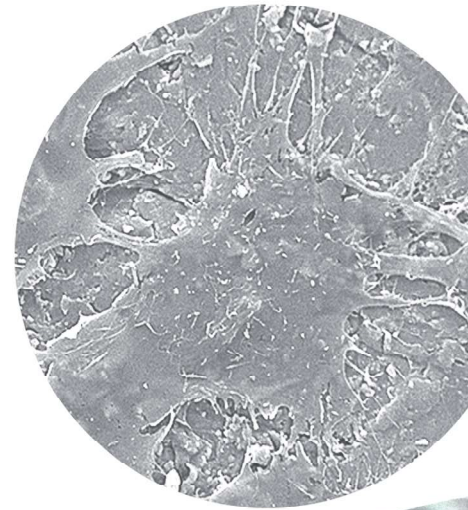




**Orthobion**  
PERFORMANCE IN ORTHOPEDICS



**TSC domed ACIF Cage**

### Why FGOIC<sup>Ti</sup> interbody fusion device?

To achieve successful fusion fast and stable bony bridging, accurately fitting implant while restoring sagittal alignment, preventing long term subsidence are the key points.

In order to find the best solution for the patient surgeons have to make a complex and delicate choice not only between implant shapes and sizes, but between materials, stiffness of the implant and risk of subsidence, hydrophilic and hydrophobic nature of materials and surfaces addressing the risk of non-union when implants are embedded in connective tissue lacking bone formation, the choice between limited imaging and artefact-free observation of the fusion process .... while sitting in front of a specific unique patient situation.

Decision making is a often a painful trade off between risk and benefit, but easier if you can have more benefits and minimizing the risks. Orthobion has done a big effort in research and development over the last years to combine the best characteristics of PEEK and Titanium in order to create an unique, outperforming and proven solution for spinal interbody fusion treatment.

### Achievements

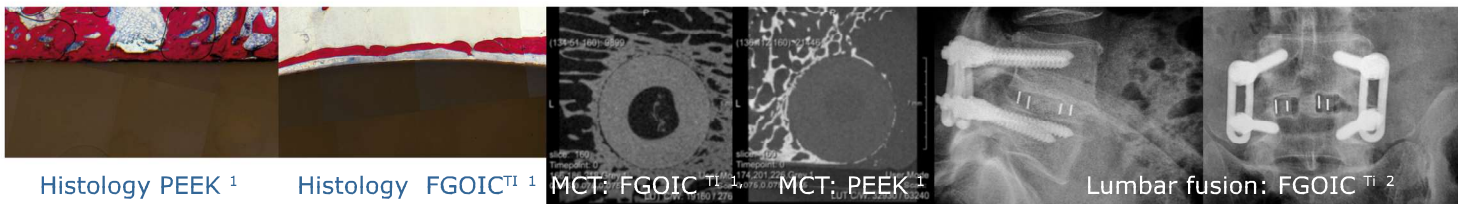
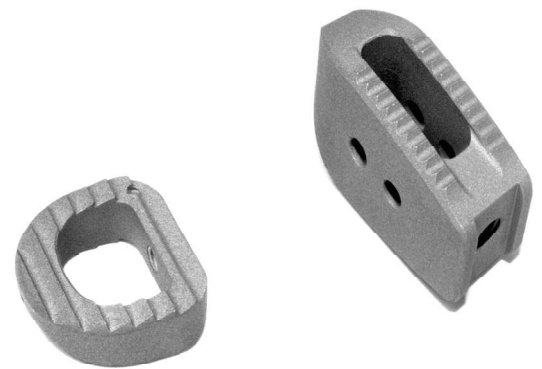
- o Increased micro and nano surface area on entire implant for faster direct bone ongrowth and new formed bone volume compared to PEEK<sup>1</sup>
- o Significant faster and higher fusion rate compared to PEEK<sup>2,3,4,5</sup>
- o Significant Lower risk of flaking and debris during impaction<sup>6</sup>

### Why PEEK body?

- o Excellent long-term biocompatibility<sup>7</sup>
- o Radiolucent<sup>8</sup>
- o Modulus of elasticity similar to cortical bone<sup>9,10,11</sup>
- o Lower risk of subsidence<sup>4,5,12</sup>

### Why Titanium nano topology?

- o Nano topology is radiolucent and has no stiffening<sup>8,10,11,13</sup>
- o Reseachers have noted PEEK cage non-unions when embedded in connective tissue lacking bone formation<sup>14,15</sup>
- o Strong biological affinity<sup>15,16</sup>,
- o Ideal hydrophilic environment for bone formation<sup>16,18</sup>
- o Direct bone to implant anchorage<sup>1,2,18</sup>



Histology PEEK<sup>1</sup>

Histology FGOIC<sup>Ti</sup><sup>1</sup>

MCT: FGOIC<sup>Ti</sup><sup>1</sup>

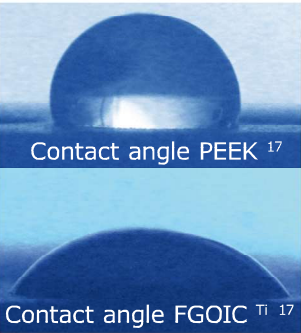
MCT: PEEK<sup>1</sup>

Lumbar fusion: FGOIC<sup>Ti</sup><sup>2</sup>

### Literature

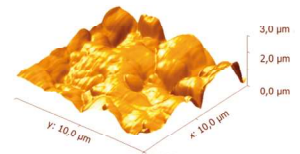
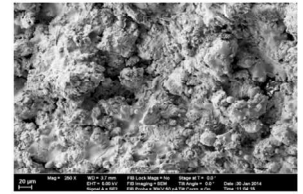
- 1 Meers et al (2015), Fine grained osseointegrative coating improves biocompatibility of PEEK in heterotopic sheep model, International Journal of Spine Surgery, <http://ijssurgery.com/10.14444/2035>
- 2 Meers et al (2018), Randomized controlled trial comparing the efficacy and safety 3 types of PEEK cages for posterior lumbar interbody fusion, to be published
- 3 Chou et al (2008), Efficacy of anterior cervical fusion: comparison of titanium cages, polyetheretherketone (PEEK) cages and autogenous bone grafts.J. Clin Neurosci, 15 1240-1245
- 4 Niu et all (2010), Outcomes of interbody fusion cases used in 1 and 2-levels anterior cervical discectomy and fusion: titanium cages versus polyetheretherketone (PEEK) cages, Spinal Disord Tech, 2010;23(5):310-316
- 5 Cabraja et al (2012), Anterior cervical discectomy and fusion: Comparison of titanium and polyetheretherketone cages, <http://www.biomedcentral.com/1471-2474/13/172>
- 6 Kienle et al (2018), Resistance of coated polyetheretherketone lumbar interbody fusion cages against abrasion under simulated impaction into the disc space, to be publ.
- 7 Rao et al, (2014), Spine interbody implants: material selection and modification, functionalization and bioactivation of surfaces to improve osseointegration, Orthop Surg 2014;6:81-9
- 8 Internal tesing on file: Imaging of FGOIC<sup>Ti</sup>
- 9 Invibio, PO-ENG-SUR-01 09/07.01





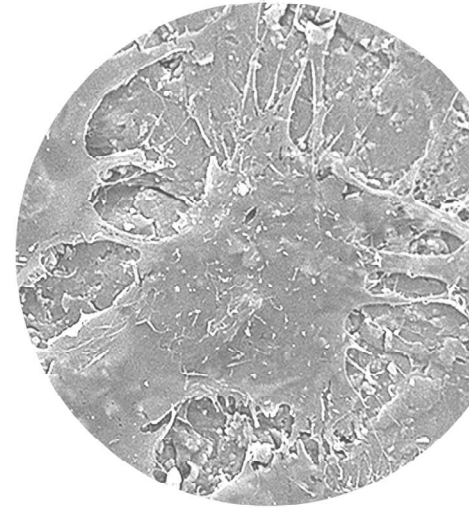
### What is FGOIC<sup>Ti</sup> nano topology?

- o Sub-micron Titanium topology applied to micro roughened PEEK body
- o Nano Ti topology covers entire implant maintaining mechanical properties of PEEK - no stiffening
- o Nano topology is radiolucent - no imaging artefacts
- o Increased micro and nano surface area on entire implant for faster direct bone ongrowth compared to PEEK
- o No flaking, no sharp debris, plastic deformation of implant fails to dislodge FGOIC layer



### Design rationale

Fine-Grained-Osseointegrativ-Coating Titanium (FGOIC<sup>Ti</sup>) is a pure titanium nano surface through a high energy, low temperature coating process. The combination of the best of two worlds results in surface benefits of the excellent osteointegrative characteristics of titanium and the uncompromised mechanical and imaging properties of PEEK body. Orthobion's TSC interbody fusion devices are made of Invibio PEEK coated with a Titanium nano-topology covering the entire implant enabling fast and stable longterm osteointegration for direct bone to implant anchorage. Small Titanium markers are placed to minimize x-ray and MRI imaging artefacts.



Internal testing: plastic deformation of implant fails to dislodge FGOIC<sup>Ti</sup> - no flaking and no sharp debris

#### Literature

10 Internal testing on file: Stiffening effect of FGOIC<sup>Ti</sup> versus Plasma spray coated PEEK  
 11 Vogel et al (2017), Characterization of thick titanium plasma spray coatings on PEEK materials used for medical implants and the influence on the mechanical properties. Journal of the Mechanical Behavior of Biomedical Materials 2017: online first  
 12 Chen et al, (2013), Comparison of titanium and polyetheretherketone (PEEK) cages in the surgical treatment of multilevel cervical spondyloticmyelopathy: a prospective, randomized control study with over 7-year follow-up, Eur Spine J DOI 10.1007/s00586-013-2772  
 13 Heary et al, Elastic modulus in the selection of interbody implants, Journal of Spine Surgery 2017; 3(2): 162-167  
 14 Trouillier et al (2003), Report on two failed posterior lumbar interbody fusions (2003) International Orthopaedics SICOT Online Report E034  
 15 Sugino et al, (2008), Surface Topography Designed to Provide Osteoconductivity to Titanium after Thermal Oxidation, MATERIALS TRANSACTIONS 49 (2008) 3  
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 17 Internal testing on file: Wettability of FGOIC<sup>Ti</sup> compared to PEEK  
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# TSC domed ACIF Cage



SMALL TSC domed ACIF		Length [L] [mm]	Width [B] [mm]	Height [H] [mm]	Lordosis [W] [°]
<b>03.500</b>	TSC domed ACIF	13	14.5	4	domed
<b>03.501</b>	TSC domed ACIF	13	14.5	5	domed
<b>03.502</b>	TSC domed ACIF	13	14.5	6	domed
<b>03.503</b>	TSC domed ACIF	13	14.5	7	domed
<b>03.504</b>	TSC domed ACIF	13	14.5	8	domed
<b>03.505</b>	TSC domed ACIF	13	14.5	9	domed
<b>03.506</b>	TSC domed ACIF	13	14.5	10	domed

MEDIUM TSC domed ACIF		Length [L] [mm]	Width [B] [mm]	Height [H] [mm]	Lordosis [W] [°]
<b>03.507</b>	TSC domed ACIF	15	17	4	domed
<b>03.508</b>	TSC domed ACIF	15	17	5	domed
<b>03.509</b>	TSC domed ACIF	15	17	6	domed
<b>03.510</b>	TSC domed ACIF	15	17	7	domed
<b>03.511</b>	TSC domed ACIF	15	17	8	domed
<b>03.512</b>	TSC domed ACIF	15	17	9	domed
<b>03.513</b>	TSC domed ACIF	15	17	10	domed

LARGE TSC domed ACIF		Length [L] [mm]	Width [B] [mm]	Height [H] [mm]	Lordosis [W] [°]
<b>03.519</b>	TSC domed ACIF	15	19	5	domed
<b>03.514</b>	TSC domed ACIF	15	19	6	domed
<b>03.515</b>	TSC domed ACIF	15	19	7	domed
<b>03.516</b>	TSC domed ACIF	15	19	8	domed
<b>03.517</b>	TSC domed ACIF	15	19	9	domed
<b>03.518</b>	TSC domed ACIF	15	19	10	domed

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