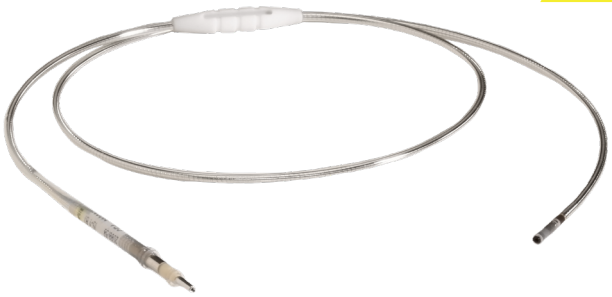
PACING LEAD

Tendril™ STS Pacing Lead with SurGrip™ Technology

2088TC



Product Highlights

- Approved by the FDA for left bundle branch area pacing (LBBAP).
- Robust distal lead tip design without a flexible zone reduces the potential for distal fatigue failure.[1]
- Novel helix locking tool accessory designed to aid with lead fixation by providing control over the extension and retraction of the helix. Proven to lock an extended helix in place during tissue burrowing without retraction.[1]
- Designed with a 2mm helix and a soft tip to provide implant stability.[1]
- Improved torque transmission to the helix with less rotations of the lead body compared to a lumenless lead.[1]
- Enhanced suture sleeve with SurGrip technology provides secure fixation and advanced lead protection.[2]
- The Tendril STS Pacing Lead is designed to allow patients to undergo MRI scans when used with an MR Conditional device if conditions for use as described in MRI-Ready Systems Manual are met and followed.*
- Soft silicone tip offers more compliance and less tip pressure at the lead tip-endocardium interface.[3]
- 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.[3]
- Optim™ lead insulation — a chemical copolymer 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 sensing.
- Lubricious Fast-Pass™ coating facilitates lead insertion through the introducer.
- Fits through a 6F introducer.

Ordering Information

Contents: Pacing Lead

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

* For additional information about MR Conditional devices and leads, including warnings, precautions, adverse conditions to MRI scanning, and potential adverse events, please refer to the Abbott MRI-Ready Systems Manual at manuals.eifu.abbott or check our MRI-Ready resources at mri.merlin.net.

***Not MR Conditional.*

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Product Specifications

PHYSICAL SPECIFICATIONS	
Model Number	2088TC
Minimum Introducer Size	6F[4] (without retained guidewire)
Type of Lead	Active-fixation, bipolar, steroid-eluting, endocardial, pacing lead
Lead Connector	IS-1 bipolar[5]
Lead Lengths	46, 52, 58, 65**, 100 cm**
Fixation Mechanism	Extendable/retractable helix
Typical Number of Rotations for Helix Extension	6–11 (straight stylet),[6] 9-14 (J-curved stylet),[6] 8-18 (LBBAP)[6]
Lead Body Diameter	1.9 mm (max)
Tip-to-Ring Spacing	10 mm
Lead Tip Electrode (Cathode)	Active TiN-coated Pt/Ir helix (2.0 mm extension)
Tip Electrode Surface Area	6.9 mm^2
Ring Electrode (Anode)	TiN-coated Pt/Ir
Ring Electrode Surface Area	15.3 mm^2
Mapping	Capable with TiN-coated Pt/Ir helix
Steroid	Silicone rubber with 460 micrograms of dexamethasone sodium phosphate (DSP)
Inner Conductor/ Outer Conductor	MP35N‡ coil
Inner Insulation	Silicone
Outer Insulation	Optim™ lead insulation[7]
Lead Body Coating	Fast-Pass™ coating

IN PACK	
Straight Stylets	1 x-soft in lead, 1 soft
J-curved Stylets	1 soft
Helix Extension/Retraction Clip-on Tools	2 clip-on tools
Suture Sleeve	1 radiopaque silicon suture sleeve attached to lead

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Product Specifications

ACCESSORY KITS			
Available Seperately	**Model Number**	**Compatible Lengths (cm)**	**Description**
Stylet Kit	DS06002 with appropriate length designation	46, 52	1 clip-on tool, 1 standard J shape, 1 wide J shape, 1 narrow J shape
Stylet Kit	DS06003 with appropriate length designation	46, 52, 58, 65**, 100**	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, 65**	Disposable implant tool to facilitate precise lead positioning and manipulation with one hand
Locator™ Plus Deflectable Stylet	1292 with appropriate length designation	46, 52, 58, 65**	Disposable implant tool to facilitate precise lead positioning and manipulation with one hand
Suture Sleeve	DS2A088 	46, 52, 58, 65**, 100**	Protect the lead from damage when it is secured to the venous entry site
Helix Locking Tool	A001HELX 	46, 52, 58, 65**	Aids with the extending and retracting of the helix

***Not MR Conditional.*

References

1. Abbott. Data on File, Engineering Technical Report. Item: 90994484 Ver C.
2. 6Fr Suture Sleeve R&T Data. Doc. 90619024.
3. Mechanical and System Product Verification Test Report Tendril STS 1988TC and 2088TC, Report No.50009843/50025428.
4. Compatible with introducers such as those manufactured by Daig and Pressure Products.
5. Abbott Medical IS-1 connector cavities comply with the international connector standard: ISO 5841-3.
6. Not to exceed 35 rotations.
7. Optim is a silicone-polyurethane copolymer.

Rx Only

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.

Indications: Tendril™ STS leads are indicated for use in combination with a compatible pacemaker, implantable cardioverter defibrillator (ICD) or cardiac resynchronization therapy (CRT-P/CRT-D) device to provide sensing and pacing for the management of chronic symptomatic bradycardia and various atrioventricular conduction abnormalities in patients who experience syncope, presyncope, fatigue, or disorientation due to arrhythmia/bradycardia, or any combination of these symptoms. The Tendril STS leads are implanted transvenously in either the right atrium, the right ventricle or the left bundle branch area.

Contraindications: Tendril™ STS Model 2088TC leads are contraindicated: in the presence of tricuspid atresia (if the lead is to be positioned in the right ventricle or left bundle branch area), for patients with mechanical tricuspid valves (if the lead is to be positioned in the right ventricle or left bundle branch area), in patients who are expected to be hypersensitive to a single dose of one milligram of dexamethasone sodium phosphate.

Adverse Effects: Potential adverse effects and their categories associated with the use of Tendril STS leads are the same as with the use of other active fixation leads and include: Arrhythmia (Accelerated arrhythmia, Induced atrial ectopy or arrhythmias, Induced atrioventricular or bundle branch block, Induced ventricular ectopy or asystole, Myocardial irritability), Cardiac perforation (Cardiac tamponade, Pericardial Effusion, Pericarditis, Septal perforation), Death, Embolism (Air embolus, Dislodgement of intracardiac thrombus, intravascular foreign body), Extra-cardiac stimulation, Heart failure (Right ventricular decompensation, Tricuspid valve dysfunction/Tricuspid valve regurgitation/insufficiency), Hypersensitivity (Hypersensitivity, including local tissue reaction or allergic reaction), Infection (Endocarditis), Lead revision or reprogramming resulting from, but not limited to, loss of pacing and/ or sensing (Electrical malfunction of the lead, Lead dislodgement, Lead dysfunction (sensing/threshold Issue), Mechanical malfunction of the lead), Lung perforation (Hemothorax, Pneumothorax), Pulmonary edema, Prolonged exposure to fluoroscopic radiation, Respiratory compromise, Tricuspid value perforation, Vascular injury (Arterial perforation, Arteriovenous fistula, Coronary sinus or coronary vein perforation/dissection, Hemorrhage/ Hematoma at device site, Venous perforation, Septal hematoma), Vascular thrombosis/ stenosis/ occlusion. The physician should discuss the patient's potential adverse events with them.

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

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