



**“To make patient-specific implants more affordable in terms of price and lead times and more widely applicable in the surgical treatment”**

## Mass Customization of Implants: The Business Model

Horizon 2020 SME Instrument project

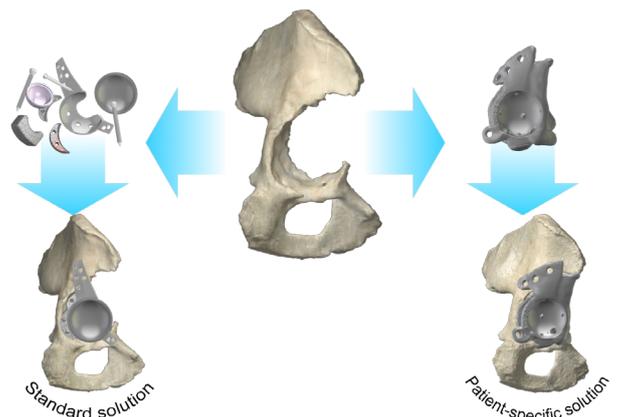
### MEDICAL IMPLANTS: WHY PATIENT-SPECIFIC?

Ortho Baltic has developed advanced design and manufacturing practises for Custom-Made Implants (CMIs) and Custom-Made Surgical Guides (CMSGs) – premium quality orthopaedic products. The main advantage of CMIs, compared to standard implants, is the patient-specific design which matches the implant to the bone and not vice-versa. This allows optimal positioning of primary fixation screws (the secondary fixation to the bone is ensured by osteointegration into the trabecular metal structures, whose depth is technologically unlimited) and provides complete biomechanical harmonisation of the replaced joint not only locally, but in respect of neighbouring joints as well. Moreover, unlike standard assembled modular implants that are used to treat severe clinical conditions, the CMIs are constructed as integral devices.

Those peculiarities combined ensure lower surgical invasiveness, shorter operation time, faster healing, reduce risks of infection, joint dislocation and revision surgeries. They provide fuller restoration of patient’s physical performance and higher quality of life by reducing or completely avoiding side effects. Even though 3D printed CMIs have been used in clinical practice for only 10 years and not enough clinical data has been accumulated on the efficiency of their use, their aforementioned advantages allow assuming a longer life span too.

Ortho Baltic produces premium quality patient-specific implants using in-house state-of-the-art technologies such as 3D segmentation of radiological images, 3D parametric and non-parametric modelling, FEA based non-destructive testing, additive manufacturing (Direct Metal Laser Sintering (DMLS) and Stereolithography (SLA)), 5+1 axis milling, as well as all the spectrum of finishing and quality control technologies, including coordinate measuring machines (CMM) and micro-CT for nominal to actual comparison, geometric inspection and detection of internal material defects, spectrometric chemical composition and surface roughness analyses.

CMIs are manufactured out of biocompatible materials such as medical titanium Ti6Al4V and/or bioceramics (HA, TCP, ZrO2) and come with anatomically adapted CMSGs, made from biocompatible polyamide



PA2200 (Nylon 12) using Selective Laser Sintering (SLS) technology. All the equipment and materials used in the supply chain are certified for production of implantable medical devices. Company's Quality Management System is certified as well and complies with ISO standards 9001, 13485 and 14001.

Ortho Baltic, unlike its competitors, offers higher personalization level of medical implants. For instance, most companies, which supply patient-specific hip cup implants, limit themselves to the adjustment of the implant to the bone with regard to hip cup anteversion and inclination angles as well as the development of individual primary fixation solutions. Meanwhile, Ortho Baltic is able to offer its customers complete biomechanical harmonisation of the artificial hip joint with regard to altered axes of neighbouring joints. Moreover, to prevent bone/implant interface infections, which have very long lasting and expensive treatment, Ortho Baltic together with Lithuanian Health Science University and Riga Technical University are involved in a research programme under the umbrella of the M-ERA.NET network. This project is focussed on the injection of a mixture of HA and TCP enriched with patient-specific encapsulated antibiotics into the functional surfaces of CMI in order to provide controlled release of antibiotics.

### HOW TO MAKE PATIENT-SPECIFIC TO WORK?

CMI currently fail to achieve large-scale commercial success over much inferior standard orthopaedic implants due to high price, long lead times, surgical approach oriented towards standard solutions, as well as existing long-standing relations between surgeons and manufacturers of standard implants. CMIs are currently used almost exclusively to treat clinical conditions that cannot be treated with standard implants.

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processes such as surgeon-manufacturer communication tool MICE (Medical Implants Customization Engine) and factory floor management system MC Dynamics (Mass Customization Dynamics) – Lean/TOC-based process optimization platform, ensuring M2M communication and processes automation, adjusted to the specific of digital in-nature CMI design, manufacturing and validation, the company has ensured high efficiency of activity processes and currently offers CMIs for a price that is lower than those from modular standard implants, which are used to treat rare and severe clinical conditions. Lead time is currently up to 4 weeks, but with the transition to mass CMI manufacturing and at least 3000 patient-specific implants produced annually, their price will be twice as low by 2023 as it is today, and lead time will not exceed two weeks (Fig. 1).

Already today Ortho Baltic offers CMIs for a lower price than those from standard modular implants because the price of standard modular implants is artificially inflated. The prime cost of CMI manufacturing by Ortho Baltic reaches up to 43% of the final price; moreover, 10% of product price is dedicated for R&D. Meanwhile the prime cost of standard implants is 10%, and only in some cases reaches up to 15%. Therefore, we understand that increasing the competitiveness of CMIs will result in decreased prices of standard modular implants. The nature of mass manufacturing of standard implants ensures lower prime cost than those from designed, manufactured and validated CMIs. But if the comparative weight of the implant costs in general treatment outlay decreased, then the significant outlay economy from using patient-specific implants should ensure the competitive advantage of the latter in comparison with standard implants in the long-run.

Ortho Baltic strongly believes that the potential applications of CMI should also include treating clinical cases where the use of CMI leads to better treatment results than standard implants, avoids side effects or minimizes their impact, ensures fuller restoration of patient's physical performance and quality of life and decreases the total accumulated pathology treatment costs for severe and moderate clinical conditions (one should not forget that the implant price is just one of the components of treatment costs).

Therefore, by developing technological solutions that ensure effective management of CMI design, manufacture and validation

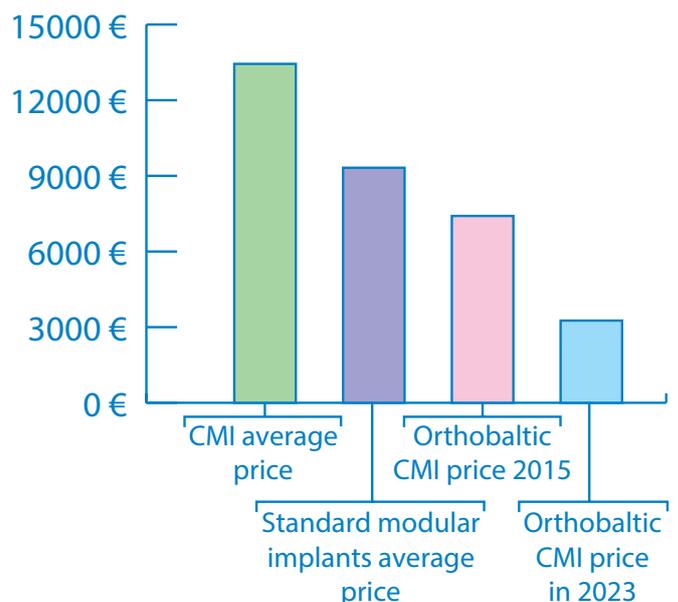


Fig.1 Comparison of prices of hip joint endoprosthetic implant

## OBJECTIVES of the PROJECT

The company's overall objective is to solve two societal challenges.

First, the project aims to incentivize surgeons to apply personalized surgical solutions more widely. This relates not only to the change of a current surgical thought paradigm, but also to a deep modification of the relations and the interest balance existing among implant market stakeholders. We know how hard it is to change things in medicine, just as it is extremely difficult for religious rituals to be altered. We also understand that it is not enough to offer surgeons (and as a result to patients) premium quality patient-specific medical implants. Together with them, we have to introduce technology-based infrastructural solutions, which would empower surgeons to describe in natural way the individual design solutions to be implemented in an implant that is going to be used in the treatment of a specific patient, in a specific clinical case instead of continuing to twist and turn trying to solve the problem of "how to make do with what we have".

The switch to personalized medicine is already slowly taking place due to changing trends in healthcare itself and in healthcare compensation systems – the payments from 'per no. of treatments' progressively moving to 'outcomes of treatments'. Personalised medicine not only improves quality of life, but contributes to more sustainable healthcare in EU countries. It drives new and faster development processes and products, providing European life sciences industries with a competitive edge that can secure growth and jobs.

Ortho Baltic project will further accelerate this transformation by developing the open access web technology-based software tool for surgeons-manufacturers communication MICE, based on 3D virtual models interface, and the software training tool to apply CMI in surgery treatment MICE Trainer. The first one provides the framework for systematic specification of the product design and for its validation in the stage of pre-surgery planning (Fig.2). MICE Trainer is based on clinical data applying CMI in surgery and is designed as Clinical Decision Support System (CDSS). Its inference engine integrates rule-based and model-based knowledge engineering instruments, while user interface design is based on gamification principles (Fig. 3). With the development of MICE Trainer, the company aims to apply the collected experiences of the CMI uses in surgical treatment for further training of surgeons and medical students on CMI application.

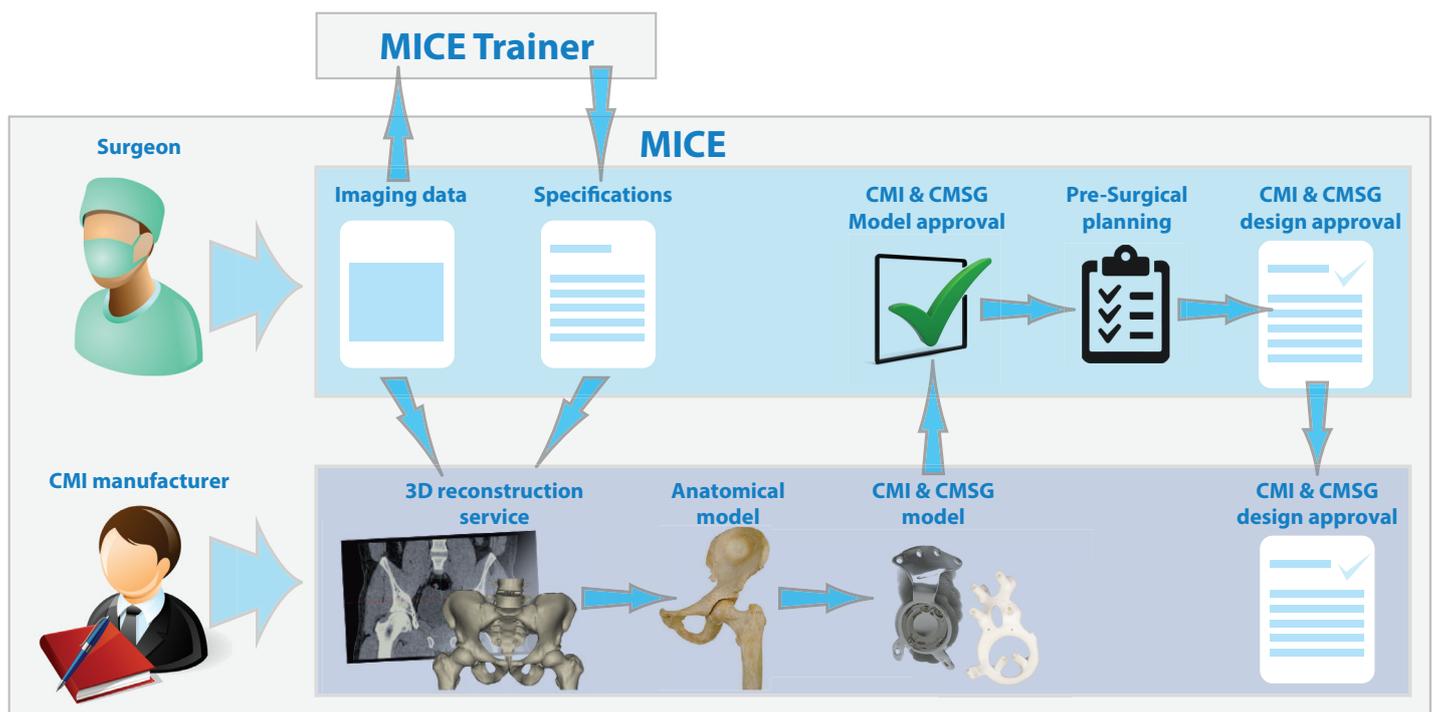


Fig.2 MICE surgeon-manufacturer communication tool

Second, and most importantly, the company is positioned to make a premium-quality medical product (patient-specific implant) more available and affordable to patients in price and supply terms. From one hand, this will be the result of the growing demand for CMIs and CMSGs which will lead to economies of scale, (including decrease of the price of Ti6Al4V - the main raw material for CMI products - from 450 EUR/kg to 190 EUR/kg.), accompanied by the boost in 3D printing equipment productivity (avg. 10% per year). From the other hand, Ortho Baltic will use MICE and MC Dynamics factory floor processes management system to make the transition from unitary to mass production more efficient than its competitors, who will then be forced to adapt and drop their currently-inflated both standard modular implants and CMI prices to remain competitive.

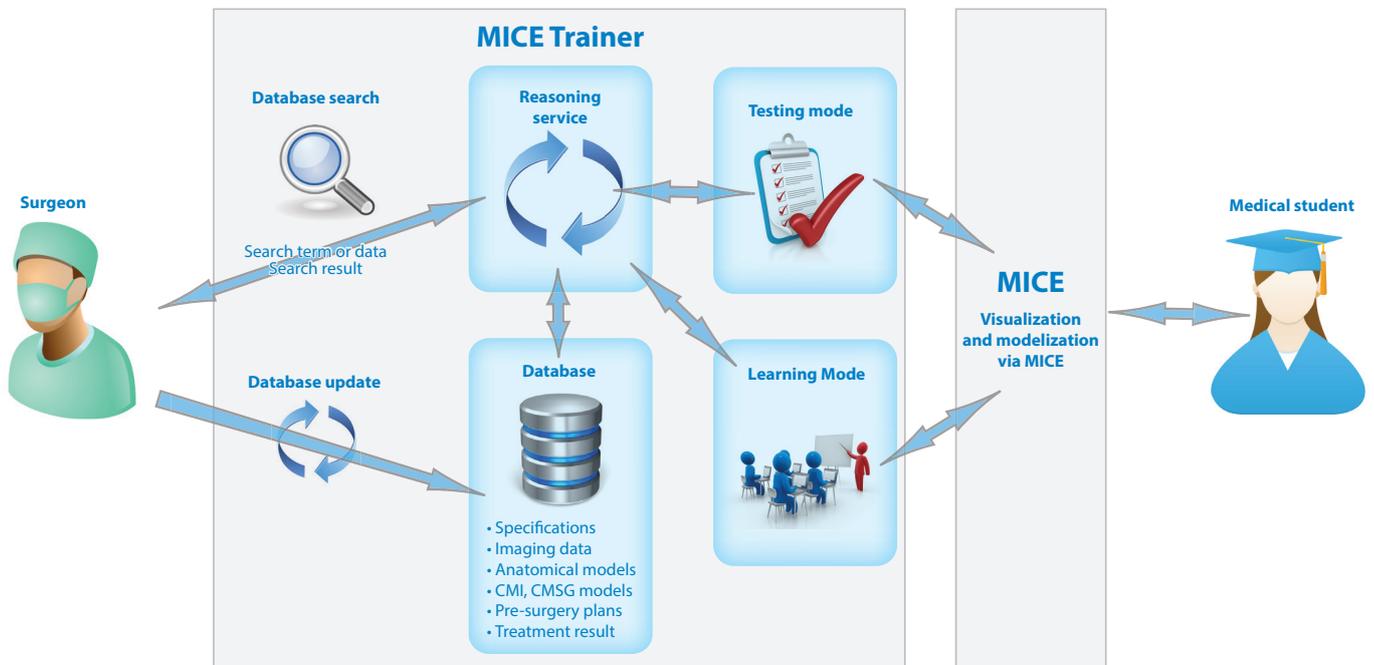


Fig.3 Mice Trainer Clinical Decision Support System

## INVOLVEMENT OF STAKEHOLDERS

Usually, the stakeholders of the implant market are patients, surgeons, health care institutions, health insurance funds and manufacturers. Patients are the end-users and main stakeholders in the implant-related decision. But surgeons have the highest power to decide which type of implant – standard or CMI – the patient needs, their recommendations have a high influence on the patients' decision. Therefore, Ortho Baltic aims at developing instruments such as MICE and MICE Trainer that would not only simplify and make the communication between surgeons and CMI manufacturers easier when specifying requirements for the CMI design, adjusting the design solutions and the implant accessories, validating the solution offered by the manufacturer during the pre-surgical planning stage, but would also help to train surgeons and medical students to employ CMIs in surgical treatment using the MICE software.

By implementing the project “Mass Customization of Implants: The Business Model”, Ortho Baltic aims at cooperating with surgeons while carrying out R&D activities and taking over their know-how in the following stages:

- Developing application-specific interfaces of the surgeon-manufacturer communication tool with different functionality sets serving for specification and validation of joints, spine and craniofacial CMIs. MICE, unlike pre-surgical planning systems offered by other manufacturers, is not only limited to pre-surgical planning but consists of separated modules dedicated for the use of different kind of implants in the surgical treatment of different clinical conditions;
- Testing MICE functionalities while implementing CMI order specification, adjustment of the design of an implant with the manufacturer and CMI validation in the stage of pre-surgical planning;
- Creating knowledge databases of the MICE Trainer (without breaching other persons' intellectual property rights) from anonymized clinical data of the patients that have undergone surgical treatment using CMI (including radiological images), virtual 3D patient-specific anatomical models, CMI design specifications prepared by surgeons, virtual 3D CMI design models, protocols of pre-surgical planning and surgery reports of long-term CMI's surgery outcomes.
- Planning and executing global clinical trials dedicated to generate evidence of the differences between costs and health outcomes applying standard and patient-specific implants when treating severe conditions. Ortho Baltic aims to involve surgeons into CMI vigilance programme through MICE Trainer system by accumulating data of CMI application's results in surgical treatments.

To that end, the company also seeks to attract the leading medical universities to conduct this project, in order to develop academic courses for the application of CMI in surgical treatment. Ortho Baltic will provide surgeons and medical students with open access software system MICE, based on web technologies with 3D user interface, which together with another sister software system MICE Trainer would serve as a practical training tool in the programme of the course.

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