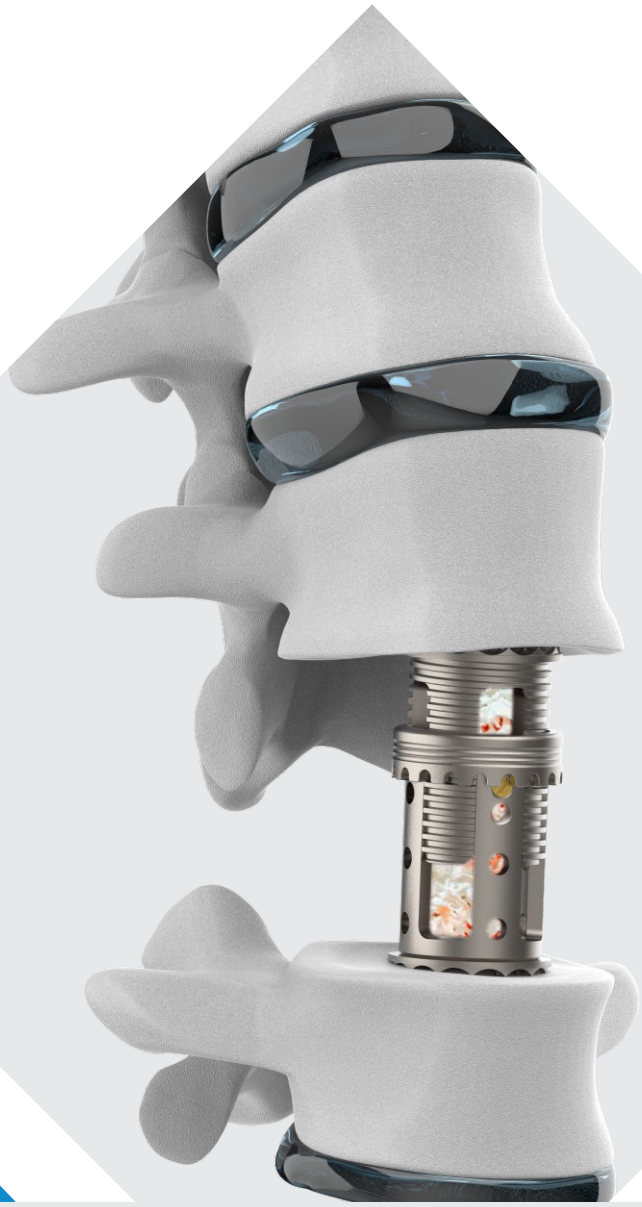
Auxein®



# Surgical Technique

## **Xpendriv Cage** Vertebral Body Replacement System

www.auxein.com

# about us

Auxein Medical is an integrated, research based, orthopaedic Implants & instruments manufacturing company, producing a wide range of quality, affordable generic implants, trusted by healthcare professionals and patients across geographies. It is the Company's constant endeavor to provide a wide basket of generic and our innovator products that exceed the highest expectations of customers in term of quality and safety. The company has world-class manufacturing unit established in india and serves customers in over 75 countries worldwide.

## Our Achievements

# Guidelines

This publication sets forth detailed recommended procedures for using Auxein Medical devices and instruments.

It offers guidance that needs to be heeded. However, with any such technical guide, each surgeon must consider the unique needs of each patient and make appropriate adjustments when and as required.

A workshop training under DAIS Academy by Auxein will provide assistance prior to first surgery. It is vital to know that all non-sterile devices must be cleaned and sterilized before use.

Moreover, multi-component instruments must be disassembled for cleaning. The surgeon must discuss all relevant risks, including the finite lifetime of the device, with the patient, when necessary.

**Please NOTE** that all the bone screws referenced in this document here are not approved for screw attachment or fixation in the areas not mentioned in this publication.

**Warning:**
This description is not sufficient for immediate application of the instrumentation. Instruction by a surgeon experienced in handling this instrumentation is highly recommended.

DAIS
Division of Auxein Institute for Surgeons

Organised by: Auxein

# Contents

# Product Overview

Titanium alloy material provides mechanical integrity during insertion and distraction, x-ray visibility, & biocompatibility

One-step locking of the distraction mechanism with a counterclockwise turn of the pre-assembled locking screw

**TI**-Xpendriv Cage Locking Pin

System design for ease of use in anterior and antero-lateral approaches

**TI**-Xpendriv Cage Lock Screw

Single pre-assembled implant

Large windows allow for optional in-situ insertion of bone graft

Optional static extensions increase height flexibility for construct sizing

Modular end caps have a wide footprint to prevent subsidence and to help maintain stabilization of the affected motion segments

# Indications for Use:

## Xpendriv Cage Vertebral Body Replacement System

The Xpendriv Cage Vertebral Body Replacement System consists of a Distractible In Situ (DIS) implant, which enables the surgeon to customize the height of the implant after implantation. The pre-assembled Xpendriv Cage implant distracts with a low profile inside thread design. Extensions (if needed) and modular end caps snap into each end of the implant for quick assembly. The end caps are available in 0° or with angulation to match either the lordosis or kyphosis of the spinal segment. The implant and end caps are composed of titanium alloy.

### System Indications

Auxein Spine's Xpendriv System is intended to replace a vertebral body or an entire vertebra. It is for use in the thoracolumbar spine (T1-L5) to replace a collapsed, damaged or unstable vertebral body or vertebra resected or excised during total and partial corpectomy and vertebrectomy procedures due to tumor or trauma (i.e., fracture). The Xpendriv System is intended to be used with supplemental internal fixation. The supplemental internal fixation systems that may be used with Xpendriv include. The use of bone graft with the Xpendriv System is optional.

# Precautions:

Use the appropriate imaging techniques to outline the patient's osseous anatomy and to determine the proper size and type of the instrumentation to be used. Identify the implant components to be used for the assembly (implants, end caps, and extensions if needed). Changes to the final implant configuration may become necessary based on intra-operative findings.

# Contraindications:

- The Xpendriv Cage is not to be used for interbody fusion.
- The Xpendriv Cage should not be implanted in patients with an active infection at the operative site.
- These devices are not intended for use except as indicated.
- Marked local inflammation.
- Any mental or neuromuscular disorder, which would create an unacceptable risk of fixation failure or complications in postoperative care.
- Bone stock compromised by disease, infection or prior implantation, which cannot provide adequate support and/or fixation to the devices.
- Open wounds.

# Surgical Steps:

## Post-operative Precautions

Physician instructions regarding full weight-bearing activities must be complied with until maturation of the fusion mass is confirmed. Failure to comply with physician instructions may result in failure of the implant, the fusion, or both.

## Caution for Patients

Based on the fatigue testing results, the physician/surgeon should consider the levels of implantation, patient weight, patient activity level, other patient conditions, etc., which may impact the performance of the system. In the United States, Federal law restricts this device to sale by or on the order of a licensed physician.

## Patient Positioning

Patient positioning on the operating table is dependent on the level(s) to be operated. For levels T1-T3 and L5, the patient is typically placed in the anterior supine position. For levels T4-L4, the patient is typically placed in the lateral decubitus position.

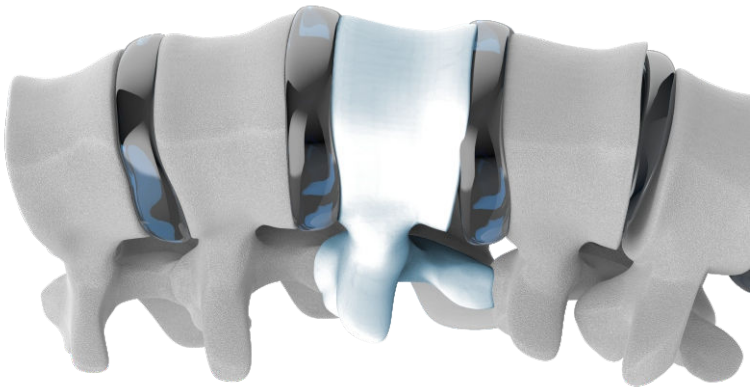
## Surgical Approach

Through a trans-sternal, trans-thoracic, retroperitoneal, or combined thoracolumbar approach, the lateral or anterior aspect of the spine column is exposed. X-ray or fluoroscopy should be used to confirm the appropriate level.

A total or partial corpectomy or vertebrectomy procedure as needed is performed.

The bony endplates are prepared for implant insertion using standard surgical procedures and instrumentation.

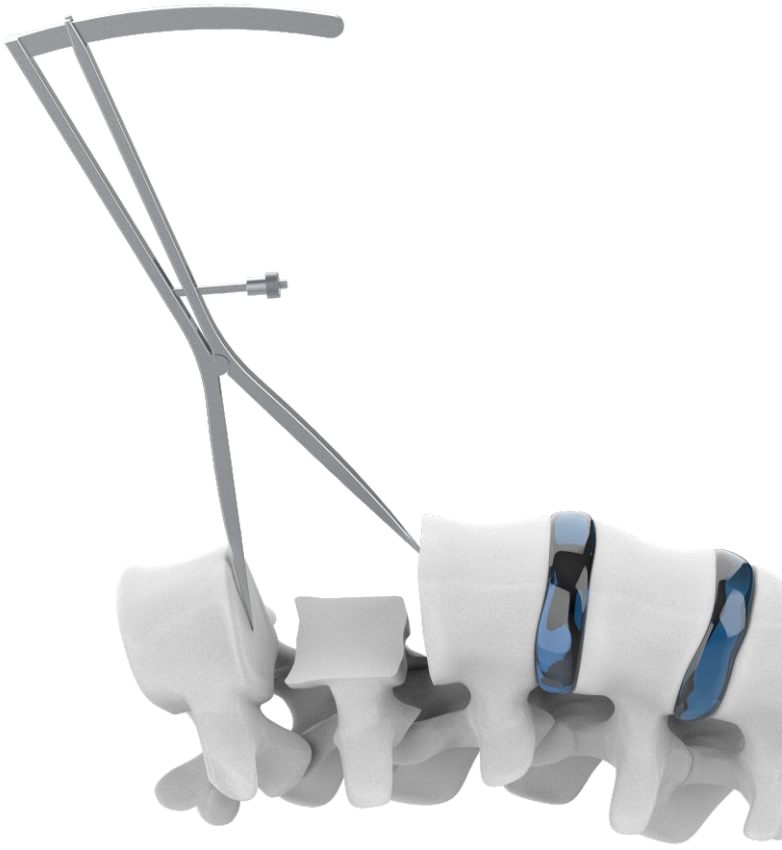
Example of a corpectomy of the L5 vertebral body



Example of a vertebrectomy of a thoracic vertebra

## STEP 1: Implant Measurement

The appropriate size implant can be determined preoperatively, by measuring the defect from the patient's films or CT scans. However, the measurement should be confirmed in situ with a caliper or ruler. It is recommended to measure in situ from the posterior aspect of the inferior endplate of the vertebral body above the affected level to the posterior aspect of the superior endplate of the vertebral body below the affected level.



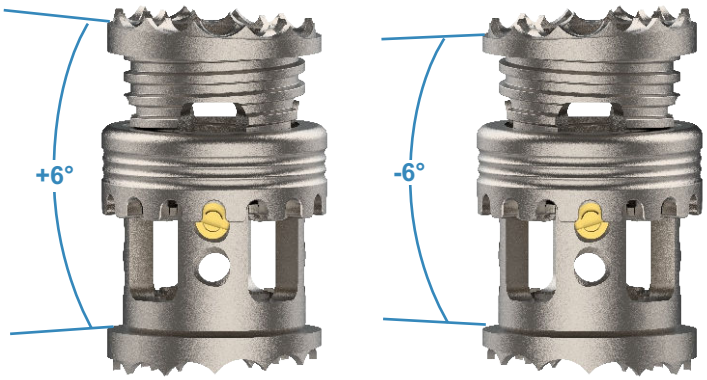
Confirm the height of the defect in situ by measuring from the posterior aspect of the motion segment(s).

## STEP 2: Implant Selection

Depending on the spinal region and patient's anatomy, either an Ø18 mm or Ø22 mm implant should be chosen. The Ø18 mm implant has a Ø22 mm footprint and the Ø22 mm implant has a Ø26 mm footprint. An end cap or an implant can be used as a template to confirm the appropriate diameter in situ. The measured implant height can be cross-referenced with a sizing template to choose the appropriate implant construct, depending on diameter.

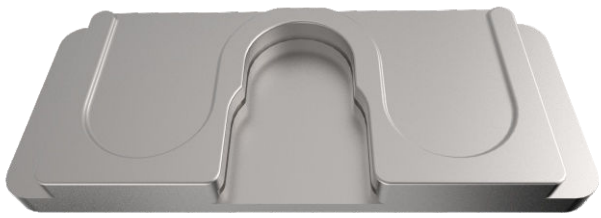
## STEP 3: End Cap Assembly

The Xpendriv Cage System offers varying end cap angles of 0°, 3°, 8° for both the Ø18 mm or Ø22 mm implants. The angled end caps are available for those cases in which lordosis or kyphosis provides enhanced sagittal alignment and increased stabilization of the implant construct.




The end caps can be rotated 180° to reconstruct either a thoracickyphotic or a lumbar lordotic curve.
Above example uses two 3° end caps.

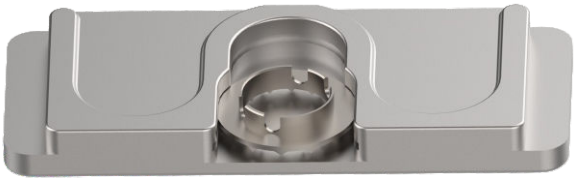
The end caps are assembled to the implant utilizing a combination of an end cap impactor and the end cap remover, which is also used as an end cap assembly station. The end cap remover contains two surfaces for end cap assembly.



X Cap Remover for Xpendriv Cage (7-003-06)

To assemble the first end cap to the implant, it is recommended to first place the end cap onto the appropriate surface of the end cap remover.

Next, the chosen implant should be placed into the end cap remover, on top of the first end cap.



**(A)**

Example of (A) Ø22 mm x 0° end cap.

**(B)**

Example of (B) Press fit the Xpendriv Cage on Ø22 mm x 0° end cap.

**(C )**

Example of (C) Press fit the Ø22 mm x 0° end cap on Xpendriv Cage assembly

**(D)**

Example of (D) Assembled Xpendriv Cage Ø22 mm x 0° end cap

After the implant and the first end cap are appropriately aligned, press fit the implant to the end cap. When angled end caps are used, it is important to assemble the end caps to the implant in a manner that accommodates the surgical approach and the sagittal alignment to be restored.

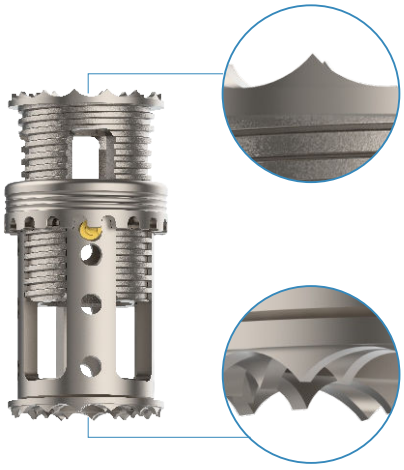
To assemble the second end cap to the implant construct, two end cap impactors are available to provide a method for alignment and a surface for impaction for each end cap diameter. An example of the Ø22 mm end cap impactor is shown.

The inferior portion of each end cap impactor has a cylinder with two sideby- side projections. The cylinder is placed into the opening of the end cap, which enables the projections to sit into the grooves of the end cap spikes. The projections can rotate in the grooves of the end cap spikes to account for whatever end cap angulation is chosen. The end cap impactors also have two wide notches, which can be used as reference points when aligning angled end caps.

Once the second end cap is chosen, it is placed on top of the implant construct, which remains in the end cap assembly station.

If the second end cap is angled, it is important to ensure the end cap is aligned to the implant construct in a manner that accommodates the surgical approach and sagittal angulation to be restored.

**Note:** If two angled end caps are used, ensure the laser-marks on the second end cap are parallel with the lasermarks on the first end cap.



Second Ø22 mm end cap is placed on top of implant construct.

The appropriate diameter end cap impactor is then placed into the second end cap. If angled end caps are chosen, the end cap impactors have notches, which can be used to aid in alignment. A mallet can be used to impact the second end cap to the implant construct.

As previously described, it is important to assemble angled end caps in a manner that accommodates the surgical approach and sagittal angulation to be restored, refer to example below.

Example: Always use the gold locking screw as your reference point when determining how to orient angled end caps to the implant. The expander will always be assembled to the implant in the threaded hole underneath the gold locking screw.

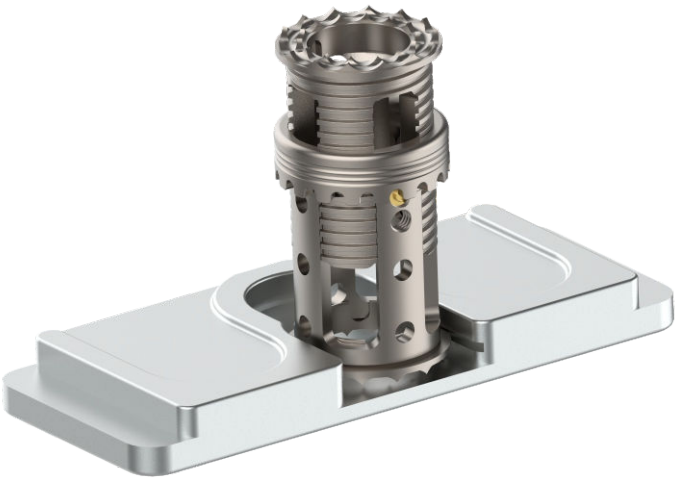
**Example #1:**

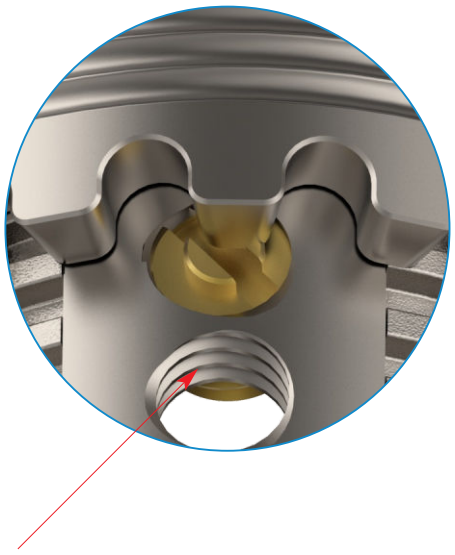
- Patient is undergoing a lumbar procedure, such as a L5 corpectomy
- Surgeon is performing an anterior approach
- Implant needs to provide a significant amount of lordosis, especially at the lumbosacral region
- Surgeon chooses to use angled end caps superiorly and inferiorly Result: The end caps need to be positioned to the implant so that the end cap laser mark is oriented parallel with gold locking screw for proper assembly.

**Example #2:**

- Patient is undergoing a lumbar procedure, such as a L3 corpectomy
- Surgeon is performing a left-sided anterolateral approach
- Implant needs to restore lumbar lordosis
- Surgeon chooses to use angled end caps superiorly and inferiorly

Result: The end caps need to be positioned to the implant so that the end cap laser mark is oriented 90° to the left of the gold locking screw for proper assembly.





The threaded hole in the implant for the expander assembly is located below the gold locking screw.

**Example #3:**

Patient is undergoing a thoracic procedure, such as a T7 corpectomy

- Surgeon is performing a left-sided anterolateral approach
- Implant needs to restore thoracic kyphosis
- Surgeon chooses to use angled end caps superiorly and inferiorly Result: The end caps need to be positioned to the implant so that the end cap laser mark is oriented 90° to the right of the gold locking screw for proper assembly.

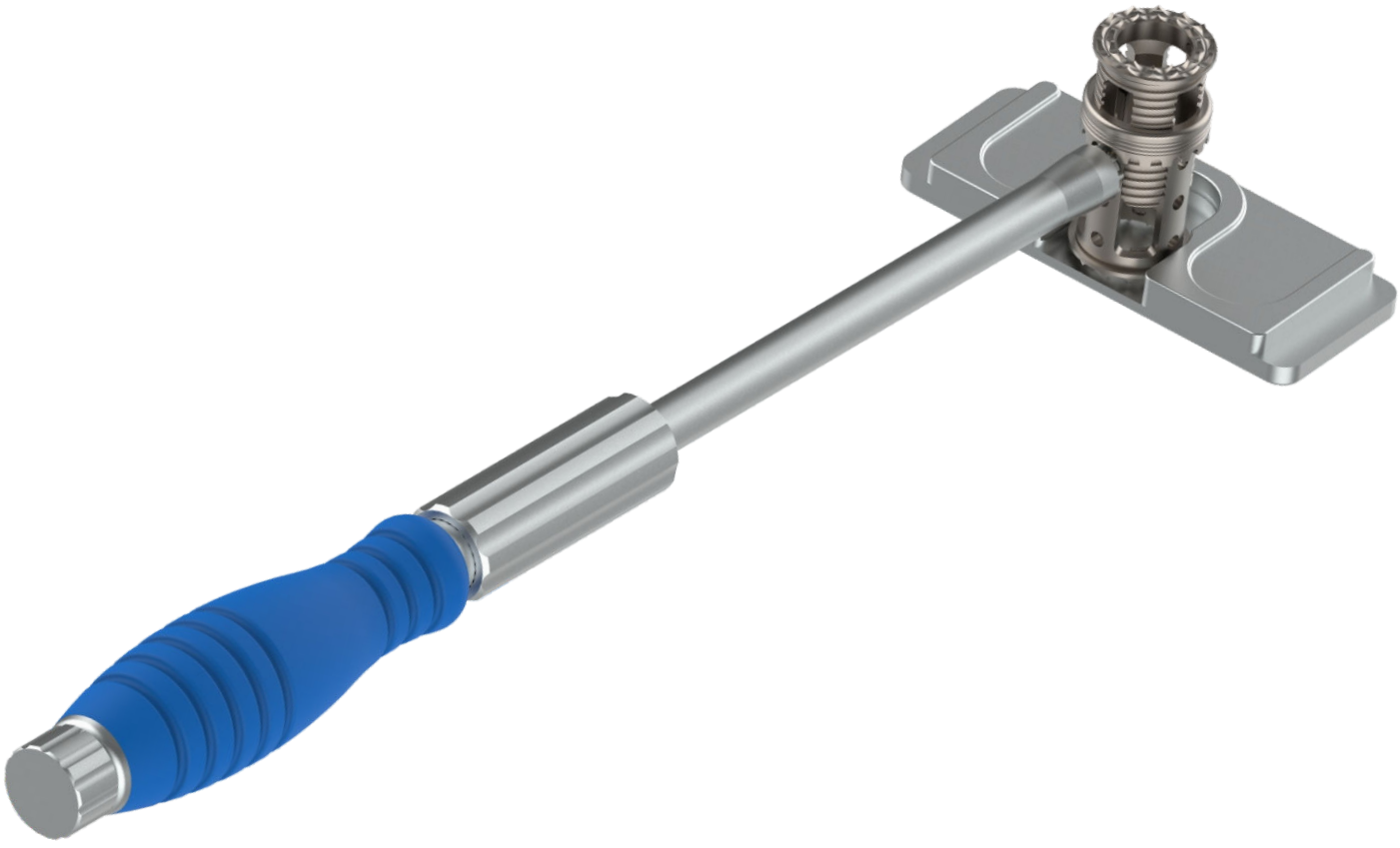
If the patient's anatomic demands require an adjustment in the end cap angulation, the end caps can be disassembled from the implant with the end cap remover. It is recommended to remove the end caps from the implant while the implant is assembled to the expander.

One side of the end cap remover removes the Ø18 mm end caps. The opposite side of the end cap remover removes the Ø22 mm end caps. For example, the appropriate technique to remove an Ø18 mm end cap is as follows:

- Retain the implant construct on the tip of the expander
- Drop the implant construct into the center of the end cap remover, then position the Ø18 mm end cap to be disassembled in the Ø18 mm removal side.
- Gently pull up and down on the expander until the end cap disassembles from the implant.

The same technique should be used when disassembling a Ø22 mm end cap, except the Ø22 mm end cap will need to be positioned in the Ø22 mm removal side of the end cap remover. It is helpful to hold the end cap remover sturdy on the back surgical table with one hand while gently leveraging the expander to disassemble an end cap with the other hand.

**Note:** When disassembling the angled end caps, it is recommended to insert the shortest end of the end cap into the appropriate end cap removal side first. Extensions can be disassembled by hand.



**STEP 4: Bone Graft Packing**

**(Optional)**

The Xpendriv Cage System can be packed with bone graft. The use of bone graft with the Xpendriv Cage System is optional.

Depending on surgeon preference, bone graft can be packed into the Xpendriv Cage implant before or after end cap assembly. However, it is recommended to assemble the end caps first in order to check the implant construct fit and sagittal alignment in situ prior to bone graft packing.

**Note:** The end cap opening = inside diameter of the implant. Thus, the assembly of the end caps does not impede the continuous opening in the implant construct to maximize bone graft packing.

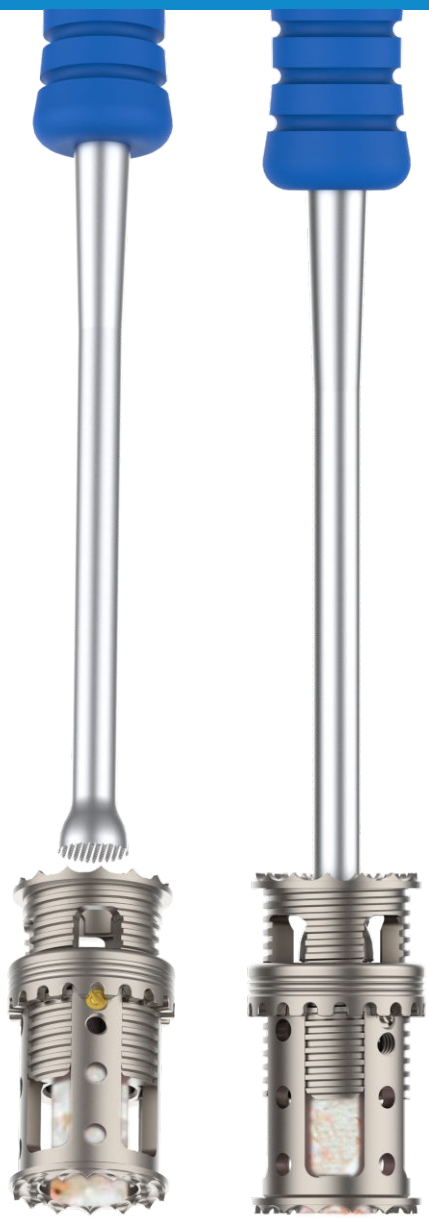
The Xpendriv Cage System includes small and standard graft impactors, which can be used to pack bone graft into the implant. Both graft impactors have knurled tips for more precise packing of the bone graft.

**Note:** The end cap remover can be used as a bone graft packing station if needed.

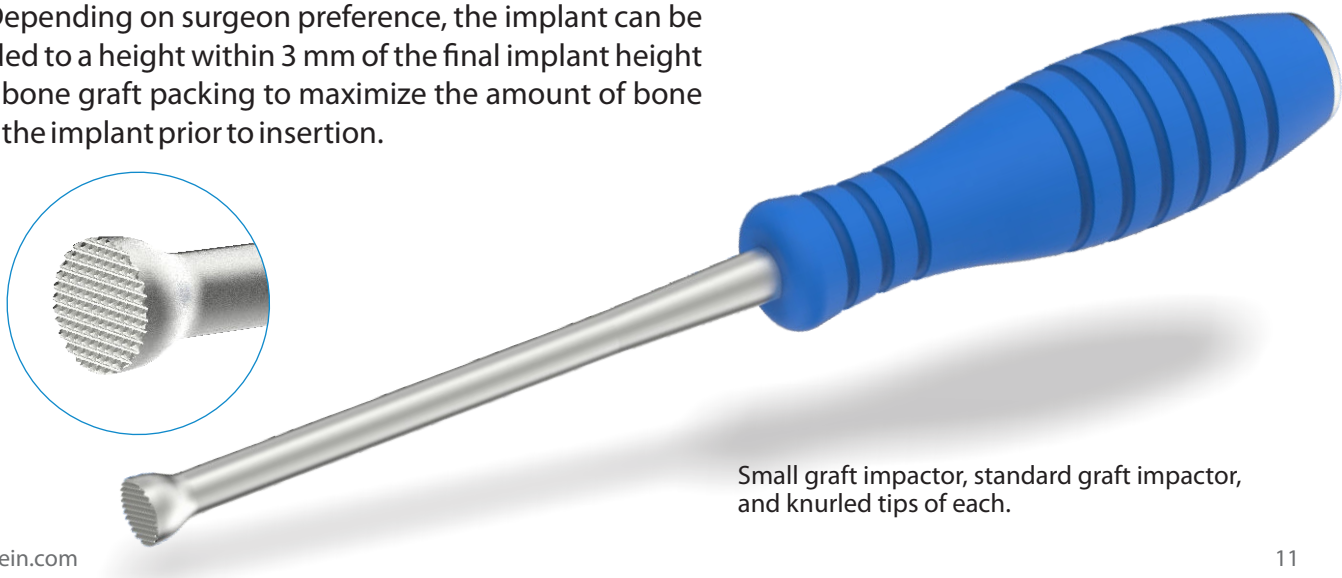
Prior to implantation, it is recommended to pack additional bone graft into the opening of the superior end cap. "Overstuffing" the implant with bone graft will more readily prevent a void of no bone graft in the implant, which may result after distraction.

The implant is now ready to be inserted.

Note: Depending on surgeon preference, the implant can be expanded to a height within 3 mm of the final implant height during bone graft packing to maximize the amount of bone graft in the implant prior to insertion.



Initial bone graft packing with the graft impactors.



Small graft impactor, standard graft impactor, and knurled tips of each.

**STEP 5: Implant Insertion**

After assembly of the implant construct (implant + end caps + extension(s) if needed) and packing of bone graft (optional), the implant is ready for insertion.

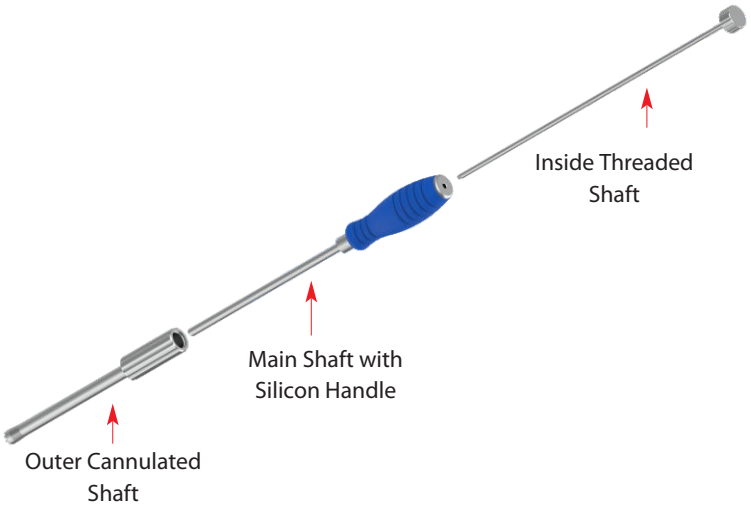
Note: Visually check the implant to ensure all extensions and end caps are properly seated prior to insertion.

The expander is used to insert the implant and distract the implant to its final height. The expander has three components: a main shaft, an inside threaded shaft, and an outer cannulated shaft.

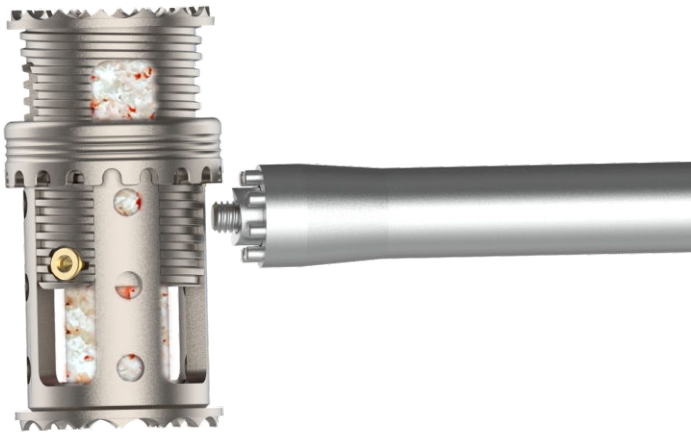
The inside threaded shaft retains the implant to the end of the expander by engaging the threaded hole of the implant.

The threaded hole of the implant is located just below the gold locking screw.

**Note:** Be sure the gold locking screw is flush with the implant prior to assembling the expander. This will allow the distraction ring to rotate freely during distraction.

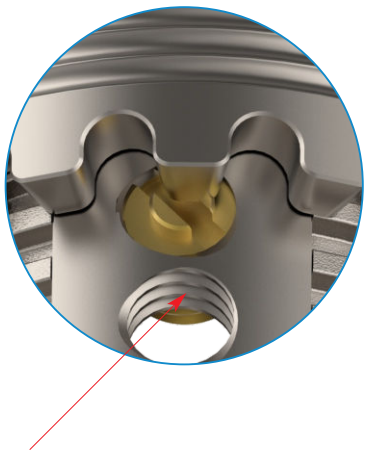



Three components of the expander

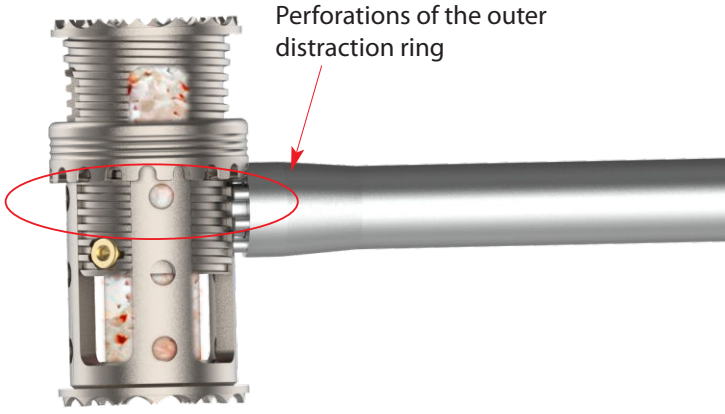


Assembly of the implant onto the inside threaded shaft

Once the inside threaded shaft fully engages the implant, the outer cannulated shaft will come into contact with the implant. The perforated tips of the outer cannulated shaft of the expander must properly line up in between the scallops of the outer distraction ring of the implant.

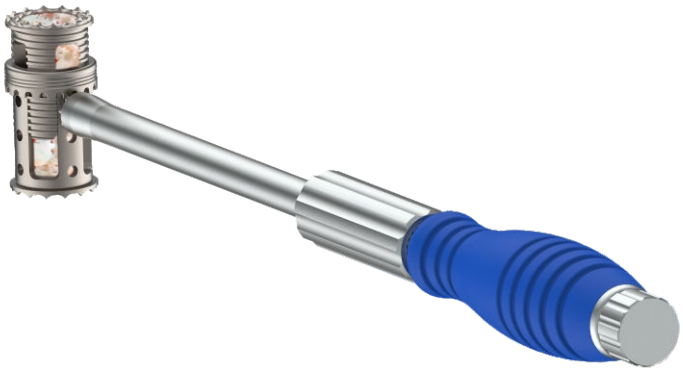


Threaded hole of the implant, which receives the inside threaded shaft of the expander.




Placement of the perforated tips of the outer cannulated shaft of the expander in between the scallops of the outer distraction ring.

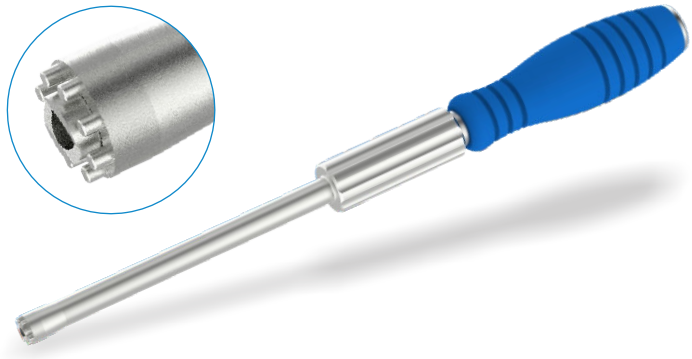
The end of the main shaft of the expander is curved, This unique tip geometry conforms to the diameter of each implant, allowing for maximum contact of the expander and implant during insertion to reduce any play. To ensure this snug fit, it is important to orient the silicon T-handle of the expander perpendicular to the implant during assembly.



The silicon T-handle of the expander must be perpendicular to the implant during the assembly.

Once the expander is in proper alignment with the implant, the implant can be placed into the defect and distracted to the appropriate height.

To distract the implant, simply rotate the outer cannulated shaft of the expander counterclockwise as indicated by the directional arrow, which is laser marked on the outside of the shaft. The counterclockwise rotation of the outer cannulated shaft will turn the outer distraction ring of the implant and result in distraction of the implant.



The end of the expander's main shaft is curved to provide maximum contact to the implant during insertion

**Note:** Prior to maximum distraction of the implant, it is recommended the surgeon stop distraction when:

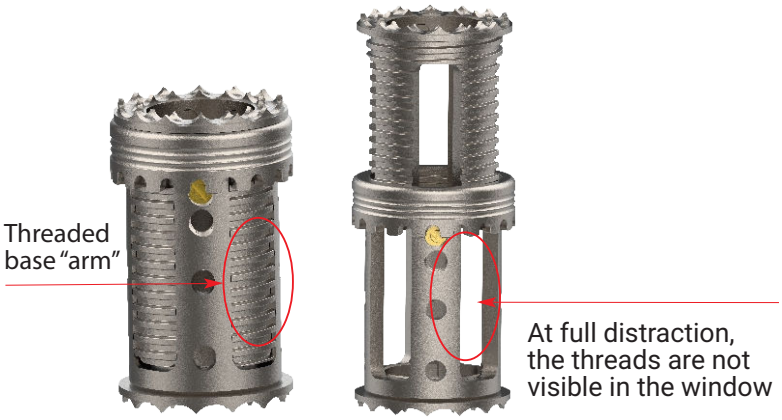
- The deformity of the defect is corrected.
- The end caps subside or embed into the bony endplate. It is also suggested to monitor distraction with fluoroscopy to prevent any progressive distraction of the facet joints and disruption of the ligaments.

**CAUTION:** Carefully monitor for overdistraction, especially in cases of spondylectomy and trauma.

Distraction of the implant by rotating the outer cannulated shaft of the expander counterclockwise

The implant has reached its final distraction height once the threaded base "arms" of the implant are no longer visible.

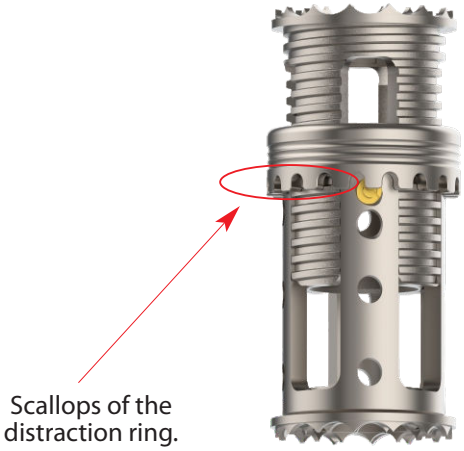
After the appropriate height of the implant is achieved, disassemble the expander from the implant construct by first unthreading the inside threaded shaft from the threaded hole of the implant and then removing the entire expander.




Full distraction of the implant is reached once the threads are no longer visible in the implant windows.

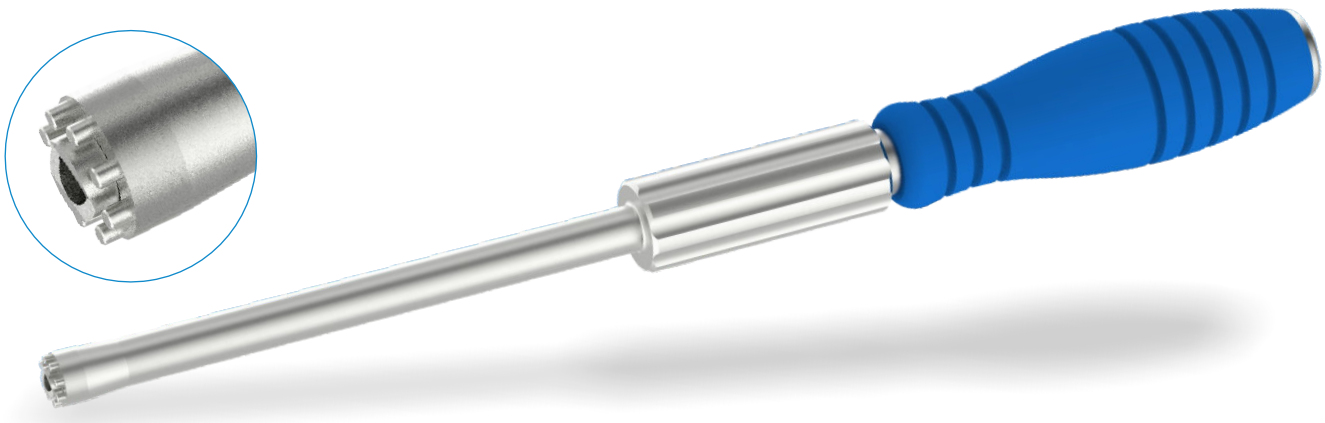
It is important to ensure the scallops of the outer distraction ring line up on either side of the gold locking screw after distraction.

Grooves on the tip of the outer cannulated shaft of the expander aid in alignment of the distraction ring scallops.




As the surgeon is completing distraction of the implant, it is recommended that one of the grooves on the tip of the outer cannulated shaft of the expander be positioned superiorly.

Following these steps will aid in providing maximum access of the locking screw to complete the locking step of the procedure.



An outer cannulated shaft "groove" should face superior, as shown in this picture, at the completion of distraction to provide access to the gold locking screw.

## Locking the Distraction

### Mechanism

Once the optimal implant height is reached via in situ distraction, the outer distraction ring can be locked with a pre-assembled gold locking screw to prevent the implant height from changing.

To lock the outer distraction ring and the implant height, place the head of the screwdriver into the head of the locking screw. Rotate the screwdriver counterclockwise two full turns, which will cause the head of the locking screw to protrude out (back-out) of the implant and contact the outer distraction ring.

**Note:** The locking screw was not designed to provide any tactile feedback during the locking step. The locking screw should back-out of the implant freely with rotation of the screwdriver. The screwdriver was also designed to be low-profile to potentially eliminate unnecessary torque transmission to the locking screw.

If the surgeon backs-out the locking screw past two full turns and reaches a point where the screw can no longer back-out, the surgeon should stop rotating the screwdriver. At this point, the implant height is locked and any further rotation of the locking screw may compromise its integrity.

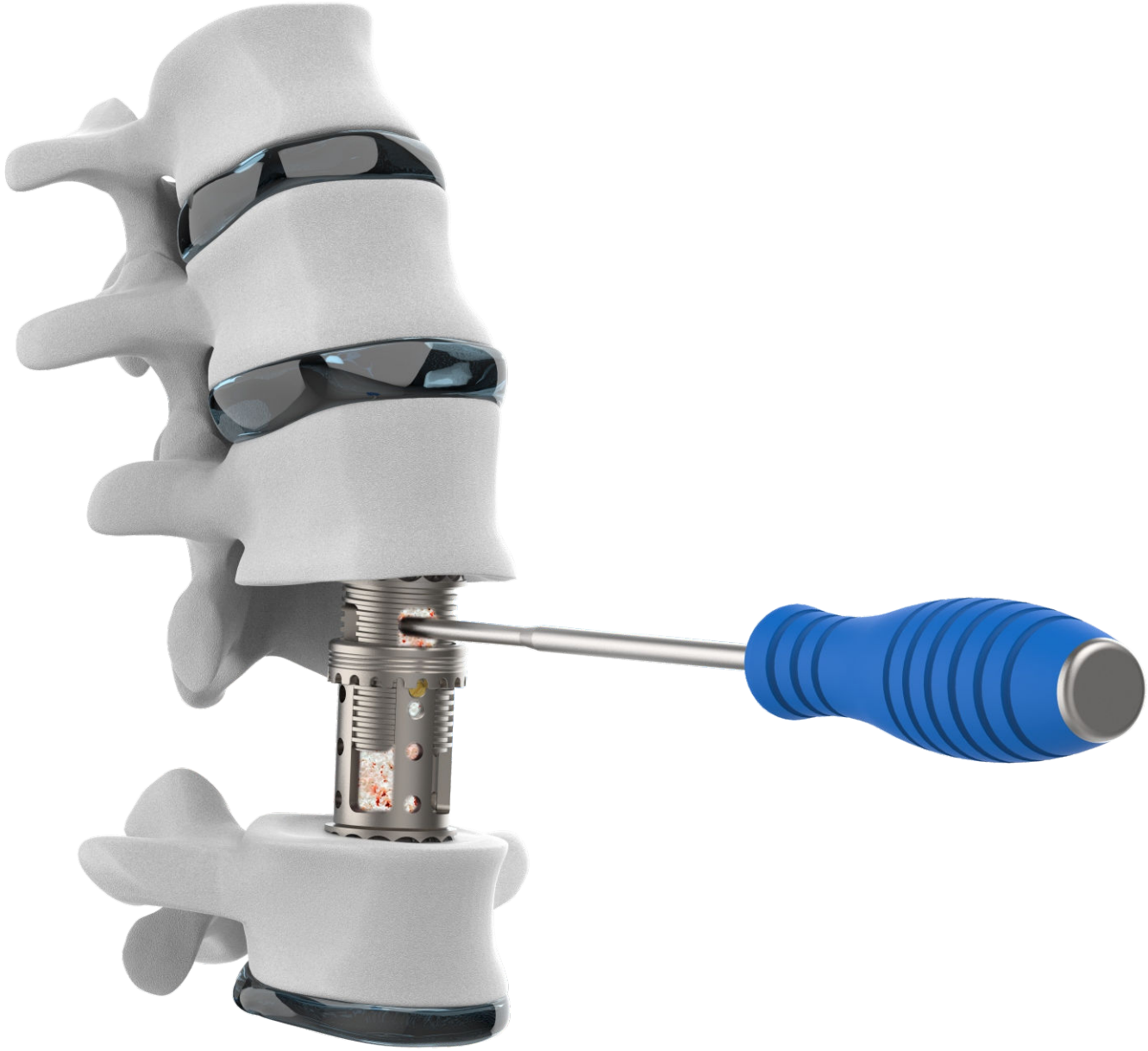
The screwdriver only needs to rotate counter-clockwise two full turns to lock the implant height.

Once the locking screw is backed-out two full turns, the implant height is now locked and the surgeon can proceed with the remaining part of the operative procedure.

The screwdriver engages the pre-assembled locking screw. Two counterclockwise turns of the locking screw with the screwdriver will lock the implant height in place.

**In-situ Bone Graft Packing (optional)**

After the implant is distracted and locked into its final position, a void may be present between the bone graft inside the implant and the bony endplate of the vertebral body. The void can be filled through the large windows in the periphery of the implant. The small graft impactor acts similar to a tamp and can be used to pack additional bone through the large implant windows, Standard O.R. instruments such as forceps or Penfields may also be used.



Insertion of bone graft with the small graft impactor through the large implant windows.

## IMPLANT REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the Xpendriv Cage is not intended for removal unless the management of a complication or adverse event requires removal. Standard instruments may be used to hold and disengage the device from the vertebrae. Any decision by a physician to remove the device should take into consideration such factors as the risk to the patient of the additional surgical procedure as well as the difficulty of removal.

The following steps can be used if the Xpendriv Cage device must be removed:

1. Insert the Xpendriv Cage screwdriver into the head of the locking screw. Rotate the set screw with the screwdriver clockwise until the gold locking screw is flush with the implant (locking screw will reach an end point and will no longer be able to be rotated clockwise). Once the gold locking screw is flush with the implant, the distraction mechanism is unlocked. Remove the screwdriver from the defect.

2. Insert the expander into the defect and ensure the silicon handle is perpendicular to the implant. Thread the inside shaft of the expander into the threaded hole of the implant. The threaded hole of the implant is located just below the gold locking screw,

3. Once the inside shaft is fully inserted into the threaded hole of the implant, ensure the perforated tips of the outer cannulated shaft of the expander properly line up in between the scallops of the outer distraction ring. Rotate the outer cannulated shaft clockwise to reduce the height of the implant until it is possible to remove the implant from the defect

Rotate the screwdriver clockwise to unlock the distraction mechanism.

To reduce the height of the implant for removal, rotate the outer cannulated shaft of the expander clockwise.

## Xpendriv Cage

| Code | Product Specification | Material |
|---|---|---|
| **4-001-020TI** | Ø18mm X 20mm | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-001-025TI** | Ø18mm X 25mm | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-001-032TI** | Ø18mm X 32mm | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-002-025TI** | Ø22mm X 25mm | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-002-032TI** | Ø22mm X 32mm | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-002-037TI** | Ø22mm X 37mm | TI |

## Xtension

| Code | Product Specification | Material |
|---|---|---|
| **4-003-018TI** | Ø18mm | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-003-022TI** | Ø22mm | TI |

## X Cap

| Code | Product Specification | Material |
|---|---|---|
| **4-004-00TI** | Ø18mm, 0° | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-004-03TI** | Ø18mm, 3° | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-004-08TI** | Ø18mm, 8° | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-005-00TI** | Ø22mm, 0° | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-005-03TI** | Ø22mm, 3° | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-005-08TI** | Ø22mm, 8° | TI |

| Code | Product Specification | Material |
|---|---|---|
| **4-005-15TI** | Ø22mm, 15° | TI |

## 4-081 Xpendriv Cage Implant Set


| Code | Set Consisting of | Qty. |
|---|---|---|
| **4-001-020TI** | Xpendriv Cage, Ø18mm X 20mm | 2 |
| **4-001-025TI** | Xpendriv Cage, Ø18mm X 25mm | 2 |
| **4-001-032TI** | Xpendriv Cage, Ø18mm X 32mm | 2 |
| **4-002-025TI** | Xpendriv Cage, Ø22mm X 25mm | 2 |
| **4-002-032TI** | Xpendriv Cage, Ø22mm X 32mm | 2 |
| **4-002-037TI** | Xpendriv Cage, Ø22mm X 37mm | 2 |
| **4-003-018TI** | Xtension, Ø18mm | 1 |
| **4-003-022TI** | Xtension, Ø22mm | 1 |
| **4-004-00TI** | X Cap, Ø18mm, 0° | 3 |
| **4-004-03TI** | X Cap, Ø18mm, 3° | 3 |
| **4-004-08TI** | X Cap, Ø18mm, 8° | 3 |
| **4-005-00TI** | X Cap, Ø22mm, 0° | 3 |
| **4-005-03TI** | X Cap, Ø22mm, 3° | 3 |
| **4-005-08TI** | X Cap, Ø22mm, 8° | 3 |
| **4-005-15TI** | X Cap, Ø22mm, 15° | 3 |
| **4-046-01** | Implant Box for Xpendriv Cage System | 1 |

## Xpendriv Cage Instruments

**7-003-01** Xpender

**7-003-02** Xpender Inside Shaft

**7-003-03** Screwdriver for Xpendriv Cage

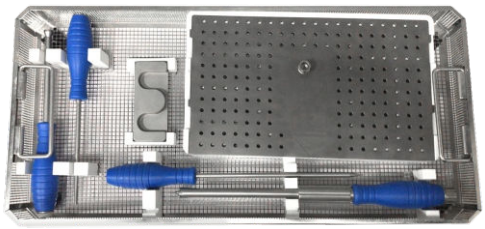
**7-003-04** Small Graft Impactor for Xpendriv Cage

**7-003-05** Graft Impactor for Xpendriv Cage

**7-003-06** X Cap Remover for Xpendriv Cage

**4-046-01** Implant Box for Xpendriv Cage System

**7-107-01** Instrument Tray, 540mm x 255mm x55mm



**7-106-02** Aluminium Sterilization Container, 560mm x 270mm x 100mm

## 7-003 Xpendriv Cage Instrument Set

| Code | Set Consisting of | Qty. |
|---|---|---|
| **7-003-01** | Xpender | 1 |
| **7-003-02** | Xpender Inside Shaft | 1 |
| **7-003-03** | Screwdriver for Xpendriv Cage | 1 |
| **7-003-04** | Small Graft Impactor for Xpendriv Cage | 1 |
| **7-003-05** | Graft Impactor for Xpendriv Cage | 1 |
| **7-003-06** | X Cap Remover for Xpendriv Cage | 1 |
| **4-046-01** | Implant Box for Xpendriv Cage System | 1 |
| **7-107-01** | Instrument Tray, 540mm x 255mm x55mm | 1 |
| **7-106-02** | Aluminium Sterilization Container, 560mm x 270mm x 100mm | 1 |

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