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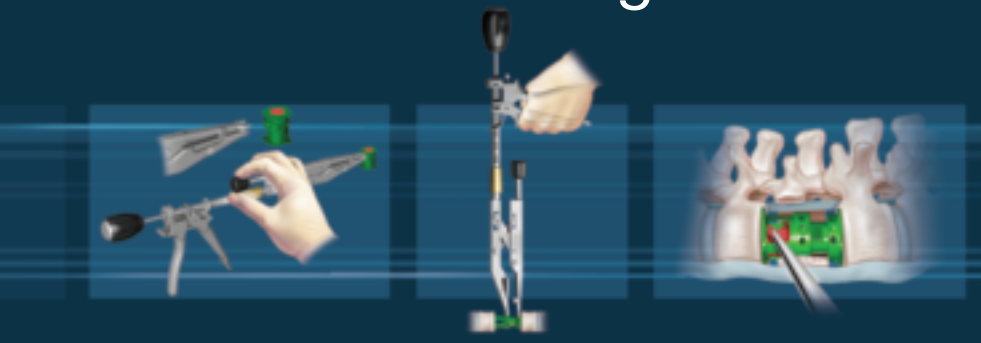
PIONEERING WHAT MATTERS

Surgical Technique
Product Catalog



X-MESH™
EXPANDABLE CAGE SYSTEM

DePuySpine™
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PIONEERING WHAT MATTERS

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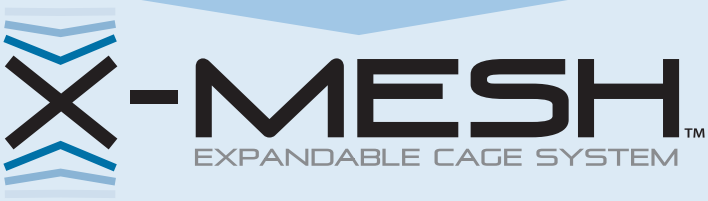

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X-MESH™ EXPANDABLE CAGE SYSTEM

INDICATIONS

The X-MESH™ Expandable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The X-MESH Expandable Cage System is also indicated for treating fractures of the thoracic and lumbar spine.

The X-MESH Expandable Cage System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The X-MESH Expandable Cage System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used include titanium plate or rod systems (i.e., KANEDA™ SR, UNIVERSITY PLATE™, M-2™ ANTERIOR PLATE, ISOLA®, VSP®, MOSS® MIAMI, TiMX™, MONARCH®, EXPEDIUM™, VIPER™, PROFILE®).

CONTRAINDICATIONS

Use of these systems is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign-body sensitivity to any of the implant materials.

Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.

Conditions that may place excessive stress on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.

Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stress on the implant during bony healing and may be at a higher risk of implant failure.

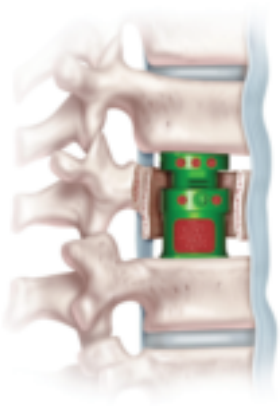
PREOPERATIVE PLAN

Anteroposterior (AP) and lateral x-rays along with computed tomography (CT) and magnetic resonance imaging (MRI) images are recommended for surgical planning. Factors considered in the planning include the side of the approach and the amount of correction desired. Assessing the height of the vertebral body(s) plus the height of the discs is useful in estimating the correct size implant (see Table I). However, exact determination of the implant size occurs intraoperatively.

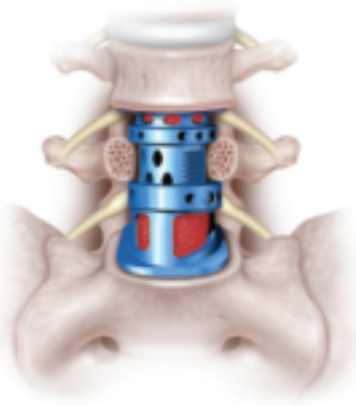
X-MESH™ EXPANDABLE CAGE SYSTEM

Implant Description

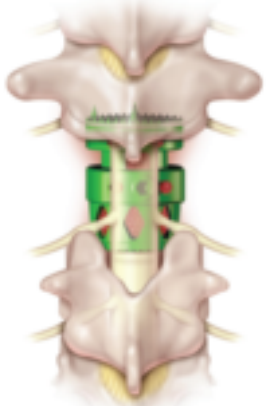
The X-MESH Expandable Cage comes in three approach-specific designs; Anterolateral, Direct Anterior, and Posterior.



Anterolateral



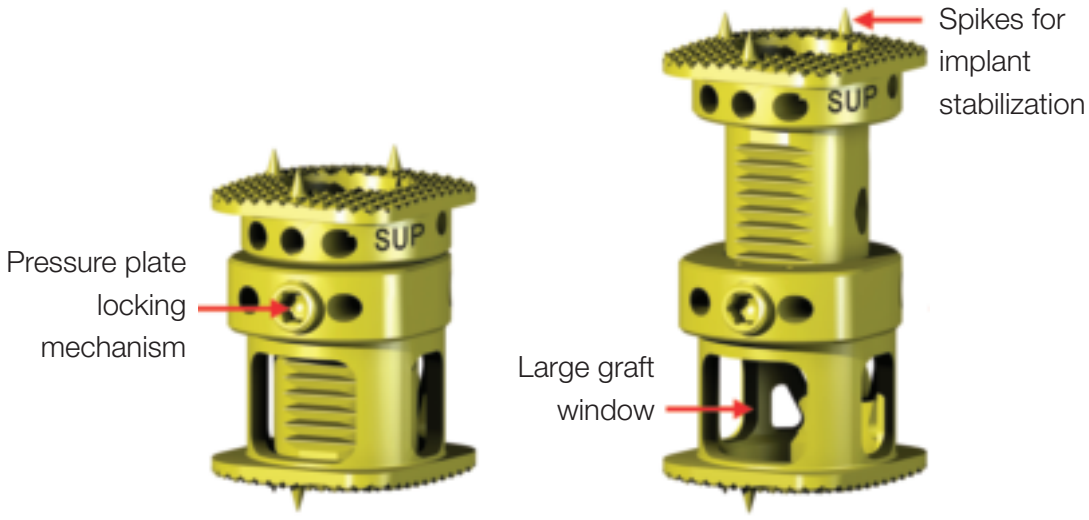
Direct Anterior



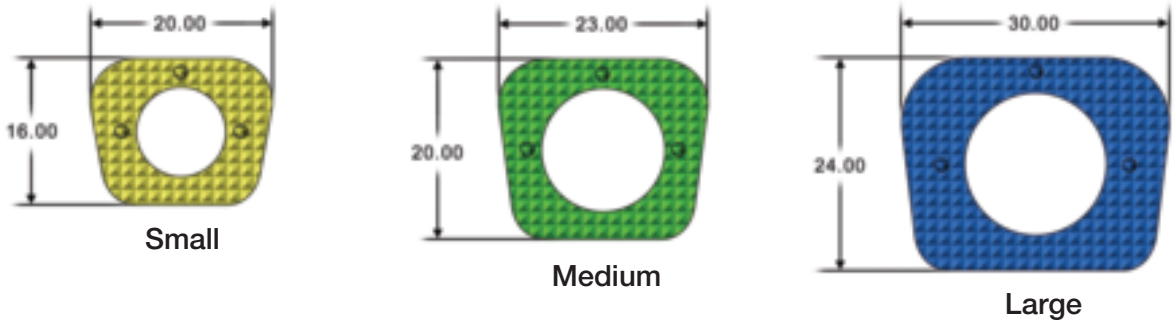
Posterior

The Direct Anterior cage features a graft window oriented so that it can be filled from an Anterior Lumbar Interbody Fusion (ALIF) approach and an instrument attachment offset by 45 degrees that allows it to be implanted while avoiding important vasculature. The Posterior cage features endplates with a smaller footprint to avoid contact with the spinal cord during implantation.

The X-MESH Expandable Cage is designed to allow bony ingrowth. Each cage comes fully assembled with rough, convex endplates containing spikes for an ideal fit and to prevent cage migration. The endplate spikes are 2.5 mm high. The cage also contains side slots and large graft windows for insertion of graft material after expansion of the cage in-situ.



The X-MESH System has three footprint options:

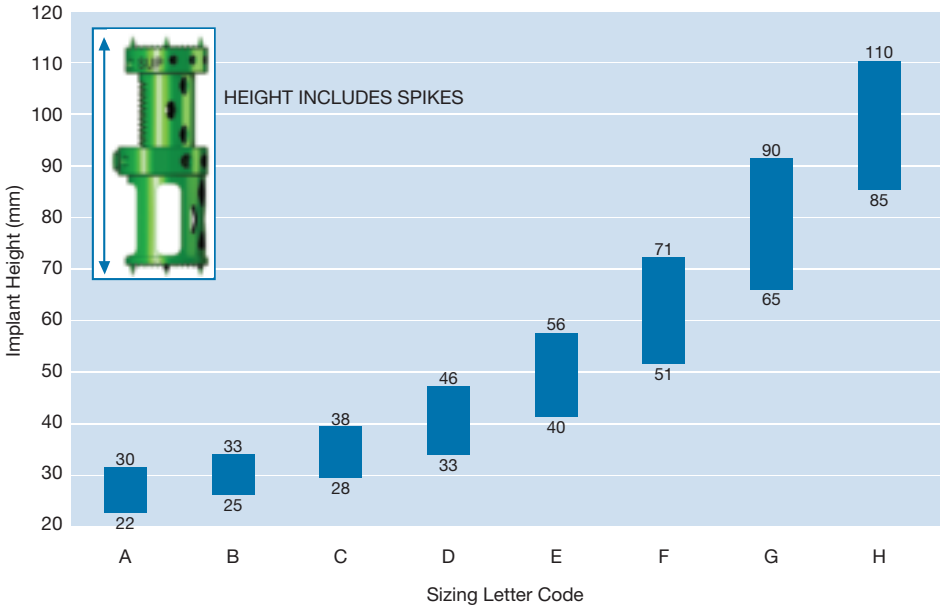


(Anterolateral and Direct Anterior footprints)

The X-MESH System also provides 8 cage height options. The small footprint cages range in height from 22-71 mm, medium cages range from 22-110 mm, and the large footprint cages are available in heights ranging from 28-110 mm.

Table 1: Size Capability

X-MESH SIZE OVERVIEW



A broad range of lordosis and kyphosis options are also offered for each implant, as shown in the table below. For kyphotic implants, kyphosis is applied to the superior endplate of the implant. For lordotic implants, lordosis is applied to the inferior endplate of the implant.

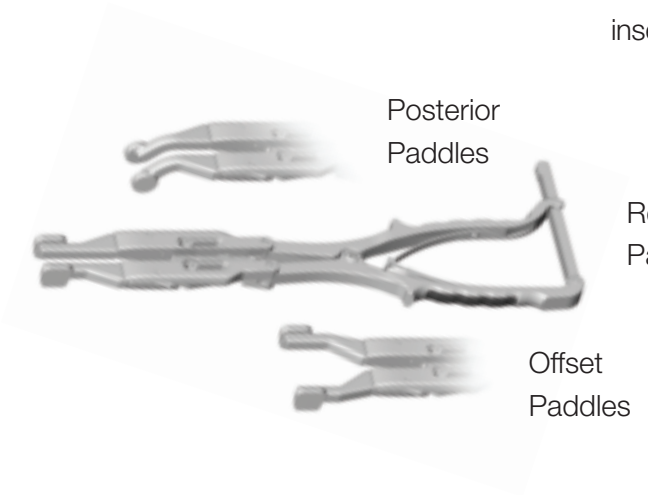
Approach	Diameter (mm)	Height Range (mm)	Angle Offerings (superior degrees/ inferior degrees)
Anterior Lateral	16	22-71	-6/0, 0/0
	20	22-38	-6/0
		22-110	0/0
		33-90	0/6
	24	28-71	0/0
		33-90	0/6
		40-110	0/12
Direct Anterior	24	40-90	0/24
Posterior	16	22-71	0/0
	20	22-71	0/0

The X-MESH Expandable Cage System comes with a unique pistol-grip inserter/ expander that allows for continuous expansion and tactile feedback. The cage's locking mechanism allows for continuous expansion and locking within a 0.75-mm range from the point of final expansion.

Instruments

SECONDARY DISTRACTOR

Used to distract vertebral bodies to allow for cage insertion and to measure defect height as well.



TRIALS

Used to size the cage diameter and footprint.

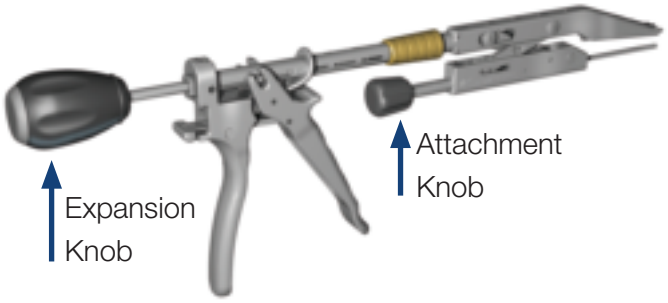
CALIPER

Can be used to measure defect heights when the secondary distractor is not feasible.

X-MESH™ EXPANDABLE CAGE SYSTEM

INSERTER/EXPANDER

Cage attaches to the tip of this instrument using the attachment knob. It is then inserted into the defect and expanded using either the pistol grip or expansion knob mechanism.



- To reduce **instrument** clicking and to ensure smooth pistol grip movement make sure to lubricate with Codman Preserve® or “instrument milk” when needed.

DRIVER

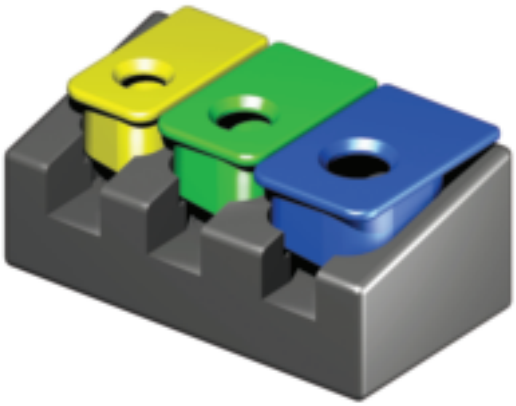
Torque-limiting driver (3 Nm) is inserted into the guide on the inserter/expander and then turned clockwise to lock the cage.

GRABBER

Can be used to hold the cage while unlocking it in situ, or to place the cage in a defect space.

BONE GRAFT LOADING BLOCK AND BONE TAMP

Loading block has 3 openings to be used with the 3 different footprint sizes. Three different bone tamps, each with a different diameter, can be used to push bone into the cages.



Bone Tamp

POSITIONING IMPACTORS

Angled and straight impactors can be used to tamp cage into place.

Angled Impactor

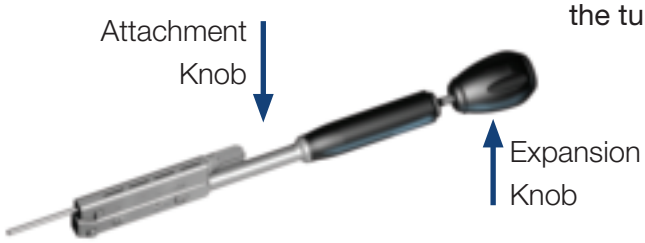
Straight Impactor

X-MESH™ EXPANDABLE CAGE SYSTEM

Posterior System

POSTERIOR INSERTER/EXPANDER

Posterior version of the inserter/expander with curved tips. Cage attaches to this instrument and then is inserted into defect and expanded using the turning knob mechanism.



Modular tips are available for the posterior inserter that allow for use by either a right-sided (RS) or left-sided (LS) approach to the pathology. The top tip corresponds to the cage diameter (Small or Medium) and the bottom tip is standard. All 3 tips (Small Top, Medium Top, Standard Bottom) are available in both right-sided (RS) and left-sided (LS) configurations.

UNIVERSAL JOINT DRIVER

Version of the driver with universal joint for posterior applications. Inserted into the guide on the posterior inserter/expander and then turned clockwise to lock the cage. The straight tip driver can also be used with the posterior inserter if that is preferred.

NOTE: Use only with RS tips.

POSTERIOR CAGE IMPACTOR

Posterior version of the angled impactor. Tip of the angled impactor fits into the graft window on the cage to allow for directed impaction.

Small Posterior Cage Impactor

Medium Posterior Cage Impactor

X-MESH™ EXPANDABLE CAGE SYSTEM

Cage Implantation: Anterolateral Approach

Anterolateral Approach and Corpectomy

Surgical Sequence and Assembly Review — Please see the EXPEDIUM™ Anterior Spine System Surgical Technique for further information.

Preoperative Evaluation

AP and lateral radiographs, along with CT and MRI images may be needed for planning the side of approach and succession of surgical steps. The height of the affected vertebral bodies plus the height of the adjacent discs are used to plan the correct height and footprint of the X-MESH Expandable Cage. The side of the approach may be determined by the location of the paraspinal lesion or individual patient anatomy.

Positioning

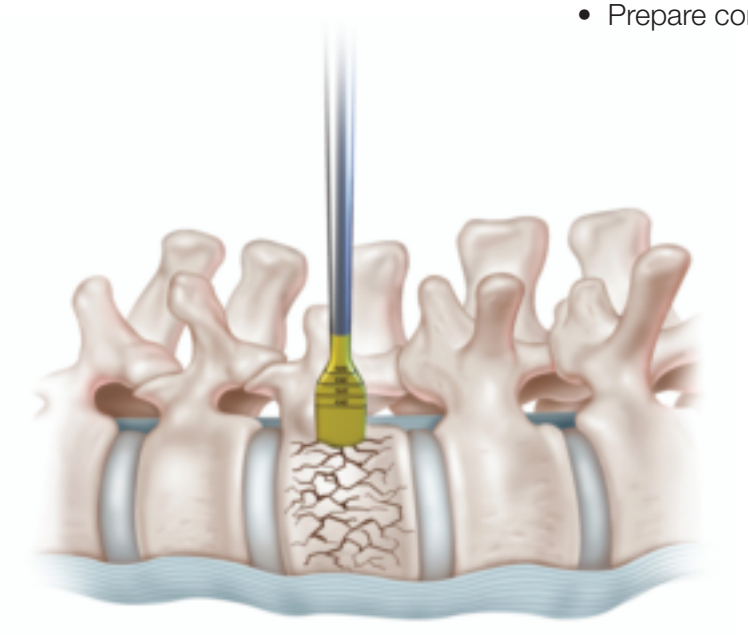
Access to the left flank is achieved by positioning the patient in a right lateral decubitus position. Cross-table lateral radiographic verification (an AP view of the spine) will show the spinous process centered between the pedicles. The patient is held securely and the peripheral nerves are protected. The table can be flexed to 45 degrees and kidney rests elevated to the level of the affected vertebral body.

Exposure

The level of the affected vertebral body will determine the incision site and the surgical approach. Segments above the thoracolumbar junction are most easily reached through a transthoracic approach while access to vertebrae near the thoracolumbar junction may require a thoracoabdominal approach. The incision is placed directly over the rib located 2 levels above the affected vertebral body (e.g., if resection of T10 is planned, the 8th rib should be removed). Removal of the rib improves the exposure and provides autologous graft material. Lumbar segments are more easily exposed through a retroperitoneal approach.

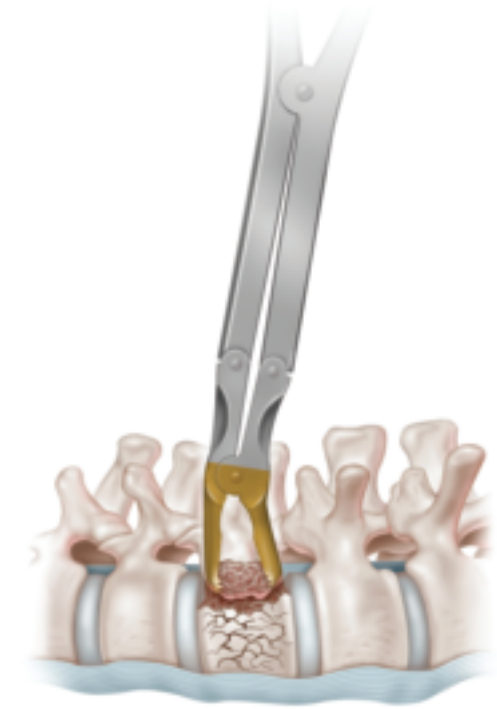
Once the spine is exposed 1 level cephalad and caudal to the affected vertebral body, the segmental vessels at all 3 levels are identified, isolated, and ligated. The mediastinal or the retroperitoneal structures are dissected from the spine and a pair of malleable retractors are positioned in order to protect nearby soft-tissue structures. All disc material cephalad and caudal to the affected vertebral body is removed. The affected vertebral body corpectomy is performed. For optimal biomechanical integrity, the X-MESH Expandable Cage is positioned between intact endplates.

Corpectomy



STEP 1

- Prepare corpectomy.

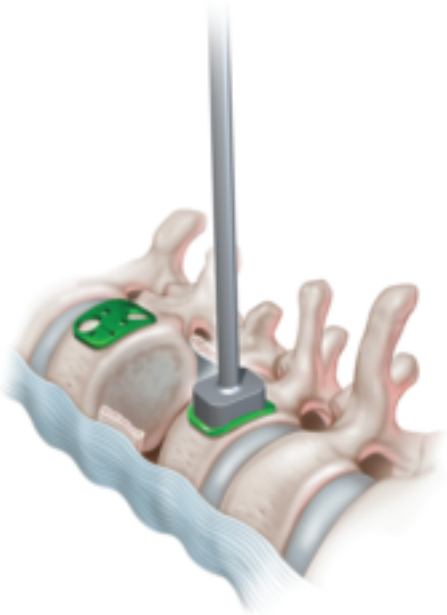


STEP 2

- Remove bone. Removed bone should be retained for bone graft. However, in the presence of tumor, alternative materials are used.

X-MESH™ EXPANDABLE CAGE SYSTEM

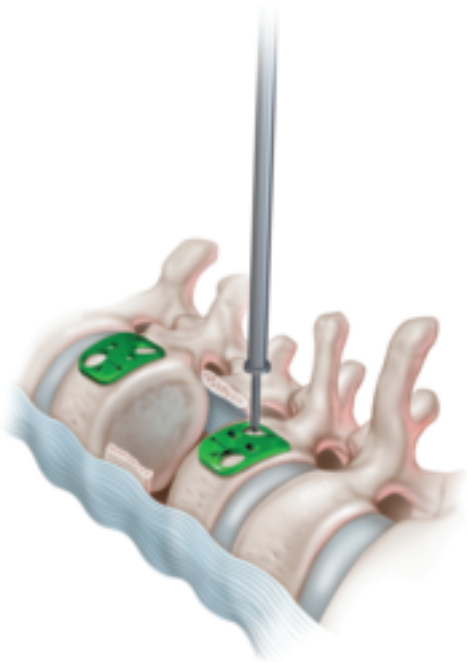
Initial EXPEDIUM Anterior Implantation



STEP 3

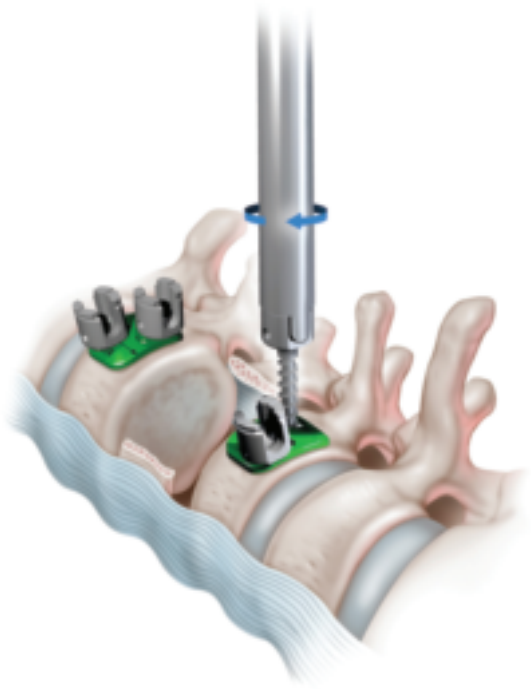
- Place staples.

NOTE: Consult EXPEDIUM Anterior Surgical Technique for more information on staple and screw placement.



STEP 4

- Puncture corticocancellous shell with the awl to facilitate screw placement and guide screw trajectory.
- Follow the awl's path with a tap.
- Palpate the path with a ball-tipped probe to confirm intraosseous path.
- Measure appropriate size of screw with depth gauge.



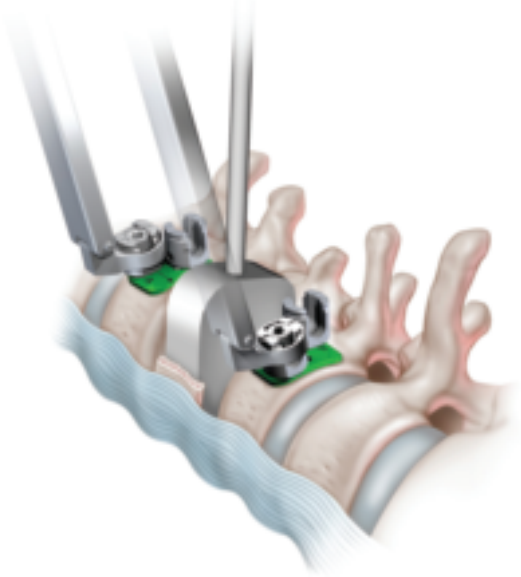
STEP 5

- Place screws; bicortical purchase is recommended.

NOTE: Distraction may be achieved directly from the X-MESH Expandable Cage as opposed to distracting off of the EXPEDIUM screws.

X-MESH™ EXPANDABLE CAGE SYSTEM

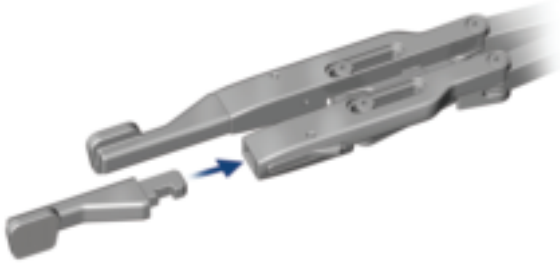
Cage Sizing



STEP 6

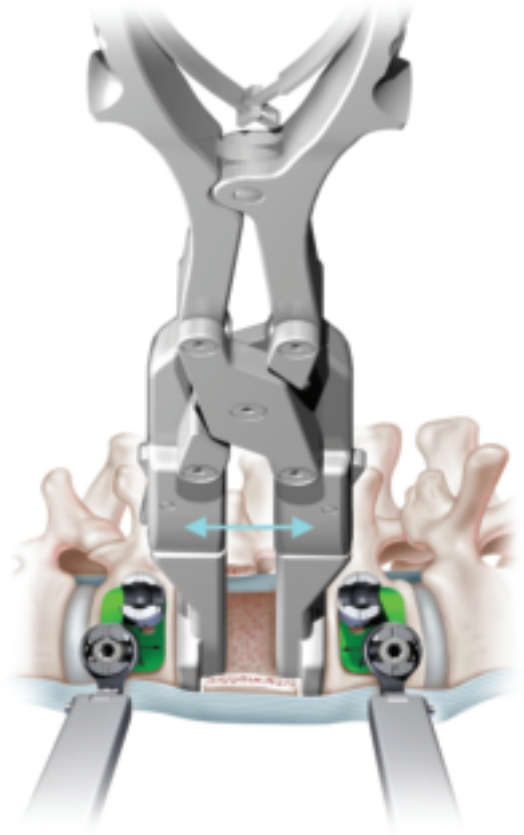
- Confirm proper “footprint” of X-MESH Cage with an anterolateral trial (i.e., small, medium, or large). The optimal cage footprint will be the largest cage that fits within the cortical margin of the superior and inferior vertebral bodies. **Use caution to make sure the trial does not hit the spinal cord during placement.**
- Use the color on the trial to pick the correct implant diameter. See color coding table below.
- Determine the lordosis of the defect through preoperative x-rays and intraoperative fluoroscopy.

Color (Diameter) Coding System	
Color	Corresponding Size
Yellow	Small (16 mm x 20 mm)
Green	Medium (20 mm x 23 mm)
Blue	Large (24 mm x 30 mm)



STEP 7

- Assemble the secondary distractor instrument by attaching paddles to the empty slots at the tip of the distractor.
- Use the regular paddles for defects smaller than 50 mm. Use the offset paddles for defects between 50-100 mm. If the defect is larger than 100 mm, then use the calipers to measure the defect. Defects greater than 110 mm in height exceed the size of the tallest cage in this system (110 mm).



Distractor Handle

- Letter codes for regular paddles on top of handle (A - E).
- Letter codes for offset paddles on back side of handle (F - G).

STEP 8

- Measure defect height utilizing the X-MESH Expandable Cage secondary distractor instrument. The cage should easily fit in the defect in the compressed form. This allows for appropriate distraction of the cage without unnecessary force.

  Exercise caution distracting the vertebral bodies in patients with poor bone quality as overdistraction may damage the endplates.

- The handle of the secondary distractor has an indicator that can be used to read the defect height in millimeters and the matching cage height letter.
- Match the letter on the secondary distractor indicator to the appropriate letter implant (actual height measurements are also located on the distractor).
- Choose the appropriate sized implant based on footprint, lordosis, and height.

Letter (Height) Coding System	
A	22 mm – 30 mm
B	25 mm – 33 mm
C	28 mm – 38 mm
D	33 mm – 46 mm
E	40 mm – 56 mm
F	51 mm – 71 mm
G	65 mm – 90 mm
H	85 mm – 110 mm

- Make sure to pick a cage height that is at least 4 mm larger than the defect as this will allow the spikes to seat into the endplates.

X-MESH™ EXPANDABLE CAGE SYSTEM

Bone Graft Filling

STEP 9

- **Using the bone graft filling block can aid in protecting the surgical team from perforating gloves with endplate spikes, packing the bone graft material tightly, and avoiding any displacement of bone graft material prior to implantation.**

- Assemble block by sliding cage lids into the matching cage loading zones (1 lid each for small, medium, and large sizes). **The color of the cage should match the color of the bone graft block lid.**

- Put cage into filling block (match the location in the block with the appropriate size cage). It is recommended to place the cage in the bone block with the superior side facing downwards (upside down). This will allow for easier filling, as the inferior lumen of cage is wider than the superior lumen. Cover top of cage with lid.

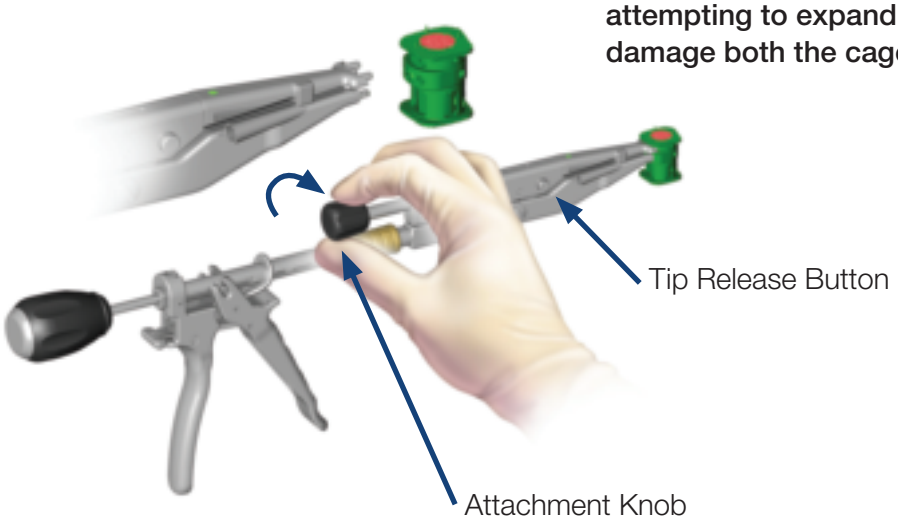
- Fill cage with graft material. **Use cage lid to protect fingers from the spikes on the cages.**

- Use tamps to pack bone graft material into cages. Match the correct tamp to the correct cage diameter. Small tamp fits 16 x 20 mm cage, medium tamp fits 20 x 23 mm cage, and large tamp fits 24 x 30 mm cage.

Cage Insertion

STEP 10

- Match the implant footprint with the correct sized inserter tip. Connect the inserter tip to the inserter. The inserter tips are color coded to match each cage (i.e., use blue coded tip with blue large footprint implant).
- If the tip needs to be removed at any point in the procedure, press on the button on the side of the inserter/expander to release the tip. The inserter must be opened at least 5 mm to connect or remove tip.
- Match the tip marked SUPERIOR to the superior side of the cage. Match the INFERIOR tip to the inferior side of the cage.
- Attach the implant to the inserter by mating the inserter tip posts to the implant inserter holes and turning the **small** attachment knob clockwise until finger tight.
- When implanting the cage via a right-sided approach, flip the cage upside down.
- **Make sure the set screw on the cage is unlocked (turned completely counter-clockwise) prior to expanding the cage as attempting to expand a locked cage may damage both the cage and the instrument.**



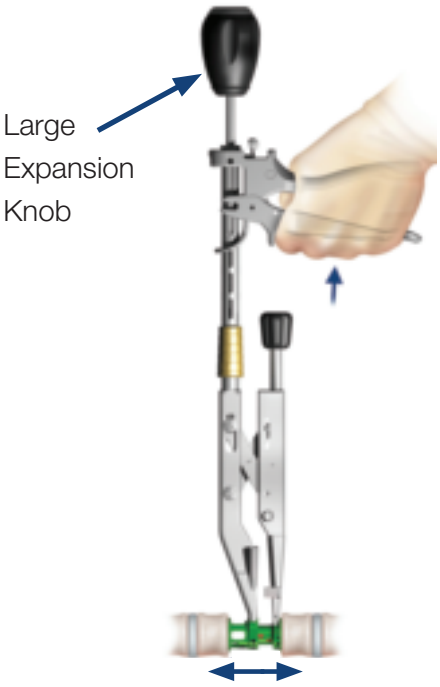
X-MESH™ EXPANDABLE CAGE SYSTEM

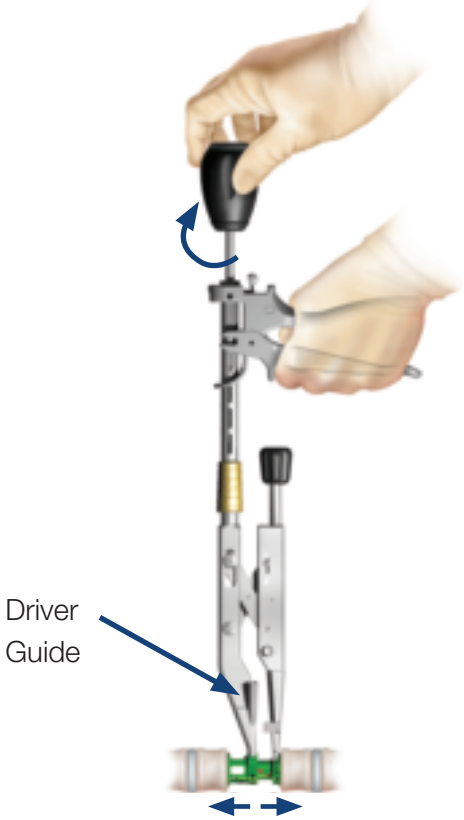
STEP 11

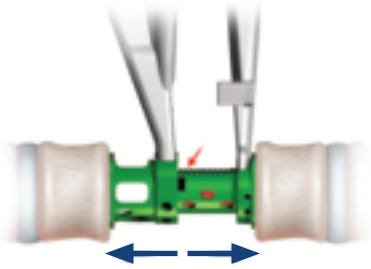
- The tips of the inserter can rotate in 90 degree increments to allow for insertion at the proper angle.

- To rotate the tips, 1 slide the gold sleeve on the inserter shaft forward, and then 2 rotate the tip 90 degrees.

- Continue rotation to the right or left until the proper angle is chosen.



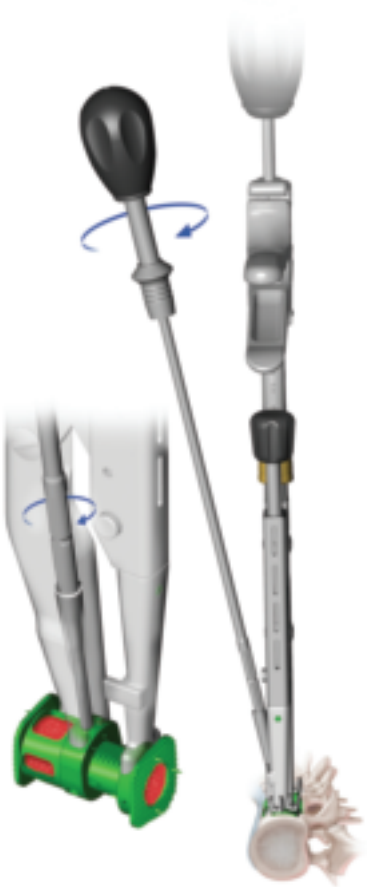


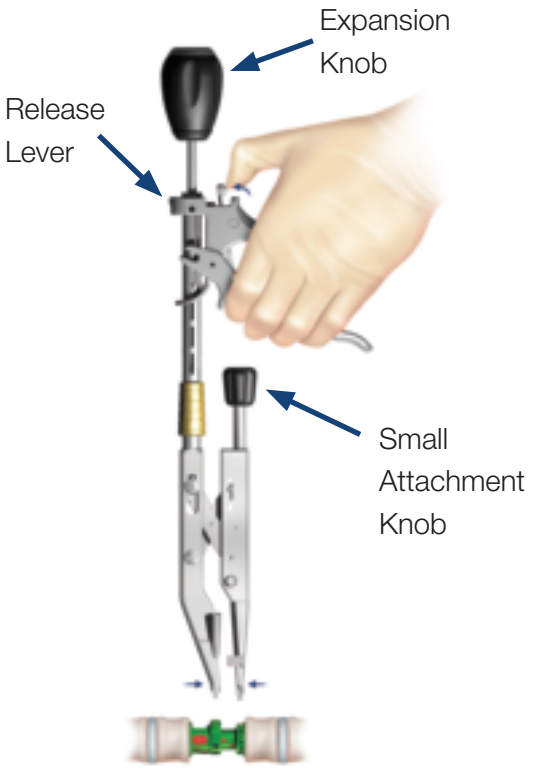


STEP 12

- Insert the cage into the defect.
  - Make sure that the widest side of the cage goes anteriorly.
- Expand the cage to the desired height:
  - Squeeze the pistol grip to expand the cage so the cage spikes are touching the vertebral body endplates.
  - Turn the **large** expansion knob clockwise for final expansion. Expand until the spikes are seated into the vertebral body endplates. The cage should securely fit within the defect. Each complete turn expands the cage 2 mm.
  - The pistol grip allows for more rapid expansion, while the expansion knob allows for fine-tuning the expansion.
  - Both the pistol grip and the large expansion knob mechanisms will stop when the cage is expanded to its maximal height. Do not push either mechanism past this point, as this may result in both implant and instrument damage.
  - **Exercise caution when expanding the cage prior to implantation as over-expansion will make it difficult to insert the cage in the defect.**
  - **Be careful of overexpanding the cage when implanting in a patient with poor-quality bone.**
  - **When the cage has reached its maximum expansion height, black lines on the inner diameter of the cage (next to the pressure plate) will be exposed.**

X-MESH™ EXPANDABLE CAGE SYSTEM





STEP 13

- Lock the cage in the expanded position.
  - Insert the torque-limiting driver into the driver guide on the inserter and seat the driver into the implant set screw. **Note that the driver will be blocked from mating with the set screw until the implant has been expanded at least 5 mm.**
  - Turn the driver clockwise until it torques out (an audible click will be heard). Do not turn the driver past the point when it clicks, as this may result in both implant and instrument damage.
  - If the driver is accidentally turned in the wrong direction (counterclockwise), then the locking screw will continue to turn until it reaches a stopping point. This stop point keeps the screw from being accidentally removed from the implant housing. Turning the driver past this point can result in both implant and instrument damage.

STEP 14

- To release the cage from the inserter instrument unscrew the **small** attachment knob counterclockwise until the locking mechanism releases.

- To release the instrument from its height, press the **release lever** on the end of the inserter. This lever may be pressed at any time to return the inserter back to its original contracted state.

- If the large knob has been used for expansion, it will need to be turned counter-clockwise after pressing the release lever to return the instrument to its fully collapsed state.

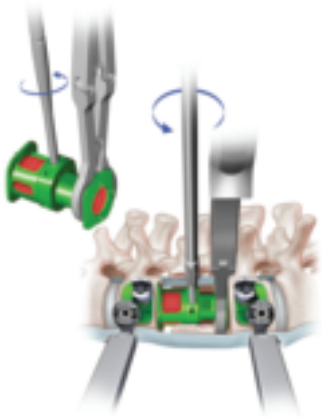
- Avoid adjusting the **large** expansion knob after releasing the cage from the inserter. This will facilitate reattachment of the cage to the inserter in case the cage's height needs to be adjusted.

Impact cage anywhere except ⊗ marked areas.

STEP 15

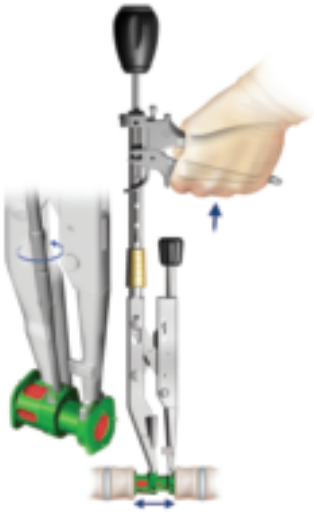
- To adjust the position of the cage once implanted, use the straight and curved tip impactors.
- Impact the cage anywhere except directly on the pressure plate as this may cause damage to the cage locking mechanism.
- **Do not impact the cage too far off center as this may cause damage to both the cage and the patient's anatomy.**

STEP 16



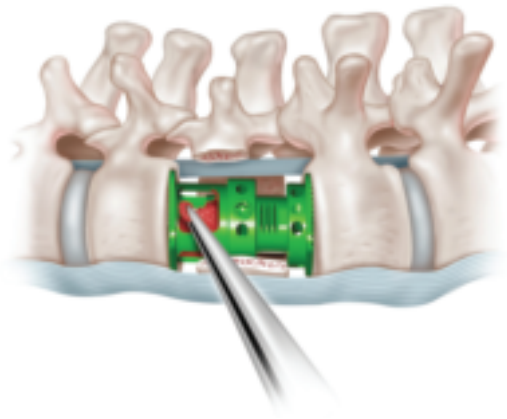
- Use fluoroscopy to verify correct cage placement.
- To reposition the cage:
  - Unlock the cage by holding the cage with the grabber instrument; insert the torque driver into the set screw; turn the torque driver counterclockwise.
  - The cage will collapse. Remove the cage, reattach to the inserter, reposition and expand the cage.

Or



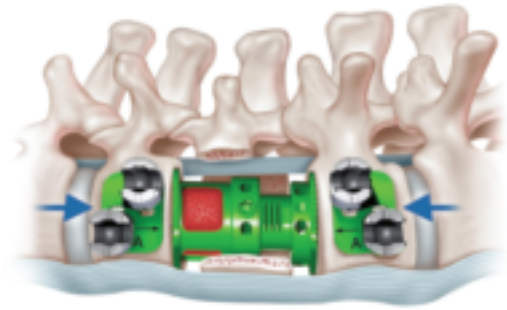
- Reattach the inserter to the implant while it is still in the defect. Ensure that the inserter instrument is expanded to the corresponding cage height.
- Insert the torque driver into the driver guide on the inserter, and turn the driver counterclockwise to unlock and collapse the cage.
- The cage will contract with the inserter. Reposition and expand the cage.

X-MESH™ EXPANDABLE CAGE SYSTEM



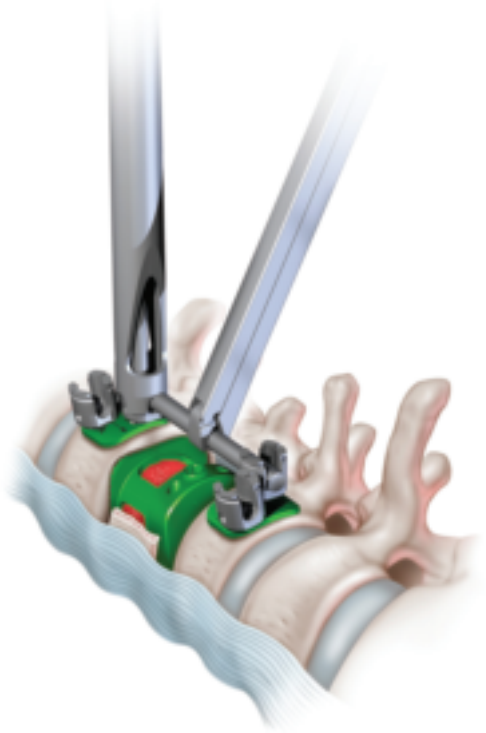
STEP 17

- Backfill the empty space (created during cage expansion) in the cage by inserting morselized local bone into the cage's graft window.
- This will help to facilitate bone growth through the cage.



STEP 18

- If EXPEDIUM Anterior screws have been distracted, release the distraction; vertebral bodies will settle on cage.



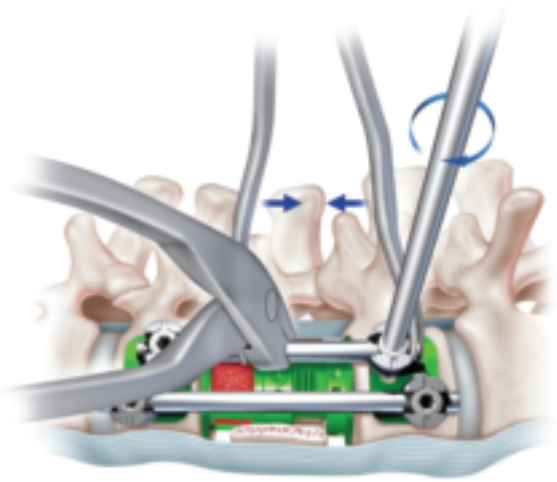
STEP 19

- Introduce EXPEDIUM Anterior rods.

STEP 20

- Place inner set screws and provisionally tighten one side to the rods.

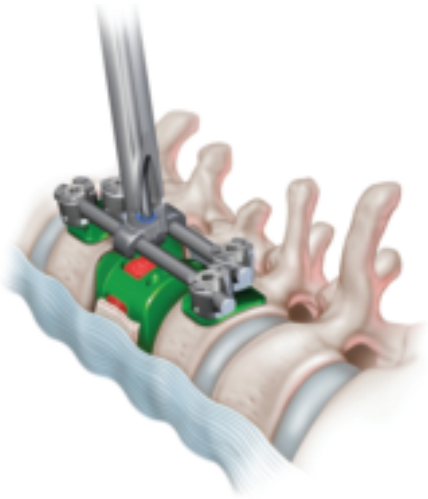
X-MESH™ EXPANDABLE CAGE SYSTEM



STEP 21

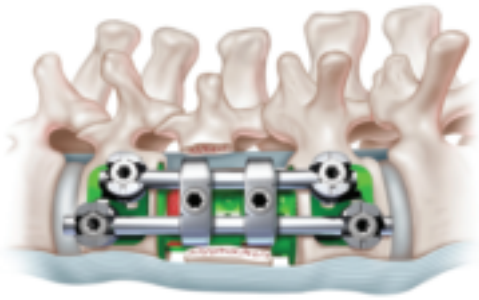
- Compress construct.
- After compression, perform final tightening on all set screws.

Note: Any anterior device can migrate in the absence of adequate compression.



STEP 22

- Determine appropriate cross connector size and apply cross connector to rods.



STEP 23

- Fully tighten set screws to complete construct.

Cage Implantation: Direct Anterior Approach

Preoperative Evaluation

AP and lateral radiographs, along with advanced imaging studies including a CT and MRI, are required for planning the approach to the lumbosacral junction (L4 to S1). Care should be taken to analyze the anatomic course of the great vessels, including the aorta, vena cava, iliocaval junction, and common iliac arteries and veins. The height of the affected vertebral bodies and adjacent discs may be used to plan the proper length and footprint of the X-MESH Expandable Cage.

Positioning

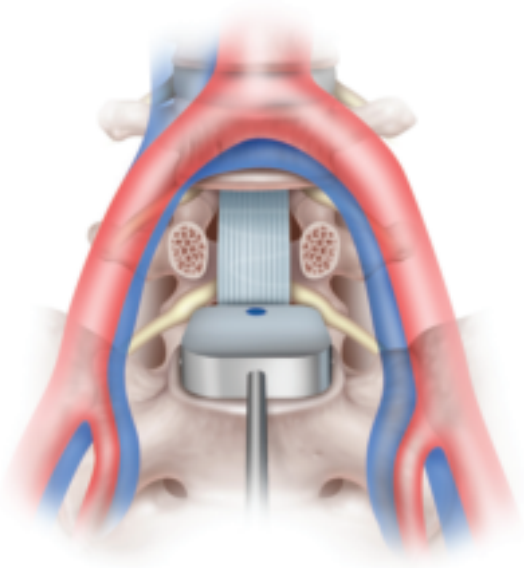
Typically, the lumbosacral junction can be approached by positioning the patient in either a lateral decubitus position, supine position, or somewhere in between these two positions. Radiographic verification of the targeted level is performed to plan the surgical incision. Often, an inflatable bag assists in securing the patient position. All extremities are cushioned and protected to prevent postoperative positioning palsies.

Exposure

The level of the affected vertebral body will determine the incision site. Typically, the lumbosacral junction (L4 to S1) is approached via a retroperitoneal approach. The incision is taken down to the rectus fascia. The rectus fascia is incised and blunt retroperitoneal dissection (typically on the left side) is performed down to the spine. Care is taken to stay medial to the psoas muscle. To expose the lower lumbar vertebrae, the iliolumbar vein must be ligated to prevent a tethering effect when beginning to mobilize the great vessels. All vascular structures are thus swept from left to right providing adequate visualization of the discs and vertebral bodies involved. Segmental vessels running across the valleys on the anterior surface of the bodies can be transected between clips and swept to the sides with blunt dissection. It may be necessary to work between the vessels at the level of the L5/S1 disc. Self-retaining retractors are placed. All disc material cephalad and caudal to the affected vertebral body are removed. A corpectomy of the affected vertebral body is performed. For optimal mechanical reconstruction, the largest X-MESH Expandable Cage is positioned between intact endplates.

Cage Implantation

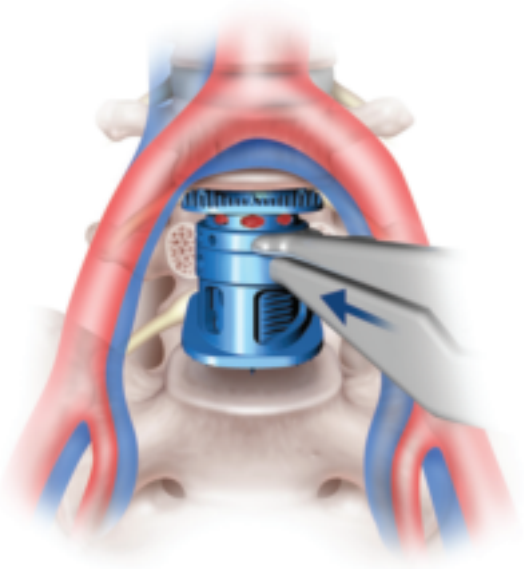
The steps for cage implantation via this approach are the same as the Anterolateral Approach with a few exceptions:



Cage Sizing

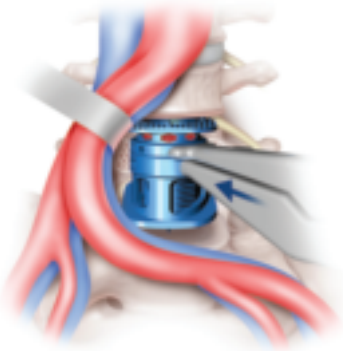
- Use the direct anterior trials to pick the right cage footprint. These trials are designed for use via an anterior exposure. **Use caution to make sure the trial does not hit the cauda equina or vessels during placement.**

- Note that the direct anterior implants come in only the large 24-mm diameter. If smaller footprints are preferred, then the anterolateral small and medium implants can be used.



Cage Insertion

- Direct anterior implants attach to the inserter/expander at a 45-degree angle. This angle allows for avoidance of vascular anatomy during the insertion of the cage from an anterior approach.



Cage Implantation: Posterolateral Approach

Preoperative Evaluation

Preoperative evaluation consists of a thorough history and physical examination, and a thorough radiographic evaluation. It is important to know which nerve roots, if any, are involved in the thoracic spine as it is common to sacrifice a thoracic nerve root to place the cage from a posterior approach. Functioning nerve roots in the cervical and lumbar spine cannot be sacrificed. This, combined with the fact that anterior approaches are far less morbid in the cervical and lumbar regions than in the thoracic region, posterior approaches are largely reserved for thoracic pathology.

Radiographic evaluation consists of a combination of AP and lateral plain x-rays, CT with sagittal and coronal reconstructions, and MRI. These are not only important for preoperative planning, but also for intraoperative localization. Preoperatively, the surgeon needs to know whether the spine is stable, the extent of the sagittal and coronal deformity, the number of levels involved to estimate the height of the reconstruction, and the size of the endplates of the vertebral bodies at the superior and inferior edges of the reconstruction. The increased availability of intraoperative navigation systems obviates the need for preoperative MRIs with markers and intraoperative plain films to confirm the proper location.

Positioning

The patient is positioned in the straight prone position, usually on a Jackson frame. The patient is then secured with belting or tape to allow the frame to be rotated side to side as needed. The patient's head positioning depends on the level of the pathology and the length of the case. For upper thoracic, cervical, and long cases the head is often secured with the Mayfield head holder. Otherwise, a face pillow is adequate. Upper extremity positioning is also a function of the level of the fusion. Patients requiring mid- to lower-thoracic fusions have their arms positioned on arm boards at 90-degree angles and all of their pressure points padded. Patients requiring their upper thoracic fixation have their arms positioned at their sides.

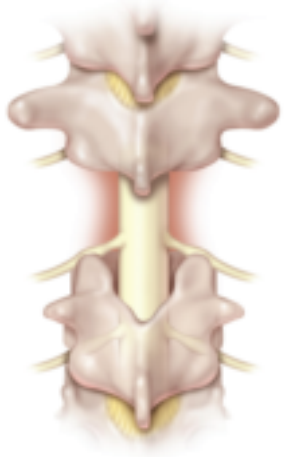
Exposure

Depending on the level of the involved vertebral body(s), the ease of which the pathology is seen on plain films, and the equipment available for intraoperative localization, the patient may need a preoperative MRI with markers to help plan the incision. The incision is made in the midline and the posterior elements are exposed with a Bovie. The exposure is extended laterally until 3-4 cm of rib are exposed. Depending on the pathology, adequate removal of the vertebral body may occur through a unilateral approach, otherwise bilateral costotransversectomies are needed. Using a rongeur and/or a high-speed burr the posterior elements are removed, including the facets and the transverse process. The soft tissue is freed from the rib using a periostial elevator and a Bovie. The rib is exposed circumferentially with an angled curette, and the segmental arteries are controlled with bipolar cautery or 2.0 silk sutures. The rib is then divided at the lateral aspect of the exposure with a Kerrison punch or Lexel rongeur. Ligamentous attachments between the rib and the vertebral body are resected with a forward angled curette. The rib and the entire head of the rib are removed with a rongeur. This affords unobstructed access to the lateral aspect of the vertebral body.

After the posterior bony elements are removed, the nerve root may need to be tied with 2-0 silk ties and cut to provide adequate access. The retractor is positioned so the intercostal muscles are pushed laterally and anteriorly. Portions of the inferior rib may need to be removed for better access for the corpectomy and discectomies. Remove the pedicle from the vertebral body. Using a high-speed cutting burr, the vertebral body is removed leaving a shell of bone anteriorly and laterally if possible. If the entire body is involved curettes and a diamond burr can be used, taking care to always direct movement and force away from the spinal cord. The endplates are prepared by removing the inferior and superior discs.

The proper sized cage is chosen based on measuring the endplates and the height of the removed vertebral body and disks from the CT, preoperative X-rays, and intraoperative fluoroscopy. The cage is then packed with autograft and/or allograft and inserted.

Vertebrectomy



STEP 1

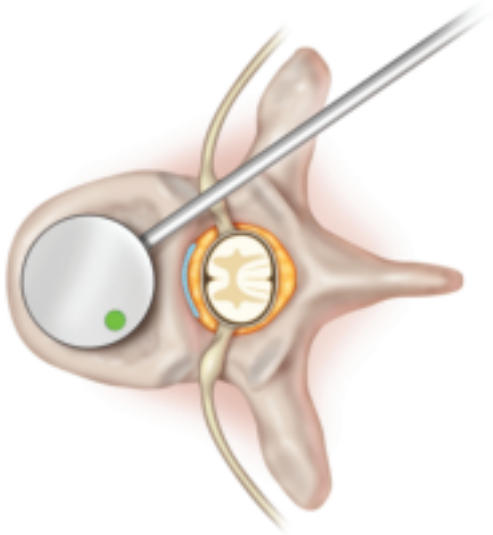
- Prepare the corpectomy or vertebrectomy site by a lateral extracavitary, transpedicular, or costotransversectomy approach.

- Remove bone. Removed bone should be retained for bone graft. However, in the presence of tumor, alternative bone graft materials are required.

- **Removal of vertebral segment can lead to destabilization of the spine. Hence, provisional stabilization of the segment by pedicle screw and rod instrumentation is recommended prior to the vertebrectomy and placement of the X-MESH Expandable Cage.**

X-MESH™ EXPANDABLE CAGE SYSTEM

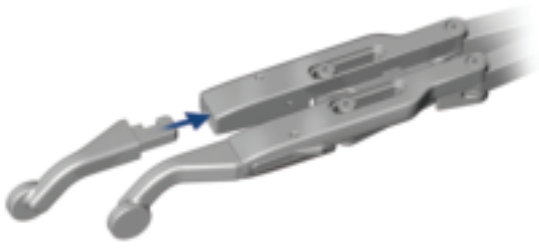
Cage Sizing



STEP 2

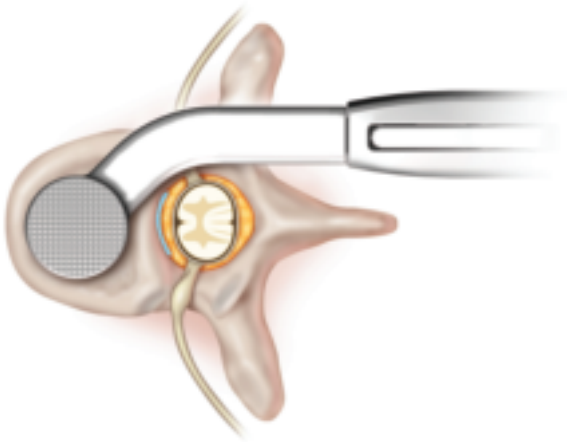
- Confirm proper “footprint” of X-MESH Expandable Cage with a posterior trial (i.e., small or medium). The optimal cage footprint will be the largest cage that fits within the cortical margin of the superior and inferior vertebral bodies. **Use caution to make sure the trial does not hit the spinal cord during placement.**
- Use the color on the trial to pick the correct implant diameter. See color coding table below.
- Determine the appropriate lordosis for the defect through preoperative X-rays and intraoperative fluoroscopy.

Color (Diameter) Coding System	
Color	**Corresponding Size**
Yellow	Small (16 mm)
Green	Medium (20 mm)



STEP 3

- For defects below 50 mm in height, use the secondary distractor to measure the defect size. For defects over 50 mm in height, use the caliper.
- If needed, assemble the secondary distractor instrument by inserting the posterior paddles into the empty slots at the tip of the distractor.



STEP 4

- Measure defect height utilizing the X-MESH Expandable Cage secondary distractor instrument. The cage should easily fit in the defect. This allows for appropriate distraction of the cage without unnecessary force. **Exercise caution distracting the vertebral bodies in patients with poor bone quality, as overdistraction may damage the endplates.**

- The handle of the distractor has an indicator, which can be used to read the defect height in millimeters and the matching cage-height letter.

- Match the letter on the distractor indicator to the appropriate letter implant (actual height measurements are also located on the distractor).

- Choose the appropriate sized implant based on footprint, lordosis, and height.

Letter (Height) Coding System	
A	22 mm – 30 mm
B	25 mm – 33 mm
C	28 mm – 38 mm
D	33 mm – 46 mm
E	40 mm – 56 mm
F	51 mm – 71 mm

- Make sure to pick a cage height that is at least 4 mm larger than the defect as this will allow the spikes to seat into the endplates.

X-MESH™ EXPANDABLE CAGE SYSTEM

Bone Graft Filling

STEP 5

- **Using the bone graft filling block can aid in protecting the surgical team from perforating gloves with endplate spikes, packing the bone graft material tightly, and avoiding any displacement of bone graft material prior to implantation.**

- Assemble block by sliding cage lids into the matching cage loading zones (1 lid each for small, medium, and large sizes). **The color of the cage should match the color of the bone graft block lid.**

- Put cage into filling block (match the location in the block with the appropriate size cage). It is recommended to place the cage in the bone block with the superior side facing downwards (upside down). This will allow for easier filling, as the Inferior lumen of cage is wider than the superior lumen. Cover top of cage with lid.

- Fill cage with graft material. **Use cage lid to protect fingers from the spikes on the cages.**

- Use tamps to pack bone graft material into cages. Match the correct tamp to the correct cage diameter. Small tamp fits 16 x 20 mm cage, and medium tamp fits 20 x 23 mm cage.

STEP 6

- The posterior inserter allows for 2 directional choices of cage insertion: left-sided insertion and right-sided insertion. Choose the tips that match the surgical approach.

- Use the bottom tip that matches the insertion approach (i.e., left-sided bottom tip or right-sided bottom tip). Connect the bottom tip to the bottom connection on the inserter.

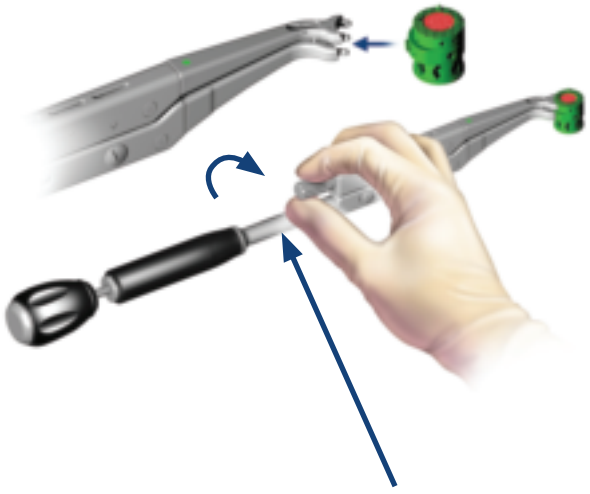
- Match the implant footprint with the correct sized top inserter tip. Use the top inserter tip that matches the approach and cage size (i.e., left-sided small top tip). Connect the inserter tip to the top connection on the inserter. The inserter tips are color coded to match each cage (i.e., use green coded tips with green implant).

- Match the tip marked SUPERIOR to the superior side of the cage. Match the INFERIOR tip to the inferior side of the cage.

- If the tips need to be removed at any point in the procedure, press on the button on the side of the inserter/expander to release the tips. The inserter must be expanded at least 5 mm to allow for connection and removal of tips.

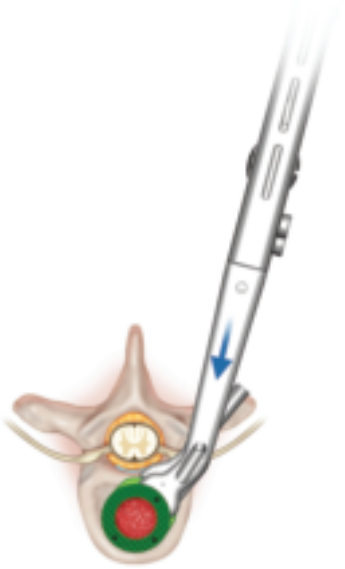
- Attach the implant to the inserter by mating the inserter tip posts to the implant inserter holes and turning the **small** attachment knob clockwise until finger tight.

- **Make sure the set screw on the cage is unlocked (turned completely counter-clockwise) prior to expanding the cage as attempting to expand a locked cage may damage both the cage and the instrument.**



Attachment Knob

X-MESH™ EXPANDABLE CAGE SYSTEM

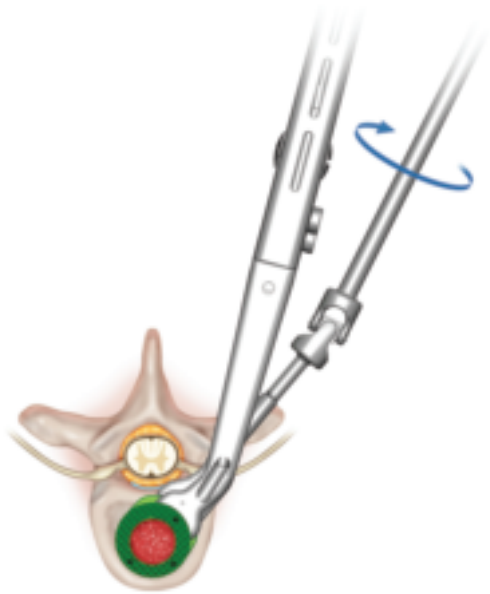


STEP 7

- Insert the cage into the defect. Turn the shaft of the posterior inserter upwards to expose the driver guide prior to expansion.

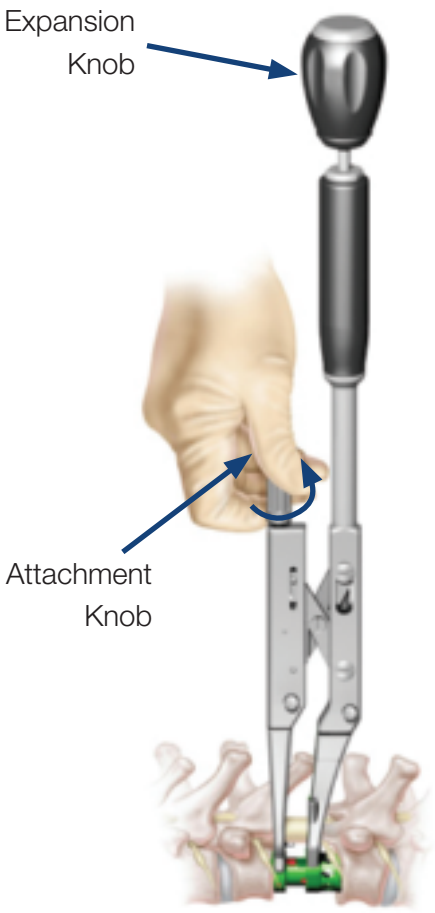
- Expand the cage to the desired height:
  - Turn the **large** expansion knob clockwise to expand the cage. Expand until the spikes are seated into the vertebral body endplates. Cage should securely fit into the defect.
  - When the cage has reached its maximum expansion height, black lines on the inner diameter of the cage (next to the pressure plate) will be exposed. See page 21 for image of black line indicator.

- The inserter expansion mechanism (large expansion knob) will stop when the cage is expanded to its maximal height. Do not push this mechanism past this point, as this may result in both implant and instrument damage.
  - **Exercise caution when expanding the cage prior to implantation as over-expansion will make it difficult to insert the cage in the defect.**
  - **Be careful of overexpanding the cage when implanting in a patient with poor-quality bone.**



STEP 8

- Lock the cage in the expanded position.
  - Either a universal joint or straight driver can be used to lock the posterior cage. Choose the driver shaft that best fits the extent of lateral exposure. Insert the chosen driver shaft into the torque handle. Universal joint driver can only be used with right-sided tips. Straight driver can be used with both tips.
  - Insert the torque-limiting driver into the driver guide on the inserter and seat the driver into the implant set screw. **Note that the driver will be blocked from mating with the set screw until the implant has been expanded at least 5 mm.**
  - Turn the driver clockwise until it torques out. Do not turn the driver past the point when it clicks, as this may result in both implant and instrument damage.
  - If the driver is accidentally turned in the wrong direction (counterclockwise), then the locking screw will continue to turn until it reaches a stopping point. This stop point keeps the screw from being accidentally removed from the implant housing. Turning the driver past this point can result in both implant and instrument damage.



STEP 9

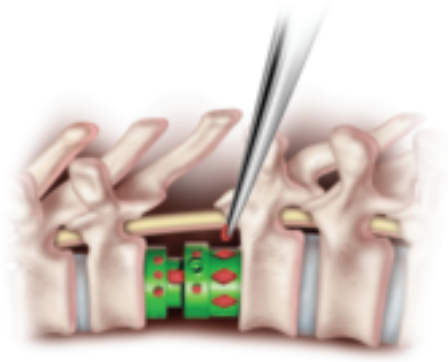
- To release the cage from the inserter, first release tension on the implant by turning the **large** expansion dial counterclockwise for 1 turn.

- Then unscrew the **small** attachment knob counterclockwise until the locking mechanism releases. Turning the small attachment knob will separate the device from the cage. The inserter can then be removed from the implant.

- Avoid adjusting the **large** expansion knob after releasing the cage from the inserter. This will facilitate reattachment of the cage to the inserter in case the cage's height needs to be adjusted.

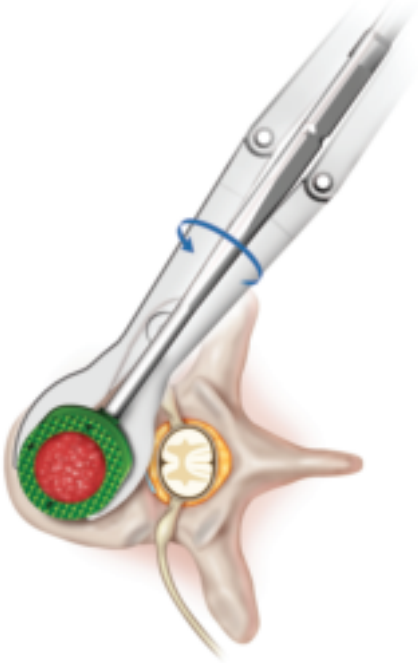
STEP 10

- To adjust the position of the cage once implanted, use the posterior angled impactor. Mate the impactor with the cage window opening prior to impaction.
- Impact the cage anywhere except directly on the pressure plate as this may cause damage to the cage locking mechanism. (See page 23 for image of where to impact cage.)
- Use extreme caution when impacting cage to ensure that cage does not move too far off center and damage any crucial anatomy.



STEP 11

- Backfill the empty space (created during cage expansion) in the cage by inserting morselized local bone into the cage's graft window.
- This may help to facilitate bone growth through the cage.



STEP 12

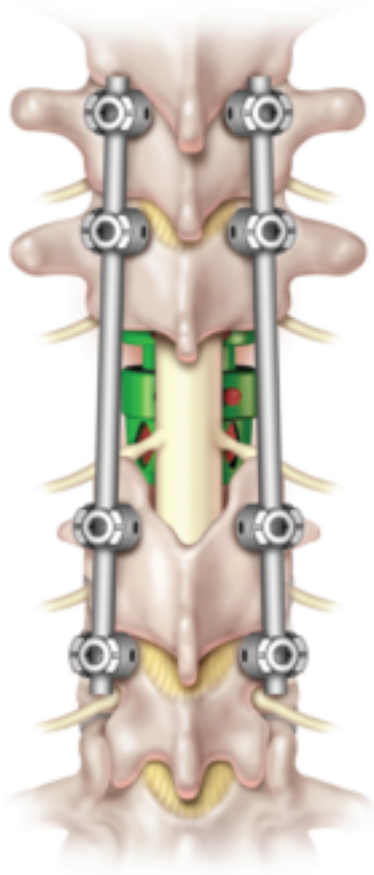
- Use fluoroscopy to verify correct cage placement.
- To reposition the cage:
  - Reattach the inserter to the implant while it is still in the defect. Place the inferior tips into the implant first.
  - Turn the small attachment knob to draw the inserter to the device.
  - Insert the torque driver into the driver guide on the inserter; turn the driver counterclockwise to unlock the cage.
  - The cage will contract with the inserter. Reposition and expand the cage.

Or

  - Remove the superior tip and the threaded small attachment knob from the inserter.
  - Connect the inserter to the cage using the inferior tip. Use the inserter to stabilize the cage while unscrewing the set screw with the torque driver.
  - Collapse the cage with a Kocher and remove it.
  - Attach superior tip and attachment knob to the inserter. Reattach cage to inserter and reimplant cage.

Or

  - Unlock the cage by holding the cage with the grabber instrument; insert the torque driver into the set screw; turn the torque driver counterclockwise.
    NOTE: Grabber instrument available in Regular X-MESH set.
  - The cage will collapse. Remove the cage, reattach to the inserter, reposition and expand the cage.



STEP 13

- Add supplementary posterior fixation as needed. This may include pedicle screw/rod systems such as the EXPEDIUM System.

WOUND CLOSURE

Wound closure is dependent on the surgical approach used and may involve repair of the diaphragm or placing a chest tube.

POSTOPERATIVE MANAGEMENT RECOMMENDATIONS

Consider fitting the patient with a thoracolumbar spinal orthotic and restrict activity for 4 to 6 months following the operation. A program of isometric muscle exercise is recommended. Radiographic evaluation is recommended to assess fusion across the graft site.

REVISIONS

In the case that an X-MESH cage needs to be revised or removed from a patient, the surgeon should first remove any bone or materials holding the cage to the fusion site. The surgeons should then follow the steps for grabbing the cage and removing it as shown in Step 16 on page 23 of the surgical technique guide:

- Unlock the cage by holding the cage with the grabber instrument; insert the torque driver into the set screw; turn the torque driver counterclockwise.

- The cage will collapse. Remove the cage using the grabber tool.

Product Catalog

The X-Mesh™ Expandable Cage System has three case and tray components: the **Regular Set**, the **Posterior Set**, and the **Extreme Tray**. The system is able to support the full range of clinical situations, as shown below:

Procedure	SINGLE LEVEL ANTEROLATERAL CASE	EXTREME CASE 2+ AL Levels DA Case	POSTERIOR CASE 1-3 Levels
Set Needed	Regular Set Implants and Instruments	Regular Set Instruments	Posterior Set Instruments and Implants
		Extreme Tray Implants	

- **Single Level Anterolateral Case:** This is defined as a one-level corpectomy that is performed by an Anterolateral approach (i.e. thoracotomy, retroperitoneal). Use the implants and instruments in the Regular Set.
- **Extreme Case:** This is defined as a surgical case that involves multiple Anterolateral Levels or a Direct Anterior approach corpectomy. Use the instruments in the Regular Set along with the implants in the Extreme Tray.
- **Posterior Case:** This is defined as a surgical case that involves one to three levels from a Posterior Approach (i.e. costotransversectomy, lateral extracavitary, transpedicular). Use the implants and instruments in the Posterior Set.

X-MESH™ EXPANDABLE CAGE SYSTEM

Regular Set - Instruments

The following instruments are included in the Regular Set:

Product Code	Description
2889-00-000	X-MESH Pistol Grip Inserter / Expander
2889-00-001	Pistol Grip Inserter Foot (Small)
2889-00-002	Pistol Grip Inserter Foot (Medium)
2889-00-003	Pistol Grip Inserter Foot (Large)
2889-00-009	X-MESH Pistol Grip Inserter Replacement Shaft
2889-00-010	X-MESH Anterolateral Trial (Small/Medium)
2889-00-011	X-MESH Anterolateral Trial (Medium/Large)
2889-00-020	X-MESH Straight Impactor
2889-00-021	X-MESH Angled Impactor
2889-00-030	X-MESH Bone Tamp (Small)
2889-00-031	X-MESH Bone Tamp (Medium)
2889-00-032	X-MESH Bone Tamp (Large)
2889-00-040	X-MESH Bone Graft Loading Block
2889-00-050	X-MESH Torque Driver Handle
2889-00-051	X-MESH Torque Driver Shaft
2889-00-060	X-MESH Grabber
2889-00-070	X-MESH Distractor
2889-00-071	Distractor Paddle (Inferior)
2889-00-072	Distractor Paddle (Superior)
2889-00-073	Offset Distractor Paddle (Inferior)
2889-00-074	Offset Distractor Paddle (Superior)
2752-13-000	Caliper
2889-00-080	X-MESH Regular Set Instrument Tray
2889-00-081	X-MESH Regular Set Implant Tray
2889-00-082	X-MESH Anterolateral Implant Caddy
2889-00-090	X-MESH Lid

Regular Set - Implants

The following implants are included in the Regular Set:

Anterolateral Implants

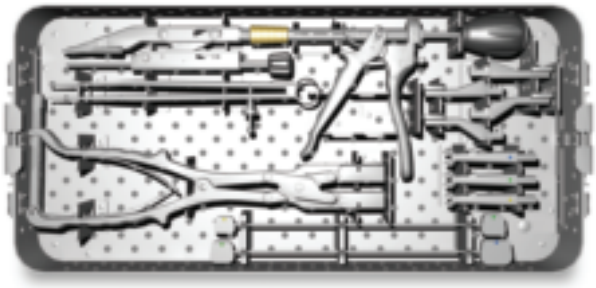
Product Code	X-MESH Implant Name	Diameter (mm)	Height Range (mm)	Endplate Angles (Top/Bottom)
1889-00-022	Lateral Small 0 DEG 22-30mm	16	22-30	0/0
1889-00-122	Lateral Small -6 DEG 22-30mm	16	22-30	-6/0
1889-00-025	Lateral Small 0 DEG 25-33mm	16	25-33	0/0
1889-00-125	Lateral Small -6 DEG 25-33mm	16	25-33	-6/0
1889-00-028	Lateral Small 0 DEG 28-38mm	16	28-38	0/0
1889-00-128	Lateral Small -6 DEG 28-38mm	16	28-38	-6/0
1889-01-022	Lateral Medium 0 DEG 22-30mm	20	22-30	0/0
1889-01-122	Lateral Medium -6 DEG 22-30mm	20	22-30	-6/0
1889-01-025	Lateral Medium 0 DEG 25-33mm	20	25-33	0/0
1889-01-125	Lateral Medium -6 DEG 25-33mm	20	25-33	-6/0
1889-01-028	Lateral Medium 0 DEG 28-38mm	20	28-38	0/0
1889-01-128	Lateral Medium -6 DEG 28-38mm	20	28-38	-6/0
1889-01-033	Lateral Medium 0 DEG 33-46mm	20	33-46	0/0
1889-01-233	Lateral Medium 6 DEG 33-46mm	20	33-46	0/6
1889-01-040	Lateral Medium 0 DEG 40-56mm	20	40-56	0/0
1889-01-240	Lateral Medium 6 DEG 40-56mm	20	40-56	0/6
1889-01-051	Lateral Medium 0 DEG 51-71mm	20	51-71	0/0
1889-02-028	Lateral Large 0 DEG 28-38mm	24	28-38	0/0
1889-02-033	Lateral Large 0 DEG 33-46mm	24	33-46	0/0
1889-02-233	Lateral Large 6 DEG 33-46mm	24	33-46	0/6
1889-02-040	Lateral Large 0 DEG 40-56mm	24	40-56	0/0
1889-02-240	Lateral Large 6 DEG 40-56mm	24	40-56	0/6
1889-02-340	Lateral Large 12 DEG 40-56mm	24	40-56	0/12
1889-02-051	Lateral Large 0 DEG 51-71mm	24	51-71	0/0
1889-02-265	Lateral Large 6 DEG 65-90mm	24	65-90	0/6

X-MESH™ EXPANDABLE CAGE SYSTEM

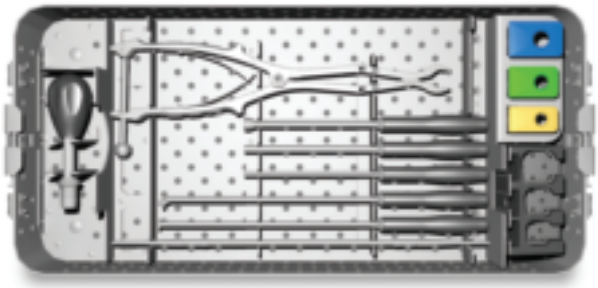
Regular Set - Trays & Caddy

The Regular Set has two trays and one implant caddy:

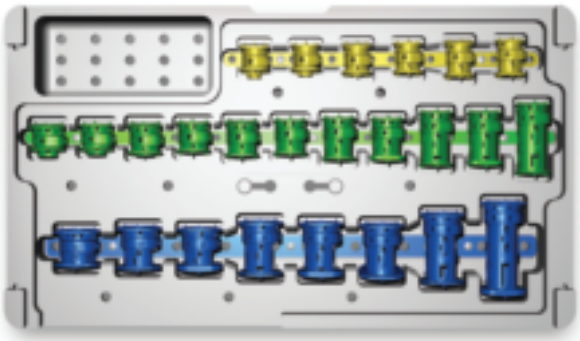
Anterior Instrument Tray



Anterolateral Implant Tray



Anterolateral Implant Caddy



Extreme Tray - Instruments and Implants

The following implants and instruments are included in the Extreme Tray:

Product Code	Description
2889-00-013	X-MESH Direct Anterior Trial (Medium/Large)
2889-00-084	X-MESH Extreme Tray
2889-00-184	X-MESH Extreme Implant Caddy
2889-00-090	X-MESH Lid

Anterolateral Implants

Product Code	X-MESH Implant Name	Diameter (mm)	Height Range (mm)	Endplate Angles (Top/Bottom)
1889-00-033	Lateral Small 0 Degree 33-46mm	16	33-46	0/0
1889-00-133	Lateral Small –6 Degree 33-46mm	16	33-46	-6/0
1889-00-040	Lateral Small 0 Degree 40-56mm	16	40-56	0/0
1889-00-140	Lateral Small –6 Degree 40-56mm	16	40-56	-6/0
1889-00-051	Lateral Small 0 Degree 51-71mm	16	51-71	0/0
1889-00-151	Lateral Small –6 Degree 51-71mm	16	51-71	-6/0
1889-01-065	Lateral Medium 0 Degree 65-90mm	20	65-90	0/0
1889-01-265	Lateral Medium 6 Degree 65-90mm	20	65-90	0/6
1889-01-085	Lateral Medium 0 Degree 85-110mm	20	85-110	0/0
1889-02-365	Lateral Large 12 Degree 65-90mm	24	65-90	0/12
1889-02-385	Lateral Large 12 Degree 85-110mm	24	85-110	0/12

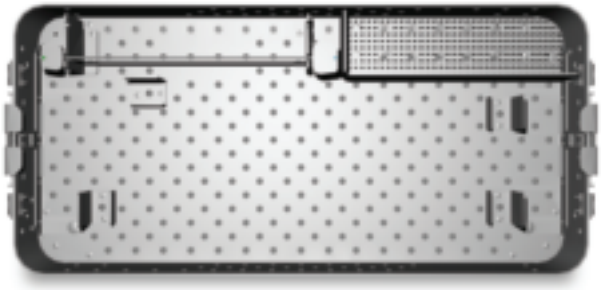
Direct Anterior Implants

Product Code	X-MESH Implant Name	Diameter (mm)	Height Range (mm)	Endplate Angles (Top/Bottom)
1889-12-540	Anterior Large 24 DEG 40-56mm	24	40-56	0/24
1889-12-551	Anterior Large 24 DEG 51-71mm	24	51-71	0/24
1889-12-565	Anterior Large 24 DEG 65-90mm	24	65-90	0/24

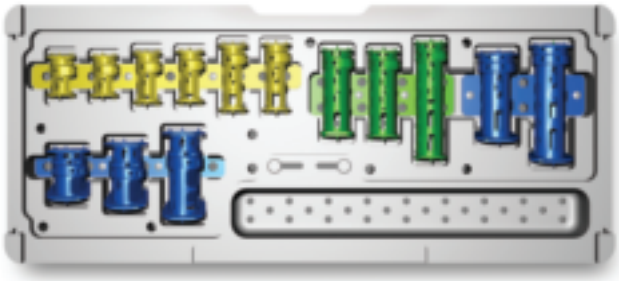
Extreme Tray - Tray & Caddy

The Extreme Tray has one tray and one implant caddy:

Extreme Implant Tray



Extreme Implant Caddy



Posterior Set - Instruments

The following instruments are included in the Posterior Set:

Product Code	Description
2889-00-100	X-MESH Posterior Inserter/Expander
2889-00-005	Posterior Inserter Foot (Right-Side Small)
2889-00-006	Posterior Inserter Foot (Right-Side Medium)
2889-00-008	Posterior Inserter Foot (Right-Side Standard)
2889-00-105	Posterior Inserter Foot (Left-Side Small)
2889-00-016	Posterior Inserter Foot (Left-Side Medium)
2889-00-018	Posterior Inserter Foot (Left-Side Standard)
2889-00-070	X-MESH Distractor
2889-00-075	Posterior Distractor Paddle (Inferior)
2889-00-076	Posterior Distractor Paddle (Superior)
2889-00-101	X-MESH Posterior Inserter Replacement Shaft
2889-00-050	X-MESH Torque Driver Handle
2889-00-051	X-MESH Torque Driver Shaft
2889-00-102	X-MESH Universal Torque Driver Shaft
2889-00-022	Posterior Angled Impactor (Small)
2889-00-023	Posterior Angled Impactor (Medium)
2889-00-014	X-MESH Posterior Trial (Small/Medium)
2889-00-030	X-MESH Bone Tamp (Small)
2889-00-031	X-MESH Bone Tamp (Medium)
2889-00-040	X-MESH Bone Graft Loading Block
2752-13-000	Caliper
2889-00-083	X-MESH Posterior Set Implant Tray
2889-00-085	X-MESH Posterior Set Instrument Tray
2889-00-183	X-MESH Posterior Implant Caddy
2889-00-090	X-MESH Lid

Posterior Set - Implants

The following implants are included in the Posterior Set:

Posterior Implants

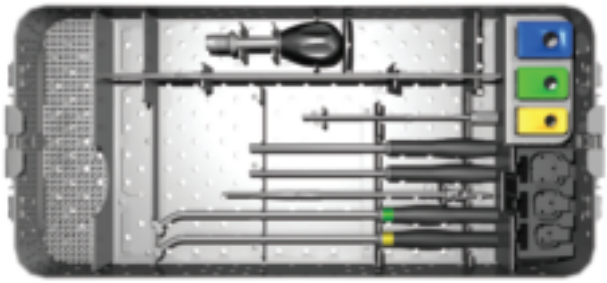
Product Code	X-MESH Implant Name	Diameter (mm)	Height Range (mm)	Endplate Angles (Top/Bottom)
1889-20-022	Posterior Small 0 Degree 22-30mm	16	22-30	0/0
1889-20-025	Posterior Small 0 Degree 25-33mm	16	25-33	0/0
1889-20-028	Posterior Small 0 Degree 28-38mm	16	28-38	0/0
1889-20-033	Posterior Small 0 Degree 33-46mm	16	33-46	0/0
1889-20-040	Posterior Small 0 Degree 40-56mm	16	40-56	0/0
1889-20-051	Posterior Small 0 Degree 51-71mm	16	51-71	0/0
1889-21-022	Posterior Medium 0 Degree 22-30mm	20	22-30	0/0
1889-21-025	Posterior Medium 0 Degree 25-33mm	20	25-33	0/0
1889-21-028	Posterior Medium 0 Degree 28-38mm	20	28-38	0/0
1889-21-033	Posterior Medium 0 Degree 33-46mm	20	33-46	0/0
1889-21-040	Posterior Medium 0 Degree 40-56mm	20	40-56	0/0
1889-21-051	Posterior Medium 0 Degree 51-71mm	20	51-71	0/0

Posterior Set - Trays & Caddy

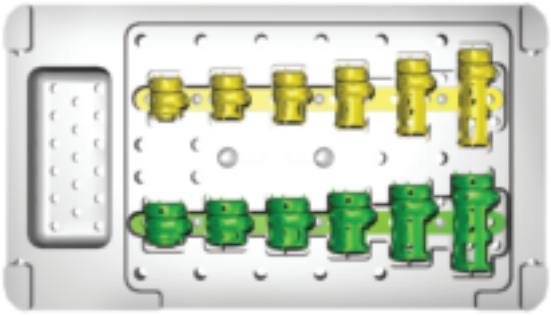
The Regular Set has two trays and one implant caddy:

Posterior Instrument Tray

Posterior Implant Tray



Posterior Implant Caddy



INDICATIONS

The X-MESH™ Expandable Cage System is indicated for use in the thoracolumbar spine (i.e., T1 to L5) to replace a diseased vertebral body resected or excised for the treatment of tumors, to achieve anterior decompression of the spinal cord and neural tissues, and to restore the height of a collapsed vertebral body.

The X-MESH Expandable Cage System is also indicated for treating fractures of the thoracic and lumbar spine.

The X-MESH Expandable Cage System is designed to restore the biomechanical integrity of the anterior, middle, and posterior spinal column even in the absence of fusion for a prolonged period.

The X-MESH Expandable Cage System is intended for use with supplemental internal fixation. The supplemental internal fixation systems that may be used include titanium plate or rod systems (i.e., KANEDA™ SR, UNIVERSITY PLATE™, M-2™ ANTERIOR PLATE, ISOLA®, VSP®, MOSS® MIAMI, TiMX™, MONARCH®, EXPEDIUM™, VIPER™, PROFILE®).

CONTRAINDICATIONS

1. Use of these systems is contraindicated when there is active systemic infection, infection localized to the site of the proposed implantation, or when the patient has demonstrated allergy or foreign-body sensitivity to any of the implant materials.
2. Severe osteoporosis may prevent adequate fixation and thus preclude the use of this or any other orthopaedic implant.
3. Conditions that may place excessive stress on bone and implants, such as severe obesity or degenerative diseases, are relative contraindications. The decision whether to use these devices in such conditions must be made by the physician taking into account the risks versus the benefits to the patient.

Use of these implants is relatively contraindicated in patients whose activity, mental capacity, mental illness, alcoholism, drug abuse, occupation, or lifestyle may interfere with their ability to follow postoperative restrictions and who may place undue stress on the implant during bony healing and may be at a higher risk of implant failure.

WARNINGS

1. **CORRECT SELECTION OF THE IMPLANT IS EXTREMELY IMPORTANT.**
2. **IMPLANTS CAN BREAK WHEN SUBJECTED TO THE INCREASED LOADING ASSOCIATED WITH DELAYED UNION OR NONUNION.**
3. **MIXING METALS CAN CAUSE CORROSION.**

PRECAUTIONS

1. **SURGICAL IMPLANTS MUST NEVER BE REUSED.**
2. **CORRECT HANDLING OF THE IMPLANT IS EXTREMELY IMPORTANT.**
3. **SUPPLEMENTAL FIXATION MUST BE REMOVED FOLLOWING COMPLETION OF ITS INTENDED USE.**
4. **ADEQUATELY INSTRUCT THE PATIENT.**

LIMITED WARRANTY AND DISCLAIMER: DePuy Spine products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

WARNING: In the USA, this product has labeling limitations. See package insert for complete information.

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

DePuy Spine is a joint venture with Biedermann Motech GmbH.

To order, call DePuy Spine Customer Service (1-800-227-6633).

www.depuyspine.com

X-MESH™
EXPANDABLE CAGE SYSTEM

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DePuy Spine™
a Johnson & Johnson company

PIONEERING WHAT MATTERS

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