PRESS RELEASE **ENGLISH Version**

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

January 18, 2021. **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 osseo-integrative properties, the industry offers a wide variety of solution methods, ranging from coating processes to novel composite materials.

Uniform evaluation system: SPEL - Safety and Performance Evidence Level

All research projects and industrial applications have one thing in common: a lack of transparent, cross-industry and generally valid systems and procedures for objective quality evaluations but also safety and performance characteristics, of these surface finishes.

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 quality standards. 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 is now developing 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.

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Abstract

For bone implants, osseointegration- realized by an early bone–implant contact and bone formation, and a firm implant anchorage- is of primary importance to secure a proper implant function and to avoid implant loosening or inflammation resulting in necessary revision surgeries causing pain to the patients and immense costs.

Particularly polyetheretherketone (PEEK) is a promising implant material due to its mechanical properties close to bone. But PEEK is entirely bio-inert, hindering osseointegration, thus making implant surface functionalization necessary.

Many different surface functionalization technologies have been reported of both physical and chemical nature. The same is true for the other prominent implant materials, titanium and ceramics. Although they already show inherently better osseointegration than PEEK, they are much harder and stiffer than bone and brittle in the case of ceramics. Surface functionalization, which can be subdivided into surface coating and material modification, needs to be judged from a quality and safety viewpoint. However, a literature research resulted in the realization that no quality standard yet exists for implant surface functionalizations. This makes it difficult to near impossible to compare the safety and performance of different surface-functionalized bone implants, clearly showing the need to establish a transparent quality evaluation system for bone implants.

This perspective article gives the state of the art and then develops a quality evaluation system based on six main categories as important benchmarks for the quality of surface-functionalized bone implant materials. A simple catalog of questions can be answered, and from the resulting scores the Safety and Performance Evidence Level (SPEL) representing the safety and quality of a given implant can be calculated as a percentage. This simple SPEL system allows an easy and transparent judgment and comparison of bone implants, ensuring the easy identification of safe and well-performing high-quality bone implants in the future.

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^{MBT} 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.

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PRESS RELEASE DEUTSCHE Version

Klinik und MedTech-Industrie fordern transparentes Qualitätssiegel auch für medizinische Oberflächen und Oberflächenfunktionalisierungen von Implantaten

stimOS stellt sich neuen Herausforderungen und setzt neue Standards zum Wohle der Patientensicherheit

18. Januar 2021. **Im Bereich der personalisierten Medizin, im Zusammenhang mit „Smart Implants" und im Zusammenspiel verschiedener Industrien werden immer neue Lösungswege erforscht, um Implantatmaterialien mit besonderen Eigenschaften auszustatten. An oberster Stelle steht der Wunsch von Materialherstellern, Klinikern und Implantatherstellern nach einem Implantatmaterial, das im Körper des Patienten bestens einheilt, verankert und frei von unerwünschten Nebenwirkungen ist.**

Um Implantatmaterialien mit diesen verbesserten osseointegrativen Eigenschaften auszustatten, werden von der Industrie unterschiedlichste Lösungsmethoden angeboten. Dies reicht von verschiedensten Beschichtungsverfahren bis hin zu neuartigen Komposite-Materialien.

Einheitliches Bewertungssystem: SPEL – Safety and Performance Evidence Level

Eins ist all diesen Forschungsarbeiten oder Industrieanwendungen jedoch gemein: Es fehlt an einem transparenten, branchenübergreifenden und allgemeingültigen System und Verfahren, um Qualitäts-, Sicherheits- und Leistungsmerkmale dieser Oberflächenveredelungen objektiv bewerten zu können.

In einem gemeinsamen wissenschaftlichen Positionspapier fordern nun Autoren aus Industrie, Forschung, Klinik und Zulassung ein einheitliches Bewertungsverfahren und haben mit SPEL ein System und eine Bewertungsmatrix geschaffen, die es Entscheidern und Wirtschaftsakteuren im Gesundheitssystem einfach und objektiv verständlich macht, den Qualitätsstandard sowie die sicherheits- und leistungsrelevanten Eigenschaften unterschiedlicher Oberflächenbehandlungen, die die Industrie anbietet, zu beurteilen.

Transparenzstrategie von Industrie, Kliniken und Zulassung gefordert

„Schließlich geht es bei diesen Eigenschaften um Patientensicherheit. Wir verstehen diese Forderung nach Transparenz", erklärt Dietmar Schaffarczyk, Geschäftsführer der stimOS GmbH. Wir werden uns dieser Herausforderung stellen.

Die stimOS GmbH erstellt in einem Pilotprojekt nun den SPEL-Report, der objektiv und vergleichbar die Sicherheits- und Leistungsmerkmale der von stimOS patentierten Oberflächenfunktionalisierung MBT (Mimicking Bone Technology) analysiert und bewertet.

„Im Zusammenhang mit der Forderung nach Transparenz" werden wir diesen Report allen interessierten Gruppen und Verbänden selbstverständlich zur Verfügung stellen", beschreibt Schaffarczyk die Transparenzstrategie der stimOS GmbH.

Oberflächentechnologien können entscheidend dazu beitragen, den Gesundheitssektor zu entlasten, da mit den richtigen Technologien Infektionen, langwierige Reha-Maßnahmen oder Re-Operationen vermeiden werden können

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