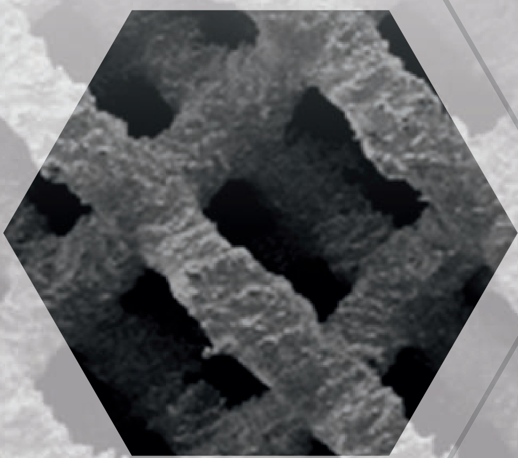
EIT
Emerging
Implant
Technologies

EIT Cellular Titanium®

For Natural Bone Ingrowth and Fast Fusion



3-D PRINTED
TITANIUM
IMPLANTS

Complications and Problems with Spinal Fusion Cages

Four Main Issues

Pseudoarthrosis

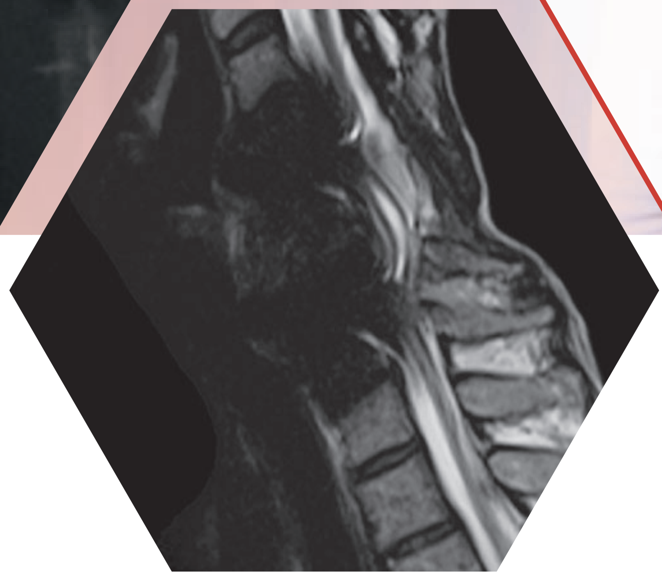
- Pseudoarthrosis is reported up to 30% depending on evaluation method and region (cervical or lumbar)
- Lack in standardization of fusion definition (ROM ≤ 2 ° or ≤ 5 °) results in significant differences in observed fusion percentages

Subsidence and Migration

- PEEK implants are more related to migration, whereas solid titanium cages are more prone to subside in the cervical spine[12,13]
- Difference in stiffness between implant and bone can lead to subsidence

Immune Reaction

- PEEK generates peri-implant fibrosis as a result of local inflammation and cell necrosis[11]
- Due to the lack of BMP-2, BMP-4 and BMP-7 production, there is no osteogenic environment around PEEK[9]



Artefacts

- Disturbing scattering pattern on CT scans due to solid metal and porous tantalum implants
- Significant image distortion of MRI scans around solid metal and porous tantalum implants

EIT Cellular Titanium®

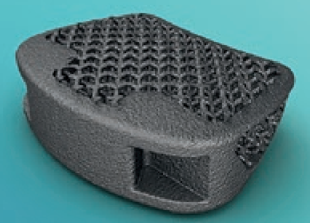
Innovation as a Solution

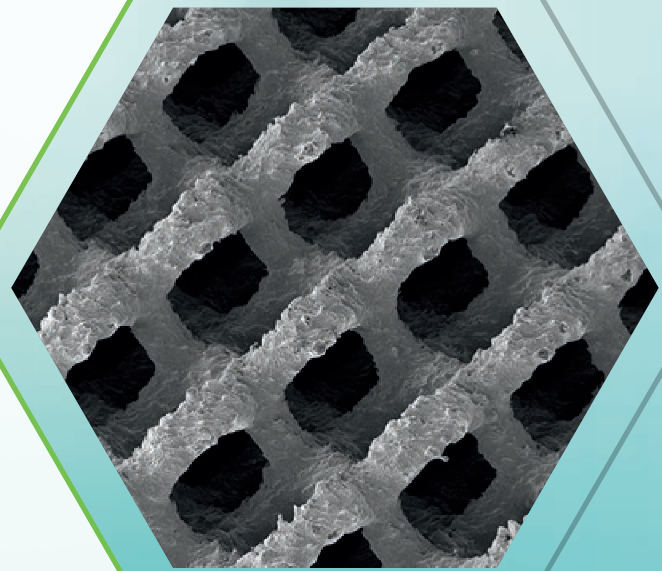
Biocompatibility and Active Osseointegration

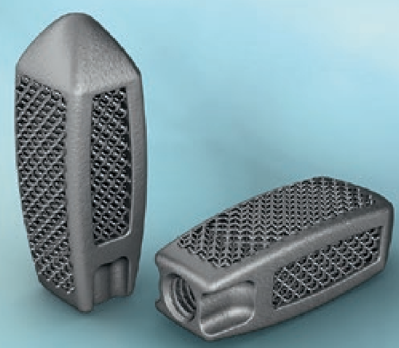
- Addresses the risk of pseudoarthrosis and immune reactions

Primary and Secondary Stability

- Good primary and secondary stability prevents migration







Modulus of Elasticity

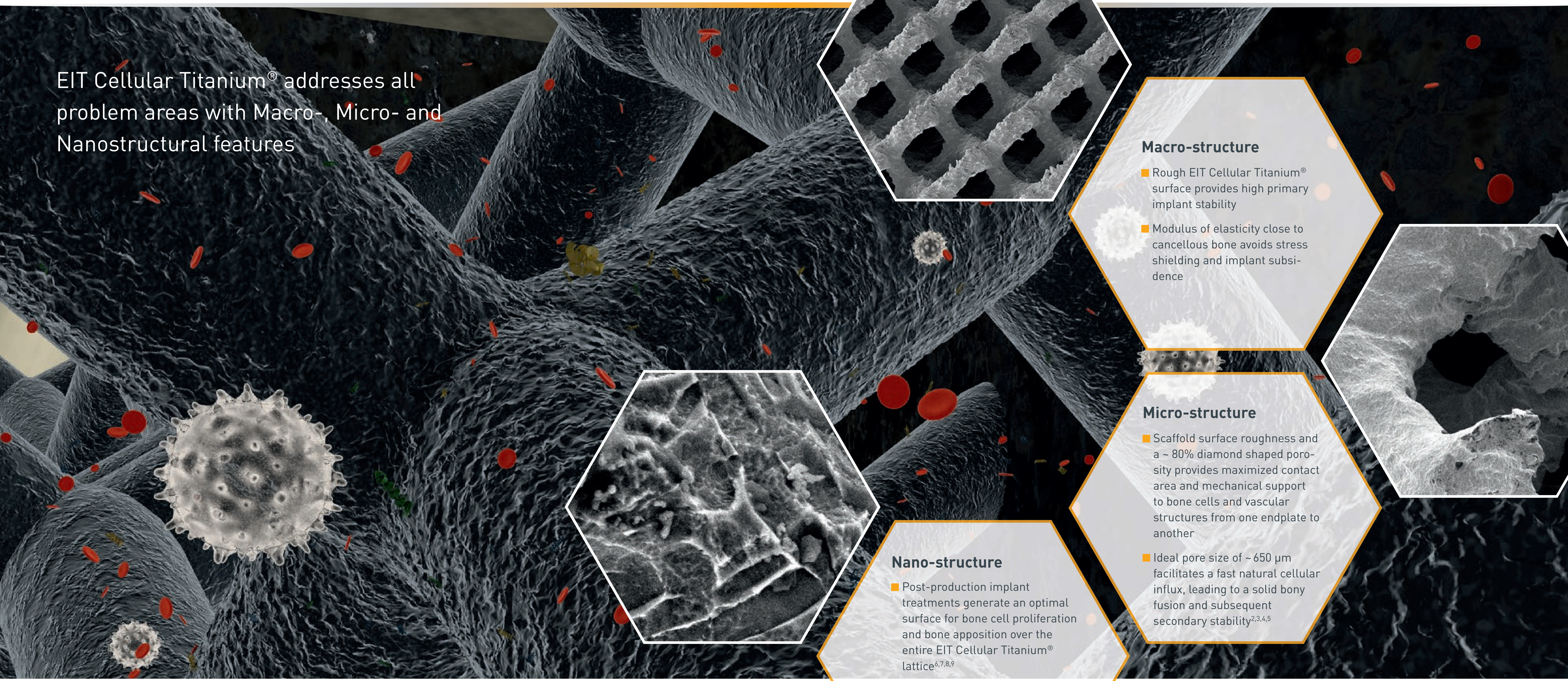
- Optimized stiffness for harmonized load transfer reduces the occurrence of subsidence

Optimal Imaging

- The highly porous titanium structure including X-ray markers ensure a good clinical evaluation with various imaging techniques

EIT Cellular Titanium®

Osteoactive Material Characteristics



EIT Cellular Titanium® addresses all problem areas with Macro-, Micro- and 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

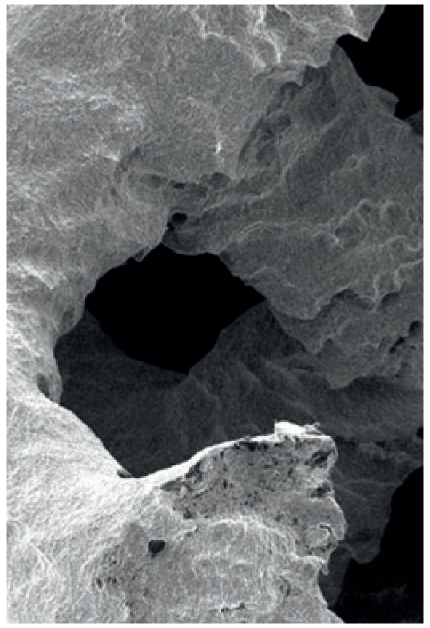
- Scaffold surface roughness and a ~ 80% diamond shaped porosity provides maximized contact area and mechanical support to bone cells and vascular structures from one endplate to another
- Ideal pore size of ~ 650 µm facilitates a fast natural cellular influx, leading to a solid bony fusion and subsequent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

Nano-structure

- Post-production implant treatments generate an optimal surface for bone cell proliferation and bone apposition over the entire EIT Cellular Titanium® lattice[6,7,8,9]
- Nano-roughened titanium alloy increases osteoblast proliferation, BMP response and stimulates an angio-osteogenic environment » enhances bone formation and fusion[9,10,11]

EIT Cellular Titanium®

Biocompatibility and Active Osseointegration



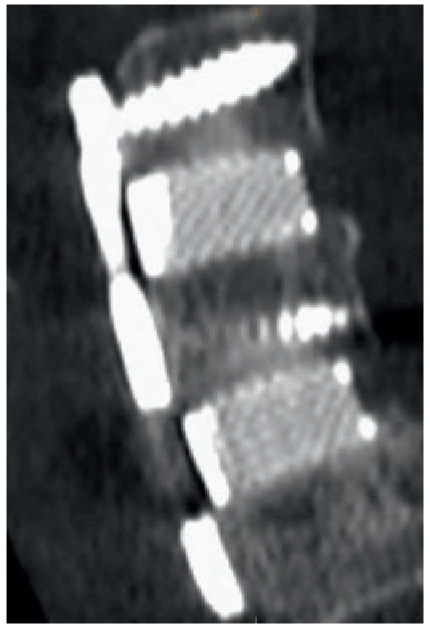
EIT Cellular Titanium® porous structure is designed according to qualitative and quantitative parameters that optimize bone healing and bone ingrowth[3,4,5,6,8,10]

EIT Cellular Titanium® consists of around 80% porosity and a diamond shaped pore size of around 650 µm, mimicking trabecular bone structure

- Bone grafting is not necessary

Porous, roughened titanium induces bone healing due to the increased production of BMP-2, BMP-4 and BMP-7 and anti-inflammatory cytokines[9,11]

- Porous titanium creates an osteogenic environment



Hydrophilic EIT Cellular Titanium®

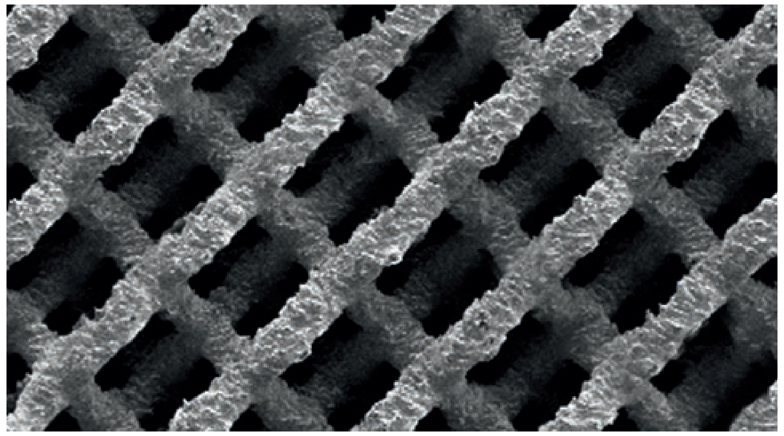
- Maximized blood contact leads to accelerated protein and mesenchymal cell attachment and bone cell differentiation
- Proven biocompatibility of titanium alloy TiAl6V[1]

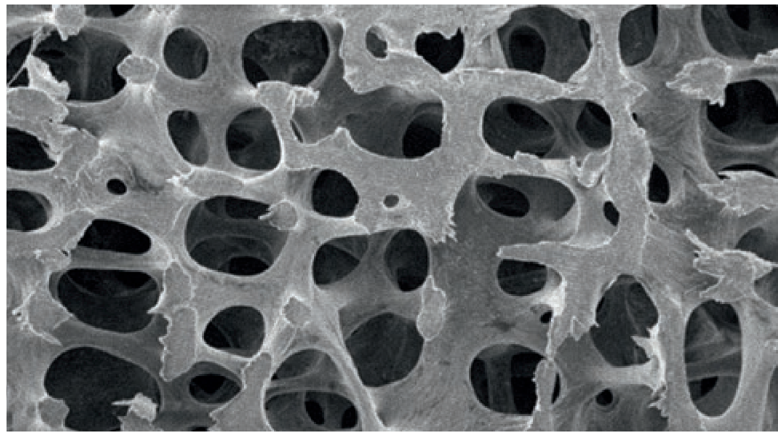
3-D printed titanium implants demonstrate significant more extensive and faster osseointegration than PEEK implants[5]**, which is in line with clinical observations 3 months postoperatively**

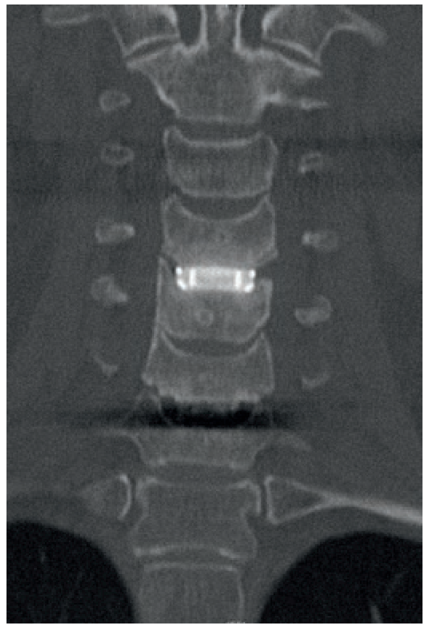
- Intimate titanium-bone contact

EIT Cellular Titanium®

Primary and Secondary Stability







3-D printed porous titanium implants have a better primary and secondary stability compared to PEEK implants[5]

The total rough EIT Cellular Titanium® implant surface sticks onto the vertebral endplate, resulting in an enhanced primary stability

- Initial stability mandatory for successful osseointe-gration

Extensive and fast bone ingrowth generates a solid secondary stability

- Bone grafting is not necessary
- White layer in upper and lower contact area of the cervical cage, visible in CT scans, indicate extensive bone ingrowth

EIT Cellular Titanium®

Modulus of Elasticity

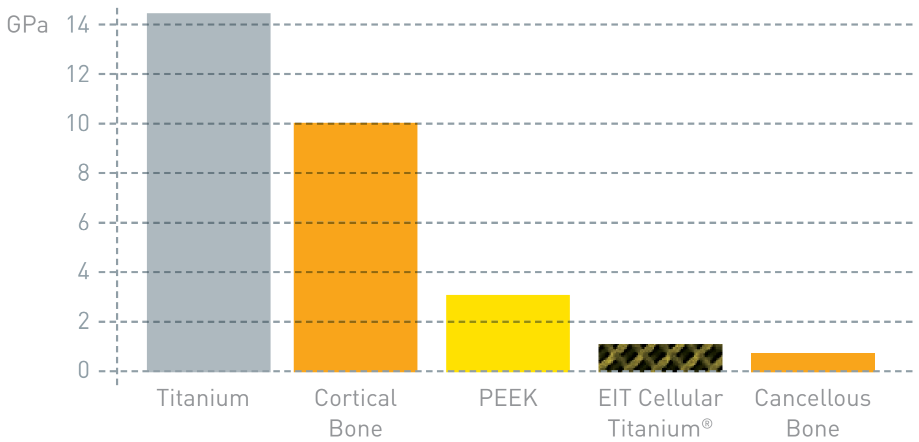
Combination of solid and cellular implant architecture facilitates the rebuilding of natural cortical and cancellous bone structure

- Provides optimal biomechanical and biological environment for natural bone ingrowth

Modulus of elasticity is comparable to bone and acts within physiological effects of Wolf's law

- Avoiding stress-shielding and point contact overloading

Modulus of Elasticity of Implant Materials in Comparison to Bone



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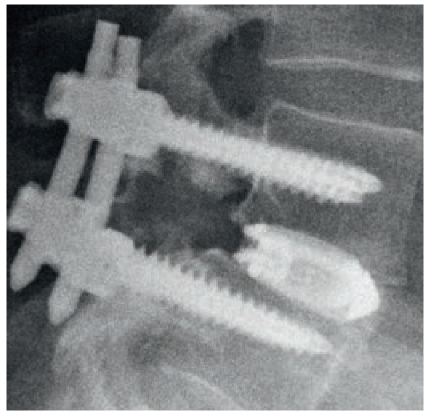
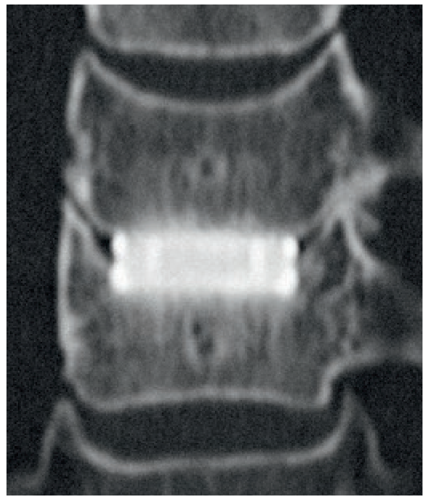
Imaging Features

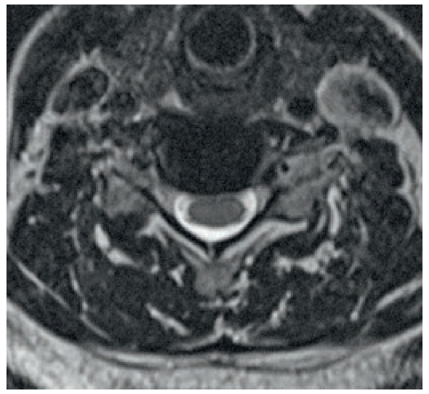
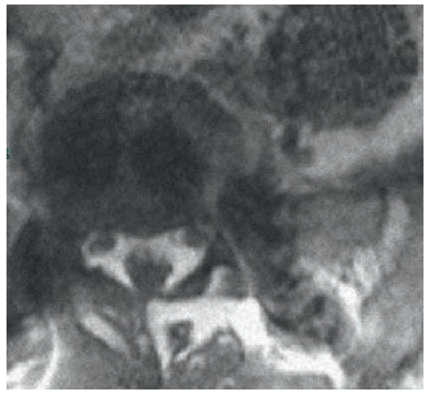
X-ray images

- Excellent imaging characteristics ensure a precise objectivation of the implant position and inter-vertebral fitting
- The porous structure and the X-ray markers can easily be visualized




CT images

- The 80% porosity of titanium reduces the occurrence of arte-facts significant
- The close bone-implant contact can be evaluated. No disturbing scattering is present at the im-plant level. The porous structure and the X-ray markers can easily be detected

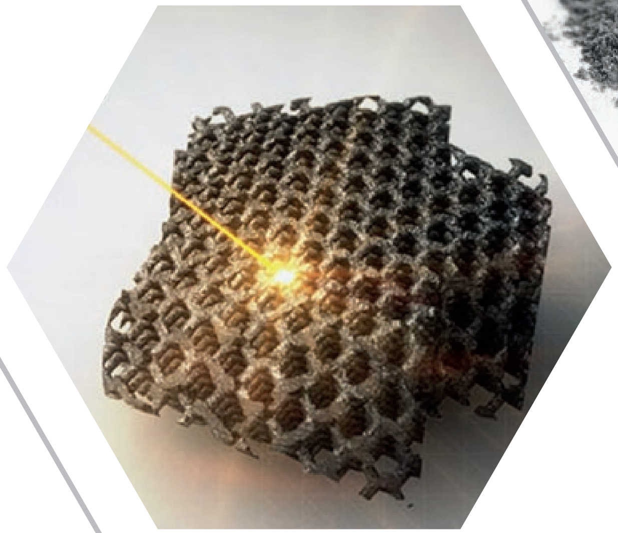



MRI images

- The EIT Cellular Titanium® implants can be evaluated with MRI using an echo space gradient (T2-spc-tra) protocol
- Clear assessment of the central canal and the nerve roots is possible

3-D Printing

Additive Manufacturing



Modern additive manufacturing technologies such as metal 3-D printing or SLM (selective laser melting) are currently revolutionizing many industries like construction, architecture, design, aircraft-industry as well as the medical device industry. Constraints on tooling and machining are eliminated. Additive manufacturing technologies allow the creation of 3-dimensional complex structures. In SLM, the laser beam selectively melts a very thin layer of titanium powder on exact pre-defined spots (programmed CAD file). By repeating this spot-specific titanium melting layer-by-layer, a 3-dimensional structure is formed. After completion of the printing process, the produced parts will be removed from the remaining titanium powder. Medical 3-D printed porous titanium implants receive special end-treatments to ensure a 100% removal of titanium powder from the porous structure. The method is cost-effective and allows a design-driven manufacturing process of geometries that can not be manufactured with traditional machining – almost without limitations. This is ideal for highly specialized spinal implants.

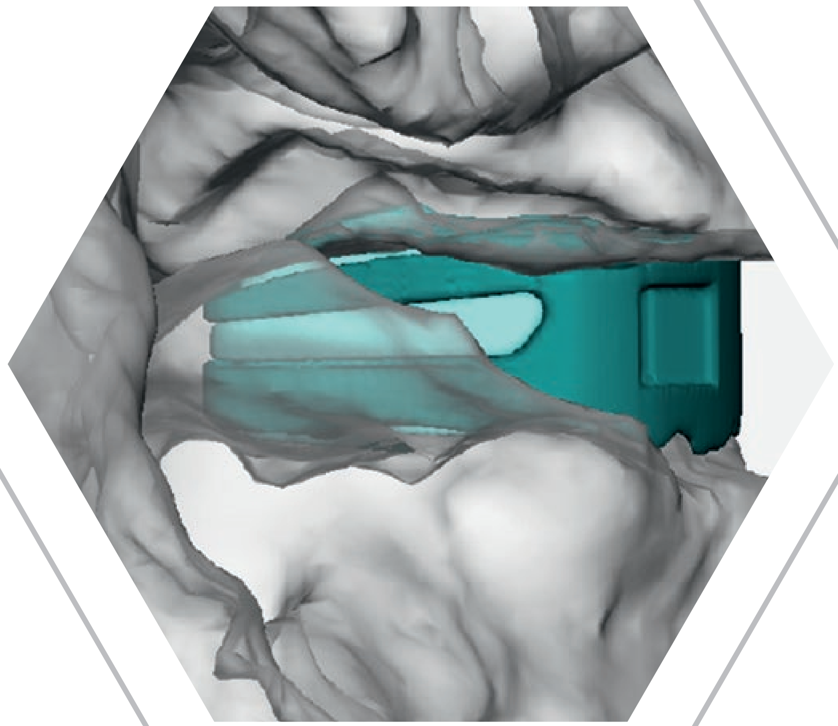
EIT Cellular Titanium® structures are produced with SLM technology and allow the creation of highly porous macro-, micro- and nano-structures in combination with solid frameworks, that mimick cortical and cancellous bone, leading to fast and extensive bone incorporation.

Patient Specific Implants

EIT is working with the Technology Leaders in Metal 3-D Printing

Supported by the German Federal Ministry of Education and Research, EIT is working on the individualization of series implants to adapt anatomical, but also structural patient specific parameters to optimize the bone-implant contact area, allowing an optimal load transfer through the implant. The world first individual cervical 3-D printed titanium cage was realized together with Prof. Spetzger from Karlsruhe for a patient with low bone density and a significant anatomical variation.

Goal of the individualization of series implants is to further reduce typical implant related complications such as implant migration, subsidence into the vertebral bone or delayed fusion.



Literature

EIT Cellular Titanium®

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