



New data show positive outcome when using OSSDSIGN Cranial PSI for cranial reconstruction

OssDsign AB (publ) ("OssDsign" or the "Company") today announced that updated outcome data on the use of OSSDSIGN Cranial PSI in 670 cases of cranioplasty and cranial reconstructions have been made public via the company's website. All data were collected as part of post-market surveillance of product performance in Europe, US and selected Asian markets in compliance with MEDDEV 2.7/1 rev.4 and MDR 2017/745. After a median follow-up time of 17 months, rate of infections leading to implant removal remained low at 2.4%

Reconstruction of cranial defects can be a complex surgical procedure associated with an underestimated morbidity. This post-market surveillance report describes the outcome of 670 cranioplasties using OSSDSIGN Cranial PSI, a patient-specific implant made from a calcium phosphate material reinforced with 3D-printed titanium. All data was collected as part of post-market surveillance of product performance in Europe, US and selected Asian markets in compliance with MEDDEV 2.7/1 rev.4 and MDR 2017/745.

One of the most common causes of explantation of implants are early post-operative infections. In the medical literature, explantation rates due to infection with traditional implants range between 7 and 12%. The OssDsign post-market-surveillance data however shows that at a median follow up time of 17 months (range, 0-58 months) only 16 (2.4%) of the implants were explanted due to early postoperative infections. A peer-reviewed clinical study of OSSDSIGN Cranial reported similarly low rates of infections leading to implant removal (1.9%), as has previously reported post-market surveillance data.

Histological analysis of several implants explanted ≥ 9 months following surgery revealed bony integration between the implant and the native bone, as well as new bone formation within and around the remaining calcium phosphate material. The capacity of OssDsign's material to remodel into living bone tissue has been documented in previous peer-reviewed scientific literature as well.

"To the best of our knowledge, we are the only patients specific implant for cranioplasty that can show this type of data along with the material remodeling that we see" says Anders Lundqvist, CEO of OssDsign. "This data confirms earlier outcomes as well as previously published clinical studies and we are very proud of it".

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About OssDsign

OssDsign is a Swedish medical technology company that develops and manufactures regenerative implants for improved healing of bone defects. Providing neuro and plastic surgeons with innovative implants, OssDsign improves the outcome for patients with severe cranial and facial defects worldwide. By combining clinical knowledge with proprietary technology, OssDsign manufactures and sells a growing range of patient-specific solutions for treating cranial defects and facial reconstruction. OssDsign's technology is the result of collaboration between clinical researchers at Karolinska University Hospital in Stockholm and material scientists at the Ångström Laboratory at Uppsala University.