

ENDOTAK RELIANCE® G and ENDOTAK RELIANCE SG

Specifications and Features

ENDOTAK RELIANCE G, Dual-Coil Models 0174, 0175, 0176, 0177, 0184, 0185, 0186, 0187

ENDOTAK RELIANCE SG, Single-Coil Models 0170, 0171, 0172, 0180, 0181, 0182

The ENDOTAK RELIANCE G/SG leads are steroid-eluting, endocardial cardioversion/defibrillation, and pace/sense leads available in extendable/retractable and tined models. The silicone lead body has a lubricious coating; the electrode coils are covered with GORE™ expanded polytetrafluoroethylene (ePTFE). ENDOTAK RELIANCE G/SG passive-fixation leads feature a distal tip electrode with a small active surface area designed for high pacing impedance.



LEAD SPECIFICATIONS

Product	ENDOTAK RELIANCE G		ENDOTAK RELIANCE SG	
	Active	Passive	Active	Passive
Model/Length	0184 59 cm 0185 64 cm 0186 70 cm 0187 90 cm	0174 59 cm 0175 64 cm 0176 70 cm 0177 90 cm	0180 59 cm 0181 64 cm 0182 70 cm	0170 59 cm 0171 64 cm 0172 70 cm
Coils	Dual-coil	Dual-coil	Single-coil	Single-coil
Terminal sizes	(1) IS-1 bipolar ^a (2) DF-1 ^b	(1) IS-1 bipolar ^a (2) DF-1 ^b	(1) IS-1 bipolar ^a (1) DF-1 ^b	(1) IS-1 bipolar ^a (1) DF-1 ^b
Tip to Proximal Coil Electrode Length (cm)	18	18	N/A	N/A
Proximal Coil Active Electrode Surface Area (mm²)	660	660	N/A	N/A
EXPECTED NUMBER OF ROTATIONS ALLOWED TO FULLY EXTEND/RETRACT HELIX^c	Serial No ≤ 299999: 0184, 0185, 0186: 8 rotations 0187: 10 rotations Serial No ≥ 300000: 0184, 0185, 0186: 11 rotations 0187: 15 rotations	N/A	Serial No ≤ 299999: 0180, 0181, 0182: 8 rotations Serial No ≥ 300000: 0180, 0181, 0182: 11 rotations	N/A
Porous Tip Base Diameter (mm)	N/A	1.1	N/A	2.0
Tip Active Electrode Surface Area (mm²)	5.7	2.0	5.7	2.0
Steroid Material	Approximately 1.0 mg dexamethasone acetate	Approximately 1.0 mg dexamethasone sodium phosphate	Approximately 1.0 mg dexamethasone acetate	Approximately 1.0 mg dexamethasone sodium phosphate

^a IS-1 refers to the international standard ISO 5841.3:1992.

^b DF-1 refers to the international standard ISO 11318:1993.

^c Use the fluoroscopy markers for verification of full helix extension/retraction.



With GORE™
ePTFE-covered Coils

**Boston
Scientific**

Delivering what's next.™

LEAD SPECIFICATIONS (CONTINUED)

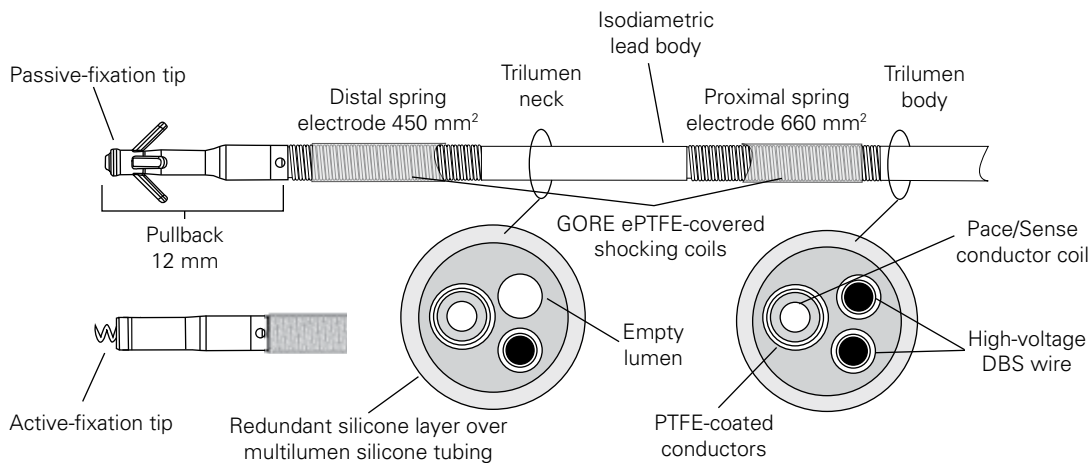
ALL MODELS OF ENDOTAK RELIANCE G AND ENDOTAK RELIANCE SG

Compatibility	Boston Scientific ICD pulse generators, ENDOTAK SQ array leads, ICD Y connector
Non Hemostatic Lead Introducer	
Without Guide Wire	9 Fr
With Guide Wire	10.5 Fr
Hemostatic Lead Introducer	
Without Guide Wire	9.5 Fr
With Guide Wire	11 Fr
Isodiametric Lead Body	
Diameter	2.7 mm (8.1 Fr)
Coil Electrode Diameter (mm)	2.7 mm (8.1 Fr)
Distal Coil Active Electrode Surface Area	450 mm ²
External Insulation Material	Silicone rubber
DF-1 Terminal Pin Material	Titanium
IS-1 Terminal Pin Material	Stainless steel
Pace/Sense Conductor Material	MP35N nickel-cobalt alloy, PTFE coated
Shocking Conductor Material	Drawn brazed strand cable, PTFE coated
Tip Electrode Covering Material	Platinum iridium
Coil Electrode Covering Material	ePTFE

FEATURES

Lifetime warranty: The ENDOTAK RELIANCE G defibrillation lead family is backed with a lifetime warranty.^d

GORE ePTFE-covered coils: The GORE ePTFE covering's unique properties enhance the lead's design. The material's pore size is large enough to allow fluid to penetrate the ePTFE covering and contact the defibrillation coils, enabling electrical conductivity. However, the pore size is small enough to prevent cell penetration, preventing fibrotic tissue from forming around and between the individual coil filars. The small edge coil sections that are not covered with GORE are backfilled with medical adhesive to aid in prevention of tissue ingrowth.



Isodiametric lead body: The isodiametric lead body contains one conductor for pacing/sensing. For defibrillation, the ENDOTAK RELIANCE G lead has two conductors; the ENDOTAK RELIANCE SG lead has one conductor. All conductors—insulated in separate lumens within the silicone rubber lead body—are coated with polytetrafluoroethylene (PTFE). A second layer of silicone covers the lead body, providing additional insulation and a uniform body diameter. The entire lead body fits through a 9-French lead introducer when not retaining a guide wire.

Silicone construction: Boston Scientific silicone leads have demonstrated reliability with over 60 million implant months with no insulation degradation.

Lubricious coating: The ENDOTAK RELIANCE G lead family utilizes a proprietary coating that makes the silicone lead surface more lubricious. The lubricious coating reduces both the static and dynamic coefficients of friction, making the lead surface feel and handle like polyurethane while providing the time-tested reliability of silicone.

Reduced pocket bulk: To complement small pulse generators, the ENDOTAK RELIANCE G family maintains two enhancements introduced with ENDOTAK RELIANCE passive-fixation leads: shorter terminal legs and a 47% size reduction of the yoke to reduce pocket bulk.

^d Limited lifetime warranty. For a full and complete description of the ENDOTAK RELIANCE family warranty, please review the warranty card included with the product labeling.

FEATURES (CONTINUED)

Steroid distal tip: The tip electrode contains a nominal dose of steroid that elutes upon exposure to body fluids. The steroid suppresses the inflammatory response believed to cause threshold rises typically associated with implanted pacing electrodes. Lower thresholds are desirable because they can increase pacing safety margins and reduce pacing energy requirements, potentially increasing pulse generator longevity.

Pullback: Pullback is the distance the defibrillation electrode is removed from the lead tip, a critical factor in helping to direct energy deep into the ventricular apex. Standard for multiple generations of Boston Scientific defibrillation leads, the 12-mm ENDOTAK pullback design is important for low defibrillation thresholds, while optimizing sensing characteristics.

High impedance: The ENDOTAK RELIANCE G/SG passive-fixation leads feature a distal tip electrode with small active surface area for high pacing impedance.

ACTIVE-FIXATION FEATURES

Terminal pin-driven extendable/retractable fixation helix: Rotating the fixation tool around the terminal pin extends/retracts the helix. The platinum-iridium helix anchors the pacing electrode to the endocardial surface without support of trabecular structures, offering various lead placement possibilities for the tip electrode in the right ventricle.

Fluoroscopic markers: The ENDOTAK RELIANCE G/SG active-fixation models have radiopaque markers near the distal tip. These markers enable clear visualization of the full extension/retraction of the helix when viewed under fluoroscopy.

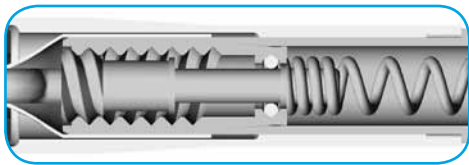
Fully retracted



Fully extended



Mapping: The ENDOTAK RELIANCE G/SG lead's electrically conductive helix nominally protrudes up to 0.015 inches from the end of the lead. This allows placement of the distal tip of the lead against the tissue for mapping of potential electrode positions through pacing and sensing thresholds measurement without helix extension into the tissue. The ability to map prior to helix extension can help save time should multiple lead positions be tested.



Nominal helix extension
of up to 0.015 inches

ICD Leads from Boston Scientific CRM

Indications

ICD leads provide pacing and rate-sensing and deliver cardioversion and defibrillation shocks for ICD systems.

Contraindications

Use of ICD leads are contraindicated in: patients who have a unipolar pacemaker, patients with a hypersensitivity to a single dose of approximately 1.0 mg of dexamethasone sodium phosphate and/or 1.0 mg of dexamethasone acetate, patients with mechanical tricuspid heart valves.

Warnings

Do not attempt to use the lead system with any device other than a commercially available ICD with which it has been tested and demonstrated safe and effective. Potential adverse consequences include but are not limited to undersensing of cardiac therapy and failure to deliver necessary therapy. The safety and efficacy of the tip electrode placement above midseptum has not been clinically established (extendable retractable helix leads). Lead fracture, dislodgment, abrasion and/or incomplete connection can cause a periodic or continual loss of rate-sensing, possibly resulting in inappropriate delivery of a PG shock or inadequate delivery of converting energy. The lead is not designed to tolerate excessive flexing, bending or tension. This could cause structural weakness, conductor discontinuity and/or lead dislodgment. Failure to obtain appropriate electrode position may result in higher defibrillation thresholds or may render lead unable to defibrillate a patient whose tachyarrhythmia(s) might otherwise be convertible by an ICD system. In order to deliver defibrillation therapy, the single-coil lead must be implanted with a separate defibrillation electrode. BSC CRM recommends using the single-coil lead with a pectorally implanted device that uses the metallic housing as a defibrillation electrode. When connecting the lead to ECD cables and/or the ICD PG it is very important that proper connections are made. Damage to the heart could result if a high-voltage defibrillating pulse were to be delivered through the pace/sense tip electrode. Use of any component of the lead system to assist in the delivery of external-source rescue shocks could cause extensive tissue damage. Do not kink, twist, or braid the lead terminals as doing so could cause lead insulation abrasion damage.

Precautions

Refer to the lead product labeling for cautions specific to handling, implanting and testing the lead. Failure to observe these cautions could result in incorrect lead implantation, lead damage, and/or harm to the patient. It has not been determined whether the warnings, precautions, or complications usually associated with injectable dexamethasone sodium phosphate/acetate apply to the use of the low concentration, highly localized, controlled-release device. For a listing of potentially adverse effects, refer to the Physician's Desk Reference. Tricuspid valvular disease may be exacerbated by the presence of a lead. Use medical judgment when deciding to place a lead in a patient with tricuspid valvular disease. The lead and its accessories are intended only for one-time use. Do not reuse.

Potential Adverse Events

Potential adverse events from implantation of the ICD lead system include, but are not limited to, the following: allergic/physical/physiologic reaction, death, erosion/migration, fibrillation or other arrhythmias, lead or accessory breakage (fracture/insulation/lead tip), hematoma/seroma, inappropriate or inability to provide therapy (shocks/pacing/sensing), infection, procedure related, and component failure. In rare cases severe complications or device failures can occur.

Refer to the product labeling for specific indications, contraindications, warnings/precautions and adverse events. Rx only.

(Rev. I)

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Cardiac Rhythm Management

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