Boston Scientific
Advancing science for life™

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

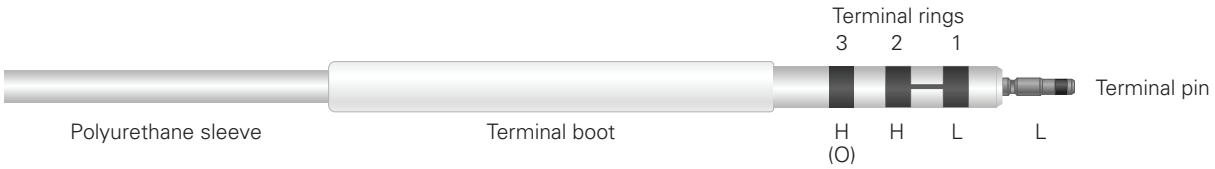
Product	Dual-coil Active	Single-coil Active	Dual-coil Passive	Single-coil Passive
Model/Length	0675 59 cm 0676 64 cm	0672 59 cm 0673 64 cm	0665 59 cm 0636 64 cm	0662 59 cm 0663 64 cm
Terminal Sizes	DF4-LLHH	DF4-LLHH	DF4-LLHO	DF4-LLHO
PG Compatibility	RELIANCE 4-FRONT Leads with the DF4-LLHH / LLHO label 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 (2.4mm)	7.3F (2.4mm)	7.3F (2.4mm)	7.3F (2.4mm)
Rotations Expected to Extend/Retract Helix†	11	11	N/A	N/A
Tip/Helix Electrode Surface Area (mm^2)	5.7	5.7	3.5	3.5
Proximal Coil Active Electrode Surface Area (mm^2)	660	n/a	660	n/a
Distal Coil Active Electrode Surface Area (mm^2)	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			

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

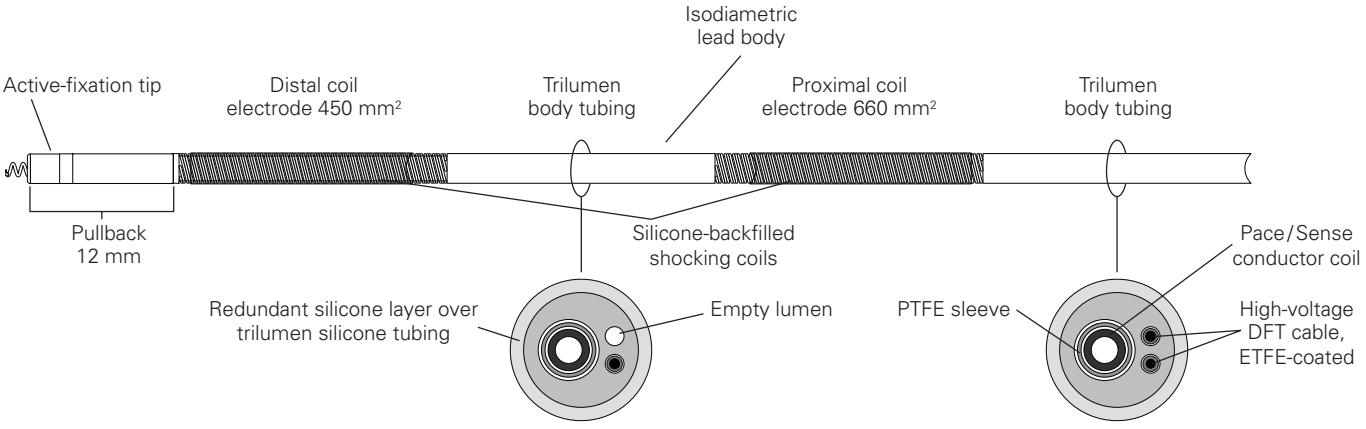
Features

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 guide 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

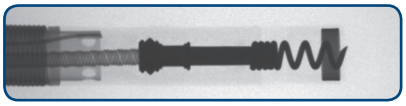
Design: Leveraged from successful FINELINE 2 family. 12 mm Tip to RV Coil spacing is identical to RELIANCE. Incorporates a flexible neck region and IROX coating for improved pacing performance.

Active-Fixation Features

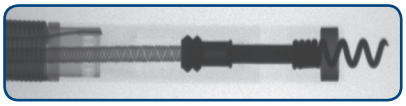
Terminal pin-driven extendable/retractable fixation helix: Rotating the knob of the EZ-4™ Connector tool rotates the terminal pin which extends/retracts the helix. The IROX coated platinum-iridium helix anchors the pacing electrode to the endocardial surface without support of trabecular structures, 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

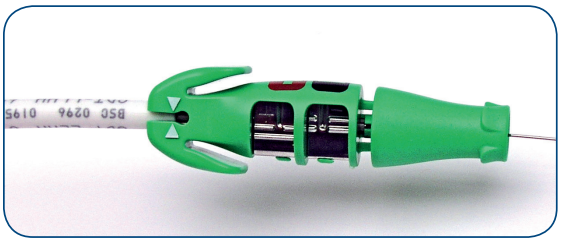


Fully extended



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.

RELIANCE 4–FRONT™ Pace/Sense and Defibrillation Lead

Indications and Usage This Boston Scientific lead is indicated for use as follows:
• Intended for pacing, rate-sensing, and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator

Contraindications Use of this Boston Scientific lead is contraindicated for the following patients:
• Patients who have a unipolar pacemaker
• Patients with a hypersensitivity to a maximum single dose of 1.1 mg dexamethasone acetate
• Patients with mechanical tricuspid heart valves

Warnings Read this manual thoroughly before implantation to avoid damage to the pulse generator and/or lead. For single patient use only. Do not reuse, reprocess, or resterilize. Always have external defibrillation equipment available during implant and electrophysiologic testing. Do not use any component of the lead system to assist in delivery of external-source rescue shocks or extensive tissue damage could occur. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing should the patient require external rescue. Lead fracture, dislodgment, abrasion, or an incomplete connection can cause a periodic or continual loss of pacing or sensing or both. The lead is not designed to tolerate excessive flexing, bending, or tension. Do not kink, twist, or braid the lead with other leads as doing so could cause lead insulation abrasion damage or conductor damage. Use caution handling the lead terminal when the Connector Tool is not present on the lead. Do not contact any other portion of the lead terminal, other than the terminal pin, even when the lead cap is in place. Implant of the system cannot be performed in an MRI site Zone III (and higher). In order to deliver defibrillation therapy, the single-coil models must be implanted with an additional defibrillation electrode. For DF4-LLHH or DF4-LLHO leads, only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. Unless all of the MRI Conditions of Use (as described in the MRI Technical Guide) are met, MRI scanning of the patient does not meet MR Conditional requirements for the implanted system, and significant harm to or death of the patient and/or damage to the implanted system may result. Refer to the MRI Technical Guide for potential adverse events applicable when Conditions of Use are met or not met, as well as for a complete list of MRI-related Warnings and Precautions. Do not subject a patient with an implanted pulse generator and/or lead to diathermy.

Extendable/Retractable Models The safety and efficacy of the tip electrode placement in the right ventricle above midseptum has not been clinically established. Use fluoroscopy to verify that the lead tip is directed toward the apex when implanted.

Precautions For specific information on precautions, refer to the following sections of the product labeling: clinical considerations; sterilization and storage, handling; implantation, hospital and medical environments, follow-up testing

Potential Adverse Events Based on the literature and on pulse generator and/or lead implant experience, the following alphabetical list includes the possible adverse events associated with implantation of products described in this literature:
• Air embolism • Allergic reaction • Arterial damage with subsequent stenosis • Bleeding • Bradycardia • Breakage/failure of the implant instruments • Cardiac perforation • Cardiac tamponade • Chronic nerve damage • Component failure • Conductor coil fracture • Death • Electrolyte imbalance/dehydration • Elevated thresholds • Erosion • Excessive fibrotic tissue growth • Extracardiac stimulation (muscle/nerve stimulation) • Fluid accumulation • Foreign body rejection phenomena • Formation of hematomas or seromas • Heart block • Hemorrhage • Hemothorax • Inability to defibrillate or pace • Inappropriate therapy (e.g., shocks and antitachycardia pacing [ATP] where applicable, pacing) • Incisional pain • Incomplete lead connection with pulse generator • Infection including endocarditis • Lead dislodgment • Lead fracture • Lead insulation breakage or abrasion • Lead tip deformation and/or breakage • Local tissue reaction • Low amplitude VF signals • Malignancy or skin burn due to fluoroscopic radiation • Myocardial trauma (e.g., irritability, injury, tissue damage) • Myopotential sensing • Oversensing/undersensing • Pericardial rub, effusion • Pneumothorax • Post-shock rhythm disturbances • Pulse generator and/or lead migration • Shunting current during defibrillation with internal or external paddles • Syncope • Tachyarrhythmias, which include acceleration of arrhythmias and early, recurrent atrial fibrillation • Thrombosis/thromboemboli • Valve damage • Vasovagal response • Venous occlusion • Venous trauma (e.g., perforation, dissection, erosion) For a list of potential adverse events associated with MRI scanning, refer to the ImageReady MR Conditional Defibrillation System MRI Technical Guide.

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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.

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CRM-553413-AB