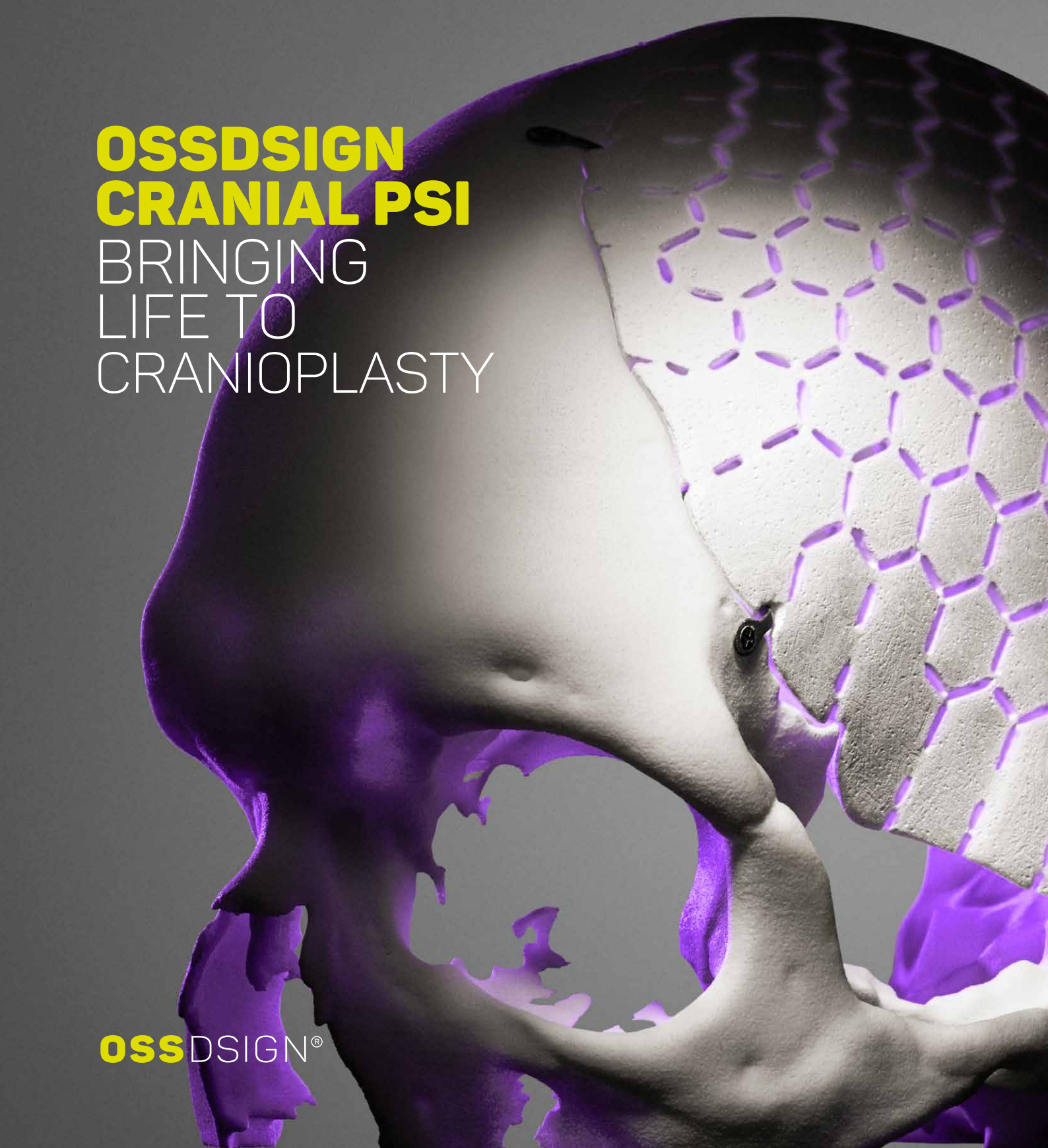
OSSDSIGN CRANIAL PSI

BRINGING LIFE TO CRANIOPLASTY



OSSDSIGN®

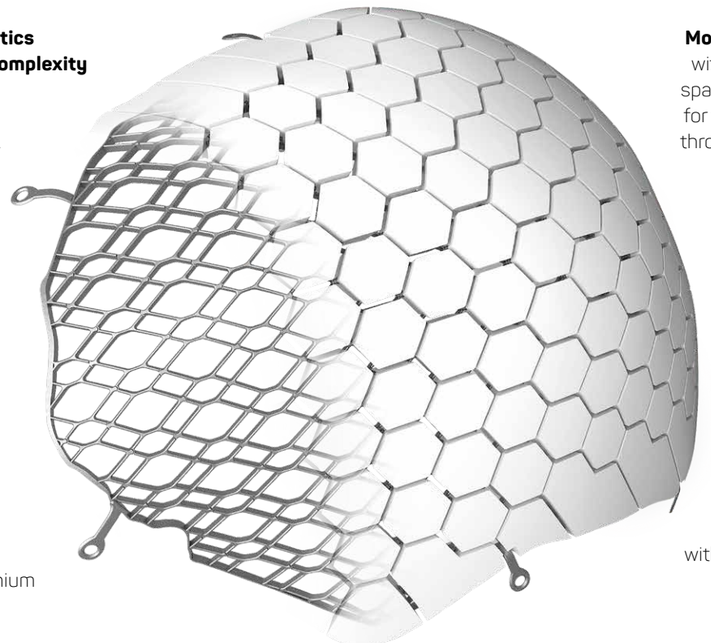
THE COMPLETE CRANIOPLASTY SOLUTION

OssDsign Cranial PSI is a unique combination of a strong, 3D-printed titanium mesh embedded in a biocompatible calcium phosphate material which published peer-reviewed literature describes as having a bone regenerative effect that may have a long-term effect on the outcome of the implant.[1]

The result is a patient-specific implant, designed with features for easy fixation and an optimal aesthetic outcome. By bringing together the best of established material science, CAD engineering and advanced 3D printing, OssDsign delivers an implant solution that provides cranioplasty patients with the protection, cosmetic outcome and reliability they deserve.

Perfect aesthetics regardless of complexity based on CAD engineering and 3D printing.

Mosaic tile design with with inter-tile spacing that allows for fluid movement through the device.

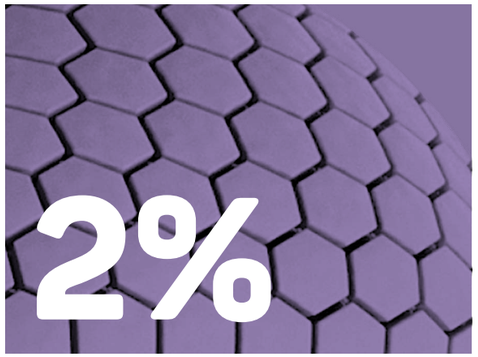


Stability and protection based on the 3D-printed titanium skeleton.

Customized fixation arms with local flexibility for fast and easy fixation.

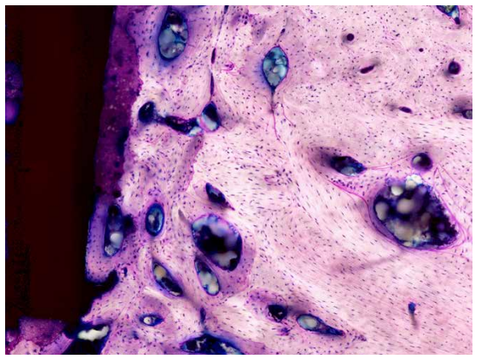
1 LOW OBSERVED RATE OF INFECTIONS

2% reported rate of post-op infections leading to implant explantation.[1] (7-12% published data for traditional technologies[3]).



2 REGENERATIVE FEATURES DESCRIBED IN LITERATURE

Patient histology at 31 months post-op showing compact, vascularized bone in contact with OssDsign material remnants and recipient bone.[1]



3 EASY AND EFFECTIVE HANDLING AND FIXATION

Implant delivered sterile with integrated fixation arms and easy-to-use custom accessories for easy fixation to the skull with standard neuro micro screws.

Screws are not provided by OssDsign.

LOW OBSERVED
RATE OF INFECTIONS

Post-operative infections following cranioplasty are considered among the most common complications, and often require readmission and surgical intervention[4,5].
Published data as well as clinical experience with OssDsign Cranial PSI show low rates of early post-operative infections of 2%[1,2] (compared to published data showing 7–12% with traditional technologies[3]).

The calcium phosphate material of all OssDsign products is porous and hydrophilic, allowing for infiltration of blood and adsorption of proteins[7], as well as soaking of the implant in an antibiotic solution prior to implantation[6]. Hydrophilic implant surfaces are known to have a positive effect on the production of pro-angiogenic growth factors, enabling rapid vascularization and tissue integration[7].

Infections (post-op) leading to explantation

1.9%
(1 of 53)
0.7 months post-op

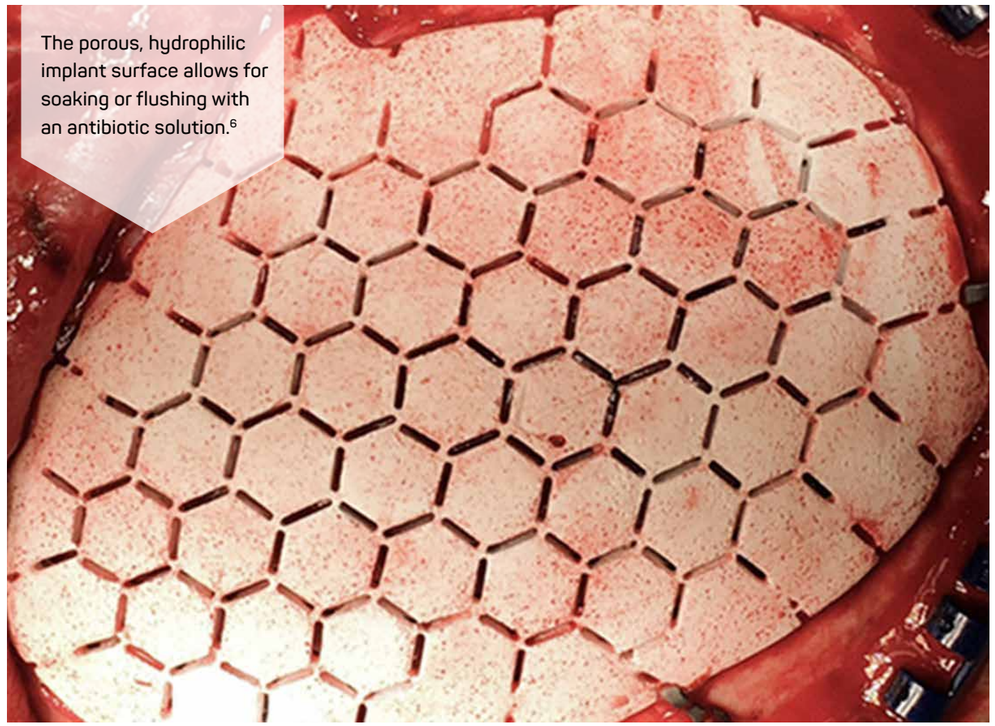
Cohort studied
- 50 patients (53 implants) studied at single center
- Complex cohort (64% previous implant failures)
- Median follow-up time 25 months

Kihlstrom et al 2019 [1]

2.4%
(16 of 670)
early post-op

Cohort studied
- Monitoring of outcome for regulatory purposes
- 670 implants at 128 hospitals in Europe, US and Asia
- Median follow-up time 17 months

OssDsign PMS 2019* [2]



The surface of OssDsign Cranial is porous and hydrophilic. A well-vascularized tissue is a prerequisite for the immune system's ability to reach the implant site and resist infections.

REGENERATIVE FEATURES DESCRIBED IN PUBLISHED LITERATURE

The calcium phosphate composition in OssDsign Cranial PSI has been shown to gradually transform into new, well-vascularized osteonal bone, indicating that new bone growth can bridge between the ceramic tiles.[1, 8, 9, 11]

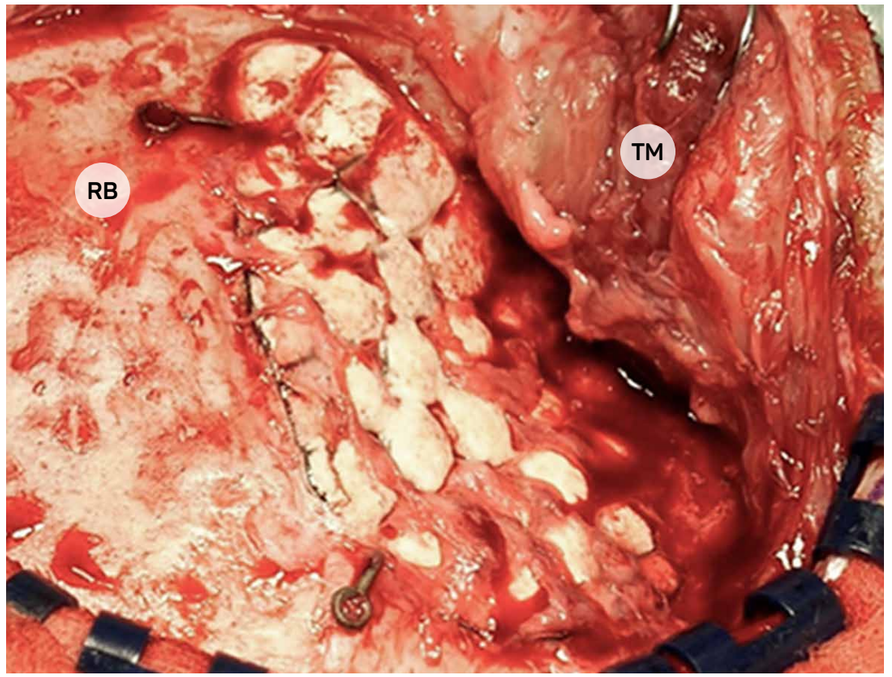
The regenerative potential of the material has also been confirmed in pre-clinical studies described in published literature.[11] This bone regenerative effect may in particular have an impact on the long-term success rate of the implant.[1, 8, 9, 11]

"The bone regenerative effect may in particular have an impact on the long-term success rate of the implant"
Kihlström et al 2018

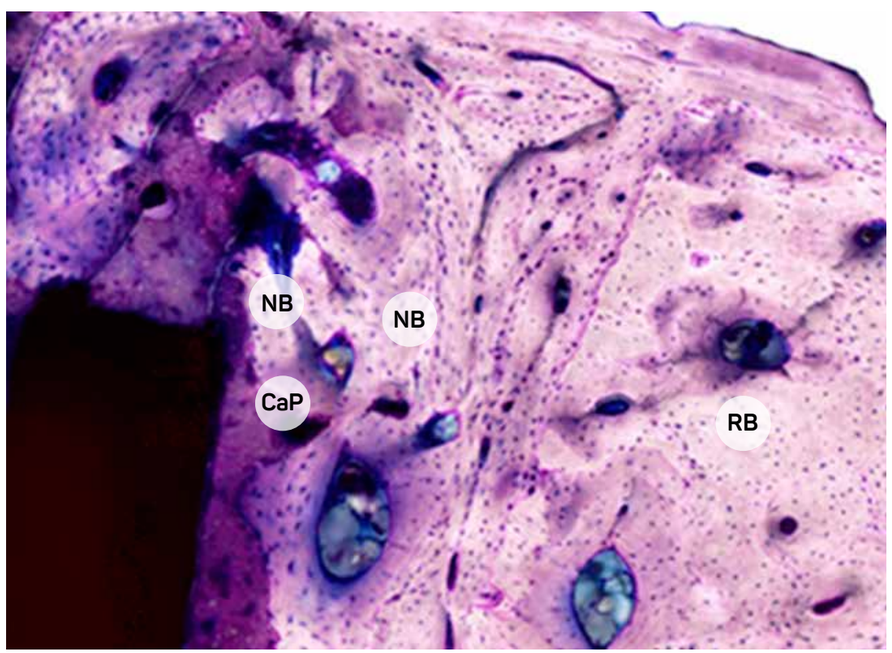
Evidence of bone and blood vessel formation

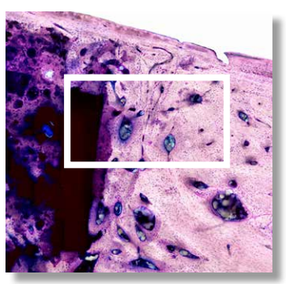
31 months post-op, a patient diagnosed with meningioma underwent a tumor resection and reconstruction[1].

The implant was preserved, stained and analyzed. The analysis showed bony integration between the implant and recipient bone, as well as new bone formation following 31 months of implantation[1, 2].



Macroscopic image of implant with evident bone formation at 31 months post-op. (RB: Recipient bone, TM: Temporalis muscle)



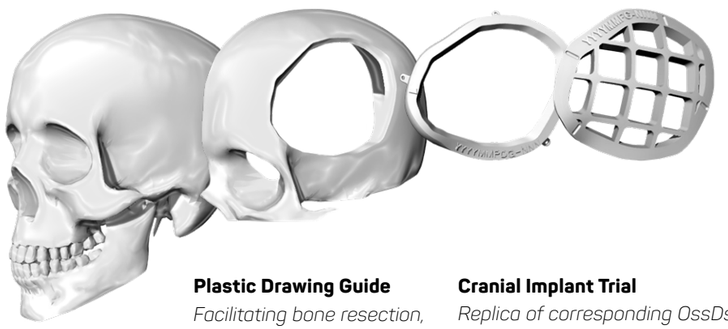


Interface between recipient bone and OssDsign® Cranial PSI following 31 months of implantation. (NB: New bone, CaP: Calcium phosphate, RB: Recipient bone)

EASY AND EFFECTIVE
HANDLING AND FIXATION

Our cranial patient specific implants are uniquely engineered to provide a solution for a variety of cranioplasty needs, both biological and mechanical, regardless of case complexity or size. The implants are always delivered sterile and ready to use and are easy to fixate to the skull with pre-designed customized fixation arms integrated into the device. OssDsign Cranial PSI can be ordered with a variety of patient-specific accessory devices designed to facilitate a safe and easy cranial reconstruction, even in the most complex cases.
The accessory devices, together with the built-in fixation arms of the implant, are useful tools that help during surgery, allowing for single-stage cranioplasty.

Cranial accessories



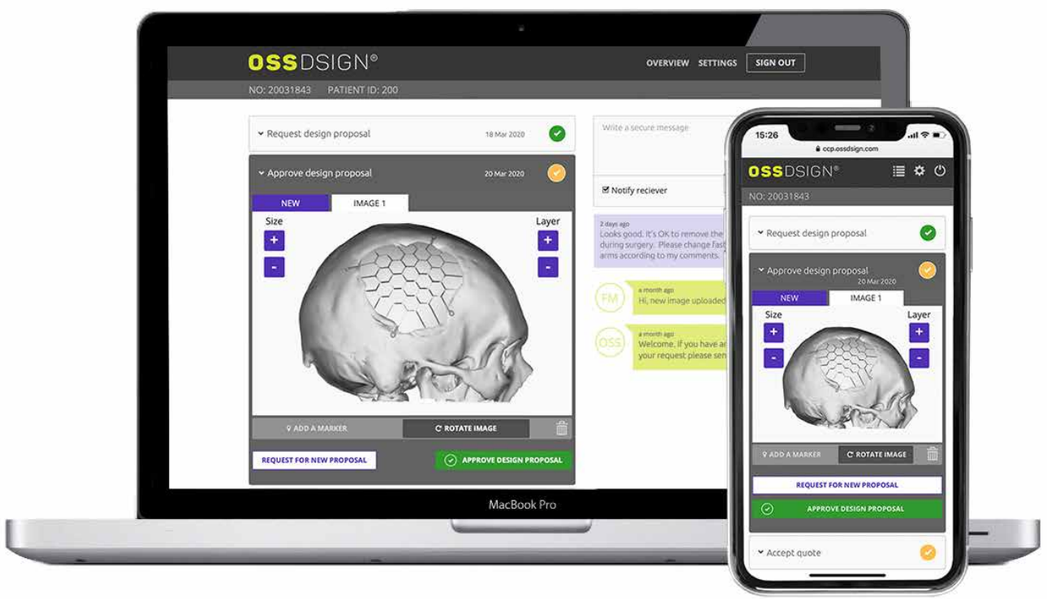
Anatomical Models
3D-printed skull replicas for pre-planning and patient communication.

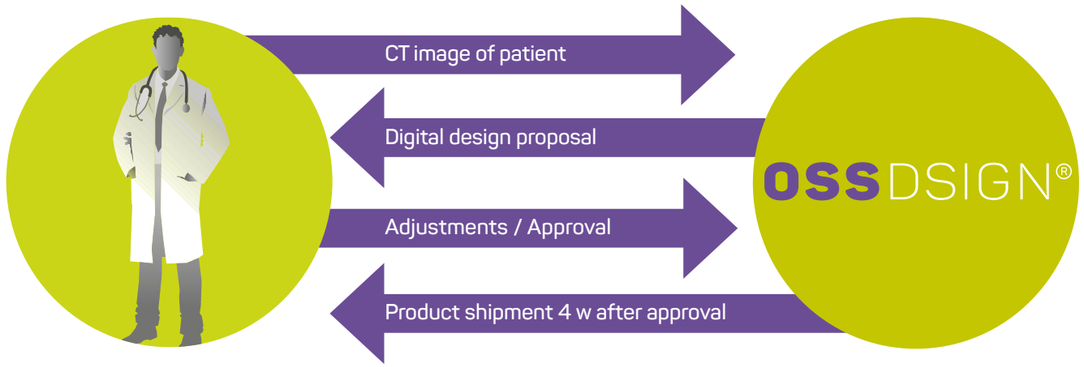
Plastic Drawing Guide
Facilitating bone resection, placement and fitting of OssDsign Cranial PSI.

Cranial Implant Trial
Replica of corresponding OssDsign Cranial PSI for evaluation of implant fit and soft tissue coverage.

SECURE AND
RELIABLE ORDERING

Ordering of OssDsign's patient-specific products is secure and easy. Through our unique communication platform, CCP (Customer Communication Platform), you have direct communication with OssDsign customer service, CAD engineers and your local product specialist. Our team of experienced CAD engineers works in close collaboration with the operating surgeon during the design process of the patient-specific implant to ensure that the optimal solution is achieved. All design proposals are presented in 3D, and approval is easily made with one click. CCP is accessible from your computer, smartphone or tablet.





1 CT SCAN

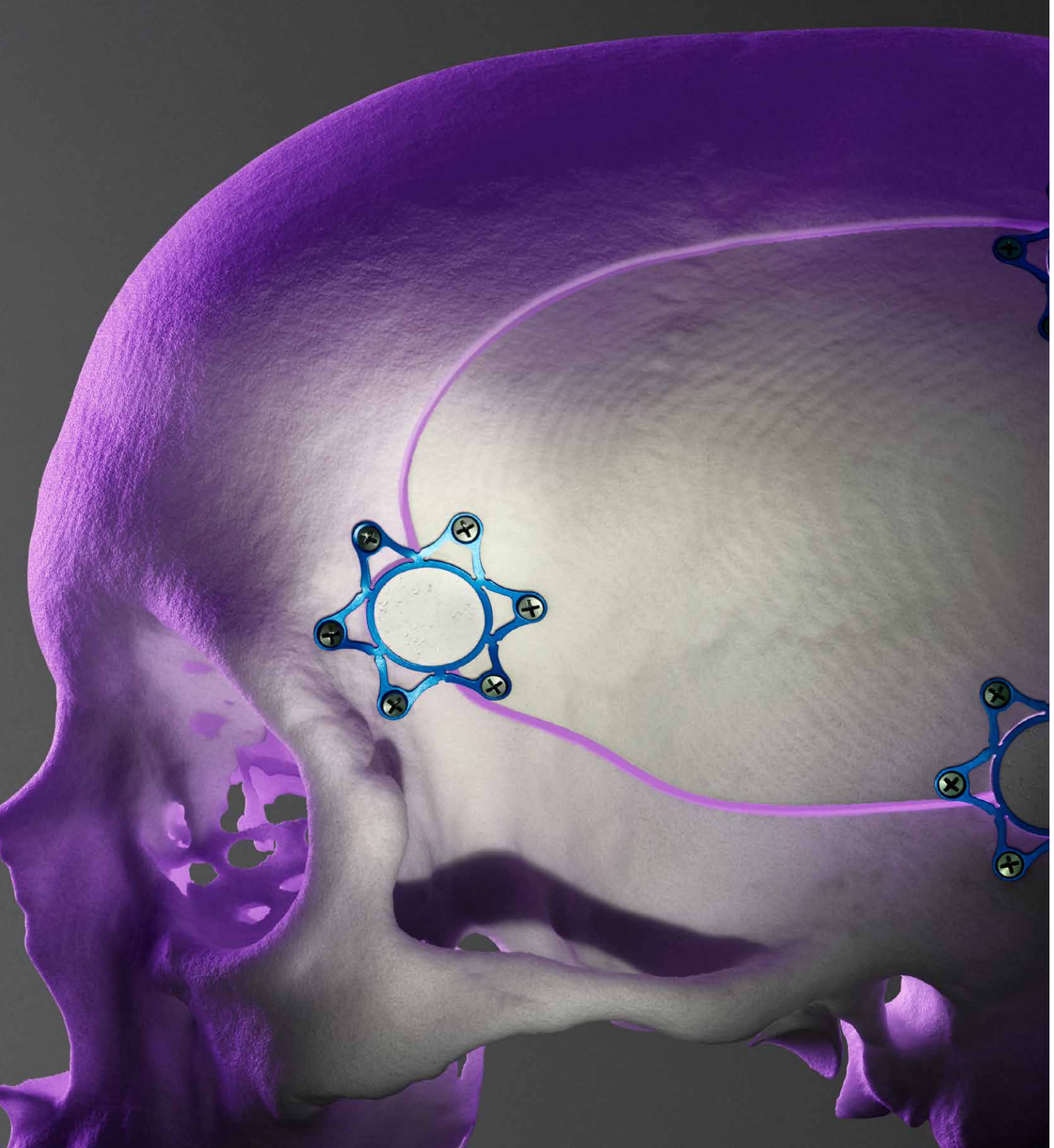
Prepare your CT data and upload it together with details about your case into our secure online system, CCP.
For the best possible results, we recommend that you follow our CT scanning guidelines, available for download at our website.

2 DESIGN AND COMMUNICATION

Within 2 working days we will provide you with a 3D digital design proposal in CCP". Once you have approved the final design, the manufacturing process will be initiated.

3 PRODUCT SHIPMENT

Your OssDsign implant will be shipped within 4 weeks of an approved design proposal. The implant is delivered sterile together with case-specific details, accessory devices and visual aid pictures.



MORE FROM OSSDSIGN

OSSDSIGN CRANIOPLUG
THE OSTEOCONDUCTIVE CRANIAL CLOSURE SYSTEM[10, 12]

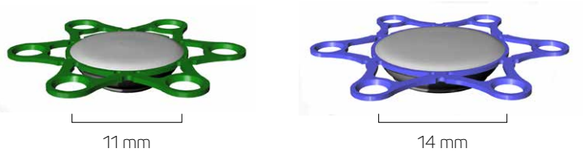
Years of successful clinical experience with OssDsign Cranial PSI has led to the development of CranioPlug, a unique burr hole cover with an osteoconductive material technology.[10, 12]

The calcium phosphate component of CranioPlug has a 3D design that fills the burr hole and restores the structural integrity. During the healing process, this component resorbs and is replaced with bone, contributing to favorable cosmetic outcome.

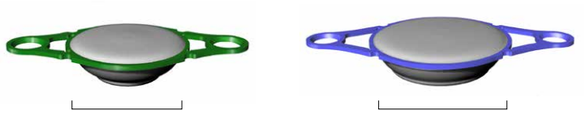
The device is available in four versions for burr-hole closure and bone flap fixation, all with a low-profile design and a slightly convex surface that contributes to reduced palpability.

OssDsign Cranioplug
for repair of cranial burr holes and bone flap fixation

6 fixation arms
for bone flap fixation



2 fixation arms
for burr hole closure



PATIENTS DESERVE
A BETTER IMPLANT SOLUTION

OssDsign is an innovator, designer and manufacturer of implants and material technology for bone regeneration. We are surgeons, scientists and engineers who are committed to improving outcomes in cranioplasty.

Our innovative technology platform is the result of collaboration between craniofacial surgeons at Karolinska University Hospital, Stockholm, and material science experts at Ångström Laboratory at Uppsala University. Throughout the years, OssDsign has continued to develop the technology in order to provide surgeons with high-quality and easy-to-use products for a variety of cranioplasty needs.

Our aim is to deliver a complete cranioplasty solution where the patient is in focus throughout the process. Our team of experienced product specialists and CAD engineers take great pride in their ability to meet the demands of any patient, regardless of case complexity or size.

References

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Always read the Instructions for Use which accompany the product for indications, contraindications, warnings and precautions.

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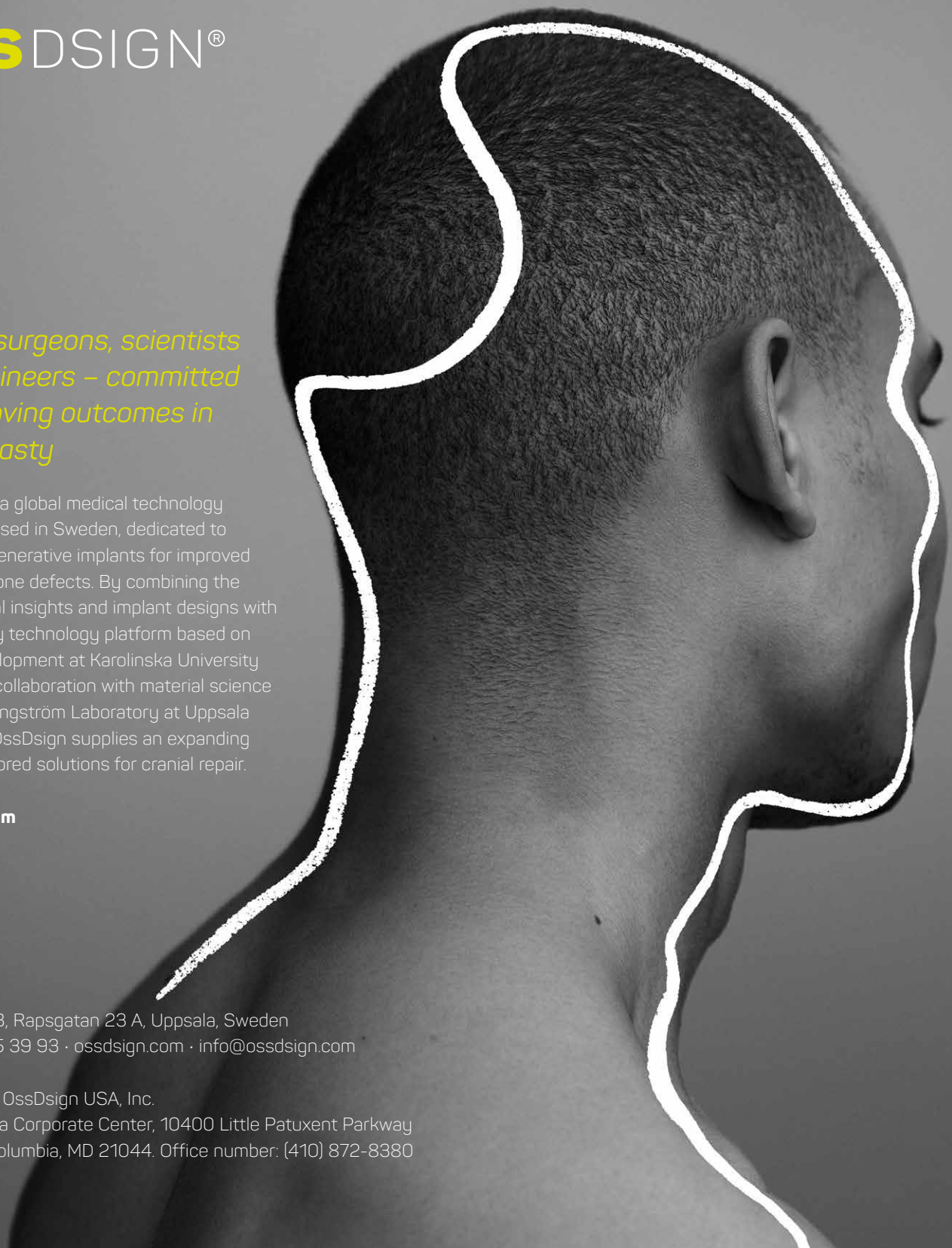

We are surgeons, scientists and engineers – committed to improving outcomes in cranioplasty

OssDsign is a global medical technology company based in Sweden, dedicated to creating regenerative implants for improved healing of bone defects. By combining the latest clinical insights and implant designs with a proprietary technology platform based on clinical development at Karolinska University Hospital, in collaboration with material science experts at Ångström Laboratory at Uppsala University, OssDsign supplies an expanding range of tailored solutions for cranial repair.

ossdsign.com

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