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IMPORTANT INFORMATION ON THE STRETTO™ CABLE SYSTEM

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WITHIN THE UNITED STATES ONLY

ENGLISH

IMPORTANT INFORMATION
ON THE STRETTO™ CABLE SYSTEM**DESCRIPTION**

The STRETTO™ Cable System is a cerclage fixation system consisting of flexible cables, crimps, and anchors. The crimps secure the cable after tensioning and the anchors may be used to connect the cable to ANTHEM® plates or screws, depending on anchor style. The Press-In Anchor mates with a plate hole, and Screw Anchors mate with screw heads. STRETTO™ implants are manufactured from titanium alloy, commercially pure titanium, stainless steel, cobalt chromium alloy, or cobalt chromium molybdenum alloy, as specified in ASTM F136, ASTM F67, ASTM F138 or F139, ASTM F90, or ASTM F1537.

INDICATIONS

The STRETTO™ Cable System is indicated for use in: general orthopedic trauma surgery (e.g., fractures of the olecranon, patella, femur - including periprosthetic, pelvis, acetabulum, humerus and ankle, and acromioclavicular dislocations); prophylactic banding during total joint procedures; and, temporary reduction techniques for ORIF (Open Reduction Internal Fixation) procedures.

STRETTO™ Screw Anchors are indicated for fractures that may not be securely held by either a screw or a cerclage device alone, and where cerclage is used in combination with bone screws and/or plates to provide internal fixation of fractured bone.

STRETTO™ Press-In Anchors are indicated for use with a cerclage cable and plate to augment long bone fracture fixation, particularly when the use of screws would be inhibited, as in the presence of intramedullary implants.

CONTRAINDICATIONS

Use of these implants is contraindicated in patients with the following conditions:

- Any active or suspended latent infection or marked local inflammation in or about the affected area.
- Compromised vascularity that would inhibit adequate blood supply to the fracture or the operative site.
- Bone stock compromised by disease, tumor, infection, severe osteoporosis, or prior implantation that cannot provide adequate support and/or fixation of the devices.
- Material sensitivity, documented or suspected.
- Patients having inadequate tissue coverage over the operative site.
- Implant utilization that would interfere with anatomical structures or physiological performance.
- Any mental or neuromuscular disorder which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Other medical or surgical conditions which would preclude the potential benefit of surgery.

WARNINGS

Components of this system are manufactured from titanium alloy, stainless steel, commercially pure titanium, and cobalt chromium and cobalt chromium molybdenum alloys. Cobalt chrome based implants may be in contact with titanium alloy or commercially pure titanium implants, or with stainless steel implants; however stainless steel implants may not be mixed with titanium alloy or commercially pure titanium implants.

PRECAUTIONS

The implantation of these devices should be performed only by experienced surgeons with specific training in the use of this system because this is a technically demanding procedure presenting a risk of serious injury to the patient.

Surgical implants are single use only and must never be reused. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Care should be taken not to scratch, unravel, cut the cables or damage any accessory components with sharp objects. The use of bone cement may prevent removal of the cable or other components.

MRI SAFETY INFORMATION

The STRETTO™ Cable System has not been evaluated for safety in the MR environment. It has not been tested for heating or unwanted movement in the MR environment. The safety of the STRETTO™ Cable System in the MR environment is unknown. Performing an MR exam on a person who has STRETTO™ devices may result in injury or device malfunction.

CAUTIONS*Pre-operative*

- These implants are for single use only.
- Implants that come in contact with body fluids should never be reused.
- Ensure that all components needed for surgery are available in the surgical suite.
- Inspection is recommended prior to surgery to determine if implants have been damaged during storage.
- While rare, intra-operative fracture or breakage of instruments can occur. Instruments which have experienced excessive use or excessive force are susceptible to fracture. Instruments should be examined for wear or damage prior to surgery.

Intra-operative

- Avoid damage of implants.
- Discard all damaged or mishandled implants.
- During the course of the operation, repeatedly check to ensure that the connection between the implant and the instrument, or between the instruments, is secure.
- After the procedure check the proper positioning of all implants.
- Do not use components from this system in conjunction with components from any other manufacturer's system unless otherwise specified.

Post-operative

- Post-operative patient activity: These implants are neither intended to carry the full load of the patient acutely, nor intended to carry a significant portion of the load for extended periods of time. For this reason, post-operative instructions and warnings to patients are extremely important. External immobilization (e.g. bracing or casting) may be employed until X-rays or other procedures confirm adequate bone consolidation.
- The implant is a short-term implant. In the event of a delay in bone consolidation, or if such consolidation does not take place, or if explantation is not carried out, complications may occur, for example fracture or loosening of the implant or instability of the implant system. Regular post-operative examinations (e.g., X-ray checks) are advisable.
- The risk of post-operative complication (e.g. failure of an implant) is higher if patients are obese and/or cannot follow the recommendations of the physician because of any mental or neuromuscular disorder. For this reason those patients must have additional post-operative follow-up.
- Implant removal should be followed by adequate postoperative management to avoid fracture or refracture of the bone.

Informing the Patient

The implant affects the patient's ability to carry loads and her/his mobility and general living circumstances. The surgeon must counsel each patient individually on correct behavior and activity after the implantation.

The surgeon must warn each patient that the device cannot and does not replicate a normally healthy bone, that the device can break or become damaged as a result of strenuous activity, trauma, mal-union or non-union and that the device has a finite expected service life and may need to be removed at some time in the future.

ADVERSE EFFECTS

In many instances, adverse results may be clinically related rather than device related. Prior to surgery, patients should be made aware of the following possible adverse effects in addition to the potential need for additional surgery to correct these effects:

- Delayed union or non-union of the fracture site.
- These devices can break when subjected to the increased loading associated with delayed unions and/or non-unions. Cables are intended to hold fracture bone surface in a position to facilitate healing. If healing is delayed or does not occur, the appliance may eventually break due to metal fatigue.

- Conditions attributable to non-union, osteoporosis, osteomalacia, diabetes, inhibited revascularization and poor bone formation can cause loosening, fraying, fracture of the device or premature loss of fixation with the bone.
- Improper alignment can cause a mal-union of the bone and/or fraying or breakage of the device.
- Increased fibrous tissue response around the fracture site due to unstable comminuted fractures.
- Early or late infection, deep or superficial.
- Deep venous thrombosis.
- Avascular necrosis.
- Shortening of the affected bone/fracture site.
- Subclinical nerve damage may possibly occur as a result of the surgical trauma.
- Material sensitivity reactions in patients following surgical implantation have rarely been reported, however their significance awaits further clinical evaluation.

PACKAGING

These implants may be supplied pre-packaged and sterile, using gamma irradiation. The integrity of the sterile packaging should be checked to ensure that sterility of the contents is not compromised. Packaging should be carefully checked for completeness and all components should be carefully checked to ensure that there is no damage prior to use. Damaged packages or products should not be used, and should be returned to Globus Medical. During surgery, after the correct size has been determined, remove the products from the packaging using aseptic technique.

Implants and instruments may be provided nonsterile and must be steam sterilized prior to use, as described in the STERILIZATION section below. Instruments must be cleaned prior to sterilization, as described in the CLEANING section below.

HANDLING

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Instruments should be checked to ensure that they are in working order prior to surgery.

Implants are single use devices and should not be cleaned. Re-cleaning of single use implants might lead to mechanical failure and/or material degradation. Discard any implants that may have been accidentally contaminated.

CLEANING

Instruments should be cleaned separately from instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable. All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The products should be cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field or (if applicable) return of the product to Globus Medical.

Cleaning and disinfecting can be performed with aldehyde-free solvents at higher temperatures. Cleaning and decontamination must include the use of neutral cleaners followed by a deionized water rinse. Note: certain cleaning solutions such as those containing formalin, glutaraldehyde, bleach and/or other alkaline cleaners may damage some devices, particularly instruments; these solutions should not be used.

The following cleaning methods should be observed when cleaning instruments and instrument trays and cases before or after use or exposure to soil, and prior to sterilization:

1. Immediately following use, ensure that the instruments are wiped down to remove all visible soil and kept from drying by submerging or covering with a wet towel.
2. Disassemble all instruments that can be disassembled, including the tensioners and flush cutter.
3. Rinse the instruments under running tap water to remove all visible soil. Flush the lumens a minimum of 3 times, until the lumens flush clean.
4. Prepare Enzo[®] (or a similar enzymatic detergent) per manufacturer's recommendations.
5. Immerse the instruments in the detergent and allow them to soak for a minimum of 2 minutes.
6. Use a soft bristled brush to thoroughly clean the instruments. Use a pipe cleaner for any lumens. Pay close attention to hard to reach areas.
7. Using a sterile syringe, draw up the enzymatic detergent solution. Flush any lumens and hard to reach areas until no soil is seen exiting the area.
8. Remove the instruments from the detergent and rinse them in running warm tap water.
9. Prepare Enzo[®] (or a similar enzymatic detergent) per manufacturer's recommendations in an ultrasonic cleaner.
10. Completely immerse the instruments in the ultrasonic cleaner and ensure detergent is in lumens by flushing the lumens. Sonicate for a minimum of 3 minutes.
11. Remove the instruments from the detergent and rinse them in running deionized water or reverse osmosis water for a minimum of 2 minutes.
12. Dry instruments using a clean soft cloth and filtered pressurized air.
13. Visually inspect each instrument for visible soil. If visible soil is present, then repeat cleaning process starting with Step 3.

CONTACT INFORMATION

Globus Medical may be contacted at 1-866-GLOBUS1 (456-2871). A surgical technique manual may be obtained by contacting Globus Medical.

STERILIZATION

STRETTO[™] cables and cable and crimp assemblies are only available sterile. STRETTO[™] crimps and anchors may be provided sterile or nonsterile. Instruments are provided nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10⁻⁶. Sterile cables and pre-assembled cable and crimp implants are packaged in a heat sealed tray-in-tray, sterile anchors and individual crimps are packaged in a heat sealed container/pouch. The expiration date is provided on the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants meet pyrogen limit specifications.

Nonsterile implants and instruments are steam sterilized as described below, and steam sterilization has been validated to ensure an SAL of 10⁻⁶. The use of an FDA-cleared wrap is recommended, per the Association for the Advancement of Medical Instrumentation (AAMI) ST79, *Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities*. It is the end user's responsibility to use only sterilizers and accessories (such as sterilization wraps, sterilization pouches, chemical indicators, biological indicators, and sterilization cassettes) that have been cleared by the FDA for the selected sterilization cycle specifications (time and temperature).

When using a rigid sterilization container, the following must be taken into consideration for proper sterilization of Globus devices and loaded graphic cases:

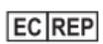
- Recommended sterilization parameters are listed in the table below.
- Only FDA-cleared rigid sterilization containers for use with pre-vacuum steam sterilization may be used.
- When selecting a rigid sterilization container, it must have a minimum filter area of 176 in² total, or a minimum of four (4) 7.5in diameter filters.
- No more than one (1) loaded graphic case or its contents can be placed directly into a rigid sterilization container.
- Stand-alone modules/racks or single devices must be placed, without stacking, in a container basket to ensure optimal ventilation.
- The rigid sterilization container manufacturer's instructions for use are to be followed; if questions arise, contact the manufacturer of the specific container for guidance.
- Refer to AAMI ST79 for additional information concerning the use of rigid sterilization containers.

For implants and instruments provided NONSTERILE, sterilization is recommended (wrapped or containerized) as follows:

Method	Cycle Type	Temperature	Exposure Time	Drying Time
Steam	Pre-vacuum	132°C (270°F)	4 minutes	30 minutes

These parameters are validated to sterilize only this device. If other products are added to the sterilizer, the recommended parameters are not valid and new cycle parameters must be established by the user. The sterilizer must be properly installed, maintained, and calibrated. Ongoing testing must be performed to confirm inactivation of all forms of viable microorganisms.

CAUTION: Federal (USA) Law Restricts this Device to Sale by or on the order of a Physician.

SYMBOL TRANSLATION			
	CATALOGUE NUMBER		STERILIZED BY IRRADIATION
	LOT NUMBER		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
	QUANTITY		