

FLEXTEND® Lead Implant Tips

BACKGROUND INFORMATION

This article provides information to enhance a user's implant experience with Boston Scientific's extendable/retractable FLEXTEND and FLEXTEND 2 leads.

This article does not contain a complete list of implant instructions and is not intended to supersede device-specific labeling. For complete implant instructions and potential risks, please refer to the appropriate *Instructions For Use* manual.

Lead fixation using an extendable helix mechanism is one risk factor for cardiac perforation. Refer to the **Product Update** entitled "Implantable Pacing Leads and Risk of Cardiac Perforation" available on www.bostonscientific.com for further information.

Exercise the Helix Before Implant

Before implanting the lead, verify the mechanical functioning of the helix by rotating the terminal pin to visually observe extension and retraction of the helix mechanism.

1. Attach the fixation tool to the terminal pin of the lead. Squeeze the handles together and place the pin in the preformed groove. Release the tension on the handles to secure the terminal pin in the fixation tool (Figure 1).

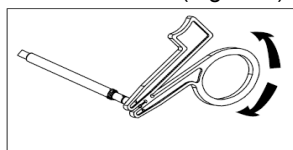




Figure 1. Fixation tool attached to terminal pin

2. Rotate the terminal pin clockwise approximately 6 to 8 turns (1 second per rotation) to fully extend the helix.
3. Rotate the terminal pin counterclockwise approximately 6 to 8 turns (1 second per rotation) to fully retract the helix into the lead body.
4. Remove the fixation tool by squeezing the handles of the tool together.

CAUTIONS:

- Do not over-extend or over-retract the helix. Exceeding the number of turns required to extend or retract the helix can damage the lead.
- Do not use the lead if the helix cannot be extended or retracted or if the helix is deformed.

Position the Lead

| Atrial position | Ventricular position |
|---|---|
|  <ol style="list-style-type: none"> 1. Advance the lead into the right atrium using a straight stylet. 2. With the lead in the low right atrium, insert the J-shaped or a curved straight stylet.* 3. Gently pull the lead/stylet combination at the venous entry site to ensure contact between the lead tip and the endocardium. <p>*Two different J-shape stylets are provided. One has a longer reach and may be suitable for most patient anatomies.</p> |  <ol style="list-style-type: none"> 1. Advance the lead into the right atrium using a straight stylet. 2. Advance the lead through the tricuspid valve or place the lead tip against the lateral atrial wall and back the curved lead body through the tricuspid valve. A curved stylet may enhance maneuverability. 3. Use fluoroscopy (lateral position) to ensure that the lead is not lodged in the coronary sinus and is in the ventricle. 4. Insert a stylet into the lead and gently push the lead/stylet combination at the venous entry site to ensure contact between the lead tip and the endocardium. <p>CAUTION:</p> <ul style="list-style-type: none"> • If the patient has a thin apical wall, consider an alternate fixation site. • If a conscious patient feels a sharp pain, this may be an indication of perforation. <ol style="list-style-type: none"> 5. Minimize the application of lead tip pressure by partially withdrawing the stylet during lead positioning. This will minimize tip stiffness. |

CRM PRODUCTS REFERENCED*

FLEXTEND Models 4086 / 4087 / 4088;
FLEXTEND 2 Models 4095 / 4096 / 4097

*Products referenced herein may not be approved in all geographies.

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The FLEXTEND helix is electrically conductive regardless of helix position. Thus, pacing and sensing thresholds can be measured without extending the helix into the tissue. Mapping of the atrium or ventricle prior to helix extension and lead fixation is recommended as it can reduce the potential need for repositioning.

Fixate the Lead Helix

With the lead in the correct position, fixate the lead in the following manner:

1. Attach the fixation tool to the terminal pin (Figure 1).
2. Apply adequate pressure to seat the distal electrode against the fixation site and slowly rotate the fixation tool clockwise approximately 6 to 8 turns (1 second per rotation) to affix the distal electrode helix into the heart wall.
3. Do not release the fixation tool—hold it stationary.
4. Verify under fluoroscopy that the radiopaque markers are joined and the fixation helix is extended outside the distal fluoroscopy marker (Figure 2).

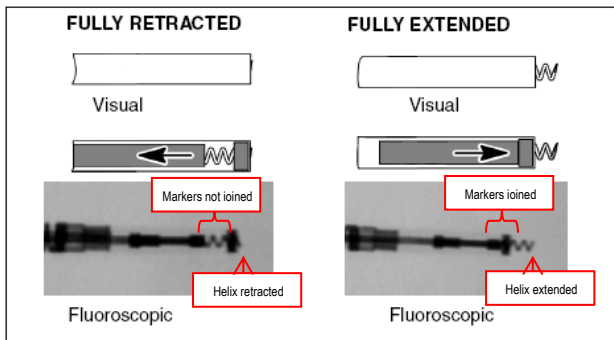


Figure 2. Fluoroscopic markers illustrating appropriate retraction/extension

5. If the markers are not joined, 1 to 2 additional turns may be necessary.

CAUTION: Minimize the number of turns. Excessive turns can cause damage to the lead, increased acute thresholds, lead dislodgement and/or lead perforation.

6. Loosely hold the proximal end of the lead and release the fixation tool.
7. Remove the fixation tool by squeezing the handles of the tool together.
8. Carefully remove the stylet. Minimize manipulation of the lead to prevent dislodgement.
9. Ensure sufficient lead slack is present to prevent dislodgement.

If the helix mechanism fails to function properly during implant, the following caution must be observed to avoid possible tissue snagging when removing the lead:

CAUTION: Do not use the lead if the helix cannot be retracted during implant. Continuous *counterclockwise* rotation of the lead body during lead removal is necessary to avoid inadvertent tissue trauma. Counterclockwise lead rotation helps to prevent accidental fixation and releases the electrode helix if tissue snagging has occurred.

Check for Lead Stability

After fixation, partially withdraw the stylet 8 to 10 cm. Check the stability of the lead using fluoroscopy. Do not tug on the lead. If possible, have the patient cough or take several deep breaths. When electrode position is satisfactory, completely withdraw the stylet.

CAUTION: Should dislodgement occur, immediate medical care is required to resolve the electrode position and minimize endocardial trauma.

Reposition the Lead

If lead repositioning is necessary,

- Verify the stylet is fully inserted into the lead
- Reattach the fixation tool and rotate the tool counterclockwise 6 to 8 turns to retract the helix. Do not over-rotate the helix.
- The use of fluoroscopy may help to verify that the helix is retracted and disengaged completely from the heart wall.
- Reaffix the electrode using the positioning, fixation and checking for lead stability procedures described previously.

Evaluate electrical performance of the lead

Verify the electrical performance of the lead *before* attaching the lead to the pulse generator and *after* allowing sufficient time for the effect of local tissue trauma to subside. If the measurements do not conform to the recommended values listed in Table 1, reposition and reaffix the electrode using the positioning technique discussed previously.

Table 1. Recommended threshold and sensing measurements^a

| | Atrial data | Ventricular data |
|--------------------------------|-------------|------------------|
| Voltage threshold ^b | ≤ 1.5 V | ≤ 1.0 V |
| Current threshold ^b | ≤ 1.5 mA | ≤ 1.5 mA |
| Intrinsic amplitude | ≥ 2.0 mV | ≥ 5.0 mV |
| Impedance | 450-1800 Ω | 450-1800 Ω |

Source: FLEXTEND Instructions For Use (355229).
^a Values measured approximately 10 minutes after fixation.
^b Pulse width setting at 0.5 ms.

NOTES:

- Electrical measurements immediately post-fixation may deviate from recommendations. Values may be dependant on patient specific factors such as tissue condition, electrolyte balance and drug interactions.
- Over-rotation of terminal pin may increase local tissue trauma and cause temporarily high thresholds.

Secure the lead

After successful lead positioning and fixation, secure the lead to the vein using the suture sleeves provided (Figure 3). Suture sleeve tie-down techniques can vary with the lead insertion technique used.



Figure 3. Suture sleeve