# Improving Outcomes In Cranioplasty – Post-Market Surveillance Data From 1995 Cranioplasties Using OssDsign® Cranial PSI

**Abstract**

Reconstruction of cranial defects can be a complex surgical procedure associated with an underestimated morbidity. This report describes the outcome of 1995 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 following introduction of the product in Europe, US and selected Asian markets in compliance with MEDDEV 2.7/1 rev.4 and MDR 2017/745. At an average follow-up time of 21 months (range, 0-88 months) 66 implants (3.31%) had been explanted; whereof 28 (1.40%) of the implants were explanted due to early postoperative infections, 29 (1.45%) due to persistent wound dehiscence, 1 (0.05%) due to unsatisfactory aesthetical outcome and 8 (0.40%) due to other reasons, such as tumor recurrence. None of explantations were due device-related complications.

Out of the 66 implants that were explanted five were available for histological analysis. These were explanted ≥ 5 months following surgery and they all revealed bony integration between the implant and the native bone, as well as new bone formation within and around the remaining calcium phosphate material.

## Introduction

Cranioplasty is sometimes perceived as a straightforward procedure, however, literature confirms the opposite. Reconstruction of the cranium, especially involving large cranial defects, has high morbidity, regardless of the choice of reconstructive material. Autologous bone flaps have been the gold standard for a long time but rates of bone resorption and infection are high[1,2]. Use of inert alloplastic materials such as titanium or PMMA, tailored to the patients defect anatomy can be used but these materials may be less than optimal as their use is correlated to high rates of implant exposure, infection and ultimately implant removal[3,4]. Known risk factors of implant failure include irradiation, previous cranioplasty failures, thin and fragile soft tissue, exposed sinus cavities, age, and previous infections[5].

OssDsign Cranial PSI is, currently (2022), the only patient-specific cranial implant that combines mechanical performance with long-term bone integration and remodeling. The implant consists of a 3D printed medical-grade titanium mesh skeleton, encased in a calcium phosphate material with clinical and pre-clinical evidence of bone regenerative characteristics. OssDsign Cranial PSI is designed to be used for non-load bearing applications in patients where cranial growth is complete, and for use with an intact dura with or without duraplasty. The device is custom-made to fit each patient-specific cranial defect.

## Materials and methods

Post-market surveillance data collection as part of regulatory requirements has been continuously performed by OssDsign in compliance with MEDDEV 2.7/1 rev.4 and MDR 2017/745.

To date (September 2022), a total of 2015 devices have been delivered worldwide.

This data presents the complaint data of 1995 cases of cranial reconstruction using OssDsign Cranial PSI until 30th September 2022, and includes all reported complications leading to implant explantation. 20 of the 2015 devices originally ordered were not implanted for patient-specific reasons.

One patient experienced a tumor recurrence 31 months following reconstructive surgery. This allowed for explantation of the implant and subsequent preparation of histological samples for analysis of bone formation.

## Results

As of 30th September 2022, a total of 1995 OssDsign Cranial PSI devices had been successfully implanted in US, European, Central America, and Asian patients. At an average follow-up time of 21 months (range 0-88 months), 66 implants (3.31%) had been explanted; whereof 28 (1.40%) of the implants were explanted due to early postoperative infections, 3 (0.15%) due to tumor recurrence, 29 (1.45%) due to persistent wound dehiscence, 3 (0.15%) due to early postoperative hematomas, 1 (<0.1%) due to a non-device related dura rift post-op, 1 (<0.1%) due to progression of autologous bone flap (ABF) resorption and 1 (<0.1%) due to unsatisfactory aesthetical outcome (Table 1).

**TABLE 1.**

| Primary cause of explantation | Number of patients (%) |
|---|---|
| Infection (Early post-op) | 28 (1.40%) |
| Tumor Recurrence | 3 (0.15%) |
| Persistant Wound Dehiscence | 29 (1.45%) |
| Hematoma (Early post-op) | 3 (0.15%) |
| Dura Rift | 1 (<0.05%) |
| ABF Resorption | 1 (<0.05%) |
| Aesthetic | 1 (<0.05%) |
| *Total* | *66 (3.31%)* |

***Reasons for explantation of OssDsign Cranial PSI.***

None of the explantations were performed due to complications that were determined to be device-related by the operating surgeon. Peer-reviewed data from a subpopulation of the material has shown similar figures in terms of device explantation due to infection[6].

Histological analysis of one retrieved implant (Figure 1-2) showed that the calcium phosphate was partly transformed into new, well-vascularized osteonal bone after 31 months, indicating that the triphasic calcium phosphate composition has osteoconductive properties and that new bone growth can bridge between the ceramic tiles. This is consistent with earlier published data on use of the exact same calcium phosphate composition for cranial reconstruction[6,7,8]. The regenerative features of the material have also been confirmed in several preclinical studies.

A 52-week preclinical implantation study in a sheep model revealed the same pattern of host bone integration of the implant along with new bone formation in and around the calcium phosphate material[9,10].

In conclusion, OssDsign Cranial PSI has shown exceptional performance with an infection rate warranting implant removal of 1.4% in a patient population having undergone 1995 cranioplasties at an average follow-up time of 21 months.

The bone-regenerative capacity of the calcium phosphate material has been substantiated in preclinical studies and is supported by clinical experience in multiple cases[6-11].

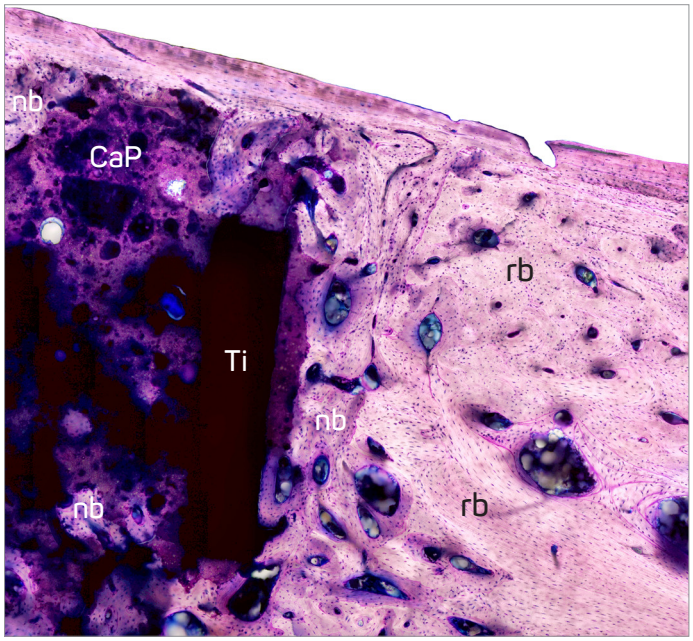


***Figure 1. Histological evidence of bone formation at 31 months post-implantation.*** *Paragon-stained sectioning of OssDsign Cranial PSI shows bony integration between the implant and the recipient bone (rb) as well as new bone formation (nb) within, and around the remaining calcium phosphate material (CaP) and supporting titanium structure (Ti).*

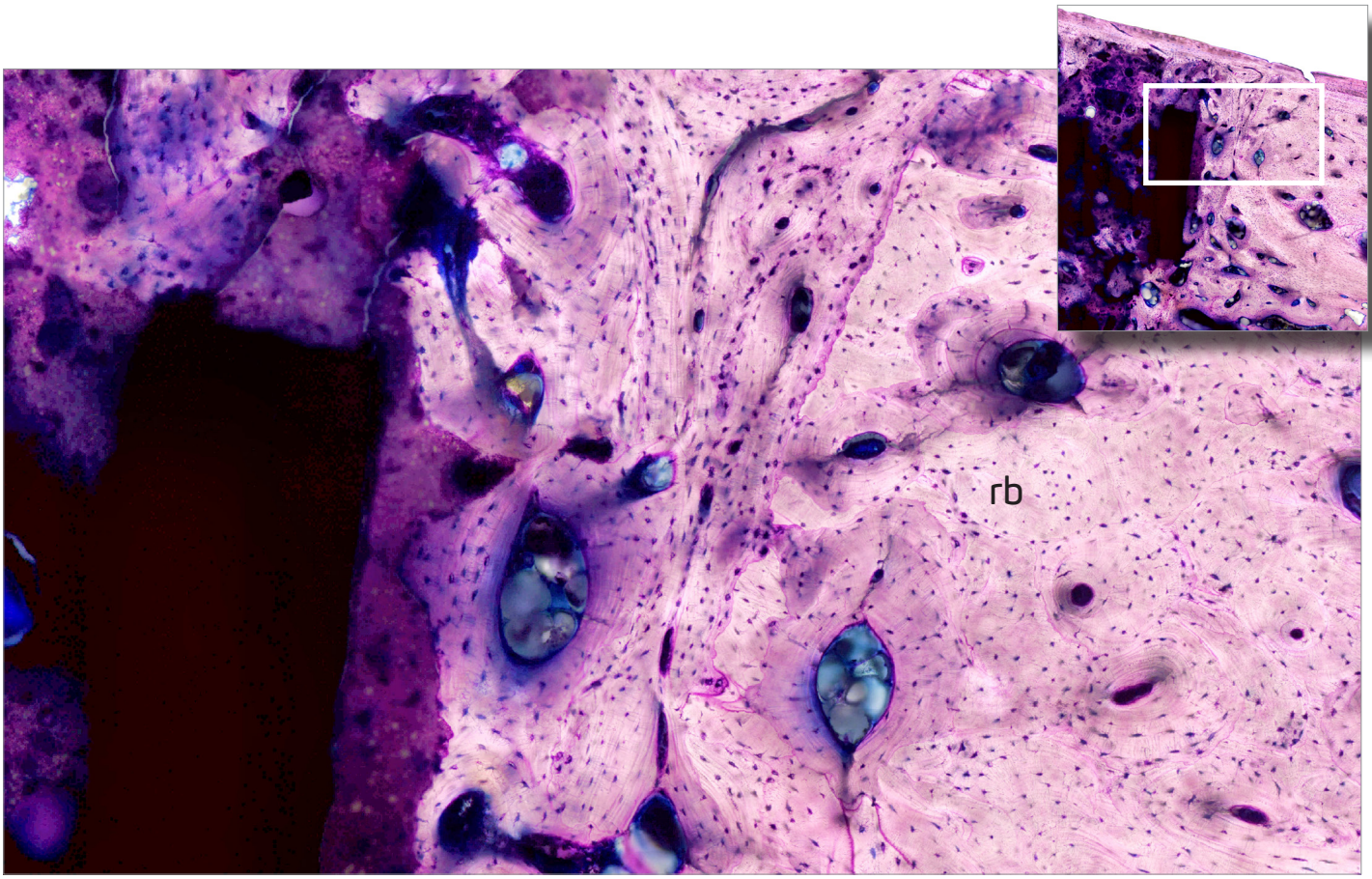


***Figure 2. Magnification of interface between recipient bone and OssDsign Cranial PSI following 31 months of implantation.*** *The magnified picture clearly shows the viable new bone (nb) growing in and around the remnants of the triphasic calcium phosphate material (CaP) of OssDsign Cranial PSI. The interface between new bone and recipient bone (rb) shows complete integration of the implant.*

**References**

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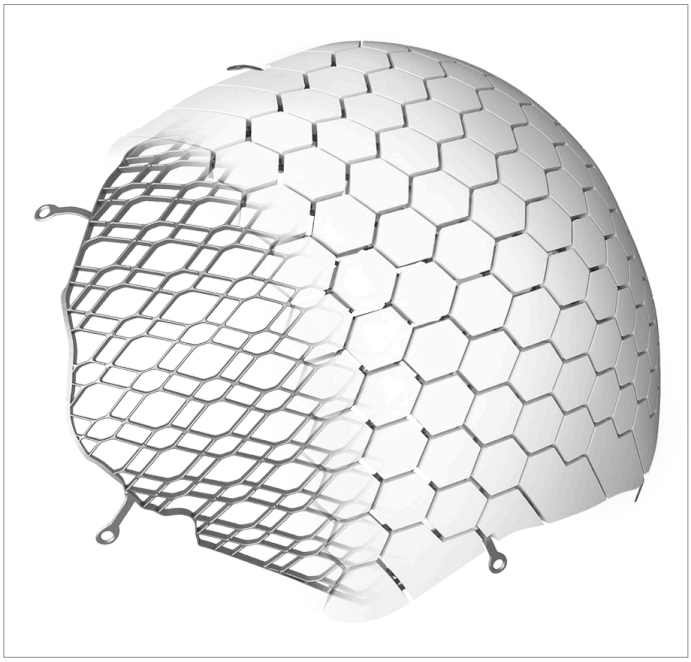
## About OssDsign Cranial PSI

OssDsign Cranial is a patient-specific implant based on a biocompatible calcium phosphate composition with a strong 3D printed titanium skeleton embedded in the core of its ceramic tiles.



OssDsign Cranial PSI is intended for the reconstruction of cranial defects. It is indicated for non-load bearing applications for patients in whom cranial growth is complete, and for use with an intact dura, with or without duraplasty. Always read instructions for use which accompany the product for indications, contraindications, warnings, and precautions.

## About OssDsign

OssDsign's vision is to provide regenerative solutions to all patients with cranial or spinal bone defects, so they can be restored and healed as naturally as possible. Driven by a commitment to give patients back the lives they deserve, OssDsign collaborates with surgeons to engineer better healing by integrating biomaterials with clinical design. Headquartered in Sweden, OssDsign supplies hospitals worldwide with implants for use in cranial reconstruction and other orthopedic surgery applications.

REF. 2018-2132 Rev07