

IsoFlex™ Optim™

Pacing Lead

Product Highlights

- Straight or J-shaped lead is available in multiple lengths to accommodate varying needs and patient anatomies
- Optim™ lead insulation—a chemical co-polymer that blends the best features of polyurethane and silicone—provides improved handling and increased durability
- Symmetrical lead body with coaxial multifilar coils for reliability
- Steroid-eluting tip for reduced inflammation at the lead-tissue interface and low pacing thresholds
- Small tip surface area for higher impedance levels and optimal device longevity
- Titanium nitride (TiN) coated tip and ring electrode for low polarization values and compatibility with the AutoCapture™ Pacing System algorithm
- Radiopaque suture sleeve for visibility under fluoroscopy to simplify invasive procedures



Ordering Information

Contents: Cardiac pacing lead

Model Number	Insulation	Fixation	Min. Introducer (F)	Connector	Lengths (cm)
1944 (J-Shaped)	Optim	Tines	7	IS-1 bipolar	46; 52
1948 (Straight)	Optim	Tines	7	IS-1 bipolar	46; 52; 58

Indications: The IsoFlex™ lead is designed for permanent sensing and pacing in the atrium with a compatible pulse generator. An active lead, such as the IsoFlex™, may be indicated for patients where permanent fixation of passive leads is suspected to be unstable. In atrial applications, the use of a screw-in lead, such as the IsoFlex™, may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The IsoFlex™ lead is contraindicated: In the presence of tricuspid atresia, for patients with mechanical tricuspid valves, in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Adverse Events: Potential complications associated with the use of IsoFlex™ leads are the same as with the use of other active fixation leads and include: cardiac tamponade, diaphragmatic stimulation, embolism, excessive bleeding, induced ventricular ectopy, infection, loss of pacing and/or sensing due to dislodgment or mechanical malfunction of the pacing lead, phrenic nerve stimulation, thrombosis. Complications reported with direct subclavian venipuncture include pneumothorax, hemothorax, laceration of the subclavian artery, arteriovenous fistula, neural damage, thoracic duct injury, cannulation of other vessels, massive hemorrhage and, rarely, death.

Refer to the User's manual for detailed indications, contraindications, warnings, precautions and potential adverse events.

Customer Support: 46-8-474-4756

Brief Summary: Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use. Devices depicted may not be available in all countries. Check with your St. Jude Medical representative for product availability in your country. Unless otherwise noted, ™ indicates that the name is a trademark of, or licensed to, St. Jude Medical or one of its subsidiaries. ST. JUDE MEDICAL, the nine-squares symbol and MORE CONTROL. LESS RISK. are registered and unregistered trademarks and service marks of St. Jude Medical, Inc. and its related companies. ©2011 St. Jude Medical, Inc. All rights reserved.



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Product Specifications

PHYSICAL SPECIFICATIONS

Model	1944	1948
Minimum Introducer Size	7 F	7 F
Type of Lead	bipolar, passive fixation lead	bipolar, passive fixation lead
Lead Connector	IS-1 bipolar	IS-1 bipolar
Lead Lengths	46; 52 cm	46; 52; 58 cm
Fixation Mechanism	tines	tines
Tip-to-ring Spacing	10 mm	10 mm
Lead Tip Electrode (Cathode)	Semi spherical shape, steroid coating	Semi spherical shape, steroid coating
Tip Electrode Surface Area	3,5 mm ²	
Ring Electrode (Anode)	Platinum-iridium, coated with titanium nitride	3,5 mm ²
Ring Electrode Surface Area	16 mm ²	16 mm ²
Steroid	< 1 mg dexamethasone sodium phosphate in silicone matrix	< 1 mg dexamethasone sodium phosphate in silicone matrix
Inner Insulation	Silicone rubber	Silicone rubber
Outer Insulation	Optim™ lead insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating	Fast-Pass™ coating

In Pack

Straight Stylets	1 x-soft in lead; 1 x-soft; 1 soft
J-curved Stylets	1 standard; 1 wide; 1 narrow
Helix Extension/Retraction Clip-on Tools	2 clip-on tools

Accessory Kits

Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	4064	40, 46, 52, 58 and 85 cm	X-Firm Stylets (2)
Stylet Kit	4062	40, 46, 52, 58 and 85 cm	Firm Stylets (2)
Stylet Kit	4060	40, 46, 52, 58 and 85 cm	Soft Stylets (2)

Limited Lifetime Warranty

Terms and conditions apply; refer to the warranty for details.



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