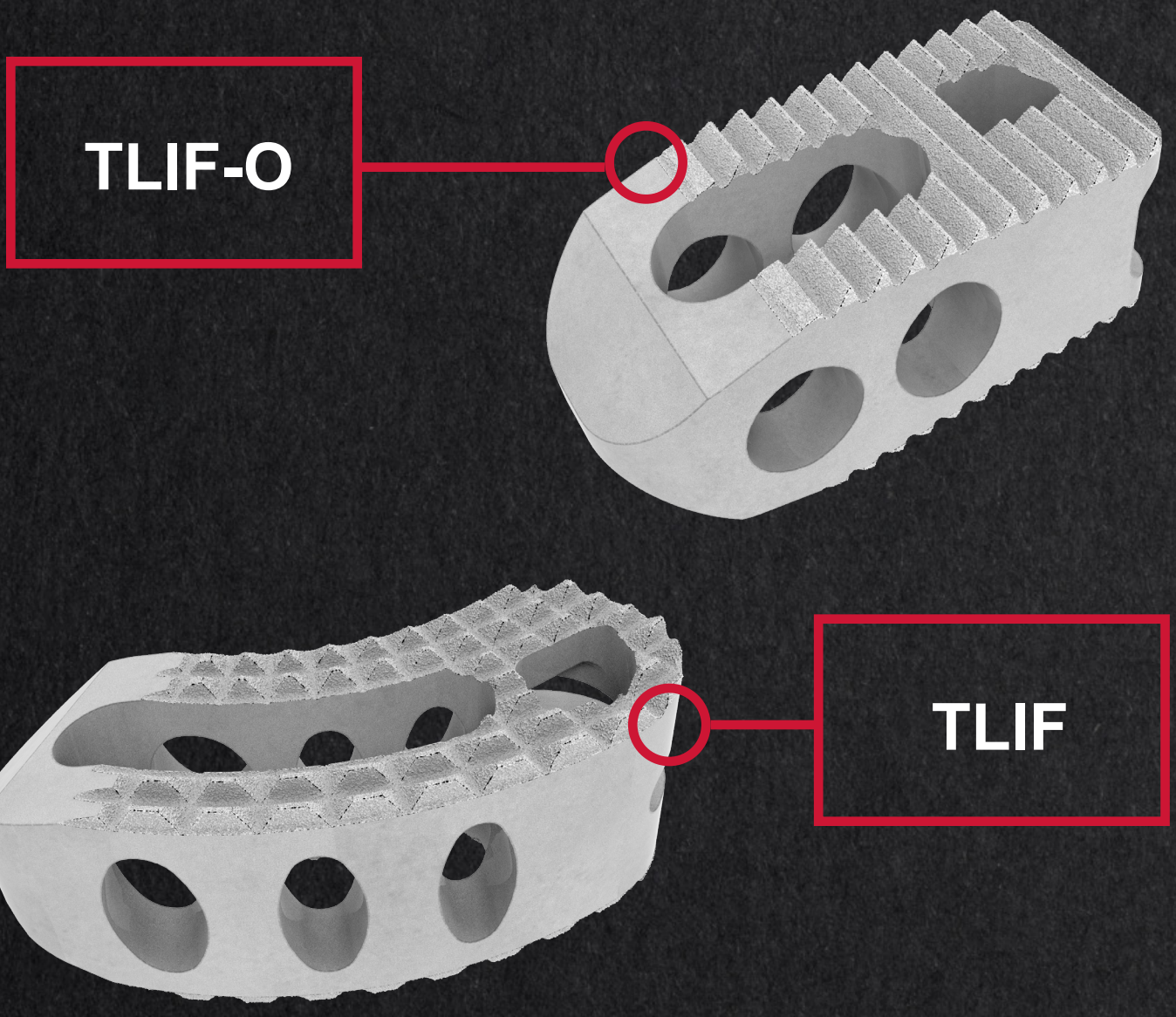
OC SPINE

Surgical Technique Guide

FOCUS-TO AND FOCUS-T CAGES



Contents

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

Description

The FOCUS Interbody System includes interbody fusion devices for lumbar implantation. The FOCUS-T and FOCUS-TO implants are designed as structural columns to provide surgical stabilization of the lumbar spine. Each interbody has a central cavity to be packed with bone graft material and inferior/superior teeth to resist expulsion. Lateral windows provide for radiographic visualization on most implant sizes. The implants are available with and without the xCELLerate surface coating and in a variety of height, length, width and lordotic angulation combinations to accommodate the patient specific anatomy and clinical circumstances. The devices are manufactured from titanium alloy (Ti6Al4V ELI per ASTM F136). The instrumentation for implantation is manufactured from medical grade stainless steel per ASTM F899 some of which feature Radel handles. The implants are provided sterile.

Indications

The FOCUS Interbody System is intended to be used as a lumbar intervertebral fusion device at one or two adjacent levels from L2 to S1. This system should be limited to skeletally mature patients who have had six months of non-operative care for the treatment of degenerative disc disease (DDD) with up to Grade 1 spondylolisthesis or retrolisthesis at the involved spinal level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. In addition, the FOCUS Interbody System can be used as an adjunct to fusion in patients diagnosed with degenerative scoliosis. The FOCUS Interbody System is intended for use with autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate. These implants are intended for use with supplemental fixation indicated for lumbar spinal fusion procedures such as the OC Medical Devices Spine Pedicle Screw System.

Contraindications

Absolute contraindications include, but are not limited to:

1. Active systemic infection or infection localized to the site of the proposed implantation
2. Prior fusion at the level(s) to be treated
3. Any condition not described in the Indications for Use

Any entity or condition that totally precludes the possibility of fusion is a relative contraindication. In addition, the patient's occupation, activity level, or mental capacity may be relative contraindications to this surgery. Relative contraindications include, but are not limited to: to: cancer, kidney dialysis, osteopenia, obesity, pregnancy, certain degenerative diseases, foreign body sensitivity, mental illness, alcoholism, or drug abuse.

Warnings and Precautions

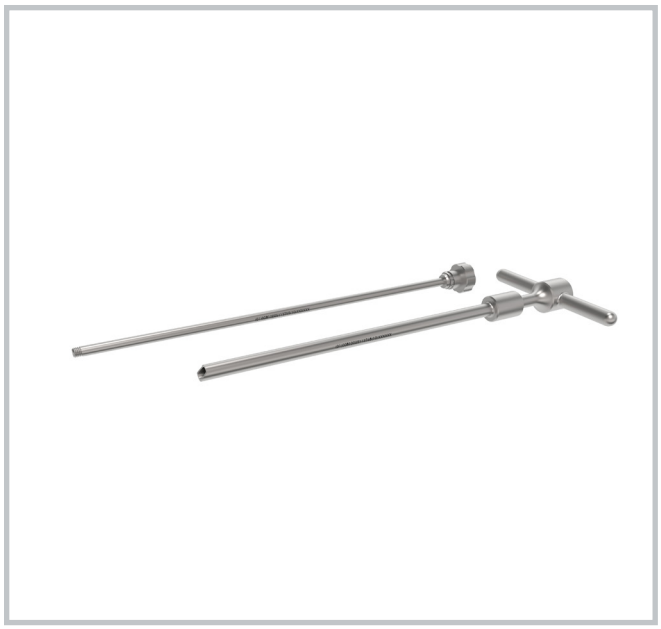
1. The FOCUS Interbody System should only be implanted by surgeons experienced in the use of these implants and the associated spinal surgery techniques. Prior to use, surgeons should be trained in the surgical procedures recommended for the implantation of these devices.
2. The correct selection of the implant is extremely important. The potential for success is increased by the selection of the proper size, shape and design of the implant. Based on the dynamic testing results, the physician should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact on the performance of the device.
3. These FOCUS Interbody System implants are provided as single use only and are not to be reused or reimplanted regardless of an apparent undamaged condition. Any retrieved devices must never be reused under any circumstances.
4. These FOCUS Interbody System implants are provided sterile. Do not clean and/or resterilize sterile implants. Do not use if package is opened or damaged or if expiration date has passed.
5. The FOCUS Interbody System cages are used to augment the development of a spinal fusion by providing temporary stabilization. This device is not intended to be the sole means of spinal support – supplemental internal fixation must be used.
6. The correct handling of the implant is extremely important. Use care in handling and storage of devices. Sterile implants must be stored in a dry area away from radiation and extreme temperatures and environments such as moisture, air, etc.
7. Patients with previous spinal surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.
8. Components of this system should not be used with components of any other system or manufacturer.
9. Potential risks identified with the use of this system, which may require additional surgery, include: device component breakage, loss of fixation/loosening, non-union, vertebral fracture, neurologic, vascular or visceral injury.
10. Mixing of dissimilar metals can accelerate the corrosion process. Stainless steel and titanium components must NOT be used together.
11. As with all orthopedic implants, none of the FOCUS System components should ever be reused under any circumstances.

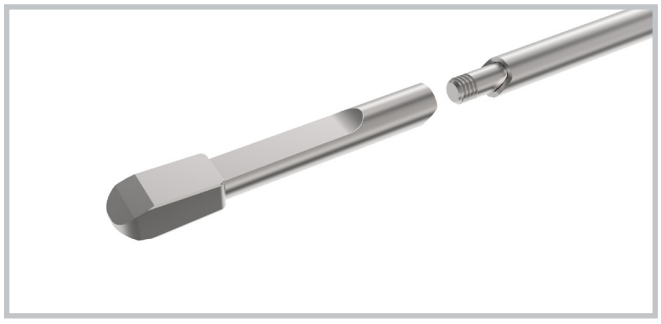
Trial/Rasp/Distractor/Shaver Attachment to Prep Tool Handle

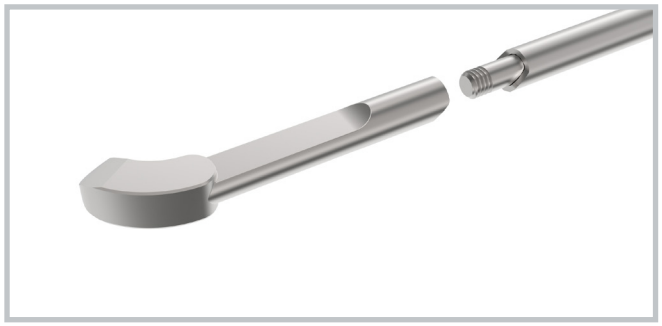
1. Prepare the prep tool handle by inserting the retention bar.

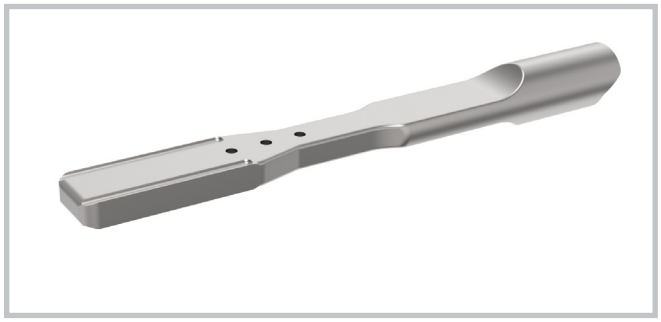
2. Place the desired instrument head over the end of the retention bar and align the 45 degree cuts at the tip of the prep tool handle.

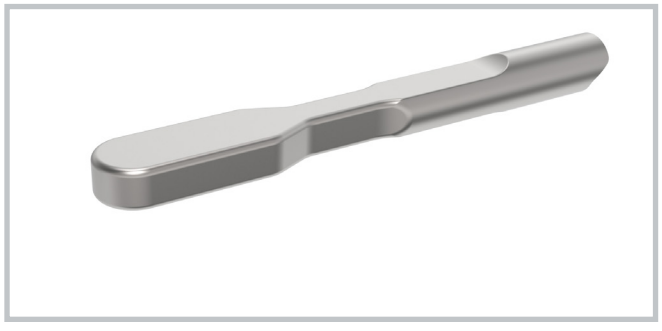
3. Thread the retention bar into the instrument head.











Patient Positioning

The patient is put under general anesthesia and placed in the prone position on a radiolucent spine table.

Take caution in positioning of the head and extremities to reduce the risk of ocular and nerve compression.

Pedicle Screw Insertion

If desired, follow the OC Medical Devices Spine Pedicle Screw System Surgical Technique

Guide for pedicle screw insertion. A posterior spinal fixation system can be placed either before or after the interbody preparation, though it is often advantageous to utilize the pedicle screw system to achieve and maintain distraction during the Cage implantation procedure.

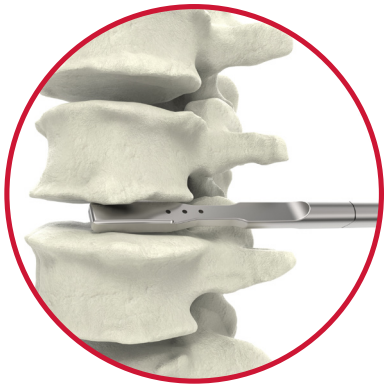
Discectomy

Follow standard surgical procedure for a complete discectomy using preferred surgical instruments. Remove disc material by making use of the Curettes, Rongeurs, and Shavers.

If necessary, achieve distraction of the disc space with properly sized Distractors or the Lamina Spreader, or using pedicle screws and spine rods.

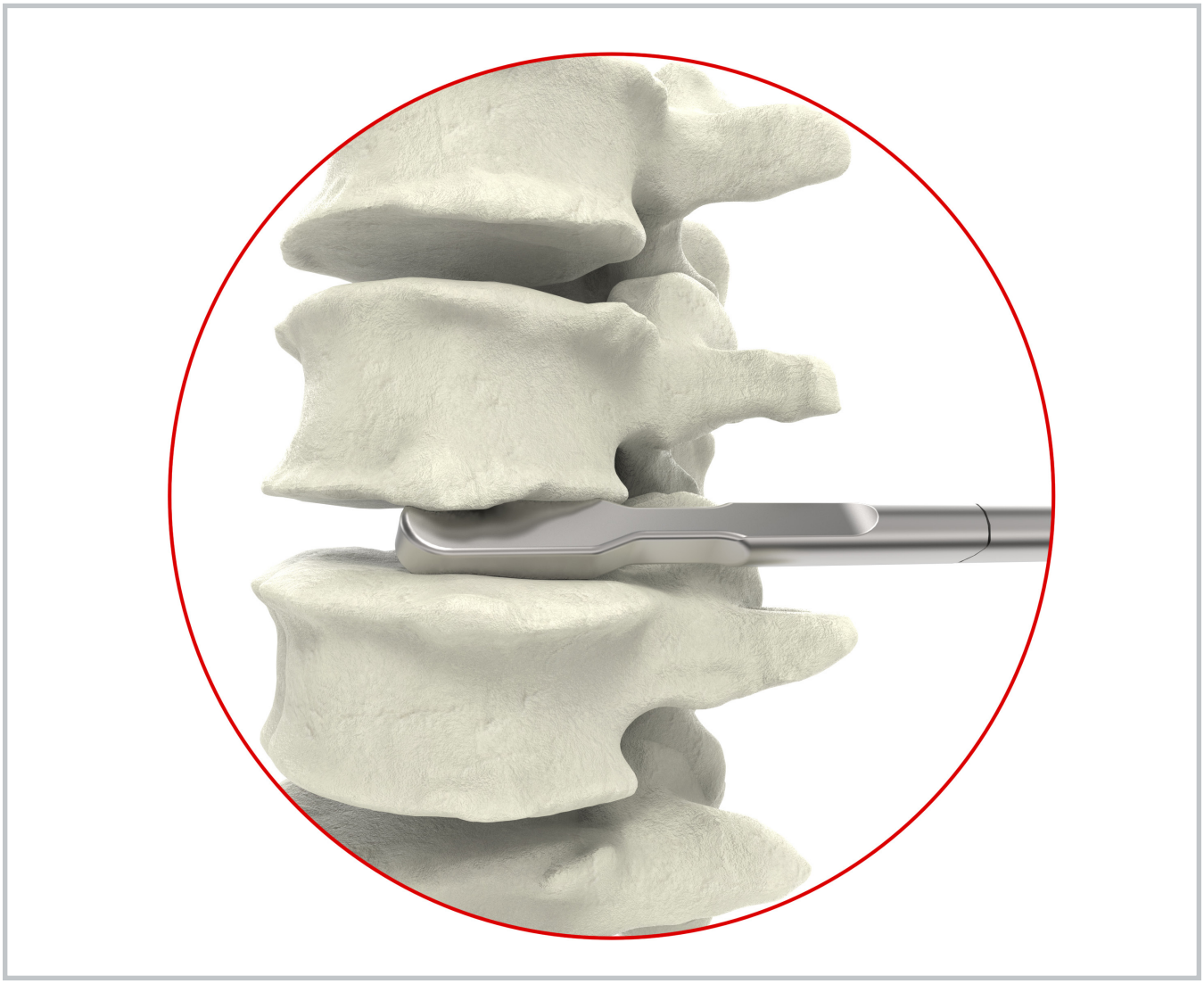
Provide enough lateral exposure to the disc to minimize Dural retraction.

Note that the annulus should be preserved to prevent migration of bone graft material as well as to provide additional support to the implant.



Distraction

Proper distraction aids in removal of the superior articularprocess, decompression of the neuroforamen, preparation of the disc space and insertion of the Implant. This may be accomplished through several techniques: pedicle screw distraction or distraction between bone elements with the Lamina Spreader and/or distraction with the **Distractor** attachments.



Decompression

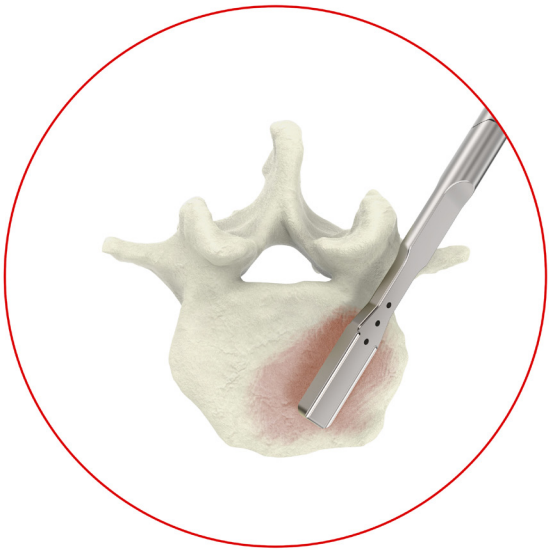
Utilizing Osteotomes and Rongeurs, a small section of the lamina and facet(s) should be removed to create an appropriately sized bony window for access to the targeted disc space. Preserve decorticated bone to pack in or around Cage implant prior to implantation.

Prepare Endplates for Implantation

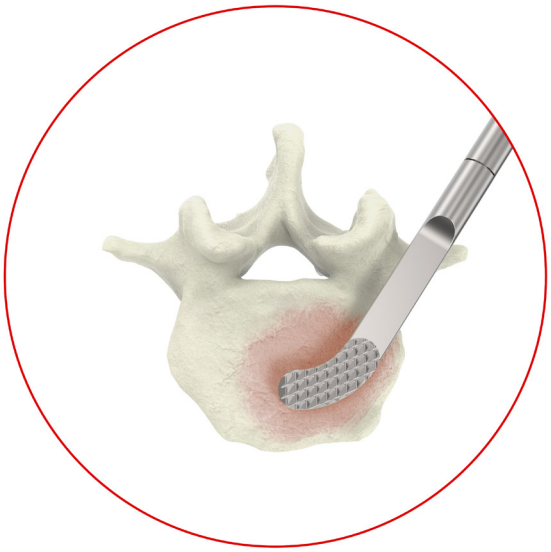
Follow standard surgical procedure for removing any remaining disc material and the superficial cartilaginous layer on endplates to expose bleeding bone with the **Shavers, Rasps,** or other instruments.

Note that one needs to exercise caution to minimize the amount of bone removed. Excessive removal of bone could weaken the endplate and may result in subsidence of the FOCUS cage implant and loss of stability.

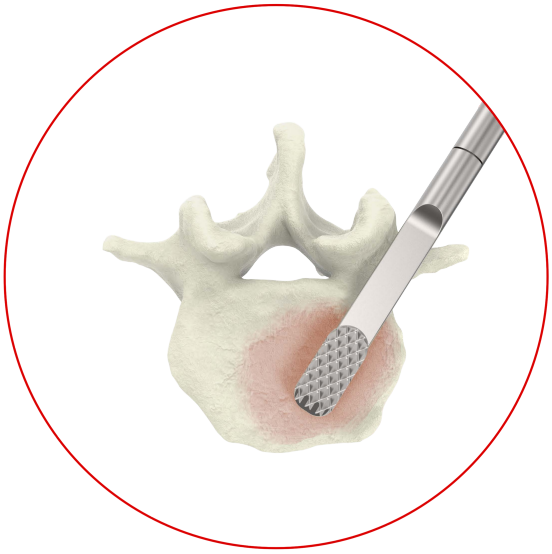
FOCUS SHAVER



FOCUS-T RASP

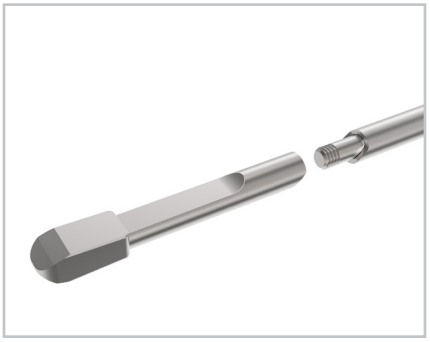


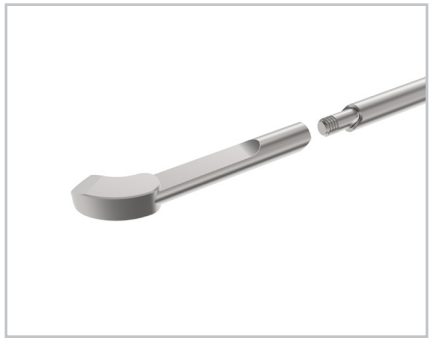
FOCUS-TO RASP

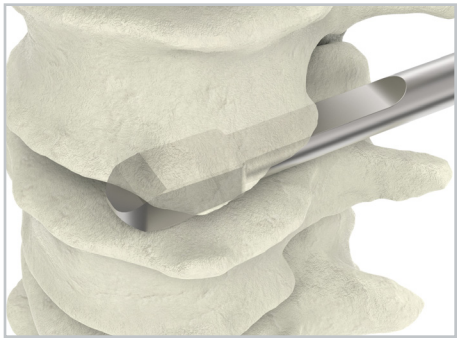


Implant Size Selection

Attach an appropriately sized Trial to the Prep Tool Inserter. If necessary, use a mallet to gently impact the Prep Tool Inserter. Insert the Trial into the disc cavity and confirm proper sizing and positioning under the fluoroscope. Find an appropriate disc height and fit of the implant within the disc space by serially increasing the size of the Trial. Note that the Trial should remain in the intended position until the Cage implant is fully prepared for implantation in order to maintain disc height.







Implant Preparation

1. Prepare the inserter by ensuring the locking nut is loose and the capture collar is in the unlocked, forward position. The T-bar should be parallel to the flats on the tip of the inserter.
2. Insert the T-bar into the slot on the rear of the implant.
3. Rotate the capture collar from the unlocked to locked position. This will rotate the T-bar inside the implant and draw the implant against the tip of the inserter.
4. Tighten the locking nut to firmly lock the implant in place.

Prior to insertion, load the bone graft (autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate) into the cavity of the Cage.

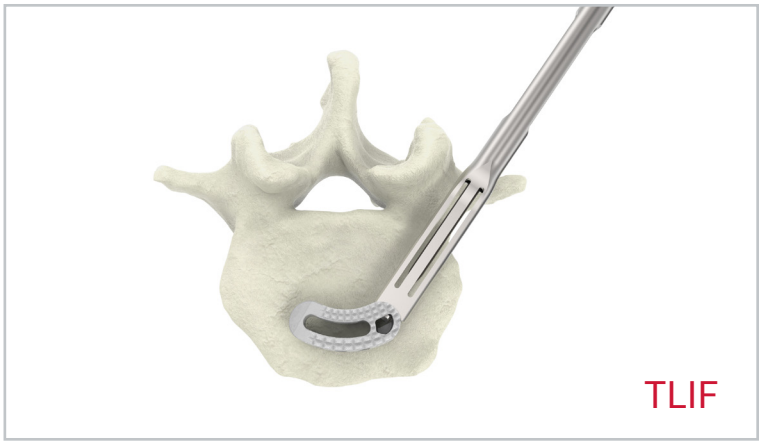
Note that bone graft material should protrude from all openings of the Cage implant

Insertion Technique

1. Attach the Cage Inserter to the previously packed Cage implant. Use a Mallet to aid insertion, if necessary. Remove the Trial from the intervertebral disc space and insert the Cage implant into the intervertebral disc space.

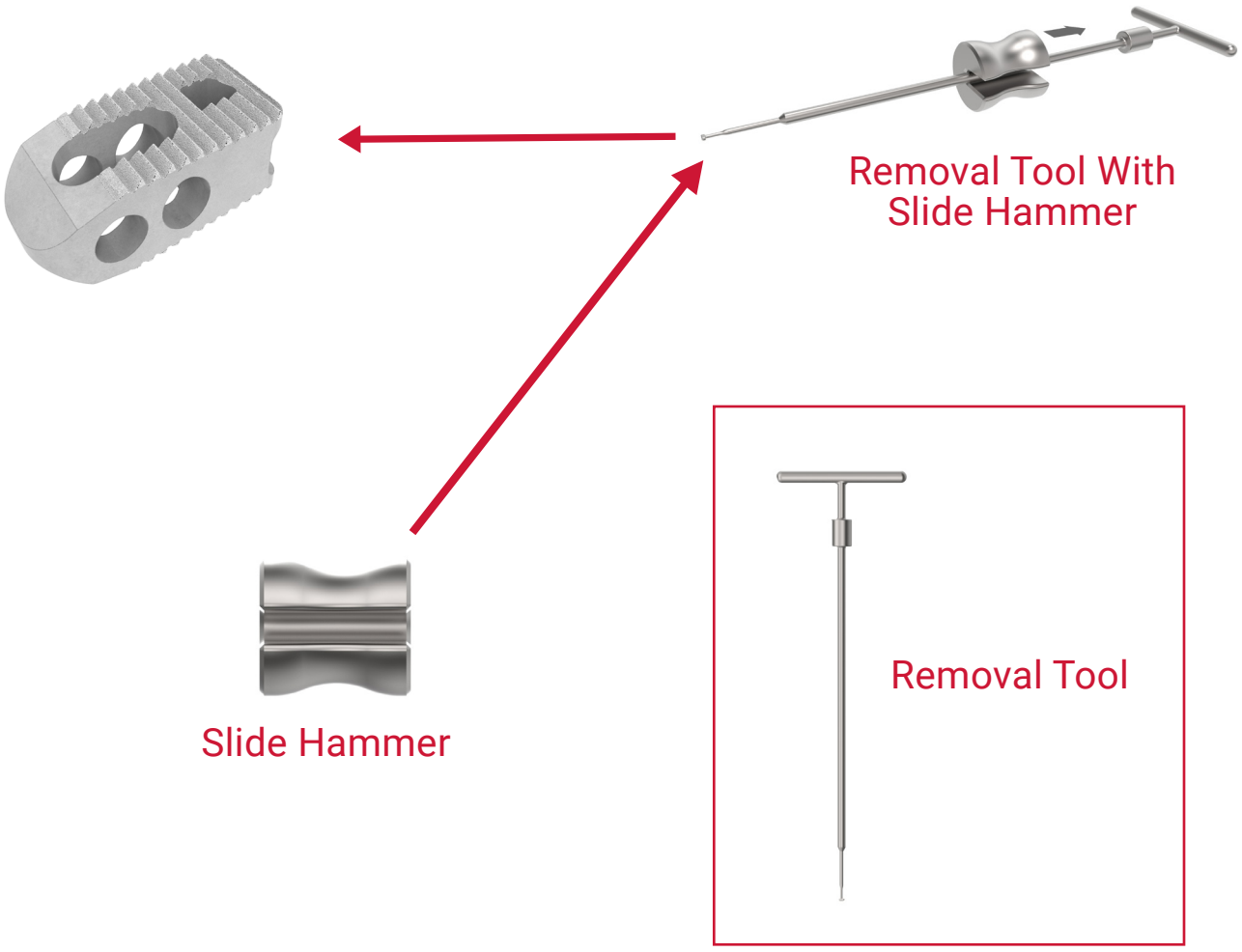
2. If necessary, make slight adjustments to the positioning of the Cage implant by using a mallet to help advance the implant to the desired position, or by detaching the Cage Inserter from the Cage implant and using the Cage Adjuster to continue to push the Cage implant into position. Confirm proper size and position of the Cage implant under the fluoroscope.

3. Detach the Cage Inserter and add any bone graft material (autograft and/or allograft comprised of cancellous and/or corticocancellous bone graft and/or demineralized allograft bone with bone marrow aspirate) to fill the remaining disc space.



Implant Removal

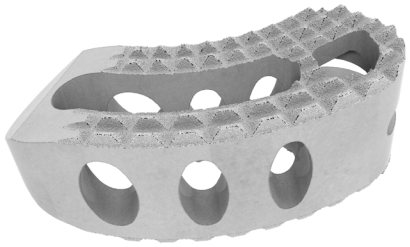
In the case that an implanted cage requires removal, attach the removal instrument. In conjunction with the removal instrument, a slide hammer may be used. To use, apply an upward force to the slide hammer until the implant is removed from the disc space.



FOCUS Interbody System cages

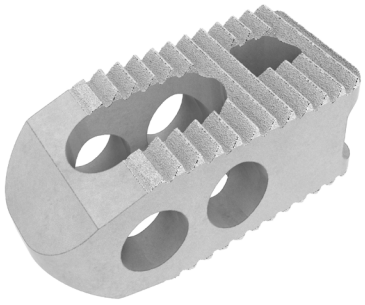
FOCUS-T (TLIF style)

Length	Width	Height	Lordosis
25mm	9mm	6-13mm	5° & 10°
31mm	10mm	7-14mm	5° & 10 °



FOCUS-TO (TLIF-O/PLIF style)

Length	Width	Height	Lordosis
22mm	10mm	7-14mm 11-14mm	5° 10°, 18°
27mm	10mm	7-14mm 11-14mm	5° 10°, 18°
32mm	10mm	7-17mm 11-14mm	5° 10°



FOCUS Interbody System Instruments

Product Code	Description	
102.100	Cage Inserter	
102.101.01	Prep Tool Shaft	
102.102.02	Prep Tool Handle	
102.103	Removal Tool	
102.104	Slide Hammer	
102.106.xx	Distractors	
102.107.xx	Shavers	
102.108	TLIF Rasp	
102.109	TLIF-O Rasp	
102.110.xx 102.111.xx	TLIF Trials, 25mm TLIF Trials, 31mm	
102.112.xx 102.113.xx 102.114.xx	TLIF-O Trials, 22mm TLIF-O Trials, 27mm TLIF-O Trials, 32mm	

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