



EIT

Emerging
Implant
Technologies

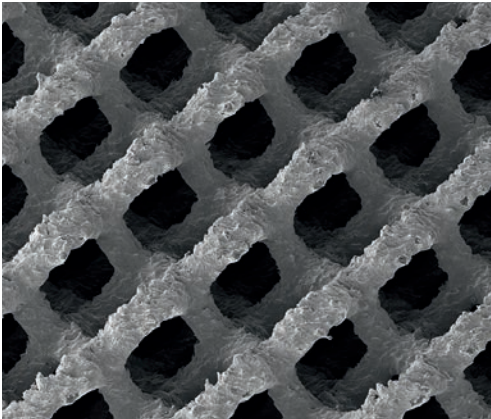


EIT Cervical Cage

Natural Bone Ingrowth with EIT Cellular Titanium®

EIT Cellular Titanium[®]

Natural bone ingrowth with EIT Cellular Titanium[®]



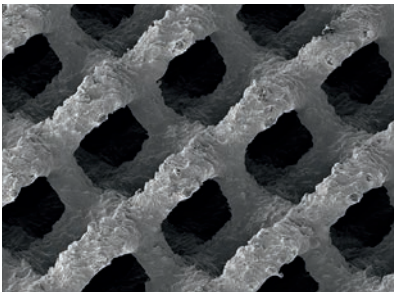
- **EIT Cellular Titanium[®] implants are produced with Selective Laser Melting (SLM) technique**
- **EIT Cellular Titanium[®] consists of ~80% porosity and a diamond pore size of ~650 μm, mimicking trabecular bone structure**
 - » Bone grafting is not necessary
- **Combination of solid and cellular implant architecture facilitates the rebuilding of natural cortical and cancellous bone structure**
 - » Provides optimal biomechanical and biological environment for natural bone ingrowth
- **Hydrophilic EIT Cellular Titanium[®]**
 - » Maximized blood contact leads to accelerated protein and mesenchymal cell attachment and bone cell differentiation
 - » Proven biocompatibility of titanium alloy TiAl6V4¹
- **Excellent imaging characteristics**
 - » Implant contours visible under x-ray. Fusion area and X-ray markers clearly visible due to high implant porosity
 - » MRI and CT compatible



¹ Geetha M, Singh AK, Asokamani R, et al. Prog Mat Sci 2009; 54:397-425

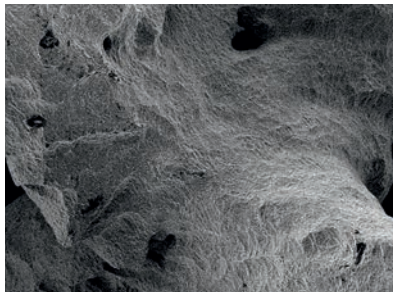
EIT Cervical Cage

Macro-, Micro-, Nanostructural features



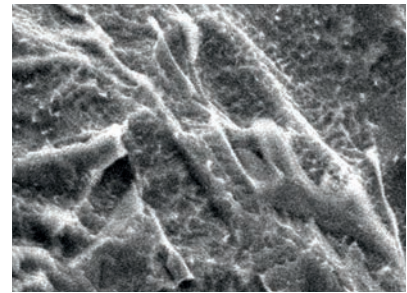
Macro-structure

- Rough EIT Cellular Titanium® surface provides high primary implant stability
- Modulus of elasticity close to cancellous bone avoids stress shielding and implant subsidence



Micro-structure

- Scaffold surface roughness and ~80% porosity provides maximized contact area and mechanical support of bone cells and vascular structures from one endplate to another
- Ideal pore size of ~650 µm facilitates a fast natural cellular influx, leading to a solid bony fusion and subsequent secondary stability^{2,3,4,5}



Nano-structure

- Chemical surface treatments create an optimal environment for bone cell formation and bone apposition over the entire EIT Cellular Titanium® lattice^{6,7,8}
- Rough titanium alloy increases osteoblast proliferation, BMP response and stimulates an angiogenic-osteogenic environment
» enhances bone formation, implant stability and fusion^{9,10}

Additive Manufacturing SLM

Modern additive manufacturing technologies such as 3D printing or SLM (selective laser melting) are currently revolutionizing many industries such as construction, architecture, design, and aeronautics as well as the medical device industry. Tooling and machining constraints are eliminated. Additive manufacturing technologies allow creation of 3-dimensional complex structures and geometries that cannot be manufactured with traditional machining. The method is cost-effective and allows a design-driven manufacturing process of smaller batch sizes – almost without limitations. This is ideal for highly specialized spinal implants.

EIT Cellular Titanium® structures are produced with SLM technology and allow the creation of highly porous macro-, micro- and nanostructures that are close to cortical and cancellous bone, leading to fast and extensive bone incorporation.

² Nandi SK, Roy S, Mukherjee P, et al. Indian J Med Res 2010; 132: 15-30

³ Fukuda A, Takemoto M, Saito T, et al. Acta Biomater 2011; 7: 2327-2336

⁴ Van Bael S, Chai YC, Truscello S, et al. Acta Biomater 2012; 8:2824-2834

⁵ Wu S-H, Li Y, Zang Y-Q, et al. Art Organs 2013; 37:191-201

⁶ Pattanayak D, Fukuda A, Matsushita T, et al. Acta Biomater 2011; 7:1398-1406

⁷ Gittens R, Olivares-Navarrete R, Cheng A, et al. Acta Biomater 2013; 9:6268-6277

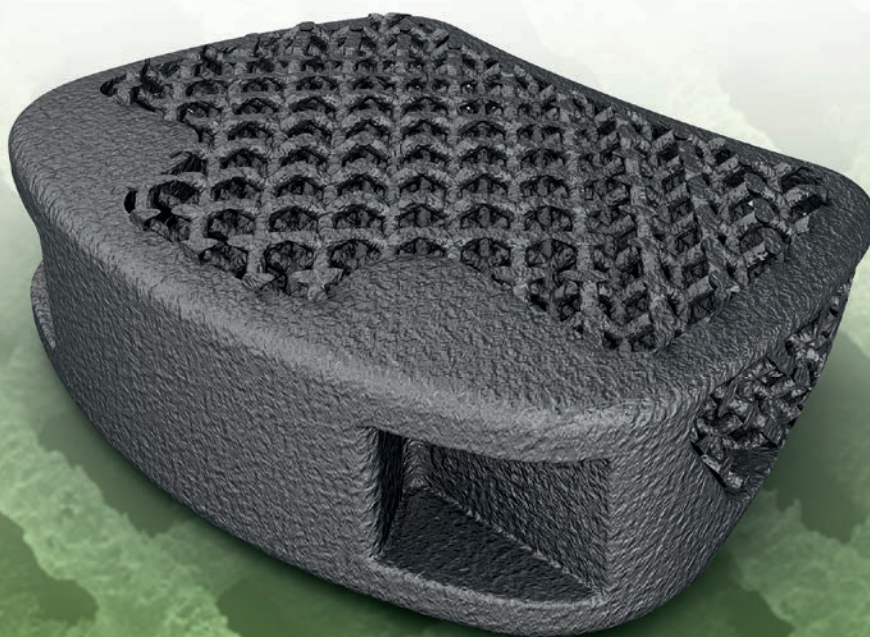
⁸ Amin Yavari S, Wauthle R, Bottger AJ, et al. App Surf Sci 2014; 290:287-294

⁹ Olivares-Navarrete R, Gittens RA, Schneider JM, et al. Spine J. 2012; 12:265-272

¹⁰ Sollazzo V, Massari L, Pezzetti F, et al. ISRN Mat Sci 2011; art ID 392763

EIT Cervical 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
- **Dome shaped to endplate anatomy**
- **Suitable elasticity modulus avoids stress shielding and bone resorption**
- **Rough elevated surface provides high primary stability**
- **2 footprint sizes for maximized endplate contact**
 - » Small (S) = 12x16 mm
 - » Large (L) = 14x18 mm
- **5 heights in 1mm increments**
 - » 4-8 mm
- **4° lordosis angle for spinal alignment and sagittal balance**
- **Lateral wedge design for maximal contact of the uncovertebral joint**
- **X-ray markers support ideal intraoperative implant positioning**



EIT Cervical Cage

Imaging characteristics X-Ray



Patient 1 level C5-C6



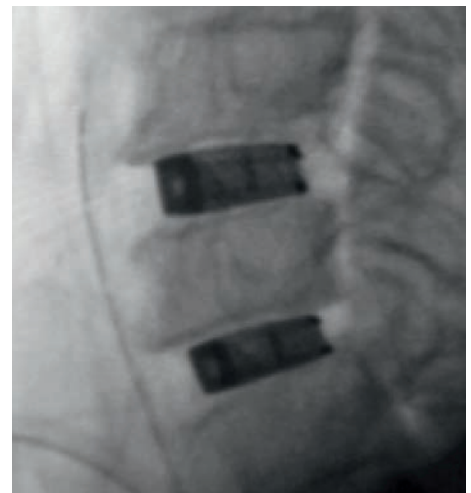
Patient 2 level C5-C6

X-ray appearance of the EIT cervical cage

The four images show one-level and two level x-rays of different cages implanted by different surgeons. The reproducible postoperative results demonstrate that both one and two levels have been treated successfully without supplemental fixation. In cases of segmental instability, supplemental internal fixation using a cervical plating system should be considered.



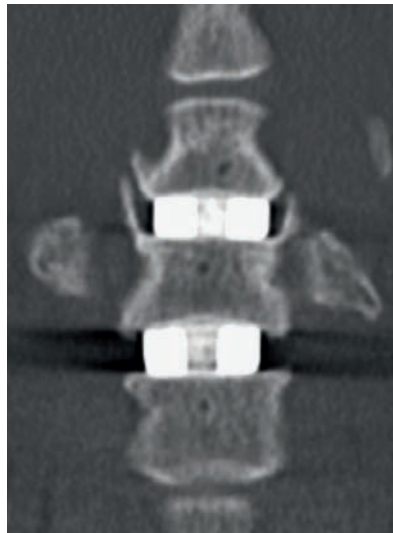
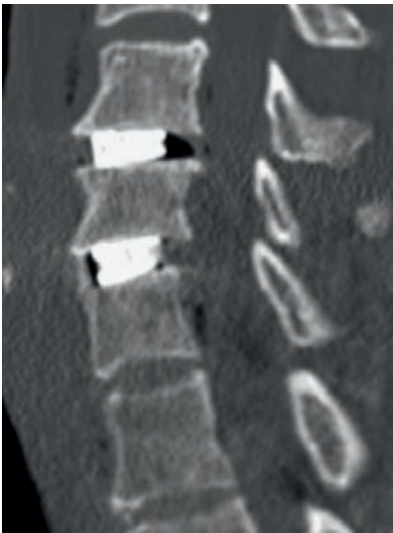
Patient 3 level C5-C6



Patient 4 two level

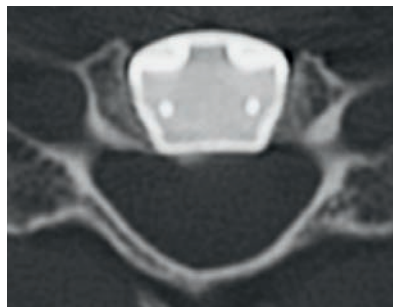
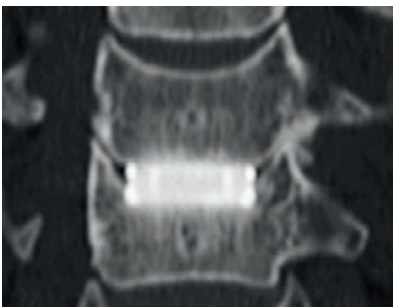
EIT Cervical Cage

Imaging characteristics CT and MRI



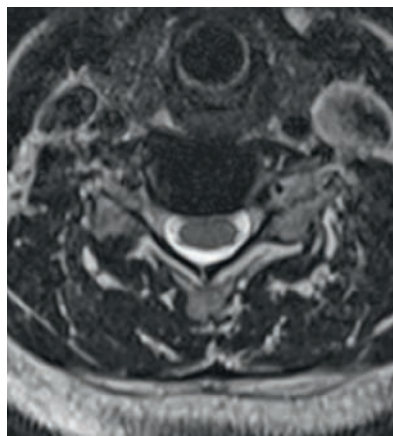
CT images

- Two level C4C5/ C5C6
- Bone-implant interface is well defined and the fusion process can be assessed over time.



CT images

- One level C5C6
- Intimate bone-implant interface. No scattering present at implant level.



MRI images

- One level C5C6
- Adjusted MRI protocol (T2-spc-tra / echo space gradient) ensures good visibility enabling assessment of the central canal and the nerve roots.

Surgical Technique

Preparation and Approach

The patient is positioned using the standard positioning in cases of anterior cervical fusion. X-ray shall be used to confirm identification of the affected disc. Medial anterior approach to C2-T1 is used and the affected disc space is dissected per surgeon's standard operating procedure for anterior cervical discectomy and fusion.



Discectomy and Endplate Preparation

Distraction shall be provided using a Caspar Distractor. Microsurgical decompression is performed relieving all points of neural compression and prominent ventral spondylosis ridges, but care should be taken to preserve the uncovertebral joints and the subchondral bone as much as possible. Use preferred surgical approach and technique for the discectomy using curettes, rongeurs, rasps or high speed drills. The vertebral endplates need to stay intact as supporting surfaces for the maintenance of the distraction and to minimize the risk of subsidence. The implant is intended to laterally rest on the uncovertebral joints. Carefully prepare the disc space symmetrically to ensure an optimal width for a perfect cage fit.



Determination of Cage Size

"Lollipop" Trials are provided in the same overall height, footprint, angulation and dome shape as the final implants to determine the required cage size. Select a Trial based on the suspected height and footprint of the intervertebral space. Two footprints, Small and Large, are available per height. Make sure the side marked "TOP" is cranial and position the Trial in the intervertebral disc space. Evaluate the fit by tactile feedback and if necessary fluoroscopy. Repeat until satisfactory fit is found and then remove Trial. Please note implants are slightly higher (0.25 mm) than the Trials and have a rough contact area to enhance primary stability.

Surgical Technique



Implant - Inserter connection

Open the sterile packaging of the implant size (height and footprint) that was determined with the Trial. Attach the implant to the Inserter:

- » Make sure the Inserter is in open position (tips are apart).
- » Place the implant between the tips. Make sure the side marked 'TOP' on the implant is cranial.
- » Lock the implant with the grip notches between the tips by pressing the grips together and turning the wheel of the Inserter.
- » Confirm that the implant is securely connected to the Inserter.



Implant Insertion

Gently insert the implant into the intervertebral disc space. Make sure the side marked 'TOP' is cranial.

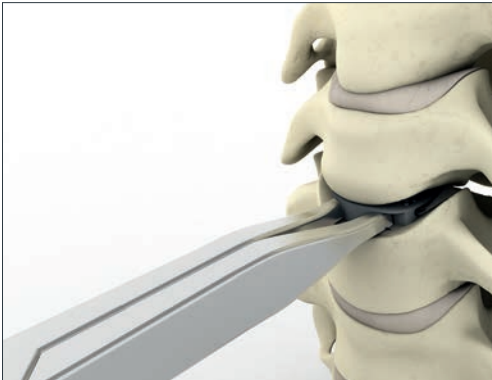
The implant should be positioned posterior to fit the concavity of the inferior endplate of the superior vertebral body. Confirm adequate positioning of the implant with a correct medial and inline implantation; additional markers inside the trabecular structure provide reference points for assessment of the implant's position on X-rays. Care must be taken that the posterior edge of the implant has a 2-3 mm separation from the dura.

Detach the Inserter from the implant.

If desired, gently tap the implant deeper into the vertebral disc space with the Impactor. The vertebral body stops of the Impactor allow the implant to be inserted up to 3 mm deeper into the intervertebral space.

The use of fluoroscopy is recommended during any or all of the implantation steps to ensure proper positioning.

Surgical Technique



Completion of Surgery / Postoperative Care

After implantation of the cage and removal of the Caspar Distractor, wound closure can be performed as usual. Please document which implant was used in the patient files. Patient labels are supplied with each implant for your convenience. The use of the EIT Cervical Cage does not require any specific postoperative care and the patient should be treated according to hospital and medical standards.

Implant Removal / Revision surgery

Removal with the Removal Forceps:

- » Make sure the forceps are in open position (tips are apart).
- » Place the tips of the Removal Forceps into the implant and close the forceps. The tips should now grasp the implant inside the cavities.
- » Gently remove the implant from the intervertebral disc space.

Indications & Contraindications

Indications

The EIT Cellular Titanium® Cervical Cages are indicated for use in skeletally mature patients with degenerative disc disease (defined as discogenic neck pain with degeneration of the disc confirmed by patient history and radiographic studies) and instabilities at one or more levels of the cervical 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® Cervical Cages are used to restore the intervertebral height and to facilitate intervertebral body fusion in the cervical spine (C2-T1) and are placed via an anterior approach. In cases of segmental instability, supplemental internal fixation using a cervical plating system should be considered.

Contraindications

Do not use the EIT Cellular Titanium® Cervical 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 may prevent 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 place excessive stresses on bone and implants, such as severe obesity or degenerative diseases
- » Pregnancy
- » Dependency on pharmaceutical drugs, drug abuse, or alcoholism resulting in a lack of patient cooperation
- » Prior fusion at the level(s) to be treated
- » Demonstrated allergy or foreign body sensitivity to the implant material

Implants & Instruments



Implants

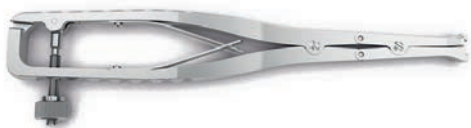
↗	H	S	L
4°	4 mm	CEI4040S	CEI4040L
	5 mm	CEI4050S	CEI4050L
	6 mm	CEI4060S	CEI4060L
	7 mm	CEI4070S	CEI4070L
	8 mm	CEI4080S	CEI4080L

Instruments

EIT Cervical Trials



↗	H	S	L
4°	4 mm	CET2040S	CET2040L
	5 mm	CET2050S	CET2050L
	6 mm	CET2060S	CET2060L
	7 mm	CET2070S	CET2070L
	8 mm	CET2080S	CET2080L



Inserter	CET30101
Impactor	CET30201
Removal forceps	CET60100
Cervical instrument tray	CEC00101





EIT

Emerging
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CEM00002 rev. A

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