sodium phosphate steroid collar was used in the clinical investigation.

The Polyurethane THINLINE³ II Sterox clinical investigation, as of April 14, 2000, involved 461 devices implanted in 238 patients (mean implant duration was 7.5 months, range 0.1 to 12.5 months). There were 30 observations and 6 complications reported during the study (see Table 1, Table 2, Table 3 and Table 4).

Thirteen deaths were reported during the clinical investigation; none were related to the lead.

The only difference between the THINLINE II Sterox silicone and THINLINE II Sterox polyurethane leads is the insulation material. Because of this, the safety and effectiveness profile for the THINLINE II Sterox silicone leads is expected to be similar to that of the THINLINE II Sterox polyurethane leads that were studied clinically. Therefore, the data presented on the THINLINE II Sterox polyurethane leads can be applied to the silicone version of the THINLINE II Sterox leads.

CLINICAL SUMMARY

The THINLINE II Sterox pacing lead models 430-35S, 432-35S, and 438-35S were evaluated in a multi-center study with a randomized control comparison and a comparison to a historical control lead. The commercially available control leads in the randomized study were THINLINE I model 432-

3. THINLINE is a registered trademark of Intermedics Inc., St. Paul, Minnesota, U.S.A.

04 (atrial), and 430-10 (ventricular), and 438-10 (atrial/ventricular). As of April 13, 2000, the investigation involved 461 devices implanted in 238 patients.

Objectives

- To demonstrate the effectiveness of the Polyurethane THINLINE II Sterox model 430-35S, 432-35S, and 438-35S pacing lead by comparing pacing thresholds to a randomized commercially available control lead (model 430-10, 432-04, and 438-10).
- To demonstrate the effectiveness of the Polyurethane THINLINE II Sterox model 438-35S by comparing pacing thresholds to a commercially available steroid-eluting active fixation lead.
- To demonstrate the safety of the lead by establishing the comparability of the incidence rate of device-related observations and complications to that of the control lead.

Methods

Follow-ups to collect electrical performance data occurred at 2 weeks, 4 weeks, 6 weeks, and three months. Safety data was taken from all reported information.

Results

Table 5 provides a comparison of pacing thresholds for Objective 1 (test model 430-35S, 432-35S and 438-35S compared to control model 430-10, 432-04, and 438-10).

For Objective 2, model 438-35S atrial electrical performance was equivalent to commercially available steroid-eluting active fixation (atrial) lead.

Also for Objective 2, model 438-35S ventricular electrical performance was significantly better than commercially available steroid-eluting active fixation (ventricular) lead at 3 months.

Table 6 shows summary patient information and principal safety results for the polyurethane THINLINE II Sterox leads.

Table 1. Adverse events for the THINLINE II Sterox clinical study (Model 438-35S atrium)

	# of Patients (n=169)	% of Patients (95% CI)	# of Leads ^a
OBSERVATIONS (total)^b	17	10.1 [6.1, 15.7]	17
Attempted, not used	1	0.6 [0.0, 3.3]	1
Brady capture - none or loss	1	0.6 [0.0, 3.3]	1
Oversensing - atrium pace	2	1.2 [0.2, 4.3]	2
PEG capsule came off	13	7.7, [4.3, 12.9]	13
Undersensing - atrium pace	1	0.6 [0.0, 3.3]	1
COMPLICATIONS (total)^c	1	0.6 [0.0, 3.3]	1
Lead Dislodgement - Right	1	0.6 [0.0, 3.3]	1
Patients and leads may have multiple AE's			

- a. The number of leads is also the number of adverse events (lead and non-lead related) as there were no patients who had the same event multiple times.
- b. Observations are defined as symptomatic or asymptomatic clinical events with potential adverse effects which do not require surgical intervention (can be corrected by reprogramming alone).
- c. Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require surgical intervention. Explants are included as complications.

Table 2. Adverse events for the THINLINE II Sterox clinical study (Model 438-35S ventricle)

	# of Patients (n=118)	% of Patients (95% CI)	Number of Leads ^a
OBSERVATIONS (total)^b	8	6.8 [3.2, 13.1]	8
Helix related (screw tip)	1	0.8 [0.0, 4.7]	1
PEG capsule came off	7	5.9 [2.6, 12.0]	7
COMPLICATIONS (total)^c	2	1.7 [0.3, 6.1]	1
Diaphragmatic stimulation	1	0.8 [0.0, 4.7]	1
Placement difficulty, difficulty positioning	1	0.8 [0.0, 4.7]	1
Patients and leads may have multiple AE's			

- a. The number of leads is also the number of adverse events (lead and non-lead related) as there were no patients who had the same event multiple times.
- b. Observations are defined as symptomatic or asymptomatic clinical events with potential adverse effects which do not require surgical intervention (can be corrected by reprogramming alone).
- c. Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require surgical intervention. Explants are included as complications.

Table 3. Adverse events for the THINLINE II Sterox clinical study (Model 430-35S ventricle)

	# of Patients (n=115)	% of Patients (95% CI)	Number of Leads ^a
OBSERVATIONS (total)^b	1	0.9 [0.0, 4.0]	1
Suture sleeve, probable fracture	1	0.9 [0.0, 4.0]	1
COMPLICATIONS (total)^c	1	0.9 [0.0, 4.0]	1
Lead dislodgment - ventricle	1	0.9 [0.0, 4.0]	1

Patients and leads may have multiple AE's

- The number of leads is also the number of adverse events (lead and non-lead related) as there were no patients who had the same event multiple times.
- Observations are defined as symptomatic or asymptomatic clinical events with potential adverse effects which do not require surgical intervention (can be corrected by reprogramming alone).
- Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require surgical intervention. Explants are included as complications.

Table 4. Adverse events for the THINLINE II Sterox clinical study (Model 432-35S)

	# of Patients (n=37)	% of Patients (95% CI)	Number of Leads ^a
OBSERVATIONS (total)^b	2	5.4 [0.9, 18.1]	2
Opened by mistake	1	2.7 [0.1, 14.1]	1
Placement difficulty, difficulty positioning.	1	2.7 [0.1, 14.1]	1
COMPLICATIONS (total)^c	0	NA	1

Patients and leads may have multiple AEs.

- The number of leads is also the number of adverse events (lead and non-lead related) as there were no patients who had the same event multiple times.
- Observations are defined as symptomatic or asymptomatic clinical events with potential adverse effects which do not require surgical intervention (can be corrected by reprogramming alone).
- Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require surgical intervention. Explants are included as complications.

Table 5. Mean Pulse Width Threshold at 2.5 V (Objective 1. Pooled Data from all Test Leads*: 430-35S, 432-35S and 438-35S)

Follow-up	Randomized Leads			Control Leads			Comparison p-value
	N	Mean (ms)	Std. Dev.	N	Mean (ms)	Std. Dev.	
Implant (PSA)	280	0.11	0.12	271	0.10	0.09	0.0320
2 weeks	273	0.09	0.07	243	0.17	0.18	0.0000
4 weeks	262	0.10	0.15	232	0.16	0.16	0.0000
6 weeks	268	0.10	0.15	245	0.16	0.15	0.0000
3 months	252	0.09	0.08	236	0.15	0.16	0.0000

Statistical significance is defined as $p \leq 0.05$. t-test

Table 6. Patient information and principal safety results, polyurethane THINLINE II Sterox clinical study (at test leads, 238 patients)

	Total
Patients	238
Devices *	461
Device Exposure, Months	3276
Duration, Mean \pm SD, (Range), Months	7.5 \pm 13.0 (0.1-12.5)
Patient age per implant, Mean \pm SD, (Range), Years	73.0 \pm 13.0(15-96)
Sex, Female, Number,%	105, 44%
Clinical Complications, Number, Event Rate%	6, 0.18%
Clinical Observations, Number, Event Rate%	30, 0.92%

*Some patients implanted with multiple leads.

IMPLANT INFORMATION

Proper surgical procedures and techniques are the responsibility of the medical professional. The described implant procedures are furnished for informational purposes only. Each physician must apply the information in these instructions according to professional medical training and experience.

Sterilization

This product is supplied in a sterile package for direct introduction into the operating field. The package and its contents have been exposed to ethylene oxide gas, and sterility is verified on each lot. Before the package is opened, it should be examined carefully for damage that may have compromised sterility. (For instructions on opening the sterile package, see Figure 1 and 2.) If such damage is detected, the entire contents should be returned to Guidant.

Storage

The lead should be stored at temperatures between -5°C (23°F) and 55°C (131°F).

Handling

The conductor or its insulating material may be damaged if stretched, crimped or crushed. Avoid subjecting the lead to these or other unusual stresses.

The lead's insulating material has an electrostatic affinity for particulate matter and thus should not be exposed to lint, dust or other similar contaminants.

Precautions

- Avoid the use of excessive force or surgical instruments, as damage to the insulation could cause leakage and/or prevent proper lead function.
- Do not wipe or immerse the electrode in fluid.
- Use the suture sleeve when securing the lead to avoid placing the lead under extreme tension.

- Avoid bending the conductor coil, since attempts to restore the original shape may weaken the structure.

General Information

It is important to position the lead so as to minimize mechanical stresses and maximize electrical contact with the cardiac wall. Implantation should, therefore, be performed in a facility permitting fluoroscopic verification of satisfactory lead tip placement.

Available transvenous implantation routes include the cephalic, subclavian and external or internal jugular veins. Venous access can be gained by employing either the venipuncture (suitable for the subclavian or internal jugular routes) or cutdown (suitable for the cephalic or external jugular routes) techniques.

If the subclavian route is selected and access by venipuncture is preferred, a percutaneous lead introducer (7 French or larger) should be used, and its application should be guided by the following considerations:

Precautions

- The subclavian venipuncture technique for lead introduction may be associated with an increased risk of conductor failure due to compressive forces generated in the medial angle between the clavicle and the first rib; thus, an extremely medial introduction site should be avoided.
- Remove the stylet and funnel/cap before connecting the lead to the pulse generator. Leaving

the stylet in the lead could cause coil fracture and/or heart perforation.

- Do not suture directly to the insulation. Always use the suture sleeve to anchor the lead.

Insertion Procedures

The dissolvable mannitol capsule surrounding the fixation helix is designed to facilitate passage through the blood vessels and into the heart and to protect the helix from damage. As soon as the capsule is inserted into the vein, the capsule begins to dissolve. The fixation helix remains encapsulated for approximately five minutes.

NOTE: The mannitol capsule has varying dissolution rates based on the patient's cardiac anatomy, lead placement, and various implant conditions.

CAUTION: Approximately five minutes after introduction of the lead, the fixation helix will be exposed. If resistance is encountered and the dissolution time has expired, the lead should be rotated **counterclockwise** during advancement.

To employ the cutdown technique, expose and incise the desired vein. For the venipuncture technique, insert a lead-introducer sheath into the desired vein (see instruction sheet packaged with introducer). Under fluoroscopic observation and with a straight stylet fully inserted into the lead, either introduce the lead into the incised vein (for cutdown), or advance the lead through the lead-introducer sheath and into the desired vein (for venipuncture - see Figure 5). If desired, the vein

lifter included in the sterile package may be used to facilitate lead introduction (see Figure 6) when employing the cutdown technique.

Cautiously advance the lead. If resistance is encountered, simultaneously rotate the lead counterclockwise several turns while gently retracting it a short distance.⁴ Then continue advancing the lead, maintaining the **counterclockwise** rotation, until it enters the right atrium. The lead tip can be advanced into the desired stimulation site by following one of the two procedures below:

Atrial Placement

1. After advancing the lead tip into the right atrium, withdraw the straight stylet and replace it with a J-shaped or curved stylet, fully inserted. (The straight stylets included in the sterile package may be shaped to the desired curve, as shown in Figure 7.)
2. Under fluoroscopic observation, rotate the stylet to direct the J curve anteriorly and toward the midline of the body.

NOTE: Generally, the atrial appendage is the preferred site, and it is recommended that the lateral wall of the atrium be avoided to minimize the possibility of phrenic nerve stimulation. Use care to avoid perforating the atrial wall.

3. When the lead tip is in the desired position, and at a 90-degree angle to the atrial wall, secure the tip in the endocardium using the following procedure: Rotate the lead

clockwise at the lead introduction site (the stylet should remain stationary), allowing the entire lead body to rotate -- approximately 4 turns for the polyurethane model 438-35S (4469/4470/4471) or 6 turns for the silicone model 438-25S (4472/4473/4474).

4. Verify fixation by releasing the excess torque in the lead body. If the tip is securely fixed, the lead body will unwind slightly (counterclockwise) when released. Enough slack should be left in the lead for the lead body to retain a loose J curve and for the lead tip to form a 90-degree angle with the atrial wall.

Ventricular Placement

1. After advancing the lead tip into the right atrium, withdraw the straight stylet 10 to 12 cm and continue advancing the lead.
2. When the tip contacts the atrial wall or some other atrial structure, a curve or loop will form in the lead body. Direct this loop into the tricuspid valve.
3. Gently advance the stylet back into the lead, taking care not to damage the conductor or its insulation, while guiding the loop through the tricuspid valve. Make sure to guide the lead through the tricuspid valve, rather than into the inferior vena cava. As the loop in the lead body is advanced into the right

4. If resistance persists, withdraw the stylet 2 or 3 cm to render the lead tip flexible, and carefully maneuver it around the obstruction.

ventricle, the lead tip will be drawn backward through the tricuspid valve.⁵

4. When the lead enters the ventricle, fully reinsert the straight stylet and continue advancing the lead until the tip is situated at or near the apex. Exercise care to avoid perforating the ventricular wall.
5. Verify with lateral fluoroscopy that the lead is not in a posterior position, which would probably indicate that the lead has entered the coronary sinus and should be repositioned.
6. When the lead tip is in the desired position and at a 90-degree angle to the ventricular wall, secure the tip in the endocardium using the following procedure: Rotate the lead *clockwise* at the introduction site (the stylet should remain stationary), allowing the entire lead body to rotate -- approximately 4 turns for the polyurethane model 438-35S (4469/4470/4471) or 6 turns for the silicone model 438-25S (4472/4473/4474).
7. Verify fixation by releasing the excess torque in the lead body. If the tip is securely fixed, the lead body will unwind slightly (counterclockwise) when released. When *gentle* traction is applied to the lead, resistance should be felt.

Repositioning or Removing

To reposition or remove a lead, fully insert the appropriate stylet in the lead (a J-shaped or curved stylet for lead placed in the atrium, a straight stylet for a lead placed in the ventricle), and rotate the lead counterclockwise until the tip is freed from the endocardium. Once the lead tip is freed, whether the lead is to be repositioned or removed, continue rotating it counterclockwise while retracting it.

CAUTION: Once the mannitol capsule has dissolved, exposing the fixation screw, the lead must be rotated counterclockwise during any stage of withdrawal.

If the lead is to be repositioned free the lead tip from the endocardium, and repeat the appropriate procedure for attaching the lead tip (see "Insertion Procedures" on page 8).

CAUTION: When removing a lead from the patient, it is best not to cut off the proximal end. If the proximal end is removed, however, firmly grasp both conductor coil and outer tubing before applying tension to the lead.

Threshold Measurements

A pacemaker system analyzer is recommended for measuring the stimulation threshold and the appropriate sensing signal amplitude. During this procedure, the stylet should be withdrawn.

The lowest possible pacing threshold should be sought to assure optimal long term pacemaker operation. Usually, using a 500 Ω load, an acute ventricular stimulation

5. This maneuver is important for fixed-screw leads, as it prevents the tip from catching as it passes the valve.

threshold can be obtained below 0.6 V or 1.2 mA; however, maintaining the same resistance, it should not exceed 1.0 V or 2.0 mA.

Acute stimulation thresholds in the right atrial appendage are generally higher than those obtained in the right ventricle with a stimulating electrode of similar surface area. Acute atrial stimulation thresholds below 1.0 V or 2.0 mA with a 500 Ω load are common. But any acute atrial threshold substantially higher than 1.5 V or 3.0 mA (using a 500 Ω load) indicates a need to reposition the lead.

For satisfactory sensing, the ventricular sensing signal amplitude should be at least 5.0 mV. The atrial sensing signal will typically range from 0.5 to 4.0 mV, but a value of 1.5 mV or above is preferable. The atrial sensing signal will typically range from 0.5 to 4.0 mV, but a value of 1.5 mV or above is preferable.

CAUTION: Be sure that the stylet has been removed before connecting the lead to the implanted pulse generator. Leaving the stylet in the lead could cause coil fracture and/or heart perforation. Also be sure that any funnel/cap installed over the lead connector(s) (as a guide for the stylet and to maintain lubrication of the connector) has been removed.

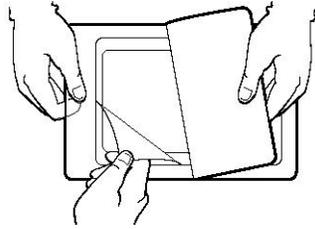
Securing the Lead

Once electrode stability and a satisfactory stimulation threshold have been attained, slide the pre-installed suture sleeve into position at the desired anchor point. Secure the sleeve to the lead by tying a non-absorbable suture around the

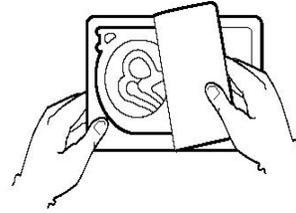
sleeve near its middle (see Figure 8). Pass an end of the same suture through subcutaneous tissue and, once again, tie it around the sleeve.

Notes:

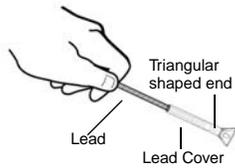
- The suture should be tied tight enough to prevent the lead from moving within the sleeve, but not so tight that it might deform the lead's conductor coil.
- Do not tie the suture directly to the lead body.



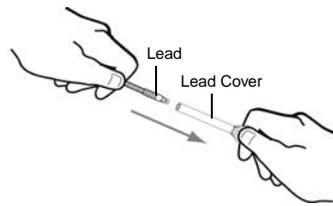
1. Peel back the cover from the outer tray. Using the folded corner flap, remove the sterile inner tray (Figure 1).



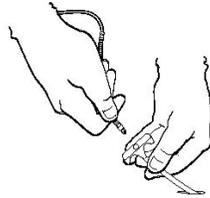
2. Peel the lid from the inner tray to present the lead and accessories (Figure 2).



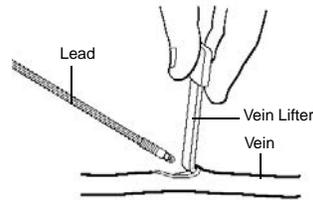
3. Remove the lead from the tray and note the protective cover on the distal end of the lead. The cover must be removed prior to insertion (Figure 3).



4. To remove the cover, grasp the triangular shape at the end of the cover and pull gently (Figure 4).



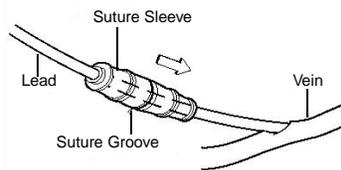
5. Advance the lead through the sheath of a percutaneous introducer and into the vein (Figure 5).



6. The vein lifter may be used to lift and dilate the incised vein for introducing the lead (Figure 6).



7. Impart a gentle curve to the stylet by drawing it through a gloved hand or across a smooth, sterile instrument (Figure 7).



8. Slide the integral suture sleeve into the desired anchor position, and secure with a nonabsorbable suture (Figure 8).

RETURNING EXPLANTED PRODUCTS

CAUTION: Return all explanted leads to Guidant.

Examination of explanted leads can provide information for continued improvement in system reliability. Use a Guidant Returned Product Kit to properly package the lead and complete an Observation/Complication/Out-of-Service Report form. Send the form and kit to Guidant at the address on the back of this manual.

NOTE: Disposal of explanted devices is subject to local, state, and federal regulations. Contact your sales representative or call the telephone number on the back of the manual for a Returned Product Kit.

SYMBOLS ON PACKAGING

Symbol	Definition
	Opening instructions
	Do not reuse
	Consult instructions for use
	Temperature limitation
	Sterilized using ethylene oxide
	Reference number
	Use by
	Date of manufacture
	Lot number
	Serial number

Specifications

Table 7. Specifications

	4469/4470/4471 (Atrial/Ventricular)	4472/4473/4474 (Atrial/Ventricular)
Polarity	Bipolar	Bipolar
Distal Assembly		
Introducer size/insertion diameter (minimum)	7 Fr (1 lead)/10Fr (2 leads)	7 Fr (1 lead)/10Fr (2 leads)
Eluting Collar	Silicone rubber	Silicone rubber
Steroid	Dexamethasone acetate (less than 1.0 mg)	Dexamethasone acetate (less than 1.0 mg)
Electrode		
Tip (cathode)		
Shape	Ring	Ring
Diameter	1.9 mm (5.7 French)	1.9 mm (5.7 French)
Surface area	5 mm ²	5 mm ²
Materials	IROX (Iridium oxide coated titanium)	IROX (Iridium oxide coated titanium)
Sleeve (anode)		
Surface area	31 mm ²	33 mm ²
Materials	Platinum iridium	Platinum iridium
Separation between electrodes	16 mm	16 mm
Corkscrew tip (electrically isolated)		
Length	1.6 mm	1.6 mm
Number of turns in helix	1.5	1.5
Material	Nickel-cobalt alloy	Nickel-cobalt alloy
Insulating material	Conformal polymer	Conformal polymer
Coating (soluble) ^a	Mannitol	Mannitol
Lead Body		
Conductor construction	Parallel-wound bifilar coil	Parallel-wound bifilar coil
Conductor material	Nickel-cobalt alloy with silver core	Nickel-cobalt alloy with silver core
Conductor wire insulation	Polymer material	Polymer material
Insulation	55D polyurethane	80A Silicone Rubber
Length ^b	4469: 45 cm 4470: 52 cm 4471: 58 cm	4472: 45 cm 4473: 52 cm 4474: 58 cm
Diameter	1.7 mm (5 Fr)	2 mm (6 Fr)
Resistance		
To tip	40 Ω maximum	40 Ω maximum

Table 7. Specifications

	4469/4470/4471 (Atrial/Ventricular)	4472/4473/4474 (Atrial/Ventricular)
To sleeve	40 Ω maximum	40 Ω maximum
Connector Assembly		
Diameter	3.2 mm (IS-1 ^o)	3.2 mm (IS-1 ^o)
Materials	Silicone rubber, 316L stainless steel	Silicone rubber, 316L stainless steel
Retention Strength ^d	10 N	10 N
Connector pin diameters		
Cathode	1.6 mm	1.6 mm
Anode	2.7 mm	2.7 mm
Connector pin length	5 mm	5 mm
Accessories included	Stylets Funnel Vein lifter	Stylets Funnel Vein lifter

- a. The mannitol dissolves in approximately 5 minutes, exposing the corkscrew for easy fixation in either the atrium or the ventricle
- b. Available in 30-cm (resistance: 35 Ω maximum) to 110-cm (resistance: 50 Ω maximum) lengths
- c. European Standard EN 50 077: 1993
- d. Maximum proven connector retention strength in Intermedics' Side-Lock™ connector. Tested according to prEN45502-2, September 16, 1996.







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