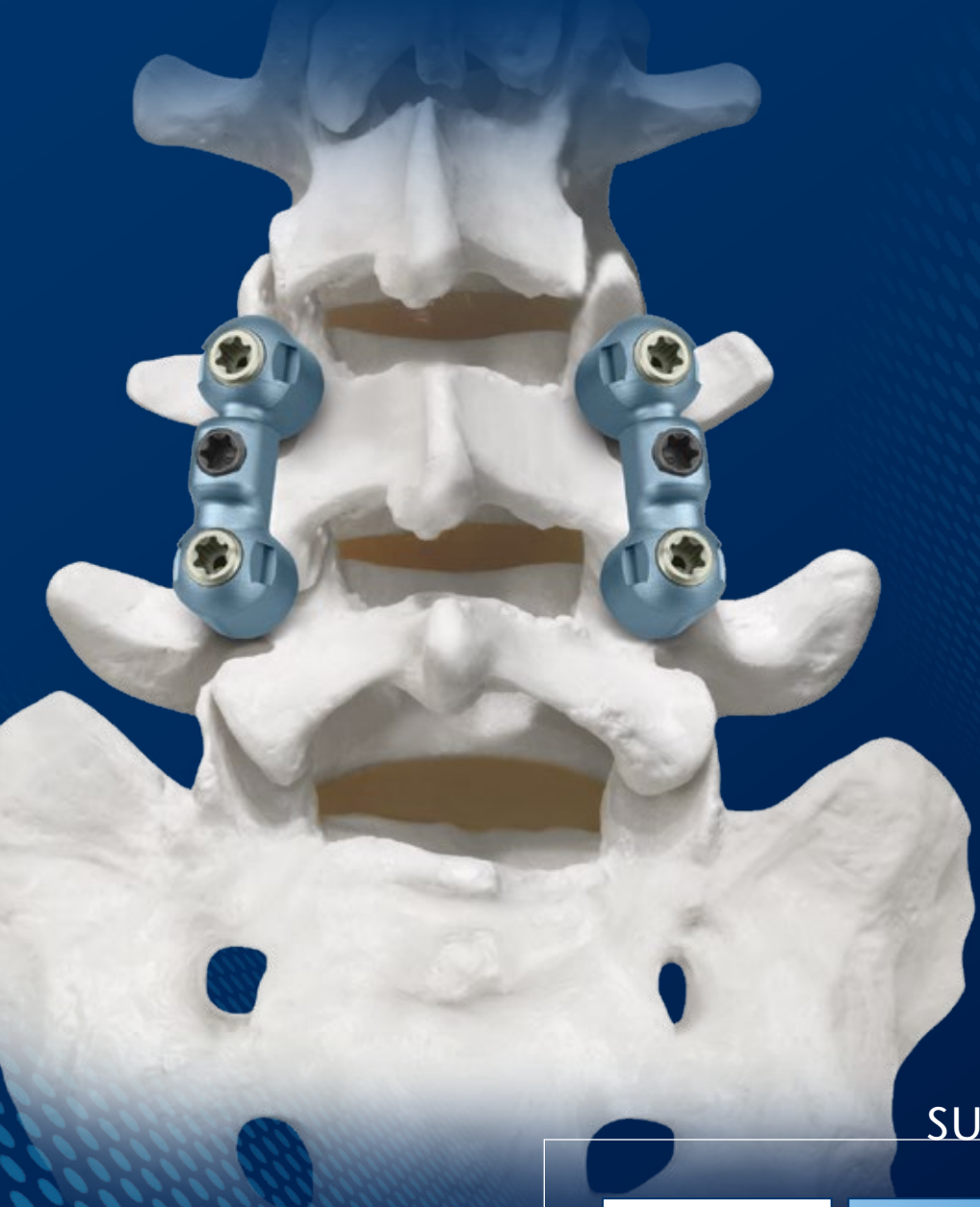

Life moves us

SURGICAL TECHNIQUE

CREO LINX™

Single Level Connector for CREO AMP® Stabilization System

GLOBUS MEDICAL

Life moves us

At Globus, we move with a sense of urgency to deliver innovations that improve the quality of life for patients with spinal disorders. We are inspired by the needs of these patients and also the needs of the surgeons and health care providers who treat them.

This passion combined with Globus' world class engineering transforms clinical insights into tangible spine care solutions. We are driven to provide the highest quality products to improve the techniques and outcomes of spine surgery so patients can resume their lives as quickly as possible. We extend our reach beyond our world class implants, instrumentation, and service by partnering with researchers and educators to advance the science and knowledge of spine care.

The energy and enthusiasm each of us bring everyday to Globus is palpable. We are constantly in the pursuit of better patient care and understand that speed is critical because life cannot wait.

GLOBUS
MEDICAL

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CREO LINX™

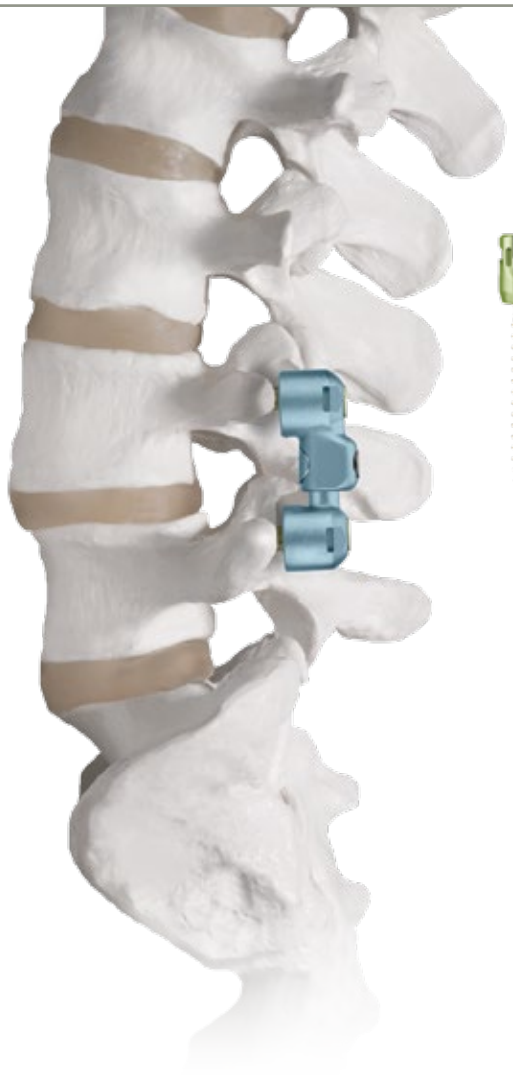
The CREO LINX™ connector is an innovative single level connector option for the CREO AMP® system. This implant locks to the modular screw posts, replacing one rod, two screw heads, and two locking caps on each side of the construct. Due to the integration of these components the CREO LINX™ connector minimizes the steps for a single level lumbar fusion.

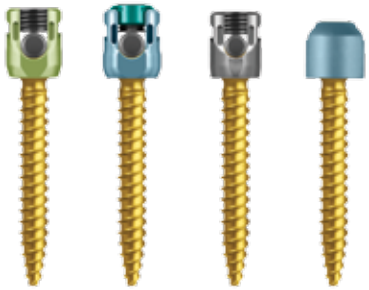
The CREO LINX™ connector is low profile and is compatible with minimally invasive procedures.

CREO LINX™ is designed with the ability to translate interoperatively, allowing for compression and distraction, and providing the optimum fit for varying patient anatomy.

CREO LINX™

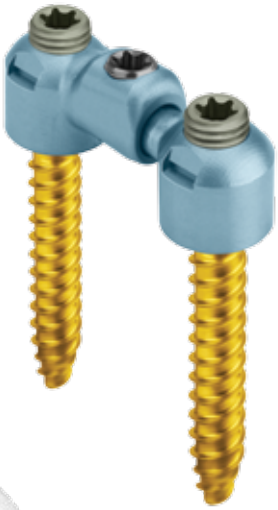
DISTINGUISHING CHARACTERISTICS





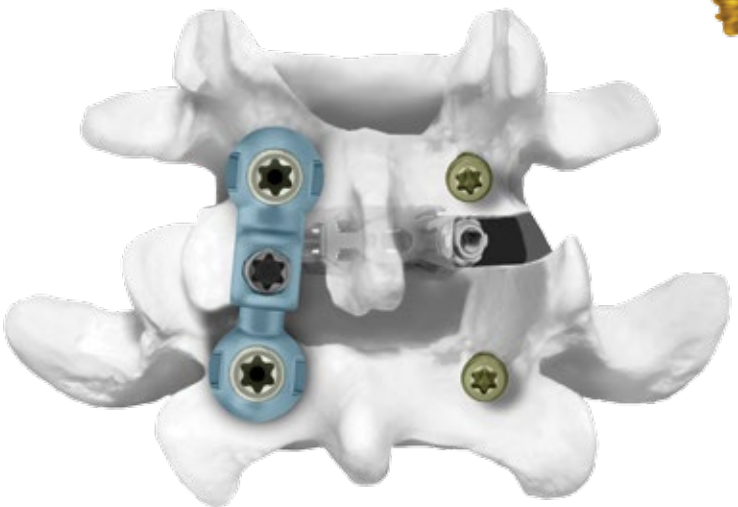
Low-Profile

The CREO LINX™ connector provides a competitively low profile with a rounded design to decrease prominence and allow for improved anatomical fit.



Efficiency

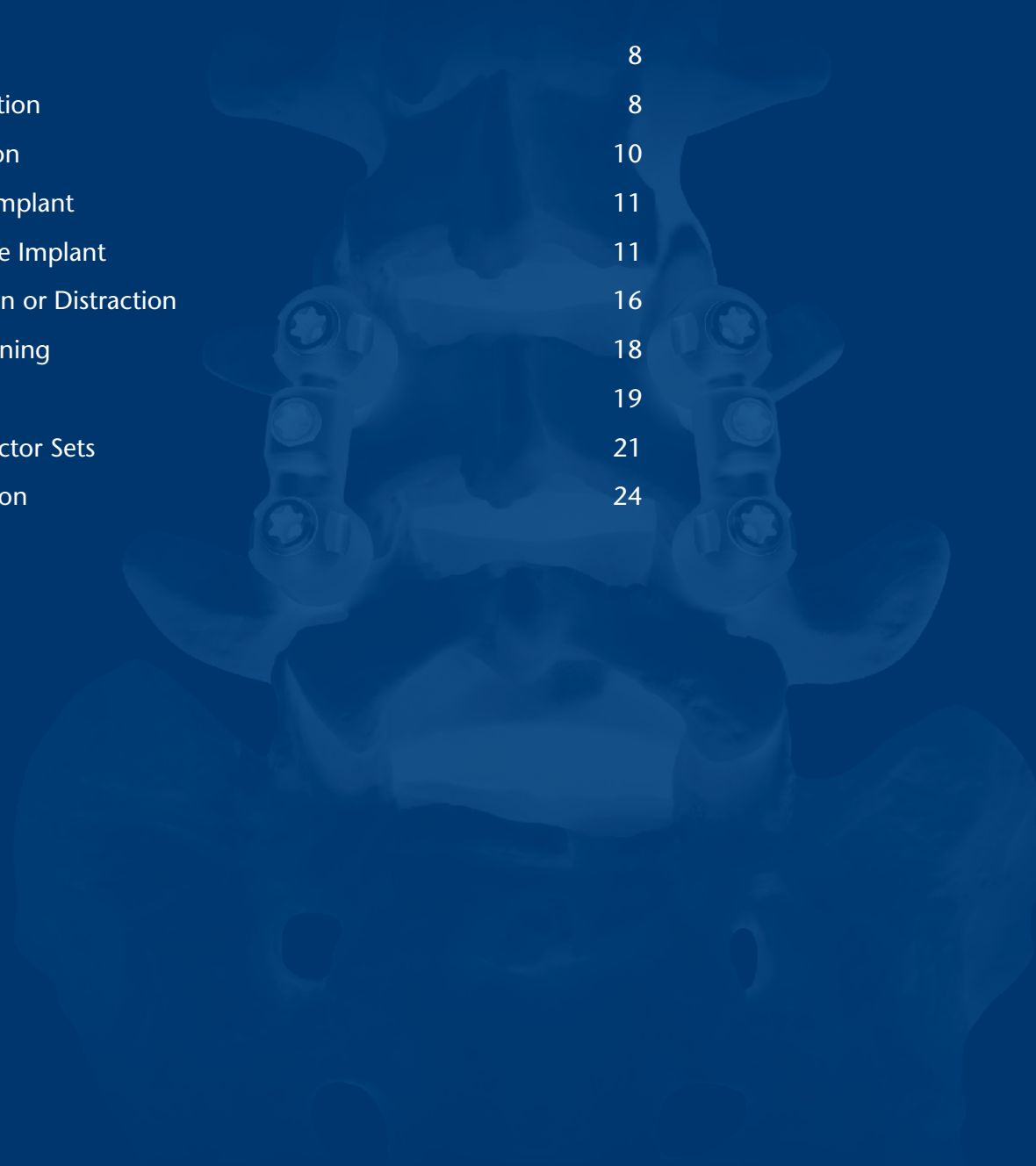
The CREO LINX™ connector integrates five components into one, reducing the number of steps in a single level construct.



Multiple Surgical Applications

CREO LINX™ can be used in open, minimally invasive, and CentraLIF™ procedures. The set screws are cannulated to accommodate insertion over a K-wire.

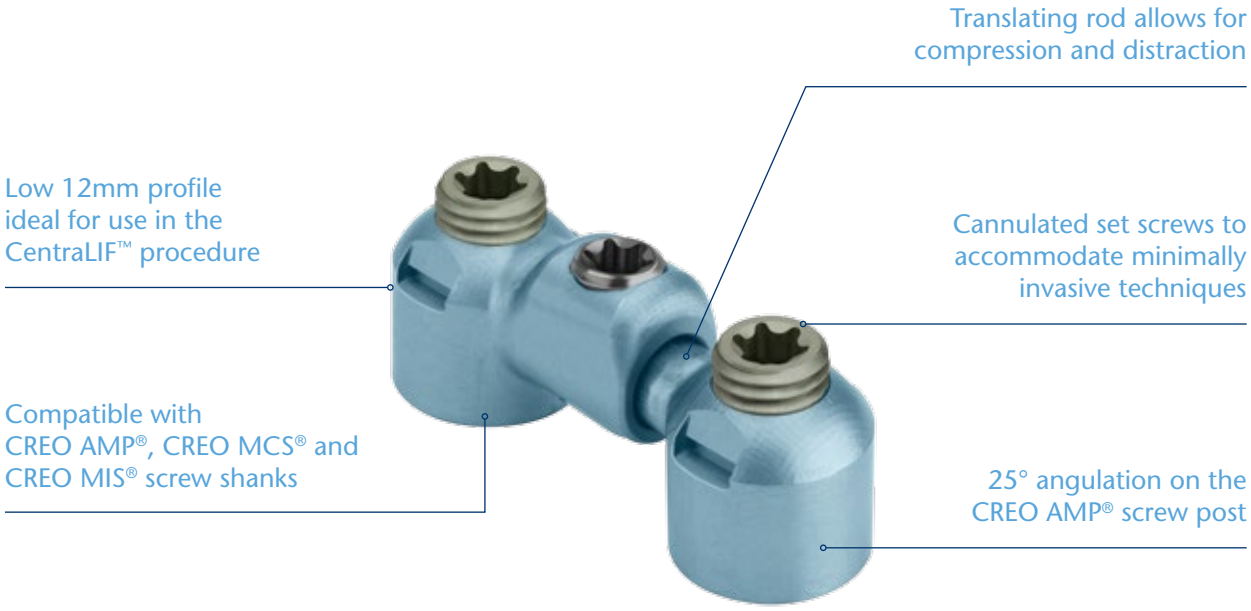
CONTENTS



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.

IMPLANT OVERVIEW

CREO LINX™ Connector



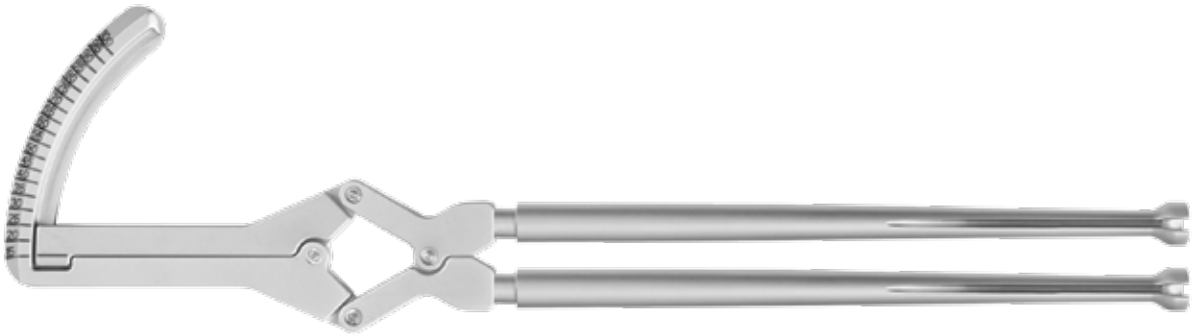
4 Length Options

Lengths		
22–25mm		
25–30mm		
30–35mm		
35–45mm*		

**Additionally Available*

INSTRUMENT OVERVIEW

Insertion Instruments



CREO LINX™ Caliper 6119.6060

Decortication Tool, Radial Cutting, Threaded, 1/4" Quick-Connect 6120.0070

Low Profile Connector Inserter 6119.6040

Low Profile Connector Inserter Driver 6119.6041

Compression Instrument

CREO LINX™ Compressor 6119.6050

Locking Instruments

Connector Counter-Torque 6119.6015

Connector Counter-Torque, Center 6119.6016

Disassembly Instrument

Low Profile Connector Inserter Disassembly Tool 6119.6042

CREO® Core Set Instruments*

Driver Shaft, 1/4" Quick-Connect, Short 6067.0050

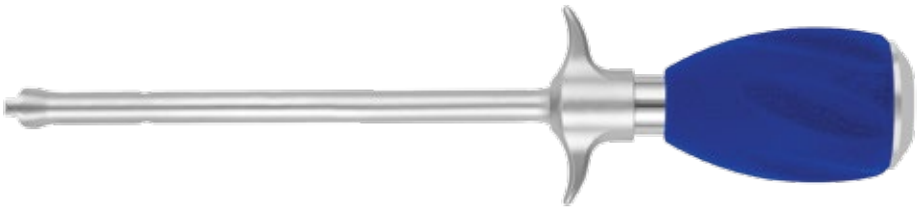
Straight Handle, Ratcheting, 1/4" Quick-Connect 6067.0010

Ratcheting Torque-Limiting Handle, 1/4" Quick-Connect 6067.0040

Additionally Available Instruments

CREO LINX™ Forceps 6119.6043

CREO LINX™ Distractor 6119.6055



Connector Inserter 6067.6000

**CREO LINX™ Connector Set is not a stand-alone set*

CREO LINX™ SURGICAL TECHNIQUE

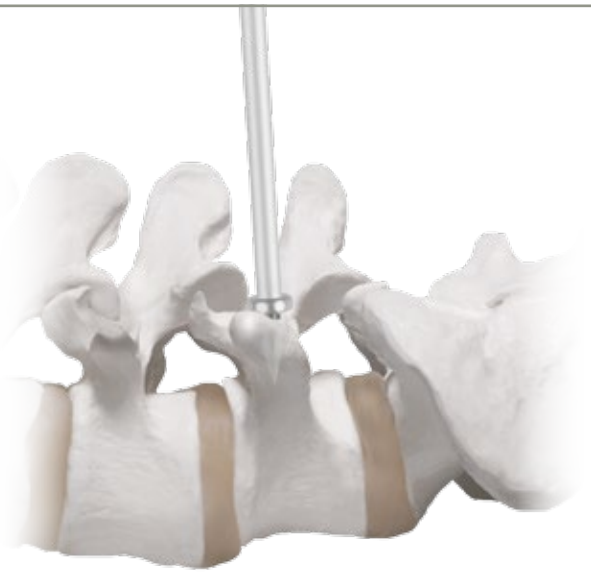
CREO LINX™ is not a stand-alone set. CREO® Core Instruments, CREO AMP® Degen Implants and CREO AMP® Degen Instrument sets are required.

Step 1 Approach

The patient is placed under anesthesia and positioned prone. The operative area is carefully cleaned and an incision is made at the appropriate level(s). Lateral C-arm fluoroscopy or other radiographic methods can be utilized throughout surgery to ensure correct screw placement. Preoperative planning is recommended to estimate screw location and sizes. Radiographic evaluations may be completed prior to surgery. Interbody fusion technique may be completed prior to or following screw insertion.

There are various techniques for pedicle screw and rod insertion. For the purposes of this technique guide, a Wiltse paramedial approach and building of an L4-L5 construct is shown.

The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels. Please refer to the product insert printed at the back of this technique guide for complete description, indications, contraindications, warnings, and precautions.



Preparing pedicle pathway

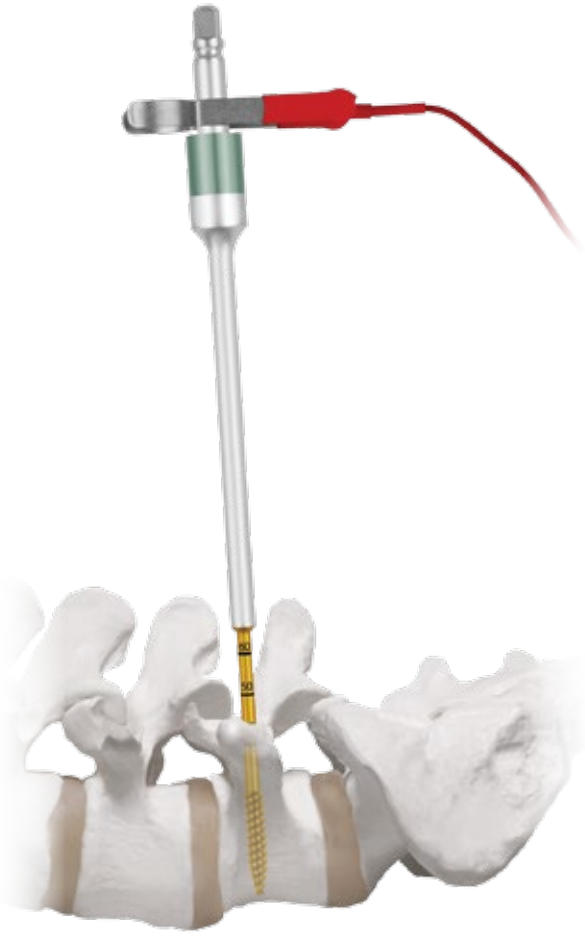
Step 2 Screw Insertion

Pedicle Preparation

Locate the pedicles and remove bone and/or soft tissue as needed using standard instruments. Use the **Pedicle Awl** to perforate the pedicle cortex.

Use a **Pedicle Probe** to open the pedicle pathway. Demarcations every 10mm on the probe indicate the depth of the pathway and help determine proper screw length. Use a **Ball Tip Probe** to verify that the walls of the prepared pedicle pathway are not violated. Demarcations every 10mm on the probe indicate the depth of the pathway and can also help determine proper screw length.

Pedicle access may be monitored for neurophysiological response by attaching the **Spring Clip** on the selected taps.*



Using the Spring Clip

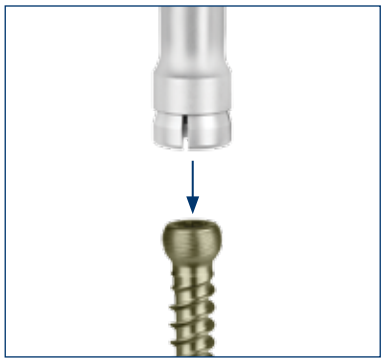
**Globus Medical does not provide intraoperative neurophysiological monitoring equipment.*

Screw Insertion (cont'd)

Loading the Screwdriver

Select the appropriate pedicle screw diameter and length. CREO AMP® screws are self-tapping, however if tapping is preferred, the appropriate size tap may be used. Assemble the **Modular Rigid Driver** to the **Straight Handle, Ratcheting, 1/4" Quick-Connect** or **T-Handle, Ratcheting, 1/4" Quick-Connect**.

Ensure finger grip is pulled back towards the handle, and knob is fully loosened. Holding the threaded portion of the selected screw, engage the driver tip into the screw post.



Engaging the screw

Once fully engaged, rotate the knob of the screwdriver clockwise until tight. Push the oblong button above the knob to activate the lock. The lock will automatically slide distally, meeting the knob, and securing the screw post to the screwdriver. The screw post is now ready for insertion.

Note: The knob may be further tightened, after the lock has been activated, by rotating the knob clockwise for increased rigidity. The lock prevents the screwdriver from loosening and disengaging the screw.

To disengage, grasp the lock by the finger grips on each side. Pull the lock back towards the screwdriver handle. There is an audible click as the button is released. Rotate the knob counterclockwise to loosen and disengage the screwdriver from the screw post.

Alternatively, the **Self-Retaining Driver Shaft, 1/4" Quick-Connect** attached to the Straight Handle, Ratcheting, 1/4" Quick-Connect or T-Handle, Ratcheting, 1/4" Quick-Connect may be used.

Screw loaded on the screwdriver

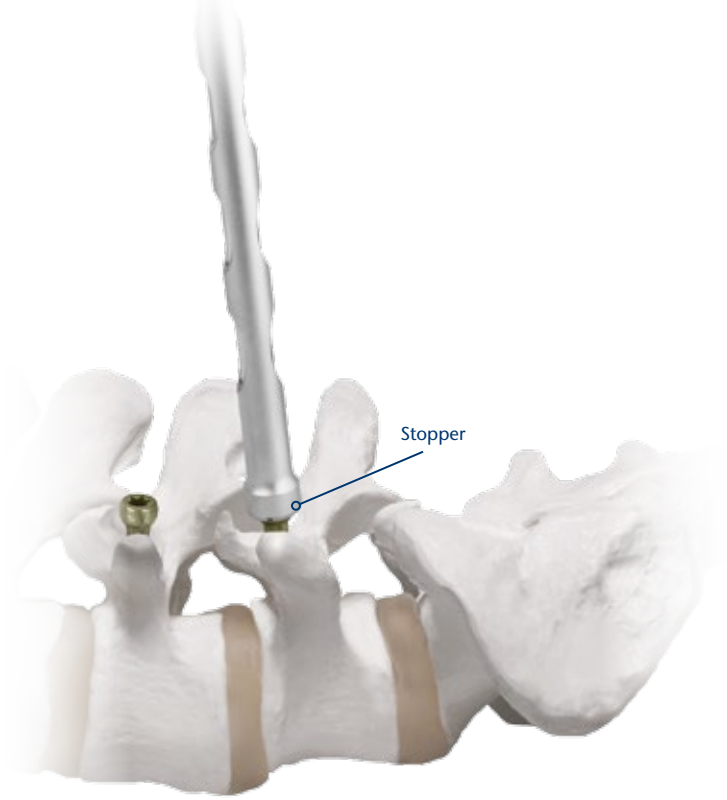
Disengaging screw

Screw Insertion (cont'd)

Inserting Screws Posts

Drive the screw posts into the prepared pedicles using the Modular Rigid Driver Assembly. The driver stopper indicates that the screw is implanted to the desired depth. When complete, disengage the driver from the screw. If the screws need to be removed or repositioned, the Self-Retaining Driver Shaft, 1/4" Quick-Connect may be used.

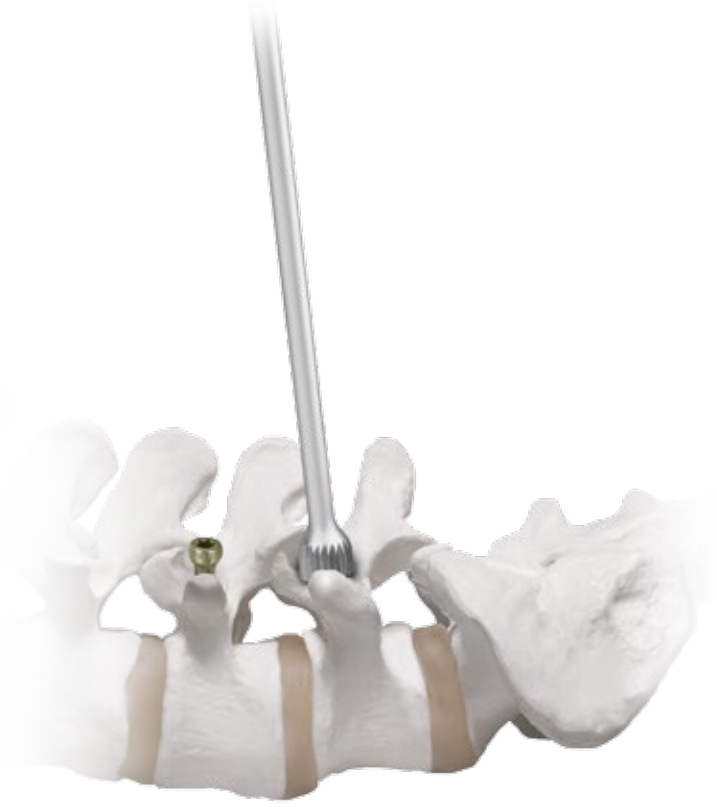
Screw insertion into the prepared pedicle may also be neuromonitored. The **Insulated Probe** may be used for triggered EMG monitoring while introducing the screw into the pedicle.*



Screw Insertion

Step 3 Decortication

To ensure optimal clearance for connector attachment, use the **Decortication Tool Radial Cutting, Threaded, 1/4" Quick-Connect** and T-handle, Ratcheting, 1/4" Quick-Connect to remove any surrounding tissue and bone that is immediately adjacent to the screw post.



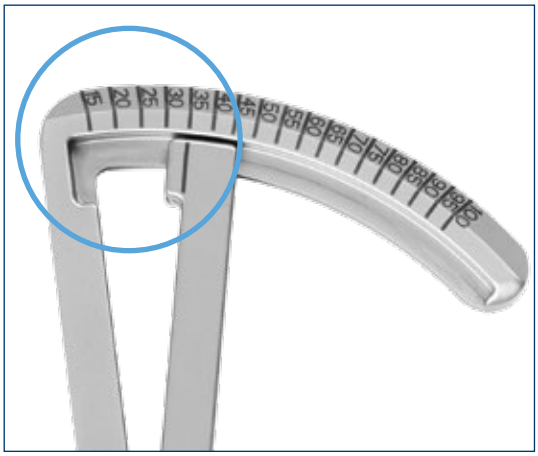
Using the decortication tool

**Globus Medical does not provide intraoperative neurophysiological monitoring equipment.*

Step 4 Sizing the Implant

The **CREO LINX™ Caliper** is used to determine implant size. Place the legs of the caliper over each screw post. Ensure the screw heads are fully seated in the pocket of each leg. The caliper scale indicates the distance between the two screw posts. Select the appropriate implant length based on this measurement. If the value is between implant sizes, the smaller size should be used.

Measuring the distance between screws



Reading the measurement

Step 5 Inserting the Implant

Loading the Inserters

Ensure the **Low-Profile Connector Inserter** is in the unlocked position and hold it over the implant module. Align the tabs on the inserter tip with the cutouts on the implant.

Unlocked

Locked

Inserting the Implant (cont'd)

Lower the inserter directly over the implant, and apply light pressure. Listen for an audible click; the implant is now attached to the inserter.

Attaching the implant

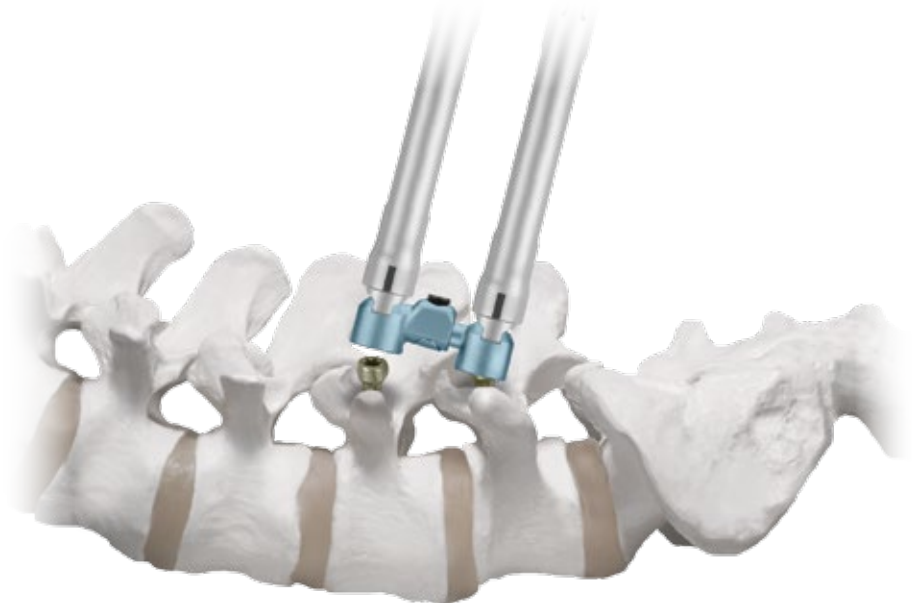
Implant attached to the inserter

Repeat the previous steps to attach the second inserter to the other end of the connector. Lift the implant out of the module, keeping the inserters aligned.

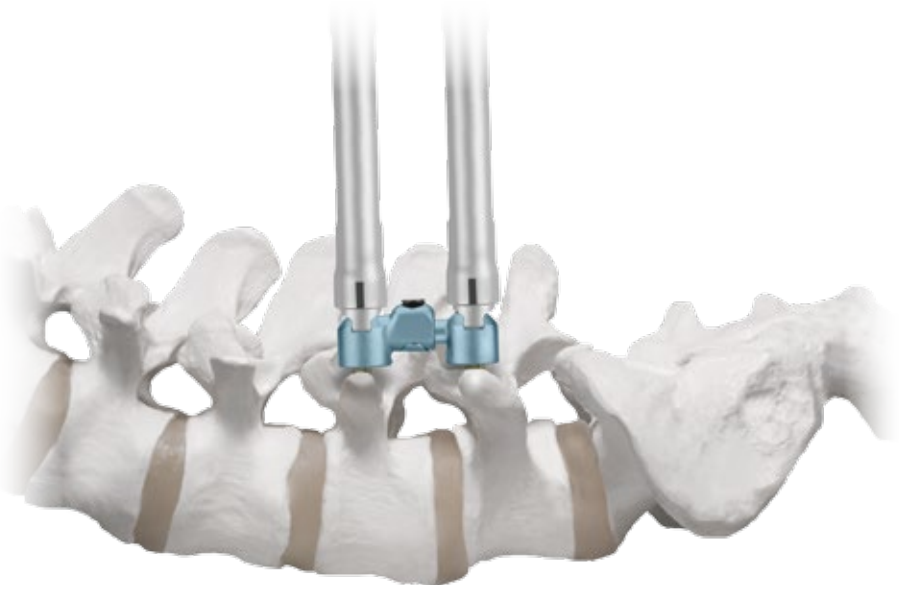
Inserting the CREO LINX™ Connector

Hold both inserters with the implant attached over the screw posts. Lower one side of the implant to the top of one of the screw posts, and apply axial force. Listen for the audible click; one side of the implant is now attached to the screw post.

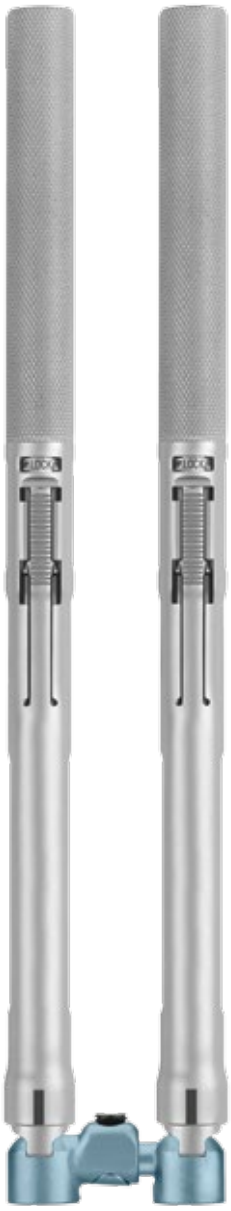
Repeat the steps above to attach the other side of the implant.



Attaching implant to first screw post



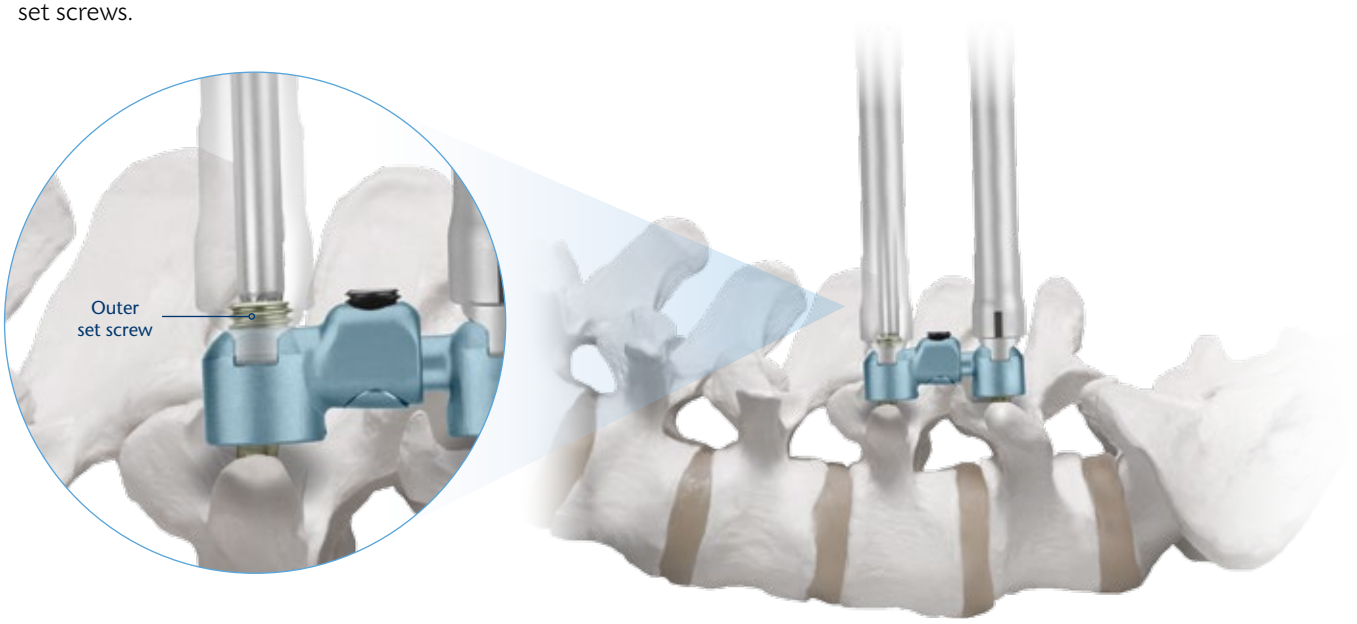
Attaching implant to second screw post



Implant with both inserters attached

Inserting the Implant (cont'd)

Insert the **Low Profile Connector Inserter Driver** through the inserter. Fully seat the driver into one of the outer set screws.

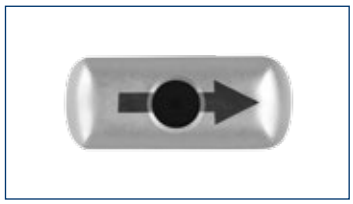


Engaging the driver into the set screw

Provisionally tighten the first outer set screw by rotating the driver clockwise approximately one turn or until the shoulder on the driver is flush with the top of the inserter. **DO NOT advance the set screw any further.**

Repeat the above steps for the other outer set screw. The implant is now locked onto the screw posts.

Driver fully seated in set screw



Use the arrow at the end of the driver to count rotations

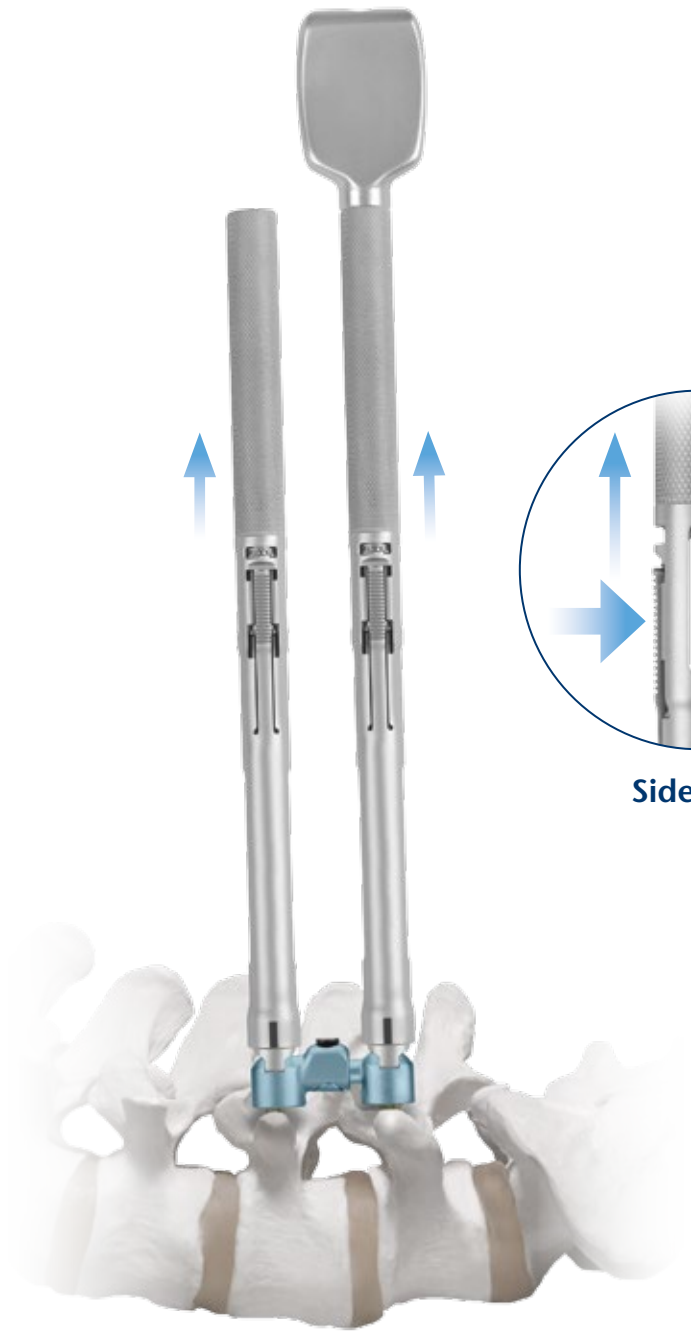
Driver FLUSH with inserter

Holding the knurled portion of both inserters, pull upward to confirm that the implant is secured to the screw posts.
Note: Avoid compressing the side tabs on the inserter when confirming that the implant is secured.

If the connector disengages from the screw post during this step, rotate the driver counterclockwise until it reaches a hard stop to fully back out the set screw. Repeat the previous insertion steps.

Disengaging the Inserters

Remove both inserters by compressing the side tabs and pulling upward.



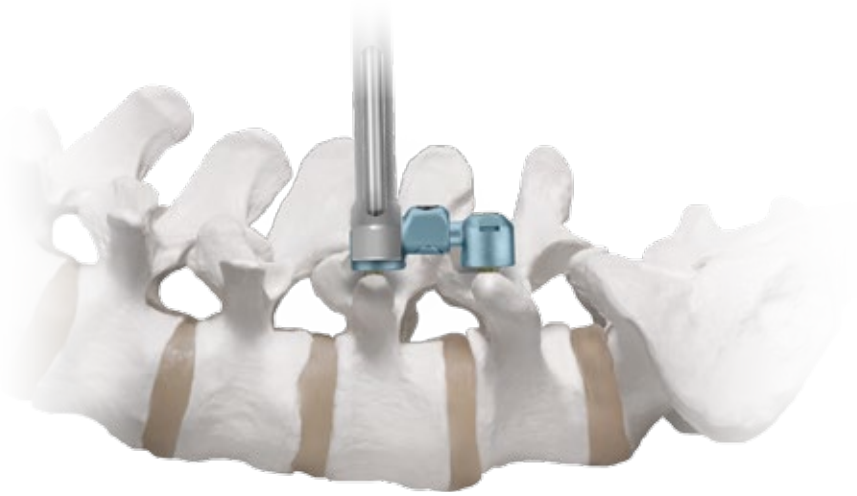
Confirming the implant connection to the screw post

Disengaging the inserters

Step 6 Compression or Distraction

The CREO LINX™ Connector may be compressed or distracted along the rod as necessary using the **CREO LINX™ Compressor** or **CREO LINX™ Distractor**

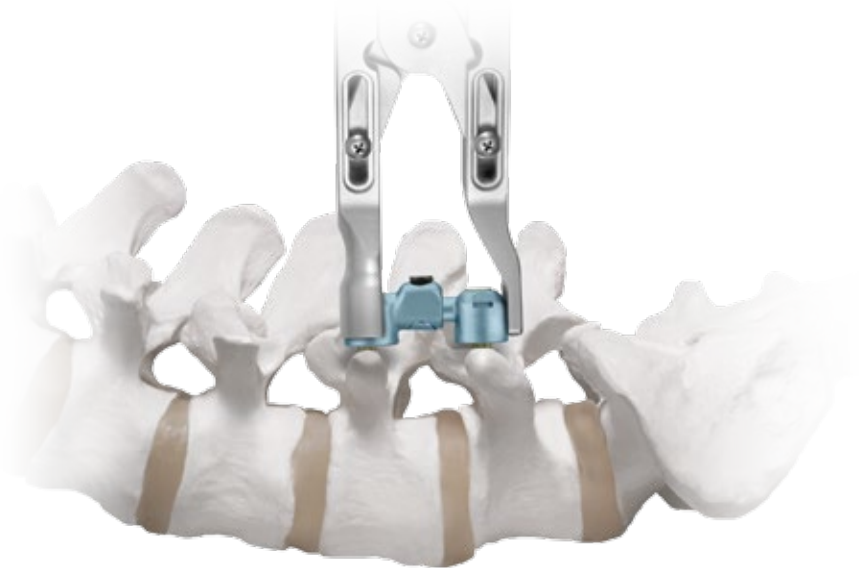
Attach the **Driver Shaft 1/4" Quick-Connect, Short** to the Straight Handle, Ratcheting, 1/4" Quick-Connect or T-Handle, Ratcheting, 1/4" Quick-Connect. Insert the driver assembly into the **Connector Counter-Torque** and lower the driver tip into one of the outer set screws. Slide the counter-torque over the connector, ensuring it is fully seated. Provisionally tighten the set screw. Repeat for the other outer set screw.



Provisionally tighten

Compression

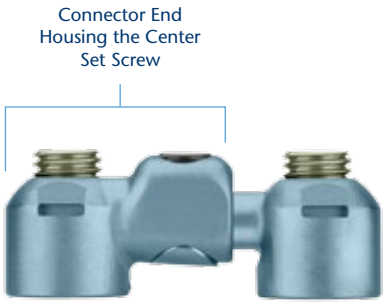
Align the rounded compressor tip with the end of the connector. Place the flat compressor tip around the ***outside*** of the other end. Compress the implant as needed.



Compression

Distraction

Align the rounded distractor tip with the connector end housing the center set screw. Place the flat distractor tip on the ***inside*** of the other end. Distract the implant as needed.



Distraction

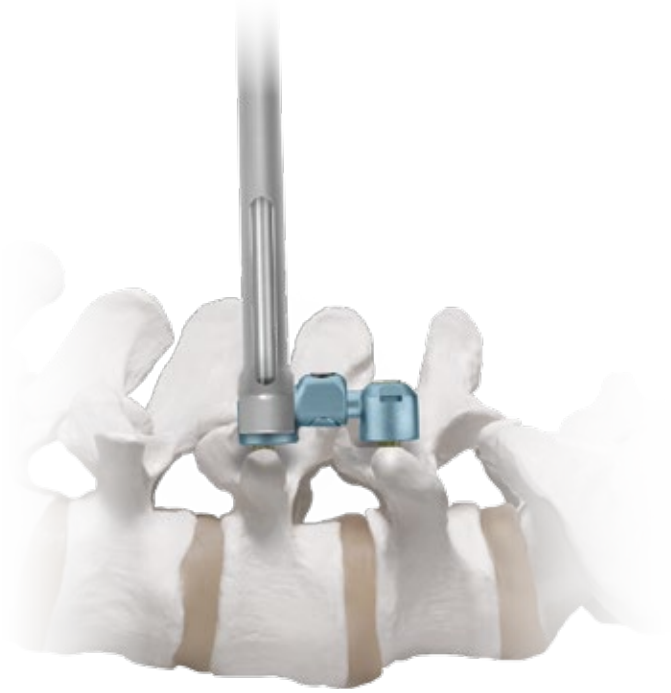
When the appropriate amount of compression or distraction is achieved, provisionally tighten the center set screw using the Driver Shaft, 1/4" Quick-Connect, Short**,** attached to the Straight Handle, Ratcheting, 1/4" Quick-Connect.

Provisionally tightening the center set screw

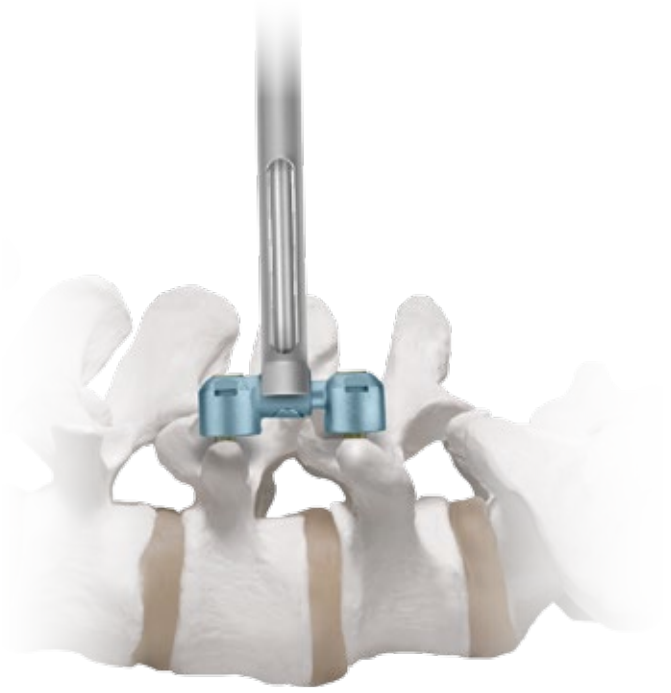
Step 7 Final Tightening

Final tightening of the three set screws is necessary to secure the construct. Attach the Driver Shaft, 1/4" Quick-connect, Short, to the **Ratcheting Torque-Limiting Handle, 1/4" Quick-Connect**. Starting with the outer set screws, insert the torque-limiting driver assembly into the connector counter-torque. Lower the driver tip into the set screw and visually confirm that it is fully engaged. Slide the counter-torque over the connector, ensuring that it is fully seated. Rotate the torque-limiting driver assembly until it reaches the torque limit (5.5Nm), two audible clicks. Repeat for the second outer set screw.

To final tighten the center set screw, insert the torque-limiting driver assembly into the **CREO LINX™ Counter Torque, Center**. Lower the driver tip into the set screw and visually confirm it is fully engaged. Slide the counter-torque over the connector, ensuring that it is fully seated. Rotate the torque-limiting driver assembly until it reaches the torque limit (5.5Nm), two audible clicks. Repeat steps 1–7 on the contralateral side.

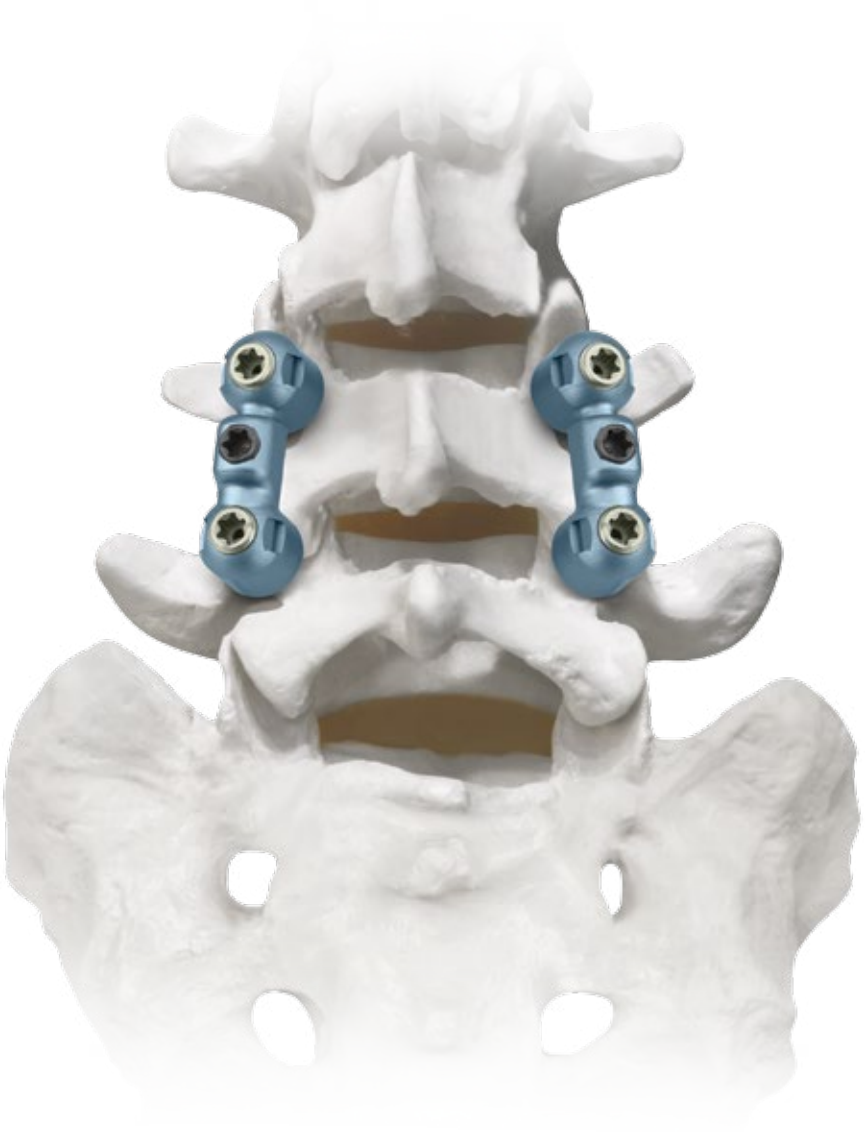


Final tightening the outer set screw

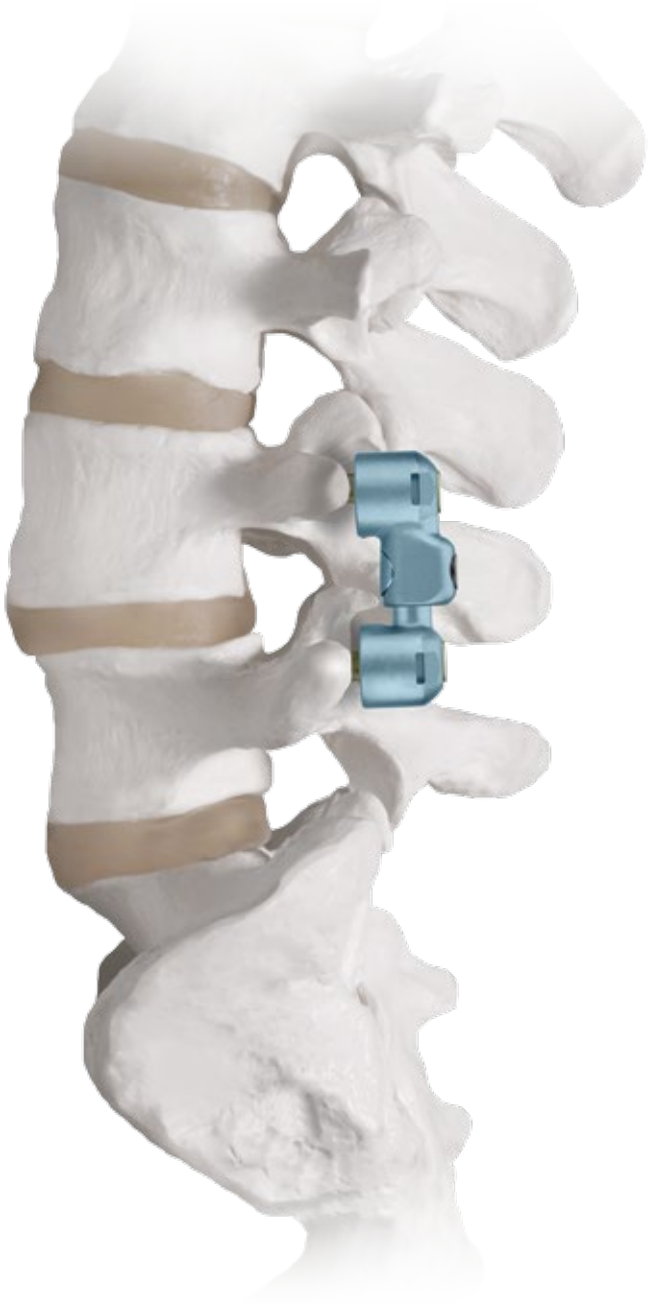


Final tightening the center set screw

Final Construct



Final Construct

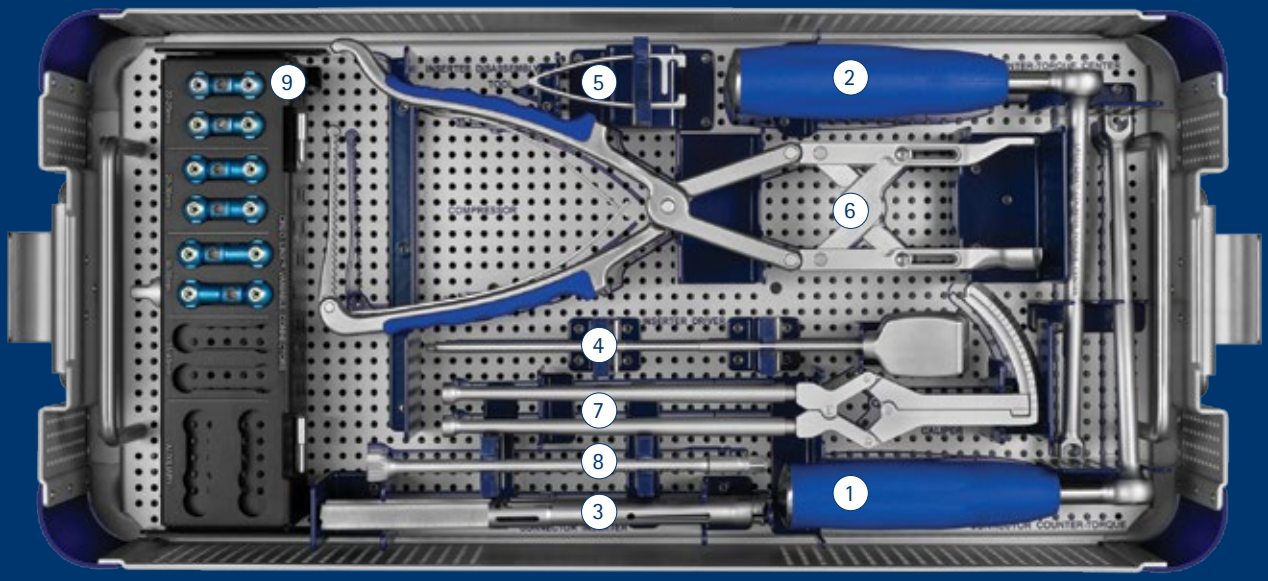


CREO LINX™ Connector Sets

CREO LINX™ is NOT a stand-alone set. The following sets ware needed for a procedure:

Set ID	Set Name
9067.9000	CREO® Core Instruments Set
9119.9026	CREO LINX™ Connector Set
PLUS ONE OF THE FOLLOWING PAIRS	
9119.9010 9119.9014	CREO AMP® 5.5 Degen Implants Set CREO AMP® 5.5 Degen Instruments Set
OR	
9120.9010 9120.9014	CREO AMP® Threaded Degen Implants Set CREO AMP® Threaded Degen Instruments Set

CREO LINX™ CONNECTOR SET



CREO LINX™ Connector Set 9119.9026

Implants

Part No.	Description	Qty
1119.7320	CREO LINX™ Variable Connector, 22-25mm	2
1119.7325	CREO LINX™ Variable Connector, 25-30mm	2
1119.7330	CREO LINX™ Variable Connector, 30-35mm	2
1119.7335	CREO LINX™ Variable Connector, 35-45mm	

Instruments

	6067.6000	Connector Inserter	
1	6119.6015	Connector Counter Torque	1
2	6119.6016	CREO LINX™ Counter Torque, Center	1
3	6119.6040	Low Profile Connector Inserter	2
4	6119.6041	Low Profile Connector Inserter Driver	2
5	6119.6042	Low Profile Connector Inserter Disassembly Tool	1
	6119.6043	CREO LINX™ Forceps	
6	6119.6050	CREO LINX™ Compressor	1
	6119.6055	CREO LINX™ Distractor	
7	6119.6060	CREO LINX™ Caliper	1
8	6120.0070	Decortication Tool, Radial Cutting, Threaded, 1/4" Quick-connect	1
9	9119.0026	CREO LINX™ Connector Graphic Case	1
	9119.0126	CREO LINX™ Connector Module	

Items highlighted in gray are additionally available.

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

DESCRIPTION

The CREO® Stabilization System consists of rods, hooks, monoaxial screws, uniplanar screws, polyaxial screws, reduction screws, locking caps, t-connectors, head offset connectors, trans-iliac connectors, staples, and associated manual surgical instruments. Implants are available in a variety of sizes to accommodate individual patient anatomy. CREO® implants mate with 4.75mm, 5.5mm, and 6.35mm diameter rods. In addition, CREO® 5.5 Threaded screws and locking caps mate with 6.0mm diameter rods. Implant components can be rigidly locked into a variety of configurations for the individual patient and surgical condition. Polyaxial screws, hooks, and t-connectors are intended for posterior use only. Staples are intended for anterior use only. Rods and monoaxial screws may be used anteriorly or posteriorly. Locking caps are used to connect screws or hooks to the rod and trans iliac connectors.

The most common use of this screw, hook, and rod system in the posterior thoracolumbar and sacral spine is two rods, each positioned and attached lateral to the spinous process via pedicle screws and/or lamina, pedicle or transverse process hooks.

The most common use of this screw, hook, and rod system in the anterior thoracolumbar spine is one rod, positioned and attached to the vertebral bodies via monoaxial screws through an appropriate size staple.

Screws and hooks attach to the rods using a locking cap with an inner set screw. The size and number of screws are dependent on the length and location of the rod. Screws are inserted into a pedicle of the thoracolumbar and/or sacral spine. Screws may be used with a staple. The type and number of hooks are also dependent on the location in the spine needing correction and/or stabilization. Hooks are attached to the laminae, pedicles, or transverse process of the posterior spine.

T-connectors are modular components designed to connect the two rods of a construct and act as a structural cross member. The rod-clamping set screws secure the t-connectors to the rods. Additional set screws secure the adjustable cross members at the desired length. Additional connectors may be used to connect two rods, and are also secured using set screws.

CREO® Stabilization System S-rods and unit rods are specifically excluded for use in adolescent idiopathic scoliosis patients.

CREO® implants are composed of titanium alloy, cobalt chromium molybdenum alloy, or stainless steel, as specified in ASTM F136, F1295, F1472, F1537 and F138. Rods are also available in commercially pure titanium, as specified in ASTM F67. Screws are also available with hydroxyapatite (HA) coating per ASTM F1185. Due to the risk of galvanic corrosion following implantation, stainless steel implants should not be connected to titanium, titanium alloy, or cobalt chromium-molybdenum alloy implants.

The CREO® System includes manual surgical instruments manufactured from stainless steel, as specified in ASTM F899. Navigation Instruments are nonsterile, reusable instruments that can be operated manually, that are intended to be used with the Medtronic StealthStation® System.

INDICATIONS

The CREO® Stabilization System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1-S2/ilium), posterior hook fixation (T1-L5), or anterolateral fixation (T8-L5). Pedicle screw fixation is indicated for skeletally mature patients (including small stature) and for pediatric patients (CREO® 4.75 only). These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, and failed previous fusion (pseudoarthrosis). When used as an adjunct to fusion, the CREO® Stabilization System is intended to be used with autograft and/or allograft.

In addition, the CREO® Stabilization System is intended for treatment of severe spondylolisthesis (Grades 3 and 4) of the L5-S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implants after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3-sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the CREO® 4.75 Stabilization System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The CREO® 4.75 Stabilization System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

In order to achieve additional levels of fixation in skeletally mature patients, the CREO® Stabilization System rods may be connected to the REVERE® Stabilization System (5.5mm or 6.35mm rod), REVERE® 4.5 Stabilization System (4.5mm rod) or ELLIPSE® Occipito-Cervico-Thoracic Spinal System (3.5mm rod) using corresponding connectors. In order to achieve additional levels of fixation in pediatric patients, the CREO® Stabilization System rods may be connected to the REVERE® 4.5 Stabilization System using corresponding connectors. Refer to the REVERE®, REVERE® 4.5, or ELLIPSE® system package insert for instructions and indications of use.

Globus Navigation Instruments are intended to be used during the preparation and placement of CREO® screws during spinal surgery to assist the surgeon in precisely locating anatomical structures in either open or minimally invasive procedures. These instruments are designed for use with the Medtronic StealthStation® System, which is indicated for any medical condition in which the use of stereotactic surgery may be appropriate, and where reference to a rigid anatomical structure, such as a skull, a long bone, or vertebra, can be identified relative to a CT or MR based model, fluoroscopy images, or digitized landmarks of the anatomy.

WARNINGS

The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to degenerative disc disease, degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.

One of the potential risks identified with this system is death. Other potential risks which may require additional surgery, include:
- device component fracture,
- loss of fixation,
- non-union,
- fracture of the vertebrae,
- changes to spinal curvature,
- neurological injury, and
- vascular or visceral injury.

The safety and effectiveness of this device has not been established for use as part of a growing rod construct. This device is only intended to be used when definitive fusion is being performed at all instrumented levels.

Components of this system should not be used with components of any other manufacturer.

The components of this system are manufactured from titanium alloy, pure titanium, stainless steel and cobalt chromium-molybdenum alloy. Mixing of stainless steel implant components with different materials is not recommended for metallurgical, mechanical and functional reasons.

ADDITIONAL WARNINGS FOR PEDIATRIC PATIENTS

The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients not skeletally mature that undergo spinal fusion procedures may

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities ("crankshaft phenomenon") due to continued differential growth of the anterior spine.

Pediatric patients may be at increased risk for device-related injury because of their smaller stature.

PRECAUTIONS

The implantation of screw, hook and rod systems should be performed only by experienced spinal 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. Preoperative planning and patient anatomy should be considered when selecting screw diameter and length, and hook size.

The CREO® Stabilization System includes 4.75 implants intended for use with a 4.75mm rod, 5.5 implants intended for use with a 5.5mm rod, and 6.35 implants intended for use with a 6.35mm rod. CREO® 5.5 Threaded screws and locking caps are also intended for use with a 6.0mm rod.

Surgical implants are SINGLE USE ONLY and must never be reused. An explanted implant must never be reimplanted. Even though the device appears undamaged, it may have small defects and internal stress patterns which could lead to breakage.

The CREO® Stabilization System has not been evaluated for safety and compatibility in the MR environment. The CREO® Stabilization System has not been tested for heating or migration in the MR environment.

Based on fatigue testing results, when using the CREO® Stabilization System, 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.

ADDITIONAL PRECAUTIONS FOR PEDIATRIC PATIENTS

The implanting surgeon should consider carefully the size and type of implants most suitable for the pediatric patient's age, size, weight and skeletal maturity.

Since pediatric patients may have additional growth potential following implant surgery, the likelihood of a subsequent removal and/or revision surgery is greater than in adult patients.

CONTRAINDICATIONS

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.

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

1. Active systemic infection, infection or inflammation localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign body sensitivity to any of the implant materials.
2. Prior fusion at the level(s) to be treated.
3. Severe osteoporosis, which may prevent adequate fixation.
4. Conditions that may place excessive stresses on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.
5. Patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stresses on the implant during bony healing and may be at a higher risk of implant failure.
6. Any patient not willing to cooperate with postoperative instruction.
7. Any condition not described in the indications for use.
8. Fever or leukocytosis.
9. Pregnancy.
10. Any other condition which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors or congenital abnormalities, fracture local to the operating site, elevation of sedimentation rate unexplained by other diseases, elevation of the white blood count (WBC), or a marked left shift in the WBC differential count.
11. Any case not needing a fusion.
12. Patients with a known hereditary or acquired bone friability or calcification problem should not be considered for this type of surgery.
13. These devices must not be used for pediatric cases or where the patient still has general skeletal growth.
14. Any case where the implant components selected for use would be too large or too small to achieve a successful result.
15. Any case that requires the mixing of metals from two different components or systems.
16. Any patient having inadequate tissue coverage at the operative site or inadequate bone stock or quality.
17. Any patient in which implant utilization would interfere with anatomical structures or expected physiological performance.

PACKAGING

These implants and instruments 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 instrument sets are provided nonsterile and are steam sterilized prior to use, as described in the STERILIZATION section below. Following use or exposure to soil, instruments must be cleaned, as described in the CLEANING section below.

HANDLING AND USE

All instruments and implants should be treated with care. Improper use or handling may lead to damage and/or possible malfunction. Products should be checked to ensure that they are in working order prior to surgery. All products should be inspected prior to use to ensure that there is no unacceptable deterioration such as corrosion (i.e. rust, pitting), discoloration, excessive scratches, notches, debris, residue, flaking, wear, cracks, cracked seals, etc. Non-working or damaged instruments should not be used, and should be returned to Globus Medical.

Any implant that has not been used, but has become soiled, should be handled according to hospital protocol. Any implant with evidence of damage, residue, debris, or other defects should not be used, and should be returned to Globus Medical.

CLEANING

All instruments that can be disassembled must be disassembled for cleaning. All handles must be detached. Instruments may be reassembled following sterilization. The instruments 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 of instruments 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 after use or exposure to soil, and prior to sterilization:

IMPORTANT INFORMATION ON THE CREO® STABILIZATION SYSTEM

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 and instruments may be available sterile or nonsterile. HA-coated implants are only available sterile.

Sterile implants and instruments are sterilized by gamma radiation, validated to ensure a Sterility Assurance Level (SAL) of 10^{-6}. Sterile products are packaged in a heat sealed double pouch or container/pouch. The expiration date is provided in the package label. These products are considered sterile unless the packaging has been opened or damaged. Sterile implants and instruments that become nonsterile or have expired packaging are considered nonsterile and may be sterilized according to instructions for nonsterile implants and instruments below, with the exception of HA-coated implants, which cannot be resterilized and should be disposed of according to hospital protocol.

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.

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		

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Notes

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