



# spineFuse Implant System

## TP-LIF

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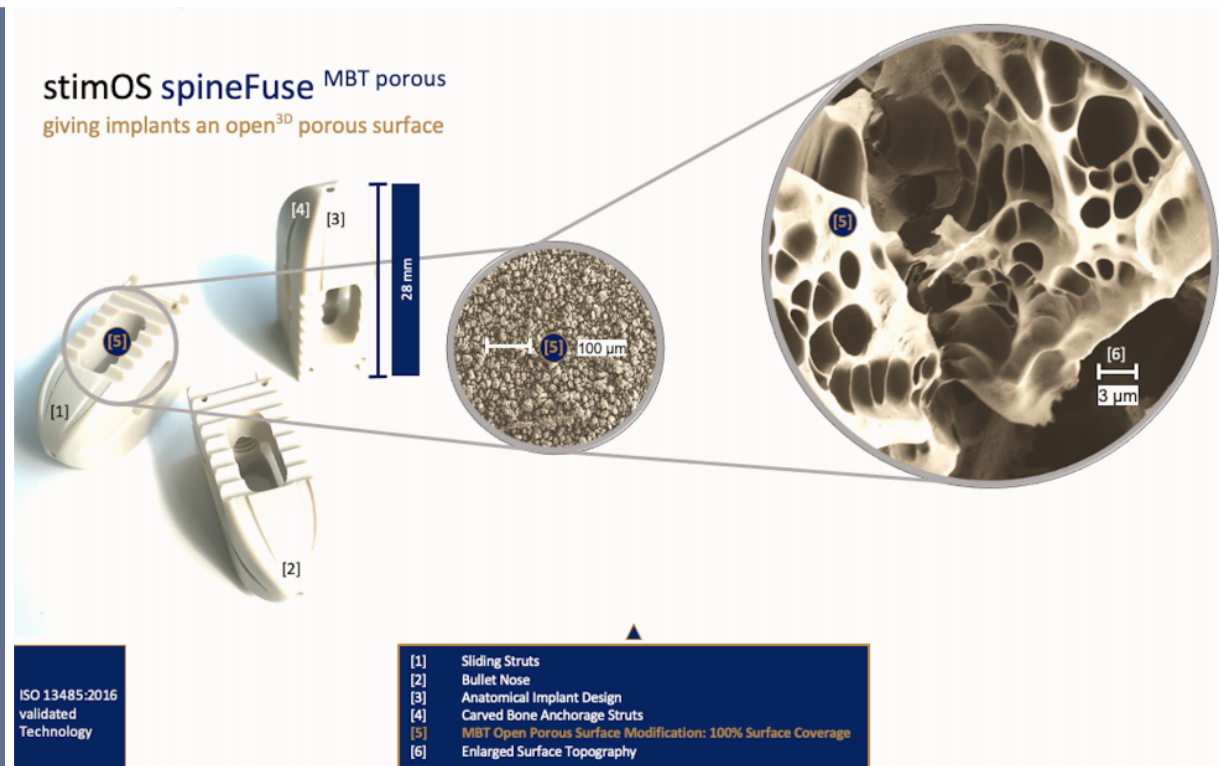
### About stimOS

stimOS GmbH, a privately held research-company and 13485:2016 certified legal manufacturer, was founded in 2015. stimOS develops innovative technologies and procedures to refine, functionalize and activate implant materials. As a supplier and service provider, stimOS makes this technology available to implant manufacturers. In addition, the company also offers services in the field of product development and certification and develops with the product line spineFuse<sup>MBT</sup> implants for spinal fusion surgery.

stimOS products, for implant surface functionalization under the label MBT, are available in three different categories: MBTg, MBTv and MBTti. All stimOS surface functionalization technologies show superiority regarding the growth of bone cells. Comparative data made by the Universities of Constance, Zurich and Charité Berlin demonstrate excellent results for all MBT surface treatments compared to currently available implant materials.

### Contact

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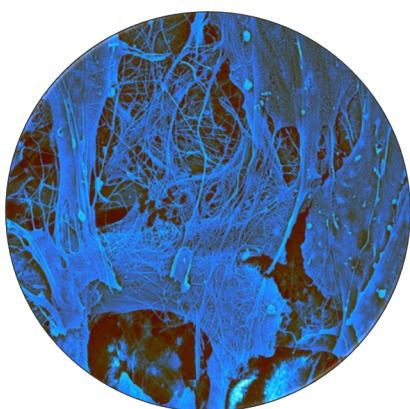
spineFuse – MBT surface technology: principle of operations. stimOS GmbH.

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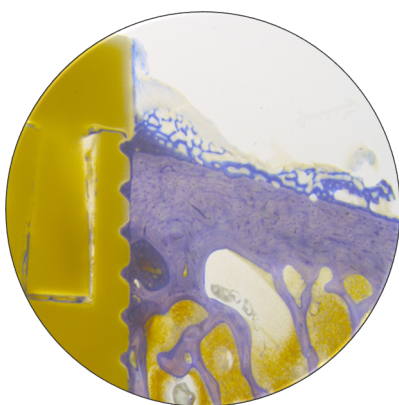
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spineFuse – implant geometry. stimOS GmbH.



spineFuse – MBT surface initiates early bone formation. In-vitro cell test result. stimOS GmbH.



spineFuse – MBT surface results in dense, early and high % BIC. Comparative animal model results. stimOS GmbH.

## Material and characteristics

**Pure PEEK implant core.** Compared to titanium, PEEK materials have X-ray transparency and an elasticity that corresponds to bone. Because of these properties, PEEK has become the most important thermoplastic substitute and alternative for titanium implants. As implants are supposed to last a lifetime, the materials used for them must be biostable as well as mechanically durable. For long, this was an exclusive domain of titanium\* or cobalt-chromium\*. However, spine implants made of PEEK are now being used more and more frequently.

**The higher elasticity of PEEK compared to titanium reduces stress peaks at the interface between bone and spinal implant.**

**stimOS' MBT surface functionalization.** To improve the anchorage of implants in the body, implants are coated. Two (main) technologies are available on the market: titanium plasma spray coatings and CaP dip coatings. Both methods have disadvantages: they don't adhere sufficiently to the implant surface. Titanium coatings also have the problem of corrosion. In addition, there is experimental evidence of the carcinogenicity of TiO<sub>2</sub> in mammals\*.

**spineFuse implant are metal free\*.** MBT is a unique biochemical procedure that initiates early and healthy bone formation, giving optimal anchorage in healthy bone but also in osteoporotic bone.

In addition, MBT is anti-inflammatory.

**Next generation material characteristics.** With spineFuse implants, stimOS has developed 3D-open-porous polymer implants that guarantee stable healing by means of a bone-like topography of the implants and a bone-identical implant surface. Therefore, the implant is not perceived by the body as a foreign material, but as "the body's own" bony material. The healing process is initiated more quickly, and the implant is anchored stably in the body.

**stimOS MBT technology: Stealth technology for implants.**

\* Wang JJ, Sanderson BJS, Wang H (2007) Cyto- and geno- toxicity of ultrafine TiO<sub>2</sub> particles in cultured human lymphoblastoid cells. *Mutat Res*

Broggini N, McManus LM, Hermann JS, Medina R, Schenk RK, Buser D, Cochran DL (2006) Peri-implant inflammation defined by the implant-abutment interface. *JDent Res*

Haynes DR, Rogers SD, Hay S et al (1993) The differences in toxicity and release of bone-resorbing mediators induced by titanium and cobalt-chromium wear particles. *JBone Joint Surg*

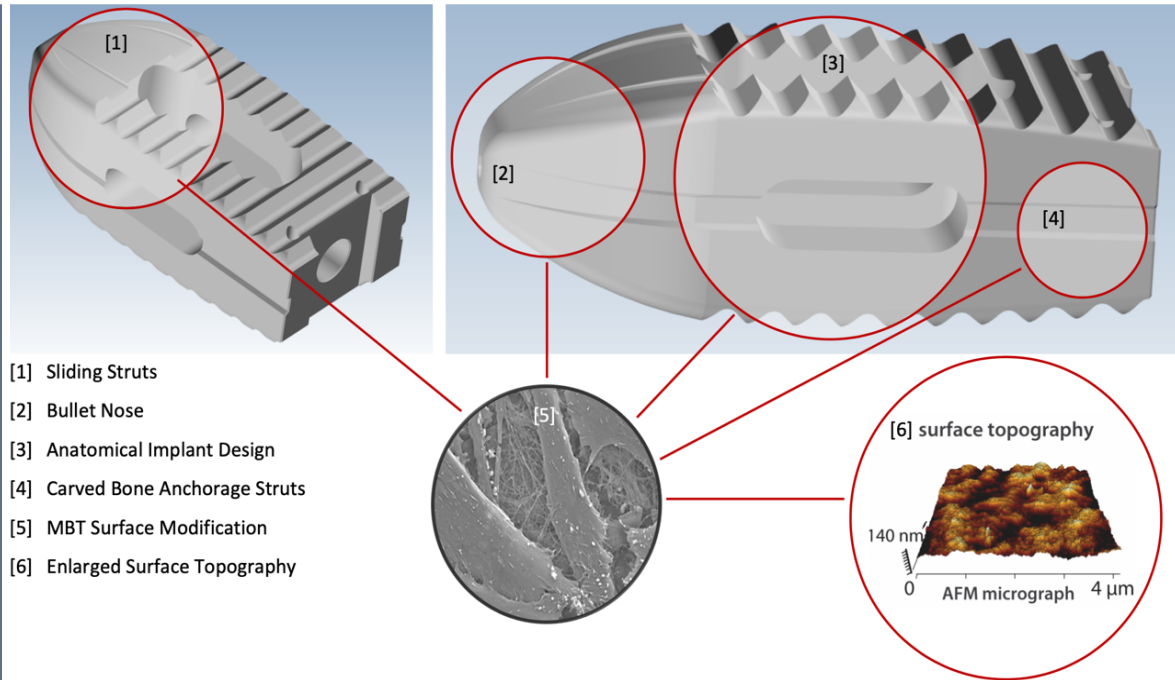
Maloney WJ, Lane Smith R, Castro F, Schurman D (1993) Fibroblast response to metallic debris in vitro. *JBone Joint Surg*

Case CP, Langkamer VG, James C, Palmer MR, Kemp AJ, Heap PF, Solomon L (1994) Widespread dissemination of metal debris from implants. *JBone Joint Surg*

Urban RM, Jacobs JJ, Tomlinson MJ, Gavrilovic J, Black J, Peoc'h M (2000) Dissemination of wear particles to the liver, spleen, and abdominal lymph nodes of patients with hip or knee replacement. *JBone Joint Surg*

Goodman SB (2007) Wear particles, periprosthetic osteolysis and the immune system. *Biomaterials*

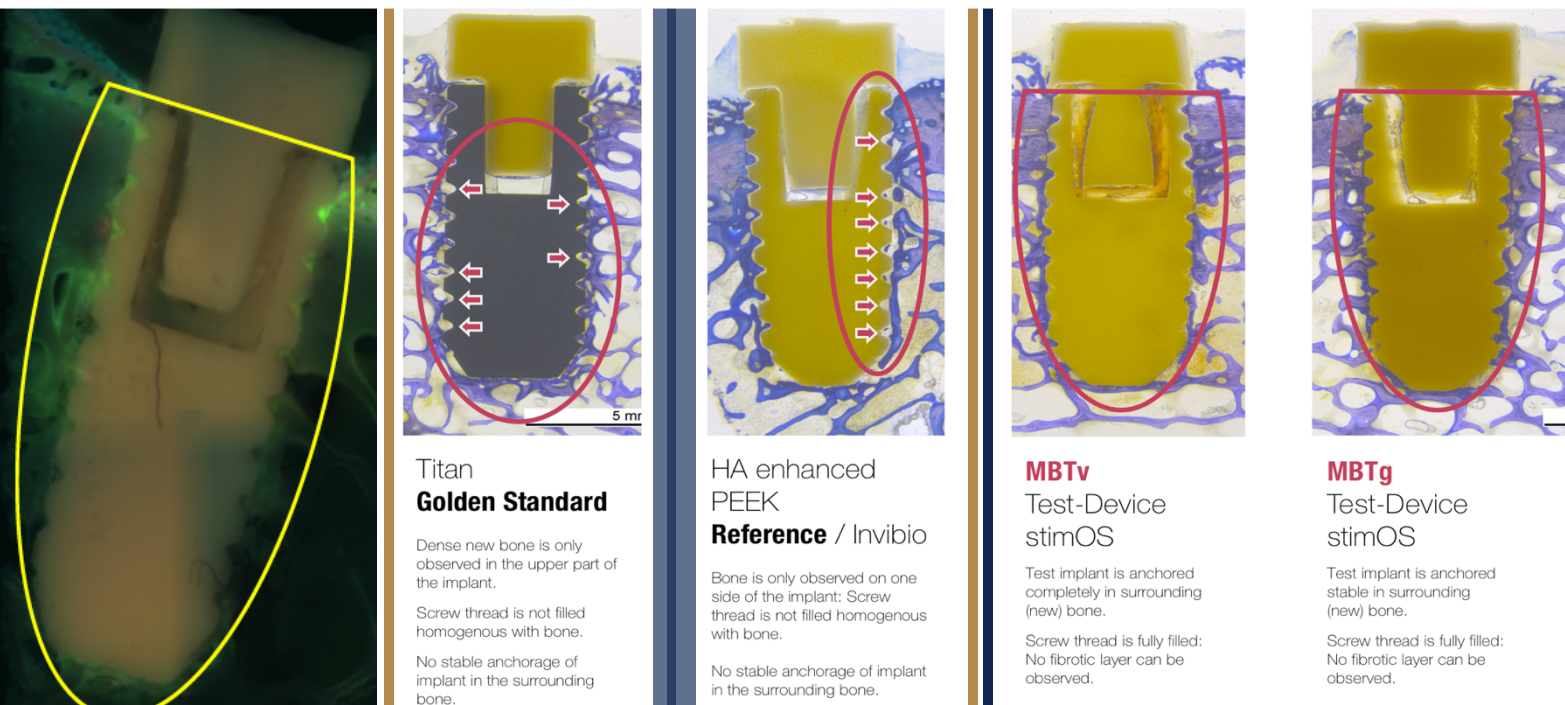
Afaq F, Abidi P, Matin R, Rahman Q (1998) Cytotoxicity, pro-oxidant effects and antioxidant depletion in rat lung alveolar macrophages exposed to ultrafine titanium dioxide. *J Appl Toxicol*



spineFuse – Design study. stimOS GmbH.

## Implant design

spineFuse implants have a geometry that follows the patient's anatomy of the spine. All implants are designed to restore the natural shape of the spinal column. Sliding struts [1] on the implants body and it's bullet nose [2] guarantee an easy insertion by sliding in the implant between the vertebrae. The anatomical implant design [3] guarantees a perfect fit. Carved out bone-anchorage struts [4] allow bone cells to better adhere to the implant's surface by providing ideal grip. MBT surface modification and finish [5] provide for an enlarged surface topography [6] resulting in optimal primary stability and best anchorage of the implant - avoiding migration and subsidence.



spineFuse – Comparative animal model results. stimOS GmbH.

## Implant characteristics

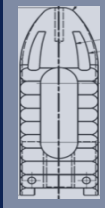
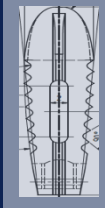
spineFuse implants are defined by the three characteristics of ideal osseointegration: The (a) highest possible BIC value in combination with the (b) highest possible proportion of healthy mature bone and the (c) lowest possible proportion of new bone, which can result in sclerotic bone.

Comparative data - including a comparative sheep model - performed by the Universities of Constance, Zurich and Charité Berlin demonstrate excellent results for all MBT surface treatments compared to currently available implant materials. In-vivo testing showed an (a) overall high BIC in combination with the (b) highest proportion of healthy mature cortical bone and the (c) lowest proportion of newly formed bone and therefore met the three characteristics of stable osseointegration.

# spineFuse Implant System

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### Implant Sizing

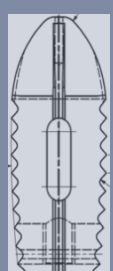
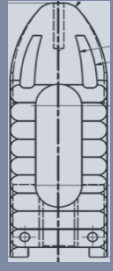
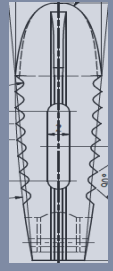

Description of Product: spineFuse Lumbar Cages PEEK <sup>MBT</sup>					
Reference	Length	Width	Height	Lordosis	TP-LIF
01.001	25 mm	10 mm	8 mm	0°	
01.002	25 mm	10 mm	9 mm	0°	
01.003	25 mm	10 mm	10 mm	0°	
01.004	25 mm	10 mm	11 mm	0°	
01.005	25 mm	10 mm	12 mm	0°	
01.006	25 mm	10 mm	13 mm	0°	
01.007	25 mm	10 mm	8 mm	4°	
01.008	25 mm	10 mm	9 mm	4°	
01.009	25 mm	10 mm	10 mm	4°	
01.010	25 mm	10 mm	11 mm	4°	
01.011	25 mm	10 mm	12 mm	4°	
01.012	25 mm	10 mm	13 mm	4°	
01.013	25 mm	10 mm	8 mm	8°	
01.014	25 mm	10 mm	9 mm	8°	
01.015	25 mm	10 mm	10 mm	8°	
01.016	25 mm	10 mm	11 mm	8°	
01.017	25 mm	10 mm	12 mm	8°	
01.018	25 mm	10 mm	13 mm	8°	

spineFuse – References conventional PLIF. stimOS GmbH.

# spineFuse Implant System

## TP-LIF

### Implant Sizing

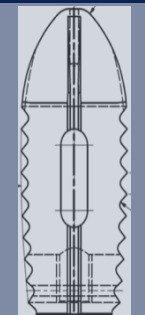
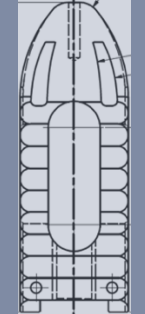
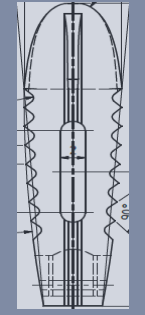

Description of Product: spineFuse Lumbar Cages PEEK <sup>MBT</sup>					
Reference	Length	Width	Height	Lordosis	TP-LIF
01.019	28 mm	10 mm	8 mm	0°	
01.020	28 mm	10 mm	9 mm	0°	
01.021	28 mm	10 mm	10 mm	0°	
01.022	28 mm	10 mm	11 mm	0°	
01.023	28 mm	10 mm	12 mm	0°	
01.024	28 mm	10 mm	13 mm	0°	
01.025	28 mm	10 mm	14 mm	0°	
01.026	28 mm	10 mm	15 mm	0°	
01.027	28 mm	10 mm	8 mm	4°	
01.028	28 mm	10 mm	9 mm	4°	
01.029	28 mm	10 mm	10 mm	4°	
01.030	28 mm	10 mm	11 mm	4°	
01.031	28 mm	10 mm	12 mm	4°	
01.032	28 mm	10 mm	13 mm	4°	
01.033	28 mm	10 mm	14 mm	4°	
01.034	28 mm	10 mm	15 mm	4°	
01.035	28 mm	10 mm	8 mm	8°	
01.036	28 mm	10 mm	9 mm	8°	
01.037	28 mm	10 mm	10 mm	8°	
01.038	28 mm	10 mm	11 mm	8°	
01.039	28 mm	10 mm	12 mm	8°	
01.040	28 mm	10 mm	13 mm	8°	
01.041	28 mm	10 mm	14 mm	8°	
01.042	28 mm	10 mm	15 mm	8°	

spineFuse – References Long PLIF. stimOS GmbH.

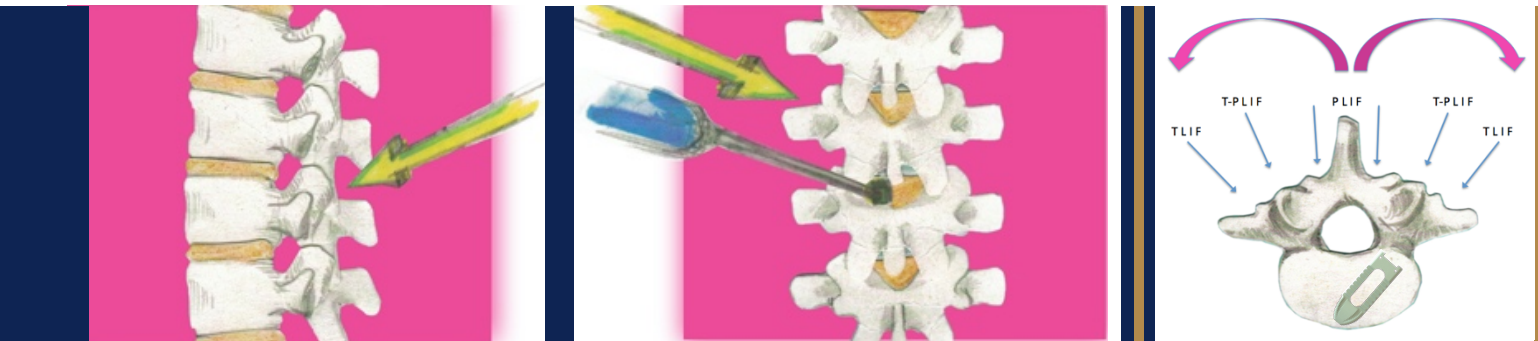
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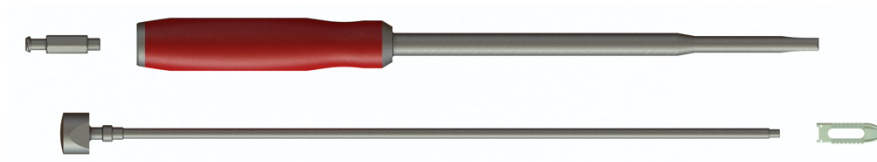
### Implant Sizing

Description of Product: spineFuse Lumbar Cages PEEK <sup>MBT</sup>					TP-LIF
Reference	Length	Width	Height	Lordosis	
01.043	32 mm	10 mm	8 mm	0°	
01.044	32 mm	10 mm	9 mm	0°	
01.045	32 mm	10 mm	10 mm	0°	
01.046	32 mm	10 mm	11 mm	0°	
01.047	32 mm	10 mm	12 mm	0°	
01.048	32 mm	10 mm	13 mm	0°	
01.049	32 mm	10 mm	14 mm	0°	
01.050	32 mm	10 mm	15 mm	0°	
01.051	32 mm	10 mm	8 mm	4°	
01.052	32 mm	10 mm	9 mm	4°	
01.053	32 mm	10 mm	10 mm	4°	
01.054	32 mm	10 mm	11 mm	4°	
01.055	32 mm	10 mm	12 mm	4°	
01.056	32 mm	10 mm	13 mm	4°	
01.057	32 mm	10 mm	14 mm	4°	
01.058	32 mm	10 mm	15 mm	4°	
01.059	32 mm	10 mm	8 mm	8°	
01.060	32 mm	10 mm	9 mm	8°	
01.061	32 mm	10 mm	10 mm	8°	
01.062	32 mm	10 mm	11 mm	8°	
01.063	32 mm	10 mm	12 mm	8°	
01.064	32 mm	10 mm	13 mm	8°	
01.065	32 mm	10 mm	14 mm	8°	
01.066	32 mm	10 mm	15 mm	8°	
01.067	32 mm	10 mm	12 mm	12°	
01.068	32 mm	10 mm	13 mm	12°	
01.069	32 mm	10 mm	14 mm	12°	
01.070	32 mm	10 mm	15 mm	12°	Available also in custom made sizes and geometries

spineFuse – References TP-LIF. stimOS GmbH.

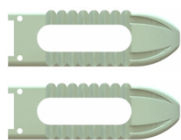


spineFuse – Surgical approach. Options and alternatives. stimOS GmbH.



## Surgical technique and indications

### spineFuse PLIF



- Mechanical back pain (usually attributed to disc degeneration, called degenerative disc disease)
- Spinal stenosis (where there is an associated deformity)
- Isthmic spondylolisthesis
- Fractures
- Tumors

### spineFuse TLIF oblique



- Mechanical back pain (usually attributed to disc degeneration, called degenerative disc disease)
- Spinal stenosis (where there is an associated deformity)
- Isthmic spondylolisthesis
- Fractures
- Tumors



# Hospital and MedTech industry demand transparent quality standards for medical surfaces and implant surface functionalization

## **stimOS takes on new challenges for the benefit of patient safety, and aiming for new standards and benchmarks**

In the field of personalized medicine, in connection with "smart implants" and in the interaction of various industries, new solutions are constantly being researched to give implant materials, special properties and enhanced characteristics. On several levels and multiple MedTech market segments, there is a need for implant materials that heal optimally within a patient's anatomy and remaining stably anchored as well as free of any adverse effects.

To provide implant materials with such improved osseointegrative properties, the industry offers a wide variety of solution methods, ranging from coating processes to novel composite materials.

### **Uniform evaluation system: S.P.E.L. - Safety and Performance Evidence Level**

In a joint scientific positioning paper, experts from industry, research, clinics and regulatory affairs are now calling for uniform evaluation procedures and, with S.P.E.L., have created such a system. An evaluation matrix that makes it easy and objectively understandable for decision-makers and economic players in the healthcare system to assess the safety and performance-relevant properties of different surface treatments, which are being offered by industry today.

### **Transparency strategy called for by industry, clinics and regulatory authorities**

*"Ultimately, these properties concern patient safety. We understand this demand for transparency," explains Dietmar Schaffarczyk, Managing Director of stimOS GmbH. "We will take this challenge and aim to set new standards and benchmarks."*

In a pilot project, stimOS GmbH has developed the S.P.E.L. report, which objectively and comparably analyzes and evaluates the safety and performance characteristics of the surface functionalization MBT (Mimicking Bone Technology), patented by stimOS.

*"In connection with the demand for "transparency", we will make this report available to all interested groups and parties," says Schaffarczyk, describing the transparency strategy of stimOS GmbH.*

Surface technologies can make a decisive contribution to relieving the burden on post-op patient healing, clinic costs, medico-economic burdens and all other unmentioned stakeholders involved, as the right technologies can avoid infections, long recovery times, rehabilitation measures or potential re-operations.

The scientific article is published by John Wiley & Sons Ltd on behalf of Society of Chemical Industry and is made available by the publisher in the open access procedure.

**Title:** Polyetheretherketone implant surface functionalization technologies and the need for a transparent quality evaluation system

**DOI:** <https://doi.org/10.1002/pi.6162>

**Publication:** Polymer International

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stimOS GmbH is committed to providing highest quality products, services and technologies. stimOS is an ISO 13485:2016 certified Legal Manufacturer of spinal and dental implants. In addition, stimOS is a supplier of Golden Standard surface functionalization technologies. By using the latest technologies and applying strict quality control procedures, we've become known for having the best products in the industry. Get in touch to learn more.

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