

Case study: Analysis of direct and indirect performance indicators of stimOS spineFuse implants reveals enormous savings potential for healthcare system

By analysing the benefits of the company's biomimetic technology, stimOS GmbH, a German R&D Start-up and Legal Manufacturer of spinal fusion implants, performed a case-study showing critical indirect performance indicators for key decision makers to assess the overall effectiveness for spine surgery implants.

Konstanz, Germany. R&D start-up, alongside the Medical Innovations Incubator of Tübingen, investigated, by way of a case-study and literature research, how critical stakeholders and decision makers alike, should assess the overall effectiveness of innovative medical devices, more in particular spine surgery implants. As a reference product, biomimetic spine implants (stimOS GmbH's spineFuse MBT-technology) were used to determine both direct – and indirect performance indicators, split up by way of the company's own dataset, as well as both literature as well as available statistics, out of its domestic market, Germany.

The indicators applied in this case study have been differentiated in direct and indirect indicators, summarized and evaluated in two categories: (1) safety and (2) performance. The safety and performance indicators are derived from the intended purpose, the product specifications, risk management, usability, and from the Medical Device Regulation (EU) 2017/745, Annex 1. In addition to these forementioned indicators, there are also financial, economic, and sociopolitical indicators for each product.

Direct indicators have been demonstrated by the company through verification and validation measures that include a wide variety of standardized tests that were performed by the University of Konstanz, by Vetsuisse of University of Zurich and Charité Universitätsmedizin Berlin.

Regulatory and financial indicators are generally considered to be direct performance indicators. Socioeconomic indicators are usually discussed as indirect performance indicators. While direct indicators are often readily identifiable, identifying indirect indicators requires a precise analytical approach, detailed knowledge of the ecosystem, as well as the healthcare system in which the medical devices are used, invoiced and reimbursed.

For the verification of indirect performance indicators, discussion with health economists have been held. In order to evaluate medical implants with regard to all its performance indicators, a multidisciplinary approach is required and shall be considered in the decision-making process of stakeholders and economic operators, such as purchasing departments and/or - associations, healthcare insurance companies, politicians and other decision makers.

The author, and CEO of stimOS GmbH, Dietmar Schaffarczyk says: "I hope that this case study sparks the necessary discussions to demonstrate that not only the direct performance indicators should be taken into account, when evaluating the effectiveness of medical implants, but also the indirect performance indicators. We aim to, at least, offer more perspectives of how analysis and measurements should be perceived and looked at in the future."

About the case study

The case study will be published in the Q1/21 issue of Meddev Quarterly News and is made available by the publisher in the open access procedure.

Title: Indirect performance indicators as often neglected criteria in decision making – a case study for spinal interbody fusion implants, using biomimetic technologies

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About stimOS

stimOS GmbH was founded in May 2015 and 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 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: MBT^g, MBT^v and MBT^{ti}. All stimOS surface functionalization technologies show superior results concerning the growth of bone cells. A comparative study made by the Universities of Constance, Zurich and Charité Berlin demonstrates excellent results for all MBT surface treatments compared to commonly available implant materials.

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