



ORTHO BALTIC

PATIENT-SPECIFIC

CRANIAL IMPLANTS

WHO WE ARE

Baltic Implants is a trademark owned by the company *Ortho Baltic*. Started in 2001 as a producer of custom-made prosthetic-orthotic devices, in 2012 we have invested in additive manufacturing technology and expanded our made-to-order services to the design and production of patient-specific joints, cranial and spinal implants, bone plating systems, dental & jaw restoration implants and single-use patient-specific surgical guides as well.

Ortho Baltic is pioneer in developing of patient-specific implants in Eastern Europe. In manufacturing of custom-made products, we apply different 3D printing technologies and biocompatible materials such as: titanium alloy (Ti6Al4V), cobalt-chrome alloy (Co-Cr-Mo), polyamide (Nylon-12) and ceramics powders. Our company employs a team of highly qualified biomechanical, mechanical, materials science engineers, physicists and ITC professionals, and work closely cooperating with Lithuanian University of Health Sciences, Vilnius University and a number of university's hospitals. Ortho Baltic carries industrial doctorship studies in partnership

with Kaunas University of Technology and actively participates in Horizon 2020 program. We are SME Instrument Phase 2 Champion.

We are closely cooperating with medical institutions in developing new medical devices, to have direct touch with end-users of our products, also Ortho Baltic is running its own specialized Consulting Clinic for patients with orthopaedic issues and subsidiary Baltic RAD (www.balticrad.com) that provides remote radiology reporting services to hospitals, both locally and for export.

Ortho Baltic applies mass customization business model in production of medical devices starting from Class I and ending Class III. Our Quality Management System has been approved to ISO 9001, ISO 13485, and ISO 14001 standards. All Ortho Baltic products and services meet the highest requirements of quality and security for medical devices, are registered and have Free Trade Certificates for distribution in EU countries. 99% of our output goes for export. Main markets - Benelux, Scandinavia, Germany and Switzerland.

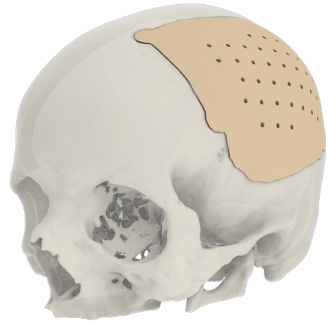


DESIGN AND MANUFACTURING

of patient-specific cranial implant

Each patient's case is individual and dealing with complexity in today's cranial vault reconstruction surgeries, a personalized approach is recommended. Instead of letting surgeons continue to twist and turn trying to solve the problem of "how to make with what we have", we ask them to describe the individual structural and functional properties to be implemented in an implant that is going to be used in treatment of a specific patient in a specific clinical case.

When the skull is damaged due to trauma or illness (tumour, congenital malformation, etc.), and usual treatment methods become impossible to administer or are ineffective, the skull undergoes reconstructive surgery – the missing or damaged bone is replaced with an artificial one. In severe cases (for very large bone defects, complex deformities, complex shape of the reconstruction or complications of existing implants), the use of a patient-specific cranial implant is then recommended. Free-



form modelling, 3D metal printing and CNC milling we apply enable us to create unique shapes of implants that match individual anatomy and to fulfil the surgeon's specifications for the design of the implant and single-use surgical instruments assisting the surgeon during surgery to perform precise resection and positioning of the implant.

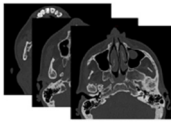


Advantages of patient-specific cranial implants:

- Better anatomical and mechanical compatibility;
- Better aesthetic outcome;
- Choice of materials (Ti6Al4V, PEEK, HA/TCP) to match each specific case;
- Lower risk of surgical and postsurgical complications;
- Lower risk of revision;
- Reduced surgery, hospitalization and rehabilitation time.

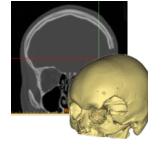
HOW IT WORKS

Order specification and safe data transfer



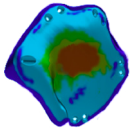
Surgeon fills the Order form, prescribes a CT scan for a patient; and transfers DICOM files and filled Order form to Ortho Baltic.

In the Order form, surgeon provides information about the patient's condition, specifies requirements for a patient-specific implant and its accompanying set, which includes patient-specific surgical guides, pre-surgical planning models, screws, and additional reusable surgical instruments (optional).



Anatomical 3D reconstruction

3D reconstruction of patient anatomical model is performed by medical imaging engineers, who work under the supervision of radiologists. The result of 3D reconstruction is virtual 3D models of the patient's anatomy.



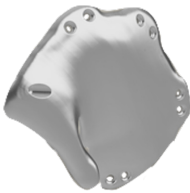
Implant design & non-destructive testing

Primary implant is designed and then tested by non-destructive ways (FEA) in order to achieve the optimum strength characteristics. The design is then send to the surgeon in order to perform final reviews and additional markings, which in term will lead to the best possible solution for the patient.

Manufacturing

After the surgeon's approval concerning the designs of the implant and surgical guides, the set of screws and the reusable instruments, the manufacturing process begins.

Patient-specific cranial implants can be 3D printed (DMLS) from Ti6Al4V, 3D printed from HA/TCP or milled from PEEK material. Pre-surgical planning models, patient-specific surgical guides and implant trials are 3D printed (SLS) from biocompatible polyamide PA2200 (Nylon-12).



Surgeon's approval



The primary design of solution in a form of patient-specific pre-surgical planning models (anatomical models, implant model, models of surgical guides) are sent to the surgeon in order to perform review and additional markings. The surgeon submits feedback and additional specifications for potential corrections in aim to achieve the highest product quality for the patient.

Quality control and validation



Each manufactured part undergoes a strict Quality Assurance processes including non-destructive testing (based on Finite Element Analysis, FEA) for ensuring the fulfillment of strength characteristics, and a final quality control with the inspection of chemical composition, geometrical accuracy, inside voids and surface roughness.

Packaging & Sterilization

Implants are sterilized using gamma irradiation (> 25 kGy) in a certified sterilization laboratory.

Patient-specific implant set (implant, surgical guides, screws, reusable instruments (if requested)), as well as related documents (instructions for use, patient's guide, implant passport, screw map) are delivered to the hospital. Surgeon performs the surgery and gives us feedback.



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