

## IsoFlex™ Optim™

## Pacing Lead

## Product Highlights - Pacing Leads

- The IsoFlex Optim lead allows patients to undergo an MRI scan when used in conjunction with a MRI Ready pacemaker from St. Jude Medical\*
- 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

\*See MRI Conditional Parameters



## Ordering Information - MRI-Ready Pacing System

Model Number	Description	Insulation	Fixation	Min. Introducer (F)	Connector	Length (cm)
1944 (J-Shaped)	IsoFlex™ Optim™ Pacing Lead	Optim™	Tines	7	IS-1 bipolar	46*; 52*
1948 (Straight)	IsoFlex Optim Pacing Lead	Optim	Tines	7	IS-1 bipolar	46; 52*; 58*

\* Indicates lead lengths that are MRI conditional with a scan exclusion zone.

Model Number	Description	Dimensions (H x W x T, mm)	Weight (g)	Volume (cc)	Connector
PM1140	Endurity™ Core Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2140	Endurity Core Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1152	Endurity Core Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2152	Endurity Core Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1162	Endurity Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2162	Endurity Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1172	Endurity MRI™ Pacemaker	41 x 50 x 6	19	9,7 (± 0,5)	IS-1
PM2172	Endurity MRI Pacemaker	46 x 50 x 6	19	10,4 (± 0,5)	IS-1
PM1272	Assurity MRI™ Pacemaker	47 x 50 x 6	20	10,4 (± 0,5)	IS-1
PM2272	Assurity MRI Pacemaker	47 x 50 x 6	20	10,4 (± 0,5)	IS-1

**Indications:** IsoFlex™ Optim™ Model 1948 leads are 7F, steroid eluting (DXA), passive fixation (tined) straight body leads designed for use with compatible pulse generators to provide permanent pacing and sensing in either the right atrium or right ventricle. IsoFlex Optim Model 1944 leads are 7F, steroid eluting (DXA), passive fixation (tined) J-shaped leads designed for use with compatible pulse generators to provide permanent pacing and sensing in the right atrium.

**Contraindications:** The use of IsoFlex™ Optim™ leads is contraindicated in patients who are expected to be hypersensitive to a single dose of 1.0 milligram of dexamethasone sodium phosphate

The use of the Model 1948 is also contraindicated in the presence of tricuspid atresia and in patients with mechanical tricuspid valves.

**Adverse Events:** Potential complications associated with the use of the IsoFlex Optim family of leads are the same as with the use of any lead and include:

Cardiac perforation, Cardiac tamponade, damage to vessels, embolism, excessive bleeding, induced atrial or ventricular arrhythmias, infection, loss of pacing and or sensing due to dislodgment or mechanical malfunction of the lead, phrenic nerve stimulation, tissue necrosis, thrombosis, valve damage. Phrenic nerve or direct diaphragmatic stimulation may also be a result of lead position. 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.

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## Product Specifications - Pacing Leads

## 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 <sup>2</sup>	
Ring Electrode (Anode)	Platinum-iridium, coated with titanium nitride	3,5 mm <sup>2</sup>
Ring Electrode Surface Area	16 mm <sup>2</sup>	16 mm <sup>2</sup>
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 soft in lead; 1 soft; 2 firm

## Accessory Kits

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

## Limited Lifetime Warranty

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

## MRI Conditional Parameters

Magnet strength: 1.5 Tesla

SAR: ≤ 2 W/kg

Scan region: Isocenter must be inferior to L4 or superior to C1



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.

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