



RELIANCE 4-FRONT™

Pace/Sense and Defibrillation Lead

RELIANCE 4-FRONT, Single-coil RELIANCE 4-FRONT, Dual-coil

The RELIANCE 4-FRONT Leads are 7.3F (2.4 mm; 8F / 2.6 mm introducer), steroid-eluting, endocardial cardioversion/defibrillation and pace/sense leads available in extendable/retractable models as well as in passive fixation models. These leads utilize the DF4 connector and incorporate the IROX™ (iridium oxide) coating on the tip electrode. The silicone lead body has a lubricious coating, and the electrode coils are silicone-backfilled.



Lead Specifications

Product	Dual-coil Active	Single-coil Active	Dual-coil Passive	Single-coil Passive
Model/Length	0675 59 cm 0676 64 cm	0672 59 cm 0673 64 cm	0665 59 cm 0636 64 cm	0662 59 cm 0663 64 cm
Terminal Sizes	DF4-LLHH	DF4-LLHO	DF4-LLHH	DF4-LLHO
PG Compatibility	RELIANCE 4-FRONT Leads with the DF4-LLHH / LLHO label are compatible with a device containing a DF4-LLHH port			
Lead Introducer without Guide Wire	8F (2.6 mm)	8F (2.6 mm)	8F (2.6 mm)	8F (2.6 mm)
Lead Introducer with Guide Wire	10.5F (3.5 mm)	10.5F (3.5 mm)	10.5F (3.5 mm)	10.5F (3.5 mm)
Isodiametric Lead Body Diameter	7.3F (2.4 mm)	7.3F (2.4 mm)	7.3F (2.4 mm)	7.3F (2.4 mm)
Rotations Expected to Extend/Retract Helix [†]	11	11	N/A	N/A
Tip/Helix Electrode Surface Area (mm²)	5.7	5.7	3.5	3.5
Proximal Coil Active Electrode Surface Area (mm²)	660	N/A	660	N/A
Distal Coil Active Electrode Surface Area (mm²)	450	450	450	450
Tip to Proximal Coil Electrode Length (mm)	180	N/A	180	N/A
Tip to Distal Coil Electrode Length (mm)	12	12	12	12
Lead Body Insulation Material	Layer of silicone, layer of polyurethane (for the first ~ 12 cm) and then the silicone trilumen			
Terminal Pin Material	MP35N nickel-cobalt alloy			
Pace/Sense Conductor Material	Low titanium, MP35N nickel-cobalt alloy, PTFE sleeve			
Terminal Ring Material	MP35N nickel-cobalt alloy			
Shocking Conductor Material	1X19 Low titanium MP35N nickel-cobalt alloy, silver-core, drawn filled tube, ETFE coated			
Tip Electrode Material	IROX coated platinum/iridium			
Coil Electrode Material	Platinum clad tantalum clad titanium with silicone backfill			
Steroid Material	Approximately 0.96 mg dexamethasone acetate nominally			

Features

Limited Lifetime Lead Warranty available: For full terms and conditions, please visit www.BostonScientific.com/warranty.

Terminal configuration: The RELIANCE 4-FRONT™ Lead is DF4-LLHH for dual-coil leads and DF4-LLHO for single-coil leads. This suffix provides functional identifications of conductors:

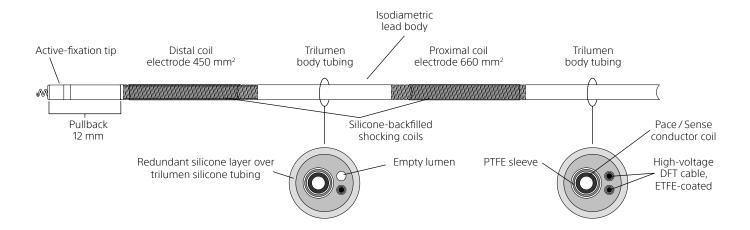
L = Low Voltage

H = High Voltage

O = Inactive Ring Contact (Single-Coil Leads Only)



Rings 1 and 2 are electrically connected within the terminal for integrated bipolar pacing / sensing. Cable conductors are utilized for both shock coils. Ring 2 is connected to the distal shock coil, and ring 3 connects to the proximal coil.



Isodiametric lead body: The isodiametric lead body contains one conductor for pacing / sensing. For defibrillation, the lead has two conductors in dual-coil models and one for the single-coil models leaving one lumen empty in single-coil models. The conductors are insulated in separate lumens within the silicone rubber lead body. A second layer of silicone covers the lead body, providing additional insulation and a uniform body diameter. RELIANCE 4-FRONT™ has a 7.3F (2.4 mm) lead body which fits through an 8F (2.6 mm) non-hemostatic introducer when not retaining a quide wire.

Insulation:

- Silicone construction: Silicone has been used in Boston Scientific leads for nearly 4 decades.
- **Polyurethane sleeve:** The first 12 cm of the lead distal to the terminal boot incorporates a polyurethane sleeve underneath the outer silicone rubber insulation for enhanced abrasion resistance within the pocket.
- Lubricious coating: The RELIANCE 4-FRONT Lead family utilizes a proprietary coating that makes the silicone lead surface more lubricious. This 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.

Backfilled coils: The silicone backfill enhances the lead's extractability by preventing fibrotic tissue from forming around and between the individual coil filars.

IROX™ coating: RELIANCE 4-FRONT features an IROX (iridium oxide) coated pace/sense cathode electrode, which may improve pacing performance. Lower and more predictable pacing thresholds may increase the longevity of the pulse generator.

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 RELIANCE 4-FRONT pullback design is important for low defibrillation thresholds, while optimizing sensing characteristics.

Radiopaque suture sleeve: The radiopaque suture sleeve is visible under fluoroscopy and is used to secure and protect the lead at the venous entry site after lead placement. The window feature is designed to aid compression of the sleeve onto the lead during suturing.

Passive-Fixation Features

Design: Leveraged from successful FINELINETM II family. 12 mm Tip to RV Coil spacing is identical to RELIANCE. Incorporates a flexible neck region and IROX coating for improved pacing performance.



Active-Fixation Features

Terminal pin-driven extendable/retractable fixation helix: Rotating the knob of the EZ-4[™] Connector tool rotates the terminal pin which extends / retracts the helix. The IROX coated 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 RELIANCE 4-FRONT active fixation model incorporates a radiographic marker system to enable clear visualization of the helix position under fluoroscopy.

Fully retracted



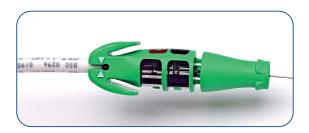
Fully extended



Mapping: The RELIANCE 4-FRONT tip and helix design allows mapping even with the helix fully retracted. Helix is flush to prevent snagging while enabling mapping.

EZ-4™ Connector Tool





When connected to the lead, the EZ-4 Connector Tool performs the following functions:

- 1. Protects the lead terminal during the implant procedure.
- 2. Provides a safe and secure connection between the pacing system analyzer (PSA) patient cables and the lead terminal.
- 3. Guides the stylet into the lead through the stylet funnel.
- 4. For leads with an extendable / retractable helix, rotates the terminal pin clockwise or counterclockwise to extend or retract the helix. The EZ-4 Connector Tool is intended to be left on the lead for the duration of the implant, until the lead terminal is inserted into the header.



 $\underline{RELIANCE\ 4\text{-}Front}^{\underline{TM}}\underline{-Indications, Safety\ and\ Warnings\ -Boston\ Scientific}$

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CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. Rx Only.



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