EIT
Emerging
Implant
Technologies

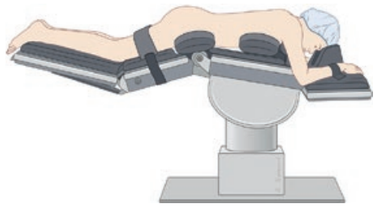
EIT TLIF Cage

For Natural Bone Ingrowth with EIT Cellular Titanium®

EIT TLIF Cage

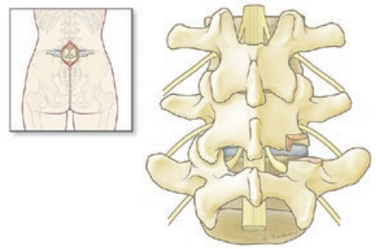
- **EIT Cellular Titanium® provides active fusion area**
  - » ~ 80% porosity
  - » ~ 650 µm diamond pore size
  - » open interconnected framework for optimal cell migration and proliferation
  - » Bone grafting is not necessary
- **Bullet banana shape in combination with solid edges for smooth introduction along soft tissues and to adapt to endplate anatomy**
- **Suitable elasticity modulus avoids stress shielding and bone resorption**
- **Rough elevated surface provides high primary stability**
- **Various footprint sizes for maximum endplate contact**
  - » 10x28 mm » 10x32 mm » 12x32 mm
- **9 heights in 1 mm increments**
  - » 7-15 mm
- **0°, 8° and 12° lordosis angle for spinal alignment and sagittal balance**
- **X-ray markers support ideal intraoperative implant positioning and postoperative follow-up**

Surgical Technique



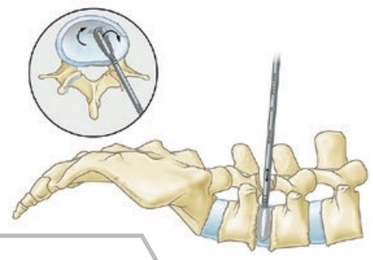
Preparation and Approach

The patient is placed on the OR table using the standard positioning in cases of transforaminal lumbar interbody fusion. Make sure the abdomen is free positioned to avoid pressure on the large vessels and to minimize blood loss. A radiolucent OR table is recommended, as X-ray shall be used to confirm identification of the affected disc and in a later stage the position of the implant.



Decompression and Discectomy

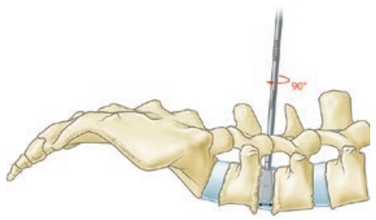
Mark the affected segment after c-arm control. A standard incision is performed over the level(s) to be instrumented. Expose the facets and the lateral parts of facet joints on the affected side. Normally (part of) the inferior facet of the upper vertebra and (part of) the superior facet of the lower facet are removed on the approach side with an osteotome, burr or kerrison. According to patient and indication the surgeon may choose a more lateral approach, leaving the facet joint intact. To ease the discectomy procedure, insertion of pedicle screws and performing a slight distraction over the pedicle screws prior to the discectomy can be advantageous. The neural foramen and central spinal canal are decompressed as necessary.



The posterolateral portion of the annulus is exposed and a window is created to gain access to the intervertebral space. The dura and nerve root are protected using nerve root retractors. If necessary, use the Disc Space Opener to open up a severely collapsed disc. Disc material is removed through the window created by the Disc Space Opener using rongeurs and forceps until only the anterior and lateral annuli remain. Shavers can also be used to remove disc material and prepare the endplates.

Applied grooves on the Shaver mark a length of 22, 26 and 30 mm respectively. Additional circular lasermarkings on the shaft represent a depth of 35, 40 and 45 mm respectively. After the disc is cleared, the endplate cartilage should be removed carefully, leaving the upper and lower bony endplate intact. Injury to the bony endplates may lead to implant subsidence.

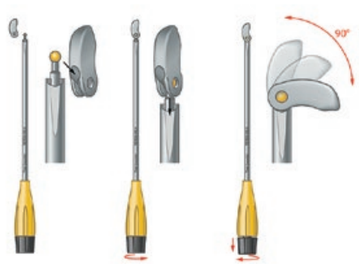
Surgical Technique



Distraction

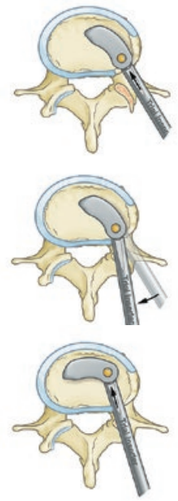
An adequate distraction of the intervertebral disc space is one of the pre-conditions for the primary stability required after cage implantation. For this purpose Distractors are available in heights of 7 mm to 15 mm in 1 mm increments. Each size of Distractor has grooves, that indicate a depth of 22, 26 and 30 mm respectively. It should be considered to start with the smallest size Distractor to avoid over distraction. Apply the Distractor parallel to the intevertebral space and carefully turn clockwise to open up the disc space, avoiding injury of the endplates. Proceed with one size bigger until sufficient distraction is achieved.

Trial - Inserter connection



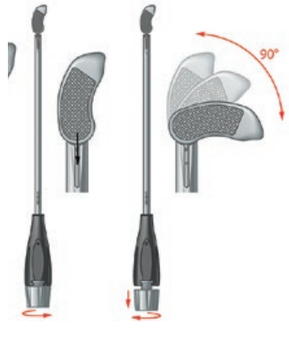
Determine the appropriate implant size with the Trial. Trials are available that match the footprint, height and angle of each implant. Attach the Trial to the Inserter:

» Make sure the Inserter is properly assembled having the Inner Pin with spherical tip into the Inserter Tube with the yellow handle. The components are gripped by tightening the screwcap on the end of the handle.
» Glide the spherical tip into the Trial implant. Secure the Trial to the Inserter by turning the screwcap on the back of the Inserter, thereby keeping the Trial in line with the Inserter. The Trial can be positioned in stepless angles between 0 - 90° by unscrewing the screwcap. This feature is very beneficial to reposition the Trial without changing instruments and thereby mimicking the final implantation procedure.
» Be careful not to use high forces on the Inserter when the screwcap is unscrewed more than two full turns, as the screw thread could be damaged.



Determination of Cage Size and Trial Insertion

The stable longitudinal alignment of the Trial and the Inserter ensures a straight introduction of the Trial along the transforaminal route. Insert the Trial with gentle taps on the back of the Inserter until the Trial is just in the intervertebral space and change the pushing direction of the Inserter to the Trial. The position of the Inserter relative to the Trial can be changed by unlocking the screwcap and moving the Inserter to medial. After locking the screwcap the Trial is fixed in the new position and can gently be tapped further. Repeat this procedure until the desired position has been obtained. Fluoroscopy should be used to check the secure fit and final position of the Trial implant. Remove the Trial Implant after cage size determination using the slot of the Hammer.



Implant - Inserter connection

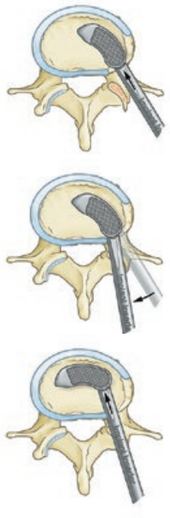
Open the sterile packaging of the implant size that was determined with the Trial.
Attach the implant to the Inserter:

» Make sure the Inserter is properly assembled having the Inner Pin with T-bar tip into the Inserter Tube with the black handle. The components are gripped by screwing the screwcap on the end of the handle.
» Place the T-bar in the opening of the implant and turn the Implant 90°. Then push the Inserter with its two guiding ends in the slid opening of the Implant. Turn the screwcap on the back of the Inserter, while keeping the Implant in line with the Inserter, until the Implant is securely fixed.

The implant can be positioned in stepless angles between 0 - 90° relative to the Inserter by unscrewing the screwcap and change the position of the Inserter-Implant connection.

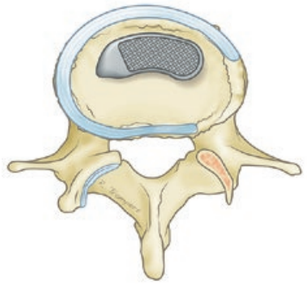
Depending on surgical preference, the disc space can be filled prior to and after cage implantation, respectively ventral and/or lateral/posterior, with remaining autograft or other suitable bone graft material.

Surgical Technique



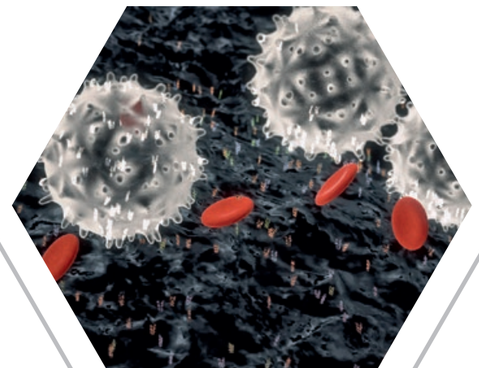
Implant Insertion

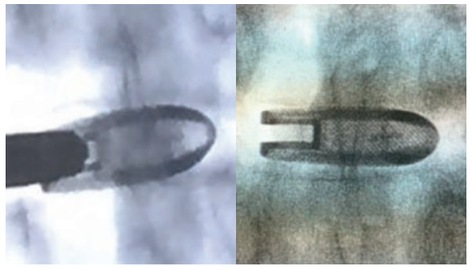
The stable longitudinal alignment of the Implant and the Inserter ensures a straight introduction of the Implant along the transforaminal route. Insert the Implant with gentle taps on the back of the Inserter. The position of the Inserter relative to the Implant can be changed by unlocking the screwcap and moving the Inserter to medial. After locking the screwcap the Implant is fixed in the new position and can be gently tapped further. Make sure the Implant is fixed to the Instrument before further insertion. This procedure can be repeated until the desired position has been obtained. Fluoroscopy should be used to check the final position of the Implant.



Final Implant positioning

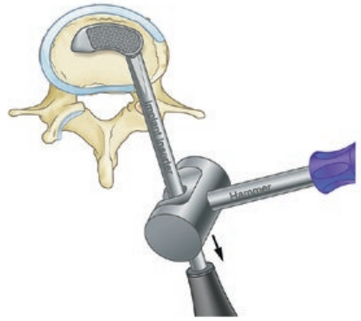
The Implant should be positioned as anterior as possible in the anterior-posterior alignment. The use of fluoroscopy is recommended during all of the implantation steps to ensure proper positioning. Two hooked X-ray markers should form a cross when the Implant is placed central on and perpendicular to the anterior-posterior central axis. Once proper placement is confirmed using X-ray, the Inserter is detached by turning the screwcap at the end of the shaft several times counter clockwise. Rotate the Inserter 90° and pull the Inserter away from the Implant, releasing the T-bar connection. An Impactor is available for definite cage positioning. This instrument can be used after removal of the Inserter for the post-positioning of the Implant. The Impactor can also be used to impact the remaining patients bone material into the intervertebral space.





Completion of Surgery / Postoperative Care

After Implantation of the cage a final check of the position of the cage under fluososcopy is advised. Posterior supplemental fixation (e.g., pedicle screws or other posterior fixation device) is strongly recommended. Perform wound closure as usual. Please document which implants were used in the patient files. Patient labels are supplied with each implant for your convenience. The use of the EIT TLIF Cage does not require any specific postoperative care and the patient should be treated according to hospital and medical standard.



Implant Removal / Revision Surgery

The EIT Cellular Titanium® TLIF Cage is intended for permanent implantation and is not intended for removal. However, removal may be advisable in the following situations:

» Implant breakage, migration or other clinical failure
» Pain due to the implant
» Infection

If it is necessary to correct the location, revise or remove the EIT Cellular Titanium® TLIF Cage, connect the Inserter to the Implant. Slide the slotted Hammer along the Inserter Shaft and relocate /remove the Implant using gentle taps of the Hammer.

Implant Removal / Revision Surgery with Slap-hammer

In case of relocation, revision or removal of the EIT Cellular Titanium® TLIF Cage, also the Inserter with Slap-hammer connection can be used. Assemble the Inserter with the “Knob-S-Hammer-Connection”. Attach the Inserter to the Implant. Slide the Slap-Hammer up and down to relocate /remove the Implant.

Indications & Contraindications

Indications

The EIT Cellular Titanium® TLIF Cage is indicated for use in skeletally mature patients with degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by patient history and radiographic studies) and instabilities at one or more levels of the lumbar spine with accompanying radicular symptoms, ruptured or herniated discs, and pseudarthrosis or failed spondylodesis. Patients should have at least six (6) weeks of non-operative treatment prior to surgery.

EIT Cellular Titanium® TLIF Cage is used to restorethe intervertebral height and to facilitate interver-tebral body fusion in the lumbar spine (L2-S1) and is placed via a standard transforaminal approach.

Posterior supplemental internal fixation (e.g., using pedicle screws or other posterior fixation devices) is strongly recommended.

Contraindications

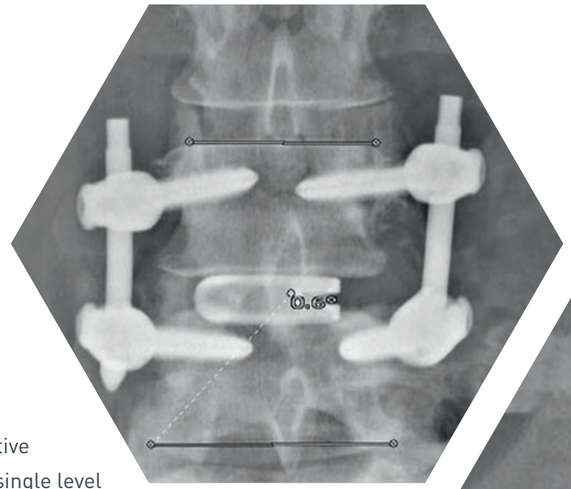
Do not use the EIT Cellular Titanium® TLIF Cage in cases of:

» Any medical or surgical condition precluding the potential benefit of spinal surgery
» Acute or chronic systemic, spinal or localized infections
» Severe osteoporosis or osteopenia which may pre-vent adequate fixation and thus preclude the use of these or any other orthopedic implant
» Severe instabilities
» Vertebral body fractures
» Spinal tumors
» Systemic and metabolic diseases
» Conditions that may provide excessive stress on bone and implants, such as severe obesity or dege-nerative diseases
» Pregnancy
» Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient coopera-tion
» Prior fusion at the level(s) to be treated
» Demonstrated allergy or foreign body sensitivity to the implant material

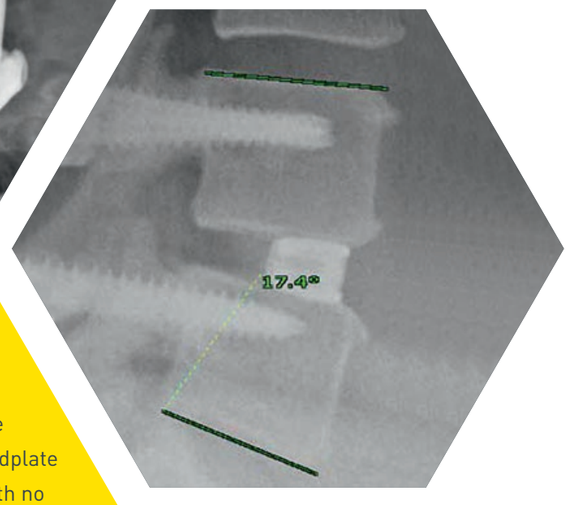
Clinical Imaging courtesy of:

- Dr. Steven van Gaalen, Diakonessenhuis Utrecht Netherlands
- Dr. John Cunningham, Epworth Medical Centre Richmond Australia

Imaging Characteristics



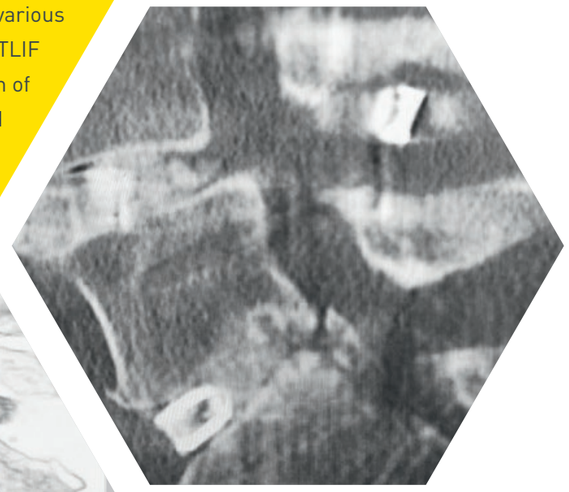
Patient 1
X-Ray AP,
degenerative
scoliosis single level
L4-L5 direct
postoperative,
neutral in AP



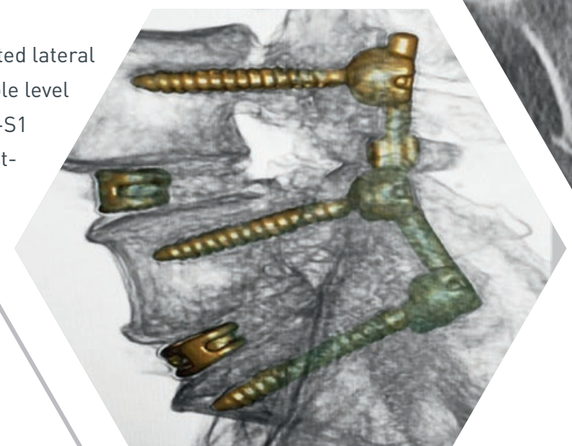
Patient 1
X-Ray lateral level L4-L5
direct postoperative,
restoration lordosis to 17.4 °

Imaging appearance of the EIT TLIF cage

The TLIF implant is clearly visible in X-Ray and CT scans. The implant-endplate contact can be very well evaluated with no disturbing scattering on CT scans. The various lordosis angles and footprints in the TLIF portfolio allow for a good restoration of the anatomical requirements and the sagittal balance.



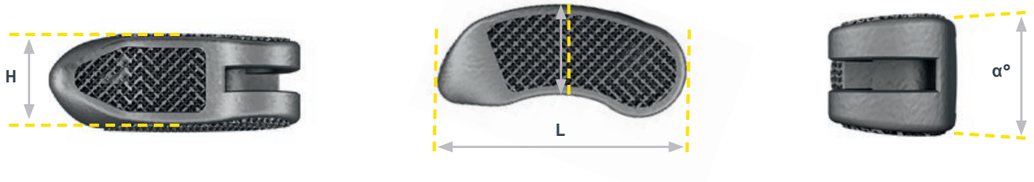
Patient 2
CT animated lateral
view double level
L4-L5/L5-S1
direct post-
operative



Patient 2
CT lateral view
double level L4-L5/L5-S1
direct postoperative

Implants & Instruments

Implants



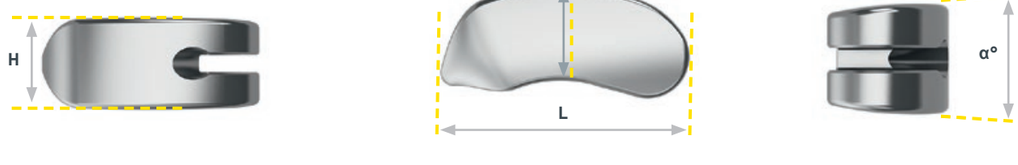
EIT TLIF Implants									
	10 mm x 28 mm (Width x Length)			**10 mm x 32 mm** (Width x Length)			**12 mm x 32 mm** (Width x Length)		
Height	Lordosis			Lordosis			Lordosis		
	0°	**8°**	**12°**	**0°**	**8°**	**12°**	**0°**	**8°**	**12°**
7 mm	TEI00728			TEI00730			TEI00732		
8 mm	TEI00828	TEI80828		TEI00830	TEI80830		TEI00832	TEI80832	
9 mm	TEI00928	TEI80928	TEI30928	TEI00930	TEI80930	TEI30930	TEI00932	TEI80932	TEI30932
10 mm	TEI01028	TEI81028	TEI31028	TEI01030	TEI81030	TEI31030	TEI01032	TEI81032	TEI31032
11 mm	TEI01128	TEI81128	TEI31128	TEI01130	TEI81130	TEI81130	TEI01132	TEI81132	TEI31132
12 mm	TEI01228	TEI81228	TEI31228	TEI01230	TEI81230	TEI31230	TEI01232	TEI81232	TEI31232
13 mm	TEI01328	TEI81328	TEI31328	TEI01330	TEI81330	TEI31330	TEI01332	TEI81332	TEI31332
14 mm	TEI01428	TEI81428	TEI31428	TEI01430	TEI81430	TEI31430	TEI01432	TEI81432	TEI31432
15 mm	TEI01528	TEI81528	TEI31528	TEI01530	TEI81530	TEI31530	TEI01532	TEI81532	TEI31532

Instruments

EIT TLIF Shaver			
H	**REF**	**H**	**REF**
7 mm	PFT10700	**12 mm**	PFT11200
8 mm	PFT10800	**13 mm**	PFT11300
9 mm	PFT10900	**14 mm**	PFT11400
10 mm	PFT11000	**15 mm**	PFT11500
11 mm	PFT11100		

EIT TLIF Distractor			
H	**REF**	**H**	**REF**
7 mm	PET10710	**12 mm**	PET11210
8 mm	PET10810	**13 mm**	PET11310
9 mm	PET10910	**14 mm**	PET11410
10 mm	PET11010	**15 mm**	PET11510
11 mm	PET11110		

Trials



EIT TLIF Trials									
	10 mm x 28 mm (Width x Length)			**10 mm x 32 mm** (Width x Length)			**12 mm x 32 mm** (Width x Length)		
Height	Lordosis			Lordosis			Lordosis		
	0°	**8°**	**12°**	**0°**	**8°**	**12°**	**0°**	**8°**	**12°**
7 mm	TET00728			TET00730			TET00732		
8 mm	TET00828	TET80828		TET00830	TET80830		TET00832	TET80832	
9 mm	TET00928	TET80928	TET30928	TET00930	TET80930	TET30930	TET00932	TET80932	TET30932
10 mm	TET01028	TET81028	TET31028	TET01030	TET81030	TET31030	TET01032	TET81032	TET31032
11 mm	TET01128	TET81128	TET31128	TET01130	TET81130	TET81130	TET01132	TET81132	TET31132
12 mm	TET01228	TET81228	TET31228	TET01230	TET81230	TET31230	TET01232	TET81232	TET31232
13 mm	TET01328	TET81328	TET31328	TET01330	TET81330	TET31330	TET01332	TET81332	TET31332
14 mm	TET01428	TET81428	TET31428	TET01430	TET81430	TET31430	TET01432	TET81432	TET31432
15 mm	TET01528	TET81528	TET31528	TET01530	TET81530	TET31530	TET01532	TET81532	TET31532

Trail Inserter	TET20100
Trial Inserter S-Hammer Connection	TET20101
Implant Inserter	TET30100
Implant Inserter S-Hammer Connection	TET30101
Inserter Knob S-Hammer Connection	TET20110

Instruments

Disc Space Opener	PET10050
Impactor	TET30200
Large Impactor	TET30201
Straight handle	PET00920
T-handle	PET00910
Hammer	PET60250
Slap-Hammer	PET60251
TLIF instrument tray	TEC00100

TEM00002 Rev.C

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