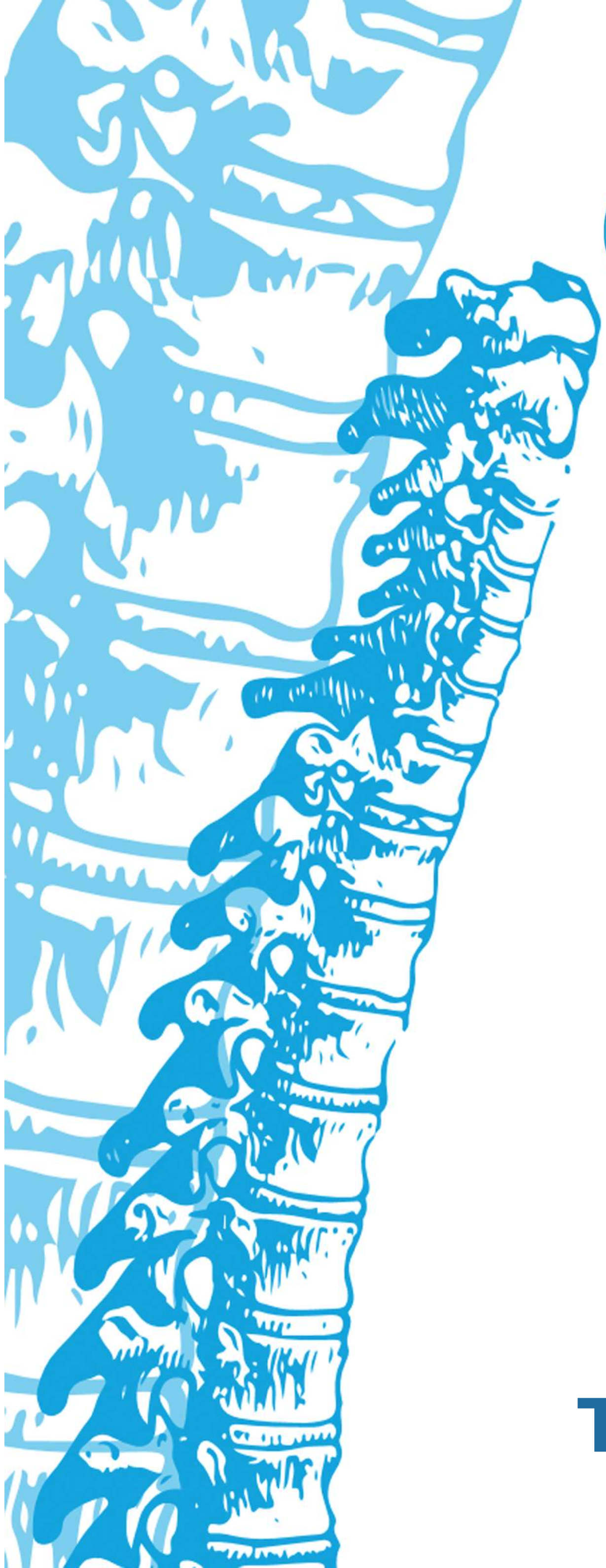

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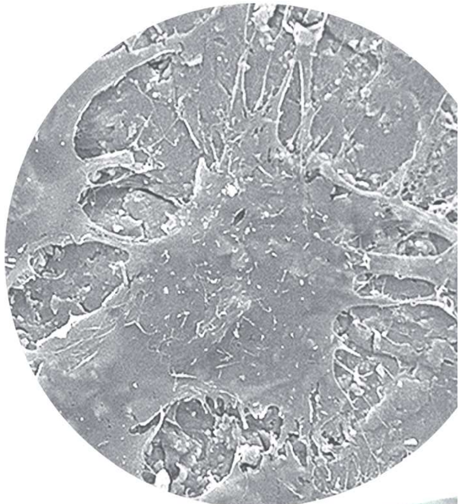
PERFORMANCE IN ORTHOPEDICS



TSC domed ACIF 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

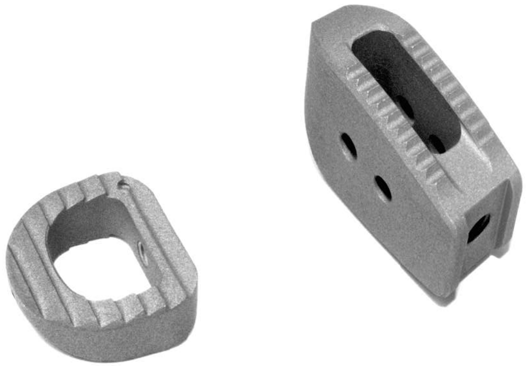
- o Increased micro and nano surface area on entire implant for faster direct bone ongrowth and new formed bone volume compared to PEEK[1]
- o Significant faster and higher fusion rate compared to PEEK[2,3,4,5]
- o Significant Lower risk of flaking and debris during impaction [6]

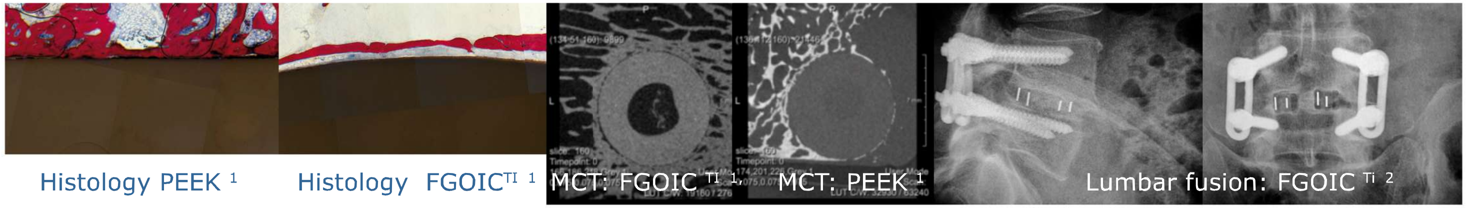
Why PEEK body?

- 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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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
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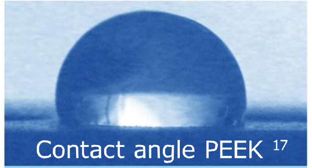
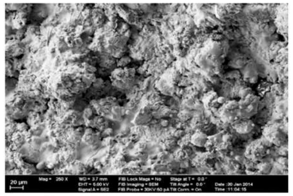
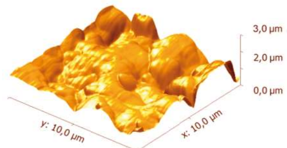


What is FGOIC^{Ti} nano topology?

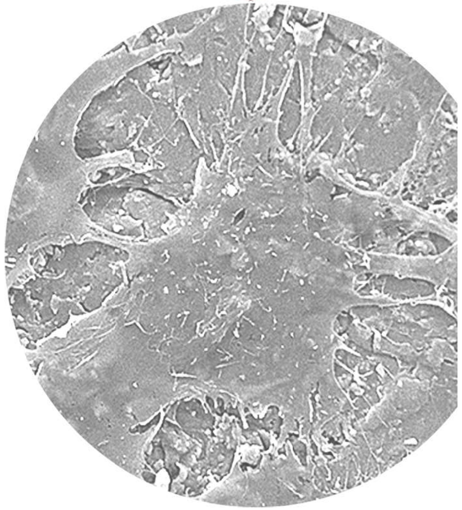
- o Sub-micron Titanium topology applied to micro roughened PEEK body
- o Nano Ti topology covers entire implant maintaining mechanical properties of PEEK - no stiffening
- o Nono topology is radiolucent - no imaging artefacts
- o Increased micro and nano surface area on entire implant for faster direct 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
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17 Internal testing on file: Wettability of FGOIC ^{Ti} compared to PEEK
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TSC domed ACIF Cage

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

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

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

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