

BANDLOC

SURGICAL TECHNIQUE

RESPONSE™
BANDLOC 5.5/6.0 SYSTEM





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Refer to the Instructions for Use (package insert) for indications, contraindications, precautions and warnings. For more information, contact OrthoPediatrics at 574-268-6379 or visit www.orthopediatrics.com.

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Indications

The RESPONSE BandLoc Spinal Fixation is a temporary implant for use in orthopedic surgery. The system is intended to provide temporary stabilization as a bone anchor during the development of solid bony fusion and aid in the repair of bone fractures. The indications for use include, but are not limited to, the following applications:

- Spinal trauma surgery, used in sublaminar, interspinous, or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as scoliosis, kyphosis, spondylolisthesis;
- Spinal degenerative surgery, as an adjunct to spinal fusions;

The RESPONSE BandLoc Spinal Fixation may also be used in conjunction with other medical implants made of titanium alloy or CoCr alloy whenever “wiring” may help secure the attachment of other implants.

Contra-Indications

Metallic bone fixation devices should not be used in patients with:

- Active systemic infection or infection localized to the site of implant.
- A demonstrated sensitivity to metals or polyester.
- Physical contact of the BandLoc metal component with any metal implant made of anything other than Titanium or Cobalt Chrome alloys.
- Severe fractures such that segments may not be maintained in satisfactory proximate reduction.
- Inadequate tissue coverage over operative site.
- An inability to follow a post-operative regimen.

Relative contraindications include any condition that precludes the possibility of fusion (e.g., cancer, kidney dialysis, osteopenia), may prevent adequate fixation (severe osteoporosis), or that produces loads on the device that could lead to failure (i.e., obesity, patient’s occupation or activity level or patient’s inability to follow post-surgical instructions due to lifestyle or because of conditions such as mental illness, alcoholism, or drug abuse).

The BandLoc 5.5/6.0 Implant Bundle (10-1102-0555) sterile-packaged box contains:

(1) Tulip Head Assembly

(1) Large Set Screw



Note: Verify that the rod diameter (5.5mm or 6.0mm) and rod material (Titanium or Cobalt Chrome) match those of the tulip head assembly.



Warning: If BandLoc Implant is used with a stainless steel rod, a galvanic reaction may occur which can lead to necrosis of tissue.

The BandLoc DUO Implant Bundle (10-1102-1555) sterile-packaged box contains:

- (1) Dual-lead Tulip Head Assembly
- (2) Large Set Screws



Note: Verify that the rod diameter (5.5mm or 6.0mm) and rod material (Titanium or Cobalt Chrome) match those of the tulip head assembly.



Warning: If BandLoc Implant is used with a stainless steel rod, a galvanic reaction may occur which can lead to necrosis of tissue.



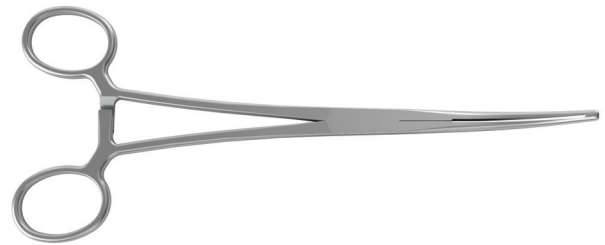
Tensioning Instrument, BandLoc
01-1102-1000



Nerve Hook
gS 25.1851



Provisional Set Screw Driver, BandLoc
01-1102-1051



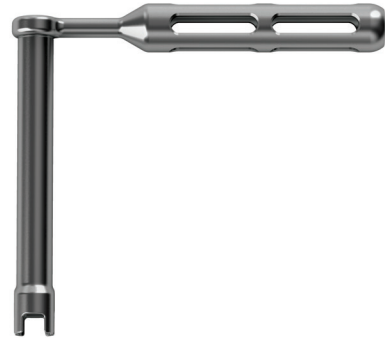
Hemostat, BandLoc
01-1102-1060



Set Screw Driver, BandLoc
01-1102-1055



Axial Handle, Fixed
01-1003-6299



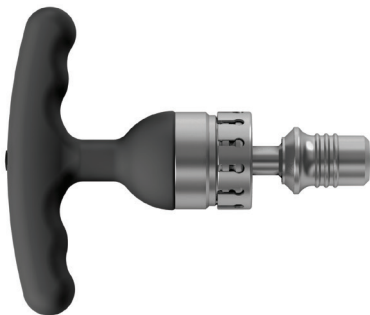
Counter Torque Handle, BandLoc
01-1102-1050



Palm Handle, Ratcheting
01-1003-6034



Reduction Driver, Short
01-1003-5100

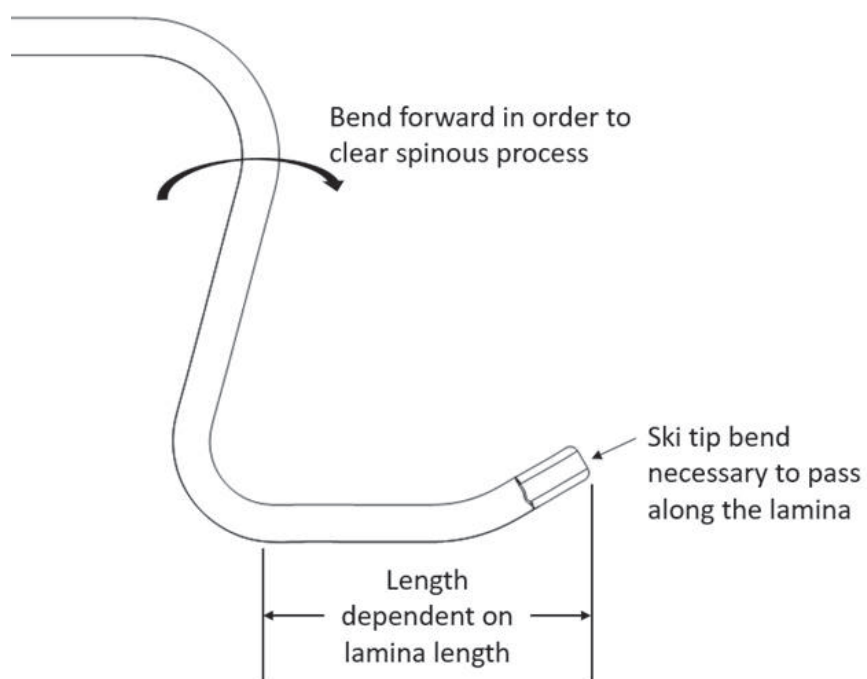


Torque Limiter, Large Set Screw
01-1300-0026

Contour the band-tip to aid in passing the band.

Note: *Contouring of the band-tip varies depending on the size and length of the sublamina.*

Contouring of the band-tip may vary depending on the level of the spine that BandLoc is being used in and also on the sublaminar distance available at that level. For example, in the lumbar spine, a gentler bend may be required to pass the sublaminar space and a more acute bend may be necessary in the thoracic spine.



Warning: *Inappropriate contouring of the band-tip to facilitate passage of the band may result in spinal cord injury or paralysis.*

Remove part of spinous process to better visualize the ligamentum flavum. Remove ligamentum flavum using Kerrison ronguer, being careful to avoid the epidural veins. Remove superior facet (optional).

Technique for Single Band Passage:

- After contouring, the band-tip should be run against the bony surface of the lamina, careful not to touch the thecal sac or disturb the spinal cord.



Warning: If the length of the band-tip insert is not long enough to access after passing, a rebend of the tip may result in fracture or damage to nerves or spinal cord.

- When the band-tip leading edge becomes visible at the cephalad or superior margin of the lamina, a forcep, or nerve hook can be used to secure the band-tip and pull it.
- Passing the band-tip under the sublamina space should be done while both pushing and pulling the band.



Warning: Passing the band in the wrong direction, or around the wrong structure can result in loss of fixation.

- Maintaining tension on the band manually is important to protect neural structures.



Technique for Passing Two Single Bands:

- Use the Single Band Passage steps as described on page 10.
- If elected to have two bands at the same level, pass the initial band using the standard technique; keep tension on that band and pass a second band through the same sublamina space on top of the initial band.
- This option reduces potential compression of the dura.
- Maintaining tension on the band manually is important to protect neural structures.

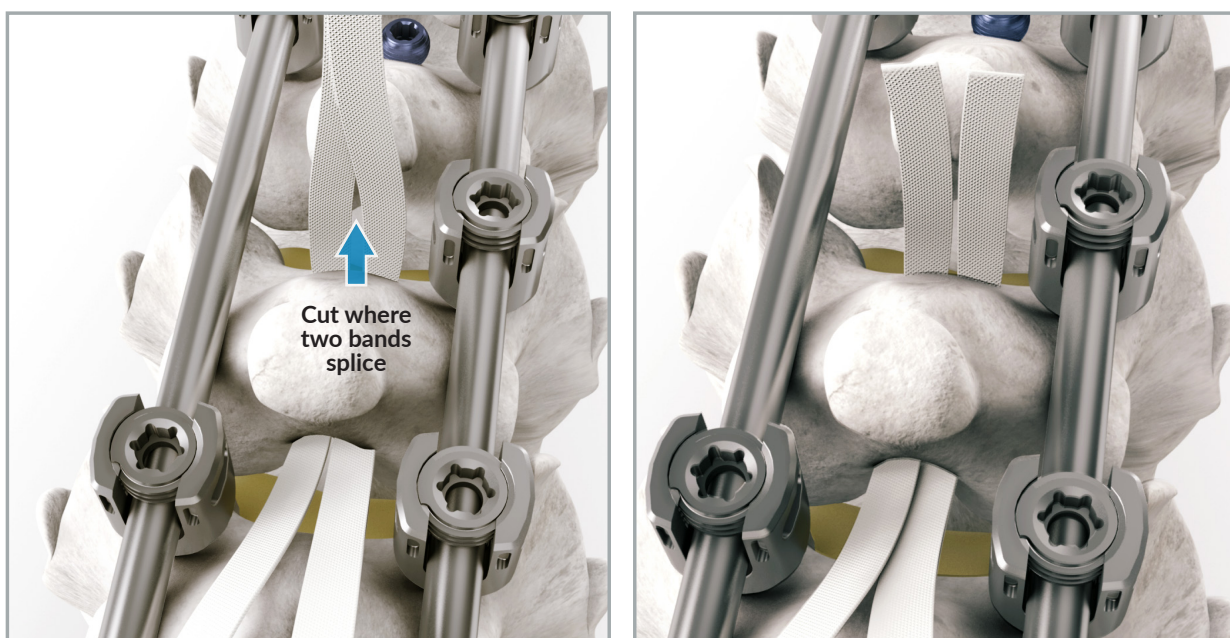
Technique for Passing BandLoc Duo

- Using the dual-lead band, follow the technique for Single Band Passage, described on page 10.
- After the dual-lead band has been passed under the lamina, cut off the lead tip in the area immediately beyond where the two bands splice.
- The two tulip heads should now be on separate bands, and can be oriented on the rod.

Note: *Neural Monitoring is recommended during passage of the band.*



Warning: *If the band is twisted during passage, it may create a high pressure point which can lead to bone or soft tissue damage.*



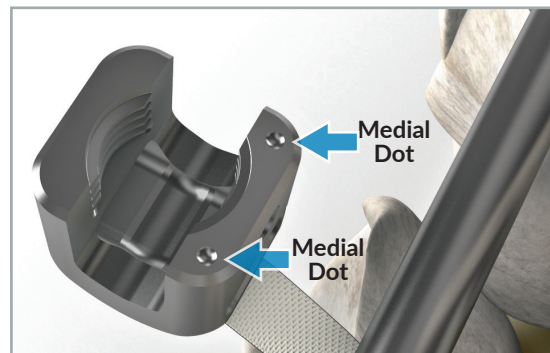
Attach Implant to the Rod

BandLoc Surgical Technique

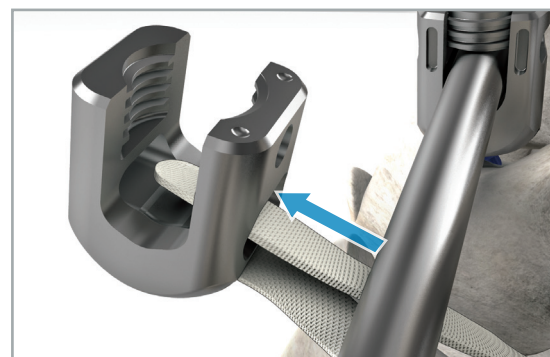
1. Orient the tulip head assembly so the dots are positioned medially.



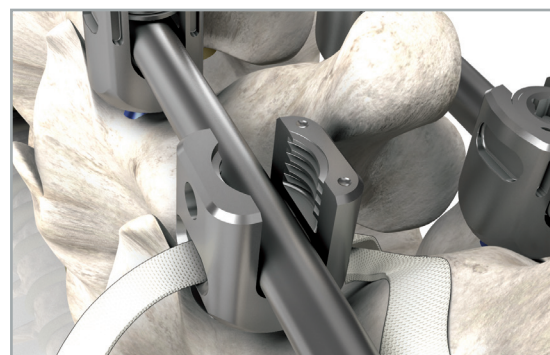
Warning: Ensure the tulip head is placed on the rod with proper orientation.



2. Straighten out the leading end of the band and pass it through the dedicated band slot from medial (dot side) to lateral.



3. Attach the tulip head assembly to the rod with the dot oriented medially, taking care to not add additional twist in the band other than what is required to contour to the anatomy.



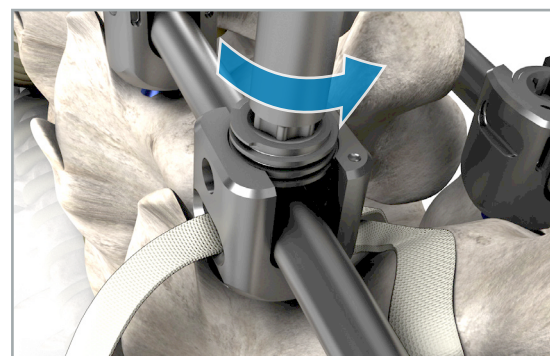
4. Install the Large Set Screw with the provisional set screw driver, finger tight. Loosen the set screw half a turn to allow for tensioning while applying a small amount of tension by hand to remove slack in the band.



Warning: Ensure the large set screw is properly placed in the tulip head to ensure fixation strength.



Warning: Do not over-tighten the large set screw; over-tightening the large set screw prevents proper band tensioning which can lead to breakage in the band.



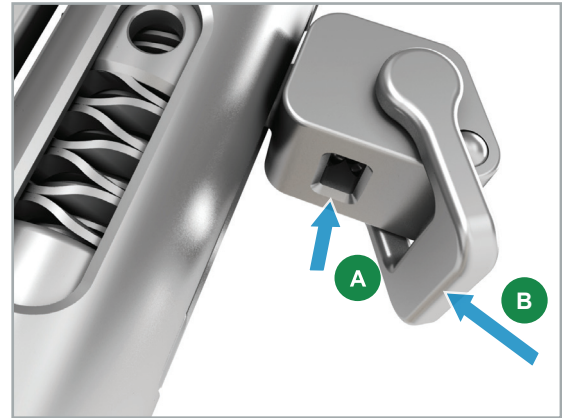
Tensioning the Band

BandLoc Surgical Technique

The figure at right shows the tensioner carriage.

“A” is the opening where the band enters the tensioner carriage.

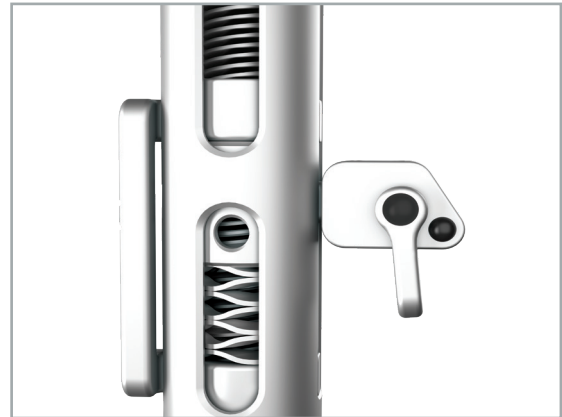
“B” is the release lever (shown in open position) that disengages the tensioner from the band.



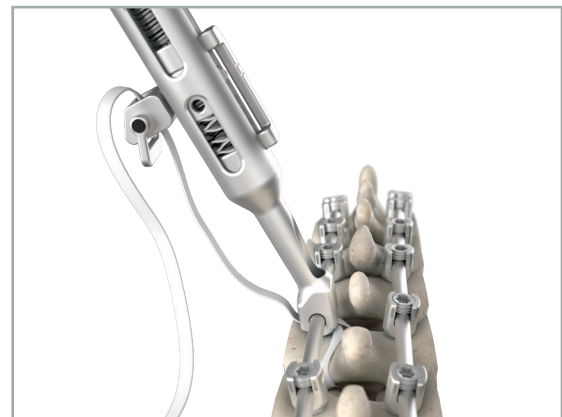
1. With the release lever in 'open' position, insert the band-tip into the tensioner carriage.

Lever is shown in the “open” position to the right.

Note: Make sure to not have a twisted band entering the tensioner carriage.

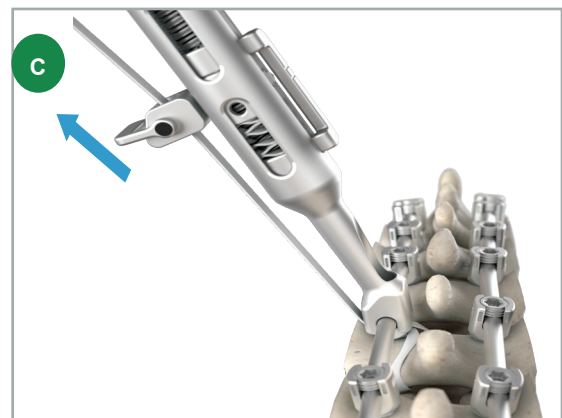


2. Orient the tensioner carriage laterally and place the rod slot of the tensioner on the tulip head.



3. Take up the slack of the band by pulling on the loose end (“C”) of the band. Once the band is taut, move the lever into the locked position.

Lever is shown in the “locked” position to the right.



4. Use the Reduction Driver in the Hex ("D") of the tensioner to apply additional tension.

Note: The Reduction Driver must be engaged correctly to achieve proper tension and construct strength.

- Under-tensioning may result in a weak construct.
- Over-tensioning can cause bone breakage due to poor bone quality.

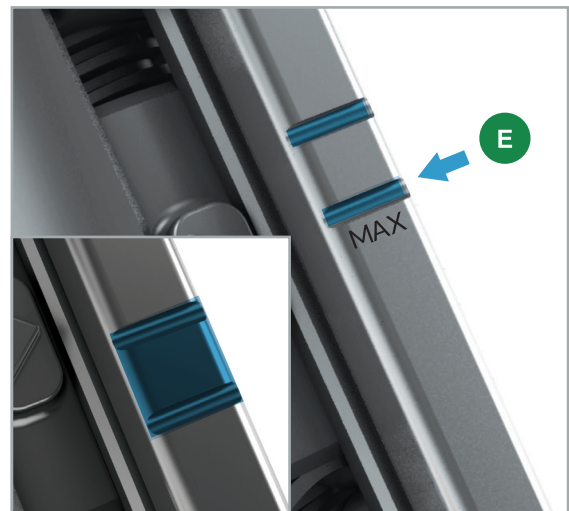


Warning: Ensure the band, and rod are appropriately attached to the tulip head assembly to maintain correct tension load.



Note: The same Reduction Driver can also be used with the Rod Reducer.

5. Reference the tension gauge on the tensioner and tighten to the max line ("E")
Inset depicts tensioning range (blue square).



Warning: While tensioning is at the surgeon's discretion, tensioning beyond the max line is not advised and could result in bone fracture or rupturing of the band.

Once the band is provisionally tensioned, the spine can be manipulated to correct spinal deformity:

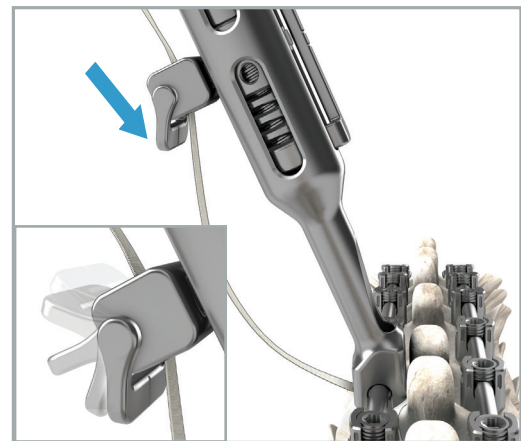
- Translation
- Compression
- Distraction
- De-Rotation



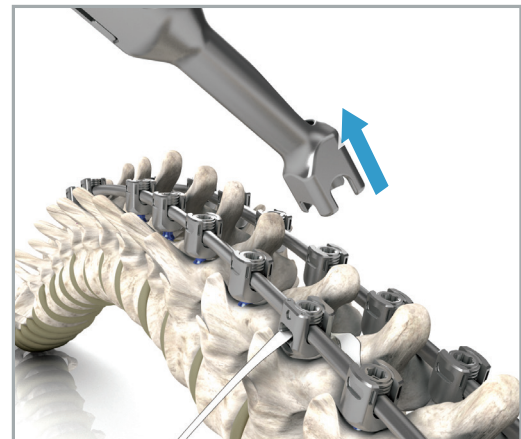
Step 1: Release tension.



Step 2: Push lever to loosen tensioner.



Step 3: Remove from tulip head assembly.



Final Tightening

BandLoc Surgical Technique

1. To final tighten all open assemblies, seat the Counter Torque Handle and Set Screw Driver Shaft onto the open screw, saddle and set screw.

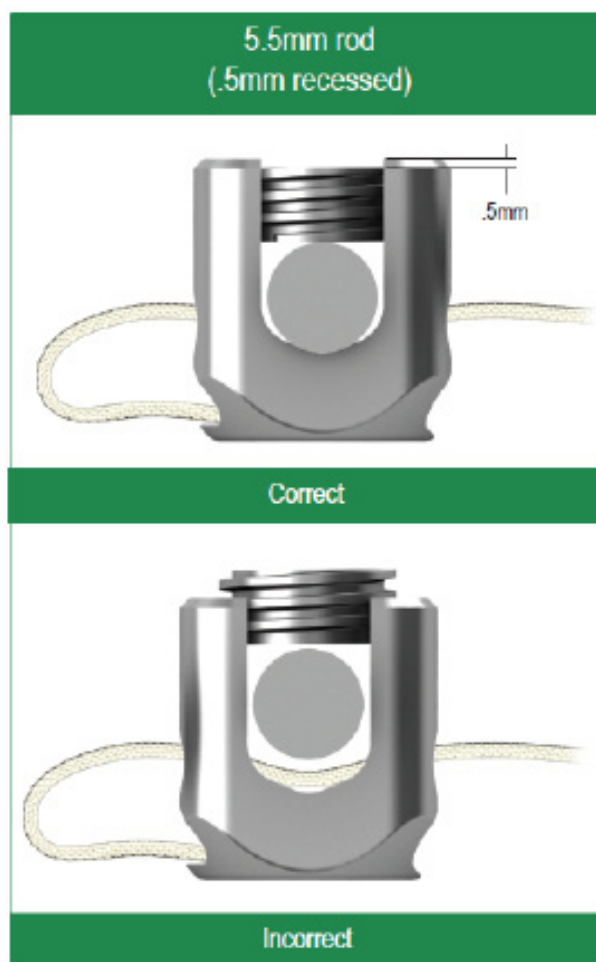
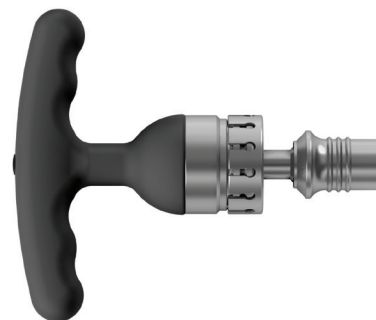
Note: Ensure Counter Torque fits appropriately on the tulip head, band and rod.

2. Place the Set Screw Torque Limiter T-Handle (95 in-lbs) on the Driver Shaft, and turn the handle clockwise while firmly holding the Counter Torque Handle.

3. Turn the T-handle until two audible clicks are heard, indicating that proper torque has been met.

Note: The black T-handle (95 in-lbs) is only to be used with the large set screw driver for large set screws.

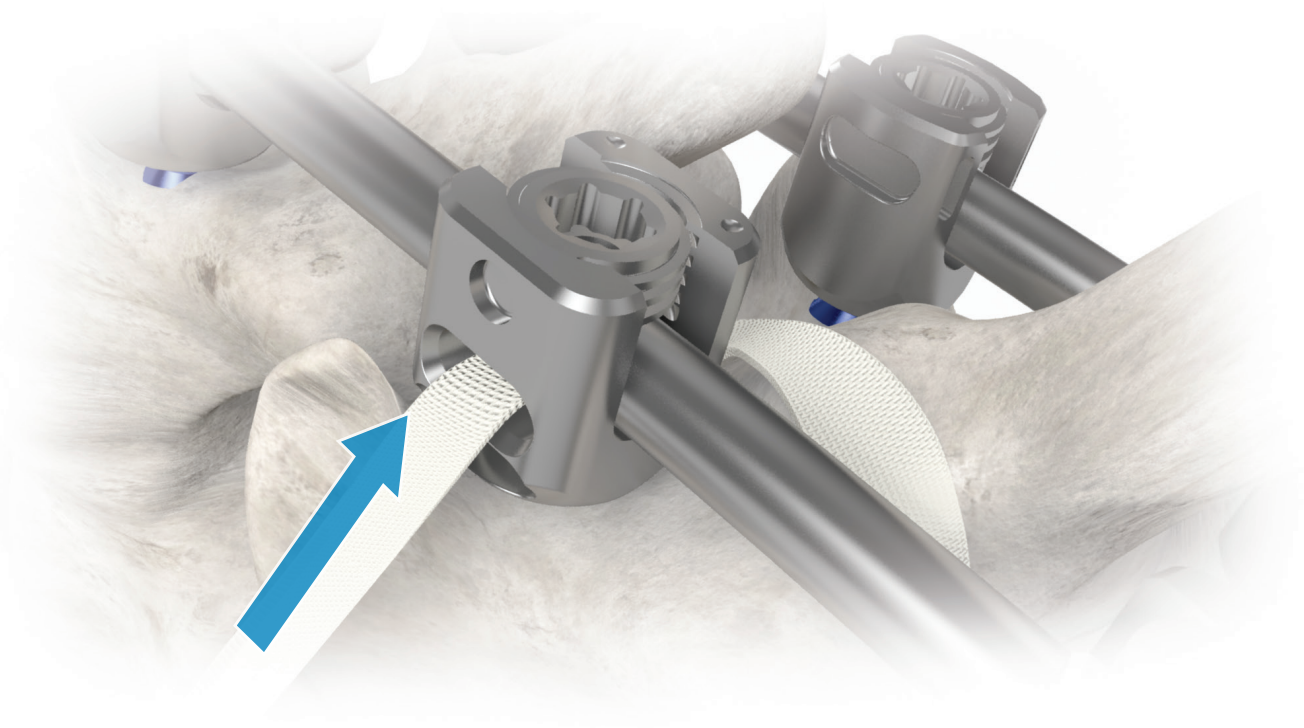
Ensure correct placement of Large Set Screw following final torque per the images below:



Once final tightening has occurred, cut off the excess band, flush with the lateral surface of the tulip head assembly, using either a scalpel or a bovi.

Note: *If excess band is not removed, soft tissue irritation may occur.*

 **Warning:** *Band-tip and excess band must be removed prior to final closure.*



Intra-Operative Removal

1. Remove band-tip from the band
2. Unscrew and remove the large set screw from the tulip head assembly
3. Disengage the tulip head assembly from the rod
4. Gently pull on the tulip head assembly to fully extract the band

Post-Operative Removal

1. Unscrew and remove the large set screw from the tulip head assembly
2. Disengage the tulip head assembly from the rod
3. Gently pull on the tulip head assembly to fully extract the band

CAUTION: Federal law restricts this device to sale by or the order of a Physician.

CAUTION: Instruments and spare set screws in the tray or screw caddy are supplied Non-Sterile. Clean and sterilize before use according to instructions. BandLoc Implant is supplied Sterile. Inspect for expiry and package integrity before use.

CAUTION: Implants components are single-use. Do not reuse.

CAUTION: Only those instruments and implants contained within this system are recommended for use with this technique. Other instruments or implants used in combination or in place of those contained within this system is not recommended, unless otherwise stated.

NOTE: **This technique has been provided by one of our medical advisors only as guidance and it is not intended to limit the methods used by trained and experienced surgeons.**

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