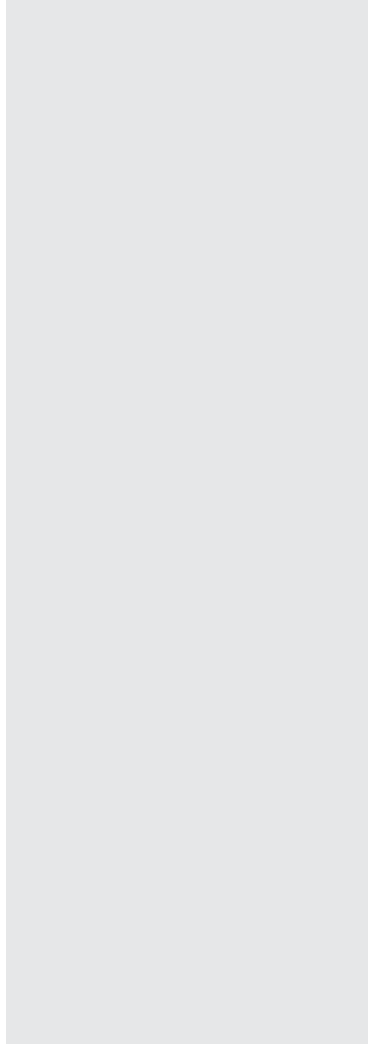


# Boston Scientific

Advancing science for life™

## Clik™ X Anchor

### Directions for Use



#### **Rx ONLY**

##### CAUTION:

Federal law restricts this device to sale, distribution and use by or on the order of a physician.

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**Trademarks**

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**Guarantees**

Boston Scientific Corporation reserves the right to modify, without prior notice, information relating to its products in order to improve their reliability or operating capacity.

Drawings are for illustration purposes only.

**Additional Information**

For contraindications, labeling symbols, warranty, or other device-specific information not included in this manual, refer to the appropriate DFU for your SCS System as listed on your *Reference Guide*.

**Product Model Numbers**

Model Number	Description
SC-4318	Clik™ X Anchor

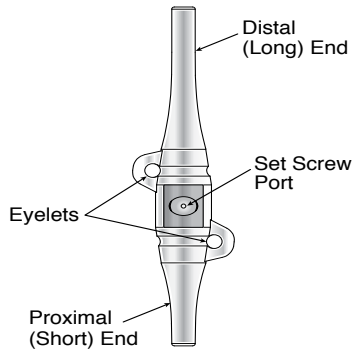
# Clik™ X Anchor

The Clik X anchor has been sterilized with ethylene oxide prior to shipment.

Inspect the condition of the sterile package before opening the package and using the contents. *Do not use the contents if the package is broken or torn, or if contamination is suspected because of a defective sterile package seal.*

- Do not use any component that shows sign of damage.
- Do not resterilize the package or the contents. Obtain a sterile package from Boston Scientific Neuromodulation.
- Do not use if “Use By” date has expired.

**Note:** *The anchors are intended for single use only.*



A Boston Scientific Neuromodulation (BSN) hex wrench is required to engage the locking mechanism. The hex wrench is packaged separately from the Clik X anchor, and is available in the IPG Kit, Lead Extension Kit and as a spares kit.

## Package contents

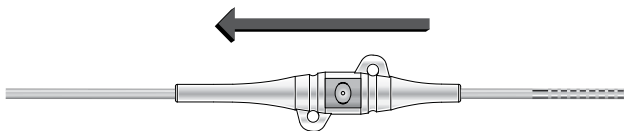
(2) Clik X anchors

**CAUTION:** Do not modify or damage anchor.

## Directions

### For standard percutaneous leads and paddle leads:

1. After the lead has been placed in the optimal location, prepare to anchor the lead.
2. Remove Clik X anchor from package and obtain hex wrench.
3. Place a suture through the supraspinous ligament or deep fascial tissue (this step is not applicable if using Fixate™ Suturing Device).
4. Dip Clik X anchor in sterile water.
5. Slide anchor onto proximal end of lead with long end of anchor first.



**Note:** If needed, wet lead with additional sterile water. Ensure that only light pressure is used while holding the anchor and rotate the anchor while advancing as necessary.

- Slide anchor to appropriate location on lead. Make sure set screw port is facing up before placing anchor (black marking on metal block faces up towards implanting physician).

**OPTIONAL:** For percutaneous leads, distal end of anchor can be inserted into fascia.

**Note:** If anchor is difficult to slide along lead, insert the hex wrench into the set screw port and turn counterclockwise to back out the screw.

**CAUTION:** Do not excessively loosen the set screw. This may cause the set screw to dislodge.

**Note:** Ensure stylet is removed from the lead prior to anchoring.

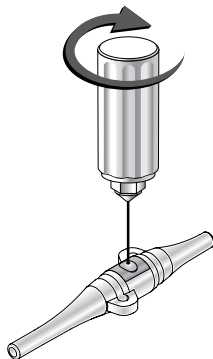
- Suture the anchor to the deep fascial tissue or supraspinous ligament using 2-0 silk, other nonabsorbable suture or Fixate™ Suturing Device. The eyelets may be used during this step.

**CAUTION:** Do not use polypropylene sutures as they may damage the anchor. Do not suture directly onto the lead or use a hemostat on the lead body. This may damage the lead insulation.

- Ensure set screw port is facing up. Insert the hex wrench into the set screw port and ensure hex wrench is fully seated.

**Note:** Smooth DeBakey forceps are recommended to be used to hold the anchor in place while locking the anchor.

- Turn hex wrench clockwise to engage locking mechanism. Once the wrench clicks, the anchor is locked to lead.



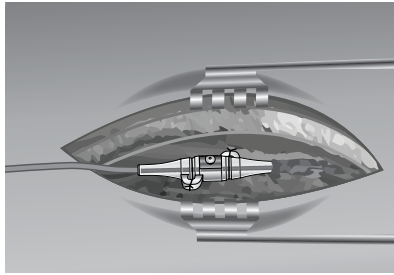
- If repositioning of the lead is required after the anchor has been secured to the lead, insert hex wrench into set screw opening and turn counterclockwise to loosen set screw.

**CAUTION:** Do not excessively loosen the set screw. This may cause the set screw to dislodge.

**OPTIONAL:** Reinsert stylet into lead

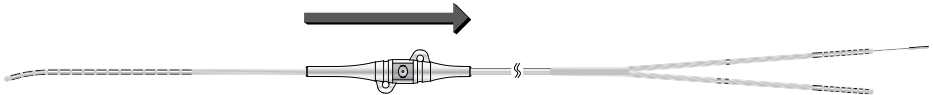
**CAUTION:** If it is difficult to reinsert the stylet, move the anchor to ensure that the set screw has been loosened sufficiently. Do not use excessive force when reinserting the stylet into the leads.

Once set screw is loosened, the anchor may be moved along the lead. Ensure that sutures have also been removed to allow for anchor to be repositioned. Once anchor is repositioned, proceed to Step 7.



### For Infinion™ CX Leads:

11. Remove Klik X anchor from package and obtain the hex wrench.
12. Dip Klik X anchor in sterile water.
13. Preload Klik X anchor onto Infinion CX lead over distal end of lead, with the short end of the anchor first. Ensure that the set screw port is facing up.



**OPTIONAL:** *Retract stylet past distal array of Infinion CX before loading Klik X anchor over distal end of lead, then seat stylet back into place.*

**Note:** *If needed, wet lead with additional sterile water. Ensure that only light pressure is used while holding the anchor and rotate the anchor while advancing as necessary.*

14. Implant Infinion CX lead per Percutaneous Leads Directions for Use.
15. After the lead has been placed in the optimal location, prepare to anchor the lead. Ensure stylet is removed from the lead.
16. Place a suture through the supraspinous ligament or deep fascial tissue (this step is not applicable if using Fixate™ Suturing Device).
17. Proceed through steps 6-10 above.

### Customer Service – USA

In USA, to order replacement parts, or for answers to any questions you might have, please contact the Customer Service Department:

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