

TSC TLIF Banana 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 a unique, outperforming and proven solution for spinal interbody fusion treatment.

Achievements

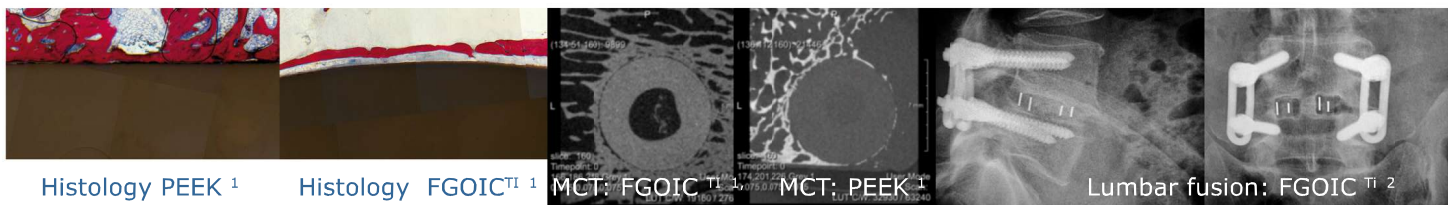
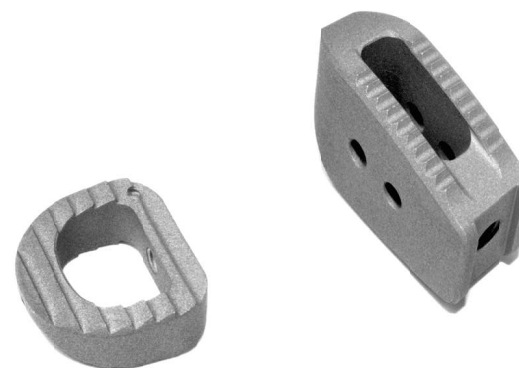
- o Increased micro and nano surface area on entire implant for faster direct bone ongrowth and new formed bone volume compared to PEEK¹
- o Significant faster and higher fusion rate compared to PEEK^{2,3,4,5}
- o Significant Lower risk of flaking and debris during impaction⁶

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 al (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

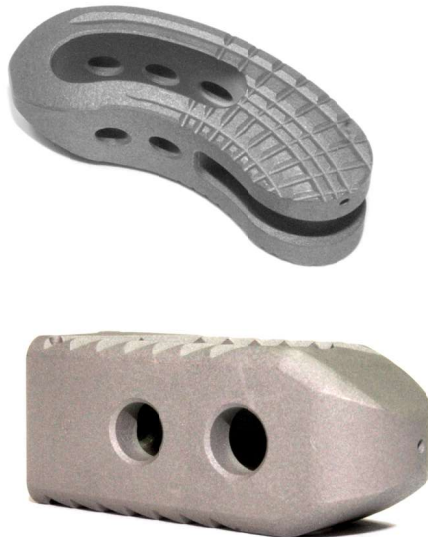
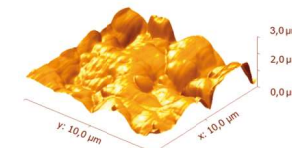
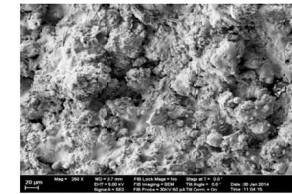
8 Internal testing on file: Imaging of FGOIC^{Ti}

9 Invibio, PO-ENG-SUR-01 09/07.01



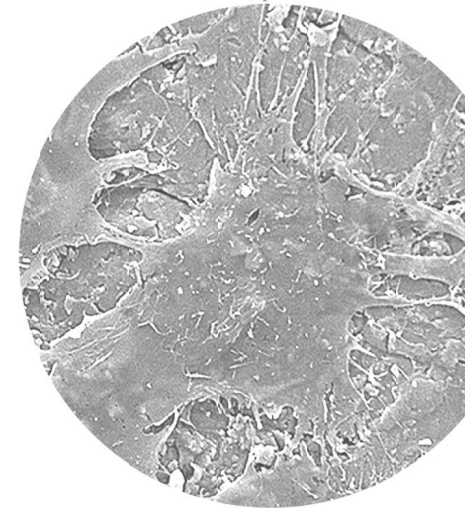
What is FGOIC^{Ti} nano topology?

- 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.



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
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- 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 TLIF Banana Cage

28 mm TSC TLIF Banana CE Reference		Length [L] [mm]	Width [B] [mm]	Height [H] [mm]	Lordosis [W] [mm]
07.100	TSC TLIF Banana	28	10	7	6°
07.101	TSC TLIF Banana	28	10	8	6°
07.102	TSC TLIF Banana	28	10	9	6°
07.103	TSC TLIF Banana	28	10	10	6°
07.104	TSC TLIF Banana	28	10	11	6°
07.105	TSC TLIF Banana	28	10	12	6°
07.106	TSC TLIF Banana	28	10	13	6°
07.107	TSC TLIF Banana	28	10	14	6°
07.108	TSC TLIF Banana	28	10	15	6°

28 mm TSC TLIF Banana CE Reference		Length [L] [mm]	Width [B] [mm]	Height [H] [mm]	Lordosis [W] [mm]
07.120	TSC TLIF Banana	28	10	7	12°
07.121	TSC TLIF Banana	28	10	8	12°
07.122	TSC TLIF Banana	28	10	9	12°
07.123	TSC TLIF Banana	28	10	10	12°
07.124	TSC TLIF Banana	28	10	11	12°
07.125	TSC TLIF Banana	28	10	12	12°
07.126	TSC TLIF Banana	28	10	13	12°
07.127	TSC TLIF Banana	28	10	14	12°
07.128	TSC TLIF Banana	28	10	15	12°

32 mm TSC TLIF Banana CE Reference		Length [L] [mm]	Width [B] [mm]	Height [H] [mm]	Lordosis [W] [mm]
07.110	TSC TLIF Banana	32	10	7	6°
07.111	TSC TLIF Banana	32	10	8	6°
07.112	TSC TLIF Banana	32	10	9	6°
07.113	TSC TLIF Banana	32	10	10	6°
07.114	TSC TLIF Banana	32	10	11	6°
07.115	TSC TLIF Banana	32	10	12	6°
07.116	TSC TLIF Banana	32	10	13	6°
07.117	TSC TLIF Banana	32	10	14	6°
07.118	TSC TLIF Banana	32	10	15	6°

32 mm TSC TLIF Banana CE Reference		Length [L] [mm]	Width [B] [mm]	Height [H] [mm]	Lordosis [W] [mm]
07.130	TSC TLIF Banana	32	10	7	12°
07.131	TSC TLIF Banana	32	10	8	12°
07.132	TSC TLIF Banana	32	10	9	12°
07.133	TSC TLIF Banana	32	10	10	12°
07.134	TSC TLIF Banana	32	10	11	12°
07.135	TSC TLIF Banana	32	10	12	12°
07.136	TSC TLIF Banana	32	10	13	12°
07.137	TSC TLIF Banana	32	10	14	12°
07.138	TSC TLIF Banana	32	10	15	12°