

CRM PRODUCT CATALOG

PACING LEADS



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PACING LEADS

Tendril™ STS

Pacing Lead



Product Highlights - Pacing Leads

- The Tendril™ STS lead allows patients to undergo 1.5 T or 3 T MRI scans when used in conjunction with an MRI Ready device from Abbott*
- Soft silicone tip offers more compliance and less tip pressure at the lead tip-endocardium interface
- Small diameter lead offers improved ease of venous passage, reduced risk of venous thrombosis or rib-clavicle crush and ability to accommodate additional leads more easily
- Optim™ lead insulation – a chemical co-polymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Titanium nitride (TiN) fractal coating on the tip and ring electrodes is designed to promote precise sensing and to provide improved contact with the myocardium
- Lubricious Fast-Pass™ coating facilitates lead insertion through the introducer and veins to ease implantation
- Fits through a 6 F introducer

Ordering Information

MODEL NUMBER	DESCRIPTION	INSULATION	FIXATION	MIN. INTRODUCER (F)	CONNECTOR	LENGTH (CM)
2088TC	Tendril™ STS Pacing Leads	Optim™	Ext/Ret helix	6	IS-1 bipolar	46**; 52**; 58**; 65; 100

*See MRI conditional parameters.

**Indicates lead lengths that are MRI conditional.

Indications: Tendril™ STS Lead is designed for permanent sensing and pacing in either the right atrium or the right ventricle, in combination with a compatible device. Active leads such as the Tendril STS lead may be indicated for patients where permanent fixation of passive leads is suspected to be unstable.

In atrial applications, the use of screw-in leads such as Tendril STS lead may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: Tendril STS 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 Tendril STS lead 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.

Product Specifications

PHYSICAL SPECIFICATIONS

Models	2088TC
Minimum Introducer Size	6 F
Type of Lead	Active-fixation, steroid-eluting, endocardial, straight pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	46**; 52**; 58**; 65; 100 cm
Fixation Mechanism	Extendable/Retractable helix
Typical Number of Rotations for Helix Extension	6-11 (straight stylet)
Lead Body Diameter	1,9 mm (max)
Tip-to-Ring Spacing	10 mm
Lead Tip Electrode (Cathode)	Active Titanium-nitride-coated Pt/Ir helix (2,0 mm extension)
Tip Electrode Surface Area	6,9 mm ²
Ring Electrode (Anode)	Titanium-nitride-coated Pt/Ir
Ring Electrode Surface Area	16 mm ²
Mapping	Capable with Titanium-nitride-coated Pt/Ir helix
Steroid	< 1 mg dexamethasone sodium phosphate
Inner Conductor/Outer Conductor	MP35N™* coil
Inner Insulation	Silicone rubber
Outer Insulation	Optim™ lead insulation
Lead Body Coating	Fast-Pass™ coating

In-Pack

Straight stylets	1 x-soft in lead, 1 x-soft, 1 soft
J-shaped stylets	2 soft
Helix extension/retraction clip-on tools	2 clip-on tools

Accessory Kits Available Separately	Model Number	Compatible Lengths	Description
Stylet Kit	DSO6003 with appropriate length designation	46; 52; 58; 65; 100 cm	1 clip-on tool, 1 J-shaped soft, 1 x-soft, 1 soft, 1 firm, 1 x-firm
Locator™ Plus Deflectable Stylet	1281 with appropriate length designation	46; 52; 58 cm	Disposable implant tool to facilitate precise lead positioning and manipulation with one hand
	1292 with appropriate length designation	46; 52; 58 cm	

MRI Conditional Parameters

MRI scan parameters vary depending on the MRI Ready device used. Consult the MRI Ready System Manual for specific product combinations and associated MRI scan parameters.

MP35N is a trademark of SPS Technologies, LLC



*See MRI conditional parameters.

**Indicates lead lengths that are MRI conditional.

PACING LEADS

IsoFlex™ Optim™

Pacing Lead



Product Highlights

- The IsoFlex Optim lead allows patients to undergo a 1.5 T or 3 T MRI scan when used in conjunction with a MRI Ready pacemaker from Abbott*
- 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

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	52; 58

*See MRI conditional parameters.

Indications: IsoFlex™ Optim™ Model 1948 leads are 7F, steroid eluting (DSP), 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 (DSP), 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.

Product Specifications

PHYSICAL SPECIFICATIONS

Models	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	52; 58 cm
Fixation Mechanism	tines	tines
Tip-to-ring Spacing	10 mm	12 mm
Lead Tip Electrode (Cathode)	Semi spherical shape, steroid coating	Semi spherical shape, steroid coating
Tip Electrode Surface Area	3,5 mm ²	3,5 mm ²
Ring Electrode (Anode)	Platinum-iridium, coated with titanium nitride	Platinum-iridium, coated with titanium nitride
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 soft in lead, 1 soft, 2 firm

Limited Lifetime Warranty

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

MRI Conditional Parameters

MRI scan parameters vary depending on the MRI Ready device used.

Consult the MRI Ready System Manual for specific product combinations and associated MRI scan parameters.



MRI READY LEAD MODEL NUMBER	LEAD LENGTHS	MAGNET (TESLA)	SCANNER MODE	SCAN REGION
1944	46, 52 cm	1.5 T, 3 T	Normal Operating Mode	Full Body
1948	52, 58 cm			

OptiSense™

Pacing Lead



Product Highlights

- OptiSense™ pacing lead technology offers optimal tip-to-ring spacing for more precise atrial sensing without inappropriately sensing extra-atrial signals:
 - Unique 1,1 mm tip-to-ring spacing enables sensing of even the finest atrial arrhythmia signals (standard atrial leads typically have a tip-to-ring spacing of 10 mm or more)
 - Accurate atrial sensing enables appropriate atrial diagnostics and therapies
- Less far-field R-wave interference with innovative far-field signal reduction technology
- Optim™ lead insulation — a chemical copolymer that blends the best features of polyurethane and silicone for improved handling and increased durability
- Thin lead body diameter of 5,8 F can be inserted using a 7 F introducer
- Steroid elution and titanium nitride fractal coating on electrodes for low thresholds
- Includes three different J-shaped stylets providing options for different patient anatomies and handling preferences

Ordering Information

Contents: Cardiac Pacing Lead

MODEL NUMBER	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	CONNECTOR	LENGTHS (CM)
1999	Optim	Ext/Ret helix	7	IS-1 bipolar	40; 46; 52

Indications: The OptiSense™ lead is designed for permanent sensing and pacing in the atrium with a compatible pulse generator. An active lead, such as the OptiSense™ lead, 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 OptiSense™ lead, may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The OptiSense™ 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 OptiSense™ 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.

Product Specifications

PHYSICAL SPECIFICATIONS

Model	1999
Minimum Introducer Size	7 F
Type of Lead	Active-fixation; bipolar; steroid-eluting; endocardial: atrial pacing lead
Lead Connector	IS-1 bipolar
Lead Lengths	40; 46; 52 cm
Fixation Mechanism	Extendable/retractable helix
Lead Body Diameter	0,076"/1,9 mm (5,8 F)
Tip-to-ring Spacing	1,1 mm
Lead Tip Electrode (Cathode)	Active titanium-nitride-coated Pt/Ir helix (1,8 mm extension)
Tip Electrode Surface Area	6,4 mm ²
Ring Electrode (Anode)	Titanium-nitride-coated titanium ring
Ring Electrode Surface Area	17 mm ²
Mapping	Capable with titanium-nitride-coated Pt/Ir helix
Steroid	< 1 mg dexamethasone sodium phosphate
Inner Conductor/ Outer Conductor	MP35N ⁺ coil
Inner Insulation	Silicone rubber
Outer Insulation	Optim™ lead insulation
Lead Body 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	Model Number	Compatible Lengths	Description
Stylet Kit	DS06000 with appropriate length designation	52 cm	1 fixation tool; 1 clip-on tool; 1 standard J shape; 1 wide J shape; 1 narrow J shape
	DS06001 with appropriate length designation	46; 52 cm	1 clip-on tool; 1 standard J shape; 1 wide J shape; 1 narrow J shape
	DS06002 with appropriate length designation	46; 52 cm	1 fixation tool; 1 clip-on tool; 1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
	DS06003 with appropriate length designation	40; 46; 52 cm	1 clip-on tool; 1 J-shaped soft; 1 x-soft; 1 soft; 1 firm; 1 x-firm
Locator™ Plus Deflectable Stylet	1281 with appropriate length designation	46; 52 cm	Disposable implant tool that facilitates precise lead positioning and allows manipulation with one hand
	1292 with appropriate length designation	52 cm	

LIMITED LIFETIME WARRANTY

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



AV Plus™ DX VDD

Product Highlights

- Depending on the model, the AV Plus DX lead is available in multiple lengths, affording physicians the flexibility to address the needs of patients with varying physical statures
- Radiopaque suture sleeve is designed to be visible on fluoroscopy, helping physicians to locate the suture sleeve during implant
- Fast-Pass™ coating makes the lead highly lubricious, helping to facilitate lead insertion through the introducer and the veins
- Durable design utilises a bipolar coaxial multifilar lead body design with silicone insulation construction
- Tip electrode surface area helps to provide higher lead impedance, thereby reducing pacing current drain and enhancing longevity
- Offers a steroid-eluting plug inside the lead's tip electrode that is designed to reduce tissue inflammation at the electrode-tissue interface
- The tip and ring electrodes are coated with titanium nitride (TiN), which is designed to expand the electrode's virtual surface area, thus providing low polarisation values and improved sensing

Ordering Information

Contents: Cardiac pacing lead

MODEL NUMBER	INSULATION	FIXATION	MINIMUM INTRODUCER (F)	CONNECTOR	LENGTHS (CM)
1368	Silicone	Tines	9	IS-1 bipolar	52; 58; 65

Indications: The AV Plus™ DX VDD lead is designed for permanent sensing and pacing in the atrium with a compatible pulse generator. An active lead, such as the AV Plus™ DX VDD, 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 AV Plus™ DX VDD, may be indicated in the presence of an abnormal, surgically altered or excised atrial appendage.

Contraindications: The AV Plus™ DX VDD 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 AV Plus™ DX VDD 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.

Product Specifications

PHYSICAL SPECIFICATIONS

Model	1368
Minimum Introducer Size	9 F
Lead Connector	IS-1 Bipolar
Lead Lengths	52; 58; 65 cm
Fixation Mechanism	Tines
Lead Body Diameter	2,0 mm
Tip to Ventricular Ring Spacing	15 mm
Tip to Atrial Ring Spacing	130 mm
Lead Tip Electrode	Semispherical shape, steroid coating
Tip Electrode Surface Area	5 mm ²
Ring Electrode	Platinum-iridium, coated with microporous titanium nitride
Ring Electrode Surface Area	32 mm ²
Steroid	< 1 mg dexamethasone sodium phosphate in silicone matrix
Insulation	Silicone

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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.

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