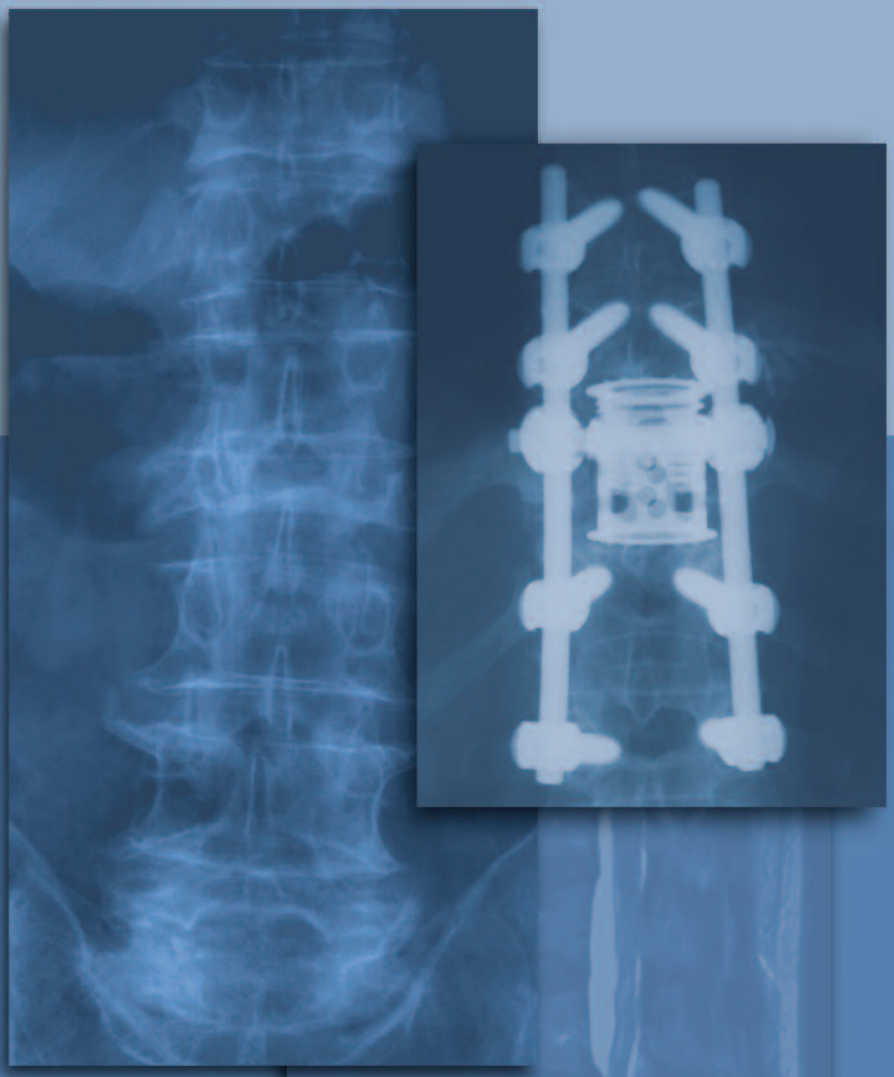
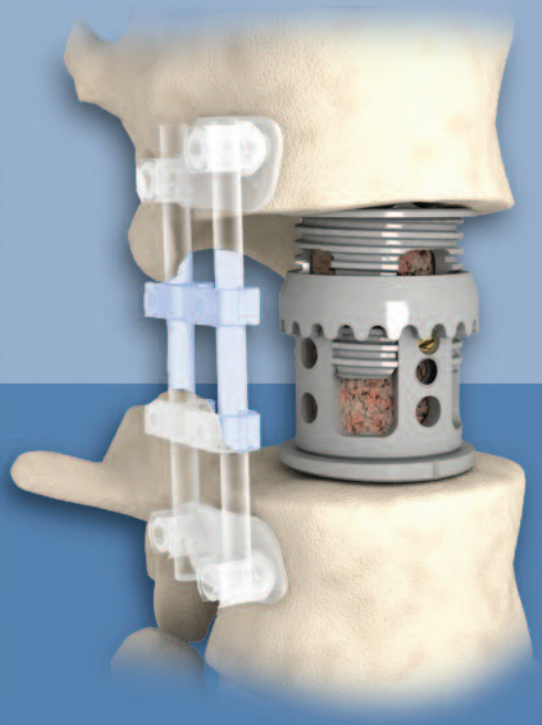
stryker

Spine

VLIFT®
Surgical Technique





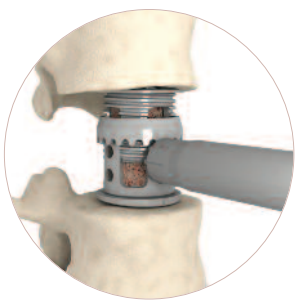
• Vertebral Body Replacement System

VLIFT System

- **Titanium alloy material provides mechanical integrity during insertion and distraction, x-ray visibility, and biocompatibility***
- **System design for ease of use in anterior and antero-lateral approaches**
- **Large open architecture to maximize bone-to-bone graft contact**

- **Large windows allow for optional *in-situ* insertion of bone graft**
- **Single pre-assembled implant**
- **One-step locking of the distraction mechanism with a counterclockwise turn of the pre-assembled locking screw**

- **Evenly spaced end cap spikes provide fixation to the bony endplate**
- **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 segment(s)**



- **Single surgical instrument for ease of insertion and distraction**

*Data on file at Stryker Spine

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VLIFT System Overview

System Description

The VLIFT 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. 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 implants, extensions, and end caps are composed of titanium alloy.

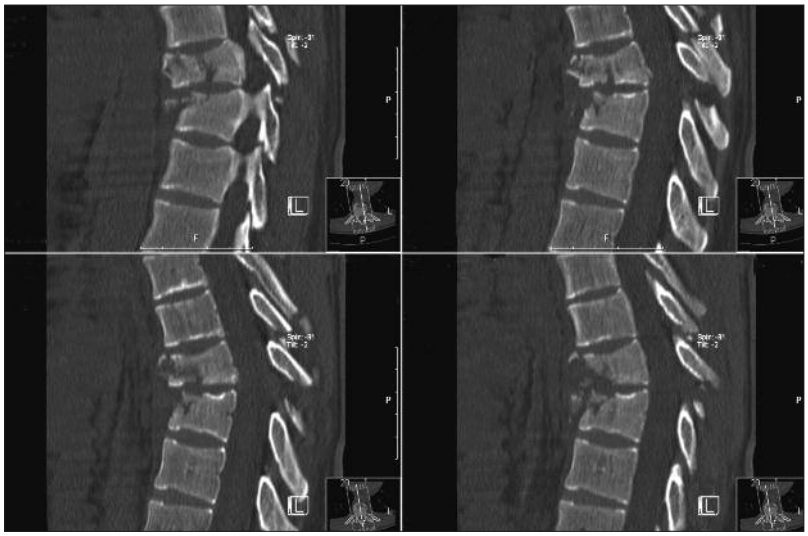
System Indications

Stryker Spine's VLIFT 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 VLIFT System is intended to be used with supplemental internal fixation. The supplemental internal fixation systems that may be used with VLIFT include, but are not limited to, Stryker Spine plate or rod systems (Xia Spinal System, Spiral Radius 90D and Trio). The use of bone graft with the VLIFT System is optional.

Note: Case study courtesy of Michael Wich, MD, Director of the Trauma Clinic, Umfallkrankenhaus Berlin, Berlin, Germany

VLIFT Case Study

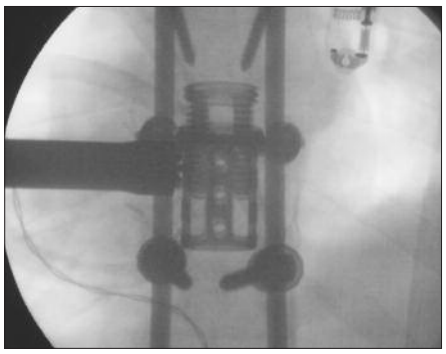
Trauma patient presented with unstable fractures of the vertebral bodies of T8 and T9 with acute kyphosis of 20° and rupture of the dorsal ligamentous structures. Patient also had right sided pneumothorax and a fracture of the 7th rib on the right side and lung contusions bilaterally.



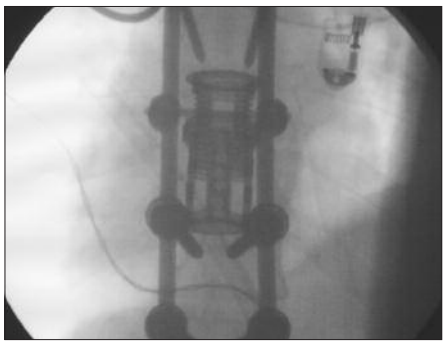
Pre-op sagittal of CT-scan showing T8 and T9 Fractures

Treatment

The patient underwent treatment of this injury in two stages. On post-injury day 1, the patient was taken to the OR for posterior fixation and fusion (T6-T12) and reduction of the kyphosis. After stabilizing the patient in intensive care for one week, anterior spinal surgery was performed on day 7 via an anterior approach. A right sided thoracotomy was performed resecting the 8th rib. Corpectomies of both vertebral bodies (T8 and T9) were performed using the resected bone as bone graft. After positioning the VLIFT implant and expanding it into final position the autologous bone was placed around the implant. Use of the VLIFT expandable implant was particularly helpful in achieving stable anterior device placement since intraoperative distraction between T7 and T10 was not possible because of the posterior fixation.



Intraoperative x-ray with c-arm picture prior to full distraction of the VLIFT implant (43 mm)



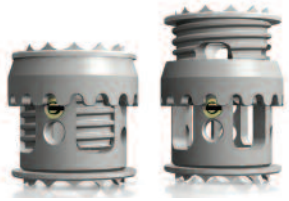
And after distraction of the VLIFT implant (61 mm)

Ten days after the traumatic injury, the patient was able to walk without brace and with crutches and full weight bearing on the left leg (due to a hip dislocation during the injury).

Note: Patient results may vary.

Single, Pre-assembled Implants

Ø18 mm Implant

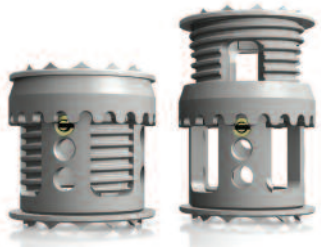


20.5 mm height distracts to 27.5 mm

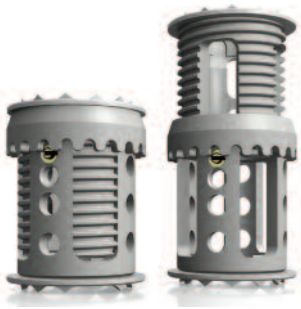
25 mm height distracts to 36.5 mm

32 mm height distracts to 50.5 mm

Ø22 mm Implant



25 mm height distracts to 36.5 mm



32 mm height distracts to 50.5 mm

37 mm height distracts to 60.5 mm

Note: **Implant heights above include the assembly of two 0° end caps.**
Each 0° end cap adds 1 mm of height. See page 6 for all possible end cap configurations.

VLIFT™ Extensions

Extensions press fit onto both ends of the VLIFT implant to build a longer implant construct when necessary. A mallet may be used to assemble the extensions.

Ø18 mm & Ø22 mm Extensions
*Each extension adds 15 mm of height

Ø18 mm

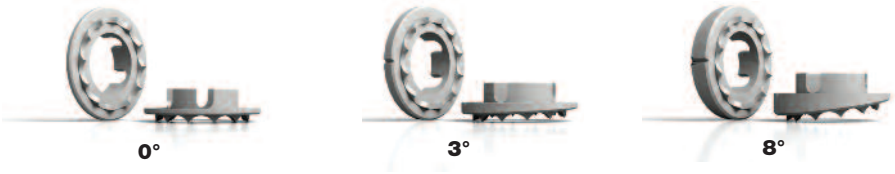
Ø22 mm

For example:
- Ø18 x 32 mm implant fully distracted + 1 extension + (2) 0° end caps = 65.5 mm
- Ø18 x 32 mm implant fully distracted + 2 extensions + (2) 0° end caps = 80.5 mm
- Ø22 x 37 mm implant fully distracted + 1 extension + (2) 0° end caps = 75.5 mm
- Ø22 x 37 mm implant fully distracted + 2 extensions + (2) 0° end caps = 90.5 mm

VLIFT System Overview

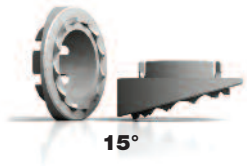
End Caps

Ø18 mm and Ø22 mm end caps are available in three angles: 0°, 3°, and 8°

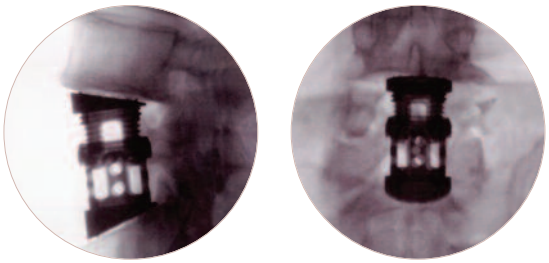


Note: The angled end cap options can be interchanged to enable the surgeon to build a 0°, 3°, 6°, 8°, 11°, or 16° implant construct.

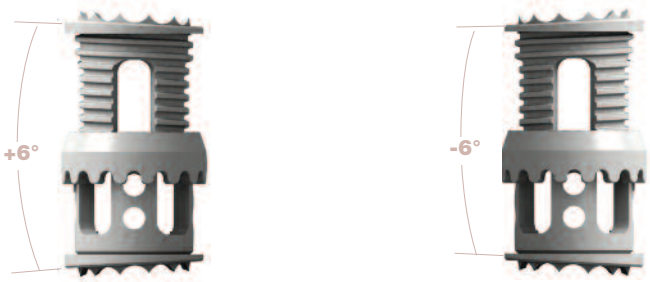
Ø22 mm end caps are also available in 15° of angulation to more readily restore lumbosacral sagittal alignment.



The 15° end caps enable the surgeon to build additional 15°, 18°, 23°, and 30° Ø22 mm implant constructs.



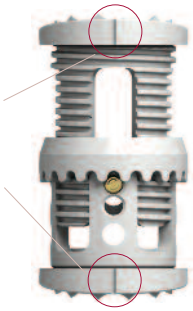
In the thoracic region, the end caps can be rotated 180° to reconstruct the thoracic kyphotic alignment. Example by using two 3° end caps:



Note: It is important to ensure the angled end caps are assembled to the implant in a manner that accommodates the surgical approach.

Example: In an anterior approach, the angled portion of the end cap should be facing the gold locking screw and thus, the expander when assembled.

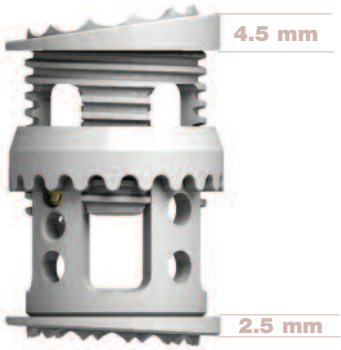
When using angled end caps, it is important to ensure their orientation is parallel.



The Ø18 mm end cap footprint = 22 mm

The Ø22 mm end cap footprint = 26 mm

Note: End cap diameter = distraction ring diameter.



Note: Each end cap adds additional height to the implant.

0°	adds	1 mm
3°	adds	2.5 mm
8°	adds	4.5 mm
15°	adds	8 mm*

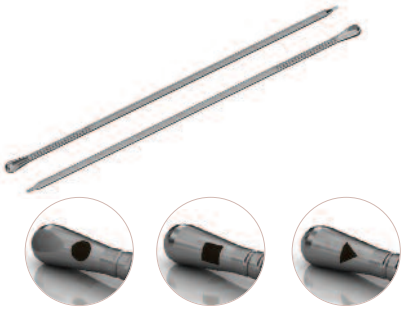
*15° only available for Ø22 mm implant

VLIFT System Overview

Expander 48300200

The VLIFT™ expander is an all-in-one instrument designed to act as an inserter and an intra-operative distractor. The inside shaft threads into the implant while the outer, cannulated shaft is turned counterclockwise to distract the implant.

Screwdriver 48300300



The VLIFT implant contains a pre-assembled locking screw, which is locked with the screwdriver to secure the implant height after distraction. The screwdriver is placed into the head of the locking screw *in situ*, which is then turned (backed-out) two full turns counterclockwise to lock the distraction mechanism in place.

The screwdriver's low-profile shaft provides ease of insertion and visualization during the locking step. There are laser-marks every 120° on the screwdriver shaft to provide a reference for each revolution of the screwdriver.

Note: Only back out the locking screw with the screwdriver <u>two full turns</u>.

Graft Impactor 33660460, Small Graft Impactor 33660450

The VLIFT graft impactors are available in two sizes and are provided to assist in packing the implant with bone graft. The tip of the shaft of each impactor has a knurled surface, which comes in contact with the bone graft.

After the implant is distracted and locked into its final position, any void in the implant resulting from distraction can be filled through the large windows in the periphery of the implant. The small graft impactor is similar to a tamp and can be used to pack additional bone graft *in situ*.

Note: Standard O.R. instruments such as forceps or Penfields can also be used to pack bone graft.

End Cap Remover 48300450

The end cap remover is a 3-in-1 instrument, which can be used to assemble end caps, pack bone graft, and remove end caps, when necessary.

The end cap remover contains two surfaces for end cap assembly:
1. surface to impact the Ø18 and Ø22 mm 0° and 3° end caps,
2. surface to impact the Ø18 and Ø22 mm 8° end caps, as well as the Ø22 mm 15° end caps.

One side of the end cap remover disassembles the Ø18 mm end caps. The opposite side of the end cap remover disassembles the Ø22 mm end caps.

Note: When removing the angled end caps, insert the shortest end of the end cap into the end cap remover. Extensions can be removed by hand.

End Cap Impactors 48300518 / 48300522

End cap impactors are available for each implant diameter to provide a method for alignment and a surface for impaction.

The inferior portion of each end cap impactor has a cylinder with two side-by-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 groove to account for whatever end cap angulation is chosen prior to impaction with a mallet.

The end cap impactors also have two wide notches, which can be used as reference points when aligning angled end caps.

Container 48300001

The VLIFT System consists of only one container, which contains all the implants, end caps, extensions, and associated instruments.

VLIFT Surgical Technique

Indications

Stryker Spine's VLIFT 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). For both corpectomy and vertebrectomy procedures, the VLIFT System is intended to be used with supplemental internal fixation. The supplemental internal fixation systems that may be used with VLIFT include, but are not limited to, Stryker Spine plate or rod systems (Xia Spinal System, Spiral Radius 90D and Trio). The use of bone graft is optional.

Pre-operative Planning

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.

Contra-indications

- The VLIFT system is not to be used for interbody fusion.
- The VLIFT system 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.
- Rapid joint disease, bone absorption, osteopenia, osteomalacia, and/or osteoporosis. Osteoporosis or osteopenia are relative contraindications, since this condition may limit the degree of obtainable correction and/or the amount of mechanical fixation.
- Metal sensitivity, documented or suspected.
- Pregnancy.
- Anytime implant utilization would interfere with anatomical structures or physiological performance.
- Inadequate tissue coverage over the operative site.

Other medical or surgical conditions that could preclude the potential benefit of surgery, such as congenital abnormalities, immunosuppressive disease, elevation of sedimentation rate unexplained by other diseases, elevation of white blood count (WBC), or marked left shift in the WBC differential count, must be carefully analyzed before surgery.

These contra-indications can be relative or absolute and must be taken into account by the physicians when making their decision. The above list is not exhaustive. Surgeons must discuss all relative contra-indications including limited life time of the decive when deemed appropriate.

Pre-operative Precautions

The surgical indication and the choice of implants must take into account certain important criteria such as:

- Patients involved in an occupation or activity that applies excessive loading upon the implant (e.g., substantial walking, running, lifting, or muscle strain) may be at increased risk for failure of the fusion and/or the device.
- Patients should be instructed in detail about the limitations of the implants, including, but not limited to, the impact of excessive loading through patient weight or activity, and be taught to govern their activities accordingly. The procedure will not restore function to the level expected with a normal, healthy spine, and the patient should not have unrealistic functional expectations.
- A condition of senility, mental illness, chemical dependence or alcoholism. These conditions among others may cause the patients to ignore certain necessary limitations and precautions in the use of the implant, leading to failure and other complications.
- Foreign body sensitivity. Where material sensitivity is suspected appropriate tests should be made prior to material implantation.
- Patients who smoke have been shown to have an increased incidence of non-unions. Such patients should be advised of this fact and warned of the potential consequences.
- Care must be taken to protect the components from being marred, nicked, or notched as a result of contact with metal or abrasive objects. Alterations will produce defects in surface finish and internal stresses which may become the focal point for eventual breakage of the implant

Surgeons must discuss these precautions pre-operatively with their patients when appropriate.

Intra-operative Precautions

The insertion of the implants must be carried out using instruments designed and provided for this purpose and in accordance with the specific implantation instructions for each implant. Those detailed instructions are provided in the surgical technique brochure supplied by Stryker Spine.

- Discard all damaged or mishandled implants.
- Stryker Spine implants must not be reshaped, unless otherwise indicated in the surgical technique instructions. The use of inappropriate instruments may result in scratches, notches, and sharp bending, causing the breakage of the implants. Improper seating of the implant may result in implant failure.
- Never reuse an implant, even though it may appear undamaged.
- Do not mix metals.

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 thoraco-lumbar 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, see Figures 1 and 2.

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

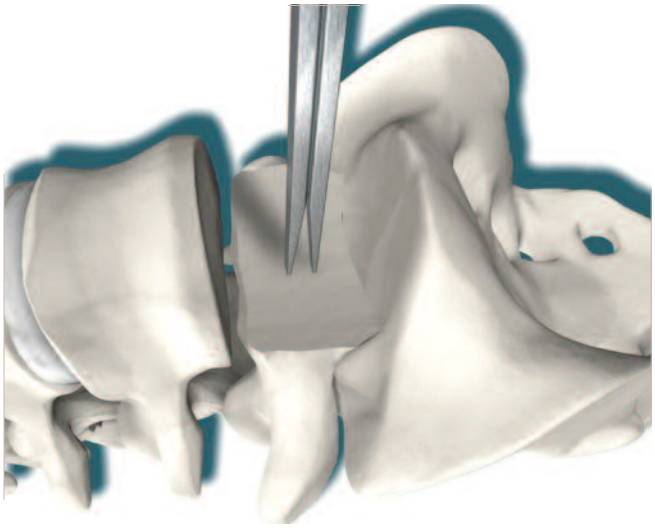


Figure 1: Example of a corpectomy of the L5 vertebral body.

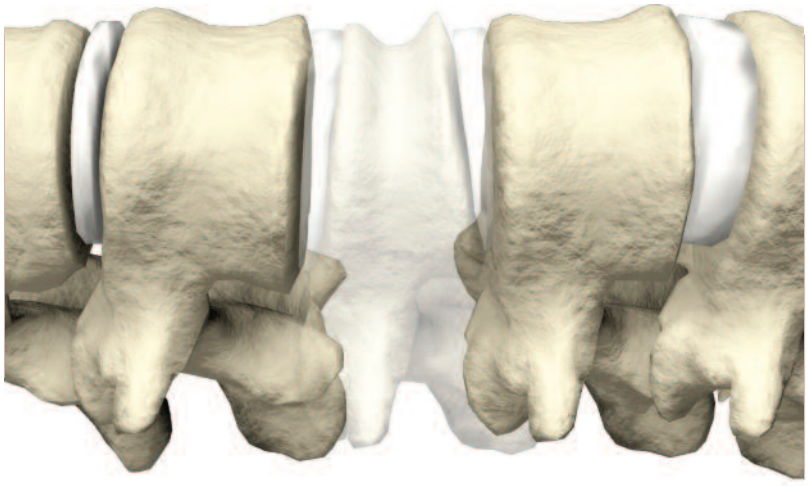


Figure 2: Example of a vertebrectomy of a thoracic vertebra.

VLIFT Surgical Technique

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, see Figure 3.

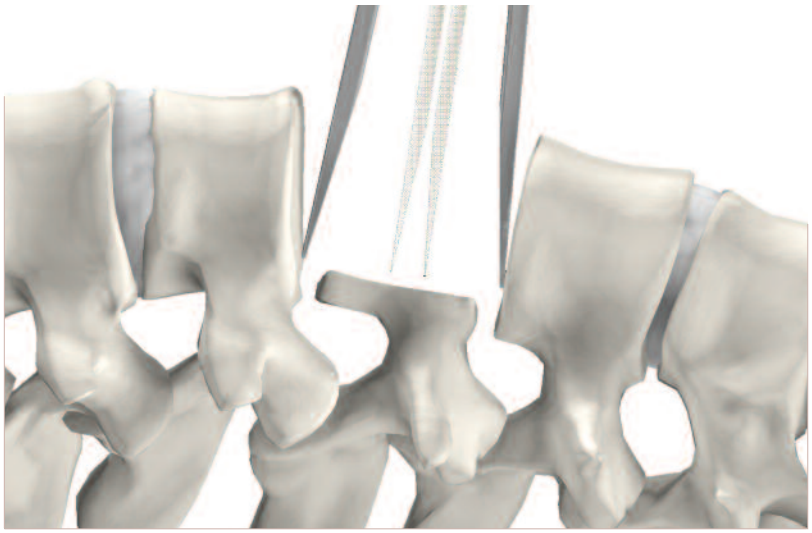


Figure 3: Confirm the height of the defect *in situ* by measuring from the posterior aspect of the motion segment(s).

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 VLIFT 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, see Figure 4.

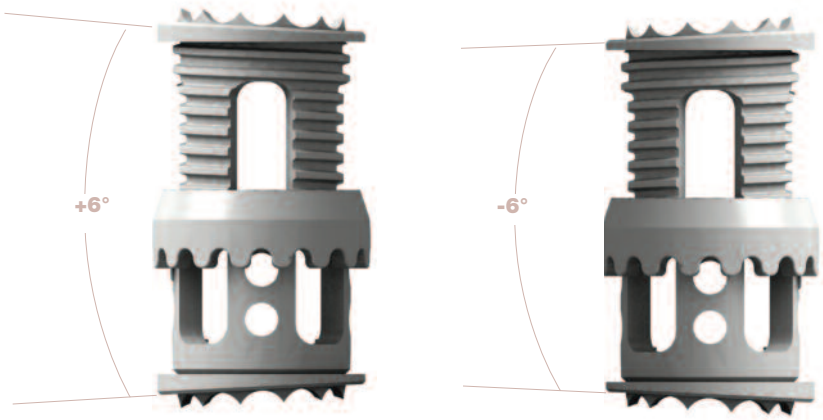


Figure 4: The end caps can be rotated 180° to reconstruct either a thoracic kyphotic or a lumbar lordotic curve. Above example uses two 3° end caps.

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, see Figure 5:

- **SURFACE 1:** to impact the Ø18 mm, 0° and 3° end caps, and Ø22 mm, 0° and 3° end caps
- **SURFACE 2:** to impact the Ø18 mm, 8° end caps, and Ø22 mm, 8° and 15° end caps

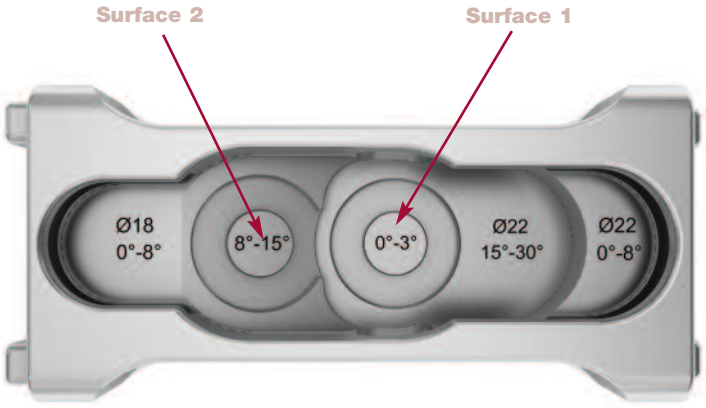


Figure 5: Assembly Surfaces of the VLIFT End Cap Remover.

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, see Figure 6.

Next, the chosen implant should be placed into the end cap remover, on top of the first end cap, see Figure 7.

After the implant and the first end cap are appropriately aligned, a mallet can be used to impact the implant to the end cap, see Figure 8. 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.

Figure 6: Example of A.) Ø22 mm x 0° end cap placed on surface 1 and B.) Ø22 mm x 15° end cap placed on surface 2.

Figure 7: Example of the Ø22 x 32 mm implant placed on top of the Ø22 mm x 15° end cap.

Figure 8: A mallet is used to assemble the implant to the first end cap.

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 in Figure 9.

The inferior portion of each end cap impactor has a cylinder with two side-by-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, see Figure 9. The projections can rotate in the grooves of the end cap spikes to account for whatever end cap angulation is chosen prior to impaction with a mallet. The end cap impactors also have two wide notches, which can be used as reference points when aligning angled end caps. Refer to Figure 10, which outlines the features of the end cap impactor.

Once the second end cap is chosen, it is placed on top of the implant construct, which remains in the end cap assembly station, see Figure 11.

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 laser-marks on the first end cap.

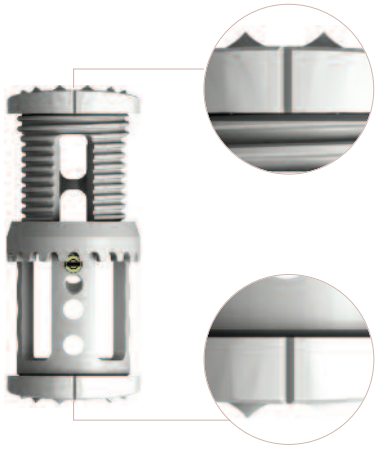


Figure 9: The Ø22 mm end cap impactor can accommodate all angles of the 22 mm end caps. Example is shown with the 15° end cap.

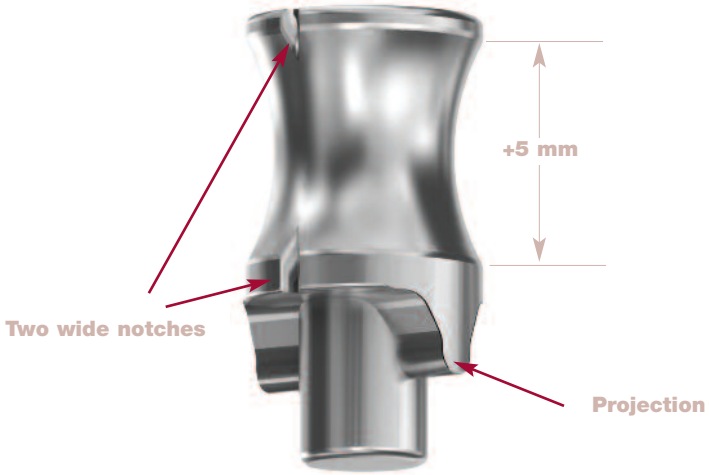


Figure 10: Key features of the end cap impactor.

Figure 11: 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, see Figure 12.

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, see Figure 13.**

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, see Figure 14.

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, see Figure 15.

Figure 12: A mallet is used in conjunction with the Ø22 mm end cap impactor to impact the second Ø22 mm end cap to the implant construct.

Figure 13: The threaded hole in the implant for the expander assembly is located below the gold locking screw.

Figure 14

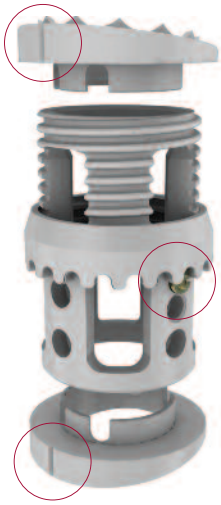


Figure 15

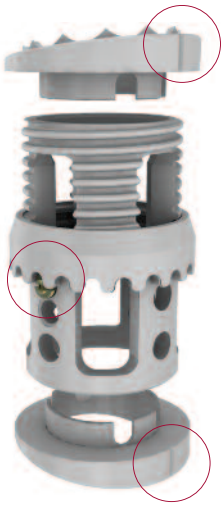


Figure 16

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, see Figure 16 on page 13.

Note: If an extension is needed, assemble the extension to the implant prior to assembling the end caps, see Figures 17a and 17b. Two extensions can also be used if needed. No specific orientation is necessary for the extensions. The end cap remover can also be used as an assembly station for the extensions.

The Ø22 mm implants have an additional angled end cap of 15°, which is part of the standard set configuration. Additional lordosis may be necessary in situations such as restoring lumbosacral sagittal alignment, see Figure 18.

The end caps add height to the overall implant height, which will need to be taken into consideration during construct assembly. Table 3 shows how much height each individual end cap and each end cap combination adds.

Figure 17a: Assemble the extension(s) prior to 17b: Assembling the end caps.

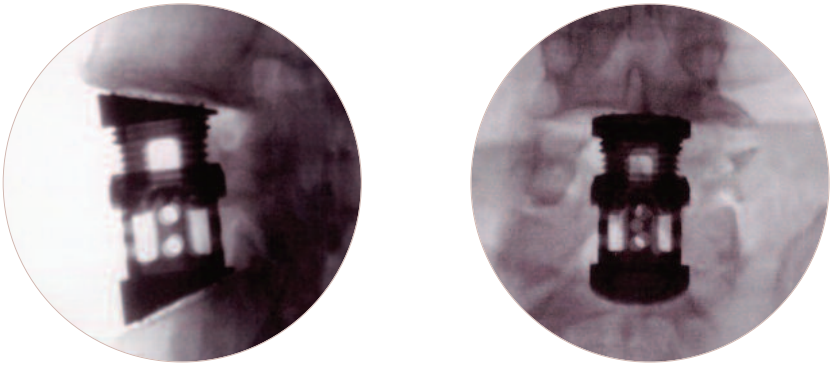


Figure 18: Sagittal reconstruction of a L5 corpectomy using a 15° end cap placed superiorly and a 20° end cap placed inferiorly on a Ø22 x 32 mm implant.

Note: 20° end caps are special order. It is anticipated that they will only be used in rare cases. See page 19 for ordering information.

Table 3: End cap and end cap combination heights

End cap(s)	Ø18 mm & Ø22 mm
0°	adds 1 mm
0° + 0°	adds 2 mm
3°	adds 2.5 mm
0° + 3°	adds 3.5 mm
3° + 3°	adds 5 mm
8°	adds 4.5 mm
0° + 8°	adds 5.5 mm
3° + 8°	adds 7.0 mm
8°+ 8°	adds 9.0 mm

End cap(s)	Ø22 mm
15°	adds 8 mm
0° + 15°	adds 9 mm
3° + 15°	adds 10.5 mm
8° + 15°	adds 12.5 mm
15° + 15°	adds 16 mm

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, see Figure 19. Step 5 on page 17 describes how to assemble the expander to the implant.

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, see Figure 20. 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.

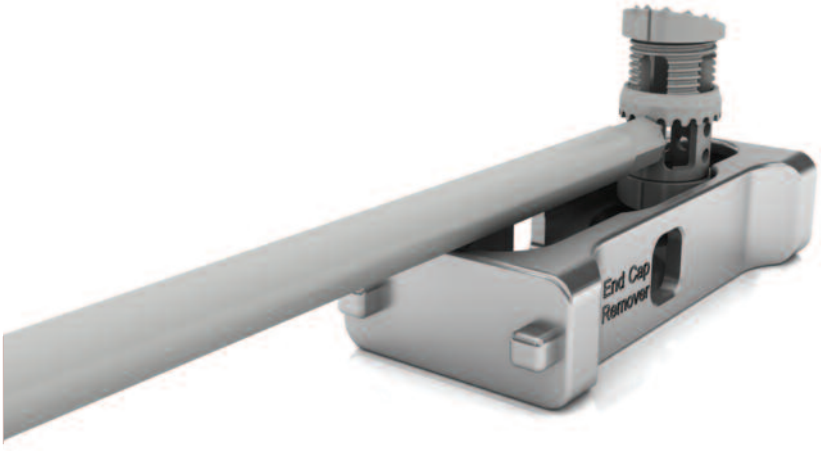


Figure 19: Implant should be retained on the expander during removal.

Figure 20: The end cap remover, made of stainless steel, can disassemble all diameter and angled end caps.

STEP 4: Bone Graft Packing
(optional)

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

Depending on surgeon preference, bone graft can be packed into the VLIFT 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 VLIFT System includes small and standard graft impactors, which can be used to pack bone graft into the implant, see Figure 21. Both graft impactors have knurled tips for more precise packing of the bone graft, see Figure 22.

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, see Figure 23. "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.

Figure 21: Initial bone graft packing with the graft impactors.

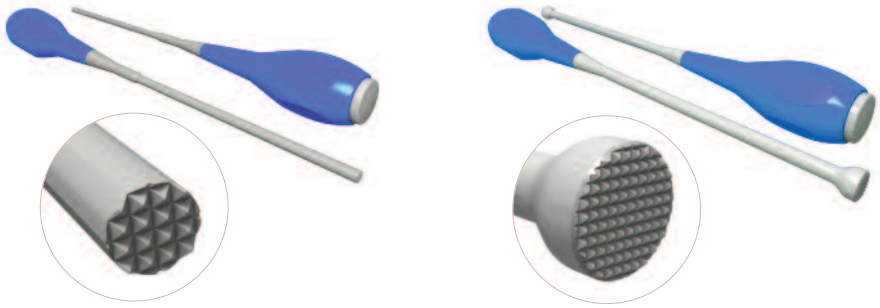


Figure 22: Small graft impactor, standard graft impactor, and knurled tips of each.

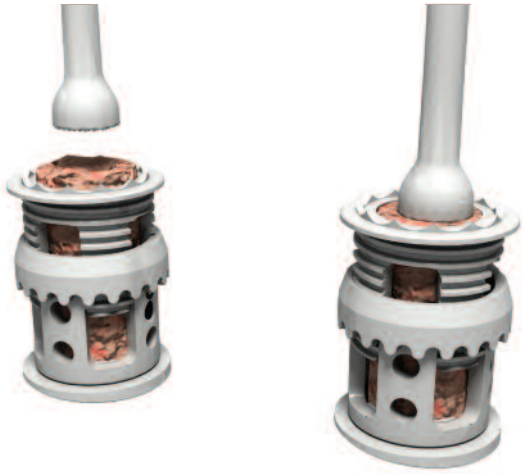


Figure 23: "Overstuffing" the implant with bone graft after assembly of both end caps.

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, see Figure 24.

The inside threaded shaft retains the implant to the end of the expander by engaging the threaded hole of the implant, see Figure 25.

The threaded hole of the implant is located just below the gold locking screw, see Figure 26.

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.

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, see Figure 27.

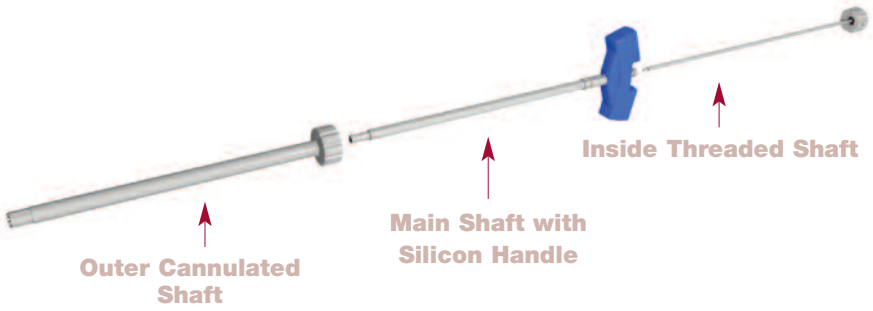


Figure 24: Three components of the expander.

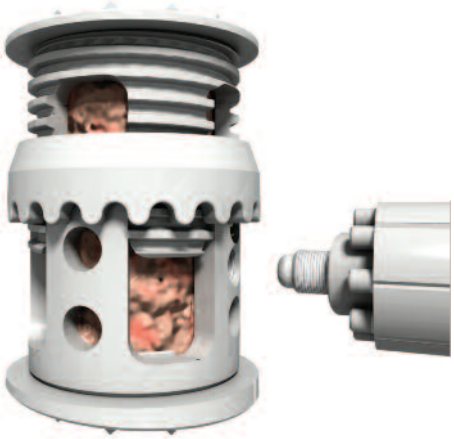


Figure 25: Assembly of the implant onto the inside threaded shaft.

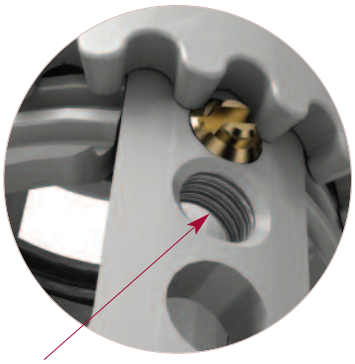


Figure 26: Threaded hole of the implant, which receives the inside threaded shaft of the expander.

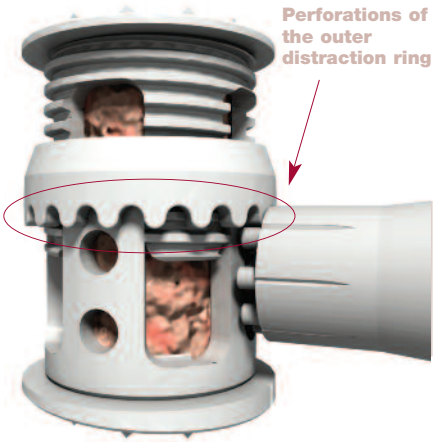


Figure 27: Placement of the perforated tips of the outer cannulated shaft of the expander in between the scallops of the outer distraction ring.

Note: During assembly of the expander, ensure the T-handle of the expander is perpendicular to the implant, see Figure 28.

The end of the main shaft of the expander is curved, see Figure 29. 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.

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, see Figure 30.

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.

Figure 28: The silicon T-handle of the expander must be perpendicular to the implant during the assembly.

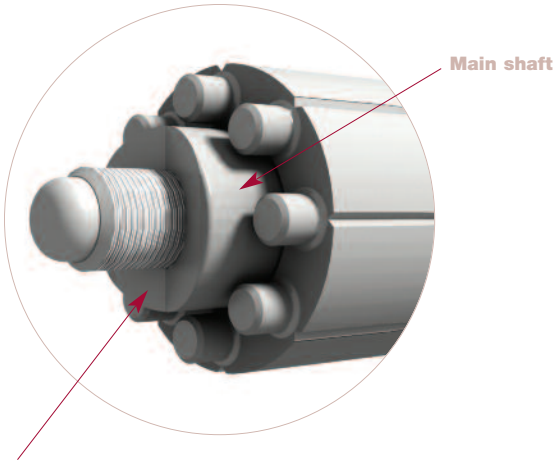


Figure 29: The end of the expander's main shaft is curved to provide maximum contact to the implant during insertion.

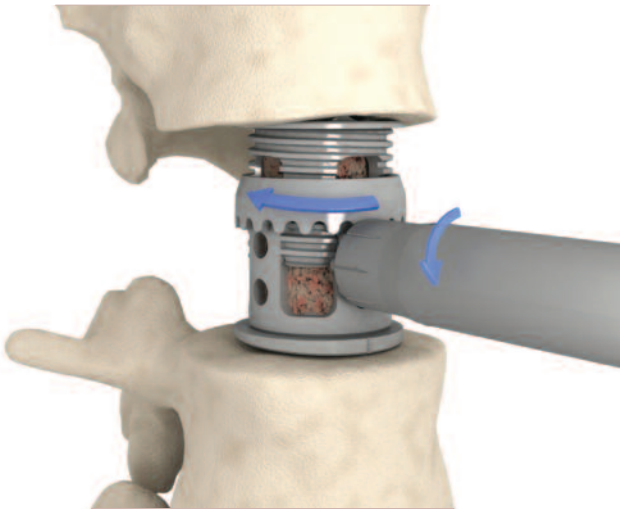


Figure 30: Distraction of the implant by rotating the outer cannulated shaft of the expander counterclockwise.

The implant has reached its final distraction height once the threaded base "arms" of the implant are no longer visible, see Figure 31.

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.

It is important to ensure the scallops of the outer distraction ring line up on either side of the gold locking screw after distraction, see Figure 32.

Grooves on the tip of the outer cannulated shaft of the expander aid in alignment of the distraction ring scallops, see Figure 33.

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, as described in Step 6 on page 20.

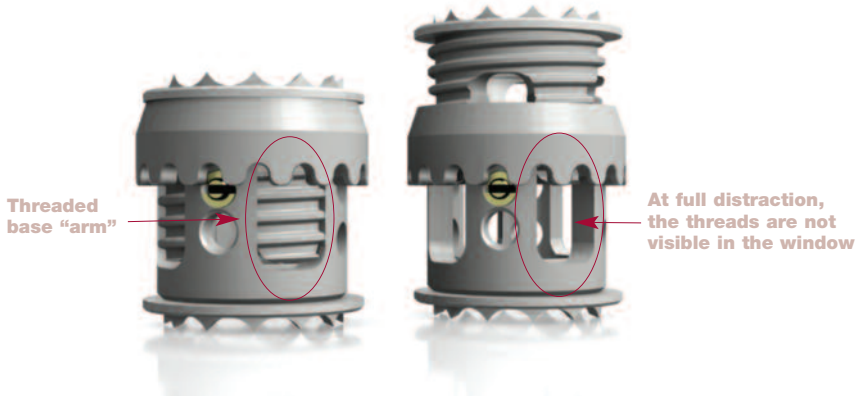


Figure 31: Full distraction of the implant is reached once the threads are no longer visible in the implant windows.

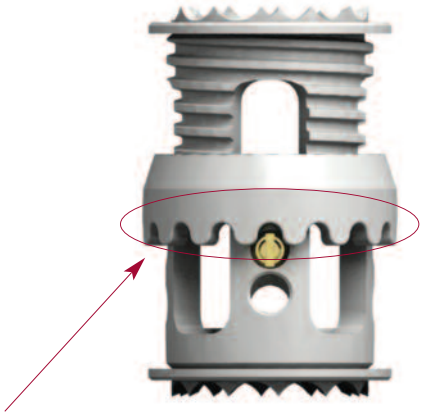


Figure 32: Scallops of the distraction ring.

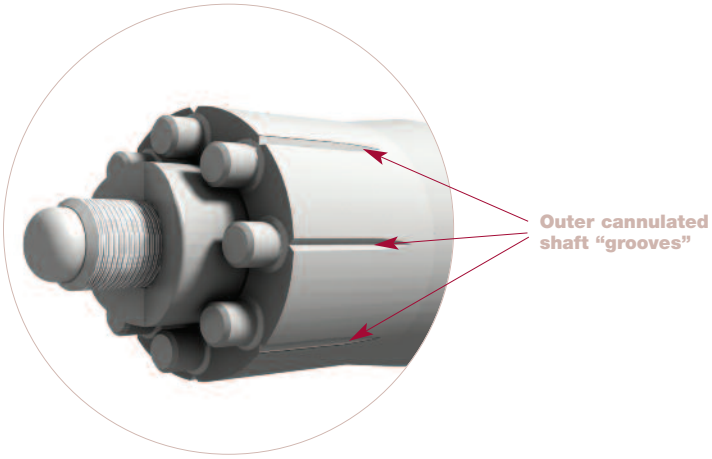


Figure 33: An outer cannulated shaft "groove" should face superior, as shown in this picture, at the completion of distraction to provide access to the gold locking screw.

STEP 6: 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, see Figure 34.

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.

120° oriented laser-marks are located on the shaft of the screwdriver, see Figure 35. Each laser-mark (circle, square, triangle) provides the surgeon with a visual reference to maintain orientation during screwdriver rotation. The screwdriver only needs to rotate counterclockwise 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.

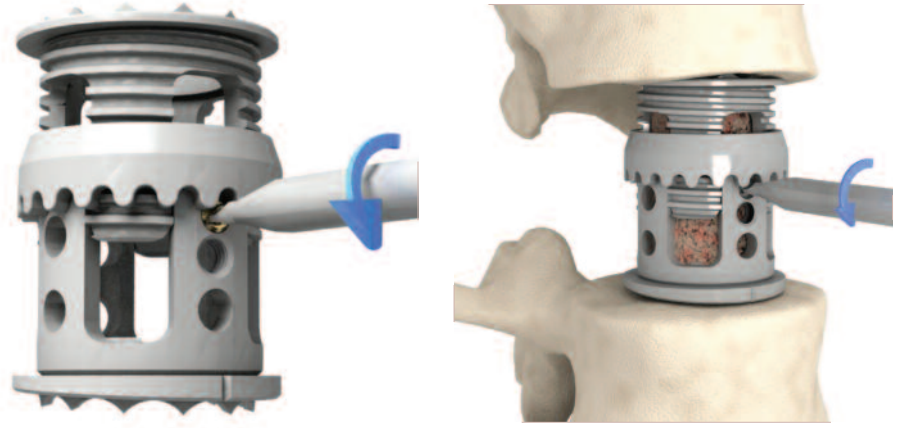


Figure 34: The screwdriver engages the pre-assembled locking screw. Two counterclockwise turns of the locking screw with the screwdriver will lock the implant height in place.

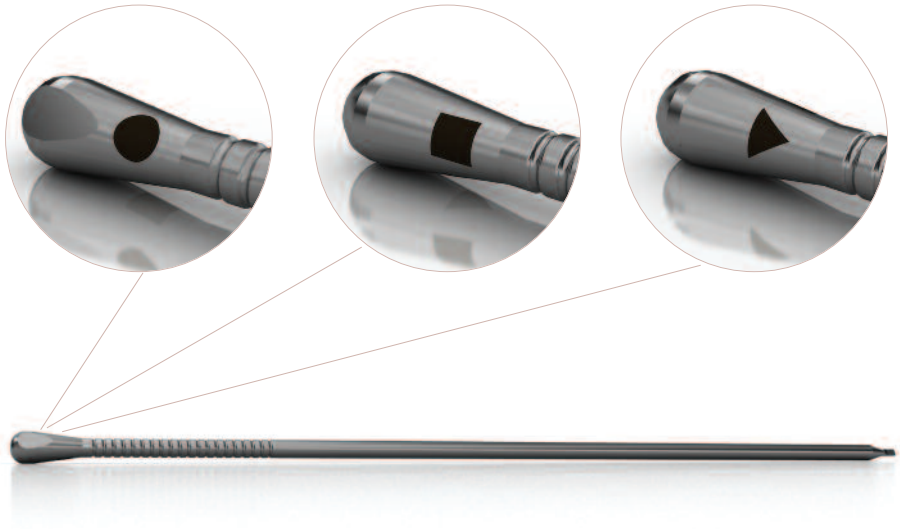


Figure 35: The screwdriver shaft contains 120° oriented laser-marks to provide a visual reference during the locking step.

STEP 7: *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, see Figure 36. Standard O.R. instruments such as forceps or Penfields may also be used.

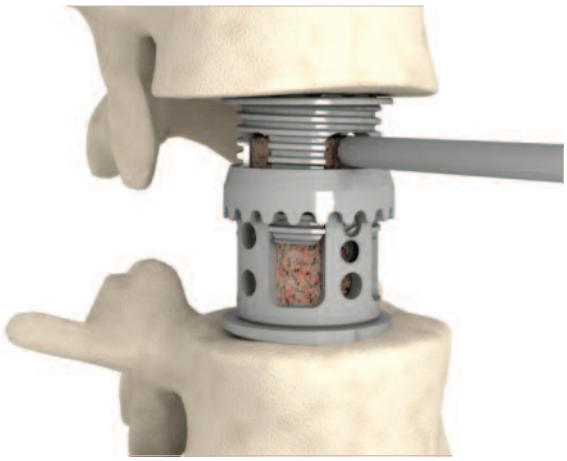


Figure 36: Insertion of bone graft with the small graft impactor through the large implant windows.

STEP 8: Supplemental Fixation

If supplemental fixation was not applied prior to the insertion of the VLIFT implant, it must be applied once the implant is in place. The supplemental internal fixation systems that may be used with VLIFT include, but are not limited to, Stryker Spine plate or rod systems (Xia Spinal System, Spiral Radius 90D and Trio), see Figure 37.

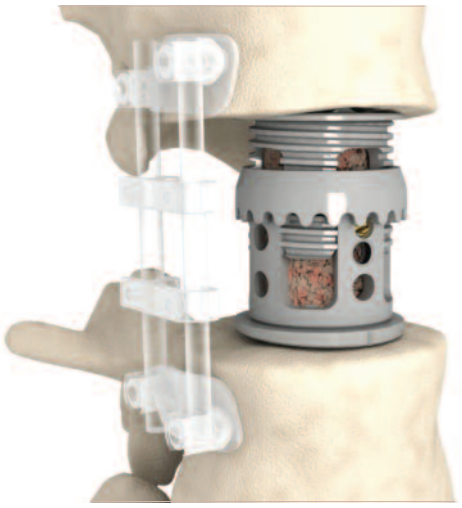


Figure 37: Addition of the Xia Anterior Spinal System to supplement the VLIFT implant.

REMOVAL

If fusion / bone graft growth occurs, the device will be deeply integrated into the bony tissues. As a result, the VLIFT system 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 VLIFT device must be removed:

1. Insert the VLIFT 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) see Figure 38. 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, see Figure 13 on page 13.

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, see Figure 39.

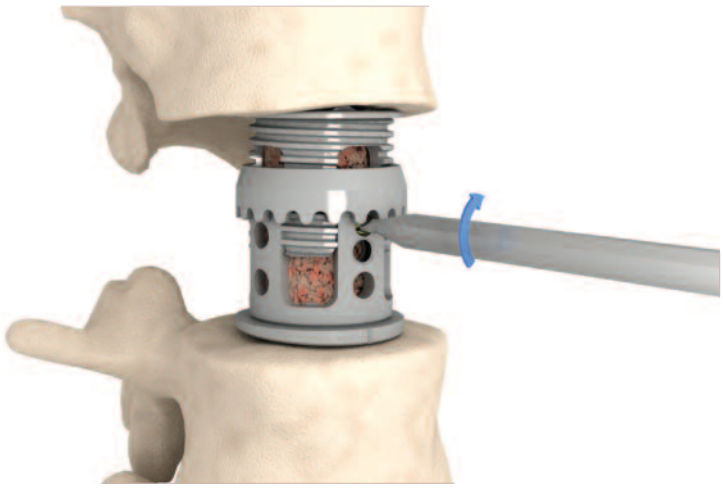


Figure 38: Rotate the screwdriver clockwise to unlock the distraction mechanism.

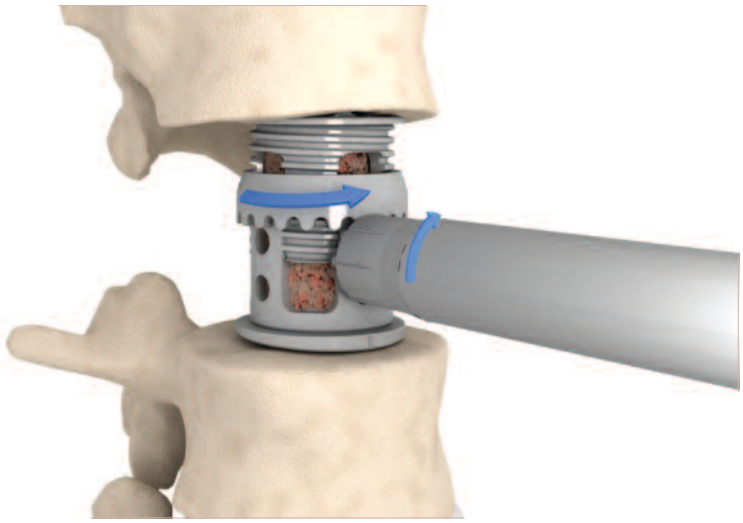


Figure 39: To reduce the height of the implant for removal, rotate the outer cannulated shaft of the expander clockwise.

VLIFT Standard Set and Ordering Information

Implants

Implants

Part Number	Description	#/Set
48291820	Ø18 mm x 20 mm Implant	1
48291825	Ø18 mm x 25 mm Implant	2
48291832	Ø18 mm x 32 mm Implant	2
48292225	Ø22 mm x 25 mm Implant	2
48292232	Ø22 mm x 32 mm Implant	2
48292237	Ø22 mm x 37 mm Implant	2

Extensions

Part Number	Description	#/Set
48291800	Ø18 mm	1
48292200	Ø22 mm	1

End Caps

Part Number	Description	#/Set
48291180	Ø18 mm End Cap, 0°	3
48291183	Ø18 mm End Cap, 3°	3
48291188	Ø18 mm End Cap, 8°	3
48291220	Ø22 mm End Cap, 0°	3
48291223	Ø22 mm End Cap, 3°	3
48291228	Ø22 mm End Cap, 8°	3
48292215	Ø22 mm End Cap, 15°	2
48290220	Ø22 mm End Cap, 20°	0*
48290225	Ø22 mm End Cap, 25°	0*
48290230	Ø22 mm End Cap, 30°	0*

Instruments

Part Number	Description	#/Set
48300200	Expander	1
48300210	Auxiliary Inside Shaft	0*
48300300	Screwdriver	1
33660450	Small Graft Impactor	1
33660460	Graft Impactor	1
48300450	End Cap Remover	1
48300518	Ø18 mm End Cap Impactor	1
48300522	Ø22 mm End Cap Impactor	1
48300001	Container	1

***Special order item, not part of standard set**

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