SUMMARY

During implantation of a Boston Scientific ENDOTAK RELIANCE® lead with a DF4 terminal, the EZ-4™ Connector tool protects the lead terminal, provides a safe and secure connection between the PSA patient cables and the lead terminal, guides the stylet into the lead lumen, and extends or retracts the helix.

This article describes how to use the EZ-4 Connector Tool.

Products Referenced
ENDOTAK RELIANCE 4-Site™ Lead, ENDOTAK RELIANCE 4-Front™ Lead, EZ-4 Connector Tool

Products referenced herein may not be approved in all geographies. For comprehensive information on device operation, reference the full instructions for use found at: www.bsci.com/ifu.

CAUTION: Federal (U.S.) law restricts this device to sale by or on the order of a physician.

All graphics produced by Boston Scientific Corporation, unless otherwise noted.

CRT-D: Cardiac Resynchronization Therapy Defibrillator
CRT-P: Cardiac Resynchronization Therapy Pacemaker
ICD: Implantable Cardioverter Defibrillator
PSA: Pacing System Analyzer

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How to Use the EZ-4™ Connector Tool

Boston Scientific ENDOTAK RELIANCE® Leads with a DF4[1] terminal (4-Site™ and 4-Front™) are packaged with an EZ-4 Connector Tool, held in position near the end of the lead terminal by a pre-inserted stylet.

The EZ-4 Connector Tool is used during lead implantation to perform the following:

- Protects the lead terminal from PSA clip damage and prevents bridging (electrical short circuit) between the (+) and (-) terminal contacts during electrical testing.
- Provides a safe and secure connection between PSA patient cables and the lead terminal.
- Guides the stylet into the lead lumen through the built-in stylet funnel.
- Facilitates extension or retraction of the helix (for active fixation models).

The Connector Tool should be attached and remain on the lead throughout the implant procedure. At any point during lead implantation where repositioning and/or PSA measurements are necessary, the Connector Tool should be attached, and should not be removed until the lead is connected to the pulse generator header.

Figure 1 illustrates features of the EZ-4 Connector Tool.

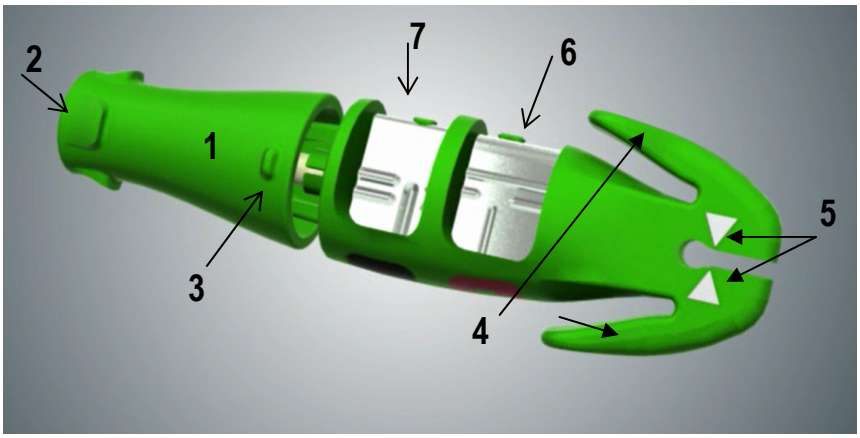


Figure 1. EZ-4 Connector Tool

[1] Fixation knob (disengaged) – engage to extend or retract helix
[2] Stylet funnel – use to guide stylet into lead lumen
[3] Rotation indicator mark – use to count turns/rotations
[4] Terminal boot levers – use to attach/remove the Connector Tool to/from lead
[5] White indicator arrows – use to align with lead's white terminal boot
[6] Anode (+) spring contact – use to attach PSA red cable
[7] Cathode (-) spring contact – use to attach PSA black cable

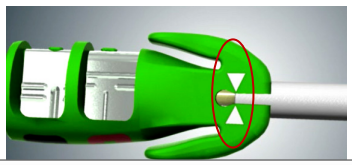
Table 1 describes functions of the EZ-4 Connector Tool. The information in Table 1 does not represent step by step lead implant instructions. For complete lead implantation instructions, reference the full device Instructions for Use for both pulse generator and lead.

[1]DF4 refers to the international standard ISO 27186:2010 - Active implantable medical devices - Four-pole connector system for implantable cardiac rhythm management devices.

Table 1. How to Use the EZ-4 Connector Tool

How to Attach the Connector Tool to the Lead

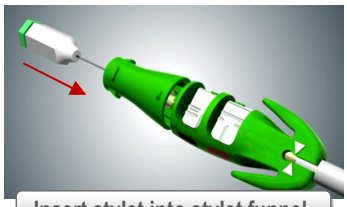
Slide the EZ-4 Connector Tool onto the proximal end of the lead. Pinch the terminal boot levers and continue sliding the Connector Tool until the white arrows align with the edge of the white terminal boot. Release the terminal boot levers to secure the Connector Tool to the lead terminal.
NOTE: *Aligning the arrows with the end of the terminal boot will help ensure proper electrical connections between the lead and the Connector Tool.*



Align indicator arrows with white terminal boot.

How to Insert the Stylet

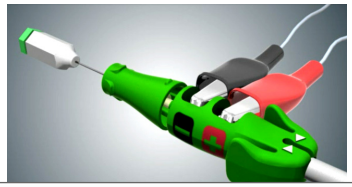
As needed, remove the pre-inserted stylet. Select a stylet according to the desired function and preferred firmness. A gently curved stylet is acceptable. Carefully insert the stylet through the funnel of the EZ-4 Connector Tool and terminal pin, which will guide the stylet into position. Ensure the stylet is fully inserted into the lead prior to inserting the lead into the vein. **TIP:** If difficulty is encountered inserting the stylet through the Connector Tool, consider engaging the fixation knob to eliminate snagging of the stylet tip. Note, that the helix can become unintentionally extended if the Connector Tool fixation knob is engaged. Be sure to disengage the fixation knob from the terminal pin prior to inserting the lead into the vein.



Insert stylet into stylet funnel.

How to Obtain Electrical Measurements

Securely attach/clamp the PSA clips to the EZ-4 Connector Tool's spring contacts. Fully engage the alligator clips on the cathode and anode spring contacts to avoid inaccurate baseline measurements, attach red to (+) and black to (-) by following the markings on the tool. **TIP:** If alligator clips are not fully seated on the spring contacts, or the clamping force of the clips is weak, the spring contacts may not compress enough to contact the lead terminal. If this happens, fully engage the clips or replace with new alligator clips. **WARNING:** Do not attach alligator clips directly to the lead terminal or damage could occur. Note, that such damage may not be immediately apparent.



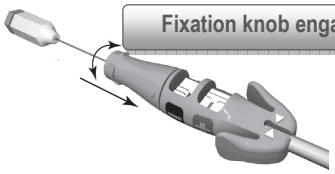
Attach alligator clips to spring contacts.

How to Extend and Retract the Fixation Helix

The mechanical function (extension and retraction of the helix) of the lead should be exercised prior to lead insertion/implantation.

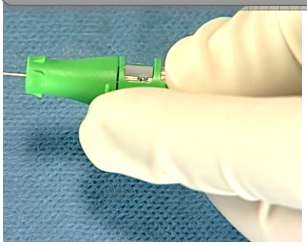
When a lead position is selected and you are ready to extend the helix,

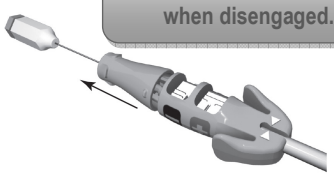
- Remove the pacing system analyzer (PSA) alligator clips from the EZ-4 Connector Tool, which will help prevent the spring contact from dragging on the terminal pin during rotations. ***NOTE:*** *The black PSA cable clip should be removed* ***whenever*** *the helix is extended or retracted.*
- Apply forward pressure to the lead body to position the distal electrode against the desired fixation site.
- Grasp the terminal boot and the flat sides of the Connector Tool boot levers and engage the knob. **TIP:** Verify the white indicator arrows are still aligned with the white terminal boot.
- Rotate the terminal pin by turning the knob clockwise to extend the helix. Grip the Connector Tool as shown, to enable the index finger to feel the rotation indicator mark. Watch and/or feel the rotation count indicator mark to ensure that each turn counted is a complete 360^0 rotation. **TIP:** It is important to carefully count rotations. Rotating the fixation knob less than 360^0 could cause rotations to be over-counted. ***NOTE:*** *The expected number of revolutions to extend the helix is 11, and the maximum allowed is 20 (found in the specifications section of Lead Instructions for Use.*
- View the lead's radiopaque markers under fluoroscopy to identify when the fixation helix is fully extended. **CAUTION:** Do not rotate the terminal pin clockwise or counterclockwise more than 20 rotations. Continuing to rotate the terminal pin once the helix is fully extended or retracted can damage the lead, cause lead dislodgment, tissue trauma, and/or cause acute pacing threshold to rise.
- Once the lead is affixed in the desired location, hold the proximal end of the lead and Connector Tool, and disengage the fixation knob. ***NOTE:*** *Any torque stored within the lead is released by disengaging the fixation knob after the helix extension or retraction.*



Fixation knob engaged

Grip the flat side of the terminal boot levers and allow the index finger to feel the indicator mark.

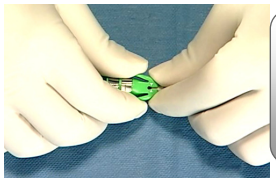




Fixation knob disengaged
NOTE: Any torque stored within the lead is released when disengaged.

How to Remove the Connector Tool from the Lead

Prior to inserting the lead into the pulse generator, pinch the tool between the thumb and the forefinger and slide the EZ-4 Connector Tool off of the proximal end of the lead. **TIP:** Pinching/depressing the levers of the Connector Tool will assist in the tool removal process.



Pinch the tool between thumb and forefinger. Depress boot levers, as needed.

ENDOTAK RELIANCE® G/SG Leads with DF4-LLHH and DF4-LLHO connectors from Boston Scientific

Indications
ENDOTAK RELIANCE G/SG leads with Integrated Bipolar DF4-LLHH and DF4-LLHO connectors is intended for pacing, rate-sensing and delivery of cardioversion and defibrillation shocks when used with a compatible pulse generator.

Contraindications
Use of ICD leads are contraindicated in: patients who have a unipolar pacemaker, patients with a hypersensitivity to a maximum single dose of 1.3 mg dexamethasone acetate, and 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 protection available during implant. Do not use any component of the lead system to assist in delivery of external-source rescue shocks. Ensure that an external defibrillator and medical personnel skilled in CPR are present during post-implant device testing. 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. The safety and efficacy of the tip electrode placement above midseptum has not been clinically established. In order to deliver defibrillation therapy, the single-coil models must be implanted with an additional defibrillation electrode. Use fluoroscopy to verify that the lead tip is directed toward the apex when implanted. Take care to obtain appropriate electrode position. When connecting the lead to the pulse generator, it is very important that proper connections are made. Do not expose a patient to MRI device scanning. Do not subject a patient with an implanted pulse generator and/or lead to diathermy. For DF4-LLHH or DF4-LLHO leads, use caution handling the lead terminal when the Connector Tool is not present on the lead and do not directly contact the lead terminal with any surgical instruments or electrical connections such as PSA (alligator) clips, ECG connections, forceps, hemostats, and clamps. Do not contact any other portion of the DF4-LLHH or DF4-LLHO lead terminal, other than the terminal pin even when the lead cap is in place. Only use the Connector Tool for electrical connections to pacing system analyzers or similar monitors. Do not attach alligator clips directly to the lead terminal or damage could occur.

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, explant and disposal.

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. A)
NOTE: Most Current Revision Found @ http://www.bostonscientific.com/cardiac-rhythm-resources/summaries/ICD-leads.html?