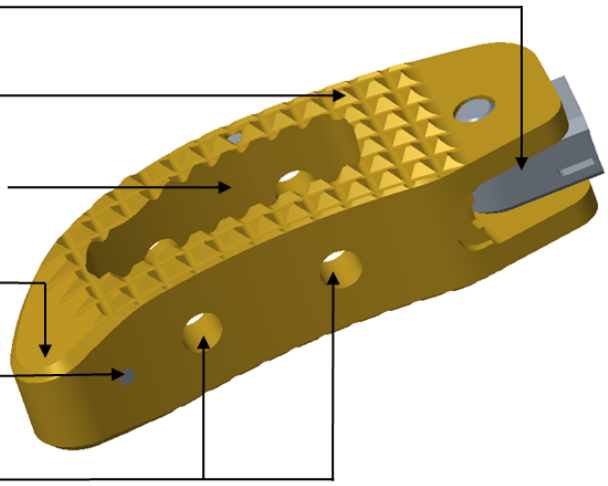
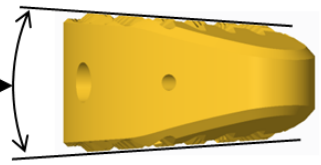
Product Overview

- **Articulating Block**
  Allows the cage to safely and accurately pivot to final position.
- **Pyramidal teeth**
  Enhances implant stability.
- **Large graft cavity**
  Accommodates bone graft packing to aid in the fusion process.
- **Self-distracting nose**
  Allows for easier of insertion.
- **Radiographic markers**
  Produces clear radiographic visualization during implant insertion and in final position.
- **Anterior and posterior side holes**
  Contributes to the vascularization of the graft.

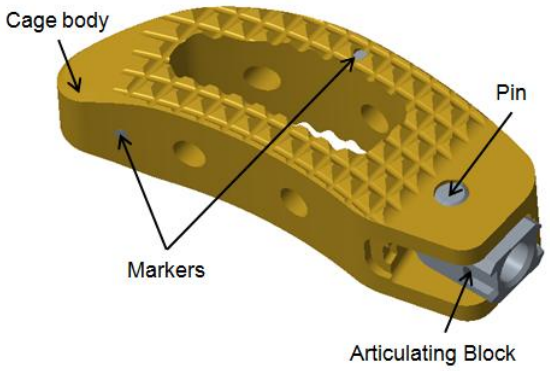


- **Lordotic angle**
  Provides extensive surface contact and restores the spine's natural lordotic curve.



The Velofix™ TLIF Cage consists of implants available in various heights, widths, lengths and lordotic angles with an open architecture to accept packing of bone graft material. The device consists of the cage body, the articulating block, and radiographic markers. The articulating block allows the cage to pivot to the final positioning.

The Velofix™ TLIF Cage may be implanted as a single device via a transforaminal approach, and can be adjusted to align with the anterior anatomy of the vertebral endplates.



PATIENT POSITIONING AND SURGICAL EXPOSURE

Identify the affected disc with fluoroscopy. Expose the intervertebral space using the surgeon's customary transforaminal approach.

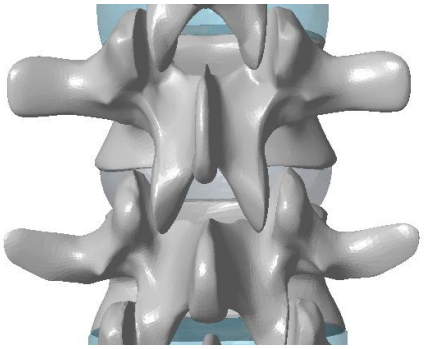


Fig 1

FACET RESECTION

In order to gain access to the disc, resect the facet joints on the desired side for implant insertion**(Fig 2)**.

Note: The facet joint can be preserved if sufficient access exists for discectomy and implant insertion or if the approach is extraforaminal.

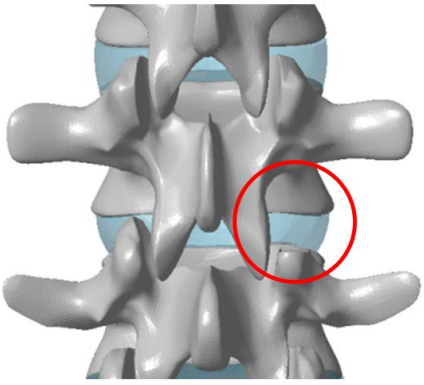


Fig 2

Pedicle screw installation

Install a pedicle screw systems (Perfix™ / Perfix™ MIS, ANAX™ 5.5 / ANAX™ 5.5 MIS) in the levels above and below the affected disc. Screws can be used for distraction, which may be necessary for the discectomy, as well as the trial and implantation steps.

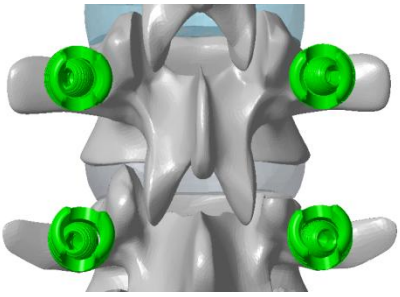


Fig 3

DISTRACTION OF THE DISC SPACE

Attach the T-Handle to the Distractor.

Insert Distractor, then rotate to restore the natural disc height**(Fig 4)**. The distractors are available in heights from 7-16mm in 1mm increments.

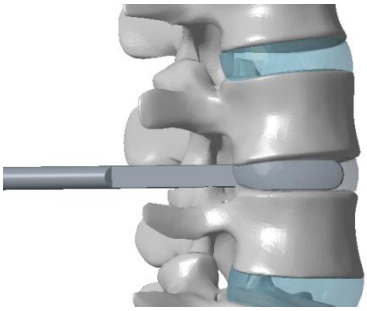


Fig 4

	Instrument
TL0380	Distractor 7mm
CB0108-CB0116	S. Distractor 8-16mm
SP0002	T-Handle

Note: In the case of an extremely collapsed disc, a rod can be installed on the side opposite implant insertion. Once preliminarily locked, the rod will help maintain distraction.

DISC SPACE PREPARATION

Connect the T-Handle with the appropriate Bone Shaver. Insert into the vertebral body and rotate to remove residual intradiscal material and to create a channel in the dorsal most endplate**(Fig 5)**.

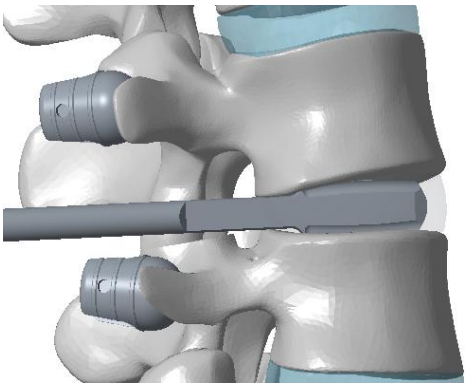


Fig 5

DISC SHAVERS

	Instrument
PL0310-PL0390	Bone Shaver 7-16mm
SP0002	T-Handle

CURETTES and BONE RASP

	Instrument
TL0400	Ring Curette – Straight
TL0410	Ring Curette – Right Curved
TL0420	Ring Curette – Left Curved
TL0440	Bone Rasp

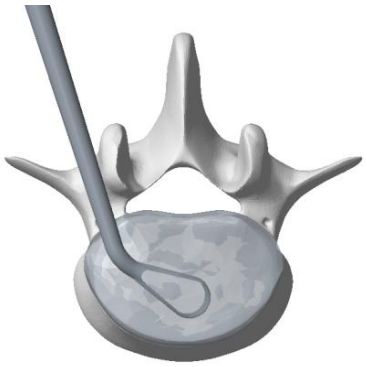


Fig 6

Remove the remaining soft tissue and cartilaginous endplate coverings using the Curettes and Bone Rasp. **(Fig 6)**

ASSEMBLY THE TRIAL

1. TRIAL ASSEMBLY

Attach the Rotating Holder to the Trial Inserter with the correct orientation**(Fig 7)**.

Select the appropriate trial head for the disc size and attach to the Trial Inserter**(Fig 8)**.

To lock, press the button on the Rotating Holder and push so the Trial Head makes contact with the Rotating Holder.

Note: The Trial Heads have the same heights as the implants and make it possible to determine the appropriate height.

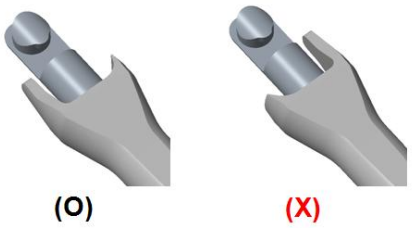


Fig 7

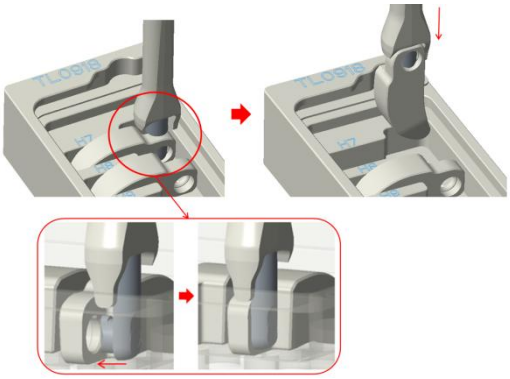


Fig 8

	Instrument
TL0060	Trial Inserter
TL0070-TL0160	Trial Head 7-16mm
TL0230	Rotating Holder

2. SIZING THE DISC SPACE

Lock the Trial Head on the Trial Inserter and insert the Trial Head into the disc space until it contacts the fibrous annulus. **(Fig 9)**

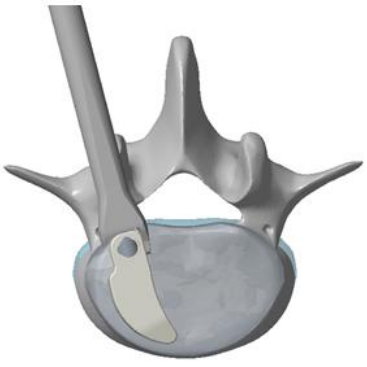


Fig 9

	Instrument
TL0060	Trial Inserter
TL0070-TL0160	Trial Head 7-16mm
TL0230	Rotating Holder

3. FINAL POSITIONING

Unlock the Rotating Holder**(Fig 11)** and advance the trial to final position**(Fig 10)**. Confirm the position by fluoroscopy.

Remove the Trial assembly using the Sliding Hammer. **(Fig 12)**

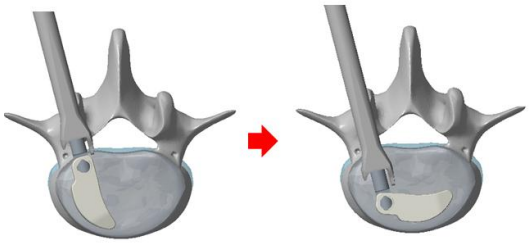


Fig 10

	Instrument
PL0430	Sliding Hammer

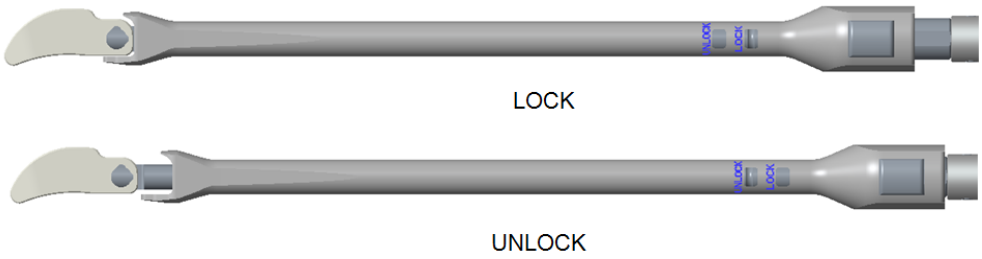


Fig 11 Locking and Unlocking the Rotating Holder

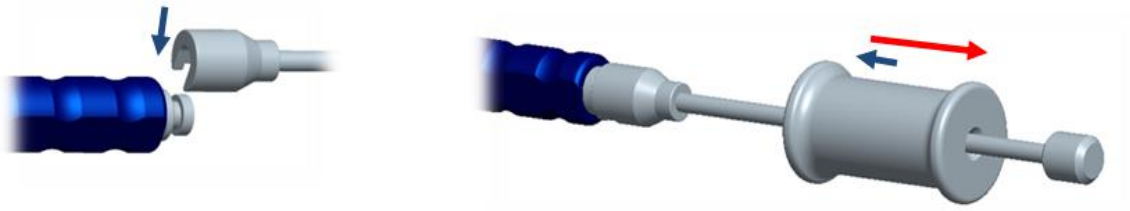


Fig 12 Assembling the Sliding Hammer

ATTACH CAGE TO INSERTER

Attach the Rotating Holder to the inserter. Set it to the LOCK position by pressing the Rotating Holder button.

Attach the appropriate Velofix™ TLIF Cage to the inserter**(Fig 13)**. Insert the Fixation Bolt into the Inserter and rotate to tighten**(Fig 14)**.

Place the Rotating Holder in the locked position by pressing the button on the Rotating Holder.

	Instrument
TL0210	Fixation Bolt-Straight
TL0220	Inserter-Straight
TL0230	Rotating Holder

** Note : Before assembly the Inserter with Cage, Check the direction of the Articulating Block.(**Fig 13**)*

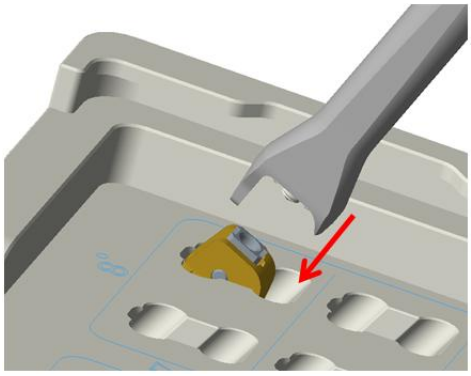


Fig 13

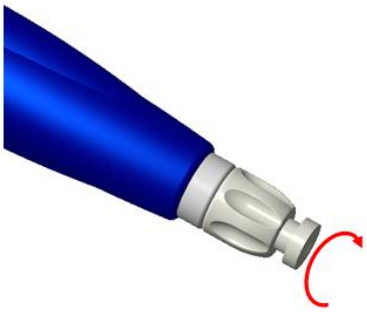


Fig 14

BONE PACKING

Place the Velofix™ TLIF Cage on the Packing Platform and carefully compact graft using a Bone Packing Bar **(Fig 15)**. Fill until graft is level with the top of the cage to ensure optimal contact with the vertebral endplates.

Note: Autologous bone is options for filling the Velofix™ TLIF Cage.

	Instrument
TL0520	Packing Platform
PL0450	Bone Packing Bar

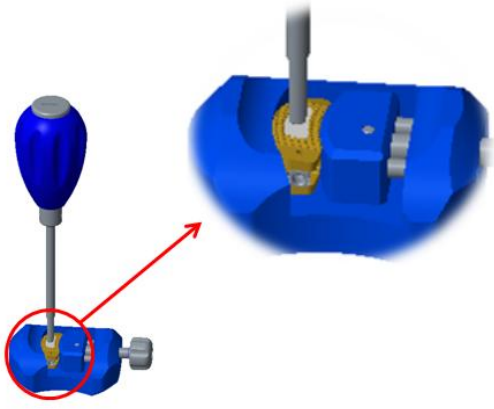


Fig 15

IMPLANT INSERTION

Insert the Velofix™ TLIF Cage into the disc space until it contacts the fibrous annulus**(Fig 16)**.

Press the button on the Rotating Holder and gently pull upwards to unlock**(Fig 17)**, and advance the implant to final position.

Confirm the position by fluoroscopy.

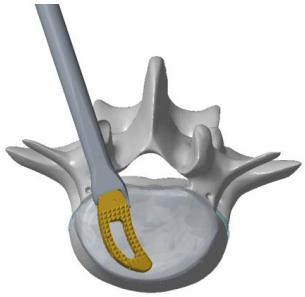


Fig 16

	Instrument
TL0210	Fixation Bolt-Straight
TL0220	Inserter-Straight
TL0230	Rotating Holder

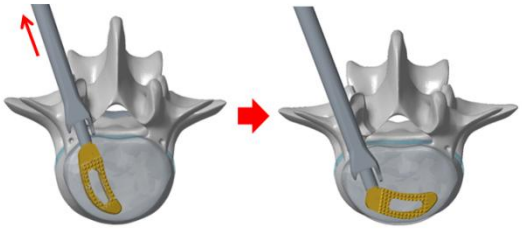


Fig 17

INSTALL POSTERIOR GRAFT

After Velofix™ TLIF Cage is implanted, fill the posterior disc space and the lateral disc space with bone graft for fusion using the Impactor**(Fig 18)**.

	Instrument
TL0510	Impactor

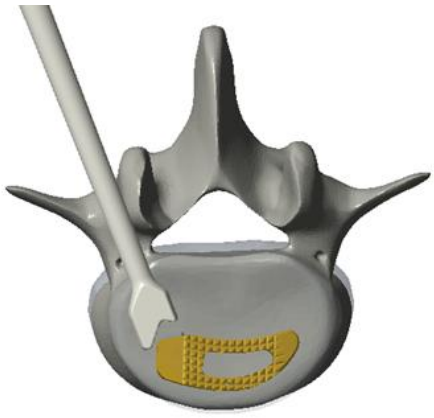


Fig 18

STABILIZATION AND COMPRESSION

Once the Velofix™ TLIF Cage is in place, compress the segment with posterior screws and rod to stabilize the Velofix™ TLIF Cage**(Fig 19)**.

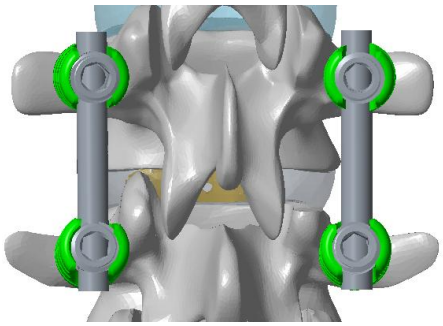


Fig 19

IMPLANT REMOVAL

Should removal or revision be deemed necessary by the surgeon, the implant can be removed by using the Inserter and the Fixation Bolt. Attach the Inserter and Fixation Bolt to the Velofix™ TLIF Cage and remove the cage frame from the disc space. If greater force is needed, attach the Sliding Hammer to the Fixation Bolt. Gently impact the Sliding Hammer to remove the implant**(Fig 20)**.

	Instrument
TL0210	Fixation Bolt-Straight
TL0220	Inserter-Straight
PL0430	Sliding Hammer

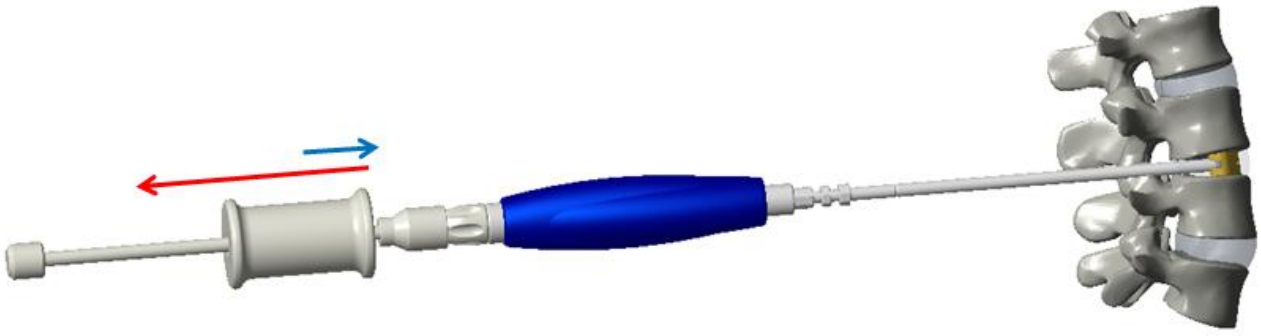
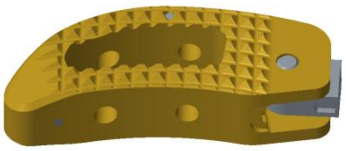


Fig 20

Order information

Implants (Single Use Only)



No.	Part No.	Part Description
TLIF Cage L28mm		
1	TLA1007	TLIF CAGE L28mm X A0° X H7mm
2	TLA1008	TLIF CAGE L28mm X A0° X H8mm
3	TLA1009	TLIF CAGE L28mm X A0° X H9mm
4	TLA1010	TLIF CAGE L28mm X A0° X H10mm
5	TLA1011	TLIF CAGE L28mm X A0° X H11mm
6	TLA1012	TLIF CAGE L28mm X A0° X H12mm
7	TLA1013	TLIF CAGE L28mm X A0° X H13mm
8	TLA1014	TLIF CAGE L28mm X A0° X H14mm
9	TLA1015	TLIF CAGE L28mm X A0° X H15mm
10	TLA1016	TLIF CAGE L28mm X A0° X H16mm
11	TLA1507	TLIF CAGE L28mm X A5° X H7mm
12	TLA1508	TLIF CAGE L28mm X A5° X H8mm
13	TLA1509	TLIF CAGE L28mm X A5° X H9mm
14	TLA1510	TLIF CAGE L28mm X A5° X H10mm
15	TLA1511	TLIF CAGE L28mm X A5° X H11mm
16	TLA1512	TLIF CAGE L28mm X A5° X H12mm
17	TLA1513	TLIF CAGE L28mm X A5° X H13mm
18	TLA1514	TLIF CAGE L28mm X A5° X H14mm
19	TLA1515	TLIF CAGE L28mm X A5° X H15mm
20	TLA1516	TLIF CAGE L28mm X A5° X H16mm
21	TLA1807	TLIF CAGE L28mm X A8° X H7mm
22	TLA1808	TLIF CAGE L28mm X A8° X H8mm
23	TLA1809	TLIF CAGE L28mm X A8° X H9mm
24	TLA1810	TLIF CAGE L28mm X A8° X H10mm
25	TLA1811	TLIF CAGE L28mm X A8° X H11mm
26	TLA1812	TLIF CAGE L28mm X A8° X H12mm
27	TLA1813	TLIF CAGE L28mm X A8° X H13mm
28	TLA1814	TLIF CAGE L28mm X A8° X H14mm

29	TLA1815	TLIF CAGE L28mm X A8° X H15mm
30	TLA1816	TLIF CAGE L28mm X A8° X H16mm
TLIF Cage L32mm		
31	TLA2007	TLIF CAGE L32mm X A0° X H7mm
32	TLA2008	TLIF CAGE L32mm X A0° X H8mm
33	TLA2009	TLIF CAGE L32mm X A0° X H9mm
34	TLA2010	TLIF CAGE L32mm X A0° X H10mm
35	TLA2011	TLIF CAGE L32mm X A0° X H11mm
36	TLA2012	TLIF CAGE L32mm X A0° X H12mm
37	TLA2013	TLIF CAGE L32mm X A0° X H13mm
38	TLA2014	TLIF CAGE L32mm X A0° X H14mm
39	TLA2015	TLIF CAGE L32mm X A0° X H15mm
40	TLA2016	TLIF CAGE L32mm X A0° X H16mm
41	TLA2507	TLIF CAGE L32mm X A5° X H7mm
42	TLA2508	TLIF CAGE L32mm X A5° X H8mm
43	TLA2509	TLIF CAGE L32mm X A5° X H9mm
44	TLA2510	TLIF CAGE L32mm X A5° X H10mm
45	TLA2511	TLIF CAGE L32mm X A5° X H11mm
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48	TLA2514	TLIF CAGE L32mm X A5° X H14mm
49	TLA2515	TLIF CAGE L32mm X A5° X H15mm
50	TLA2516	TLIF CAGE L32mm X A5° X H16mm
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52	TLA2808	TLIF CAGE L32mm X A8° X H8mm
53	TLA2809	TLIF CAGE L32mm X A8° X H9mm
56	TLA2810	TLIF CAGE L32mm X A8° X H10mm
55	TLA2811	TLIF CAGE L32mm X A8° X H11mm
56	TLA2812	TLIF CAGE L32mm X A8° X H12mm
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58	TLA2814	TLIF CAGE L32mm X A8° X H14mm
59	TLA2815	TLIF CAGE L32mm X A8° X H15mm
60	TLA2816	TLIF CAGE L32mm X A8° X H16mm

Instruments

TL0210 Fixation Bolt-Straight

TL0220 Inserter-Straight

TL0230 Rotating Holder

TL0060 Trial Inserter

TL0070 Trial Head 7mm

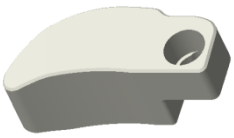
TL0080 Trial Head 8mm

TL0090 Trial Head 9mm

TL0100 Trial Head 10mm

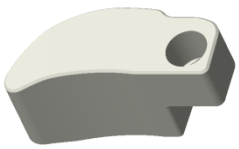
TL0110 Trial Head 11mm

TL0120 Trial Head 12mm

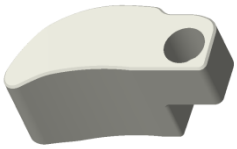


TL0130 Trial Head 13mm

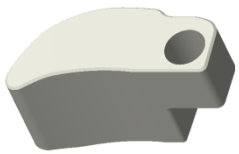
TL0140 Trial Head 14mm



TL0150 Trial Head 15mm



TL0160 Trial Head 16mm



TL0400 Ring Curette – Straight

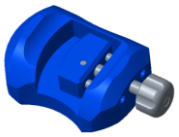
TL0410 Ring Curette – Left Curved

TL0420 Ring Curette – Right Curved

TL0440 Bone Rasp

PL0450 Bone Packing Bar

TL0520 Packing Platform



TL0510 Impactor

PL0310 Bone Shaver - 7mm

PL0320 Bone Shaver - 8mm

PL0330 Bone Shaver - 9mm

PL0340 Bone Shaver - 10mm

PL0360 Bone Shaver - 12mm

PL0380 Bone Shaver - 14mm

PL0390 Bone Shaver - 16mm

TL0380 Distractor - 7mm

CB0108 S. Distractor - 8mm

CB0109 S. Distractor - 9mm

CB0110 S. Distractor - 10mm

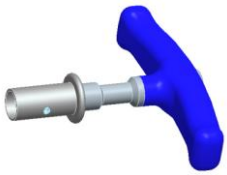
CB0112 S. Distractor - 12mm

CB0114 S. Distractor - 14mm

CB0116 S. Distractor - 16mm

PL0430 Sliding Hammer

SP0002 T-handle



♦ Intended Use / Indications For Use

The Velofix™ TLIF Cage is indicated for intervertebral body fusion at one level or two contiguous levels in the lumbar spine from L2 to S1 in patients with degenerative disc disease (DDD) with up to Grade I spondylolisthesis at the involved level(s). DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies. These patients should be skeletally mature and have had six months of non-operative treatment.

The Velofix™ TLIF Cage is to be used with supplemental internal spinal fixation. Additionally, the Velofix™ TLIF Cage is to be used with autogenous bone graft material.

♦ Contraindications

Contraindications include, but are not limited to:

- The Velofix™ TLIF Cage should not be implanted in patients with an active infection at the operative site.
- Any active or suspected latent infection in or about the spine.
- 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 fusion to the devices.
- Obesity. An overweight or obese patient can produce loads on the spinal system which can lead to failure of the fusion of the device or to failure of the device itself. Obesity is defined according to the W.H.O. standards.
- Recent infection, fever, or leukocytosis.
- Open wounds.
- Metal and / or foreign body sensitivity, documented or suspected.
- Patient having inadequate tissue coverage over the operative site.
- Pregnancy
- Excessive local inflammation.
- Prior fusion at the level(s) to be treated.
- Other medical or surgical conditions which would preclude the potential benefit of spinal implant surgery, such as the presence of tumors, congenital abnormalities, elevation of sedimentation rate unexplained by other diseases, elevation of white blood cell count(WBC), or marked left shift in the WBC differential count.
- A condition of senility, mental illness, or substance abuse. These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the implant, leading to failure or other complications.
- Any neuromuscular deficit which places an unsafe load level on the device during the healing period.
- Any abnormality present which affects the normal process of bone remodeling including, but not limited to,

severe osteoporosis involving the spine, bone absorption, osteopenia, primary or metastatic tumors involving the spine, active infection at the site or certain metabolic disorders affecting osteogenesis.

♦ ⚠ Warnings

- Benefit of spinal fusions utilizing any interbody fusion system has not been adequately established in patients with stable spines.
- Potential risks associated with the use of this system, which may require additional surgery, include: device component fracture, loss of fusion, non-union, fracture of the vertebra, neurological injury, and vascular or visceral injury.
- Discard all damaged or mishandled implants.
- Never reuse an implant, even though it may appear undamaged. Reusing of the implant can cause early fracture, deformation and patient's infection.
- Interbody fusion devices cannot withstand activity and load levels equal to those placed on normal healthy bone. Until maturation of the fusion mass is confirmed, do not subject this device to the stress of full weight bearing, or implant failure may result.
- Mixing Metal: Some degree of corrosion occurs on all implanted metal and alloys. Contact of dissimilar metals, however, may accelerate this corrosion process. The presence of corrosion may accelerate fatigue fracture of implants, and the amount of metal compounds released into the body system will also increase.
- Because different manufacturers employ different materials, varying tolerances and manufacturing specifications, and differing design parameters, the Velofix™ TLIF Cage should not be used in conjunction with components from any other manufacturer’s spinal system and instruments. Any such use will negate the responsibility of U&I Corporation for the performance of the resulting mixed component implant.
- Any decision by a physician to remove the interbody fusion 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.
- Implant removal should be followed by adequate postoperative management to avoid fracture.

♦ Precautions

PHYSICIAN NOTE: Although the physician is the learned intermediary between the company and the patient, the important medical information given in this document should be conveyed to the patient.

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- 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 have impact on the performance of the system.

- 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.
- If the patient is involved in an occupation or activity which applies inordinate stress upon the implant (e.g., substantial walking, running, lifting, or muscle strain) resultant forces can cause failure of the device.
- Safety and effectiveness have not been established for patients with the following conditions: previous fusion attempt at the involved level(s), spondylolisthesis greater than Grade I, three or more levels to be fused, concomitant conditions requiring steroids, systemic or terminal illness, active drug abuse, gross obesity and severe osteoporotic conditions.
- In some cases, the progression of degenerative disease may be so advanced at the time of implantation that it may substantially decrease the expected useful life of the appliance. For such cases, orthopedic devices can only be considered a delaying technique or temporary remedy.
- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and limitations of the interbody fusion. Requiring detailed knowledge of spinal surgery. This device is recommended for use only by surgeons familiar with preoperative and surgical techniques, cautions, and potential risks associated with such spinal surgery. Knowledge of surgical techniques, proper reduction, selection and placement of implants, and pre-/post-operative patient management are considerations essential to a successful surgical outcome.
- 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 patient should understand that a metallic or polymer implant is not as strong as normal, healthy bone and will bend, loosen or fracture if excessive demands are placed on it. An active, debilitated, or demented patient who cannot properly use weight supporting devices may be particularly at risk during postoperative rehabilitation.
- Appropriate selection, placement and fusion of the spinal system components are critical factors which affect implant service life. Also, as in the case of all prosthetic implants, the durability of these components is affected by numerous biological, biomechanical and other extrinsic factors, which limit their service life. Accordingly, strict adherence to the indications, contraindications, precautions, and warnings for this product is essential to potentially maximize service life.

  Note: While proper implant selection can minimize risks, the size and shape of human bones present limitations on the size, shape, and strength of the implants.
- 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.
- Check if implant type is appropriate for use in intended region of spine.
- Patients with previous spine surgery at the level(s) to be treated may have different clinical outcomes compared to those without a previous surgery.

  ⚠ **CAUTION: For use on or by the order of a physician only.**

  ⚠ **Federal law(USA) restricts these devices to sale by or on the order of a physician.**