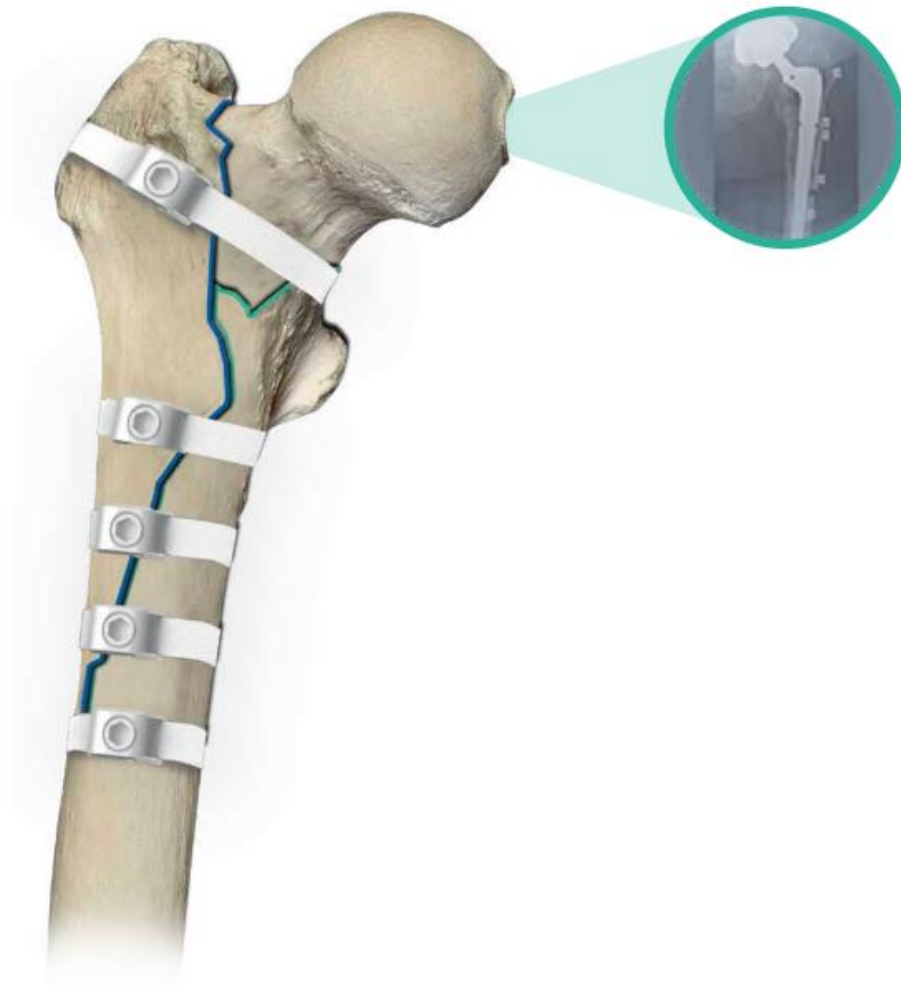


Ortholox UHMWPE Orthopedics Cerclage Band System



SURGICAL TECHNIQUE

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- © **Fixation of diaphyseal spiral fractures of long bones such as femur, tibia and humerus**
 Cerclage fixation implants can be utilized for fixation of long oblique and spiral fractures of the diaphysis. They may be used in combination with screws, plates and intramedullary rods. ^(1, 2)
- © **Fixation of avulsion fractures of the greater trochanter (femur) and greater tubercle (humerus)**
 Cerclage wiring techniques are widely used for the fixation of the greater trochanter and greater tubercle. Although isolated fractures of this type are rare they are very often seen in complex fractures of the proximal femur and humerus. Also, they are frequently seen during arthroplasty and revision arthroplasty surgeries. ^(3, 4)
- © **Fixation of Extended Trochanteric Osteotomies (ETO) of the femur during revision hip arthroplasty**
 Extended Trochanteric Osteotomy (ETO) is a widely used technique for revision hip arthroplasty procedures. After the insertion of the revision hip stem into the femoral canal, an important goal is the primary rigid fixation of the osteotomy. ⁽⁵⁾ Due to very high infection rates and the associated risk of metal debris, it is preferable to limit the use of metal cerclage devices especially in proximity to the joint. ^(6, 7)
- © **Stabilizing and prevention of splitting the proximal femur during insertion of hip stems.**
 Undisplaced linear splitting fractures of the proximal femoral cortex are not rare, especially during uncemented hip stem insertion. Proximal cerclage cable fixation is recommended in such instances and also as a prophylactic measure prior to stem insertion, preventing this type of complication. ⁽⁸⁾
- © **Fixation of olecranon fractures and osteotomies**
 Cerclage band wiring is a standard fixation technique for olecranon fractures and osteotomies. New non-metallic implants have shown to be very successful and provide more than adequate strength. ⁽⁹⁾

Indicated for orthopaedic applications

Ortholox UHMWPE Orthopedics Cerclage Bands were designed as a fast and stable alternative for metallic cable or wire and may be used anywhere cable or wire has previously been indicated. All UHMWPE Cerclage Bands are single use and implanted system components including titanium locking block should never be reused under any circumstances. An explanted device should never be reused. For further information, read instruction for use.

Warnings and Precautions

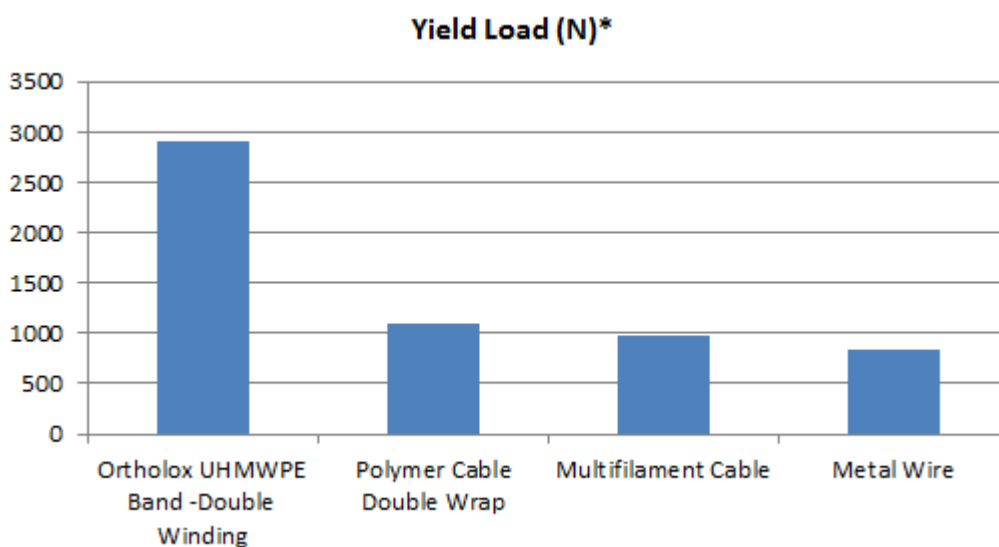
- Do not use if packaging is damaged / opened prior to use
- Operating surgeon should have a good understanding of the band system, surgical technique, and bio-mechanical principles of cerclage fixation
- Ortholox UHMWPE Orthopedics Cerclage Bands should only be used by experienced surgeons.
- Use torque limiting device to avoid over tensioning the bands.

Contraindications may include, but are not limited to:

Presence of documented infection • Patient metal allergy or intolerance to titanium alloy (TAV) components • Presence of severe osteopenia and/or osteoporosis, rapid bone absorption, metabolic bone disease, cancer, tumour, or tumour like condition of the bone • Inadequate tissue coverage of implant site • Interference with other critical anatomical structures • Undiagnosed infection, end stage malignant disease, or other unexplained disease • Severely comminuted fractures • Any patient unwilling to follow postoperative instructions • Any situation not defined by Indications

1. Ortholox is fully biocompatible
2. Ortholox has a simple and safe locking mechanism with a superior cerclage fixation capability. Its wide footprint on bone results less "pressure necrosis" unlike commonly observed in metal cables and wires ⁽¹⁰⁾
3. Ortholox has no risk of unfavourable metal debris being generated inside the tissue which may cause decreased local immunity and early loosening of the hip prosthesis. ^(11, 12)
4. The band design is characterized by a relatively short operation time, little bleeding, little soft tissue stripping and less disruption of periosteal blood supply, which is beneficial to bone healing. ⁽¹³⁾ It can be used in combination with Ortholox Locking Periprosthetic Plates
5. Ortholox combines this superior band design with a synthetic polymer material displaying enhanced mechanical properties. ⁽¹⁴⁾
6. The implants have no infection and contamination risk due to the sterile dual packaging.

Comparison Table of the Tensile Tests of Cerclage Systems ^(15, 16, 17)



*Data on file

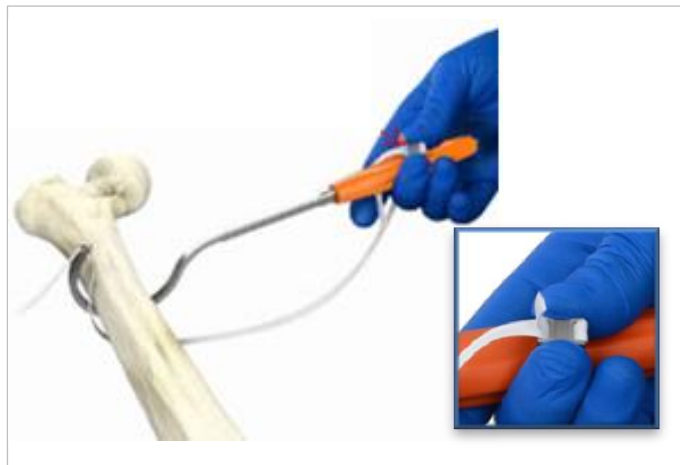


Step 1

Two sizes of Cable Sleeve, small and large, are found in the instrument set. The most suitable size should be chosen according to the individual patient's bone morphology.

Instruments

11-504-SML Ortholox Cerclage Band Sleeve - Small
11-504-LRG Ortholox Cerclage Band Sleeve - Large



Step 2

Due to flat shape of the band, it is important that due attention is paid to the orientation with respect to the titanium lock, so as to avoid twisting and ensuring a correct applic.

Instruments

N/A

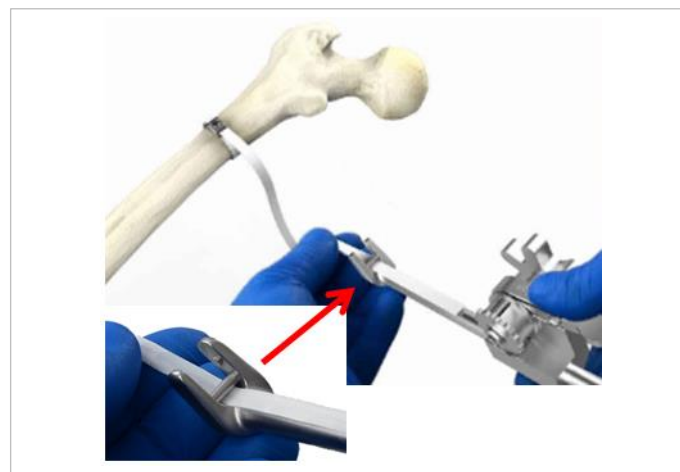


Step 3

The distal end of the band should be placed into the slot of the Band Sleeve which should be passed around the bone. The band should follow the cortex circumferentially without any folding. The band should then be threaded through the titanium lock, without twisting, and be slightly tightened manually.

Instruments

N/A

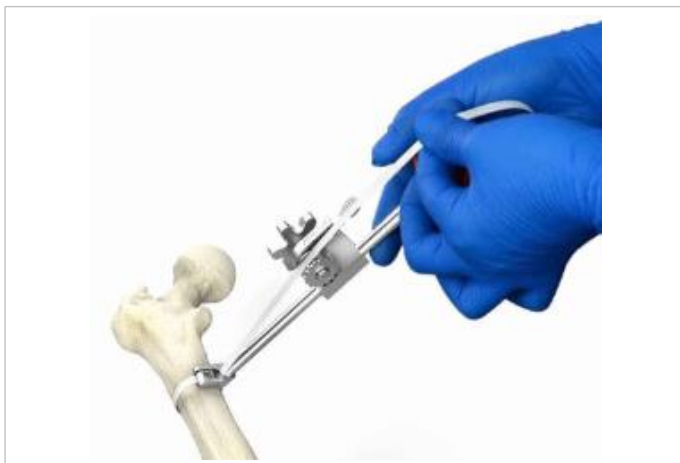


Step 4

The Cerclage Band Tensioner should be held with the star wheel positioned on the right hand side of the operating surgeon. Pass the end of the band through the narrow slot at the tip of the shaft (below the bar) towards the handle.

Instruments

11-501-000 Ortholox Cerclage Band Tensioner (Torque Handle Compatible) - Long



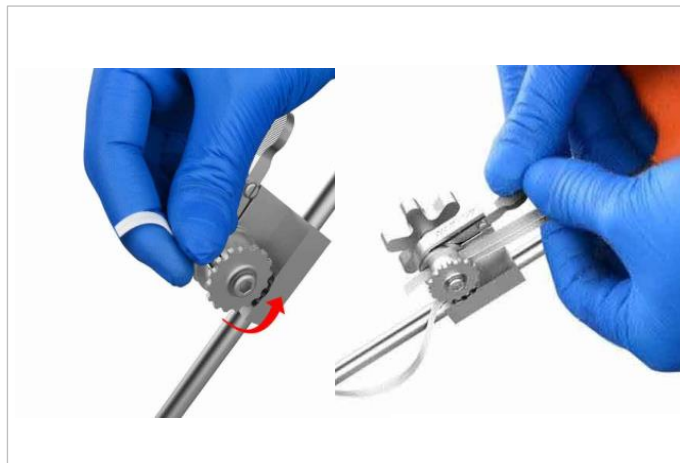
Step 5

When the tip of the tensioner is advanced against the titanium lock and is seated in the slot on either side of the titanium lock, the band should be manually pulled towards the winding mechanism.

Instruments

11-501-000

OrthoLox Cerclage Band Tensioner (Torque Handle Compatible) - Long



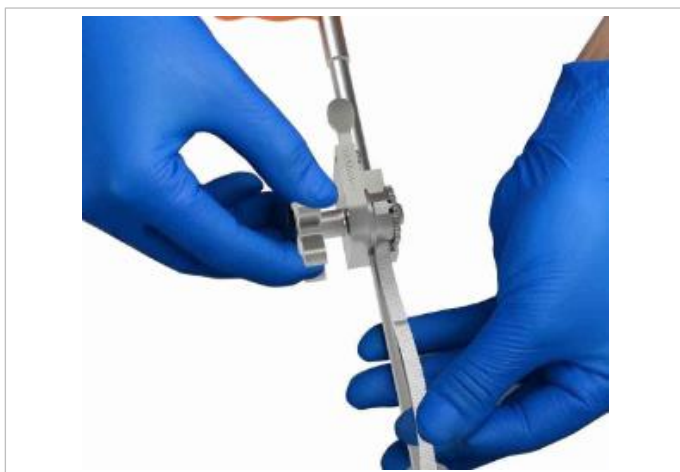
Step 6

Insert the end of the band into one of the slot on the rotating barrel and push it inside the body of the barrel in the direction of the arrow. Ensure that the twin prongs at the tip of the Tensioner are still firmly positioned on either side of the locking block.

Instruments

11-501-000

OrthoLox Cerclage Band Tensioner (Torque Handle Compatible) - Long



Step 7

To wrap the remaining band, turn the star wheel clockwise by hand until a certain tension is reached.

Instruments

11-501-000

OrthoLox Cerclage Band Tensioner (Torque Handle Compatible) - Long



Step 8

When it is impossible tightening by hand, insert the tip of the T-Torque Handle into the square hole in the center of the star wheel of the Cerclage Band Tensioner. Turn the Torque Handle clockwise until a "click" is heard, indicating that the band has reached its optimum tension.

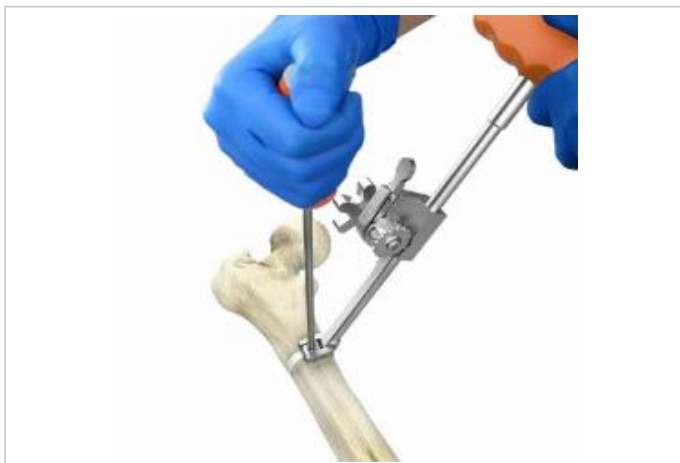
Instruments

11-501-000

OrthoLox Cerclage Band Tensioner (Torque Handle Compatible) - Long

11-300-T00

OrthoLox T-Torque Handle - 4.5Nm



Step 9

With the band at optimum tension and the Cerclage Band Tensioner attached to the titanium lock, tighten the set screw on the titanium lock with the Straight Torque Handle and Screwdriver. Turn the screwdriver attached to the Straight Torque Handle clockwise until a "click" is heard, indicating that the set screw has reached its optimum tension

Instruments

11-502-000

Ortholox Screwdriver - Long

11-300-000

Ortholox Straight Torque Handle - 4.0Nm



Step 10

After the locking the screw is secure, release the tension on the remaining part of the band by pressing down on the release trigger on the Cerclage Band Tensioner.

Instruments

N/A



Step 11

If multiple bands are to be applied, the excess lengths of band are kept loose until all the bands are in place and fully tensioned.

Then, re-check the tension on each of the cerclage bands as tension may be lost as each subsequent band is applied due to minor shifts of the fragments. If necessary, repeat all steps from Step 4 after loosening the set screw for any band that lost its tension.

Instruments

N/A



Step 12

After checking that the tension and positioning of the band(s) is optimal, the excess lengths are easily cut with a scalpel; hold up the excess band and cut in a direction away from the locked band to avoid cutting it and compromising the integrity of cerclage fixation.

Instruments

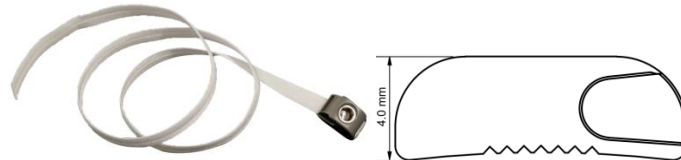
N/A

Ordering Info

Implants

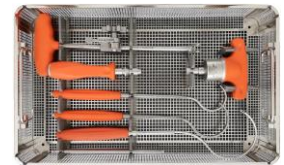
21-001-6450	Ortholox UHMWPE Orthopedics Cerclage Band System (Ti. Locking-Low Profile) - 6.0 x 450mm
21-001-6500	Ortholox UHMWPE Orthopedics Cerclage Band System (Ti. Locking-Low Profile) - 6.0 x 500mm*
21-001-6550	Ortholox UHMWPE Orthopedics Cerclage Band System (Ti. Locking-Low Profile) - 6.0 x 550mm*
21-001-6600	Ortholox UHMWPE Orthopedics Cerclage Band System (Ti. Locking-Low Profile) - 6.0 x 600mm*
21-001-6650	Ortholox UHMWPE Orthopedics Cerclage Band System (Ti. Locking-Low Profile) - 6.0 x 650mm

*On Demand



Instruments

91-000-000 Ortholox Orthopedics Cerclage Band System Instrument Set - Complete



11-300-000 Ortholox Straight Torque Handle - 4.0Nm



11-300-T00 Ortholox T-Torque Handle - 4.5Nm



11-501-000 Ortholox Cerclage Band Tensioner (Torque Handle Compatible) - Long



11-502-000 Ortholox Screwdriver - Long



11-504-SML Ortholox Cerclage Band Sleeve - Small



11-504-LRG Ortholox Cerclage Band Sleeve - Large



11-504-XLG Ortholox Cerclage Band Sleeve - X-Large (Optional)



11-900-000 Ortholox Orthopedics Instruments Container (Empty)



11-950-000 Ortholox Orthopedics Instruments Lid

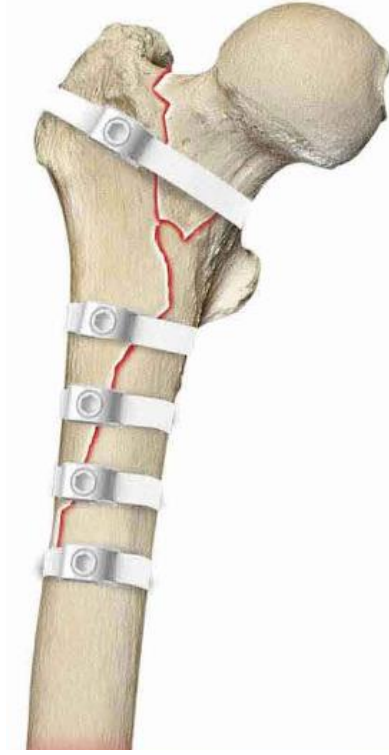


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<http://www.kinamed.com/wordpress/wp-content/uploads/SuperCable-Sternal-Closure-Test-Reports-2016.pdf>
17. Biomechanical Tests of Ortholox UHMWPE Cerclage Band System

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Ortholog®

Ortholox UHMWPE
Orthopedics Cerclage Band System



Ortolog Medikal Sanayi ve Ticaret A.Ş.

Ivedik OSB Mh. 1551. Cad. No: 35 İç Kapı No:33 Yenimahalle – Ankara/ Turkey
Tel : +90(312) 472 52 42 - Fax : +90(312) 397 43 15

www.ortolog.com

info@ortolog.com

