AERIAL™

Interspinous Fixation 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

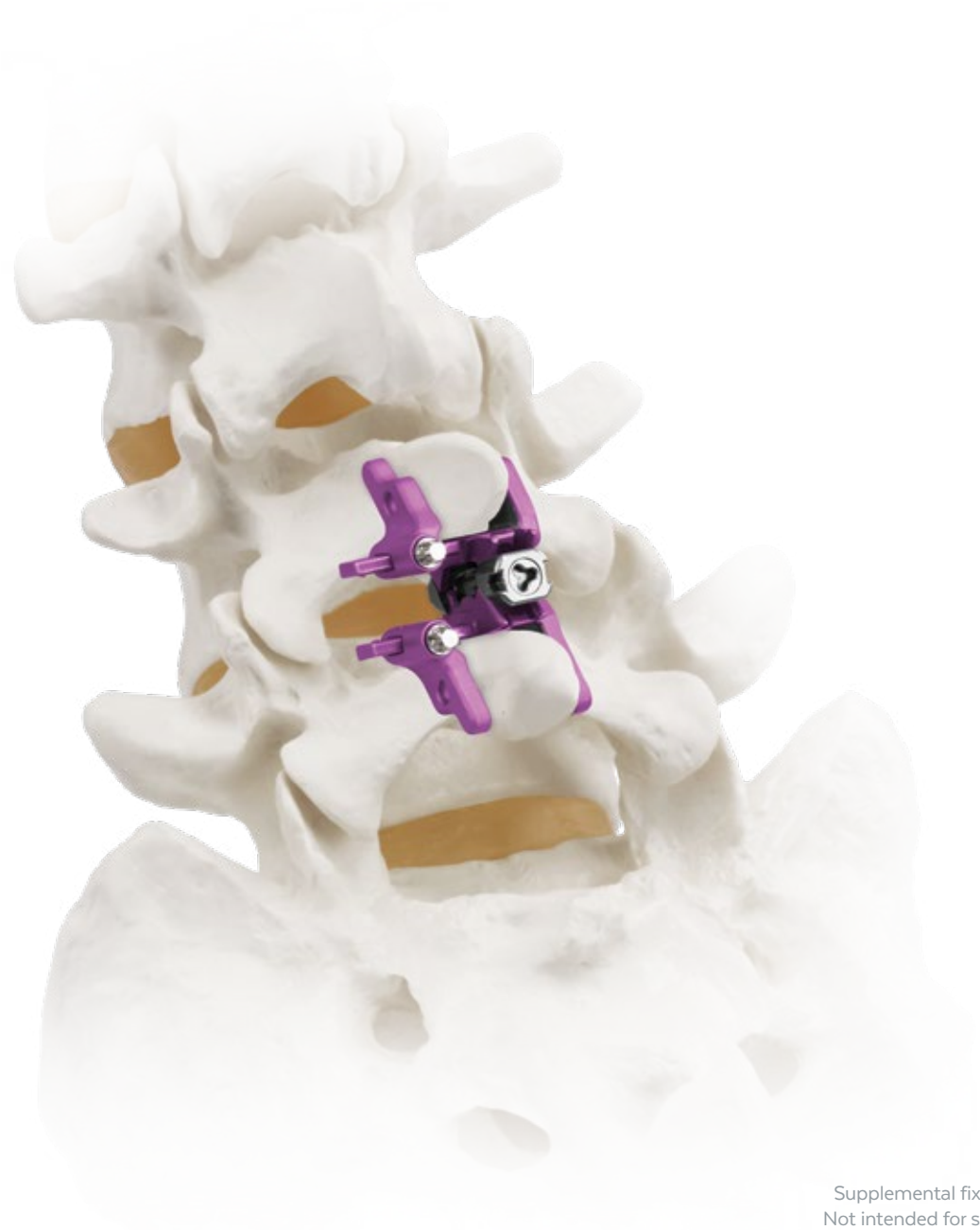
SURGICAL TECHNIQUE GUIDE

AERIAL™

AERIAL™

Interspinous Fixation System

AERIAL™ Interspinous Fixation is a minimally invasive spinous process fixation system. With its expandable core and independent locking plates, AERIAL™ offers a customized patient fit and allows for indirect decompression. AERIAL™'s easy insertion and expansion provides a simple MIS solution for interspinous fixation.



Supplemental fixation required.
Not intended for stand-alone use.

AERIAL™ features independent locking plates and SintrOS™ laser surface treatment.

Continuous Expansion

AERIAL™'s interspinous core offers continuous expansion that allows for indirect decompression while providing an anatomical fit.

Independent Locking Plates

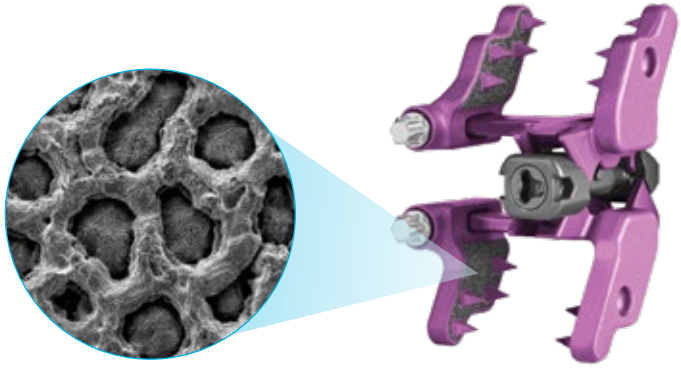
Independent locking plates adapt to patient anatomy, separately engaging into each spinous process.

Integrated Lordosis

Provides up to 15° of parallel lordotic expansion to help fit patient anatomy.

SintrOS™ Surface Technology

SintrOS™ surface technology is an innovative laser engraved treatment designed to encourage cellular activity at the bone interface.



IMPLANT OVERVIEW

Expandable Core

- Designed to help restore neuroforaminal height
- Contracted implant height to minimize impaction force during insertion
- Zero step locking mechanism reduces procedural steps
- Up to 6mm of expansion

Independent Locking Plates

- Superior and inferior locking plates are independent of each other
- Optimized spike-to-bone purchase
- Adapt to varying patient anatomy

Lordotic Options

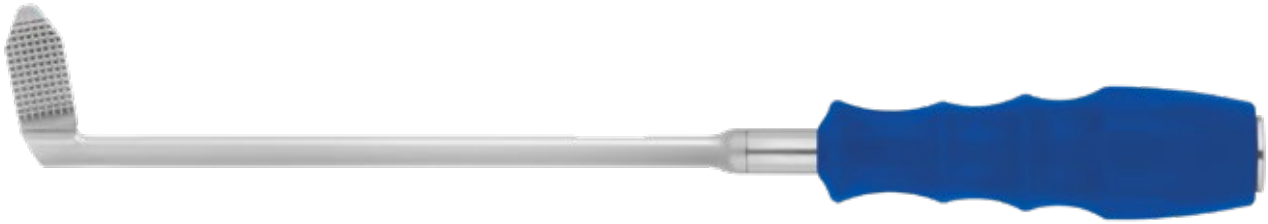
- Provides 4°, 10°, and 15° of lordosis

AERIAL™ Spinous Process Fixation System Expansion Ranges				
7	7-13mm, 4°			
8			8-14mm, 10°	
9		9-15mm, 4°		9-15mm, 15°
10				
11				
12				
13				
14				
15				
16				
17				

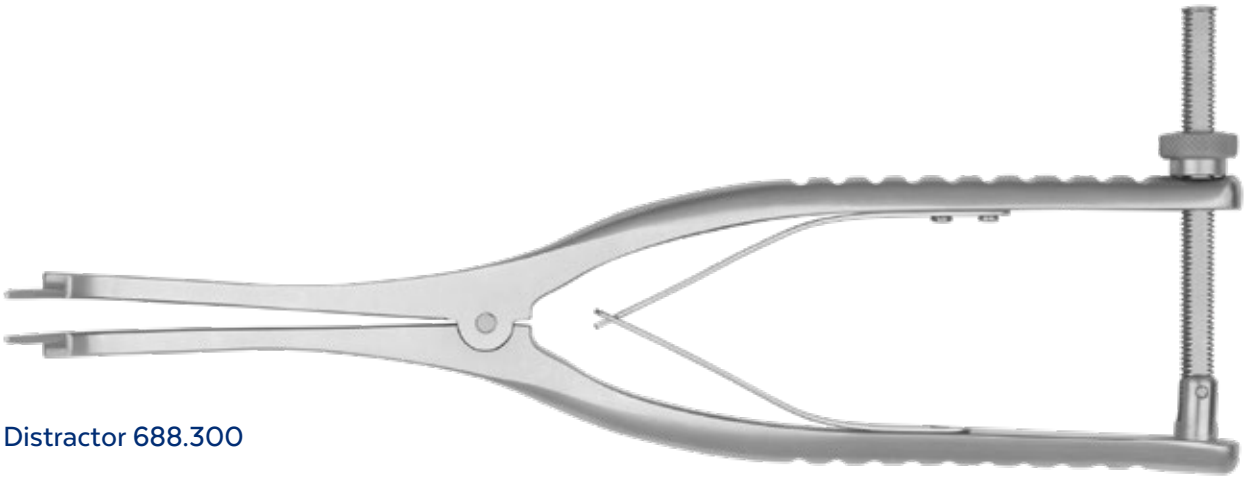
INSTRUMENT OVERVIEW

SITE PREPARATION INSTRUMENTS

Spinous Process Rake 688.060



Rasp 6117.0070



Distractor 688.300

IMPLANT INSERTER INSTRUMENTS

Spanner Wrench 687.509

IMPLANT INSERTER INSTRUMENTS (CONT'D)

Torque Limiting Implant Driver, 2.0Nm 6117.0003

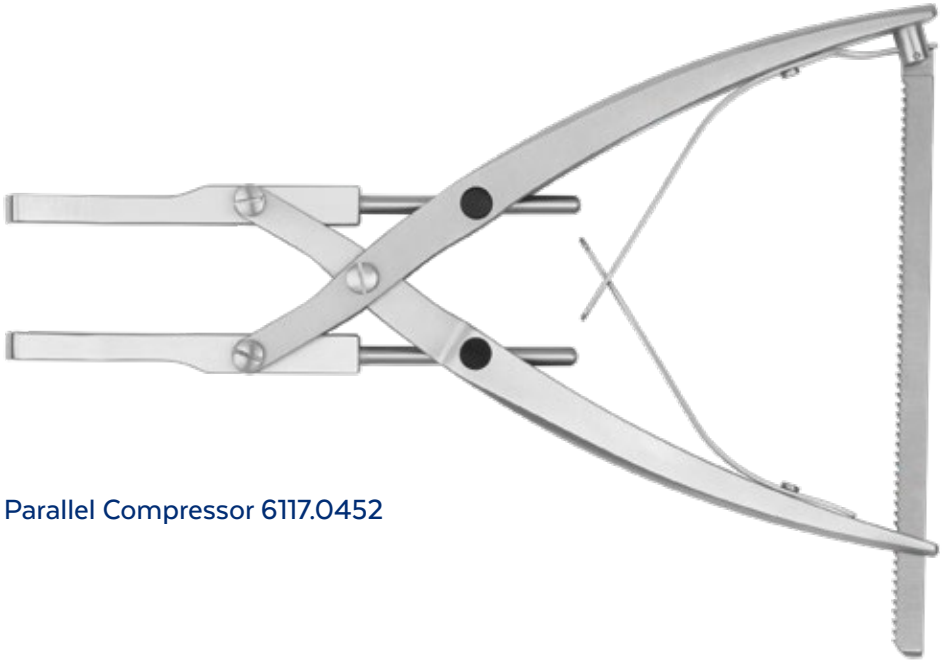
Inserter Tube 6117.0002

Inserter Handle 694.005

Inserter Fork 6117.0008

Inserter Assembled
Inserter Tube 6117.0002
Inserter Handle 694.005
Inserter Fork 6117.0008
Torque Limiting Implant Driver 6117.0003

COMPRESSOR AND FINAL TIGHTENING INSTRUMENTS



Parallel Compressor 6117.0452

Torque Limiting AO Quick Connect Handle, 1.5Nm 6117.0015

Final Tightening Driver, Short 6117.0185

SURGICAL TECHNIQUE

AERIAL™

Please refer to the product insert located in the back of this manual for a complete description, indications, contraindications, and warnings associated with this system.

STEP 1 PREOPERATIVE PLANNING

Clean the operative area prior to surgery. Place the patient under anesthesia, position prone, and in flexion.

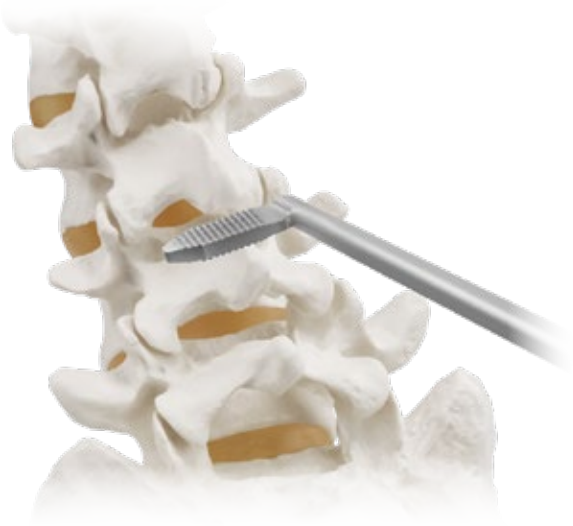
Use lateral C-arm fluoroscopy or other radiographic methods throughout surgery to ensure correct implant placement.

A posterior approach is used to implant AERIAL™.

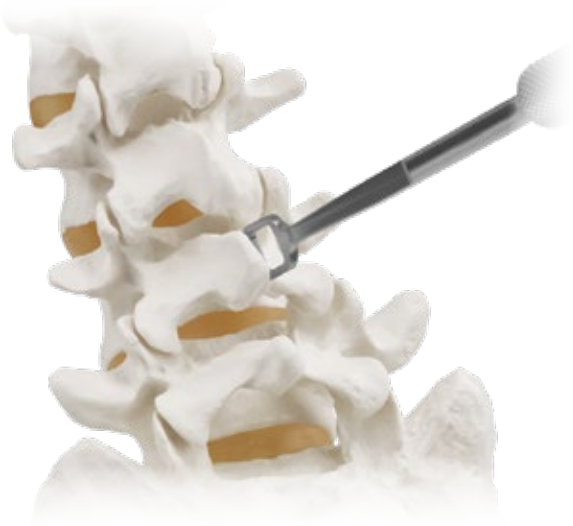
STEP 2 APPROACH AND SITE PREPARATION

Create a 3-5cm midline incision at the desired level. Retract the incision bilaterally to expose both sides of the spinous process.

Remove supraspinous and interspinous ligaments. The **Rasp** may be used to gently clear soft tissue from the interspinous space. The **Spinous Process Rake** may be used to remove soft tissue from the sides of the spinous process.



Using Rasp

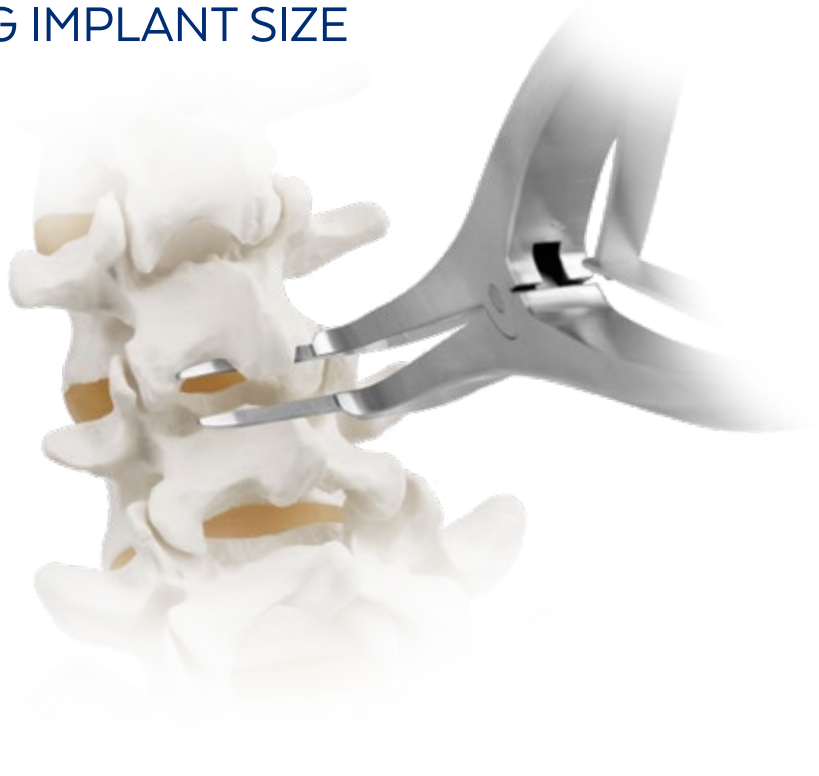


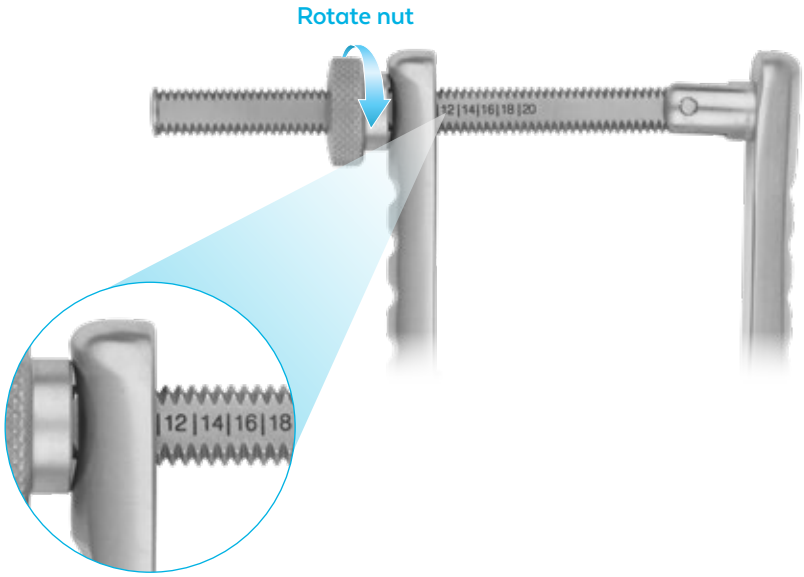
Using Spinous Process Rake

STEP 3 DETERMINING IMPLANT SIZE

Using the **Distractor**, measure the interspinous space to determine the correct implant size based on patient anatomy.

Estimate implant height by rotating the nut on the distractor clockwise. Read the indicator marks from the inside of the spindle handle.



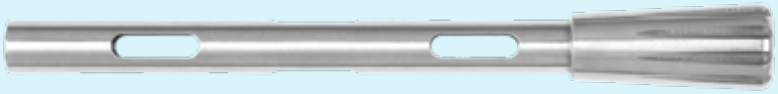


12mm measurement

ASSEMBLING THE IMPLANT INSERTER

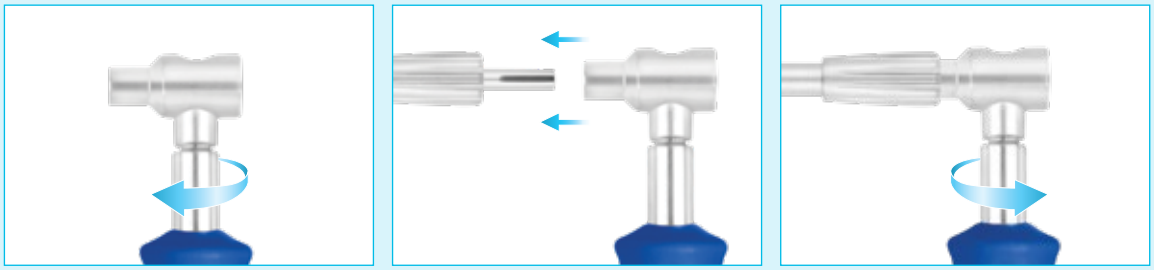
Fully thread the **Inserter Fork** into the **Inserter Tube**. Ensure that the **Inserter Handle** is in the unlocked position by rotating the handle counterclockwise until it stops. Attach the Inserter Handle to the Inserter Fork. Rotate the Inserter Handle clockwise to lock onto the Inserter Fork.

Inserter Fork



Inserter Tube

Inserter Handle



Attaching Inserter Handle to Inserter Tube

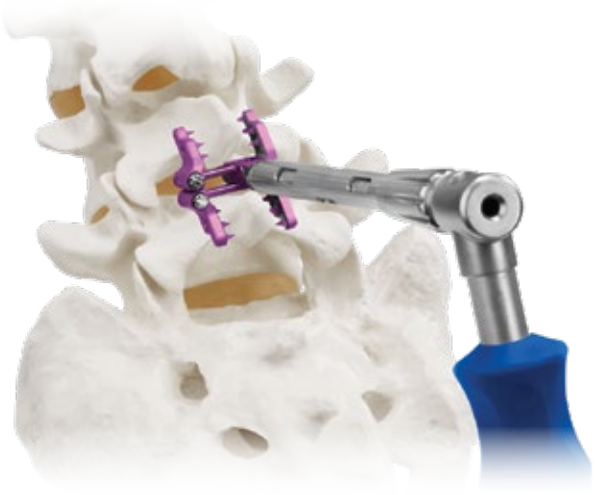
STEP 4 IMPLANT ATTACHMENT

Select the appropriate size AERIAL™ implant. Fill the graft chamber with allograft or autograft bone prior to attaching the implant to the inserter.

With the Inserter Tube fully threaded counterclockwise, attach the implant by placing it between the tips of the Inserter Fork. Rotate the Inserter Tube clockwise until the implant is secure.

STEP 5 IMPLANT INSERTION

Once secured to the implant inserter assembly, insert the implant between two spinous processes.



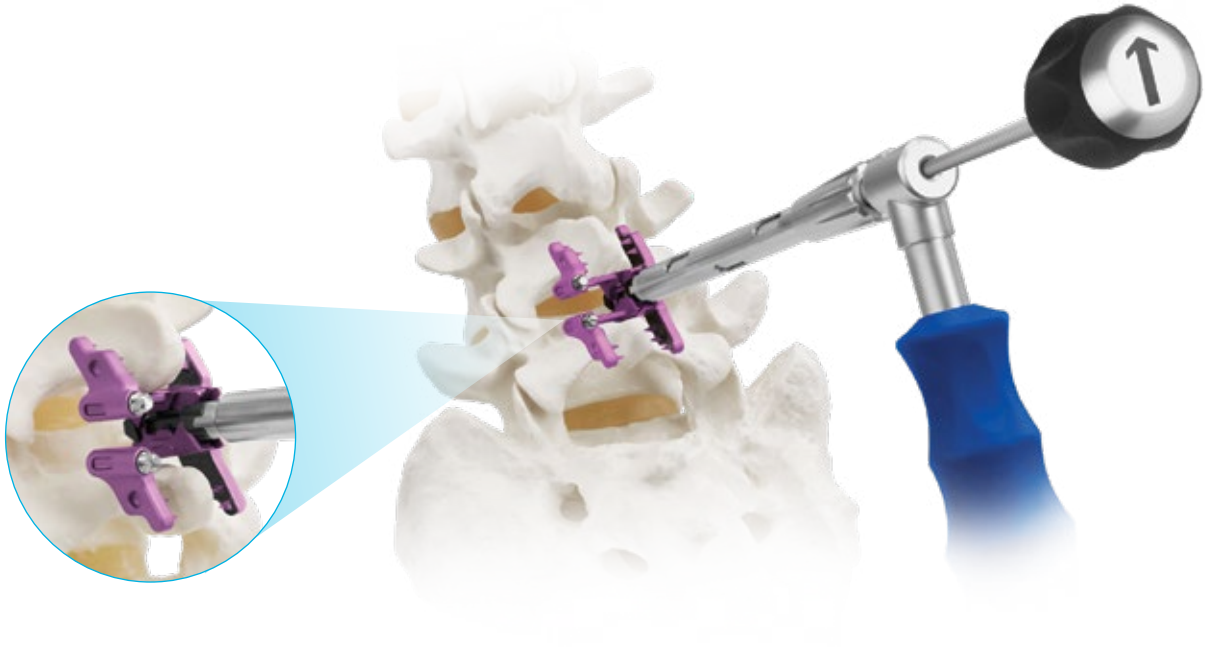
STEP 6 IMPLANT EXPANSION

Insert the **Torque Limiting Implant Driver, 2.0Nm** through the implant inserter assembly, engaging the implant. Rotate the driver clockwise to expand the implant to the appropriate height.

Use caution while expanding the implant to avoid excessive distraction and spinous process damage. Expand the implant to help restore neuroforaminal height and fit the interspinous space.

Use fluoroscopy and tactile feel in the interspinous space to determine implant expansion height.

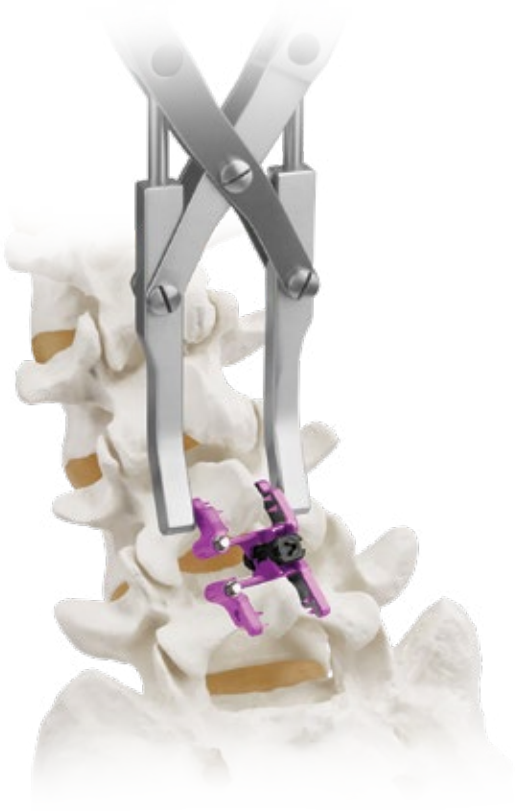
The expansion height may be determined by counting the number of revolutions of the Torque Limiting Implant Driver. Approximately 1.75 revolutions equal 1mm of expansion. Use the arrow on the back of driver to count revolutions.



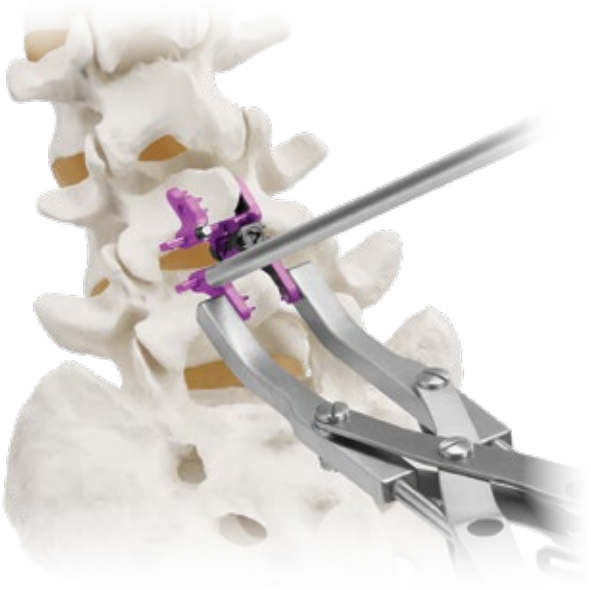
STEP 7 IMPLANT COMPRESSION AND FINAL TIGHTENING

Using the **Parallel Compressor**, compress both the inferior and superior locking plates, centering the implant, until the teeth are engaged into the spinous process.

With the compressor engaged to the locking plate, lock the set screw using the **Final Tightening Driver, Short** with the **Torque Limiting Quick Connect Handle, 1.5Nm**. Repeat for the remaining locking plate.

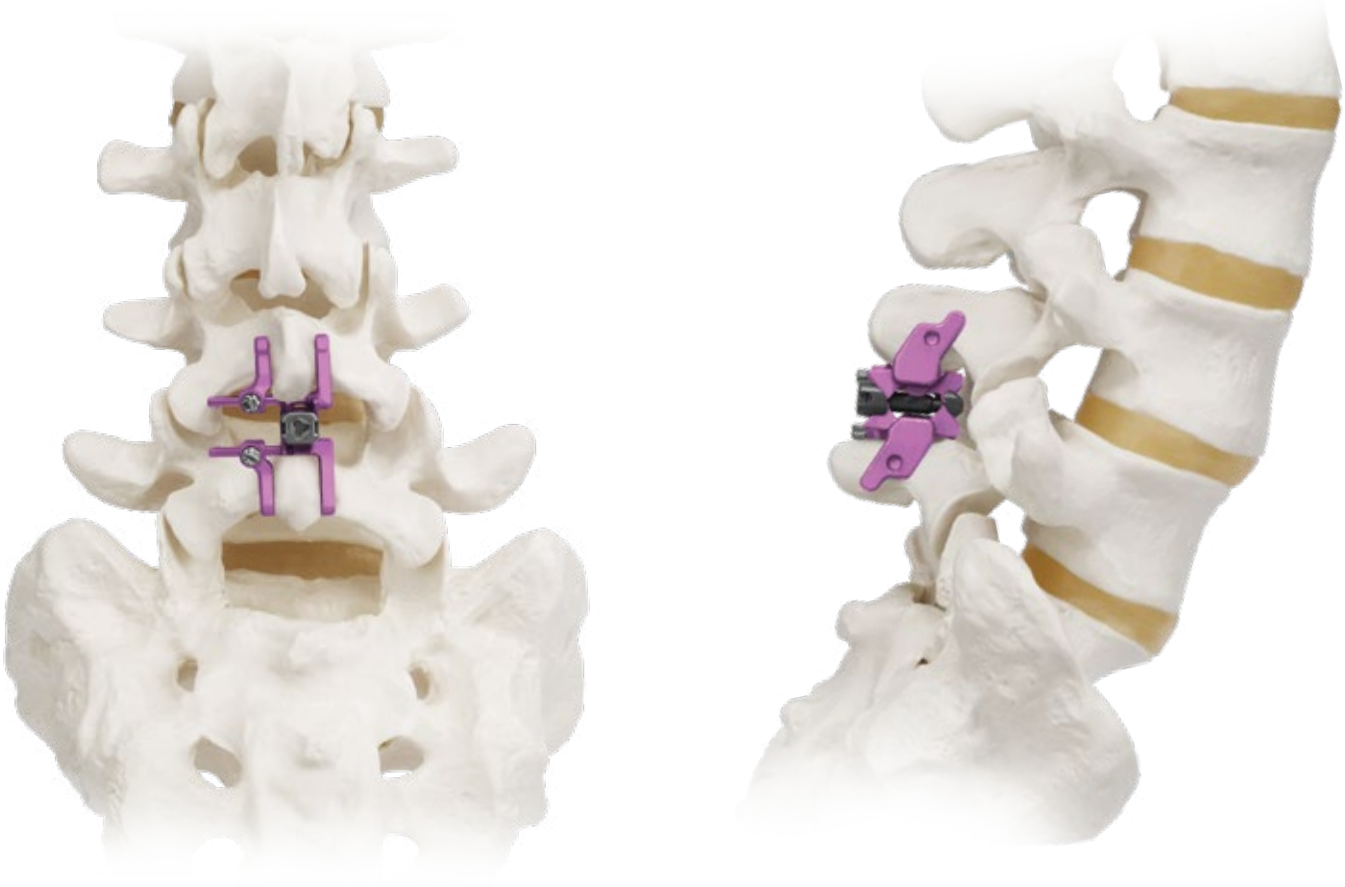


Placing the Parallel Compressor over the locking plates



Final tightening of the set screws with compressor engaged

FINAL CONSTRUCT



Supplemental fixation required.
Not intended for stand-alone use.

OPTIONAL: REPOSITIONING AND/OR REMOVAL

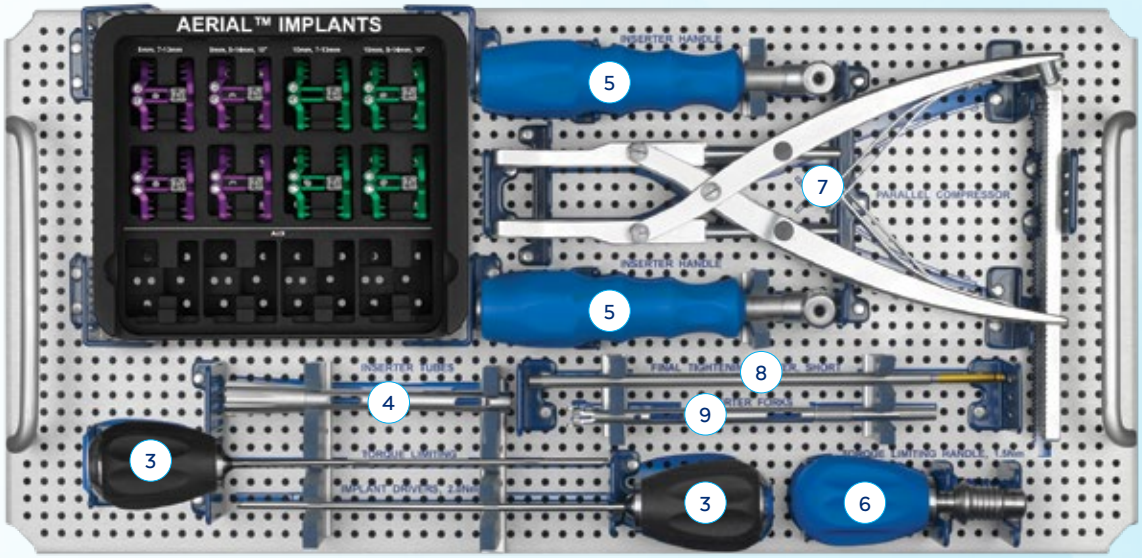
To reposition or remove, attach the implant inserter to the implant. After the inserter is reattached, loosen the set screws by using the Final Tightening Driver, Short. Release the spikes on the locking plates from the spinous process bone. Gently rock the locking plates back and forth if needed. Once the spikes are released, contract the implant height by rotating the Implant Driver counterclockwise. The implant can be repositioned or removed once the implant is fully contracted.

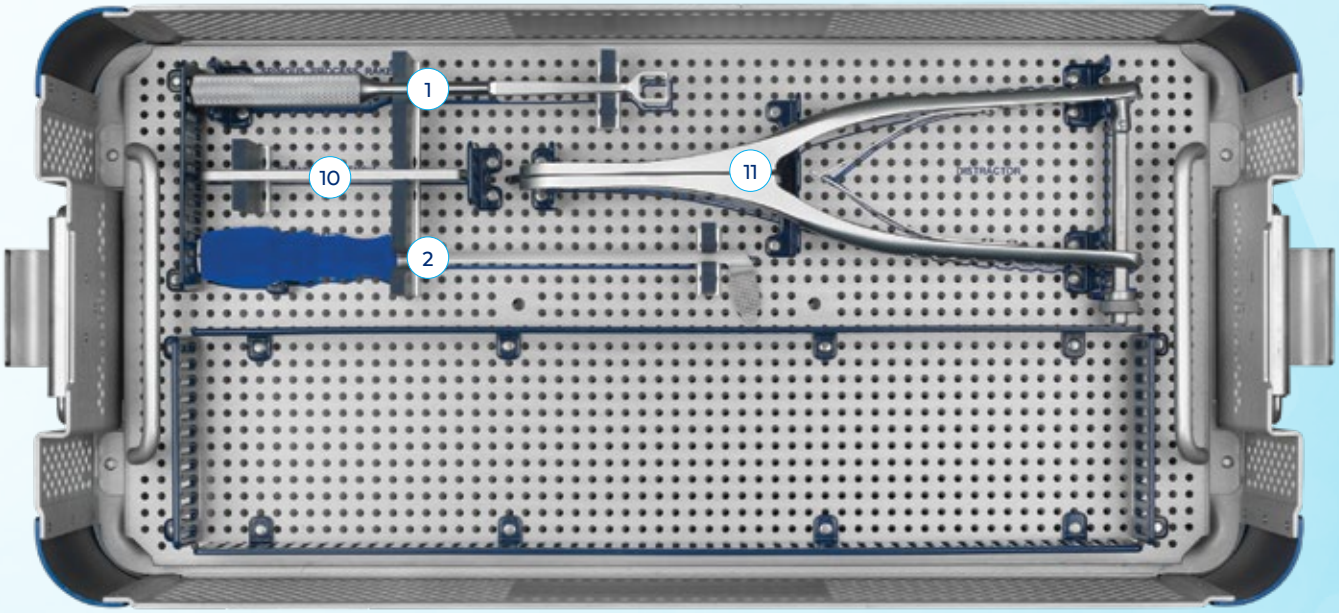
The implant may be damaged if the height is not reduced prior to repositioning, removing, or if the spikes are still engaged.

AERIAL™
IMPLANTS AND INSTRUMENTS 9117.9001

Implants		QTY
1117.0001	AERIAL™ Implant 8x22mm, 7-13mm	2
1117.0101	AERIAL™ Implant 10x22mm, 7-13mm	2
1117.0021	AERIAL™ Implant 8x22mm, 8-14mm, 10°	2
1117.0121	AERIAL™ Implant 10x22mm, 8-14mm, 10°	2

	Instruments		QTY
1	688.060	Spinous Process Rake	1
2	6117.0070	Rasp	1
3	6117.0003	Torque Limiting Implant Driver, 2.0Nm	2
4	6117.0002	Inserter Tube	2
5	694.005	Inserter Handle	2
6	6117.0015	Torque Limiting AO Quick Connect Handle, 1.5Nm	1
7	6117.0452	Parallel Compressor	2
8	6117.0185	Final Tightening Driver, Short	1
9	6117.0008	Inserter Fork	2
10	687.509	Spanner Wrench	1
11	688.300	Distractor	1
	9117.0001	Implant and Instrument Graphic Case	


AERIAL™ IMPLANTS
INSERTER HANDLE
5
INSERTER HANDLE
5
7
PARALLEL COMPRESSOR
8
4
9
3
3
6


1
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2

IMPORTANT INFORMATION ON AERIAL™ INTERSPINOUS FIXATION

DESCRIPTION

AERIAL™ Interspinous Fixation is an expandable non-cervical interspinous fixation device that is used to provide supplemental stabilization of spinal segments to support fusion. The components are available in a range of sizes to fit the anatomical needs of a variety of patients. AERIAL™ implants are composed of titanium alloy (per ASTM F136), cobalt chrome (per ASTM F1537), and PEEK radiolucent polymer (per ASTM F2026).

INDICATIONS

The AERIAL™ Interspinous Fixation is a posterior non-pedicle supplemental fixation device, intended for use at a single level in the non-cervical spine (T1-S1). It is intended for plate fixation/attachment to the spinous processes for the purpose of achieving supplemental fusion in the following conditions: degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), and/or tumor. AERIAL™ is intended for use with allograft or autograft bone and is not intended for stand-alone use.

CONTRAINDICATIONS

The contraindications include, but are not limited to: Active infectious process or significant risk of infection (immunocompromise); local inflammation, fever, or leukocytosis, morbid obesity; pregnancy; mental illness; distorted anatomy caused by congenital abnormalities; any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities; rapid joint disease, bone absorption osteopenia, and/or osteoporosis; suspected or documented material allergy or intolerance; incompetent or missing posterior arch (e.g. laminectomy, pars defect, severe osteoporosis); any case where metals must be mixed from different components; any case where the implant components selected for use would be too large or too small to achieve a successful result; any case where fracture healing is not required; any patient in which implant utilization would interfere with anatomical structures or expected physiological performance; any patient unwilling or unable to follow post-operative instructions; soft tissue deficit not allowing sound closure; any medical or mental condition which could exclude the patient at high risk from surgery of this severity; any case not described in the indications.

Certain degenerative diseases or underlying physiological conditions such as diabetes or rheumatoid arthritis may alter the healing process, thereby increasing the risk of implant breakage.

Mental or physical impairment which compromises a patient's ability to comply with necessary limitations or precautions may place that patient at a particular risk during postoperative rehabilitation.

Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an effect on the stresses to which the implant is subjected.

WARNINGS

This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

The safety and effectiveness of AERIAL™ has not been established for spinal indications beyond those stated in the Indications section.

PRECAUTION

Implantation of these devices should be performed only by experienced spinal surgeons with specific training in the use of the system due to a risk of serious injury to the patient. Preoperative planning and patient anatomy should be considered when selecting implants.

Surgical implants must never be reused. An explanted implant must never be re-implanted. Even though the device may appear undamaged, it may have small defects and internal stress patterns which could lead to breakage.

Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions. Whenever possible or necessary, an imaging system should be utilized to facilitate surgery.

Correct handling of the implant is extremely important. Implants should be protected from damage including scratches, nicks and corrosive environments. The operating surgeon should avoid any notching or scratching of the device. The implants should not be contoured as this may create stress patterns which could lead to breakage or may disrupt implant function. Aseptic handling is to be observed during the implantation.

Implants can loosen, fracture, corrode, migrate, cause pain, or stress shield bone even after fusion occurs, particularly in young, active patients. While the surgeon must have the final decision on implant removal, we recommend that whenever possible and practical for the individual patient, fixation devices should be removed once their service as an aid to healing is accomplished. Implant removal should be followed by adequate postoperative management.

Correct selection of the implant is extremely important. The potential for surgical success is increased by the selection of the proper size, shape and design of the implant. While proper selection can minimize risks, size and shape of human bones present limitations on the size and strength of implants. Internal fixation devices cannot withstand the activity levels and/or loads equal to those placed on normal, healthy bone. These devices are not designed to withstand the unsupported stress of full weight or load-bearing.

When using the device, the surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of this system.

The patient must be adequately instructed as to the risks and limitations of this system, and should be supplied with post-operative care and management instructions. Postoperative care and patient activity must be planned in such a way to avoid excess loading of the spinal column. Excessive loads or delayed or non-union may result in implant failure. The patient should be advised that non-compliance with post-operative instructions could lead to poor results, including implant failure.

Patients who smoke have been shown to have an increased incidence of non-union or pseudarthosis. These patients should be informed of this increased risk and counseled to discontinue tobacco use prior to and immediately after surgery.

Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be used in conjunction with titanium or titanium alloy implants. AERIAL™ implants should not be connected to components of other systems or manufacturer.

MRI SAFETY INFORMATION

The AERIAL™ Interspinous Fixation is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 1 W/kg

Under the scan conditions defined above, the AERIAL™ Interspinous Fixation is expected to produce a maximum temperature rise of less than or equal to 3.9°C after 15 minutes of continuous scanning.

The image artifact caused by the device is not expected to extend beyond 35mm from the device when imaged with a gradient echo pulse sequence and a 3.0 Tesla MRI 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.

The instruments are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments and instrument trays and cases must be cleaned, 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 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.
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

These implants may be available sterile or nonsterile. Instruments are available nonsterile.

Sterile implants are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed, Tyvek 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 have 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	Rx ONLY	PRESCRIPTION USE ONLY

DI206 REV A

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