GLOBUS MEDICAL

STRETTO™

Cable System

SURGICAL TECHNIQUE GUIDE

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GLOBUS MEDICAL

Our mission is to deliver cutting-edge technology, research, and innovative solutions to promote healing in patients with musculoskeletal disorders.

Life moves us

The Surgical Technique shown is for illustrative purposes only. The technique(s) actually employed in each case always depends on the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient. Additionally, as instruments may occasionally be updated, the instruments depicted in this Surgical Technique may not be exactly the same as the instruments currently available. Please consult with your sales representative or contact Globus directly for more information.

SURGICAL TECHNIQUE GUIDE

STRETTO™

Cable System

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Cable System

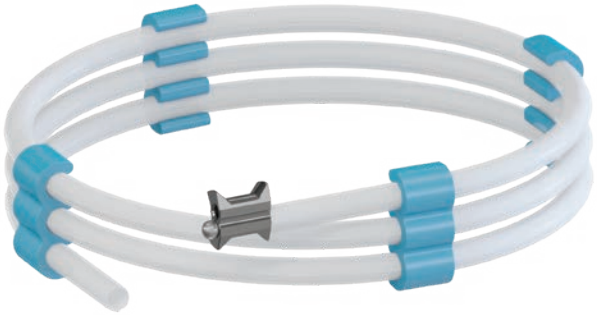
STRETTO™ is a low-profile cabling system designed to offer secure fracture fixation with minimal soft tissue disruption.

STRETTO™ offers innovative instruments to streamline cable insertion, including variable radius cable passers, a dedicated soft tissue retractor for the passers, and a dual-function cable tensioner.

STRETTO™ implants may be used in conjunction with existing Globus ANTHEM® stainless steel and titanium implants.

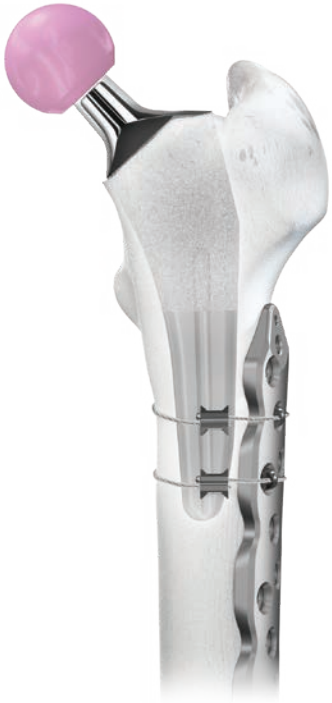
CABLES AND CRIMPS

- Specialized sterile packaging allows the cable to be removed in a controlled manner.



CABLE ANCHORS

- Press-in design allows the anchors to be firmly seated in the plate while being able to freely rotate to the desired orientation



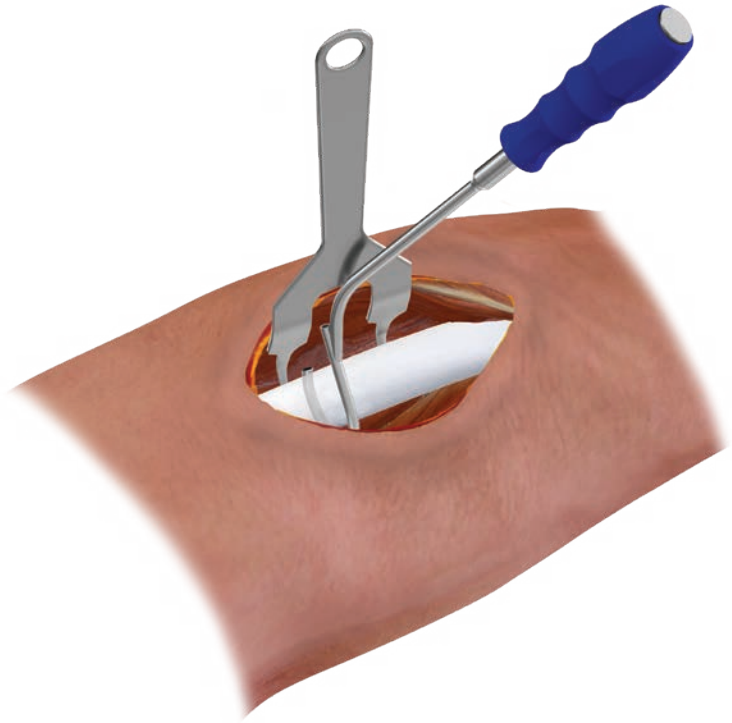
SYSTEM OVERVIEW

Cable Passers

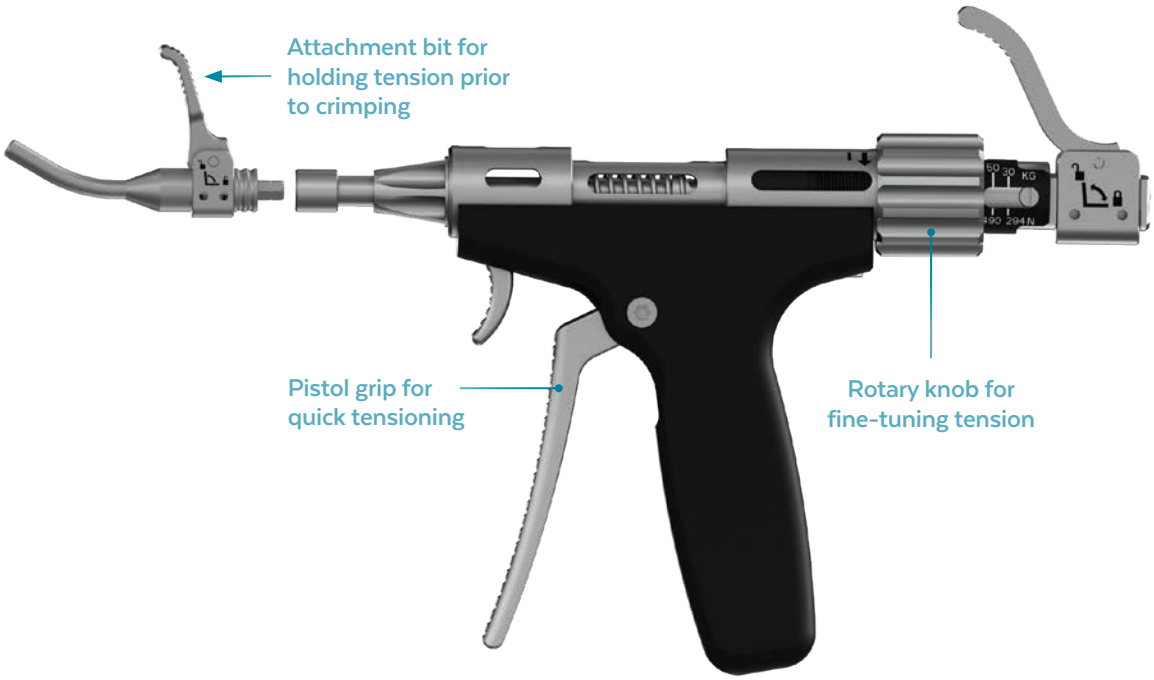
- 6 options are available to accommodate diverse patient anatomies
- Variable radius passer to keep the passer tip close to the bone

Passer Retractor

- Engineered for optimized soft tissue retraction, allowing direct visualization of the passer tip



Dual Tensioner



Flush Cutter

SURGICAL TECHNIQUE

STRETTO™ Cable System

Refer to the device insert (also printed at the back of this manual) for important information on the intended use/indications, device description, contraindications, precautions, warnings, and potential risks associated with this system.

STEP 1 PREOPERATIVE PLANNING

Assess the fracture using preoperative radiographs and/or a CT scan. Determine the desired surgical approach and auxiliary implants to be used, including cable material, cable position, and anchor placement.

STEP 2 PATIENT POSITIONING

Determine patient position based on anatomy and fracture pattern.

STEP 3 FRACTURE REDUCTION

Using fluoroscopy, examine the fracture type and fracture location.

Reduce the fracture using the appropriate method for the type of fracture. Ensure that bone length, alignment, and rotation are properly restored. Reduction should be confirmed using fluoroscopy.

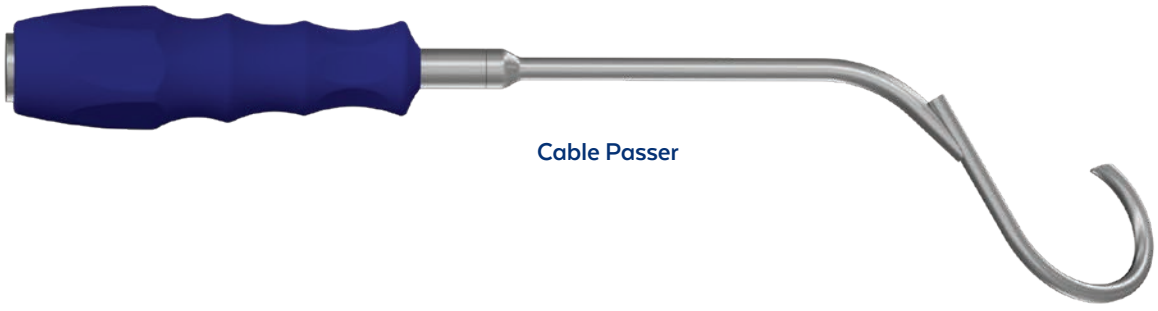
STEP 4 CABLE PLACEMENT

Select the appropriate **cable** based on the material of the other implants (if applicable), as shown below.

Cable Material	Crimp Material	Part No.	Description	Plate Material Pairing
Cobalt Chrome	Titanium	7231.9177S	STRETTO™ Crimp, Ti and Cable, 1.7mm, CoCr	Titanium
Stainless Steel	Stainless Steel	2231.9177S	STRETTO™ Crimp and Cable, 1.7mm, SS	Stainless Steel

Select the appropriate **cable passer** based on anatomy and preference, as shown below.

Part No.	Description
6231.8030	Cable Passer, Small
6231.8031	Cable Passer, Large
6231.8032	Cable Passer, Small, Angled
6231.8033	Cable Passer, Large, Angled
6231.8036	Cable Passer, Small, Variable Radius
6231.8037	Cable Passer, Large, Variable Radius

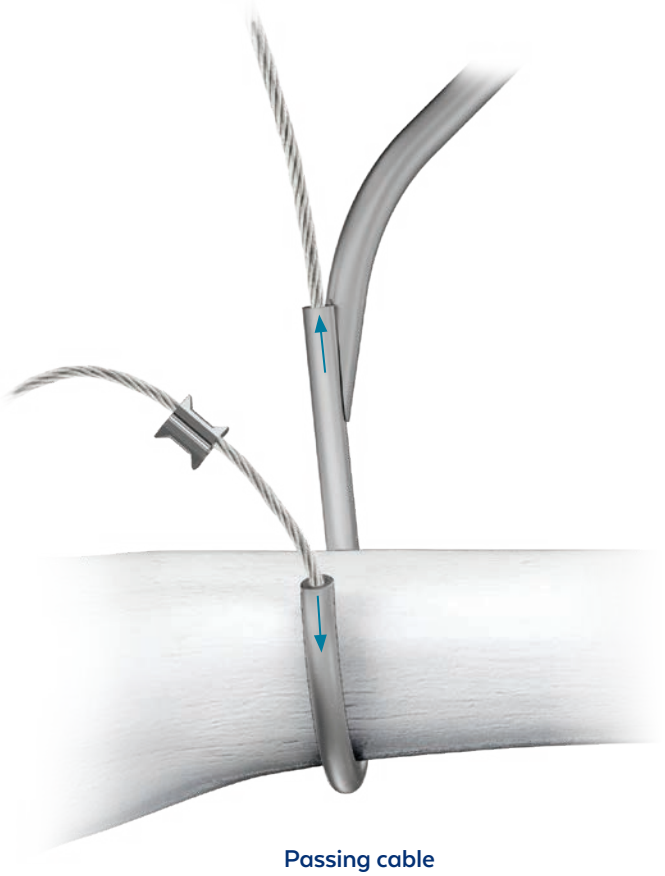


Cable Passer

CABLE PLACEMENT (CONT'D)

Insert the cable passer through the incision and place the hook of the passer around the bone. If using a separate cable and crimp, first assemble the crimp by passing the tip of the cable through one of the holes in the crimp. A cobalt chrome cable is used with a commercially pure titanium crimp and a stainless steel cable is used with a stainless steel crimp.

Pass the cable and crimp assembly through the cable passer until it exits from the opposite end of the hook. Thread the cable through the tip of the passer to prevent the cable crimp from interfering with passer removal. Hold the cable in position while removing the cable passer.

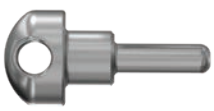


Passing cable

OPTIONAL: ANCHOR INSERTION

When using STRETTO™ cables with ANTHEM® plates with 4.5mm polyaxial holes or ANTHEM® screws with a T25 driver, STRETTO™ Anchors may be used to create an interface between the cable and plate or between the cable and screw. Anchors may be inserted into a plate or screw before or after the cable is passed around the bone.

Three anchor styles are available as shown below:

Anchor Style	Where Used	ANTHEM® Implant
Press-In Anchor 	Inserted into polyaxial screw holes within ANTHEM® plates	Any ANTHEM® plate with 4.5mm polyaxial screw holes
Solid Screw Anchor 	Inserted into solid screw heads in bone or within ANTHEM® plates	• 4.5mm locking screws • 4.5mm non-locking screws • 5.5mm cancellous screws
Cannulated Screw Anchor 	Inserted into cannulated screw heads in bone or within ANTHEM® plates	• 4.5mm cannulated locking screws • 5.5mm cannulated cancellous screws

The cable anchors may be inserted in the plate before or after the cable is passed around the bone.

For **Press-In Anchors**, the cable may be inserted into the anchor before or after positioning the anchor. Use forceps to insert the anchor into the desired 4.5mm polyaxial screw hole until fully seated. When seated, the anchor is able to rotate freely in the plate hole. Rotate the anchor to the desired orientation. For screw anchors, determine whether a solid or cannulated screws is to be used. The cable can be inserted into the anchor before or after positioning the anchor.

Use forceps to insert a **Solid Screw Anchor** directly into the screw head of a 4.5mm locking or non-locking screw or a 5.5mm cancellous screw.

Use forceps to insert a **Cannulated Screw Anchor** directly into the screw head of a 4.5mm cannulated locking or 5.5mm cannulated cancellous screw.

Insert the free end of the cable through the hole in each anchor.

Inserting solid screw anchor

Inserting cannulated screw anchor

Inserting Press-In Cable Anchor using holding forceps

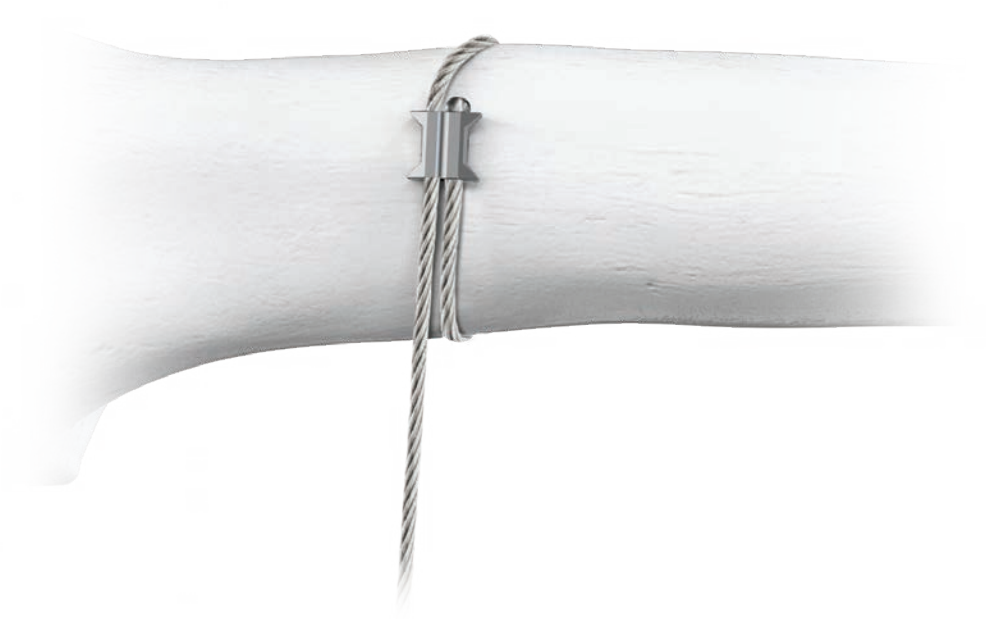
ANCHOR HOLDING FORCEPS

The Anchor Holding Forceps are designed to insert the Press-In Anchor into a plate with or without a cable.

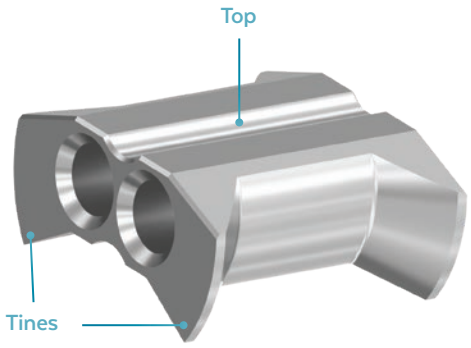
STEP 5 CRIMP PLACEMENT

Insert the free end of the cable into the open hole in the crimp and place the crimp in the desired position on the bone.

Ensure that the tines on the undersurface of the cable crimp are in contact with the bone, and the smooth surface is facing up to help prevent soft tissue irritation.



Correct orientation of crimp on bone and cable through crimp



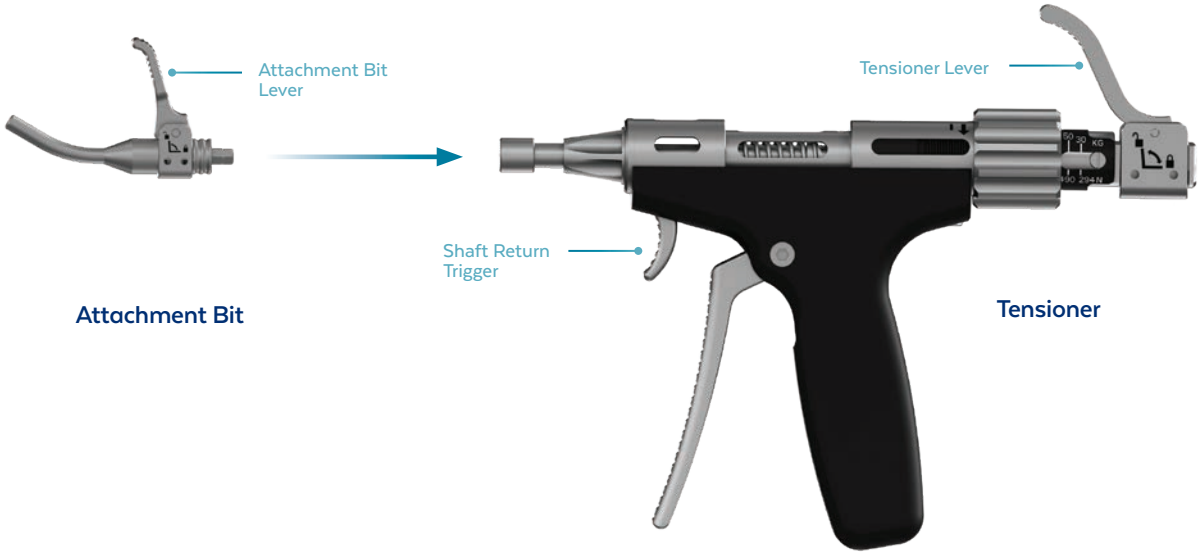
Crimp geometry

STEP 6 CABLE TENSIONING

The cable is tensioned using the **Cable Tensioner** or **Rotary Tensioner**.

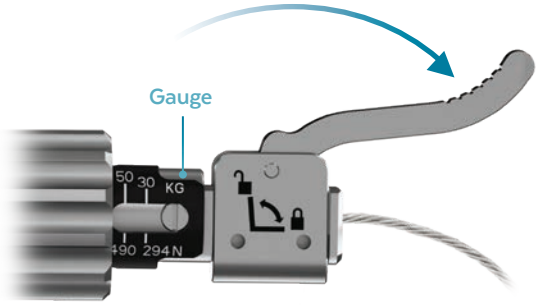
Cable Tensioner

If using the Cable Tensioner, attach the **Attachment Bit** to the Cable Tensioner. Open the levers on the tensioner and the attachment bit so that the cable can pass through.



Insert the cable into the tensioner with levers in the open position until the attachment bit contacts the crimp. Carefully take up any slack in the cable manually, then lock the lever on the back of the tensioner. Confirm placement of the crimp.


Passing cable through tensioner



Tensioner in locked position

Compress the pistol grip or rotate the knob on the tensioner clockwise until the desired tension is reached. The amount of tension applied to the cable is indicated by the gauge on the tensioner. The gauge indicates tension levels from 20kg to 50kg (196N to 490N). When the desired tension is reached, the cable is ready for crimping.

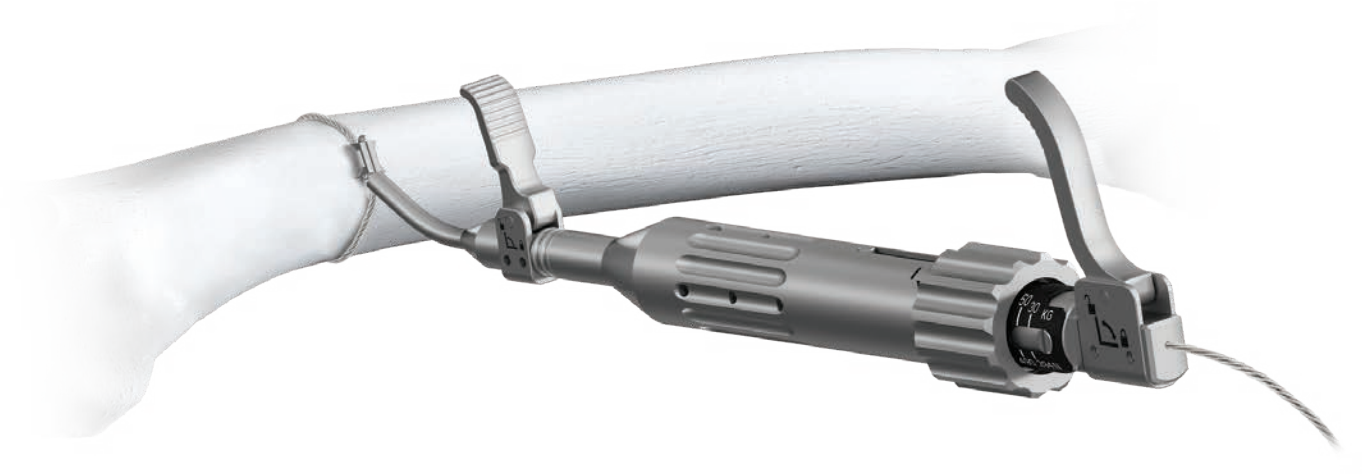
CABLE TENSIONING (CONT'D)

Rotary Tensioner

If using the Rotary Tensioner, attach the Attachment Bit to the Rotary Tensioner. Open the levers on the tensioner and the attachment bit so that the cable can pass through.

Insert the cable into the tensioner with levers in the open position until the attachment bit contacts the crimp. Carefully take up any slack in the cable manually, then lock the lever on the back of the tensioner. Confirm placement of the crimp.

Rotate the knob on the tensioner clockwise until the desired tension is reached. The amount of tension applied to the cable is indicated by the gauge on the tensioner. When the desired tension is reached, the cable is ready for crimping.

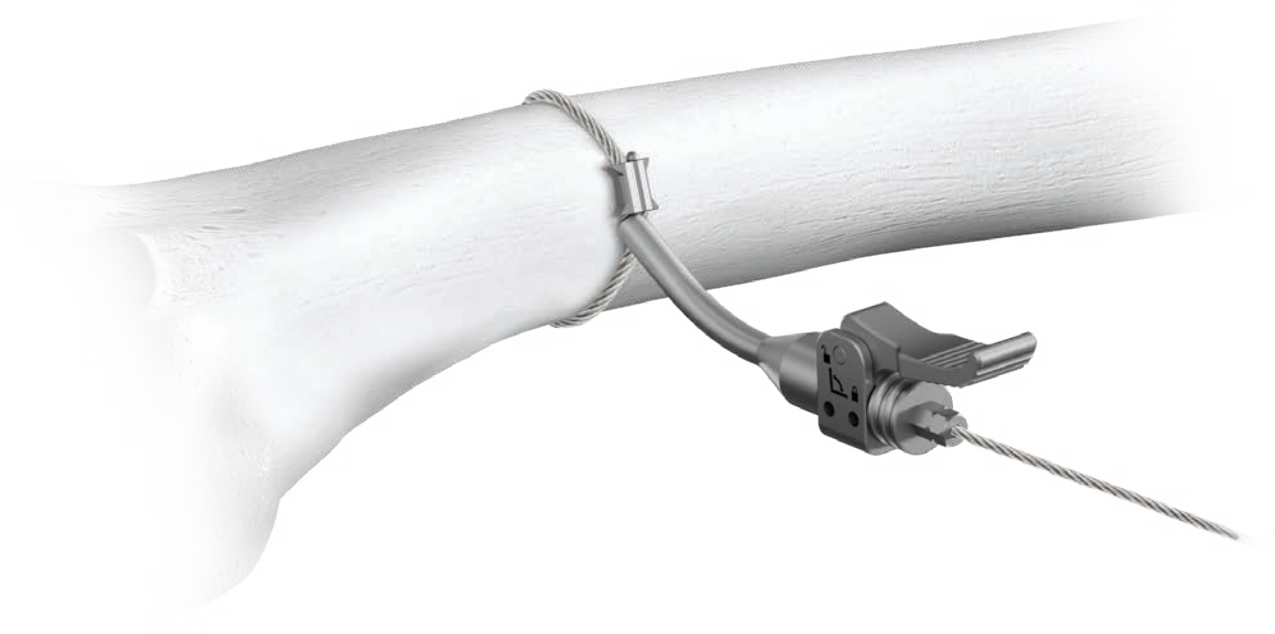


Passing cable through rotary tensioner

OPTIONAL: TEMPORARY TENSION

The lever on the attachment bit can be used to temporarily hold tension in the cable without the tensioner attached prior to crimping.

Move the lever on the attachment bit to the locked position once the cable is fully tensioned. Release the lever on the tensioner and remove the tensioner.



Temporary tension using attachment bit

STEP 7 CABLE CRIMPING

Use the **Crimper** to deform the crimp and secure the cable in place. Place the jaws of the Crimper over the crimp and ensure the jaws are fully contacting the flat sides of the crimp. Compress the handles together.

The Crimper automatically releases when the crimp has been fully deformed.

The attachment bit or Tensioner may be removed without losing tension in the cable.

Crimping cable

STEP 8 CABLE CUTTING

Cut any excess cable with the flush cutter, or a standard cable cutter.

To use the flush cutter, attach the blade cartridge to the handle. Pass the free end of the cable through the hole identified on the blade cartridge. Slide the tip of the flush cutter against the crimp to cut as close to the crimp as possible. Pull the trigger on the cable cutter to create a smooth cut.

Cable cutting

BLADE CARTRIDGE

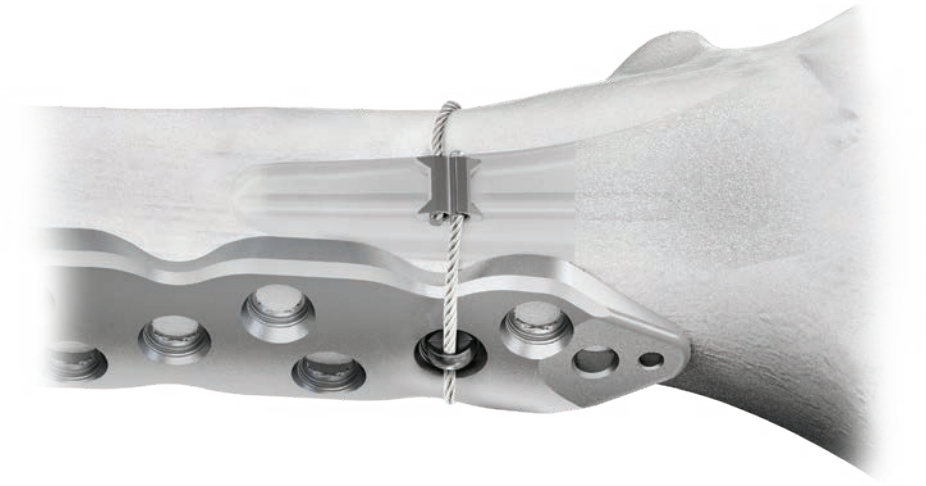
The cartridge is etched to show the direction of cable insertion.

Cable in side

Cable out side

FINAL CONSTRUCT

Final construct



Final construct with plate and anchor

OPTIONAL: REMOVAL

If removal is required, the cable may be removed by cutting with a standard cable cutter or a comparable instrument.

INSTRUMENT OVERVIEW

CABLE PASSERS

STRETTO™ Cable Passer, Small 6231.8030

STRETTO™ Cable Passer, Large 6231.8031

STRETTO™ Cable Passer, Small, Angled 6231.8032

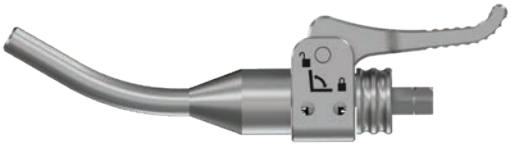
STRETTO™ Cable Passer, Large, Angled 6231.8033

STRETTO™ Cable Passer, Small, Variable Radius 6231.8036

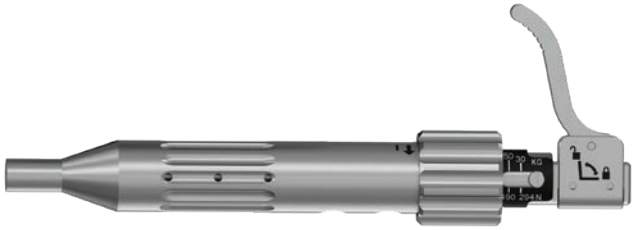
STRETTO™ Cable Passer, Large, Variable Radius 6231.8037

TENSIONERS

STRETTO™ Cable Tensioner 6231.8001



STRETTO™ Attachment Bit, Curved 6231.8003



STRETTO™ Rotary Tensioner 6231.8200

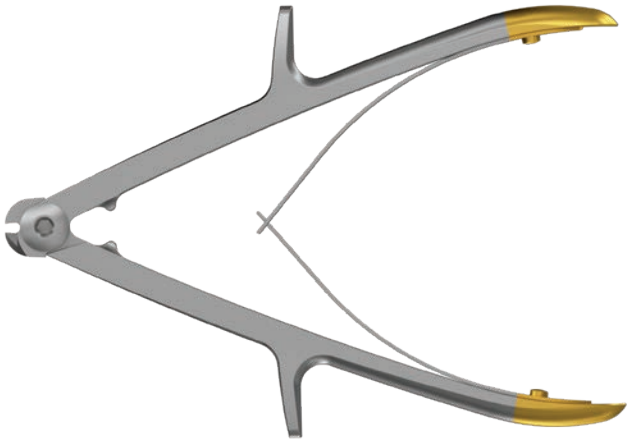
CRIMPER

STRETTO™ Crimper 6231.8010

CABLE CUTTERS

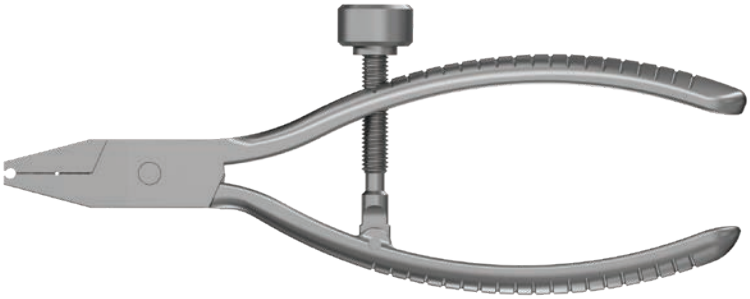
STRETTO™ Flush Cutter, Blade Cartridge 6231.8012

STRETTO™ Flush Cutter, Handle 6231.8013

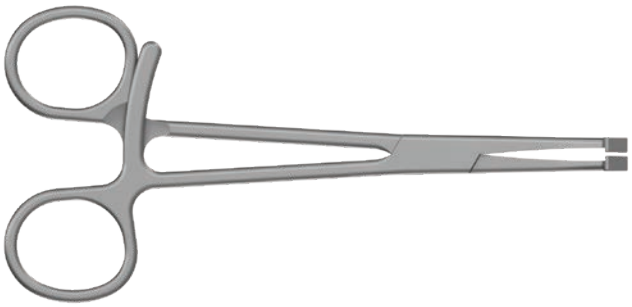


STRETTO™ Cable Cutter, Standard 6231.8023

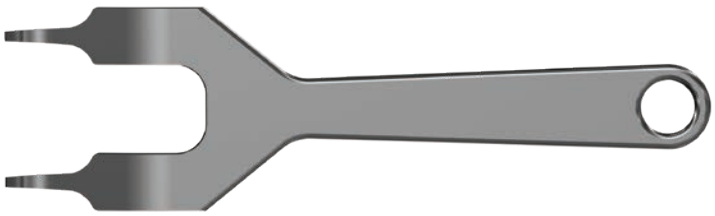
OTHER INSTRUMENTS



STRETTO™ Anchor Holding Forceps 6231.8041



STRETTO™ Crimp Holding Forceps 6231.8021



STRETTO™ Passer Retractor 6231.8025

STRETTO™ CABLE SYSTEM
IMPLANT SETS

STRETTO™ TITANIUM IMPLANT SET 9231.9002

Part No.	Description	Qty
7231.9177S	STRETTO™ Crimp, Ti and Cable, 1.7mm, CoCr	10
1231.6700S	STRETTO™ Press-In Anchor, 4.5mm, Ti	5
1231.6340S	STRETTO™ Anchor, Solid Screw, 4.5mm, Ti	0
1231.6440S	STRETTO™ Anchor, Cannulated Screw, 4.5mm, Ti	0
9231.0002	STRETTO™ Cable Implant Case	

STRETTO™ STAINLESS STEEL IMPLANT SET 9231.9003

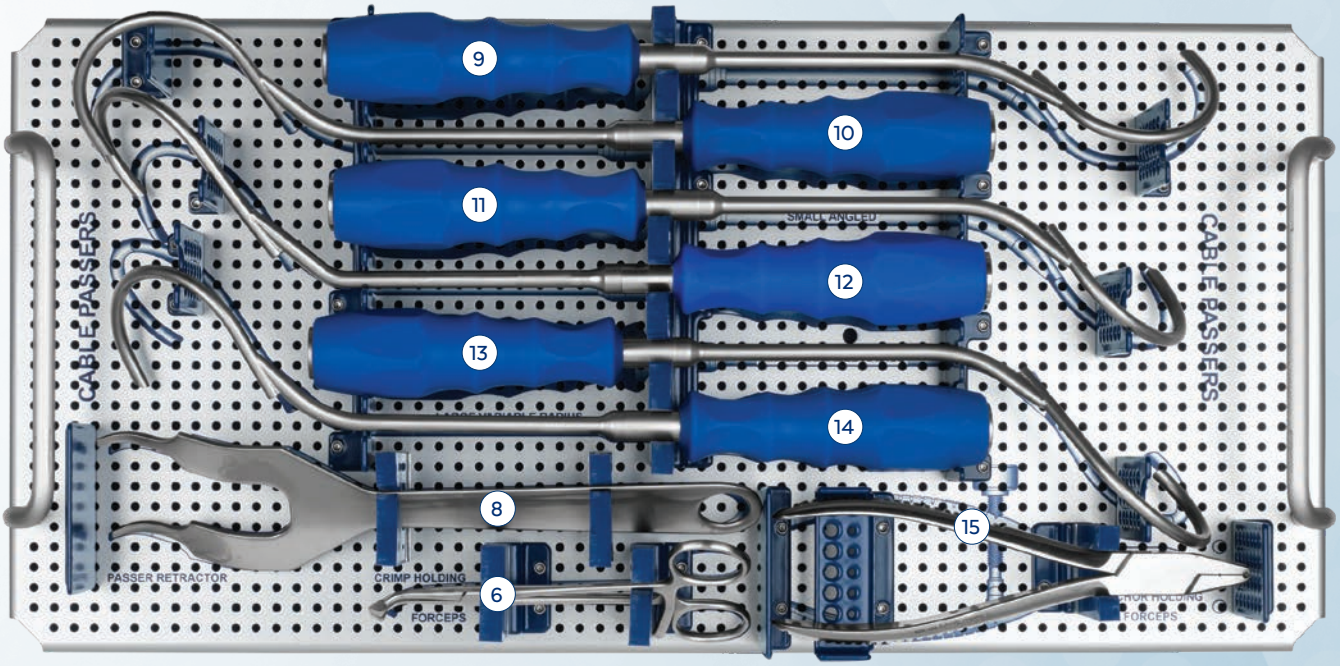
Part No.	Description	Qty
2231.9177S	STRETTO™ Crimp and Cable, 1.7mm, SS	10
2231.6700S	STRETTO™ Press-In Anchor, 4.5mm, SS	5
2231.6340S	STRETTO™ Anchor, Solid Screw, 4.5mm, SS	0
2231.6440S	STRETTO™ Anchor, Cannulated Screw, 4.5mm, SS	0
9231.0002	STRETTO™ Cable Implant Case	

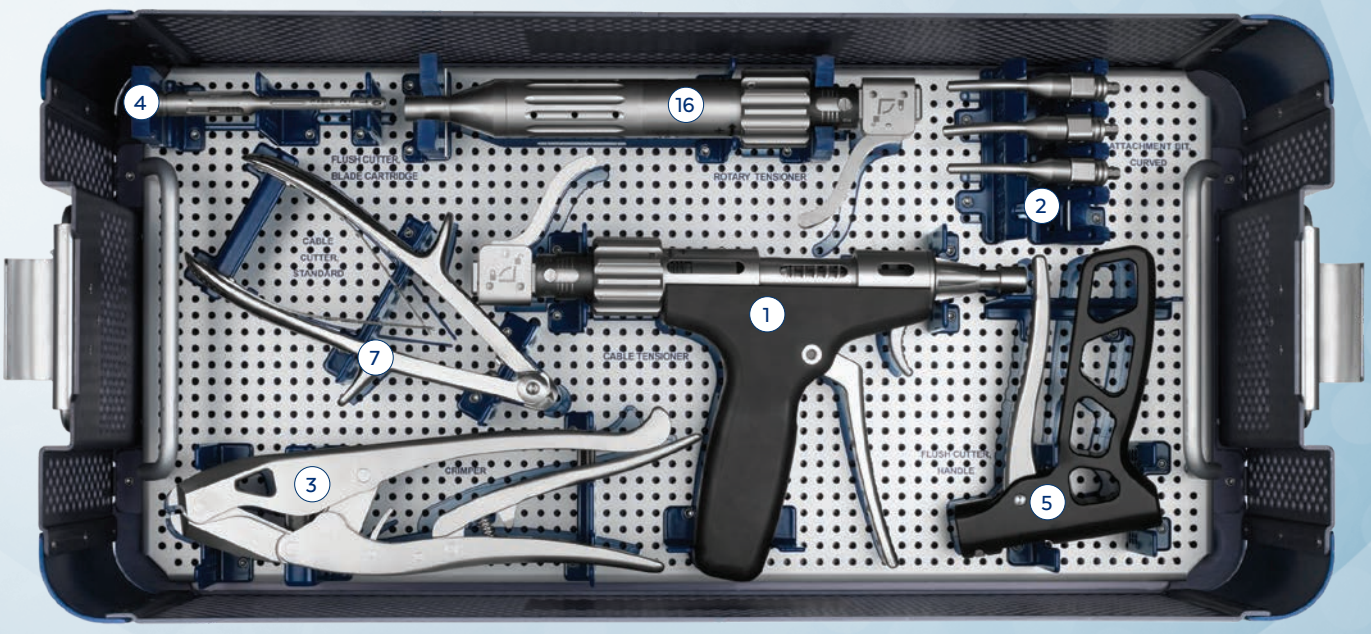
Items in gray are additionally available.

STRETTO™ CABLE SYSTEM
INSTRUMENT SET 9231.9001

	Part No.	Description	Qty
1	6231.8001	STRETTO™ Cable Tensioner	1
2	6231.8003	STRETTO™ Attachment Bit, Curved	4
3	6231.8010	STRETTO™ Crimper	1
4	6231.8012	STRETTO™ Flush Cutter, Blade Cartridge	1
5	6231.8013	STRETTO™ Flush Cutter, Handle	1
6	6231.8021	STRETTO™ Crimp Holding Forceps	1
7	6231.8023	STRETTO™ Cable Cutter, Standard	1
8	6231.8025	STRETTO™ Passer Retractor	1
9	6231.8030	STRETTO™ Cable Passer, Small	1
10	6231.8031	STRETTO™ Cable Passer, Large	1
11	6231.8032	STRETTO™ Cable Passer, Small, Angled	1
12	6231.8033	STRETTO™ Cable Passer, Large, Angled	1
13	6231.8036	STRETTO™ Cable Passer, Small, Variable Radius, Angled	1
14	6231.8037	STRETTO™ Cable Passer, Large, Variable Radius, Angled	1
15	6231.8041	STRETTO™ Anchor Holding Forceps	1
16	6231.8200	STRETTO™ Rotary Tensioner	1
	9231.0001	STRETTO™ Cable Instrument Set	

STRETTO™ CABLE SYSTEM
INSTRUMENT SET 9231.9001





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, osteomalicia, 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.

IMPORTANT INFORMATION ON THE STRETTO™ CABLE SYSTEM

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 accidently 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 Enzol® (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 Enzol® (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 in^2 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			
REF	CATALOGUE NUMBER	STERILE R	STERILIZED BY IRRADIATION
LOT	LOT NUMBER	EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
⚠	CAUTION		MANUFACTURER
	SINGLE USE ONLY		USE BY (YYYY-MM-DD)
QTY	QUANTITY		

DI214A Rev A

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