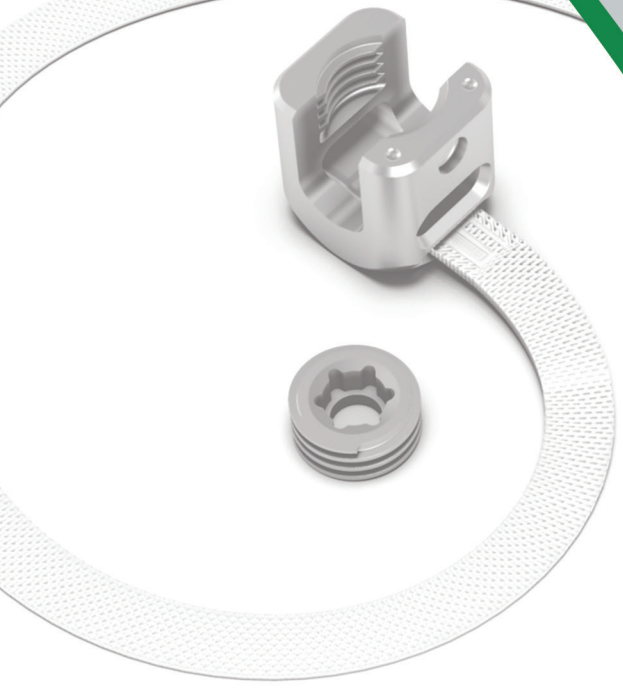
BANDLOC

SURGICAL TECHNIQUE

RESPONSE™

BANDLOC 5.5/6.0 SYSTEM



OrthoPediatrics®

Leading Innovation in Pediatric Orthopedics

Table of Contents

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.

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 the following applications:

- Spinal trauma surgery, used in sublaminar or facet wiring techniques;
- Spinal reconstructive surgery, incorporated into constructs for the purpose of correction of spinal deformities such as idiopathic and neuromuscular scoliosis in patients 8 years of age and older, adult 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:

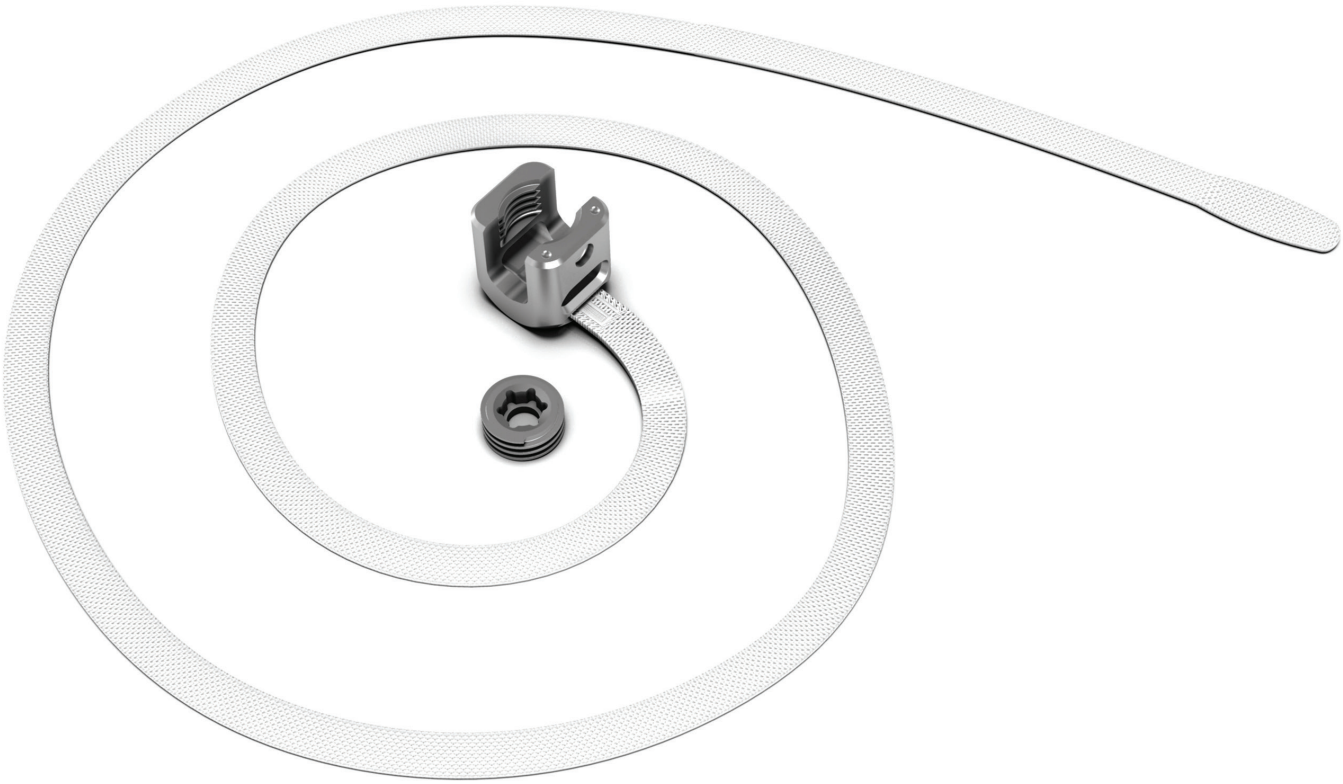
- Active systemic infection or infection localized to the site of implant.
- A demonstrated sensitivity to metals or polyester.
- Physical contact of the BandLoc metal component with any metal implant made of anything other than Titanium or Cobalt Chrome alloys.
- Severe fractures such that segments 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 (10-1102-055) 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.

Tensioning Instrument, BandLoc
01-1102-1000

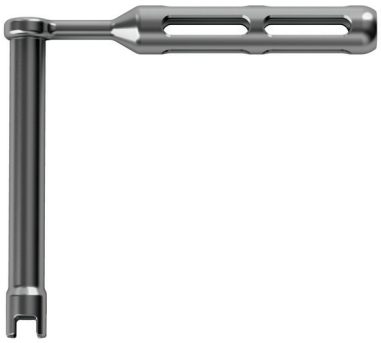
Nerve Hook
gS 25.1851

Provisional Set Screw Driver, BandLoc
01-1102-1051

Hemostat, BandLoc
01-1102-1060

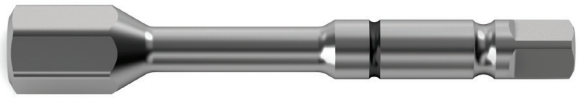
Set Screw Driver, BandLoc
01-1102-1055

Axial Handle, Fixed
01-1003-6299

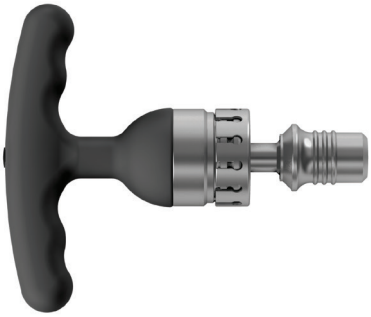


Counter Torque Handle, BandLoc
01-1102-1050

Palm Handle, Ratcheting
01-1003-6034



Jiminy Driver, Short
01-1003-5100

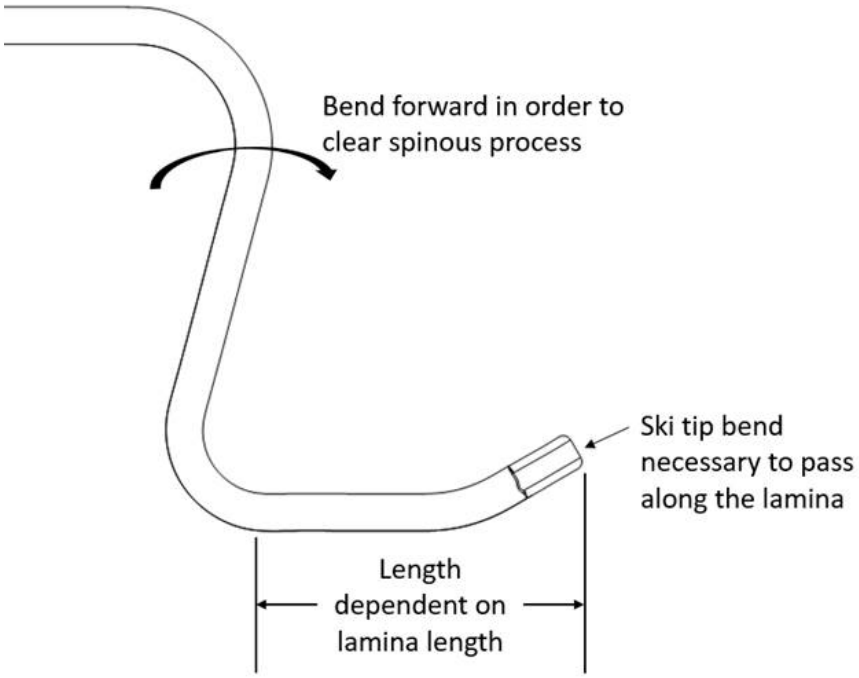


Torque Limiter, Large Set Screw
01-1300-0026

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.

Passage of the Band

Remove part of spinous process to better visualize the ligmaentum 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. Special care should be taken when passing bands during sublaminar use.

Warning: If the length of the band-tip insert is not long enough to access after passing, requiring 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.

- To avoid pushing the band into the dura, maintain upward pressure against the anterior aspect of the lamina by pulling up on the tip of the band while advancing the band-tip. Maintaining tension on the band manually is important to protect neural structures.

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

Technique for Double Band Passage:

- Use the Single Band Passage steps as described.

- 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 prevents any potential compression of the dura.

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

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

Note: Band passage around the transverse process and interspinous wiring are only for use in adult patients.

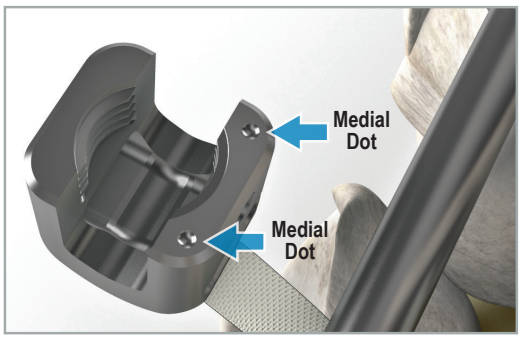
Note: Additional fixation is required at the cephalad and caudal ends of the construct in scoliosis surgery, especially in cases of obesity, extreme kyphosis or muscular weakeness, except where additional fixation would increase the risk to the patient.

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

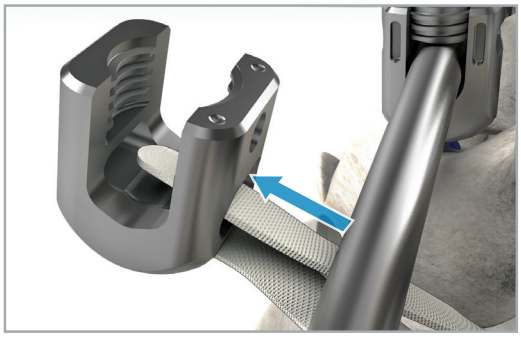
Attach Implant to the Rod

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

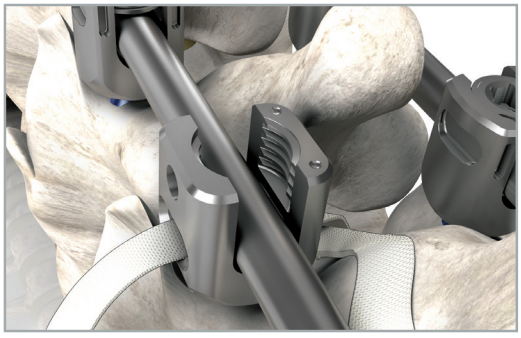
   Warning: Ensure the tulip head is placed on the rod with proper orientation.



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



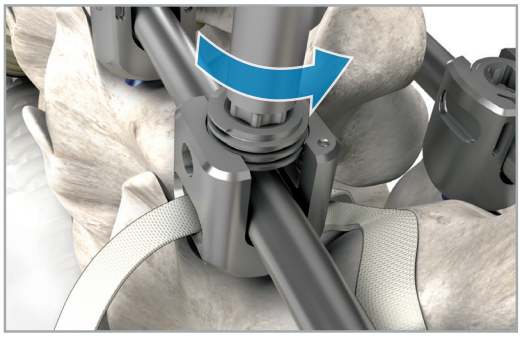
3. Attach the tulip head assembly to the rod with the dot oriented medially, taking care to not add additional twist in the band other than what is required to contour to the anatomy.



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.

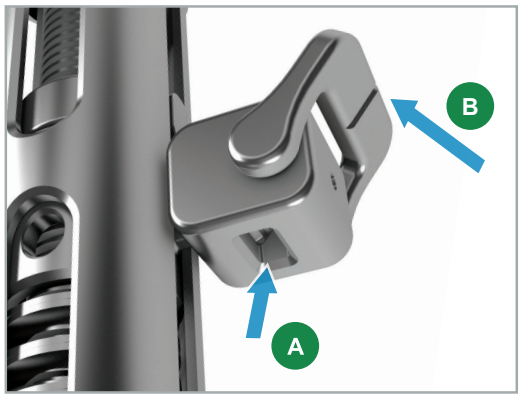


Tensioning the Band

This figure shows the tensioner carriage.

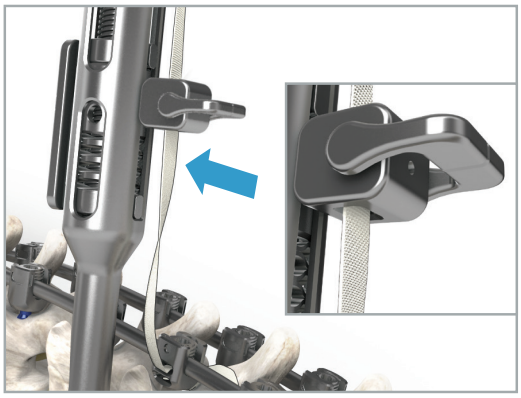
"A" is the opening where the band enters the tensioner carriage.

"B" is the release lever (shown in locked position) that disengages the tensioner from the band.



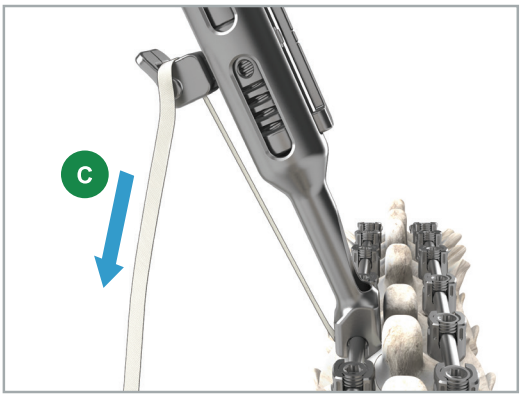
1. With the release lever in 'open' position, insert the band-tip into the tensioner carriage.

   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.

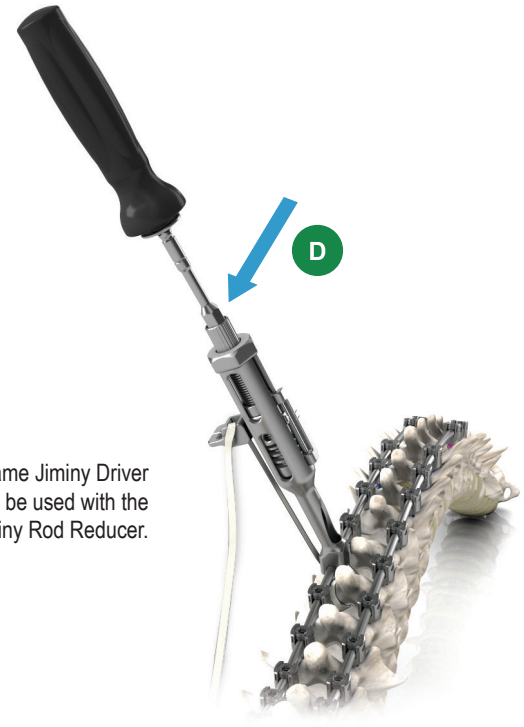


4. Use the Jiminy Driver in the Hex ("D") of the tensioner to apply additional tension.

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

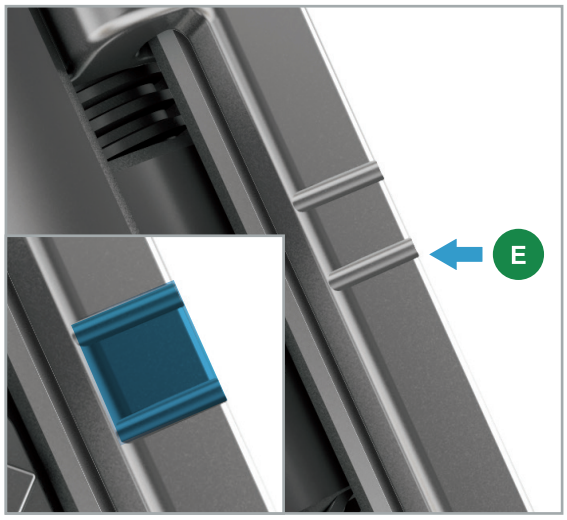
- ***Under-tensioning may result in a weak construct.***
- ***Over-tensioning can cause bone breakage due to poor bone quality.***

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



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

5. Reference the tension gauge on the tensioner and tighten to the line. This recommended line ("E") will result in 75lbf (333N) of tension.



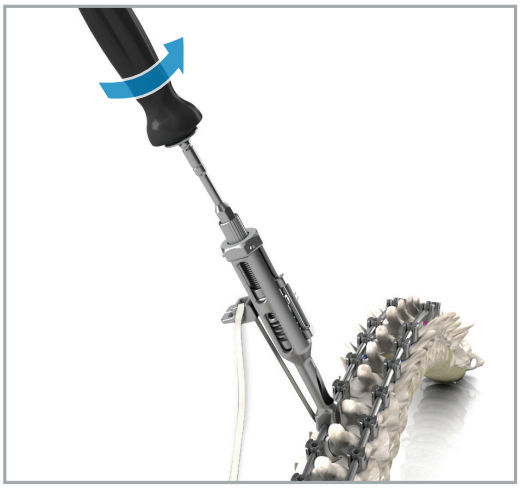
Warning: While tensioning is at the surgeon's discretion, tensioning beyond the line is not advised and could result in bone fracture.

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

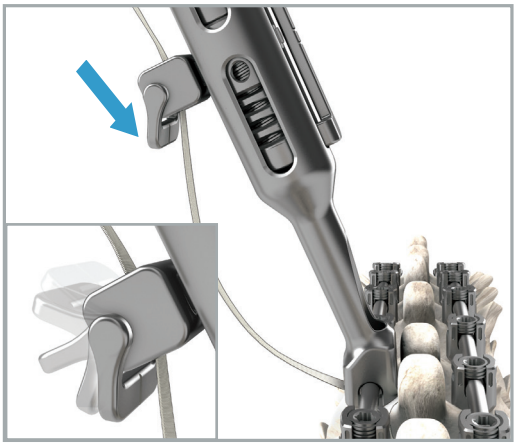
- Translation
- Compression
- Distraction
- De-Rotation

Note: Sequential tightening of multiple tulip head assemblies in the construct is recommended to achieve a smooth correction.

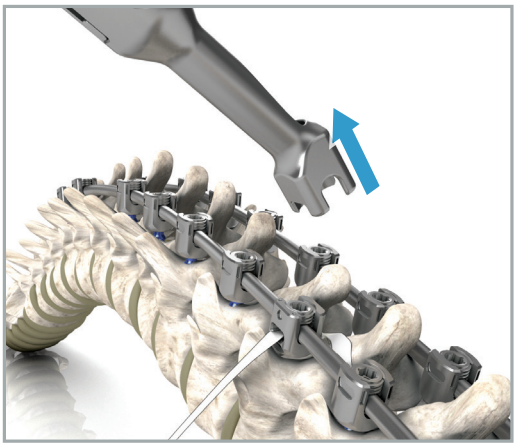
Step 1: Release tension.



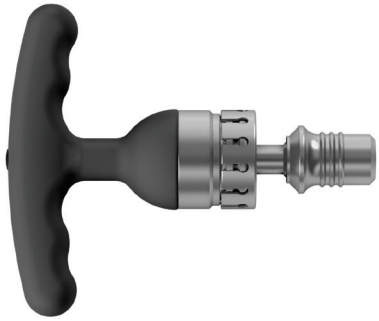
Step 2: Push lever to loosen tensioner.



Step 3: Remove from tulip head assembly.



Final Tightening



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.

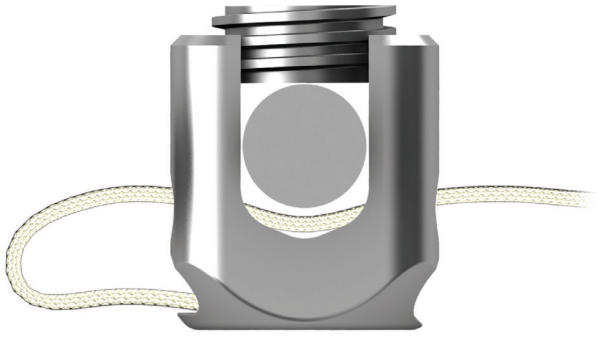
3. Turn the T-handle until two audible clicks are heard, indicating that proper torque has been met.

   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:

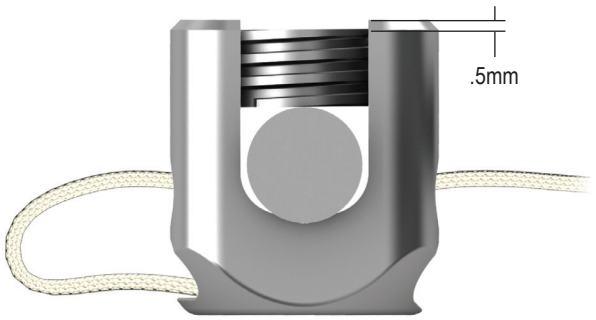
6.0mm rod
(flush)

Correct

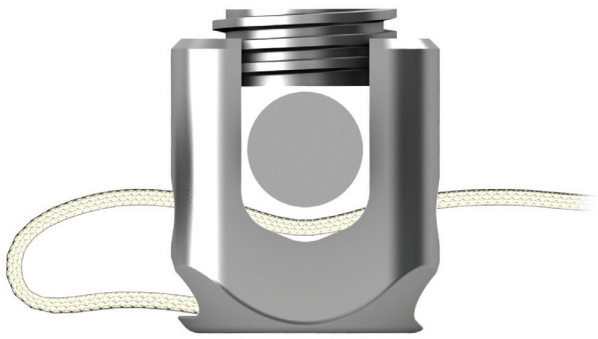


Incorrect

5.5mm rod
(.5mm recessed)



Correct

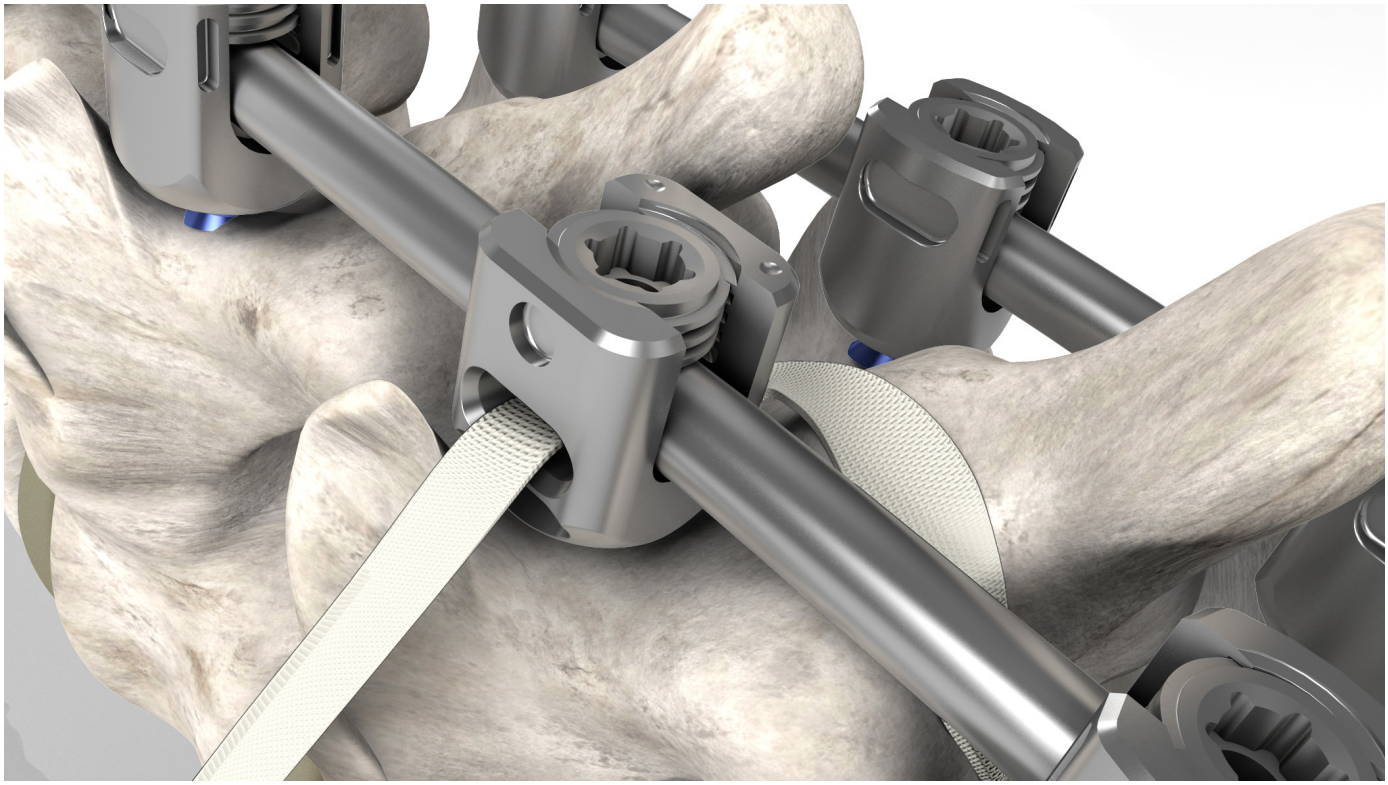


Incorrect

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.



Extraction of Implant

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

This document is intended exclusively for experts in the field, i.e. physicians in particular, and expressly not for the information of laypersons.

The information on the products and/or procedures contained in this document is of general nature and does not represent medical advice or recommendations. Since this information does not constitute any diagnostic or therapeutic statement with regard to any individual medical case, individual examination and advising of the respective patient are absolutely necessary and are not replaced by this document in whole or in part.

The information contained in this document was gathered and compiled by medical experts and qualified OrthoPediatrics employees to the best of their knowledge. The greatest care was taken to ensure the accuracy and ease of understanding of the information used and presented.

OrthoPediatrics does not assume any liability, however, for the timeliness, accuracy, completeness or quality of the information and excludes any liability for tangible or intangible losses that may be caused by the use of this information.

IFU, cleaning instructions, and surgical techniques may be obtained by calling OrthoPediatrics® Customer Service at 574-268-6379. Read and understand indications, warnings, and adverse effects explained in IFU's prior to use.

OrthoPediatrics®
Leading Innovation in Pediatric Orthopedics

2850 Frontier Drive • Warsaw, IN 46582 • ph: 574.268.6379 or 877.268.6339 • fax: 574.268.6302 • www.OrthoPediatrics.com