FINELINE™ II STEROX
Models 4456/4457/4458/4459/4479/4480
Guidant®
Implantable Pacing Lead

CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.

DESCRIPTION

The FINELINE™ II Sterox models 4456, 4457, 4458, 4459, 4479 and 4480 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 conductor wires coradially wound together to form a single conductor coil. The lead includes silicone rubber (models 4458 and 4459) or polyurethane (models 4456, 4457, 4479 and 4480) outer insulation, iridium oxide-coated (IROX™) titanium tip electrode and a platinum iridium anode. The distal slotted/blunt tip electrode is coated with polyethylene glycol. Fixation is achieved by silicone rubber tines. The lead is compatible with pulse generators having IS-1* 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 820 Ω and 950 Ω, respectively, in silicone models, and 1250 Ω and 985 Ω, respectively, in polyurethane models. 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.

Symbols Used

Attention! Consult the accompanying documentation.

INDICATIONS

This lead is intended for chronic pacing and sensing of the ventricle (4456, 4457, 4458, 4459) or the atrium (4479, 4480) when used with a compatible pulse generator.

CONTRAINDICATIONS

Do not use this lead in patients with:

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

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.

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 page 5).
- Prior to the implantation of this lead, confirm lead/pulse generator compatibility by contacting Guidant customer service.
- Defibrillating equipment should be

* International Standard ISO5841-3: 1992

kept nearby for immediate use during the implantation procedure.
- It has not been determined whether the warnings, precautions, or complications 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 coil conductor, 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 cut
- physician elected explants
- pulse generator erosion
- pocket infection
- pocket hematoma
- ventricular ectopy

ADVERSE EVENTS

NOTE:
- Clinical investigation was conducted on the Intermedics models 430-35S, 430-25S, 432-35S leads, which are identical to the FINELINE II models 4456/4457, 4458/4459, 4479/4480 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 ThinLine 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.

Table 1. Adverse events for the ThinLine II Sterox clinical study (Model 430-35S ventricle)

	# of Patients (n=115)	% of Patients (95% CI)	# of Leads[1]
OBSERVATIONS (total)[2]	1	0.9 [0.0, 4.0]	1
Suture sleeve, probable fracture	1	0.9 [0.0, 4.0]	1
COMPLICATIONS (total)[3]	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 AEs.

Table 2. Adverse events for the ThinLine II Sterox clinical study (Model 432-35S)

	# of Patients (n=37)	% of Patients (95% CI)	# of Leads[1]
OBSERVATIONS (total)[2]	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)[3]	0	NA	1

Patients and leads may have multiple AEs.

Table 3. Adverse events for the ThinLine II Sterox clinical study (Model 438-35S atrium)

	# of Patients (n=169)	% of Patients (95% CI)	# of Leads [1]
OBSERVATIONS (total)[2]	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)[3]	1	0.6 [0.0, 3.3]	1
Lead Dislodgment - Right	1	0.6 [0.0, 3.3]	1

Patients and leads may have multiple AEs.

Table 4. Adverse events for the ThinLine II Sterox clinical study (Model 438-35S ventricle)

	# of Patients (n=118)	% of Patients (95% CI)	# of Leads[1]
OBSERVATIONS (total)[2]	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)[3]	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 AEs.

1 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.
2 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).
3 Complications are defined as symptomatic or asymptomatic clinical events with potential adverse effects which require surgical intervention. Explants are included as complications.

CLINICAL SUMMARY:

The Polyurethane 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 432-04 (atrial), 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 430-35S by comparing pacing thresholds to a commercially available steroid-eluting passive 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.

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

Follow-up	Randomized Leads			Control Leads			Comparison
	N	Mean (ms)	Std. Dev.	N	Mean (ms)	Std. Dev.	p-value
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 lead clinical study
(All test leads, 238 patients)

	Total
Patients	238
Devices [1]	461
Device Exposure, Months	3276
Duration, Mean ± SD, (Range), Months	7.5 ± 2.3 (0.1-12.5)
Patient age per implant, Mean ± SD, (Range), Years	73.0 ± 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%

[1] Some patients implanted with multiple leads.

* Electrical performance of Model 430-25S and 438-25S is supported by the ThinLine II Sterox clinical data.

Results

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

For Objective 2, model 430-35S electrical performance was equivalent to a commercially available steroid-eluting passive fixation lead.

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

IMPLANTATION INFORMATION

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 Figures 1 and 2.) If such damage is detected, the entire contents may be repackaged in a gas-permeable container and resterilized once using a validated ethylene oxide gas process. Follow the manufacturer's operating instructions for the particular sterilization equipment used, as long as the temperature does not exceed 55°C (131°F). **Do not autoclave this lead.**

Following resterilization, the lead and its accessories should be stored at 43°C (110°F) for a minimum of 24 hours (or equivalent conditions) to permit aeration of ethylene oxide gas residuals prior to implantation.

Do not resterilize this device more than one time.

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

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 3). If desired, the vein lifter included in the sterile package may be used to facilitate lead introduction (see Figure 4) when employing the cutdown technique.

Cautiously advance the lead. If resistance is encountered, withdraw the lead a short distance and then readvance it. Repeat this procedure until the lead tip enters the right atrium. The tip of an atrial or ventricular lead can be advanced to the desired stimulation site by following one of the two procedures below.

Atrial Placement

1. After advancing the lead tip into the right atrium, partially withdraw the stylet so that the lead's distal end begins resuming its J shape and points anteromedially.
2. Maintaining fluoroscopic observation, advance the lead tip while holding the stylet stationary until the tip enters and becomes lodged in the atrial appendage.
3. If the lead tip is properly lodged in the appendage, the lead's J curve will straighten slightly when the lead is *gently* retracted a short distance. Under AP fluoroscopy, the lead tip should point medially toward the left atrium and should sway from side to side with each atrial contraction.

Ventricular Placement

1. After advancing the lead tip into the right atrium, replace the straight stylet with one that has been slightly curved at the distal end. (Curve the stylet as shown in Figure 5.) The curve will assist in passing the lead across the tricuspid valve into the ventricle.
2. Once the lead has entered the ventricle, the straight stylet should be used again to cautiously advance the lead until the tip is lodged in the trabeculae at the apex. Be careful not to perforate the ventricular wall.
3. Verify with lateral fluoroscopy that the lead tip is not in a posterior position, which would probably indicate that it has entered the coronary sinus and must be repositioned.

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.

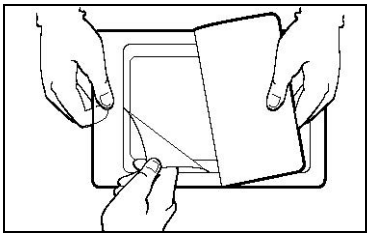
Ventricular

Using a 500 Ω load, an acute stimulation threshold below 0.6 V or 1.2 mA can usually be obtained. However, maintaining the same resistance, it should not exceed1.0 V or 2.0 mA. For satisfactory sensing, the ventricular sensing signal amplitude should be at least 5.0 mV.

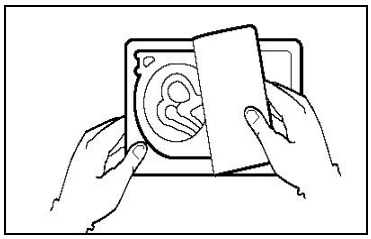
Atrial

Acute stimulation thresholds are usually lower than 1.0 V or 2.0 mA with a 500 Ω load. Acute atrial thresholds above 1.5 V or 3.0 mA (using a 500 Ω load) suggest a need to reposition the lead. The atrial sensing signal amplitude will typically range from 0.5 to 4.0 mV, but a value of 1.5 mV or above is preferable.

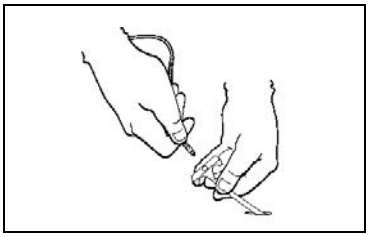
CAUTION: Be sure that the stylet has been removed before connecting the lead to the implanted pulse generator. Leaving the stylet in the lead could cause coil fracture and/or heart perforation. Also be sure that any funnel/cap installed over the lead connector(s) [as a guide for the stylet and to maintain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



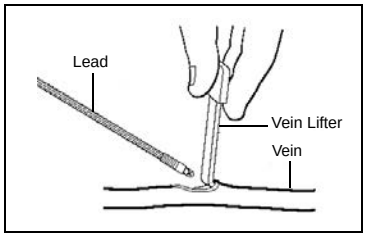
1. Peel back the cover from the outer tray. Using the folded corner flap, remove the sterile inner tray**.**



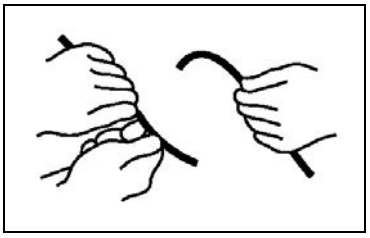
2. Peel the lid from the inner tray to present the lead and accessories.



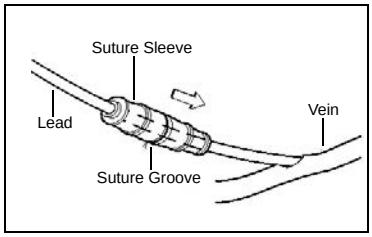
3. Advance the lead through the sheath of a percutaneous introducer and into the vein.



4. The vein lifter may be used to lift and dilate the incised vein for introducing the lead.



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



6. Slide the integral suture sleeve into the desired anchor position, and secure with a nonabsorbable suture.

Figures 1-6

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 6). 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 a suture directly to the lead body.

Specifications

	4456/4457 (Ventricular) 4479/4480 (Atrial)	4458/4459 (Ventricular)
Polarity	Bipolar	Bipolar
Distal Assembly Introducer size/insertion diameter (minimum) Tine material Eluting Collar Steroid	 7 Fr (1 lead)/10Fr (2 leads) Silicone rubber Silicone rubber Dexamethasone acetate (less than 1.0 mg)	 7 Fr (1 lead)/10Fr (2 leads) Silicone rubber Silicone rubber Dexamethasone acetate (less than 1.0 mg)
Electrode(s)		
Tip (cathode)		
Shape	Slotted/blunt	Slotted/blunt
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)
Coating (soluble) [1]	Polyethylene glycol	Polyethylene glycol
Sleeve (anode)		
Surface area	31 mm^2	33 mm^2
Materials	Platinum iridium	Platinum iridium
Separation between electrodes	16 mm	16 mm
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 [2]	4456: 52 cm 4457: 58 cm 4479: 45 cm 4480: 52 cm	4458: 52 cm 4459: 58 cm
Diameter	1.7 mm (5 French)	2 mm (6 French)
Resistance		
To tip	40 Ω maximum	40 Ω maximum
To sleeve	40 Ω maximum	40 Ω maximum
Connector Assembly		
Diameter	3.2 mm (IS-1) [3]	3.2 mm (IS-1) [3]
Materials	Silicone rubber, 316L stainless steel	Silicone rubber, 316L stainless steel
Retention Strength [4]	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

1 The tip electrode is encapsulated in polyethylene glycol (PEG), which is intended to maintain the cleanliness of the electrode during the packaging process.
2 Available in 30-cm (resistance: 35 Ω maximum) to 110-cm (resistance: 50 Ω maximum) lengths.
3 European Standard EN 50 077: 1993
4 Maximum proven connector retention strength in Intermedics' Side-Lock™ connector. Tested according to prEN45502-2, September 16, 1996.

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