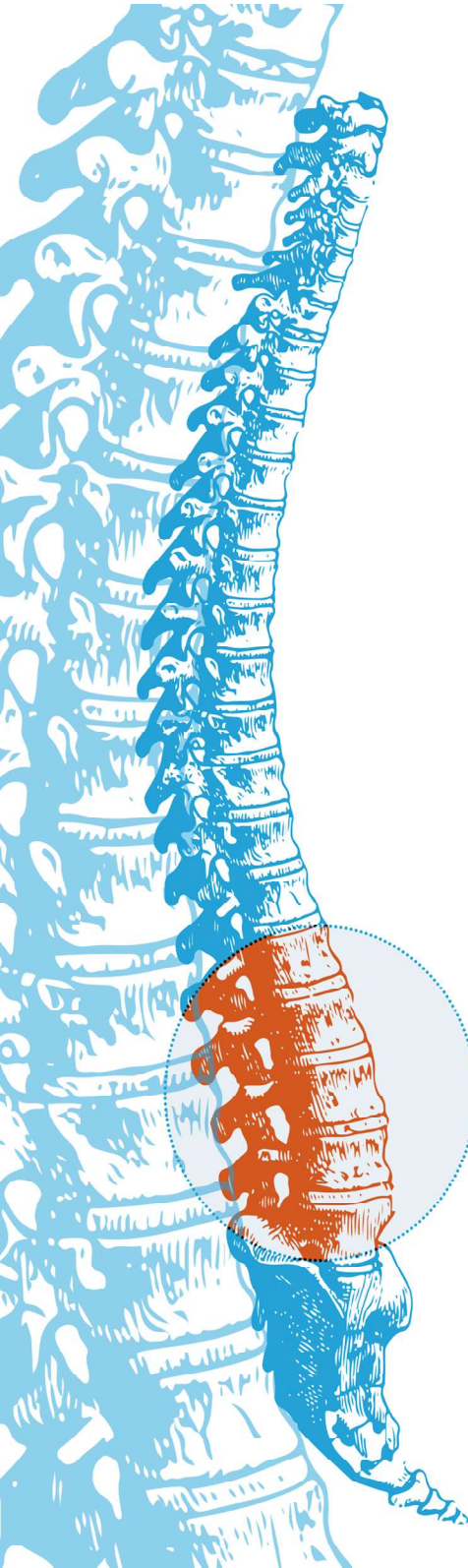


Orthobion

PERFORMANCE IN ORTHOPEDICS



TSC PTLIF Cage

Why FGOIC^{Ti} 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

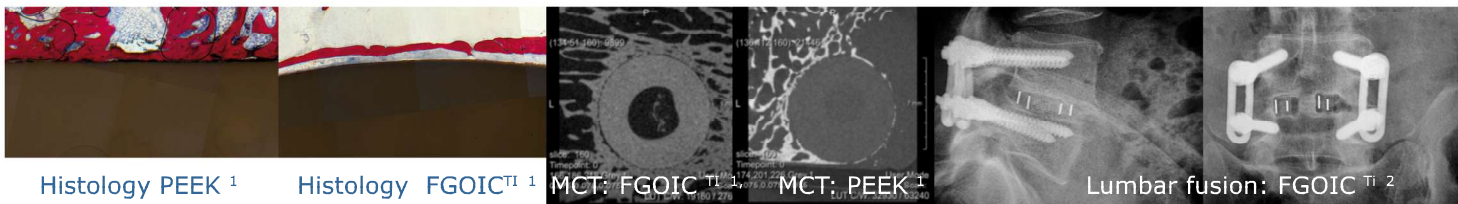
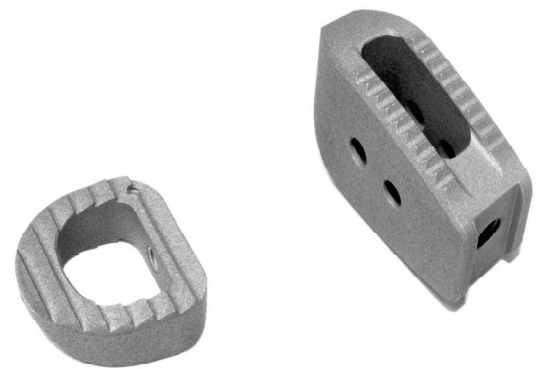
- o Increased micro and nano surface area on entire implant for faster direct bone ongrowth and new formed bone volume compared to PEEK¹
- o Significant faster and higher fusion rate compared to PEEK^{2,3,4,5}
- o Significant Lower risk of flaking and debris during impaction⁶

Why PEEK body?

- o Excellent long-term biocompatibility⁷
- o Radiolucent⁸
- o Modulus of elasticity similar to cortical bone^{9,10,11}
- o Lower risk of subsidence^{4,5,12}

Why Titanium nano topology?

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



Histology PEEK¹

Histology FGOIC^{Ti}¹

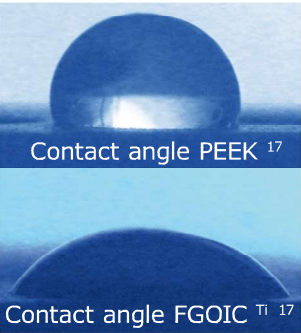
MCT: FGOIC^{Ti}¹

MCT: PEEK¹

Lumbar fusion: FGOIC^{Ti}²

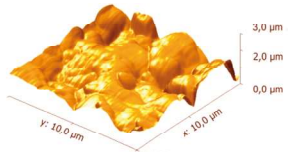
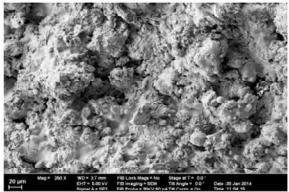
Literature

- 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^{Ti}
- 9 Invibio, PO-ENG-SUR-01 09/07.01



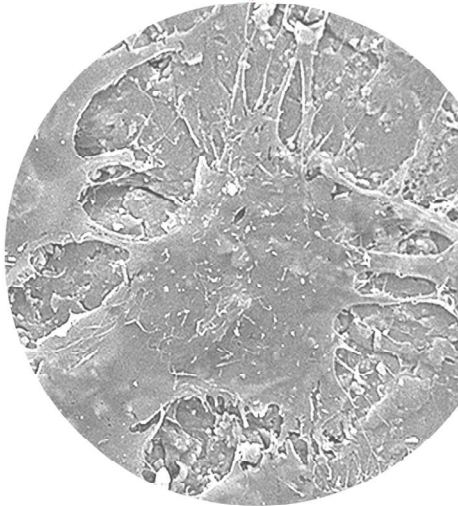
What is FGOIC^{Ti} nano topology?

- 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^{Ti}) 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^{Ti} - no flaking and no sharp debris

Literature

10 Internal testing on file: Stiffening effect of FGOIC^{Ti} 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

16 Zhao et al, (2005), High surface energy enhances cell response to titanium substrate microstructure. J Biomed Mater Res A. 2005 Jul 1;74(1):49-58

17 Internal testing on file: Wettability of FGOIC^{Ti} compared to PEEK

18 Albrektsson et al, (1981), Osseointegrated titanium implants. Requirements for ensuring a long-lasting, direct bone-to-implant anchorage in man, Acta Orthop Scand. 1981; 52(2):155-70.

TSC PTLIF Cage

22 mm TSC PTLIF CE Reference		Length [L] [mm]	Width [B] [mm]	Hight [H] [mm]	Lordosis [W] [mm]
06.120	TSC PTLIF	22	10	7	0°
06.121	TSC PTLIF	22	10	8	0°
06.122	TSC PTLIF	22	10	9	0°
06.123	TSC PTLIF	22	10	10	3°
06.124	TSC PTLIF	22	10	11	6°
06.125	TSC PTLIF	22	10	12	6°
06.126	TSC PTLIF	22	10	13	6°
06.127	TSC PTLIF	22	10	14	6°
06.128	TSC PTLIF	22	10	15	6°
06.424	TSC PTLIF	22	10	11	9°
06.425	TSC PTLIF	22	10	12	9°
06.426	TSC PTLIF	22	10	13	9°
06.427	TSC PTLIF	22	10	14	9°
06.428	TSC PTLIF	22	10	15	9°
25 mm TSC PTLIF CE Reference		Length [L] [mm]	Width [B] [mm]	Hight [H] [mm]	Lordosis [W] [mm]
06.130	TSC PTLIF	25	10	7	0°
06.131	TSC PTLIF	25	10	8	0°
06.132	TSC PTLIF	25	10	9	0°
06.133	TSC PTLIF	25	10	10	3°
06.134	TSC PTLIF	25	10	11	6°
06.135	TSC PTLIF	25	10	12	6°
06.136	TSC PTLIF	25	10	13	6°
06.137	TSC PTLIF	25	10	14	6°
06.138	TSC PTLIF	25	10	15	6°
06.434	TSC PTLIF	25	10	11	9°
06.435	TSC PTLIF	25	10	12	9°
06.436	TSC PTLIF	25	10	13	9°
06.437	TSC PTLIF	25	10	14	9°
06.438	TSC PTLIF	25	10	15	9°

28 mm TSC PTLIF CE Reference		Length [L] [mm]	Width [B] [mm]	Hight [H] [mm]	Lordosis [W] [mm]
06.140	TSC PTLIF	28	10	7	0°
06.141	TSC PTLIF	28	10	8	0°
06.142	TSC PTLIF	28	10	9	0°
06.143	TSC PTLIF	28	10	10	3°
06.144	TSC PTLIF	28	10	11	6°
06.145	TSC PTLIF	28	10	12	6°
06.146	TSC PTLIF	28	10	13	6°
06.147	TSC PTLIF	28	10	14	6°
06.148	TSC PTLIF	28	10	15	6°
06.444	TSC PTLIF	28	10	11	9°
06.445	TSC PTLIF	28	10	12	9°
06.446	TSC PTLIF	28	10	13	9°
06.447	TSC PTLIF	28	10	14	9°
06.448	TSC PTLIF	28	10	15	9°
32 mm TSC PTLIF CE Reference		Length [L] [mm]	Width [B] [mm]	Hight [H] [mm]	Lordosis [W] [mm]
06.150	TSC PTLIF	32	10	7	0°
06.151	TSC PTLIF	32	10	8	0°
06.152	TSC PTLIF	32	10	9	0°
06.153	TSC PTLIF	32	10	10	3°
06.154	TSC PTLIF	32	10	11	6°
06.155	TSC PTLIF	32	10	12	6°
06.156	TSC PTLIF	32	10	13	6°
06.157	TSC PTLIF	32	10	14	6°
06.158	TSC PTLIF	32	10	15	6°
06.455	TSC PTLIF	32	10	12	9°
06.456	TSC PTLIF	32	10	13	9°
06.457	TSC PTLIF	32	10	14	9°
06.458	TSC PTLIF	32	10	15	9°