

ENGLISH

Clik Anchor SC-4316

Rx ONLY

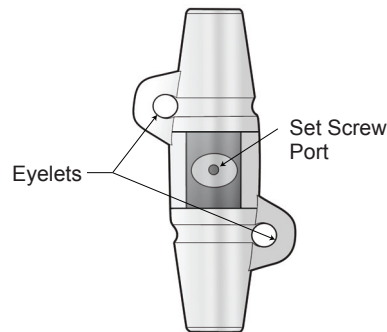
CAUTION: Federal Law restricts this device to sale, distribution, and use by or on the order of a physician.

The Clik anchor was 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 anchor, and is available in the IPG Kit, Lead Extension Kit and as a spares kit.

Package contents

Clik anchors (2)

CAUTION: Do not modify or damage anchor.



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REV B

UPN MP36590559510010

Directions:

1. After the lead has been placed in the optimal location, prepare to anchor the lead. Ensure stylet is removed from the lead.
2. Remove Clik anchor from package and obtain hex wrench.
3. Place a suture through the supraspinous ligament or deep fascial tissue.
4. 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).

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.

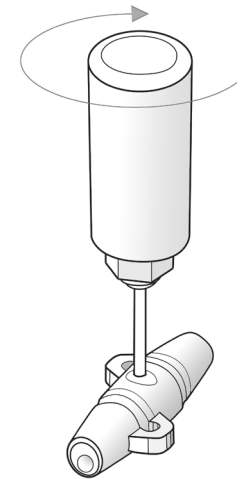
5. Suture the anchor to the deep fascial tissue using 2-0 silk or other nonabsorbable suture. The eyelets may be used during this step.

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.

6. 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.

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

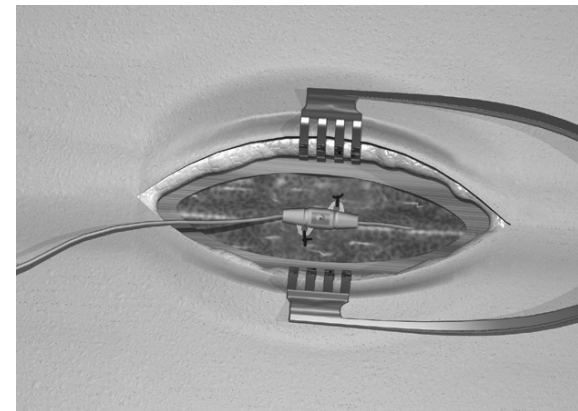


8. If repositioning of the lead is required after the anchor has been secured to the lead, insert hex wrench into set screw opening and turn counterclockwise to loosen set screw.

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

CAUTION: Move the anchor first, if the stylet is reinserted to reposition lead. Do not use excessive force when inserting the stylet into the lead.

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 5.



Customer Service – USA

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

- Phone: (866) 360-4747, +1 (661) 949-4747
- Fax: +1 (661) 949-4022

Boston Scientific Neuromodulation
25155 Rye Canyon Loop
Valencia, CA, 91355, USA