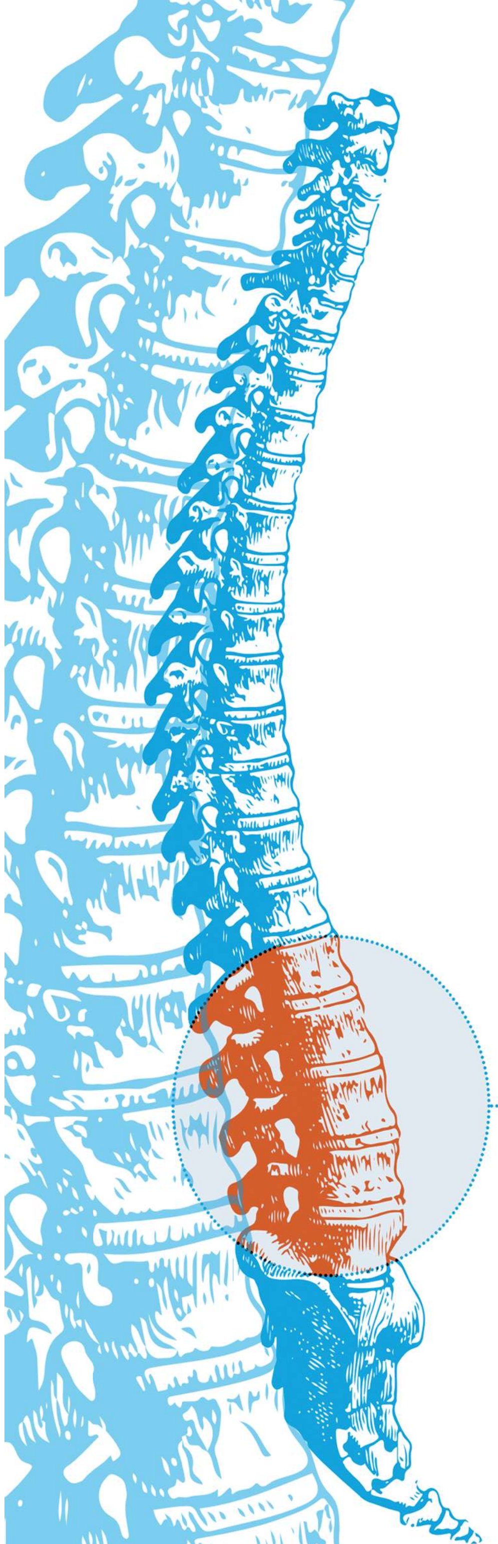
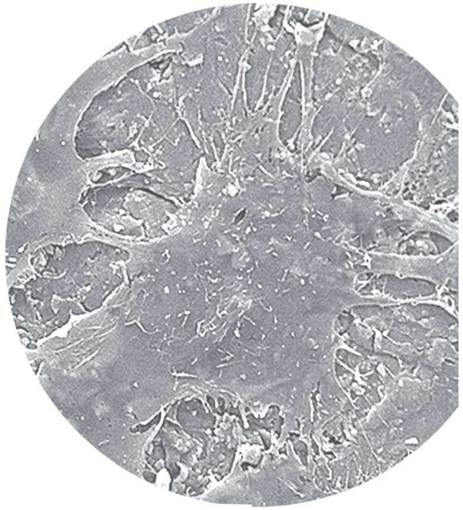


Orthobion

PERFORMANCE IN ORTHOPEDICS



TSC TLIF 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 an complex and delicate choice not only between implant shapes and sizes, but betweenmaterials, stiffness of the implant and risk of subsidence, hydrophilic and hydrophobic nature of materials and surfaces adressing 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[1]

o Significant faster and higher fusion rate compared to PEEK[2,3,4,5]

o Significant Lower risk of flaking and debris during impaction [6]

Why PEEK body?

o Excellent long-term biocompatibility [7]

o Radiolucent [8]

o Modulus of elasticity similar to cortical bone [9,10,11]

o Lower risk of subsidence [4,5,12]

Why Titanium nano topology?

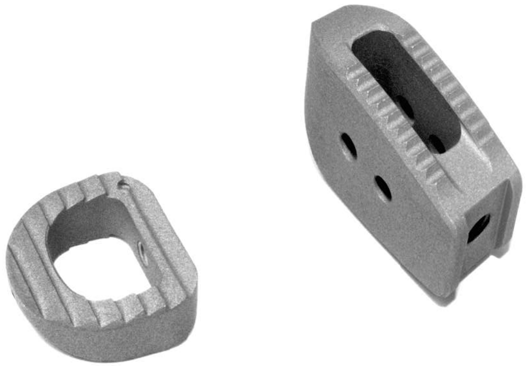
o Nano topology is radiolucent and has no stiffening [8,10,11,13]

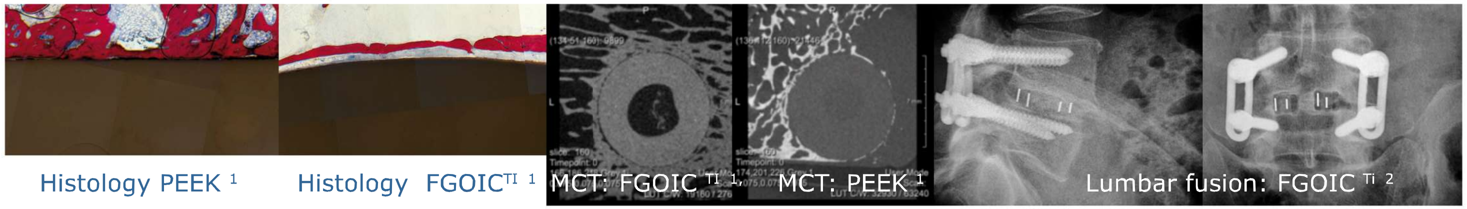
o Reseachers have noted PEEK cage non-unions when embedded in connective tissue lacking bone formation [14,15]

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 PEEK [1] Histology FGOIC[TI] [1] MCT: FGOIC [TI] [1] MCT: PEEK [1] 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

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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

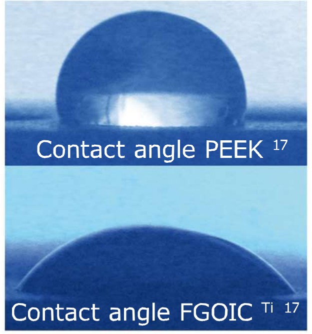
5 Cabraja et al (2012), Anterior cervical discectomy and fusion: Comparison of titanium and polyetheretherketone cages, http://www.biomedcentral.com/1471-2474/13/172

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

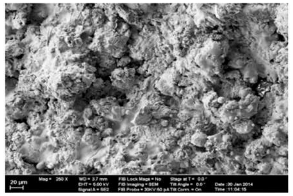
8 Internal tesing on file: Imaging of FGOIC[Ti]

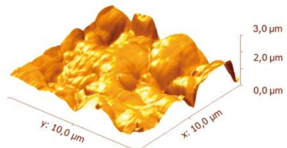
9 Invibio, PO-ENG-SUR-01 09/07.01



What is FGOIC^{Ti} nano topology?

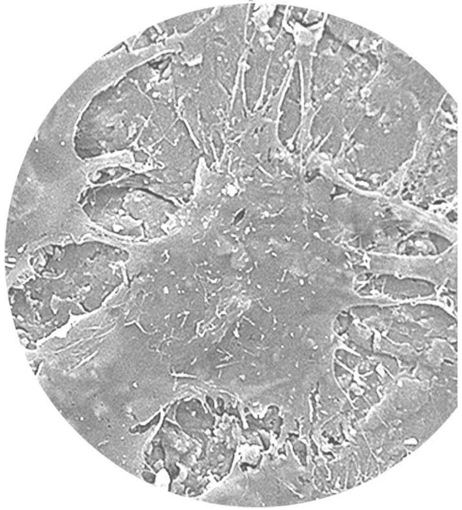
- o Sub-micron Titanium topology applied to micro roughened PEEK body
- o Nano Ti topology covers entire implant maintaining mechanical properties of PEEK - no stiffening
- o Nono topology is radiolucent - no imaging artefacts
- o Increased micro and nano surface area on entire implant for faster direct 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 enabeling 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 at 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
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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,cta Orthop Scand. 1981; 52(2):155-70.

TSC TLIF Cage

30 mm TSC TLIF CE Reference		Length [L] [mm]	Width [B] [mm]	Hight [H] [mm]	Lordosis [W] [mm]
05.550	TSC TLIF	30	12	7	2°
05.551	TSC TLIF	30	12	8	2°
05.552	TSC TLIF	30	12	9	2°
05.553	TSC TLIF	30	12	10	2°
05.554	TSC TLIF	30	12	11	2°
05.555	TSC TLIF	30	12	12	2°
05.556	TSC TLIF	30	12	13	2°
05.557	TSC TLIF	30	12	14	2°

30 mm TSC TLIF CE Reference		30 mm TSC TLIF CE Reference	
05.574	4°		
05.575	4°	**05.620**	8°
05.576	4°	**05.621**	8°
05.577	4°	**05.622**	8°
05.578	4°	**05.623**	8°
05.579	4°	**05.624**	8°
05.580	4°	**05.625**	8°

32 mm TSC TLIF CE Reference		Length [L] [mm]	Width [B] [mm]	Hight [H] [mm]	Lordosis [W] [mm]
05.558	TSC TLIF	32	12	7	2°
05.559	TSC TLIF	32	12	8	2°
05.560	TSC TLIF	32	12	9	2°
05.561	TSC TLIF	32	12	10	2°
05.562	TSC TLIF	32	12	11	2°
05.563	TSC TLIF	32	12	12	2°
05.564	TSC TLIF	32	12	13	2°
05.565	TSC TLIF	32	12	14	2°

32 mm TSC TLIF CE Reference		32 mm TSC TLIF CE Reference	
05.581	4°		
05.582	4°	**05.626**	8°
05.583	4°	**05.627**	8°
05.584	4°	**05.628**	8°
05.585	4°	**05.629**	8°
05.586	4°	**05.630**	8°
05.587	4°	**05.631**	8°

36 mm TSC TLIF CE Reference		Length [L] [mm]	Width [B] [mm]	Hight [H] [mm]	Lordosis [W] [mm]
05.566	TSC TLIF	36	12	7	2°
05.567	TSC TLIF	36	12	8	2°
05.568	TSC TLIF	36	12	9	2°
05.569	TSC TLIF	36	12	10	2°
05.570	TSC TLIF	36	12	11	2°
05.571	TSC TLIF	36	12	12	2°
05.572	TSC TLIF	36	12	13	2°
05.573	TSC TLIF	36	12	14	2°

36 mm TSC TLIF CE Reference		36 mm TSC TLIF CE Reference	
05.588	4°		
05.589	4°	**05.632**	8°
05.590	4°	**05.633**	8°
05.591	4°	**05.634**	8°
05.592	4°	**05.635**	8°
05.593	4°	**05.636**	8°
05.594	4°	**05.637**	8°

Orthobion
PERFORMANCE IN ORTHOPEDICS

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