Surgical Technique

smith&nephew

EVOS◇

Cabling System

EVOS◇ Cabling System Surgical Technique

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Note Bena

The technique description herein is made available to the healthcare professional to illustrate the suggested treatment for the procedure. It is not intended to serve as medical advice. It is the responsibility of treating physicians to determine and utilize the appropriate products and techniques, according to their own clinical judgment for each of their patients. For more information on this product, please refer to the product's label and the Instructions for Use packaged with the product.

Indications

U.S. indications for use

The EVOS® Cabling System is intended to be used in general orthopedic repair procedures including patellar fractures, general cerclage, trochanteric reattachment, femoral and tibial fractures, prophylactic banding, olecranon fractures, ankle fractures, fixation of spiral fractures in conjunction with intramedullary nail and screw fixation techniques.

CE designated markets indications for use

The EVOS Cabling System is intended to be used in orthopedic trauma and reconstructive surgeries to reduce and stabilize fractures and osteotomies. The system may be used for supplementary fracture fixation when used with bone plates or screws.

Contraindications

May include but are not limited to the following:

1. Presence of a documented infection.
2. Any suspected or documented metal allergy or intolerance.
3. The presence of severe osteopenia and/or osteoporosis, or the presence of marked or rapid bone absorption, metabolic bone disease, cancer, or any other tumor due to any tumor-like condition of the bone that may compromise the fixation achieved by the cable.
4. Any patient with inadequate tissue coverage over the site of the implantation of the cable.
5. A cable should not be used in any anatomical location in which it would interfere with other critical structures, such as nerves, blood vessels, or other vital structures.
6. This system should not be used in any medical or surgical situation that would preclude the benefit of surgery such as an undiagnosed infection, end stage malignant disease or other unexplained diseases.
7. Severely comminuted fractures in which the fragments are too small or too numerous to be adequately fixed or maintained in a reduced position.
8. Any situation not described in the above indications.

Warnings and precautions

The same medical/surgical conditions or complications that apply to any surgical procedure may also occur during or following implantation of this implant. The surgeon is responsible for informing the patient of the potential risks associated with treatment, including complications and adverse reactions. The surgeon may need to perform additional surgery to address any complications or adverse reactions, which may or may not be implant related.

The implant is designed to be an adjunct in the fixation of fractures, dislocations, and other bone fusion procedures. It is designed as a temporary implant and should be used to augment bone fusion and secure fractures until union. Prior to use the surgeon must become familiar with the device system and the surgical procedure. Use surgical instrumentation, accessories, and surgical technique guide provided with this device system.

- Mixing of implant components with dissimilar metals is not recommended, for metallurgical, mechanical and functional reasons.
- No implant system can withstand the forces of sudden dynamic loads such as falls or other accidents.
- No implant can withstand body loads indefinitely without the healing of bone and/or ligaments.
- A cable should not be used in any anatomical location in which it would interfere with other critical structures such as nerves, blood vessels or other vital structures.
- Damaged implants should never be used. Care should be taken in the handling, preparation and storage of all implants and instruments.
- Cable should not be unraveled, kinked or damaged and none of the components should be scratched.
- Implants and instruments should be carefully protected during storage from any mechanical damage or from corrosive environments.
- Instruments are subject to damage during use as well as long-term potentially damaging effects such as wear. Damage may result in significant risks to safety and/or inability to function as intended.
- If instruments are damaged or broken during use, metal fragments can be viewed by radiographic assessment. It is the surgeon's responsibility to carefully consider the risks and benefits of retrieving the fragments.
- If the fragment is retained in the patient, it is recommended that the surgeon advise the patient of specific information regarding the fragment material, including size and location and the potential risks associated with the retained fragment.

Read the entire package insert carefully prior to use.

Implants are for single patient use only, on a single occasion. If re-used, single use implants may not perform as intended and could cause serious injury. An explanted device should never be re-implanted. If reused, single use devices may not perform as intended and could cause serious injury.

Potential adverse effects

These effects may or may not be device related:

1. Irritation or inflammation of surrounding soft tissue structures including muscles, tendons, nerves and arteries.
2. Cables may cut through soft osteoporotic, osteopenic or cancellous bone if not properly protected and immobilized.
3. Bone may form around the implant or implants making removal difficult.
4. Early or late loosening of the implants.
5. Fraying, kinking, loosening and/ or breakage of the cable and/ or disassembly of any of the components.
6. Irritation from implants where there is thin or inadequate soft tissue coverage over the implant.
7. Breakdown of skin over implant from pressure on the skin.
8. Loss of reduction of fractures or dislocations secondary to loosening, disassembly or breakage of the cables or secondary to cables cutting through osteoporotic bone.
9. Infection.
10. Foreign body reaction to the implants causing possible tumor like condition.
11. Nonunion or delayed union of bone fracture or bony fusion.
12. Rare possible neurovascular compromise if improperly placed cables or assembly leading to radiculopathy, paralysis or other types of serious injury.
13. Disruption of blood circulation and/or vessel damage due to improper cable placement and/or improper assembly of the system components.
14. Cessation of growth of the operated portion of the bone.
15. Patient death.

Magnetic Resonance Imaging (MRI) safety information

Non-clinical testing[1] and electromagnetic simulations demonstrated that the EVOS Cabling System implant is MR Conditional. A patient with this implant can be scanned safely in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial field gradient of 2000 Gauss/cm (20 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of <2 W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the EVOS Cabling System implant is expected to produce a maximum temperature rise less than 3.7˚C (6.7°F) after 15-minutes of continuous scanning (i.e., per pulse sequence).

When other methods of supplemental fixation are used, also follow the MR conditional labeling for the additional components.

In non-clinical testing, the image artifact caused by the implant extends approximately 15mm from this implant when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Instructions

1. **Position patient and reduce fracture**
   Position the patient for the respective surgical approach and reduce the fracture

2. **Choose the appropriate cable passer**
   The EVOS® Cabling System includes curved, straight, and angled cable passers:

Part Number	Description
7117-5655	EVOS Curved Cable Passer, 40mm
7117-5656	EVOS Curved Cable Passer, 50mm
7117-5657	EVOS Curved Cable Passer, 60mm
7117-5682	EVOS Straight Cable Passer, 40mm
7117-5683	EVOS Straight Cable Passer, 50mm
7117-5684	EVOS Straight Cable Passer, 60mm
7117-5685	EVOS Angled Cable Passer, 40mm
7117-5686	EVOS Angled Cable Passer, 50mm
7117-5687	EVOS Angled Cable Passer, 60mm

   Select the appropriate cable passer. The size and shape of the cable passer depends upon the circumference of the bone and access to the site. Select a cable passer that will allow the instrument to pass around the bone without causing significant damage to soft tissues or excessive stripping of the periosteum.

3. **Pass the cable around the bone**
   Pass the cable passer around the bone. Thread the free end of the cable into distal opening at the tip of the cable passer until the cable exits through the opening at the proximal hook end. Remove the cable passer leaving the cable wrapped around the bone.

   Precaution Do not thread the cerclage cable through the proximal hook opening as the crimp will prevent removal of the cable passer.

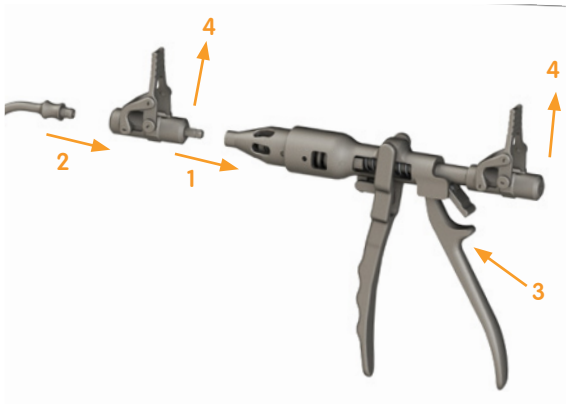
4. **Pass the cable through the open bore on the crimp and position the cable crimp**

Part Number	Description
7258-0000	EVOS® Cable, 2mm w/Crimp

5. **Insert the cerclage cable into the cable tensioner**

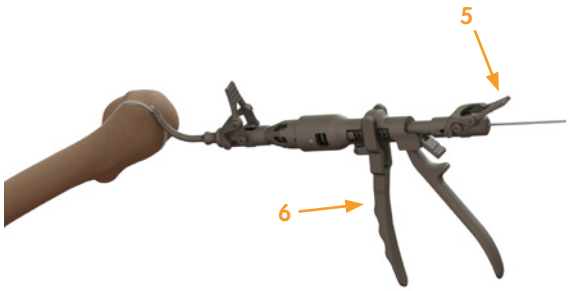
Part Number	Description
7117-5667	EVOS Nose Cone
7117-5659	EVOS Provisional Cable Tensioner
7117-5651	Cable Tensioner

Attach the provisional tensioner (1) and the Nose Cone (2) to the cable tensioner. Ensure the tensioner is re-set by actuating the thumb lever located at the origin of the rear handle (3). To enable the cerclage cable to be inserted into the cable tensioner, ensure that the Provisional Cable Tensioner and the rear cable tensioner locking device is in the unlocked and upright position (4). Insert the cerclage cable into the cable tensioner and advance the nose cone against the crimp.



Note Tensioner levers are designed to mitigate against unintentional locking or unlocking of the cable. There is an intermediate position which will not activate the locking mechanism. In order to lock or unlock the cable, the lever must be fully actuated to the parallel or upright position.

6. **Tension cerclage cable**
Remove excess cable slack by simultaneously pulling on the loose end of the cable while advancing the tensioner toward the crimp. Lock the rear tensioner cable locking device by actuating the rear tensioner lever in the locked and down position (5). To apply tension, squeeze the handles until the desired tension is reached (6), tension is shown by the markings on the tensioner (20-50kg).



It is not advised to apply tension beyond the upper limit displayed on the scale; damage to the cerclage assembly or the bone may occur.

7. **Temporary fixation (optional)**
After full tension has been achieved and prior to unlocking of the tensioner, fully lock the provisional tensioner by actuating the locking device to the locked and down position (7). Fully unlock the rear cable tensioner to the unlocked and upright position (4 on previous page).Disconnect the tensioner from the provisional tensioner by linearly removing it from the wound. Care should be taken with the loose end of the cable during removal of the tensioner. Using this procedure, any cerclage cable can be re-tensioned and/or repositioned before definitive fixation.

Note If the provisional tensioner lever is in the locked and down position, it removes the accuracy of the tensioner cable tension scale.

8. **Re-tension (optional)**
Ensure the tensioner is re-set by actuating the thumb lever located at the origin of the rear handle (3 previous page). To enable the cerclage cable to be inserted into the cable tensioner, ensure the tensioner cable locking lever is in the upright and unlocked position (4 previous page). Insert the cable into the tensioner and advance the tensioner over the cable, then attach it to the provisional tensioner. Lock the tensioner onto the cable at the rear of the tensioner by actuating the rear tensioner lever in the locked and down position (5 previous page). Unlock the provisional tensioner (4 previous page), then re-apply cable tension as desired (6 previous page).

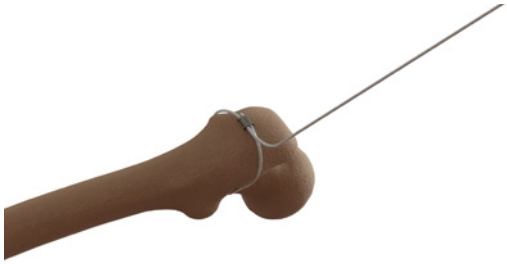
9. **Secure cerclage cable with cable crimp**

Part Number	Description
7117-5677	EVOS® Cable Crimper

When the desired cable tension is reached, the cerclage cable can be secured with the crimp. Place the jaws of the cable crimper on the crimp, ensuring that the crimp is centered and is fully seated within the crimper jaws. Squeeze the handles to complete crimping. The toothed mechanism of the cable crimper will auto-release when the handles have been actuated fully which ensures the cerclage has been fully crimped.

Precaution Incorrectly placing the cable crimper can lead to cerclage failure.

10. **Remove cable tensioner**
Unlock the tensioner cable lock, and the provisional cable tensioner if used, and remove the tensioner assembly.



11. **Cut the cable**

Part Number	Description
7117-5669	EVOS® Flush Cable Cutter

Cut the loose end of the cable using the Flush Cable Cutter. Insert the loose end of the cable into the indicated opening on the cutter. Advance cutter over the cable until it contacts the crimp, then fully actuate the handles to cut the cable.

12. **Implant removal**

Part Number	Description
7117-5670	EVOS Scissor Cable Cutter

Employ the Scissor Cable cutter for crimped cerclage removal. Position the cutter jaws close to the crimp to ensure the capture of the entire cable. Actuate the handles to cut the cable and remove the implant.

Cleaning and sterilization

Implants are provided sterile and must not be re-sterilized. Implants must be discarded if opened, but unused.

Instruments (Inclusive of the Instrument Case and Tray) are supplied non-sterile and must be cleaned and sterilized prior to introduction into a sterile surgical field (or if applicable) return of the product to the manufacturer.

- To minimize corrosion and prolong the usable life of instruments used during surgery, remove visual traces of blood and residues then thoroughly clean and dry immediately after use. Do not allow soils to dry.
- Never use steel brushes or abrasive pads, as these rupture the passive layer of the instrument surface which can lead to corrosion.
- Prior to and during use, including reprocessing, inspect instruments for:
  - Damage such as, but not limited to, wear, discoloration, corrosion, cracking, fracture, or unrecognizable markings.
  - Proper function including, but not limited to, sharpness, movement of hinges and couplings, joint stability, and legible markings.
- Detailed instructions are available per the surgical technique.
- Instruments that show signs of damage or an inability to function should not be used and should be returned to the manufacturer.

Cleaning

1. Disassemble instruments, as applicable. See surgical technique manual for specific instructions.
2. Rinse soiled device under running, cold tap water for a minimum of two (2) minutes. Remove visual soil using a soft bristle brush or soft, lint-free cloth.
3. Prepare a neutral enzymatic solution per the manufacturer's recommended instructions in warm tap water (approximately 33-43°C/92-110°F).
4. Soak devices in freshly prepared neutral pH enzymatic solution for a minimum of ten (10) minutes.
5. Rinse device using cool running tap water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels and other hard to reach areas. Actuate joints, handles and other moveable device features in order to rinse thoroughly under running water.
6. Prepare a neutral enzymatic solution per the manufacturer's recommended instructions in warm tap water (approximately 33-43°C/92-110°F).
7. Manually clean devices for a minimum of five (5) minutes in freshly prepared neutral pH enzymatic solution. Use a syringe, pipette, or water jet to flush lumens and channels.
8. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles, and other movable device features to expose all areas to enzymatic solutions. Clean device underwater to prevent aerosolization of contaminants.
9. Rinse device using deionized (DI) running water for a minimum of two (2) minutes. Use a syringe, pipette, or water jet to flush lumens and channels. Actuate joints, handles, and other moveable device features in order to rinse thoroughly under running water.
10. Visually inspect device for residual soil. If present, repeat steps 1-8 above.
11. Gently dry the device components with a soft lint-free cloth. Ensure the device is completely dry. Visually inspect the device; it should be clean, dry and residue-free.
12. Reassemble instruments, if applicable, following instructions in the surgical technique manual.

Automated (Mechanical) cleaning

Pre-cleaning

1. Disassemble instruments, as applicable. See surgical technique manual for specific instructions.
2. Rinse the device components under running lukewarm tap water (22-43°C/72-110°F) for a minimum of one (1) minute. After rinsing, remove visual soil using a soft-bristled brush or clean, soft, lint-free cloth.
3. Prepare a neutral pH enzymatic cleaning solution per the manufacturer's instructions.
4. Fully immerse the device components in the fresh, newly prepared neutral enzymatic cleaning solution for a minimum of five (5) minutes.
5. After soaking, manually clean the device components for a minimum of two (2) minutes using a soft-bristled brush to remove soil and debris from the device and device lumens. Brush the device while fully immersed to prevent aerosolization of contaminants. After cleaning, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 ml of the cleaning solution.
6. Remove the device components from the neutral enzymatic cleaning solution and place in a bath of lukewarm tap water (22-43°C/72-110°F) for a minimum of one (1) minute. Ensure the device components are fully immersed. Once the rinse time has elapsed, use a syringe, pipette, or water jet to flush the lumens and channels with a minimum of 10 ml of the water.

Automated cleaning

1. Place the device components in the automated washer.
2. Perform the automated cycle per instructions in the table below.
3. Visually inspect the device. It should be clean, dry and residue-free.
4. Reassemble instruments, if applicable, following instructions in the surgical technique manual.

Automated (Mechanical) Cleaning Parameters

Cycle	Time (minutes)	Minimum temperature	Detergent
Enzyme wash	4	Hot water 60°C (140°F)	Enzymatic cleaner (neutral pH) prepared per manfacturer's instructions
Wash	2	Hot water	Enzymatic cleaner (neutral pH) prepared per manfacturer's instructions
Rinse	2	Heated deionized or high purity water 70°C (158°F)	N/A
Dry	15	80°C (176°F)	N/A

U.S. sterilization

Use of an FDA cleared (or equivalent) wrap is recommended to ensure product sterility. The steam sterilization case shall be wrapped in a simultaneous double-wrapping: envelope fold configuration.

Steam sterilization (moist heat) is the only method permitted for sterilization. Other sterilization methods are not permitted. The values specified here (duration/temperature) can achieve a Sterility Assurance Level (SAL) of at least 10-6.

Independent testing has shown the following conditions to be effective:

Method	Steam
Cycle	Pre-vaccum (Double Wrapped)
Temperature	132° C (270° F)
Exposure time	4 minutes
Dry time	40 minutes

CE designated markets sterilization

Steam sterilization (moist heat) is the only method permitted for sterilization. Other sterilization methods are not permitted. The values specified here (duration / temperature) can achieve a Sterility Assurance Level (SAL) of at least 10-6 (according to BS EN 556).

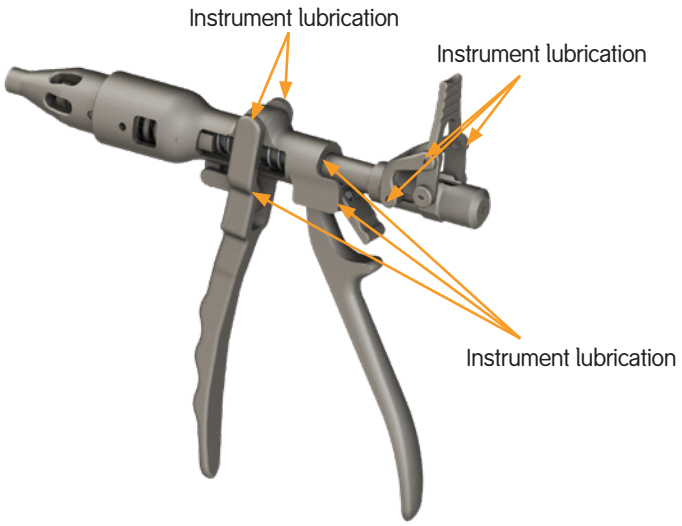
Independent testing has shown the following conditions to be effective:

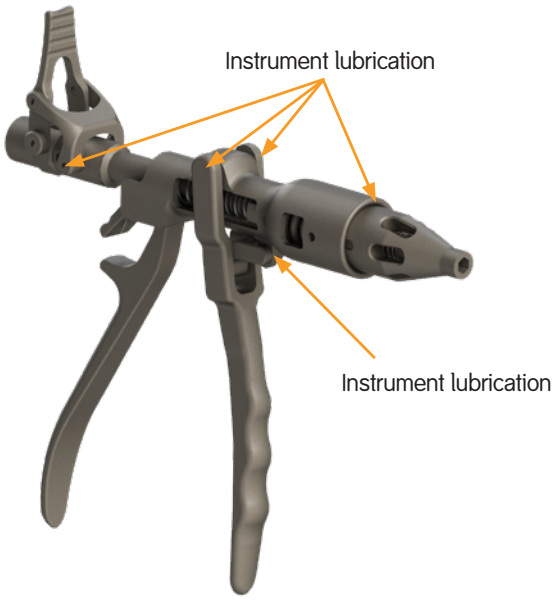
Method	Steam
Cycle	Pre-vaccum (Double Wrapped)
Temperature	134° C (273° F)
Exposure time	5-18 minutes
Dry time	40 minutes

Instrument care and maintenance

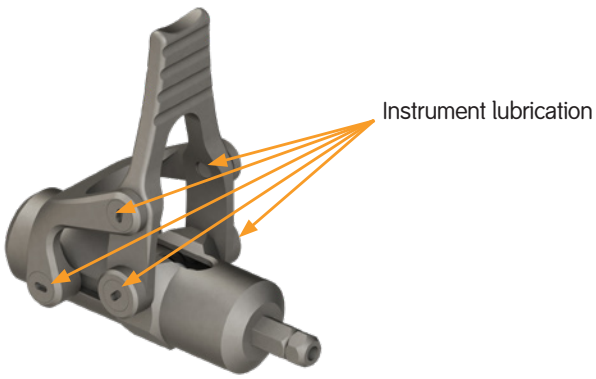
Apply 4-6 drops of Ruhof Premixslip instrument lubrication, or equivalent lubrication, to the following locations (see instrument lubrication below) to reduce maintenance and prolong instrument life.

Part Number	Description
7117-5651	EVOS® Cable Tensioner

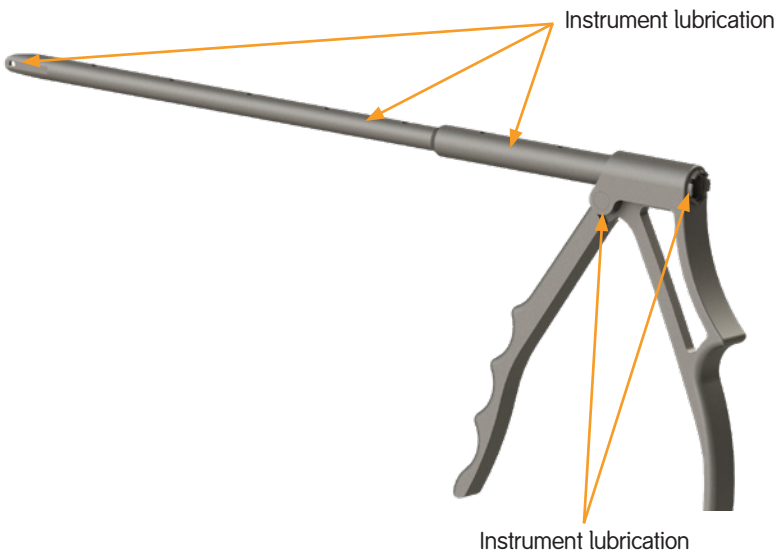




Part Number	Description
7117-5659	EVOS Provisional Cable Tensioner



Part Number	Description
7117-5669	EVOS Flush Cable Cutter

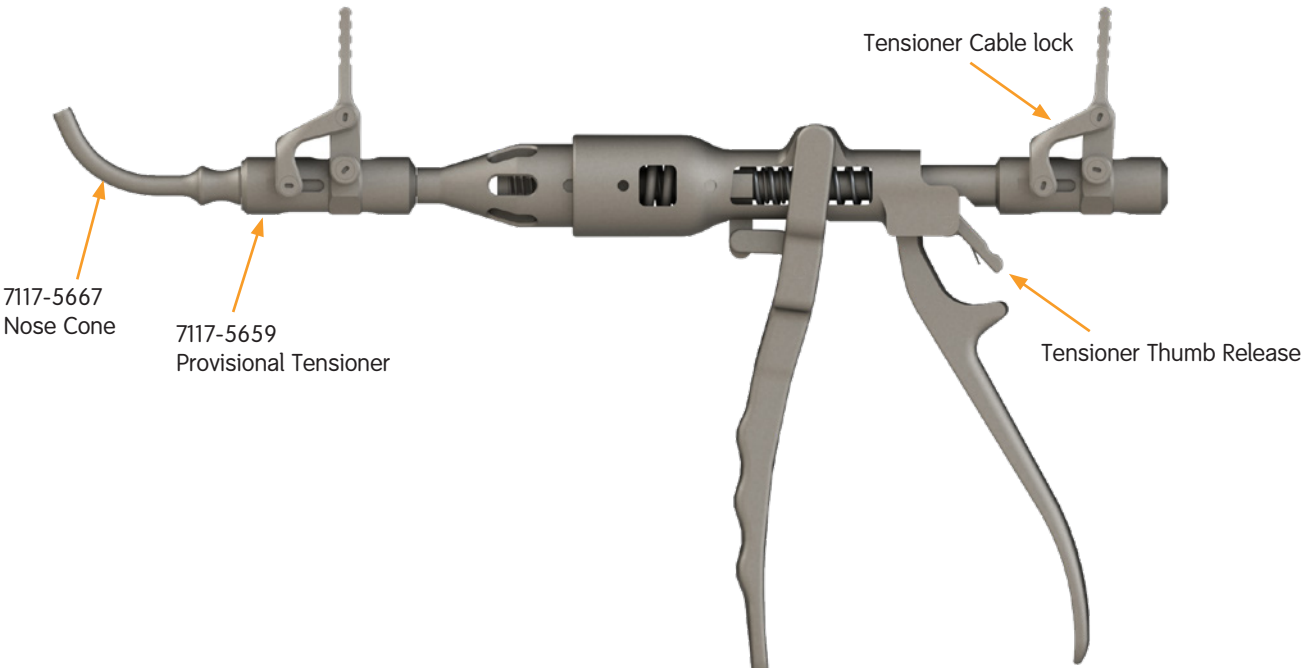


Appendix

Tensioner assembly components

Part Number	Description
7117-5669	EVOS® Nose Cone
7117-5659	EVOS Provisional Cable Tensioner
7117-5651	EVOS Cable Tensioner

Tensioner assembly



Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your sales representative or distributor if you have questions about the availability of products in your area. For detailed product information, including indications for use, contraindications, precautions and warnings, please consult the product's applicable Instructions for Use (IFU) prior to use.

Pioneer Surgical Technology, Inc.
375 River Park Circle
Marquette, MI 49855
Tel:906-226-9909
www.resolvesurg.com

EU REP

MDSS GmbH
Schiffgraben 41
Hanover 30175
Germany

www.smith-nephew.com

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References:
1. Data on file at Pioneer Surgical, Technology, Inc.

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