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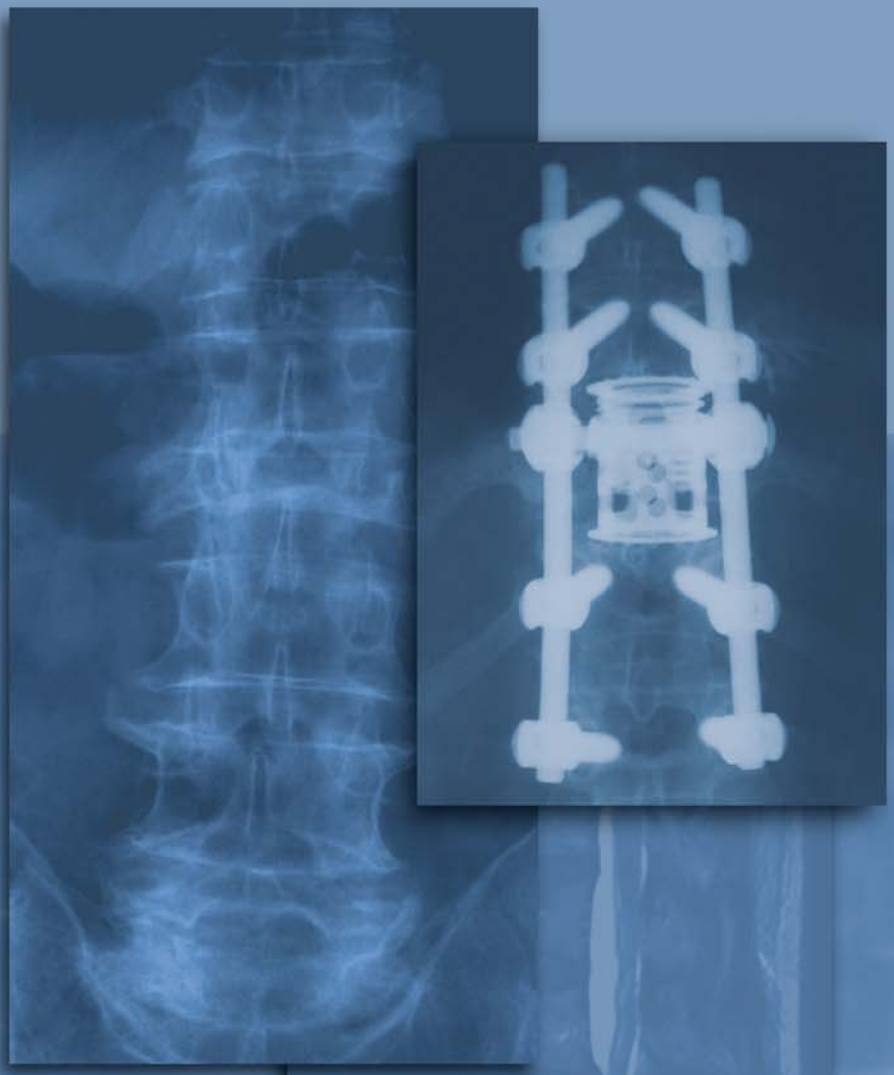
Spine

VLIFT™
System Overview



• Vertebral Body Replacement System

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. The pre-assembled VLIFT™ implant distracts with a low profile inside thread design. Extensions (if needed) and modular end caps snap into each end of the implant for quick assembly. The end caps are available in 0° or with angulation to match either the lordosis or kyphosis of the spinal segment. The implant and end caps are composed of titanium alloy.

System Indications

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

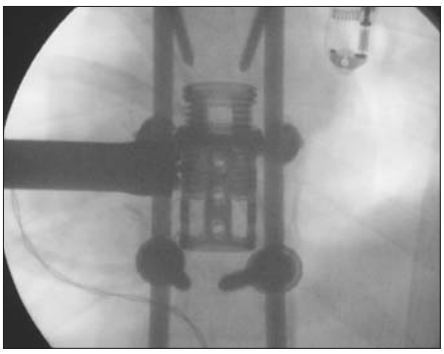
VLIFT™ Case Study

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.

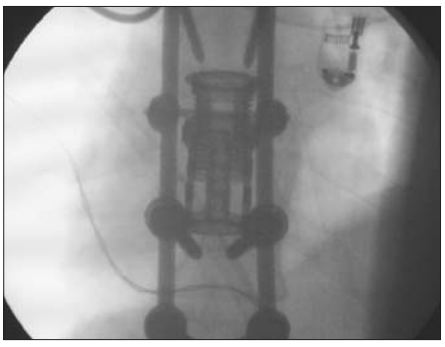
Pre-op sagittal of CT-scan showing T8 and T9 Fractures

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 distraction of the VLIFT™ implant (43 mm)



And after distraction of the VLIFT™ implant (61 mm)

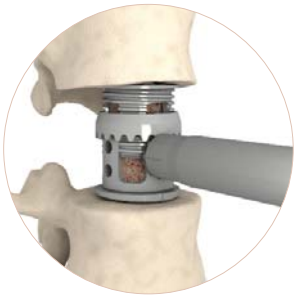
Ten days after the traumatic injury, the patient was able to walk without brace and with crutches and full weight bearing on the left leg (due to a hip dislocation during the injury).

Note: Patient results may vary.

- **Titanium alloy material provides mechanical integrity during insertion and distraction, x-ray visibility, MRI compatibility and biocompatibility***
- **System design for ease of use in anterior and antero-lateral approaches**

- **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**

- **Large open architecture to maximize bone-to-bone graft contact**
- **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

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: Each 0° end cap adds 1 mm of height. See page 6 for all possible end cap configurations.

Locking Mechanism

A pre-assembled locking screw locks the distraction mechanism and thus, the implant height in place.

- **The locking screw is anodized gold for optimal visualization.**

VLIFT™ Extensions

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

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

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

End Caps

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

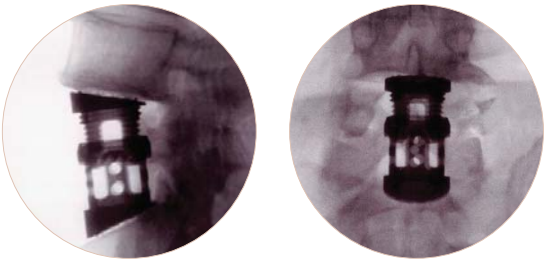
The end caps are assembled to the implant or an extension by press fitting each to the ends of the implant. A mallet may also be used to assemble the end caps.

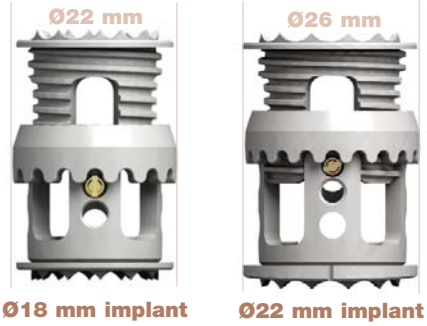
Note: The angled end cap options enable the surgeon to build a 0°, 3°, 6°, 8°, 11°, or 16° implant construct.

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

The Ø18 mm end cap footprint = 22 mm
The Ø22 mm end cap footprint = 26 mm

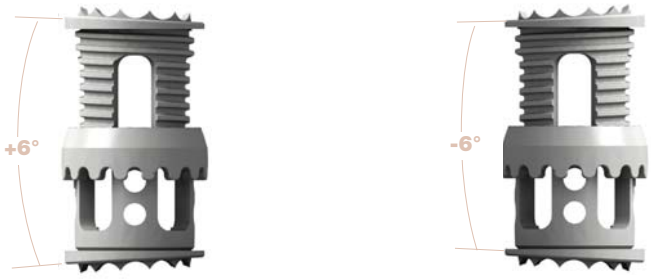
The 15° end caps enable the surgeon to build additional 15°, 18°, 23° and 30° Ø22 mm implant constructs.





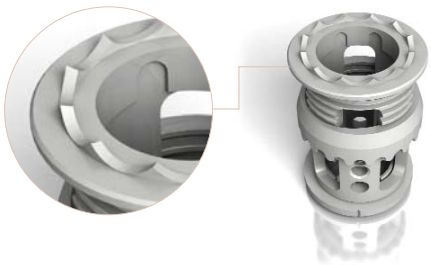
Note: End cap diameter = distraction ring diameter.

In the thoracic region, the end caps can be rotated 180° to reconstruct the thoracic kyphotic alignment. Example by using (2) 3° end caps:



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

The exterior side of the end cap features evenly spaced spikes providing fixation to the bony endplate.



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

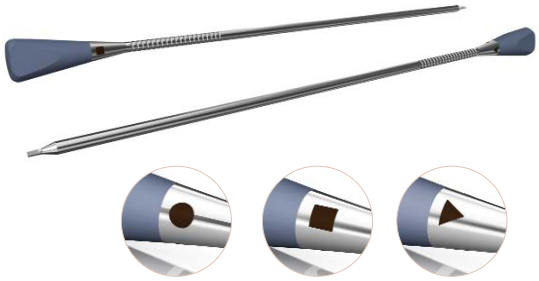
Supplemental Fixation

If supplemental fixation was not applied prior to the implantation of the VLIFT™ System, it should be applied once the implant is fully inserted, distracted and locked to its final height. 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™).

Expander 48300200

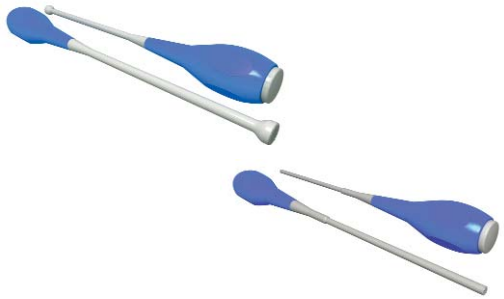
The VLIFT™ expander is an all-in-one instrument designed to act as an inserter and an intra-operative distractor. The inside shaft threads into the implant while the outer, cannulated shaft is turned to distract the implant.

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 consists of a molded silicone handle and a low-profile shaft for 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.

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 grafting material. The tip of the shaft of each impactor has a knurled surface, which comes in contact with the bone graft.

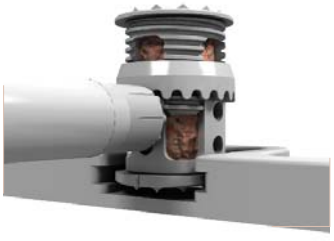
After the implant is distracted and locked into its final position, any void in the implant resulting from distraction can be filled through the large windows in the periphery of the implant. The small graft impactor is similar to a tamp and can be used to pack additional bone.

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

End Cap Remover 48300400

If the surgeon feels the end cap configuration needs to be adjusted, the end cap remover can be used to disassemble the end caps from the implant.

Note: When removing the angled end caps, insert the shortest end of the end cap into the end cap remover. The standard end cap remover can only be used to remove the 0°, 3°, and 8° end caps. An additional end cap remover is provided for the end caps 15° or greater. Extensions can be removed by hand.



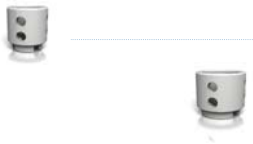
Container 48300001

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

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

Instruments

Part Number	Description	#/Set
48300200	Expander	1
48300210	Inside Shaft	0**
48300300	Screwdriver	1
33660450	Small Graft Impactor	1
33660460	Graft Impactor	1
48300400	End Cap Remover	1
48300001	Container	1

***Additional end cap sizes are available upon request.**
****Special order item, not part of standard set**

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