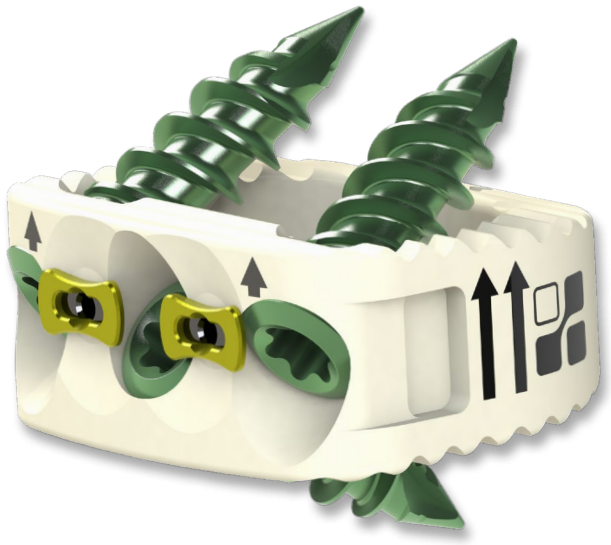
NEURO® STRUCTURES



Arco™-SA

LUMBAR CAGE SYSTEM

SURGICAL TECHNIQUE GUIDE

As described by

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Made in the USA

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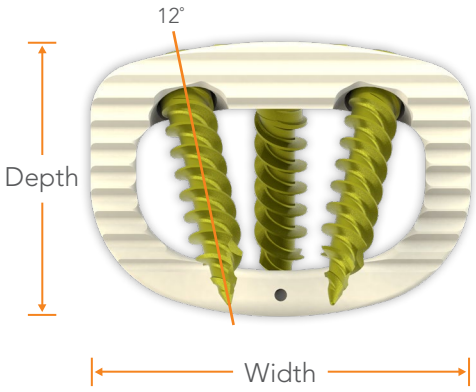
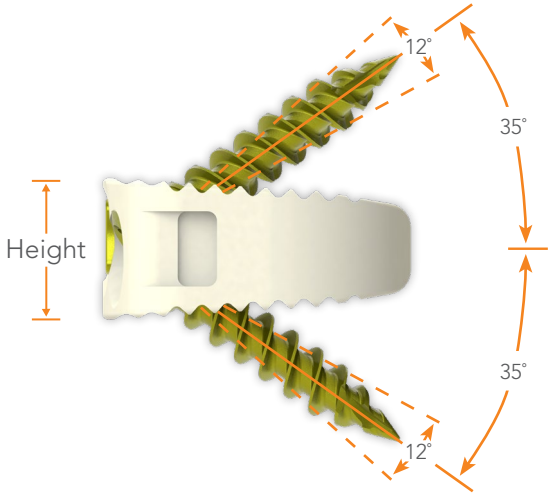
Arco™-SA

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 warning.





Cage Sizes*

		Depth (mm) x Width (mm)			
		24 x 28	26 x 33	26 x 36	29 x 38
Height (mm)	12	✓	✓	✓	✓
	14	✓	✓	✓	✓
	16	✓	✓	✓	✓
	18	✓	✓	✓	✓
	20	✓	✓	✓	✓
	22	✓	✓	✓	✓

** The Arco-SA Lumbar Cage maybe offered in 7°, 12°, 20°, and 30° lordotic angle.*

Self-Drilling – *gold*
5.0mm self-drilling

Self-Drilling – *light blue*
5.5mm self-drilling

Self-Drilling – *light green*
6.0mm self-drilling

Bone Screw Size

	Diameter (mm)	Length (mm)			
Self-Drilling	5.0	20	25	30	35
	5.5	20	25	30	35
	6.0	20	25	30	35

Self-Drilling

Trial

It is recommended that preoperative planning be used to help determine the proper entry point and trajectory. Identify the operative levels using A/P and lateral fluoroscopy *(Figure 1 & 2)*.

Trials can be used to determine the appropriate implant size.

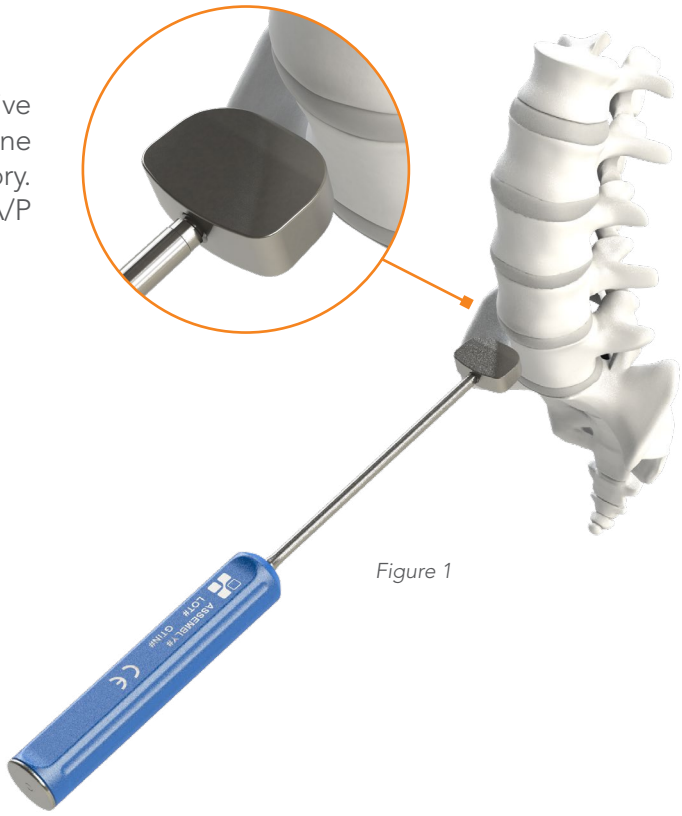


Figure 1

Trial

Figure 2

Rasp

Rasps can be used to prepare the site and determine the appropriate implant size *(Figure 3 & 4)*.

Rasp

Figure 3

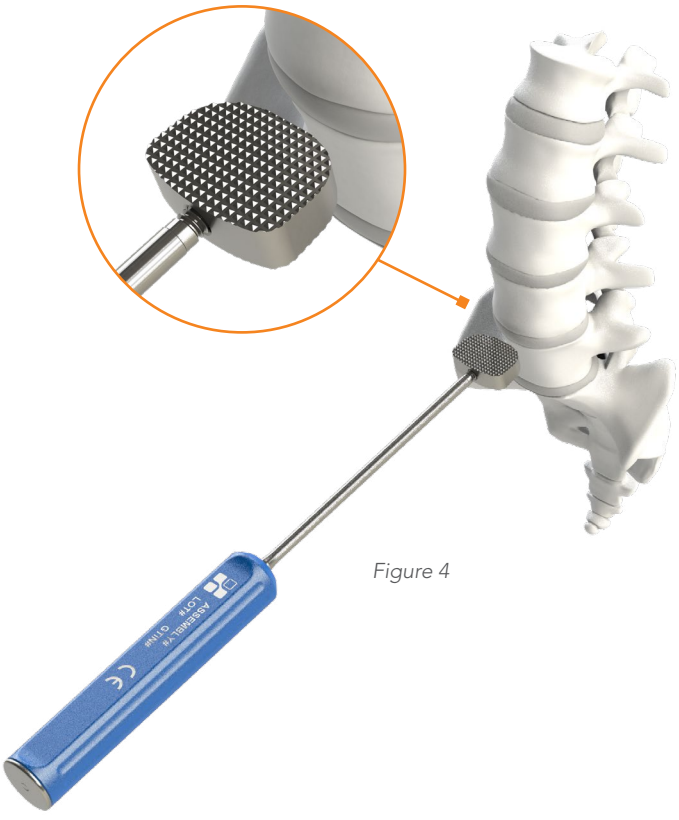


Figure 4

Standard Inserter

Select implant based on Trial/Rasp fit.

When using the Standard Inserter, connect the implant by using the two side tabs on the Standard Inserter.

Then insert the implant and Standard Inserter into the Inserter Handle. Once the Standard Inserter is fully seated into the Inserter Handle, rotate the knob on the end of the Inserter Handle clockwise to lock the Inserter Handle onto the Standard Inserter *(Figure 5)*.

Figure 5

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.

Arco-SA Trial to Implant Height

Simple Inserter

Select implant based on Trial/Rasp fit.

The Arco-SA system also includes a Simple Inserter option. Connect the cage by inserting the two pins directly into the screw holes on the front of the implant.

Then insert the implant and Simple Inserter into the Inserter Handle. Once the Simple Inserter is fully seated into the Inserter Handle, rotate the knob on the end of the Inserter Handle clockwise to lock the Inserter Handle onto the Simple Inserter *(Figure 6)*.

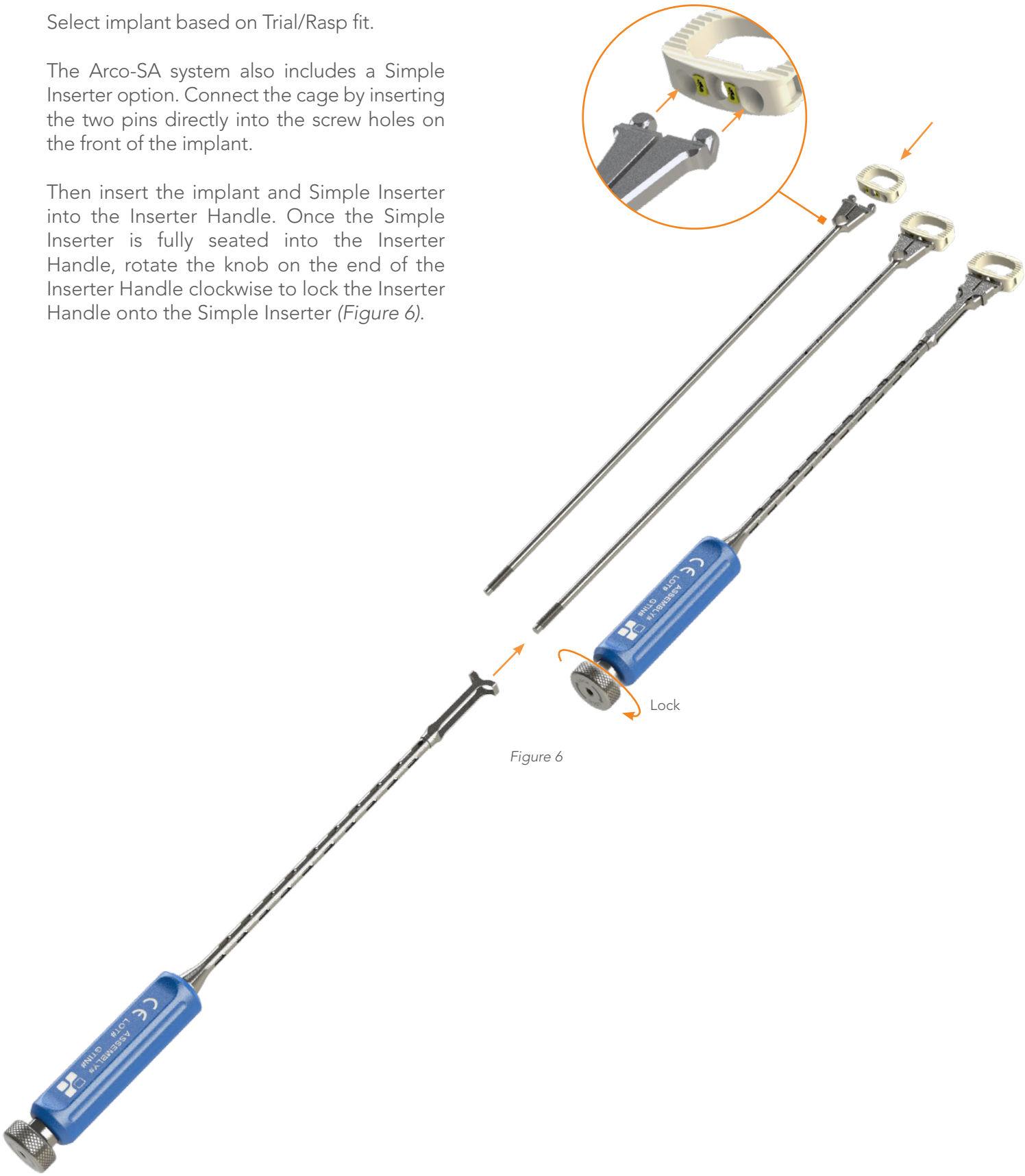


Figure 6

Standard Inserter

Insert the implant into the disc space *(Figure 7)*.

Once the implant has been inserted to the desired position, screw hole preparation and insertion will all be done through the guides *(Figure 9)*.

Caution: Confirm implant placement under fluoroscopy.

Note: If bone grafting material is needed, use the Packing Block and Packing Block Tamp to prepare the implant. Once the implant is loaded onto the inserter of choice, place it into the Packing Block. Then use the Tamp to pack it with bone graft prior to insertion.

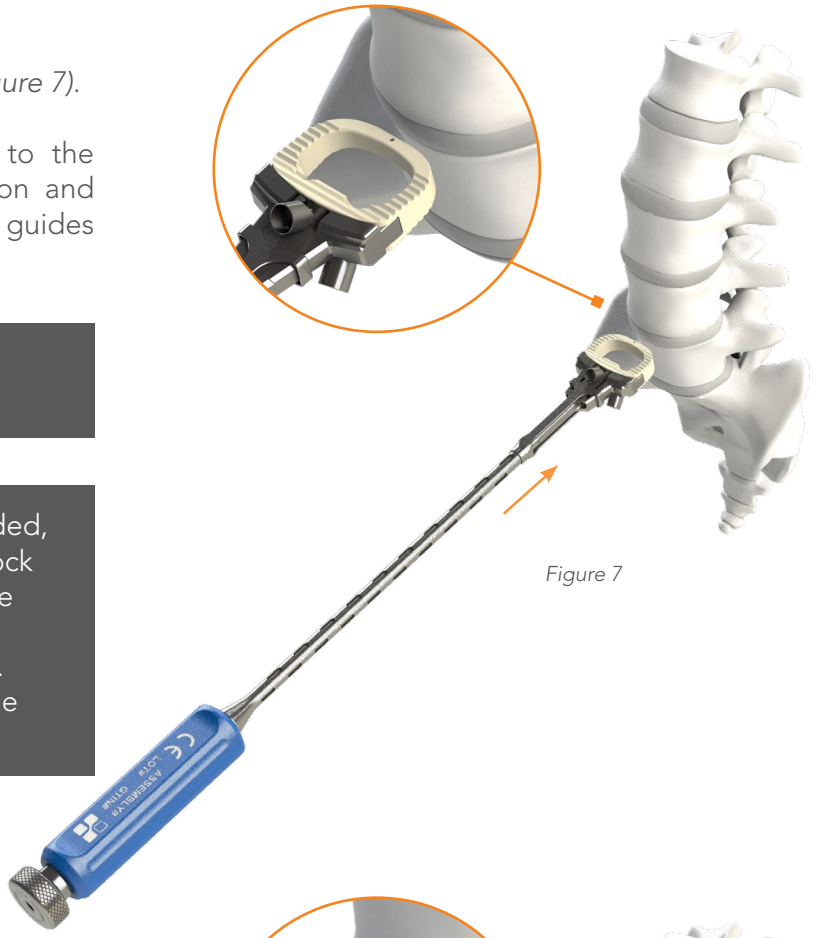


Figure 7

Use the Packing Block and Packing Block Tamp to pack the implant with bone graft prior to insertion *(Figure 8)*.

Figure 8

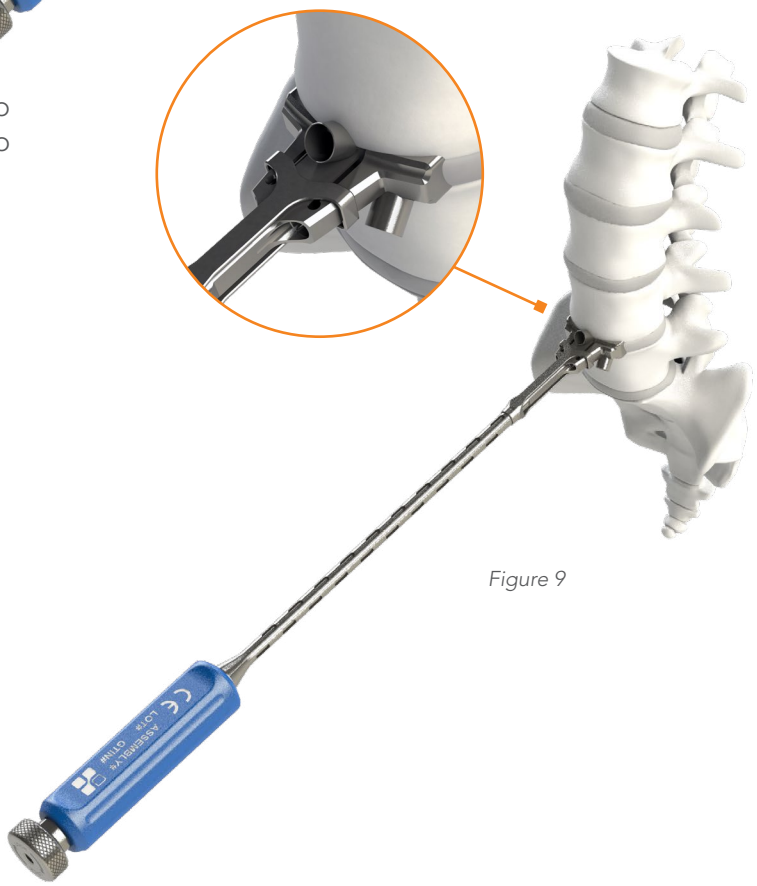


Figure 9

Simple Inserter

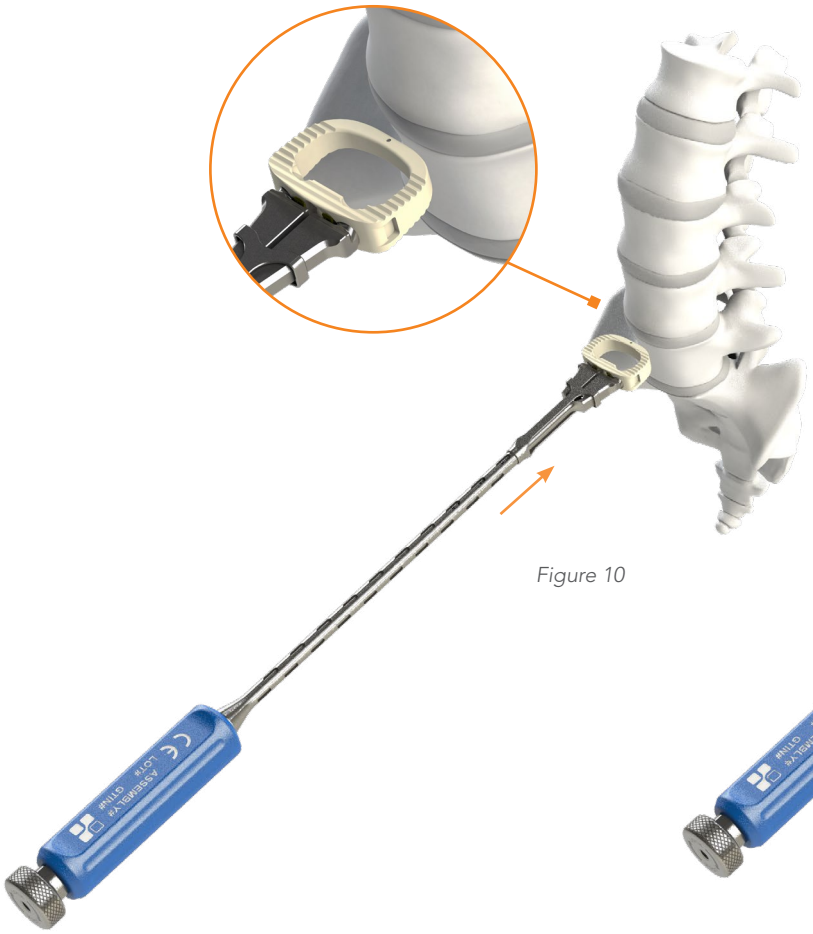


Figure 10

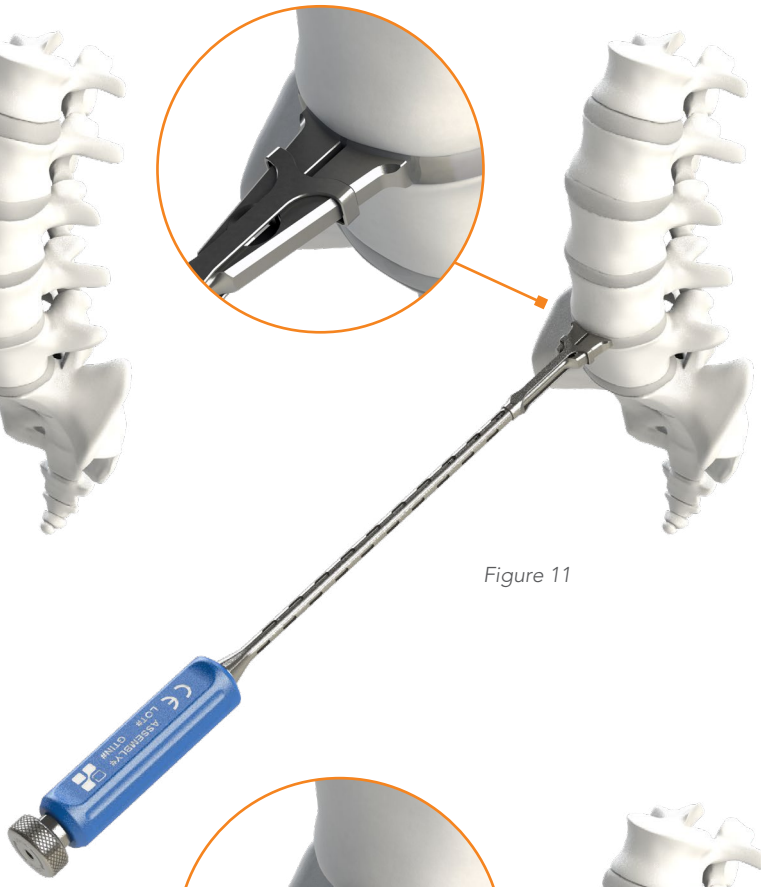


Figure 11

Insert the implant into the disc space *(Figure 10 & 11)*.

When the implant is in the desired position, rotate the knob on the Inserter Handle counter-clockwise to release Inserter Handle from Simple Inserter. Once the grip on the implant has loosened, both the Simple Inserter and Inserter Handle can be removed together *(Figure 12)*.

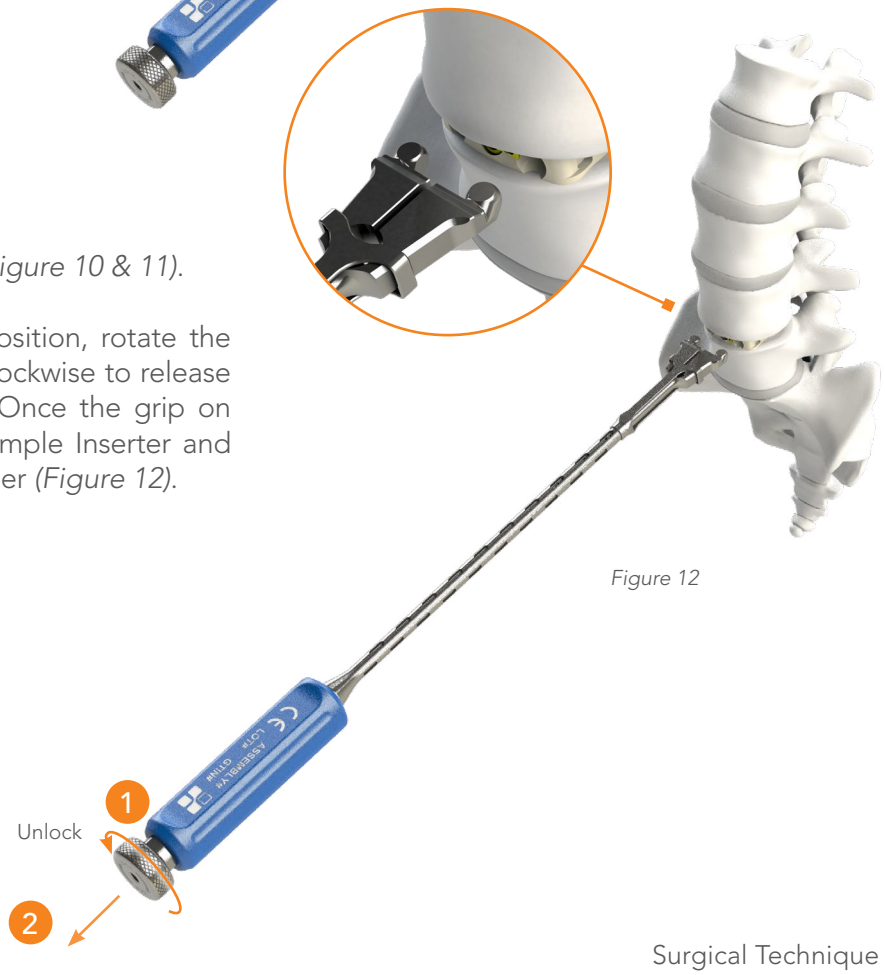


Figure 12

Standard Inserter

This is an OPTIONAL step, to be used only if needed

If the implant needs to be repositioned, the Implant Pusher may be used.

When using the Implant Pusher, the Standard Inserter must first be removed. To release the implant from the Standard Inserter, first rotate knob on Inserter Handle counter-clockwise to release Inserter Handle from the Standard Inserter. Once the grip on implant has loosened, both the Standard Inserter and Inserter Handle can be removed together *(Figure 14)*.

Figure 13

Figure 14

Connect the Implant Pusher to the implant by inserting the two pins into the screw hole on the front of the implant. Once attached, the implant may be moved to the desired position *(Figure 15 & 16)*.

When the implant has been positioned in the desired location, remove the Implant Pusher by pulling straight out.

Once the Implant Pusher has been removed, reconnect the Standard Inserter or use the Simple Inserter moving forward.

Caution: Confirm implant placement under fluoroscopy before removing instruments.

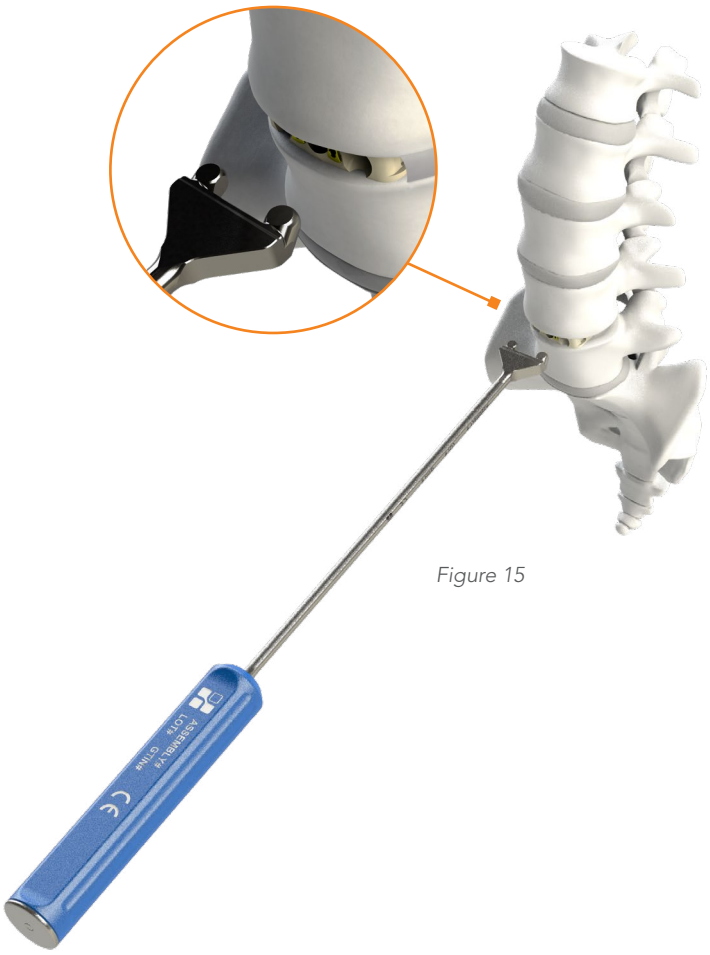


Figure 15

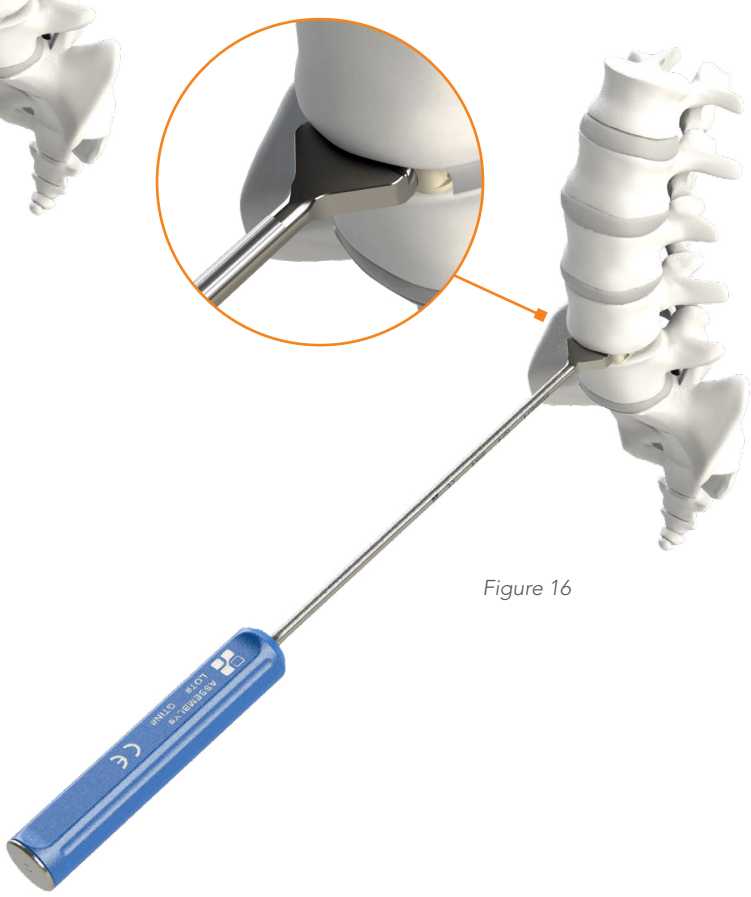
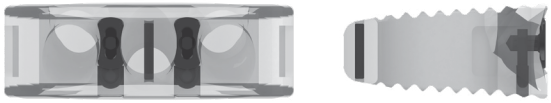


Figure 16

Arco-SA Radio Opaque Imaging



5 Screw Hole Preparation

Standard Inserter

The bone screws are self-drilling; however, creation of pilot holes is optional and recommended.

The Arco-SA system comes with an Awl, Drill, and Tap. Each comes in a Straight, Flexible, and Angulating variation. The Awl also has a Spring Loaded option for the Straight, Flexible, and Angulating variation.

These will aid in the insertion and preparation of screw holes while minimizing the size of the patient exposure site.

Straight Awl

Figure 17

Note: Awl is also available in a Flexible, Angulating, Spring Loaded Straight, Spring Loaded Flexible, or Spring Loaded Angulating variation.

Insert the Awl variation of your choice completely through the guide on the Standard Inserter *(Figure 17)*. Once inserted, lightly tap through the cortical surface to create a pilot hole.

The Awl depth is up to 15mm *(Figure 18)*, depending on the height of the spacer.

Remove the Awl by pulling straight out.

It is recommended to insert the first screw before preparing any other holes if no tapping or drilling is required.

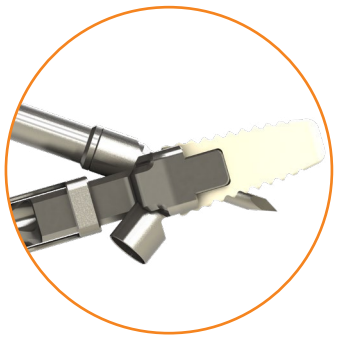


Figure 18

Standard Inserter

Insert the Drill variation of your choice completely through the guide on the Standard Inserter *(Figure 19)*. Apply pressure on the handle of the Drill with rotational motion.

The Drill depth is up to 15mm *(Figure 20)*, depending on the height of the spacer.

Remove the Drill by pulling straight out. It is recommended to insert the first screw before preparing any other holes if no tapping is required.

Straight Drill

Figure 19

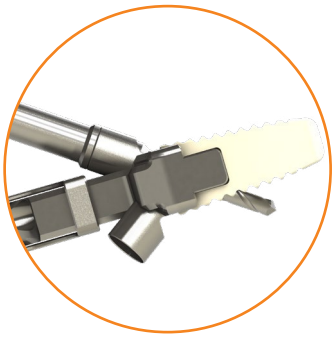


Figure 20

Note: Drill is also available in a Flexible or Angulating variation.

Note: The surgeon must take great care to properly position bone screw holes when using the awl, drill, or tap. Excessively converging hole patterns prohibit proper seating of the bone screws.

Caution: Verify instrument trajectory and placement with fluoroscopy.

Standard Inserter

Insert the Tap variation of your choice completely through the guide on the Standard Inserter *(Figure 21)*. Apply pressure on the handle of the Tap with rotational motion.

The Tap depth is up to 20mm *(Figure 22)*, depending on the height of the spacer.

Remove the Tap by turning it in a counter-clockwise rotational motion. It is recommended to insert the first screw before preparing any other holes.

Straight Tap

Figure 21

Note: Tap is also available in a Flexible or Angulating variation.

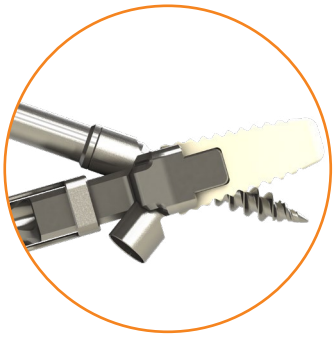


Figure 22

Single Guide Tube

The bone screws are self-drilling however, creation of pilot holes is optional and recommended.

Attach the Single Guide Tube to the implant by inserting it into the screw hole *(Figure 23 & 24)*.

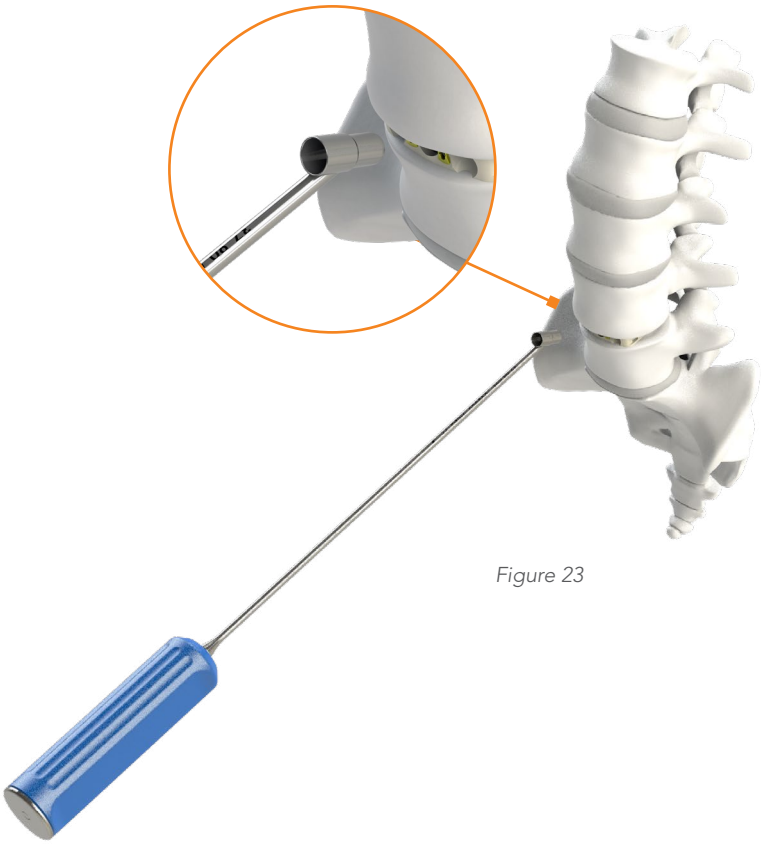


Figure 23

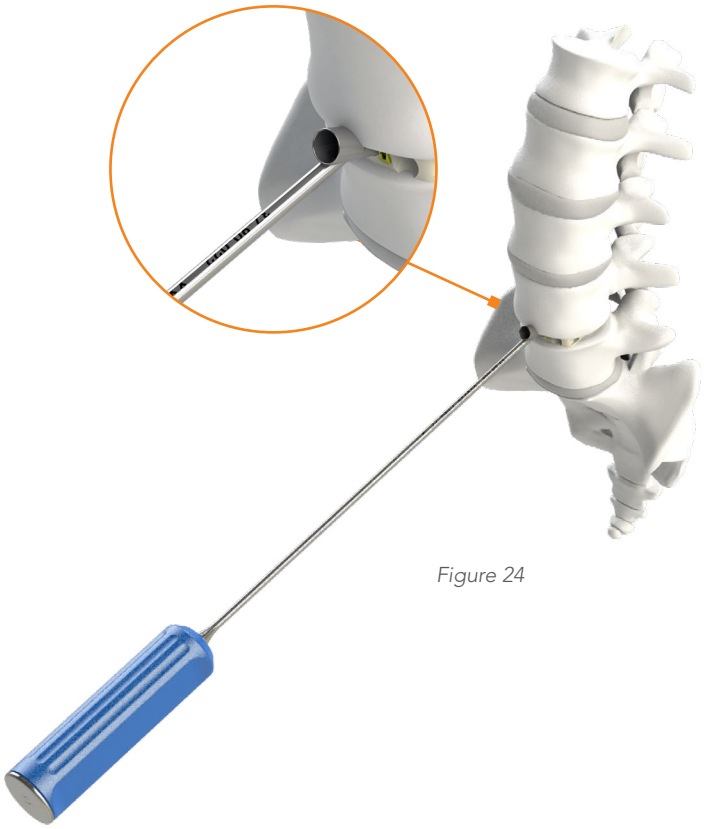


Figure 24

Note: The surgeon must take great care to properly position bone screw holes when using the awl, drill or tap. Excessively converging hole patterns prohibit proper seating of the bone screws.

Caution: Verify instrument trajectory and placement with fluoroscopy.

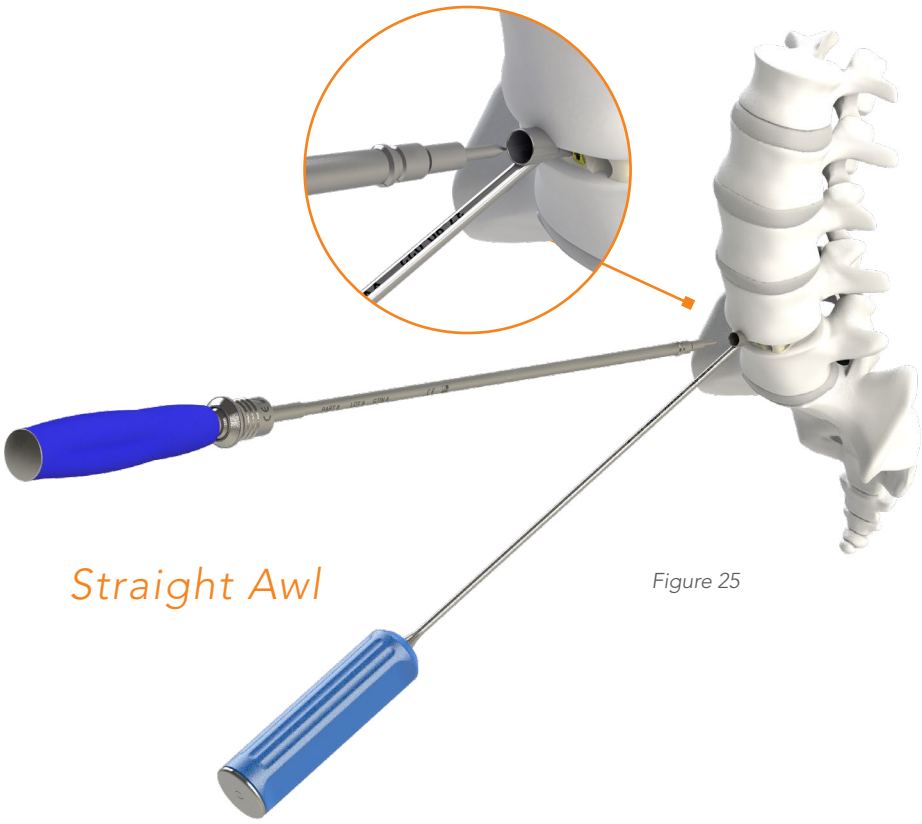
Single Guide Tube

Insert the Awl variation of your choice completely through the Single Guide Tube *(Figure 25)*. Once inserted, lightly tap through the cortical surface to create a pilot hole.

The Awl depth is up to 15mm, depending on the height of the spacer.

Remove the Awl by pulling straight out.

It is recommended to insert the first screw before preparing any other holes if no tapping or drilling is required.



Straight Awl

Figure 25

Note: Awl is also available in a Flexible, Angulating, Spring Loaded Straight, Spring Loaded Flexible, or Spring Loaded Angulating variation.

Single Guide Tube

Insert the Drill variation of your choice completely through the Single Guide Tube *(Figure 26)*. Apply pressure on the handle of the Drill with rotational motion.

The Drill depth is up to 15mm, depending on the height of the spacer.

Remove the Drill by pulling straight out. It is recommended to insert the first screw before preparing any other holes if no tapping is required.

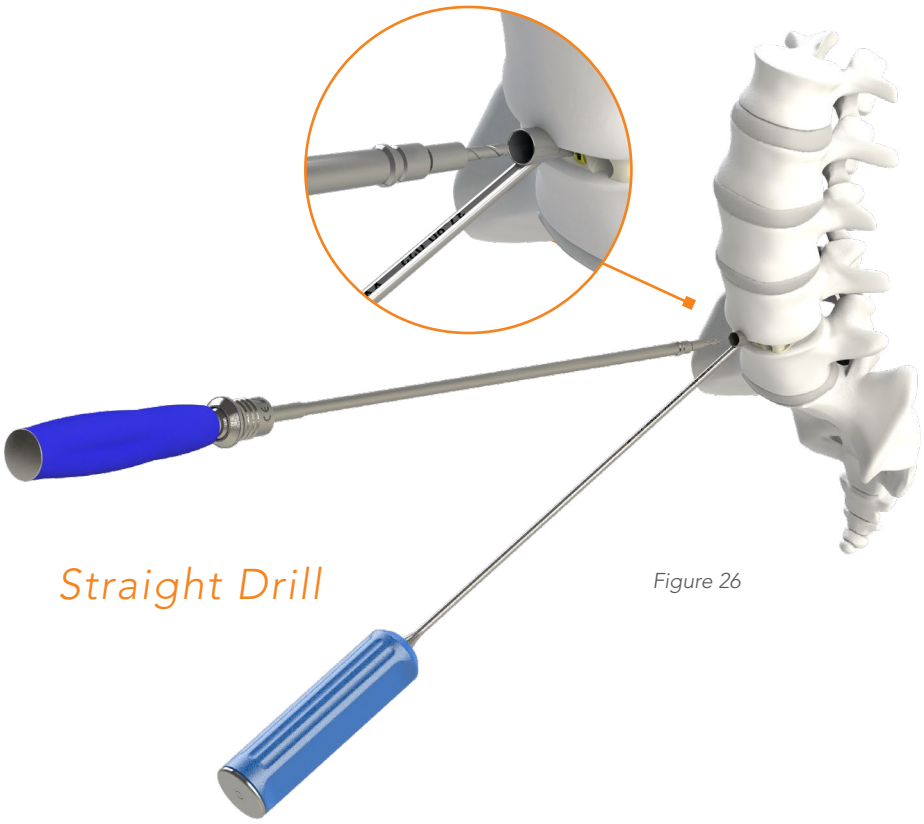


Figure 26

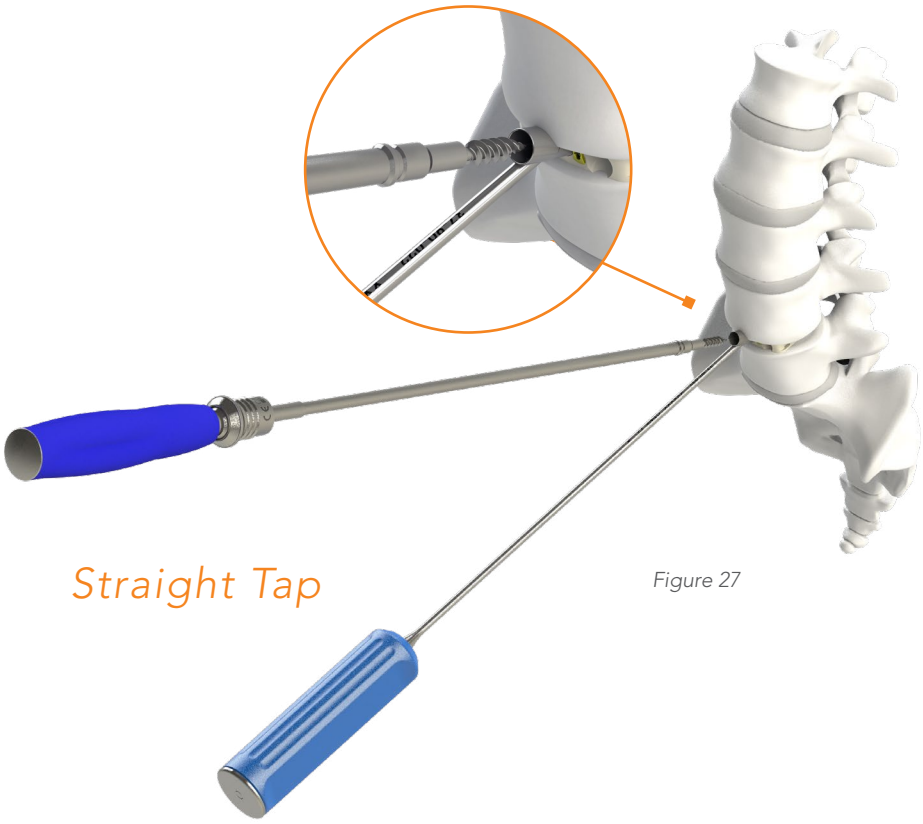
Note: Drill is also available in a Flexible or Angulating variation.

Single Guide Tube

Insert the Tap variation of your choice completely through the Simple Guide Tube *(Figure 27)*. Apply pressure on the handle of the Tap with rotational motion.

The Tap depth is up to 20mm, depending on the height of the spacer.

Remove the Tap by turning it in a counter-clockwise rotational motion. It is recommended to insert the first screw before preparing any other holes.



Straight Tap

Figure 27

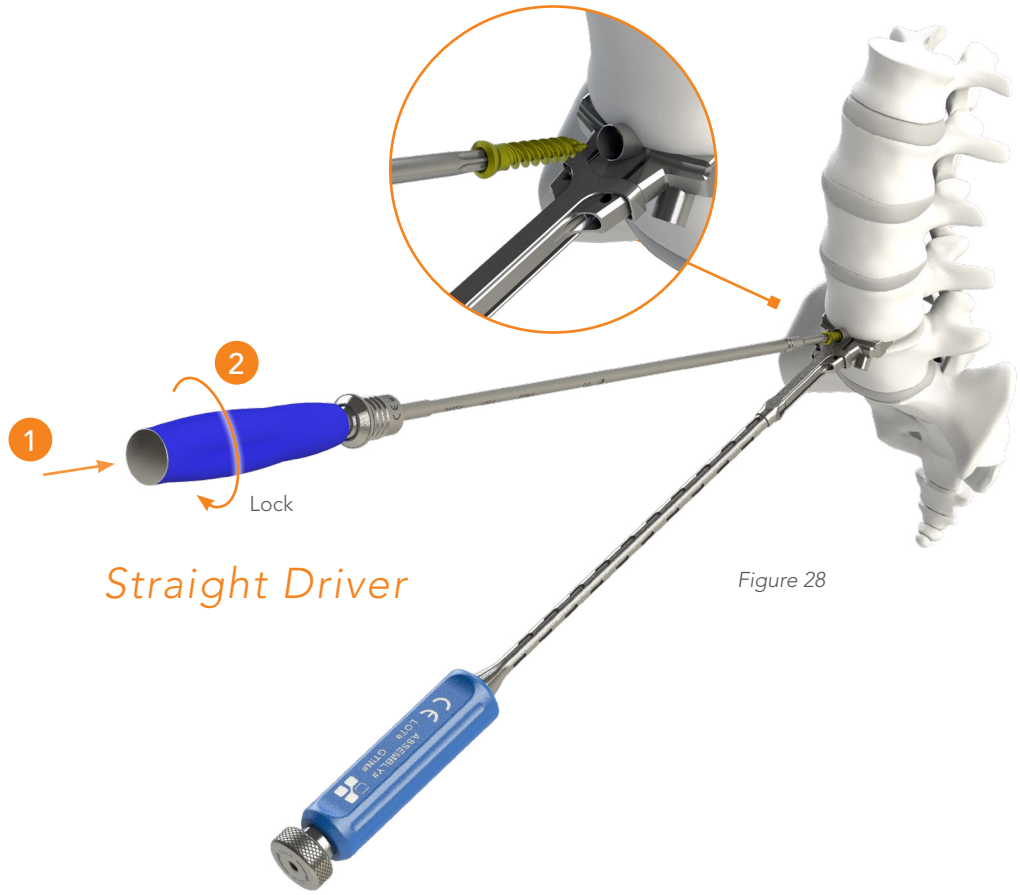
Standard Inserter

The Arco-SA system may come with a Straight, Flexible, and/or a Angulating Bone Screw Driver.

Insert the screw completely through the guide on the Standard Inserter using the Bone Screw Driver variation of your choice *(Figure 28)*.

Drive the screw into the adjacent vertebral body by turning the screw driver clockwise until solid engagement of the screw is achieved *(Figure 28)*.

Remove the Bone Screw Driver by pulling straight out *(Figure 28)*.



Straight Driver

Figure 28

Caution: Verify instrument trajectory and placement with fluoroscopy.

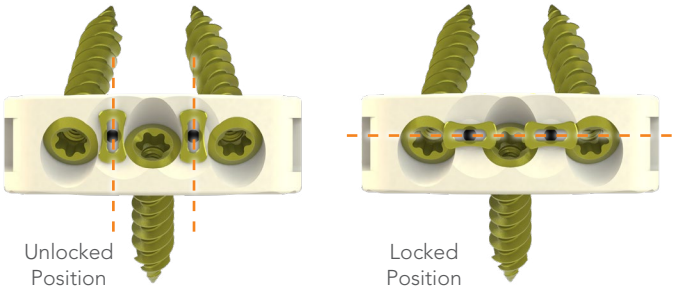


Figure 29

Note: It is important to verify the screws are properly seated under fluoroscopy before final tightening to ensure lock engagement and integrity.

Standard Inserter

The Arco-SA Cage Locking Driver comes in a Straight, Flexible, or Angulating variation.

Once the bone screws have been inserted and tightened, the cage lock can then be engaged to capture the screws *(Figure 29)*.

Insert the Cage Locking Driver variation of your choice through the Inserter handle. When the Cage Locking Driver is fully seated, turn it 90° clockwise to capture the screws and lock the cage *(Figure 30)*.

Remove the Cage Locking Driver by pulling straight out.

To release the implant from the Standard Inserter, first rotate knob on Inserter Handle counter-clockwise to release Inserter Handle from the Standard Inserter.

Once the grip on implant has loosened, both the Standard Inserter and Inserter Handle can be removed together.

Figure 30

Simple Inserter

The Arco-SA Cage Locking Driver comes in a Straight, Flexible, or Angulating variation.

Once the bone screws have been inserted and tightened, the cage lock can then be engaged to capture the screws.

Insert the Cage Locking Driver variation of your choice directly into the locking mechanism *(Figure 31)*. When the Cage Locking Driver is fully seated, turn it 90° clockwise to capture the screws and lock the cage *(Figure 32)*.

Remove the Cage Locking Driver by pulling straight out.

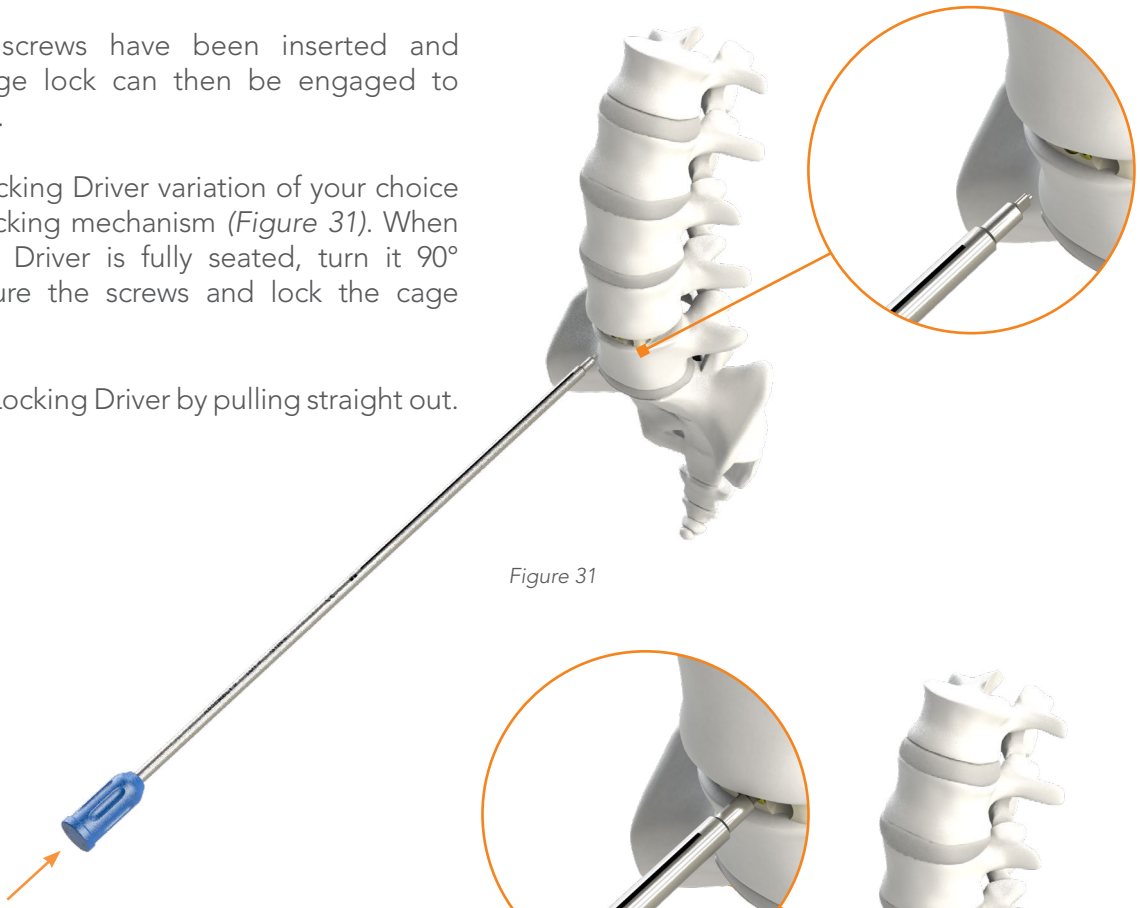


Figure 31

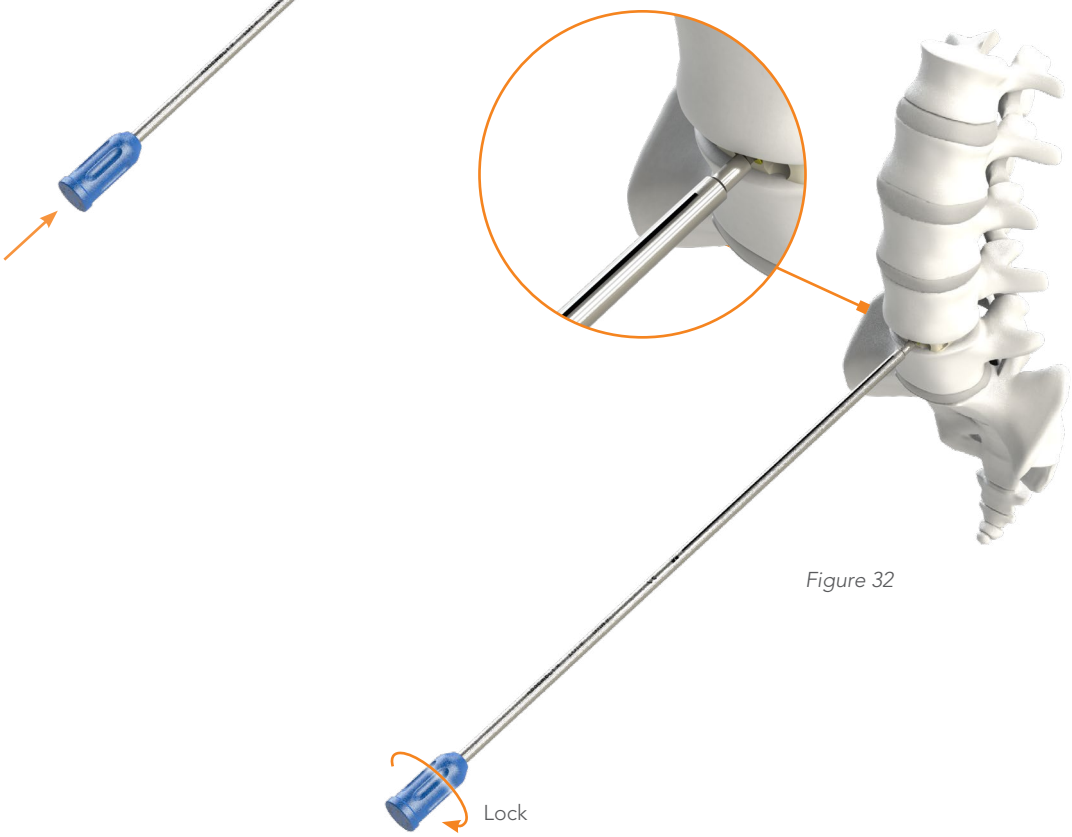


Figure 32

8 Final Position

Verify implant position using A/P and lateral fluoroscopy.

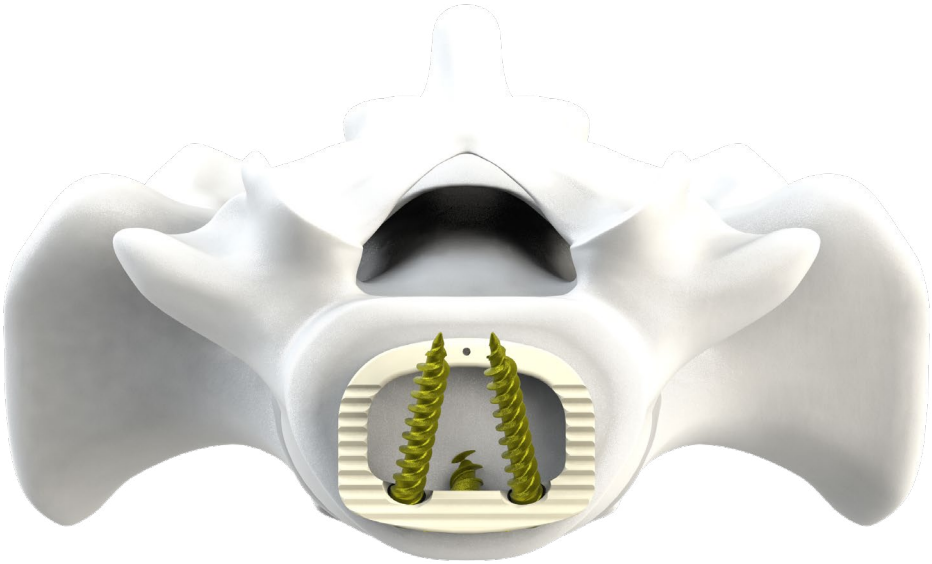


Figure 33

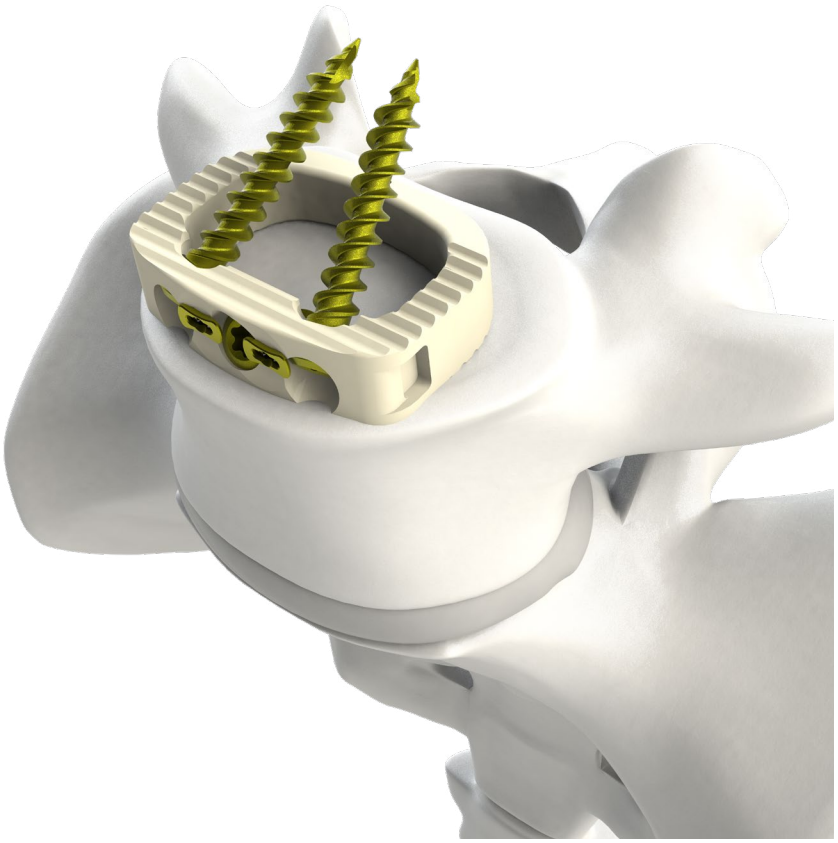


Figure 34

9 Cage Removal

If for any reason the implant needs to be removed, first insert the Cage Locking Driver into the locking mechanism *(Figure 36)*.

When the Cage Locking Driver is fully seated, turn it 90° counter-clockwise to release the screws and unlock the cage. Remove the Cage Locking Driver by pulling straight out *(Figure 37)*.

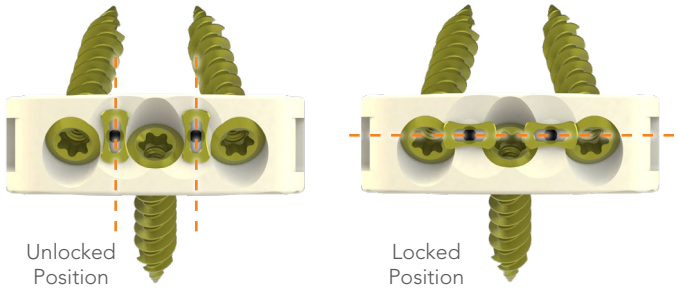


Figure 35

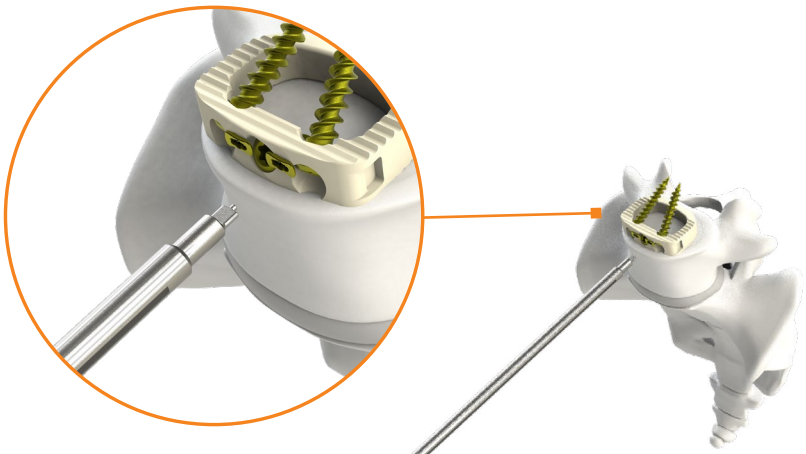


Figure 36

Figure 37

Once the locking mechanism has been unlocked, the Bone Screw Driver variation of your choice then can be used to remove the screws.

Insert the Bone Screw Driver fully into the screw head and turn counter-clockwise until screw is fully removed *(Figure 39)*.

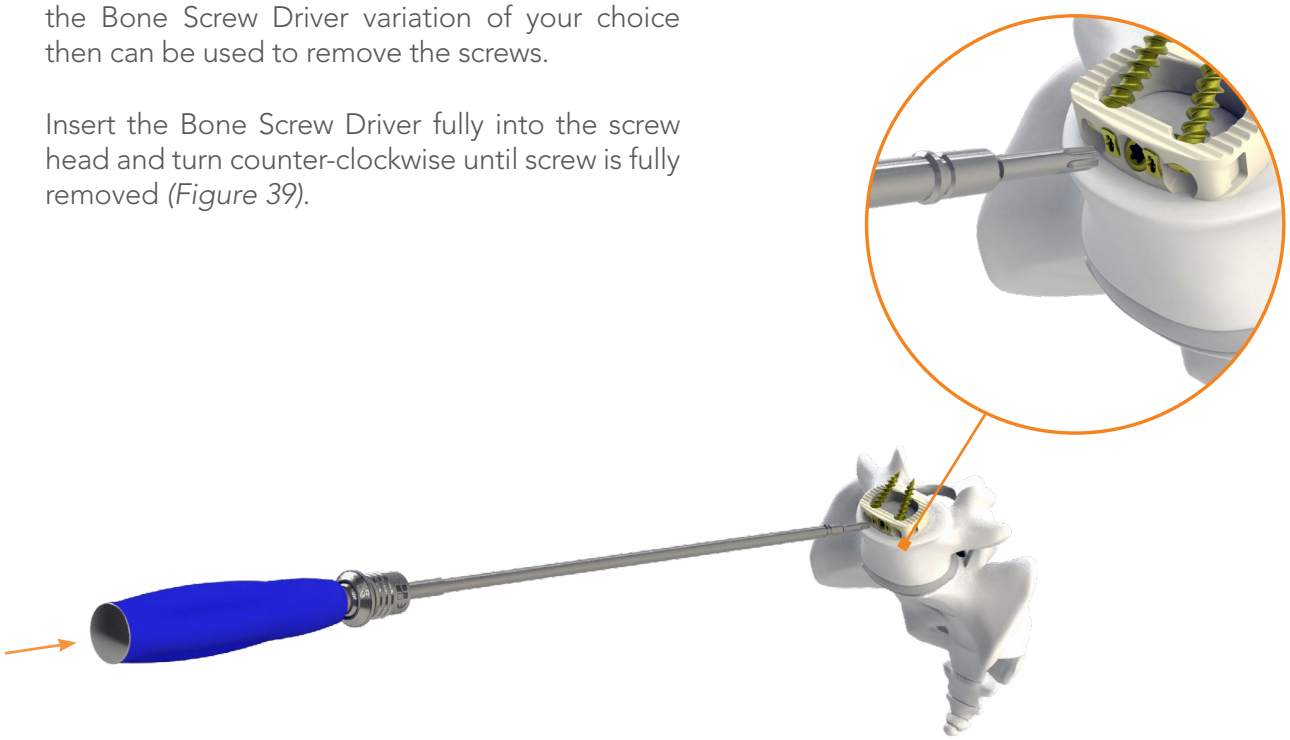


Figure 38

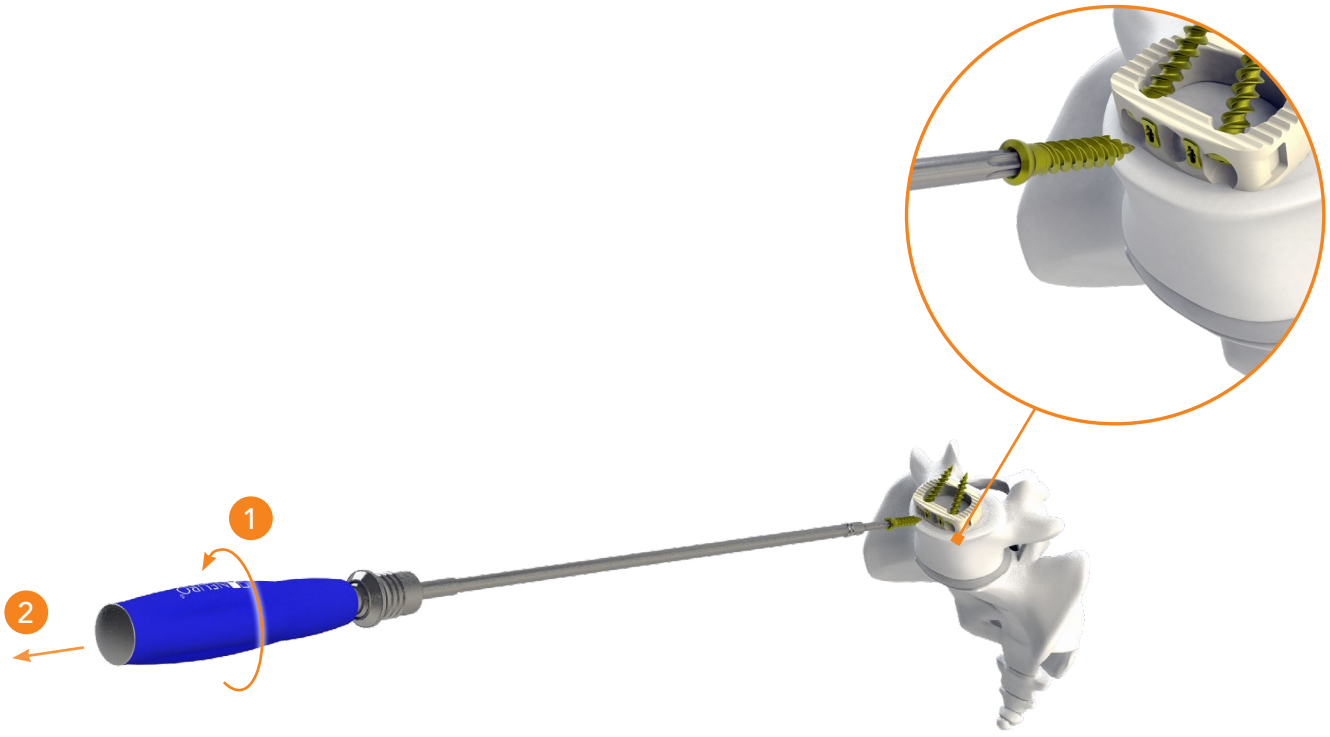


Figure 39

When all screws have been removed, then the Cage Remover can be used *(Figure 40)*.

Connect the Cage Remover to the implant by the two side tabs on the implant. When the Cage Remover is positioned on the implant, compress the handle to lock it onto the implant *(Figure 41)*.

Remove the implant by pulling straight out on the Cage Remover *(Figure 42)*.

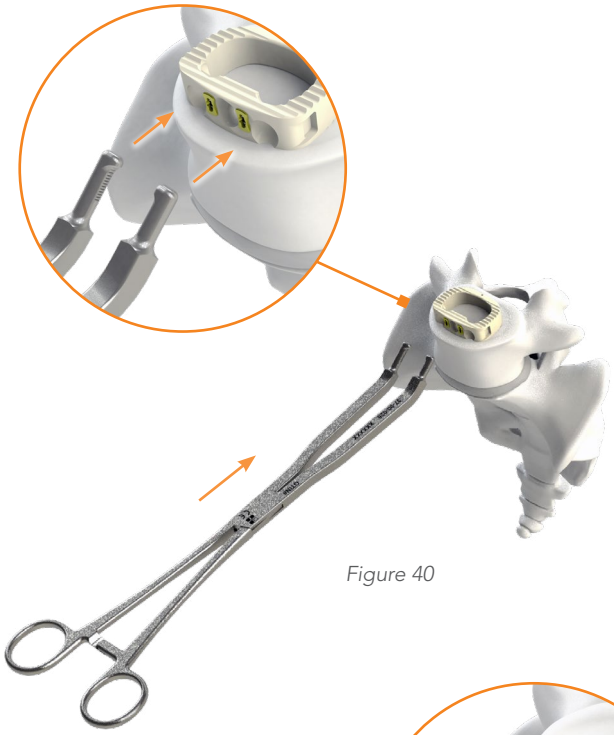


Figure 40

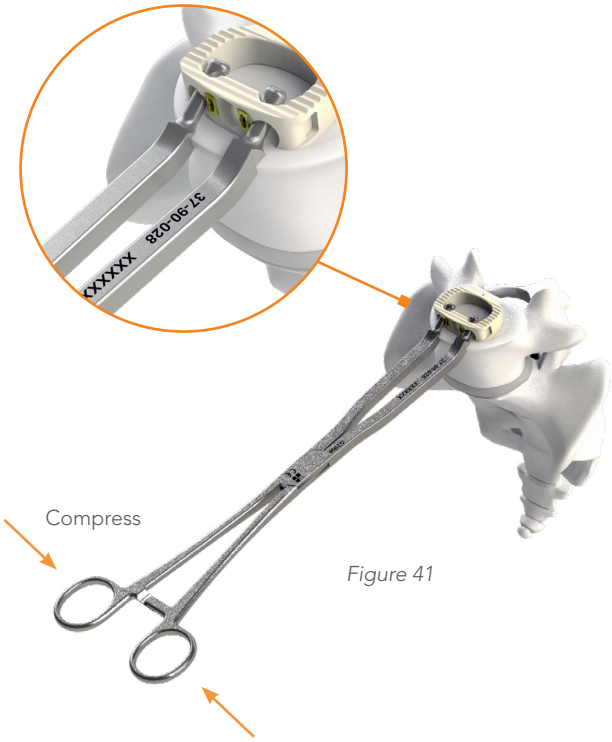


Figure 41

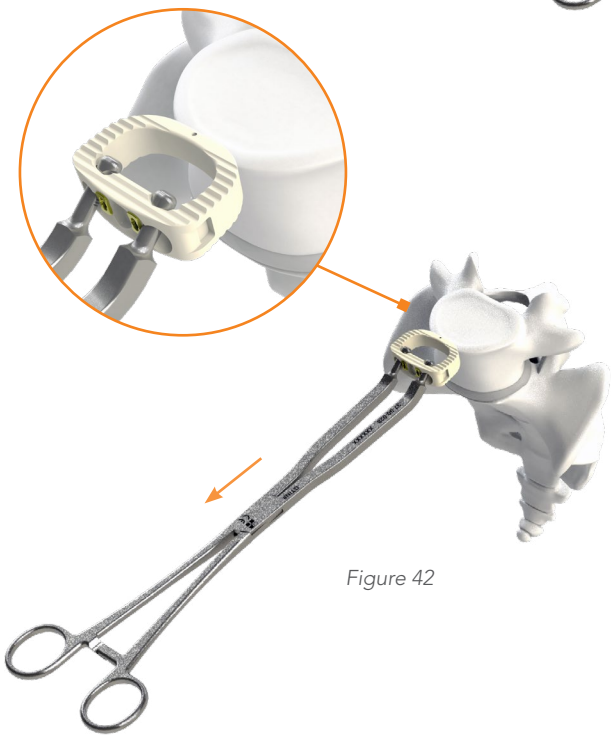


Figure 42

37-90-001-XX
Inserter

37-90-002
Inserter Handle

37-90-003
Simple Inserter

37-90-004
Flexible Awl

37-90-005
Flexible Drill

37-90-006
Flexible 5.0mm Tap

37-90-007
Flexible Bone Screw Driver

37-90-008
Flexible Cage Locking Driver

37-90-009
Flexible Spring Loaded Awl

37-90-013-XXXXXXX
Rasp with Handle

37-90-014
Straight Awl

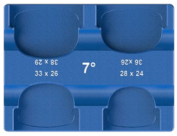
37-90-015
Straight Drill

37-90-016
Straight 5.0mm Tap

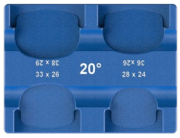
37-90-017
Straight Bone Screw Driver

37-90-018
Straight Cage Locking Driver

37-90-019
Straight Spring Loaded Awl



37-90-020
Packing Block 7˚



37-90-021
Packing Block 20˚

37-90-022
Single Guide Tube

37-90-023
Axial Non-Ratcheting Handle

37-90-024
Angulating Awl

37-90-025
Angulating Drill

37-90-026
Angulating 5.0mm Tap

37-90-027
Angulating Bone Screw Driver

37-90-028
Cage Remover

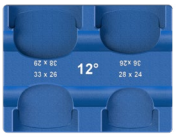
37-90-029
Angulating Spring Loaded Awl

37-90-030
Non-Ratcheting T-Handle

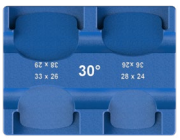
37-90-031
Implant Pusher

37-90-032
Packing Block Tamp

37-90-033-XXXXXXXX
Trial with Handle



37-90-034
Packing Block 12°



37-90-035
Packing Block 30°

Device Description:

The Arco-SA Lumbar Cage System is a stand- alone spinal intervertebral fusion device made from medical grade PEEK (polyetheretherketone) as per ASTM F2026. It is provided in a variety of footprints, styles, and sizes to accommodate various patient anatomies. The Arco-SA Lumbar Cage System is offered in 7°, 12°, 20°, and 30° angles of lordosis, and ranging from 28mm anterior-posterior x 24mm medial-lateral to 38mm anterior-posterior x 29mm medial-lateral. It is provided in heights from 12mm to 22mm in 2mm size increments with one radiographic marker pin made from tantalum, per ASTM F560.

The implants incorporate integrated anterior screw holes to allow for placement of three titanium alloy (per ASTM F136) screws, ranging in diameters of 5.0mm, 5.5mm, and 6.0mm and lengths of 20mm to 35mm in 5mm increments. Two titanium alloy locking mechanisms secure the screws once in place.

The Arco-SA Lumbar Cage System implants and instruments are provided non-sterile and will require thorough cleaning and sterilization prior to each use.

Indications:

The Arco-SA Lumbar Cage System is intended for spinal fusion procedures at one level (L2 to S1) in skeletally mature patients with degenerative disc disease (defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies) of the non-cervical spine. Implants are intended to be implanted via an open, anterior approach and packed with bone graft. These patients should be skeletally mature and have had at least six (6) months of non-operative treatment. In addition, these patients may have up to a Grade 1 spondylolisthesis or retrolisthesis at the involved level(s). These implants are used to facilitate fusion in the lumbar spine and are placed via an anterior (ALIF) approach. Hyperlordotic implants (those with a lordotic angle greater than or equal to 20°) are indicated for use with a supplemental spinal fixation system that has been cleared by the FDA. The Arco-SA Lumbar Cage System implants with a lordotic angle less than 20°, when used with the internal fixation screws, do not require use of supplemental fixation.

Contraindications:

Contraindications include, but are not limited to:

- Infection, local to the operative site.
- Allergy to PEEK, metal, titanium alloy, or tantalum.
- Signs of local inflammation.
- Fever or leukocytosis.
- Morbid obesity.
- Pregnancy.
- Mental illness.
- Grossly distorted anatomy due to congenital abnormalities.
- 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.
- 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.
- Reuse or multiple use.
- 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.
- Cessation of growth of the fused portion of the spine.
- 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 and/or wound complications.
- Dural tears, pseudomeningocele, fistula, persistent CSF leakage, and/or 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.
- Malalignment of anatomical structures (i.e. loss of normal spine contours or change in height).
- Bone loss or decrease in bone density, possibly caused by stress shielding.
- Graft donor site complications including pain, fracture, or wound healing problems.
- Subsidence of the device into the vertebral body.
- Pain or discomfort.
- Atelectasis, ileus, gastritis, herniated nucleus pulposus, and/or 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.
- Revision surgery.
- Death.

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

Warnings and Precautions:

The implantation of the Arco-SA 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 Arco-SA 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 Arco-SA Lumbar Cage is NOT intended to be used without the Arco-SA fixation screws provided and should NOT be implanted alone without the support of the fixation screws.

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.

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.

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. This may result in further injury or the need to remove the device prematurely.

Use of the Arco-SA Lumbar Cage System should only be considered when the following preoperative, intraoperative, and postoperative conditions exist.

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 Arco-SA 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 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 Arco-SA Lumbar Cage System implants 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. Lumen/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. Arco-SA Lumbar Cage System instruments must be cleaned separately from 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 7 – 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 lumen, 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 lumen and channels. Actuate joints, handles, and other moveable instrument features 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 Arco-SA 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	4 min	20 – 30 min

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

Implants and instruments are provided non-sterile.

Magnetic Resonance Environment:

The Arco-SA Lumbar Cage System has not been evaluated for safety and compatibility in the MR environment. The Arco-SA Lumbar Cage System has not been tested for heating or migration in the MR environment. The safety of Arco-SA Lumbar Cage System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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 Arco-SA 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:

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