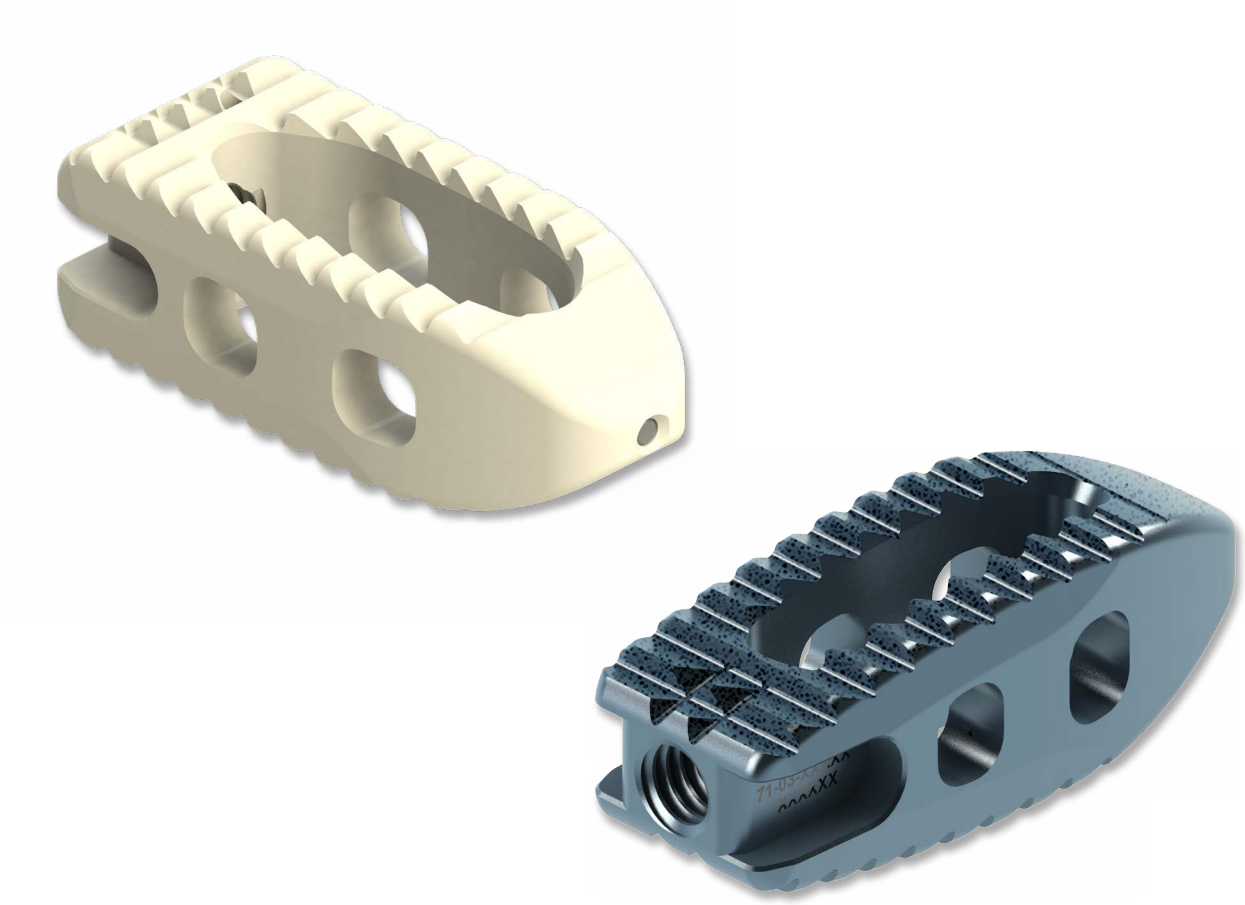
NEURO® STRUCTURES



Cortina™ [MAX]

LUMBAR CAGE SYSTEM

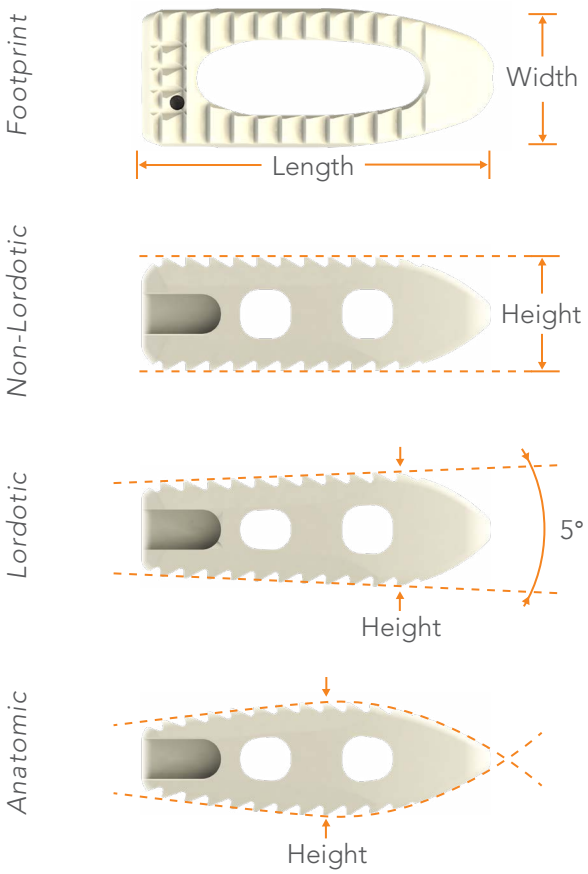
SURGICAL TECHNIQUE GUIDE

Made in the USA

neurostructures.com

Cortina™ [MAX]

PLIF



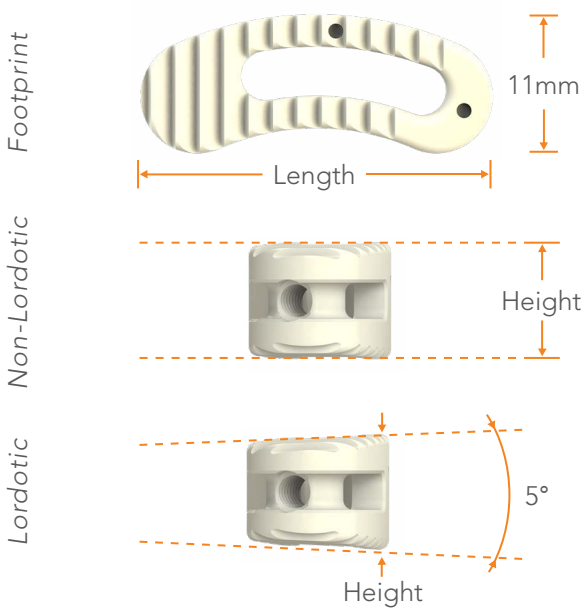
Cage Size *(Non-Lordotic, 5° Lordotic and Anatomic)*

Height (mm)	Length (mm) x Width (mm)							
	20 x 9 20 x 10 20 x 11 20 x 12	25 x 9 25 x 10 25 x 11 25 x 12	28 x 9 28 x 10 28 x 11 28 x 12	30 x 9 30 x 10 30 x 11 30 x 12	32 x 9 32 x 10 32 x 11 32 x 12	36 x 9 36 x 10 36 x 11 36 x 12	40 x 9 40 x 10 40 x 11 40 x 12	42 x 9 42 x 10 42 x 11 42 x 12
7	✓	✓	✓	✓	✓	✓	✓	✓
8	✓	✓	✓	✓	✓	✓	✓	✓
9	✓	✓	✓	✓	✓	✓	✓	✓
10	✓	✓	✓	✓	✓	✓	✓	✓
11	✓	✓	✓	✓	✓	✓	✓	✓
12	✓	✓	✓	✓	✓	✓	✓	✓
13	✓	✓	✓	✓	✓	✓	✓	✓
14	✓	✓	✓	✓	✓	✓	✓	✓
15	✓	✓	✓	✓	✓	✓	✓	✓

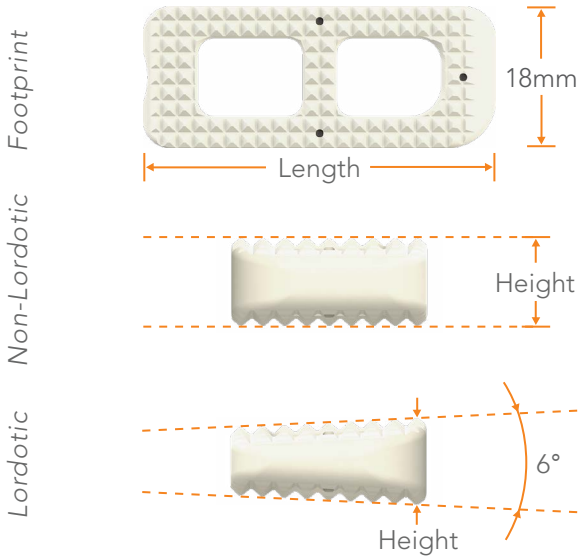
Optional | TLIF

TLIF Cage Sizes *(Non-Lordotic and 5° Lordotic)*

Height (mm)	Length (mm) x Width (mm)					
	26 x 11	28 x 11	30 x 11	32 x 11	34 x 11	36 x 11
7	✓	✓	✓	✓	✓	✓
8	✓	✓	✓	✓	✓	✓
9	✓	✓	✓	✓	✓	✓
10	✓	✓	✓	✓	✓	✓
11	✓	✓	✓	✓	✓	✓
12	✓	✓	✓	✓	✓	✓
13	✓	✓	✓	✓	✓	✓
14	✓	✓	✓	✓	✓	✓
15	✓	✓	✓	✓	✓	✓



Optional | DLIF



Cage Size *(Non-Lordotic & 6° Lordotic)*

Height (mm)	Length (mm) x Width (mm)				
	40 x 18	45 x 18	50 x 18	55 x 18	60 x 18
8	✓	✓	✓	✓	✓
9	✓	✓	✓	✓	✓
10	✓	✓	✓	✓	✓
11	✓	✓	✓	✓	✓
12	✓	✓	✓	✓	✓
13	✓	✓	✓	✓	✓
14	✓	✓	✓	✓	✓
15	✓	✓	✓	✓	✓
16	✓	✓	✓	✓	✓
17	✓	✓	✓	✓	✓

This is intended as a guide only. There are multiple techniques for the delivery of Lumbar Cages as with any surgical procedure. A surgeon should be thoroughly trained before proceeding. Each surgeon must consider the particular needs of each patient and make the appropriate adjustments when necessary and as required. Please refer to the instructions for use insert for complete system description, indications and warnings.

1 Preparation & Sizing

It is recommended that preoperative planning be used to help determine the proper entry point and trajectory. Identify the operative level(s) using A/P and lateral fluoroscopy.

Paddle Scrapers can be used to create a pathway for smooth and accurate implant insertion. Paddle Scrapers are available from 7mm to 15mm in 1mm increments.

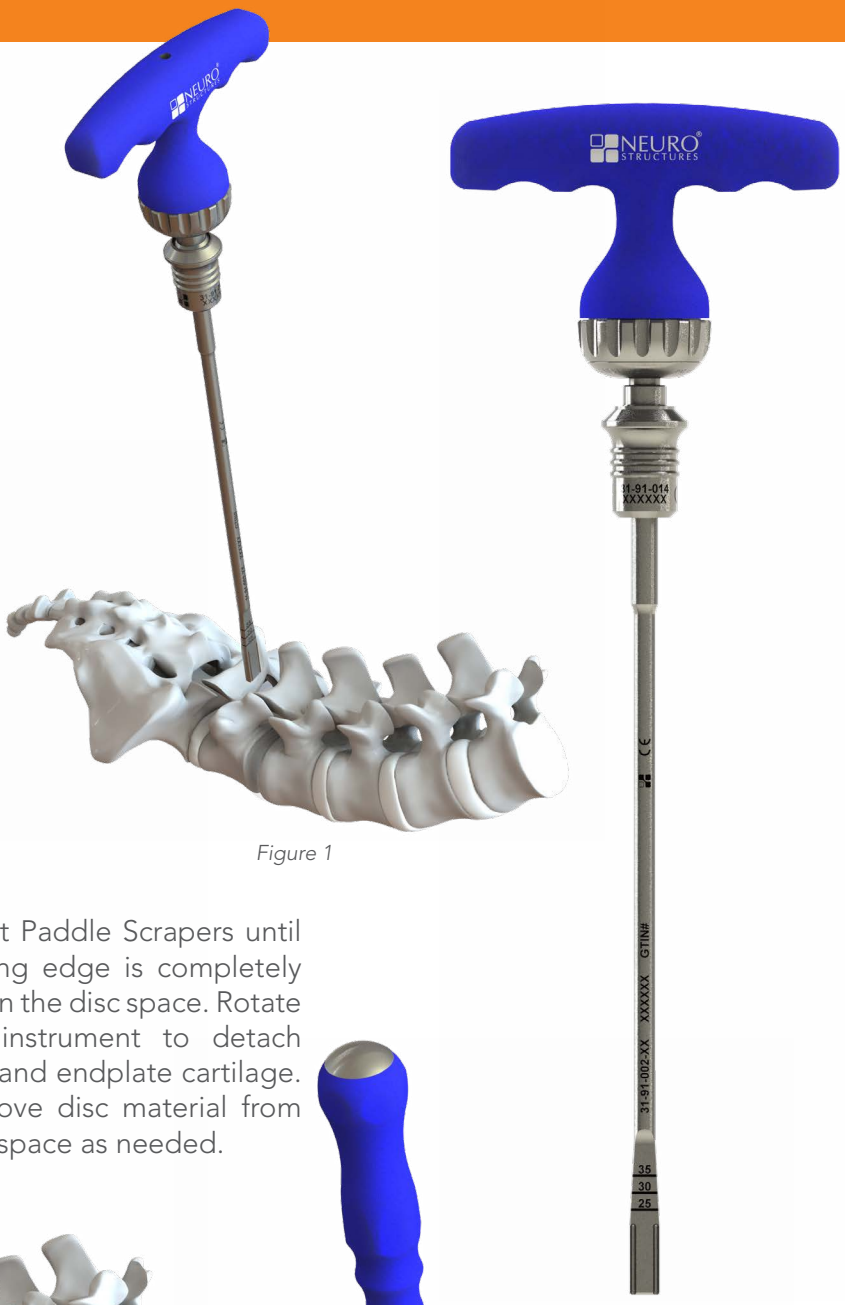


Figure 1

Insert Paddle Scrapers until cutting edge is completely within the disc space. Rotate the instrument to detach disc and endplate cartilage. Remove disc material from disc space as needed.

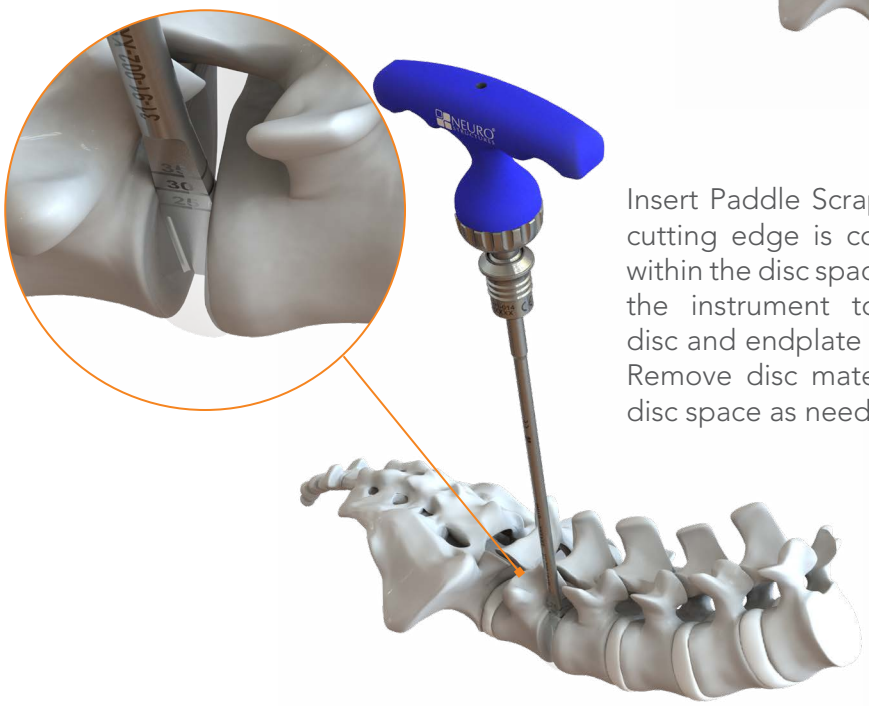


Figure 2

Rasps may also be used for endplate preparation. Rasps are available in both straight and angled versions.

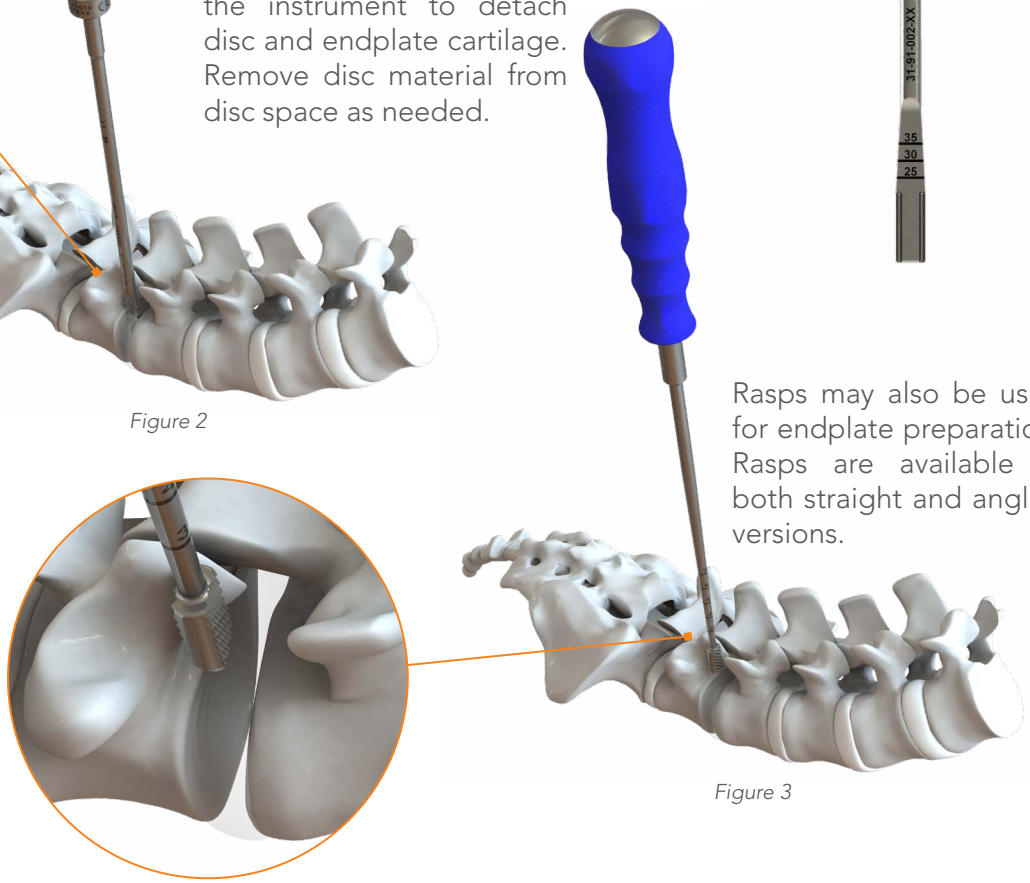


Figure 3

PLIF

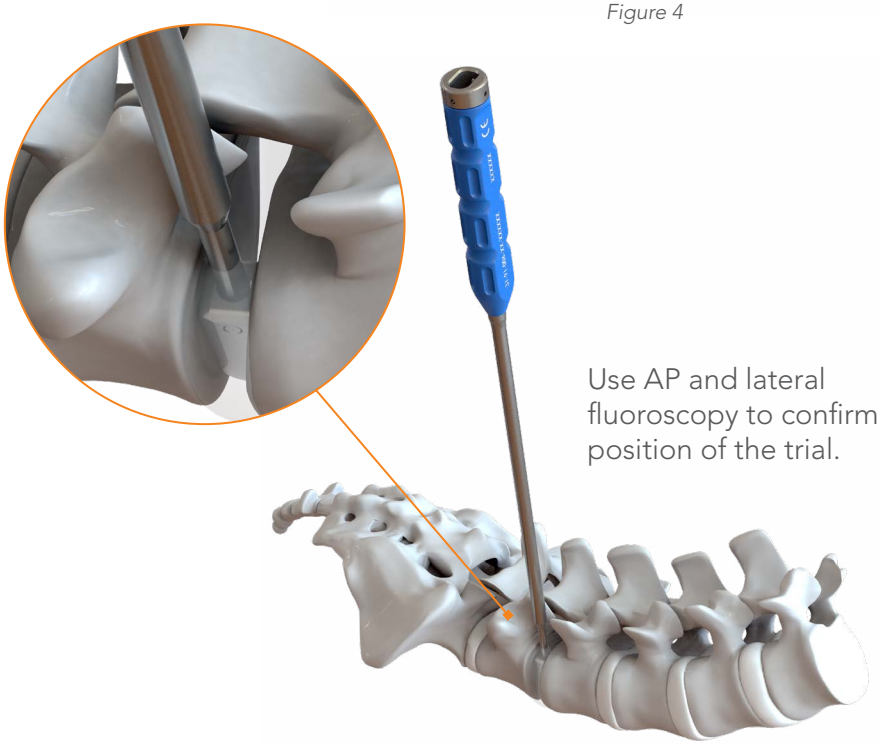
Optional TLIF

Optional DLIF

Trials can be used to determine the appropriate implant size.

Insert implant trial to confirm the correct disc height.

Figure 4



Use AP and lateral fluoroscopy to confirm position of the trial.

Figure 5

The Slap Hammer may be used to remove trials as needed. To use it, place the key into the end of the trial and turn 90° to engage.

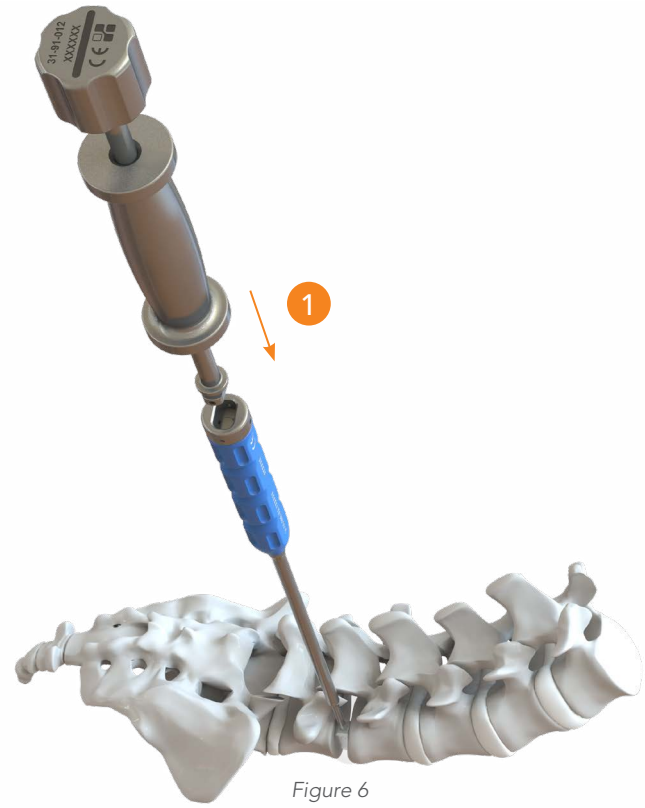


Figure 6

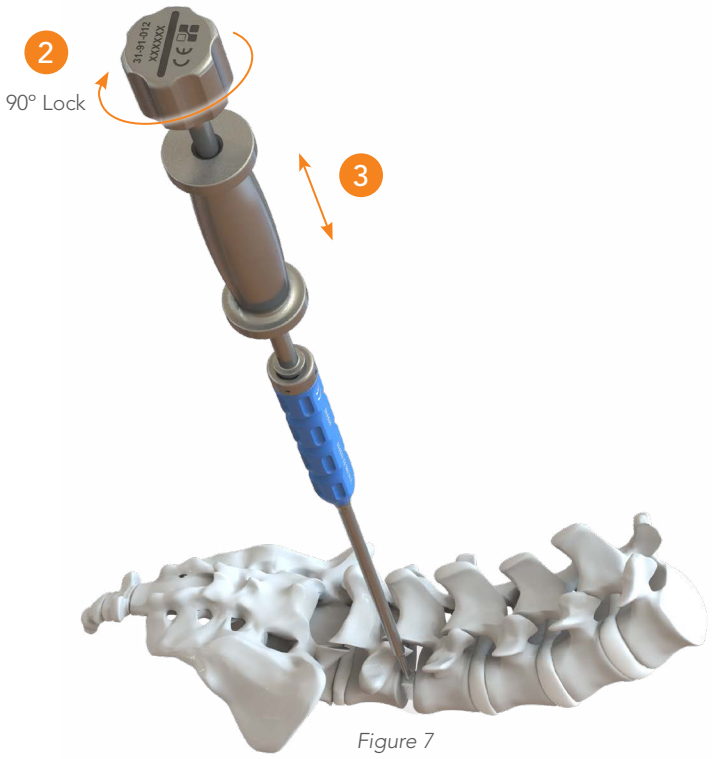
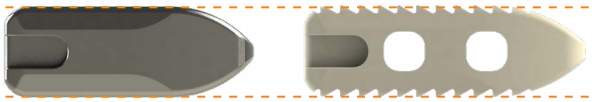


Figure 7

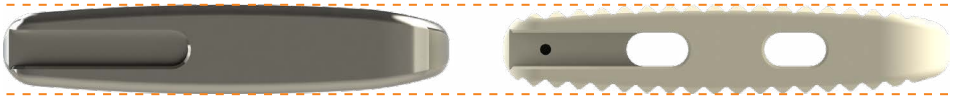
Note: The height of the implant is measured on the anterior side of the implant, from the tip of the teeth to the opposing tip of the teeth. The corresponding trial is sized to match the implant line-to-line.

PLIF Trial to Implant Heights



Optional | TLIF Trial to Implant Heights

Optional | DLIF Trial to Implant Heights



2 Implant Preparation & Delivery

Select implant based on trial fit.

Load the implant on the Inserter.

The implant is easily attached to the threaded Inserter and secured by placing the threads of the Inserter into the threaded hole at the end of the implant and turning the knob clockwise.

Use the Graft Packing Block and Graft Tamp to pack the implant with bone graft prior to insertion.

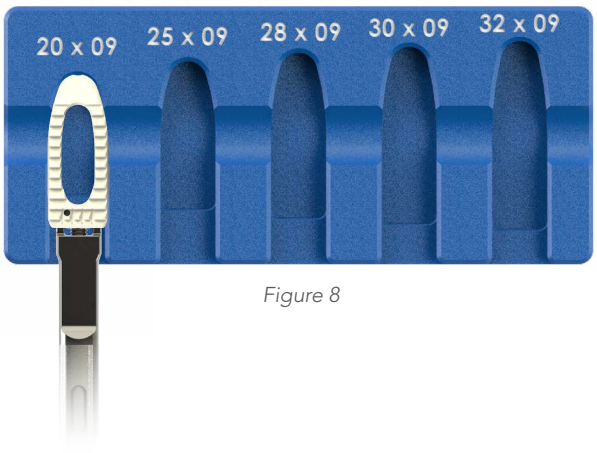


Figure 8

Inserter

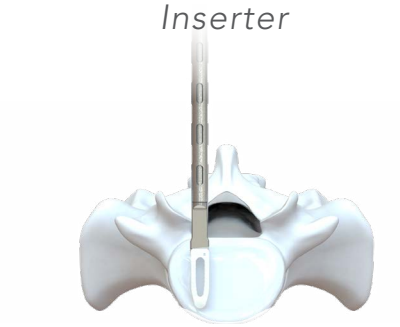


Figure 9

Release the implant by gently turning the inserter knob counter-clockwise while holding the handle. Remove the inserter from the surgical field.

If any adjustments need to be made to the implant position, the Straight or Angled Pusher may be used.

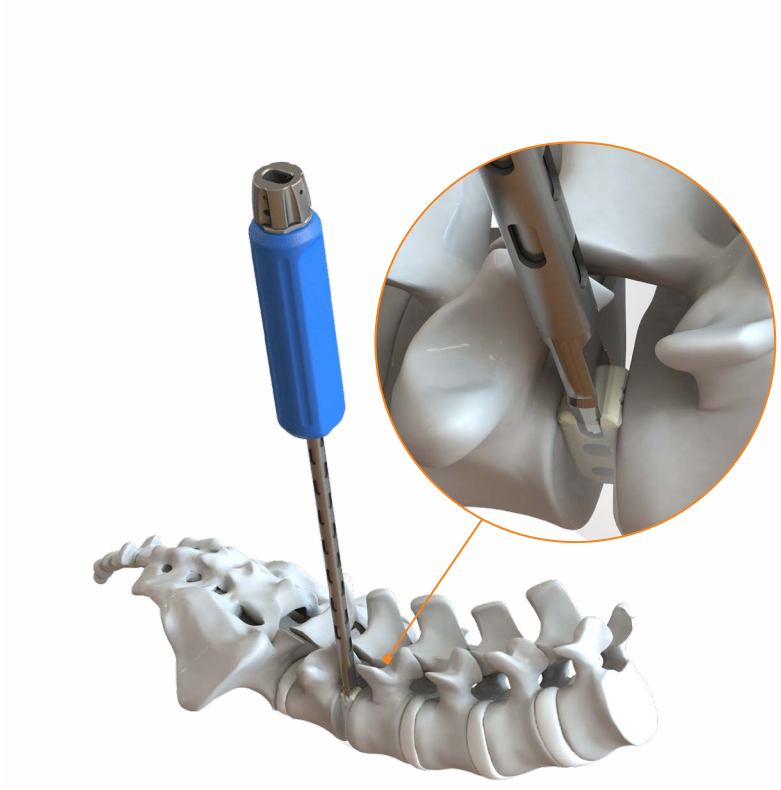


Figure 10

Pusher

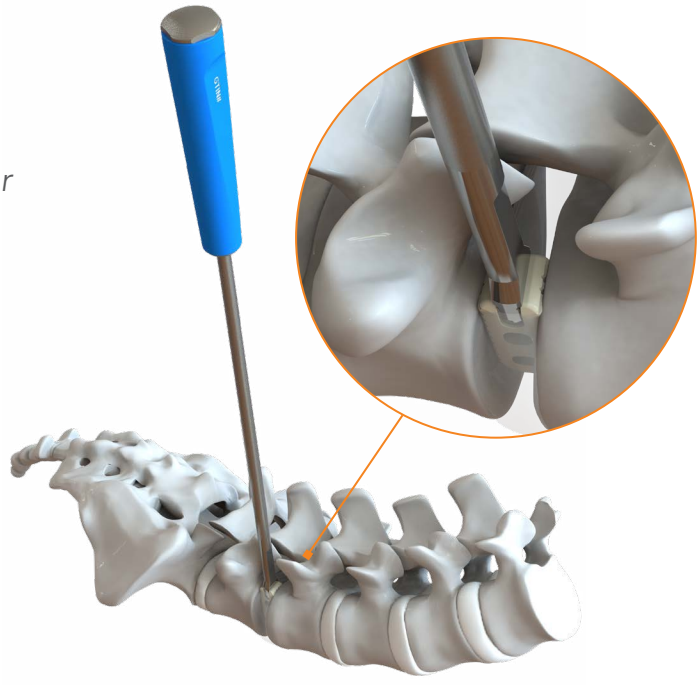


Figure 11

Optional | TLIF Implant

Select implant based on trial fit.

The TLIF set comes with an Articulating Inserter and Simple Inserter.

When using the Simple Inserter, the implant is easily attached to the inserter and secured by placing the threads of the inserter into the threaded hole at the end of the implant and turning the knob clockwise.

To remove the Simple Inserter from the implant, the knob must be turned counterclockwise.

When using the Articulating Inserter:

1. Turn the lower knob counterclockwise to retract the clamp arm.
2. Turn the upper knob clockwise and engage the thread of the Inserter into the thread of the implant.
3. Turn the lower knob clockwise to advance the clamp and grab the implant. The implant will now be secure.
4. Place the implant into the disc space.

If adjustment to the implant position is necessary, the Inserter may be articulated as follows:

1. Remove the internal threaded shaft by turning the upper knob counter clockwise.
2. Turn the lower knob counter clockwise to release the clamp from the implant.
3. Rotate the Inserter to the desired angle on the implant, then turn the lower knob clockwise to lock the clamp position.
4. Push the implant to the desired location.
5. Repeat steps 1 – 4 if further adjustment is necessary.

To remove the Articulating Inserter from the implant, the upper knob and lower knobs must both be turned counterclockwise to release the thread and clamp arm, respectively.

Use the Graft Packing Block and Graft Tamp to pack the implant with bone graft prior to insertion.

Figure 12

Optional | TLIF Implant

Simple Inserter

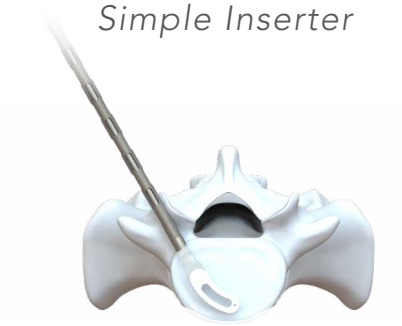


Figure 13

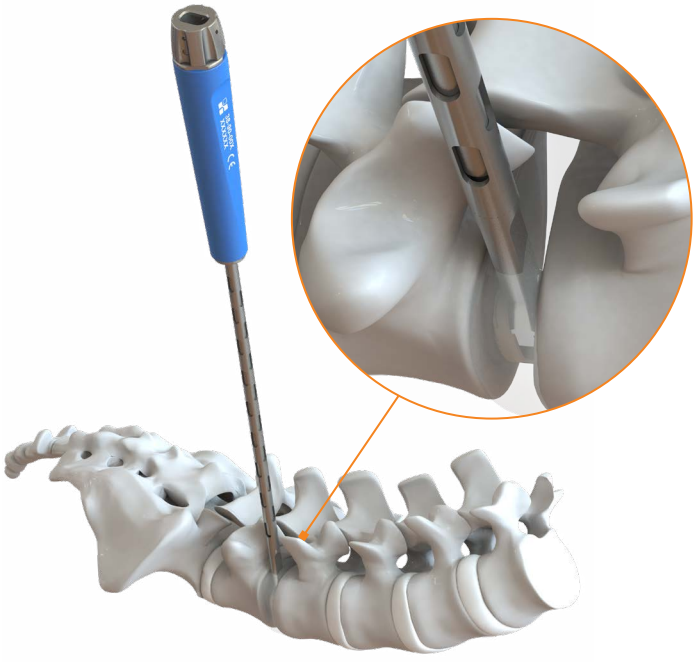


Figure 14

If any adjustments need to be made to the implant position, the Straight or Angled Pusher may be used.

Articulating Inserter

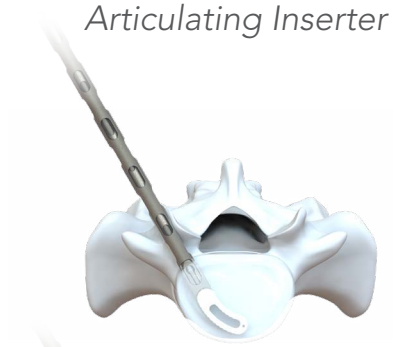


Figure 15

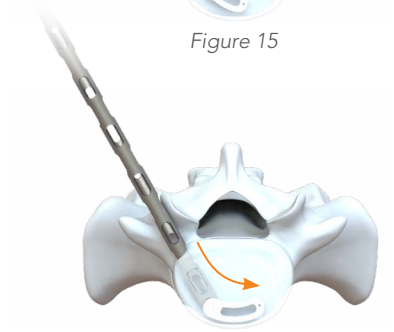


Figure 16

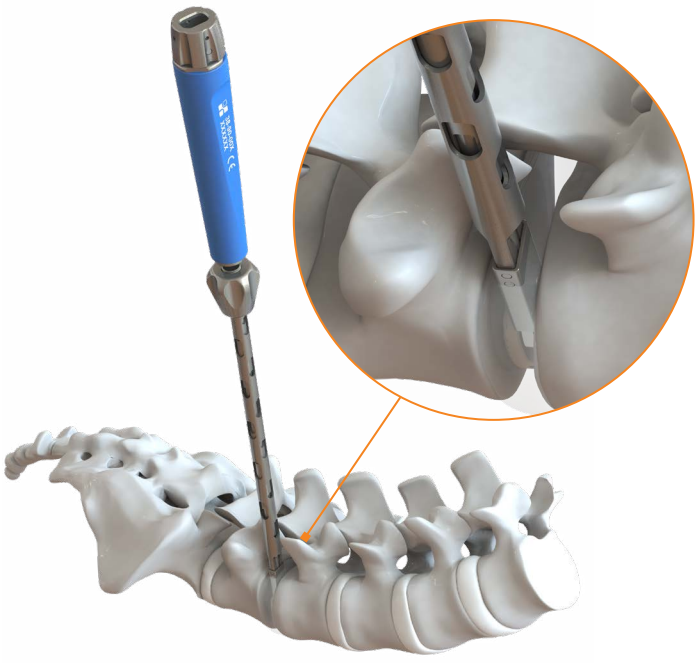


Figure 17

Optional | DLIF Implant

Select implant based on trial fit.

The DLIF set comes with a Simple Inserter.

When using the Simple Inserter, the implant is easily attached to the inserter and secured by placing the threads of the inserter into the threaded hole at the end of the implant and turning the knob clockwise.

To remove the Simple Inserter from the implant, the knob must be turned counterclockwise.

Use the Graft Packing Block and Graft Tamp to pack the implant with bone graft prior to insertion.

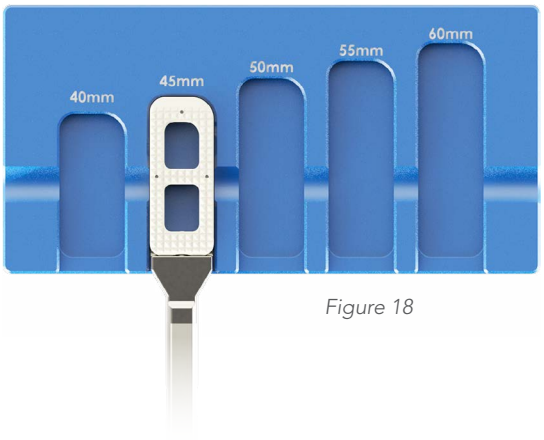


Figure 18

Inserter

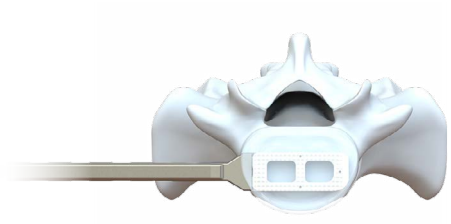


Figure 19

Release the implant by gently turning the inserter knob counter-clockwise while holding the handle. Remove the inserter from the surgical field.

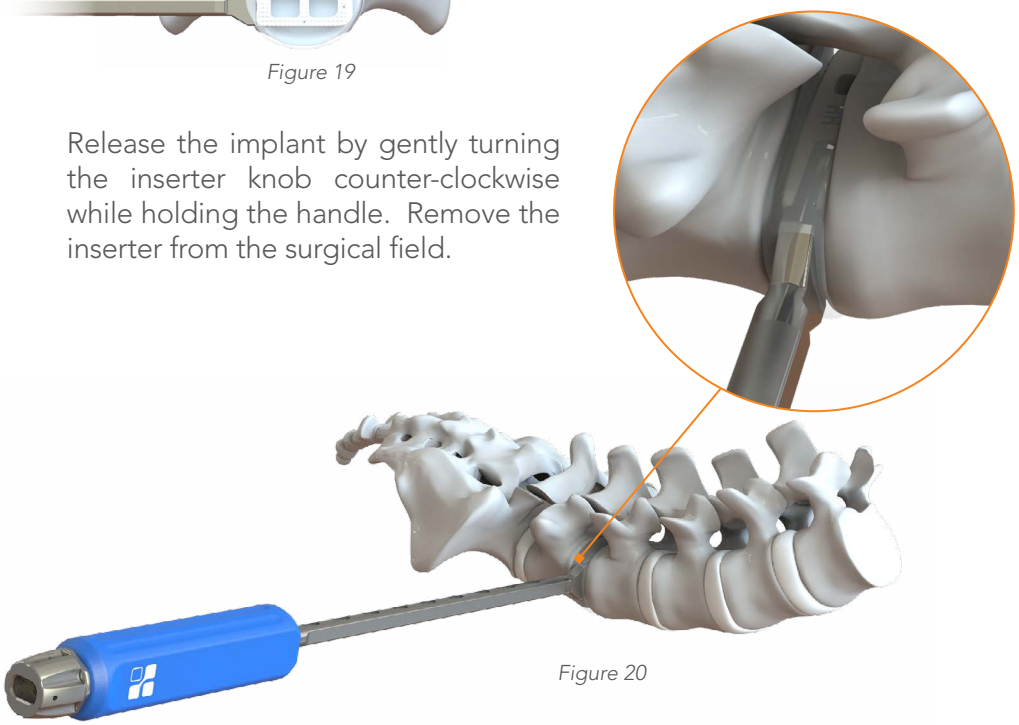
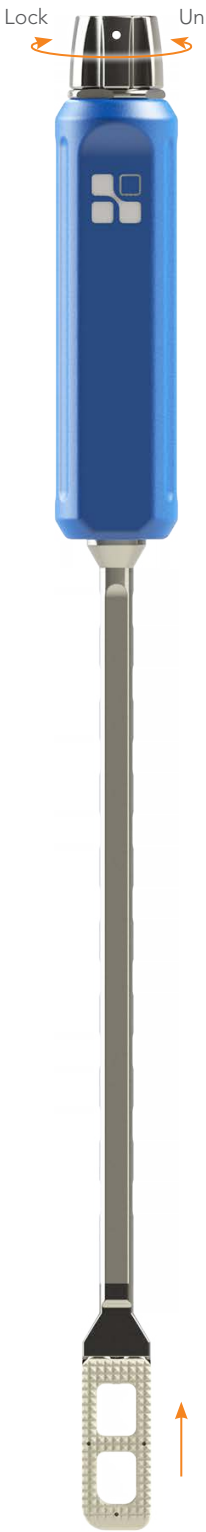


Figure 20



Verify Implant Position

PLIF Final Position

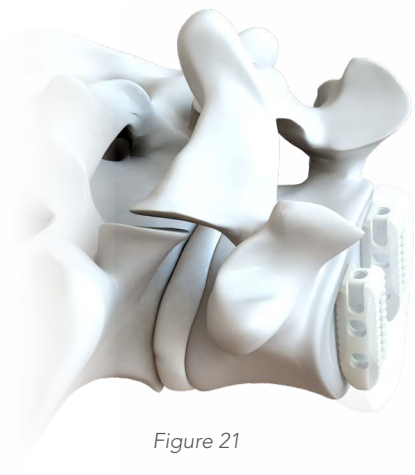


Figure 21

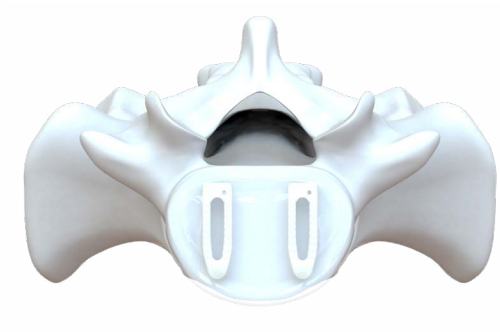


Figure 22

PLIF Radio Opaque Imaging

If any final adjustments need to be made to the implant location, the Straight or Angled Pusher may be used.

Caution: Confirm placement before removing the instruments.

Optional | TLIF Final Position

Figure 23

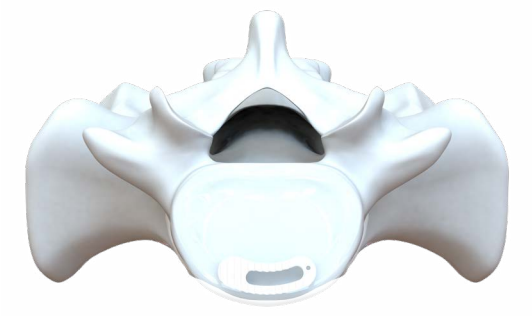
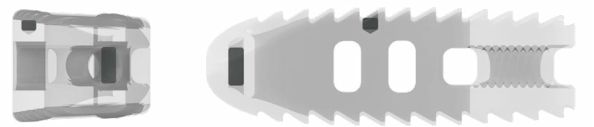


Figure 24

Optional | TLIF Radio Opaque Imaging



Optional | DLIF Final Position

Figure 25

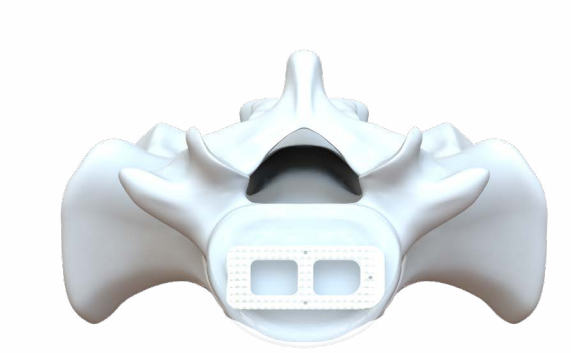


Figure 26

Optional | DLIF Radio Opaque Imaging

Use the Inserter if removal of the device must occur. Place the threads of the Inserter into the threaded hole at the end of the implant and turn the knob clockwise. Remove the implant from the disc space. The Slap Hammer can also be used in conjunction with the Inserter if further assistance is necessary.

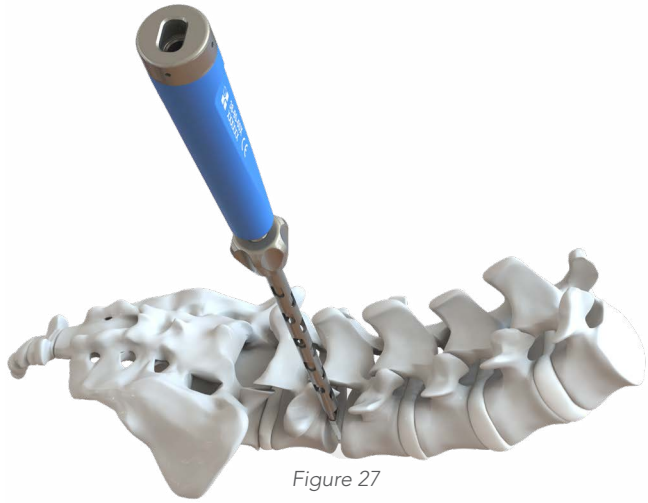


Figure 27

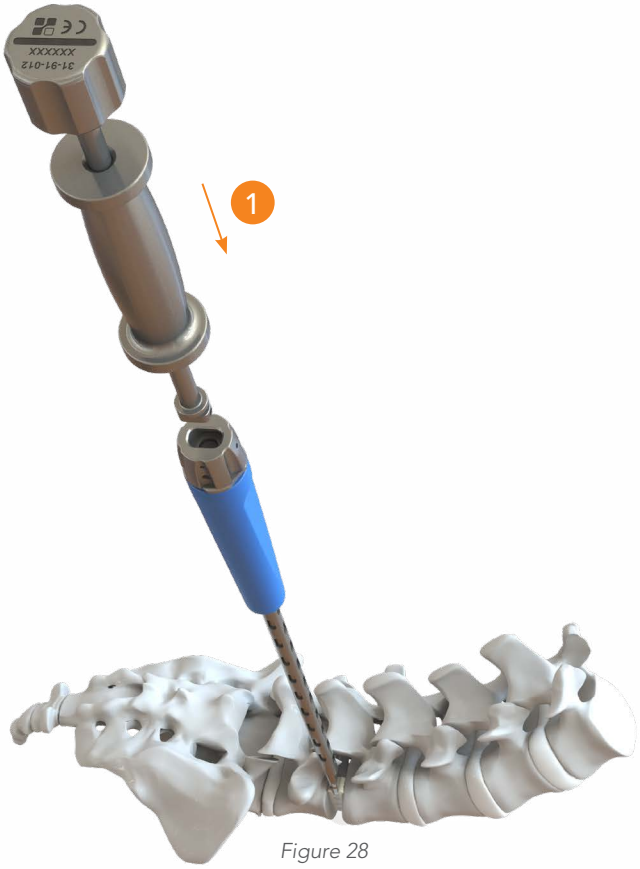
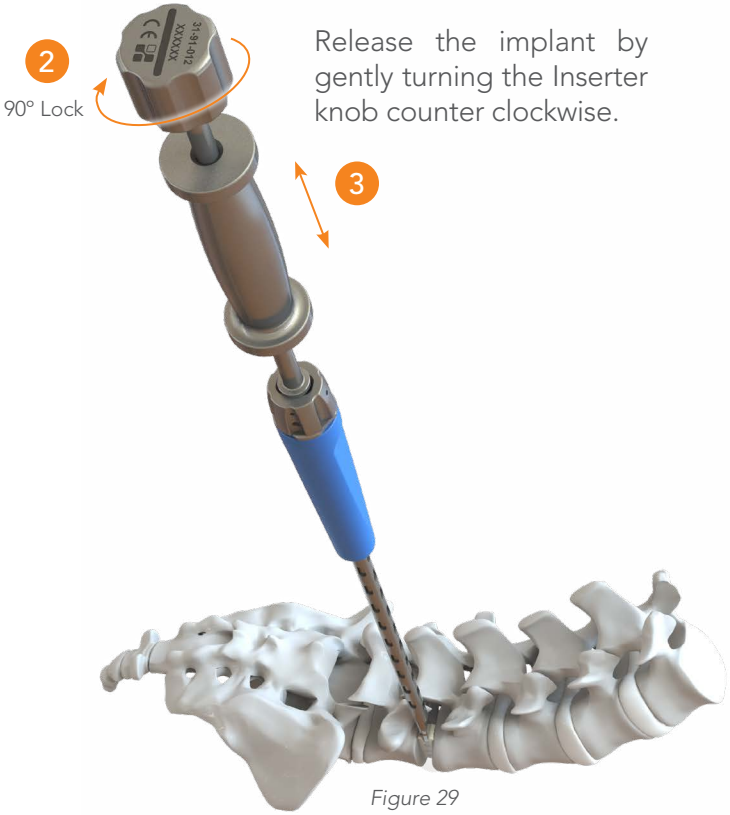


Figure 28



Release the implant by gently turning the Inserter knob counter clockwise.

Figure 29

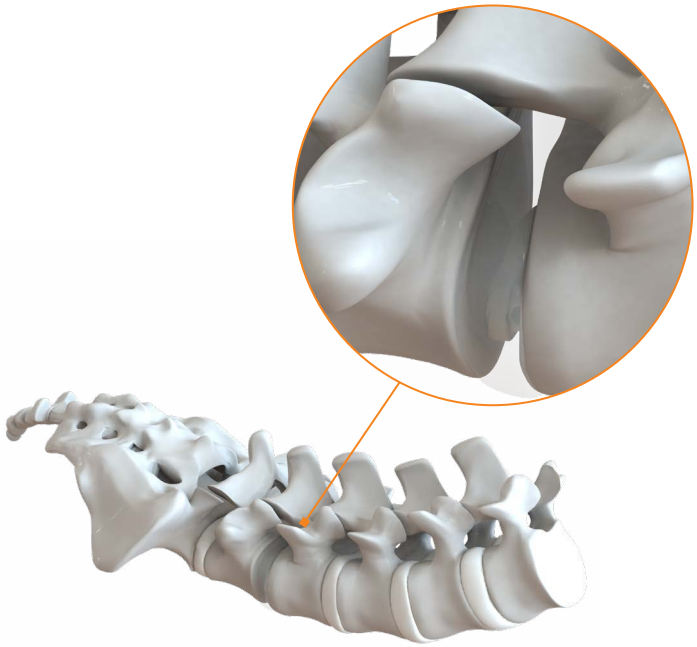


Figure 30

Optional | TLIF Implant

To remove the TLIF device the Simple Inserter or Articulating Inserter may be used. To use the Simple Inserter, place the threads of the instrument into the threaded hole at the end of the implant and turn the knob clockwise. Remove the implant from the disc space. The Slap Hammer may also be used in conjunction with the Simple Inserter if necessary. Release the implant from the Simple Inserter by gently turning the knob counterclockwise.

To use the Articulating Inserter, turn the upper and lower knobs counterclockwise. Place the threads of the instrument in the threaded hole at the end of the implant and turn the upper knob clockwise. Turn the lower knob clockwise to lock the clamp on the implant. Remove the implant from the disc space. Release the implant from the Articulating Inserter by turning the upper and lower knobs counterclockwise.

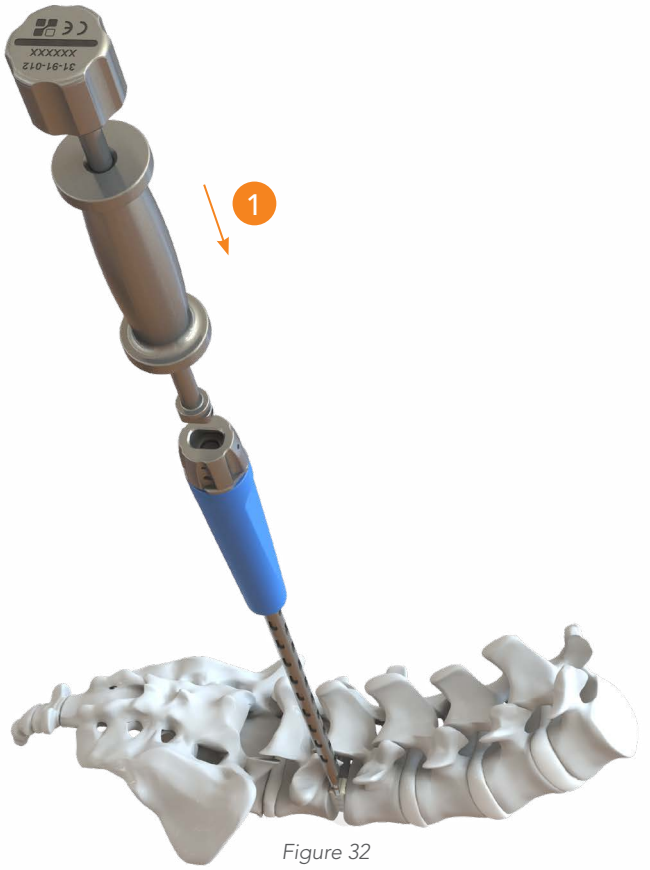
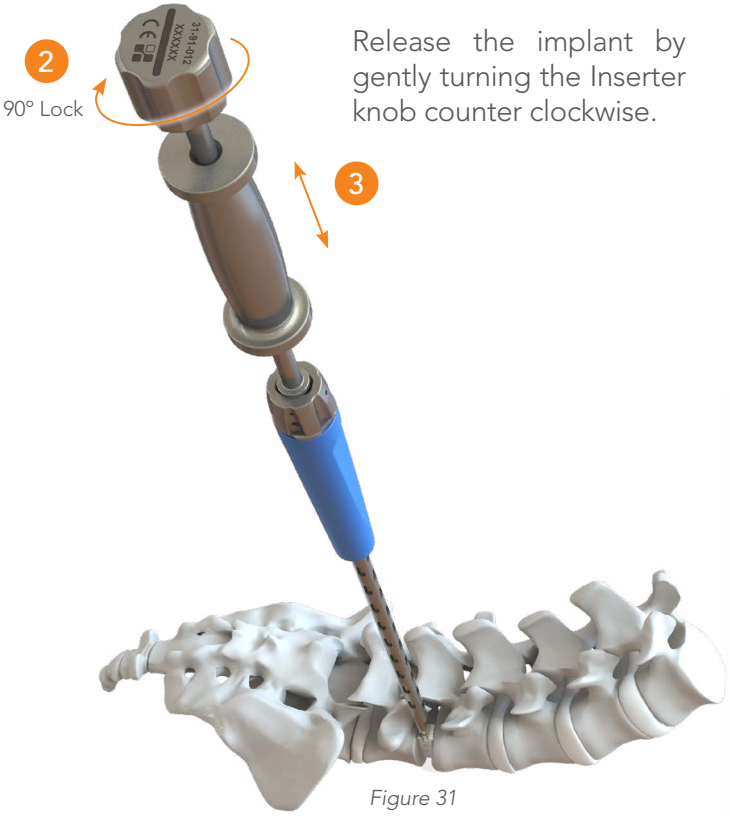


Figure 32



Release the implant by gently turning the Inserter knob counter clockwise.

Figure 31

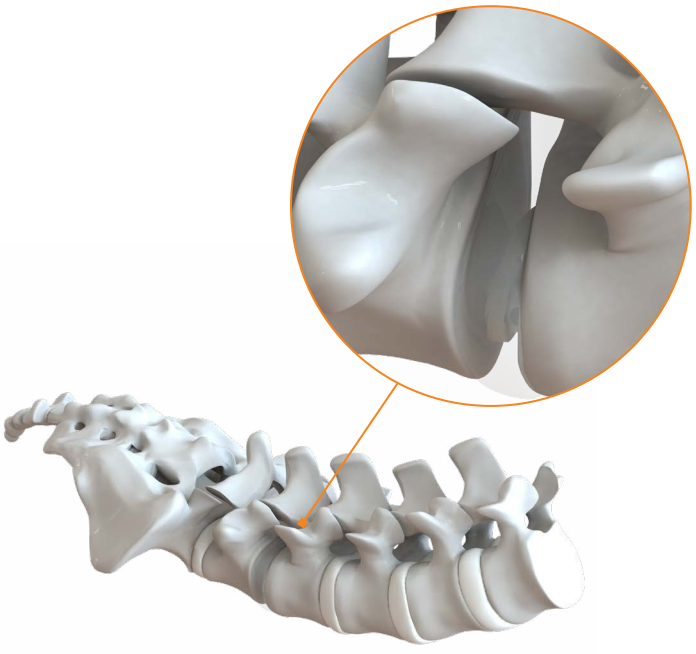


Figure 33

Optional | DLIF Implant

To remove the DLIF device the Simple Inserter may be used. To use the Simple Inserter, place the threads of the instrument into the threaded hole at the end of the implant and turn the knob clockwise. Remove the implant from the disc space. Release the implant from the Simple Inserter by gently turning the knob counterclockwise.

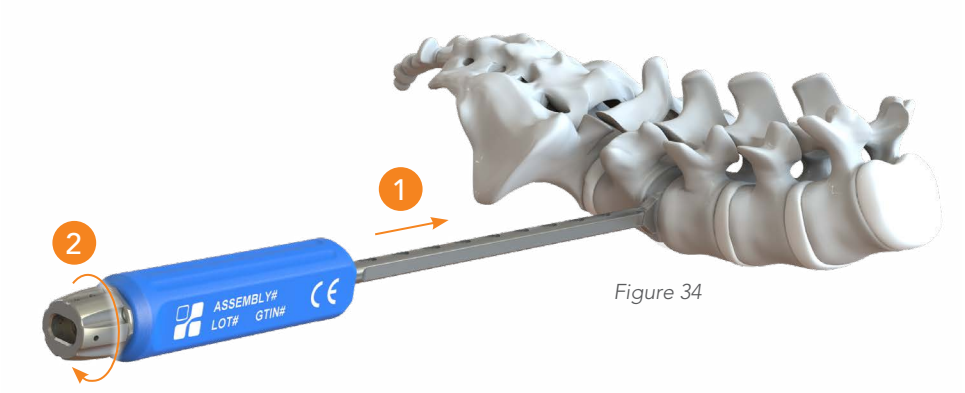


Figure 34

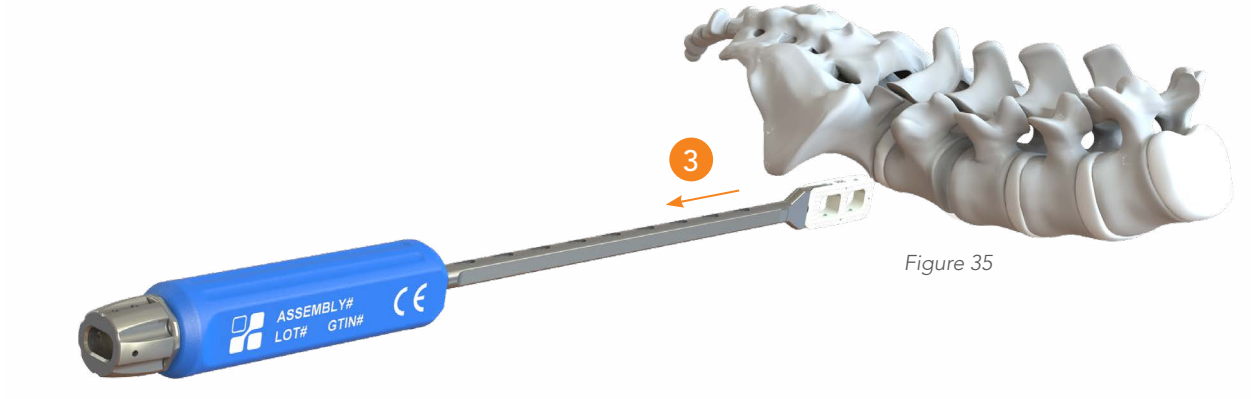


Figure 35

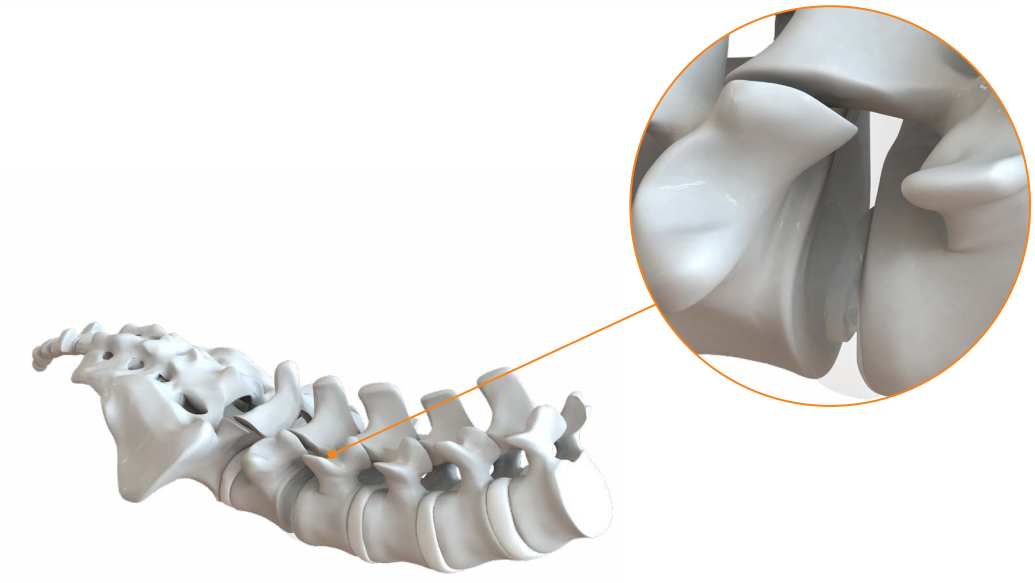


Figure 36

31-91-001
PLIF Inserter

31-91-002-XX
Paddle Scrapers

31-91-003
Straight Pusher

31-91-004
Angled Pusher

31-91-006-01-XXXXXX
Parallel Trials with Handle

31-91-006-02-XXXXXX
Lordotic Trials with Handles

31-91-007
Straight Rasp

31-91-008
Angled Rasp

31-91-009
Graft Packing Block

31-91-010
Graft Tamp

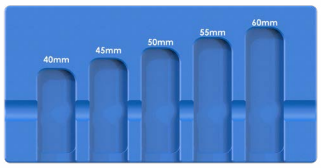
31-91-012
Slap Hammer

31-91-013
Ratcheting Axial Handle

30-91-014
Ratcheting T-Handle

32-90-001
Inserter

32-90-003-XXXXXX
Trials with Handle



32-90-004
Graft Packing Block

38-90-001
Articulating Inserter

38-90-002
Simple Inserter

38-90-004-XXXXXX
Trials with Handle

38-90-005
Angled Rasp

38-90-006
Straight Pusher

38-90-007
Angled Pusher

38-90-008-XX
Graft Packing Block

38-90-009
Graft Tamp

Device Description:

The Cortina[MAX] Lumbar Cage System is indicated for use in patients with degenerative disc disease (DDD) at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation.

The Cortina[MAX] Lumbar Cage System is an intervertebral fusion device made from medical grade PEEK as per ASTM F2026 with tantalum markers (3X-series) or Titanium 6Al-4V ELI Per ASTM F136 (7X-series) with a Tecotex® surface finish. Do not use any of the Cortina[MAX] Lumbar Cage System components with the components from any other system or manufacturer. NeuroStructures, Inc. expressly warrants that these devices are fabricated from the foregoing material specifications. No other warranties, expressed or implied, are made. Implied warranties of merchantability and fitness for a particular purpose or use are specifically excluded.

Indications:

The Cortina[MAX] Lumbar Cage System is indicated for use in patients with DDD at one or two contiguous levels from L2 to S1 whose condition requires the use of interbody fusion combined with supplemental fixation. The interior of the Cortina[MAX] Lumbar Cage System should be packed with autogenous bone graft (i.e. autograft). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

Contraindications:

Contraindications include, but are not limited to:

- Infection, local to the operative site.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Any medical or surgical condition which would preclude the potential benefit of spinal implant surgery, such as the elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or a marked left shift in the WBC differential count.
- Rapid joint disease, bone absorption, osteopenia, and/or osteoporosis. Osteoporosis is a relative contraindication since this condition may limit the degree of obtainable correction, the amount of mechanical fixation, and/or the quality of the bone graft.
- Suspected or documented allergy or intolerance to metal, PEEK, titanium, or tantalum.
- Any case not needing a bone graft and fusion or where fracture healing is not required.
- Any case requiring the mixing of metals from different components.
- Any patient having inadequate tissue coverage over the operative site or where there is inadequate bone stock, bone quality, or anatomical definition.
- Any case not described in the Indications.
- Any patient unwilling to cooperate with the post-operative instructions.
- Any time implant utilization would interfere with anatomical structures or expected physiological performance.

Potential Complications and Adverse Effects:

Potential complications and adverse effects include, but are not limited to:

- Early or late loosening of any or all of the components.
- Disassembly, bending, and/or breakage of any or all of the components.
- Foreign body (allergic) reaction to implants, debris, corrosion products, graft material, including metallosis, staining, tumor formation, and/or auto-immune disease.
- Pressure on the skin from component parts in patients with inadequate tissue coverage over the implant possibly causing skin penetration, irritation, and/or pain. Bursitis Tissue damage caused by improper positioning and placement of implants or instruments.
- Post-operative change in spinal curvature, loss of correction, height, and/or reduction.
- Infection.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, meningitis.
- Loss of neurological function, including paralysis (complete or incomplete), dysesthesias, hyperesthesia, anesthesia, paraesthesia, appearance of radiculopathy, and/or the development or continuation of pain, numbness, neuroma, or tingling sensation.
- Neuropathy, neurological deficits (transient or permanent), bilateral paraplegia, reflex deficits, and/or arachnoiditis.
- Loss of bowel and/or bladder control or other types of urological system compromise.
- Scar formation possibly causing neurological compromise around nerves and/or pain.
- Fracture, microfracture, resorption, damage, or penetration of any spinal bone and/or bone graft or bone graft harvest site at, above, and/or below the level of surgery.
- Interference with roentgenographic, CT, and/or MR imaging because of the presence of the implants.
- Non-union (or pseud-arthrosis). Delayed union. Mal union.
- Loss of spinal mobility or function. Inability to perform the activities of daily living.

- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, retropulsed graft.
- Hemorrhage, hematoma, seroma, embolism, edema, stroke, excessive bleeding, phlebitis, wound necrosis, wound dehiscence, or damage to blood vessels.
- Gastrointestinal and/or reproductive system compromise, including sterility and loss of consortium.
- Development of respiratory problems, e.g. pulmonary embolism, bronchitis, pneumonia, etc.
- Change in mental status.
- Death.

Note: Additional surgery may be necessary to correct some of these potential adverse effects.

Warnings and Precautions:

The implantation of the Cortina[MAX] Lumbar Cage System should be performed only by experienced spinal surgeons with specific training in the use of this device because this is a technically demanding procedure presenting a risk of serious injury to the patient.

A successful result may not occur in every case in which the Cortina[MAX] Lumbar Cage System is implanted. Failure rates in spinal fusion procedures are published, and spinal fusion failure is an accepted risk of the procedure. This is particularly true for patients who choose to smoke tobacco products, patients in malnourished or obese states, or who abuse alcohol products.

The device is not intended or expected to be the only mechanism of support of the spine. Regardless of the etiology of the spine pathology for which the implantation of this device was chosen, it is the expectation and requirement that adequate anterior column support exists, either by virtue of existing anatomy or by means of a spinal fusion or arthrodesis. Without solid biological anterior column support, the device cannot be expected to support the spine indefinitely, and will fail in any of several modes.

These modes may include bone-implant interface failure, implant failure, or bone failure.

Magnetic Resonance Environments:

The Cortina[MAX] Lumbar Cage System has not been evaluated for safety and compatibility in the MR environment. The Cortina[MAX] Lumbar Cage System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Cortina[MAX] Lumbar Cage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Physician Note:

Although the physician is the learned intermediary between the company and the patient, the indications, contraindications, warnings and precautions given in this document must be conveyed to the patient.

Caution:

FEDERAL LAW (USA) RESTRICTS THESE DEVICES TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

FOR USE ON OR BY THE ORDER OF A PHYSICIAN ONLY.

OTHER PREOPERATIVE, INTRAOPERATIVE, AND POSTOPERATIVE WARNINGS ARE AS FOLLOWS:

Implant Selection:

The selection of the proper size, shape, and design of the implant for each patient is crucial to the success of the procedure. Surgical implants are subject to repeated stresses in use, and their strength is limited by the need to adapt the design to the size and shape of human bones. Unless great care is taken in patient selection, proper placement of the implant, and postoperative management to minimize stresses on the implant, such stresses may cause fatigue and consequent breakage, bending or loosening of the device before the healing process is complete, which may result in further injury or the need to remove the device prematurely.

Preoperative:

Proper selection of patients and good compliance of patients with post-surgical instructions are an integral part of the realization of a successful surgical procedure. All patients contemplating implantation of this device should be apprised of the risks associated with the procedure as well as the limitations regarding activities that the patient will face following surgery.

A successful result is not achieved in every surgical case, especially in spinal surgery where many extenuating circumstances may compromise results. Preoperative planning and operating procedures, including knowledge of surgical techniques, proper reduction, and proper selection and placement of the implant are critical considerations in achieving a successful result. Longevity of the implant depends on the weight and activity level of the patient, patient mortality, or need for component replacement secondary to patient weight and activity level.

The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size of the implant. An adequate inventory of sizes should be available at the time of surgery, including sizes larger and smaller than those expected to be used.

Intraoperative:

Care should be used in the handling of the implant components. The implants should not be scratched or otherwise damaged.

Extreme caution should be used around the spinal cord and nerve roots. Damage to the nerves will cause loss of neurological functions.

Implants should be attached to the corresponding inserter such that they are fully seated on the inserter. Care should be taken not to over-tighten the implant to the inserter.

It is recommended to use an imaging system to verify that the implant is properly placed and correctly aligned within the disc space.

Different manufacturers use different materials, varying tolerances and design configurations. Components of the Cortina[MAX] Lumbar Cage System must not be used with components from any other system or manufacturer.

Postoperative:

The physician's post-operative directions and warnings to the patient and the corresponding patient compliance are extremely important. It is recommended that regular, long-term postoperative follow-up be undertaken to detect early signs of component wear and to consider the course of action to be taken if such events occur.

Periodic x-rays should be taken to detect evidence of positional changes, failed fusion, and/or device fracture. In such cases, patients should be closely monitored, and the benefits of revision surgery should be considered in order to avoid further deterioration.

Detailed instructions on the use and limitations of the device should be given to the patient. If partial weight-bearing is recommended or required prior to form bony union, the patient must be warned that loosening or breakage of the implant is a complication which can occur as a result of excessive or early weight-bearing or excessive muscular activity. It is important that immobilization of the surgical site be maintained until bony union consolidated and been confirmed by radiographic examination. The patient must be adequately warned of these hazards and closely supervised to ensure cooperation until bony union is confirmed. The risk of loosening of an implant during postoperative rehabilitation may be increased if the patient is active, or if the patient is debilitated, demented, or otherwise unable to use crutches or other such weight supporting devices. The patient should be warned to avoid falls or sudden jolts in spinal position. The patient should be advised not to smoke or consume alcohol during the autogenous bone graft healing process.

All patients should be instructed on the limitations of the device and the possibility of subsequent surgery. The patient should be instructed to limit and restrict physical activities, especially lifting and twisting motions, and any type of sport participation. Patients should be advised of their inability to bend at the point of spinal fusion and taught to compensate for this permanent restriction in body motion.

If a non-union develops or the components loosen, bend, and/or break, the device(s) should be revised and/or removed immediately before serious injury occurs. Failure to immobilize a delayed or nonunion of bone will result in excessive and repeated stresses on the implant. By the mechanism of fatigue these stresses can cause eventual bending, loosening, or breakage of the device(s).

Any retrieved devices should be treated in such a manner that reuse in another surgical procedure is not possible. As with all orthopedic implants, none of the Cortina[MAX] Lumbar Cage System components should ever be reused under any circumstances. Any implant, once used, should be discarded; even though it may appear undamaged, it may have small defects and internal stress patterns which may lead to early breakage.

Packaging:

Packages for each of the components should be intact upon receipt. If a loaner or consignment system is used, all sets should be carefully checked for completeness and all components should be carefully checked for lack of damage prior to use. Damaged packages or products should not be used, and should be returned to NeuroStructures, Inc.

Decontamination and Cleaning:

Unless just removed from an unopened package, all instruments and implants must be disassembled (if applicable), and thoroughly cleaned using neutral cleaners before sterilization and introduction into a sterile surgical field, or (if applicable) returned to NeuroStructures, Inc. 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.

PRE-CLEAN PROCEDURE – INSTRUMENTS ONLY

1. It is recommended that instruments should be reprocessed as soon as is reasonably practical following use.
2. Keep instruments moist and do not allow blood and/or bodily fluids to dry on the instruments.
3. Open instruments with ratchets, box locks, or hinges.
4. Remove sharp instruments for manual cleaning or place into a separate tray.
5. Lumens/cannula of instruments should be manually processed prior to cleaning. Lumen/cannula should first be cleared of debris. Lumen/cannula should be brushed thoroughly using appropriately sized soft-bristled brushes and twisting action. Brushes should be tight-fitting. Brush size should be approximately the same diameter of the lumen/cannula to be cleaned. Using a brush that is too big or too small for the diameter of the lumen/cannula may not effectively clean the surface of a lumen/cannula. After brushing the lumen/cannula, blow clean compressed air through the lumen/cannula to clear debris, if necessary.
6. Soak and/or rinse heavily soiled instruments or cannulated instruments prior to cleaning to loosen any dried soil or debris. Use a neutral pH enzymatic soak or detergent to soak devices. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration. Use cold tap water to rinse instruments.
7. Do not use saline or chlorinated solutions.
8. Cortina[MAX] Lumbar Cage System instruments must be cleaned separately from Cortina[MAX] Lumbar Cage System instrument trays and cases. Lids should be removed from cases for the cleaning process, if applicable.

MANUAL CLEANING PROCEDURE – INSTRUMENTS ONLY

Equipment: Use various sized soft-bristled brushes, lint-free cloths, syringes, pipettes and/or water jet, neutral enzymatic cleaner, or neutral detergent with a pH between 7 and 9.

1. Rinse soiled instrument under running cold tap water for a minimum of two minutes. Use a soft-bristled brush to assist in the removal of gross soil and debris.
2. Soak instrument in a neutral pH enzymatic cleaner or detergent solution for a minimum of ten minutes. Follow the enzymatic cleaner or detergent manufacturer's instructions for use for correct exposure time, temperature, water quality, and concentration.
3. Rinse device with cold water for a minimum of two minutes. Use a syringe, pipette, or water jet to flush lumens, channels, and other hard to reach areas.
4. Manually clean instrument for a minimum of five minutes in a freshly prepared neutral pH enzymatic cleaner or detergent solution. Use a soft-bristled brush to remove soil and debris. Actuate joints, handles, and other movable instrument features to expose all areas to the detergent solution, if applicable. Clean instrument under water to prevent aerosolization of contaminants.

   Note: Fresh solution is a newly-made, clean solution.
5. Rinse instrument thoroughly with deionized (DI) or purified (PUR) water for a minimum of two minutes. Use a syringe, pipette or water jet to flush lumens and channels. Actuate joints, handles, and other moveable instrument features in order to rinse thoroughly under running water, if applicable.
6. Visually inspect instrument. Repeat the manual cleaning procedure (steps 2 – 6) until no visible soil remains on instrument.
7. Perform a final rinse on instrument using DI or PUR water.
8. Dry device using a clean, soft, lint-free cloth, or clean compressed air.

Please see the below table for the recommended cleaning parameters:

Cycle	Minimum Time (Minutes)	Minimum Temperature/Water	Type of Detergent
Rinse 1	2	Cold tap water	N/A
Soak	10	Cold to warm tap water	Neutral enzymatic pH between 7 – 9
Rinse 2	2	Cold tap water	N/A
Wash	5	Warm tap water (>40°C)	Detergent with pH between 7 – 9
Rinse 3	2	Warm DI or PUR (>40°C)	N/A
Final Rinse	2	Cold DI or PUR	N/A

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. Also, many instruments require disassembly before cleaning. No visual contamination shall be present after cleaning, so the instruments shall be re-cleaned if they are not visually clean.

All products should be treated with care. Improper use or handling may lead to damage and/or possible improper functioning of the device.

It is recommended that devices should be reprocessed as soon as is reasonably practical following use.

Visually inspect all reusable devices for signs of wear and tear before each use. Any devices with corrosion, discoloration, or cracked seals should be returned to the manufacturer.

Sterilization:

Unless noted otherwise on the package labeling, the Cortina[MAX] Lumbar Cage System components are provided non-sterile. These products need to be steam sterilized by the hospital using the following method:

Steam Sterilization Cycle Type	Exposure Time At 132 °C (270 °F)	Drying Times
Dynamic Air Removal: Pre-Vacuum Steam	4 min	20 min
Dynamic Air Removal: Gravity Steam	15 min	30 min

Remove all packaging materials prior to sterilization. Only FDA-cleared wraps should be used. Use only sterile products in the operative field. After surgery, immediately decontaminate, clean, and re-sterilize before handling or (if applicable) return to NeuroStructures, Inc.

Implants and instruments are provided non-sterile.

Product Complaints:

Any Health Care Professional (e.g., customer or user of this system of products), who has any complaints or who has experienced any dissatisfaction in the product quality, identity, durability, reliability, safety, effectiveness and/or performance, should notify the manufacturer, NeuroStructures, Inc. Further, if any of the implanted Cortina[MAX] Lumbar Cage System component(s) ever "malfunctions," (i.e., does not meet any of its performance specifications or otherwise does not perform as intended), or is suspected of doing so, the manufacturer should be notified immediately. If any NeuroStructures, Inc. product ever "malfunctions" and may have caused or contributed to the death or serious injury of a patient, the manufacturer should be notified immediately by telephone and written correspondence. When filing a complaint, please provide the component(s) name, part number, lot number(s), your name and address, the nature of the complaint, and notification of whether a written report from the manufacturer is requested.

Further Information:

Recommended directions for use of this system (surgical operative techniques) are available at no charge upon request. If further information is needed or required, please contact:

NeuroStructures, Inc., 199 Technology, Suite 110, Irvine, CA 92618, 800-352-6103.

customerservice@neurostructures.com

www.neurostructures.com

199 Technology Drive, Suite 110
Irvine, CA 92618
Ph/Fax: 800.352.6103

neurostructures.com

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