

## 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.bostonscientific.com/cardiac-rhythm-resources/international-manuals.html](http://www.bostonscientific.com/cardiac-rhythm-resources/international-manuals.html).

CAUTION: Law restricts this device to sale by or on the order of a physician. Indications, contraindications, precautions and warnings can be found with product labeling.

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

### Contact Information

#### Americas

(Caribbean, and Central, North, and South America)

[www.bostonscientific.com](http://www.bostonscientific.com)

#### Technical Services

##### LATITUDE® Clinician Support

1.800.CARDIAC (227.3422)

+1.651.582.4000

##### Patient Services

1.866.484.3268

#### Europe, Middle East, Africa

##### Technical Services

+32 2 416 7222

[eurtechservice@bsci.com](mailto:eurtechservice@bsci.com)

##### LATITUDE Clinician Support

[latitude.europe@bsci.com](mailto:latitude.europe@bsci.com)

#### Asia Pacific

##### Technical Services

+61 2 8063 8299

[aptechservice@bsci.com](mailto:aptechservice@bsci.com)

##### LATITUDE Clinician Support

[latitude.asiapacific@bsci.com](mailto:latitude.asiapacific@bsci.com)

[japan.latitude@bsci.com](mailto:japan.latitude@bsci.com) (Japan)

© 2013 by Boston Scientific Corporation or its affiliates. All rights reserved.

## How to Use the EZ-4™ Connector Tool

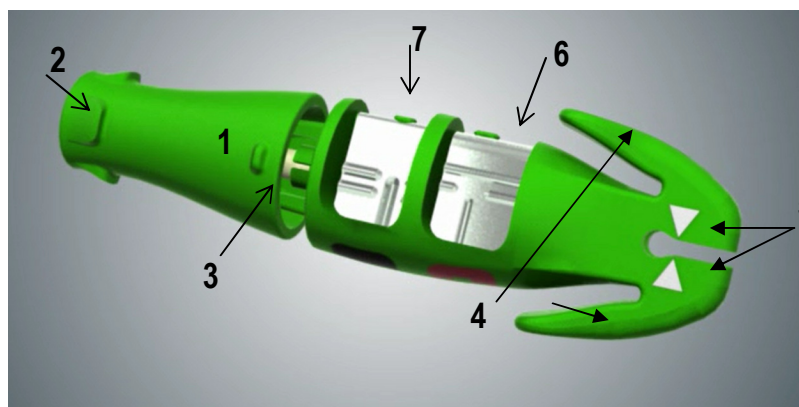
Boston Scientific ENDOTAK RELIANCE® Leads with a DF4<sup>1</sup> terminal (4-Site™ and 4-Front™) are packaged with an EZ-4 Connector Tool, held in position near the end of the lead terminal by a pre-inserted stylet.

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.

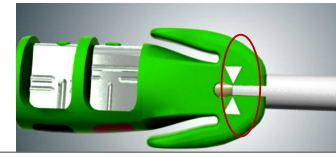
<sup>1</sup>DF4 refers to the international standard ISO 27186:2010 - Active implantable medical devices - Four-pole connector system for implantable cardiac rhythm management devices.

**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.

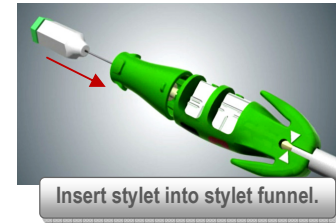
**NOTE:** Aligning the arrows with the end of the terminal boot will help ensure proper electrical connections between the lead and the Connector Tool.



Align indicator arrows with white terminal boot.

**How to Insert the Stylet**

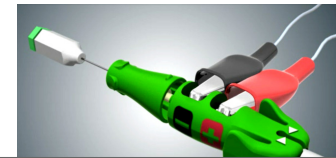
As needed, remove the pre-inserted stylet. Select a stylet according to the desired function and preferred firmness. A gently curved stylet is acceptable. Carefully insert the stylet through the funnel of the EZ-4 Connector Tool and terminal pin, which will guide the stylet into position. Ensure the 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.



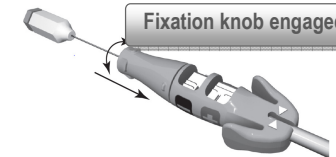
Attach alligator clips to spring contacts.

**How to Extend and Retract the Fixation Helix**

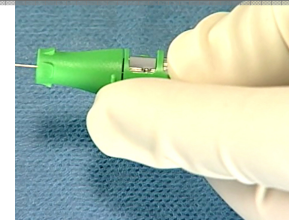
The mechanical function (extension and retraction of the helix) of the lead should be exercised prior to lead insertion/implantation.

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

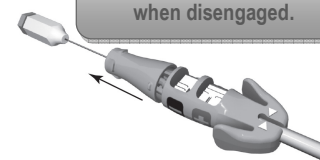
- Remove the pacing system analyzer (PSA) alligator clips from the EZ-4 Connector Tool, which will help prevent the spring contact from dragging on the terminal pin during rotations. **NOTE:** The black PSA cable clip should be removed **whenever** the helix is extended or retracted.
- Apply forward 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° rotation. **TIP:** It is important to carefully count rotations. Rotating the fixation knob less than 360° 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.



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

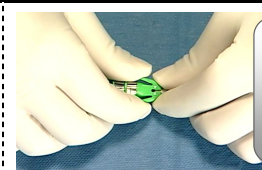


Fixation knob disengaged  
**NOTE:** Any torque stored within the lead is released when disengaged.



**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.