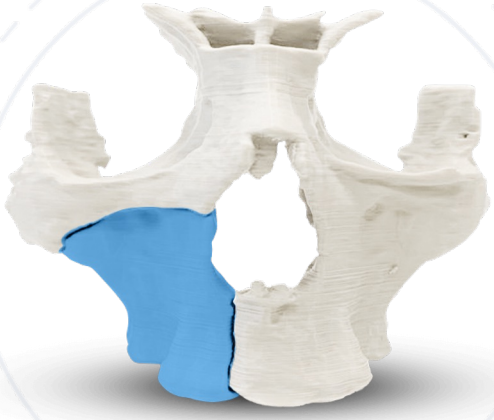

CUSTOMIZED 3D IMPLANTS BASED ON BONE-FORMING MATERIALS

cyberbone

Technology

We use self-developed materials and technologies to produce implants based on bioresorbable plastics with osteoinductive and osteoconductive (bone-forming) properties using 3D printing (FDM).

Our implants are customized for individual patient needs – we use advanced tools and software for bone defect modeling and product design.

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Personalized vs Standard

Cyberbone - personalized bioresorbable implants made on individual need / order.

According to EU low personalized procedure / implants do not need CE or long lasting clinical trials.
(art. 52 ust. 2 rozporządzenia Parlamentu Europejskiego i Rady (UE) 2017/745 z dn. 05.04.2017 r.
w sprawie wyrobów medycznych)

The decision to proceed personalized implant surgery is made by the doctor.

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Comparison of implant features

A brief comparison of existing solutions and Cyberbone, especially in the case of their use in the treatment of children.

	Personalized CYBERBONE implants	Traditional implants, e.g. made from titanium
Implant resorbability — the possibility for bone regeneration	The implant is replaced with the child's own bone in a process where the body naturally reconstructs the implant into its own bone tissue	The implant, most often made of metal or plastic, remains in the child's body or needs to be replaced for a larger one as the child grows
Implant shape	Individually designed and fitted with 3D technology, guaranteeing important things such as aesthetics and psychological comfort in the case of the craniofacial bones	Implant not fitted to the anatomical features of a given child, standardized
Number of operations related to the application of implants	1 implant, 1 operation	A few implants which need to be replaced, fitted to the growing bones, several operations for the child
Dedicated implant composition for a specific patient (almost everybody has a unique bone structure).	Possibility to regulate the composition of each implant's filament. The possibility of admixing additional substances for accelerated healing or securing the implant. This is a custom-made product — personalized for a specific child.	Not possible. Standardized medical devices.
Costs	Due to the use of 3D technology and the adopted solutions, it was possible to reduce the cost of such implants to a minimum. They are cheaper than their standardized counterparts.	Production by the largest medical companies. The costs are calculated for the richest countries in the world. They are very rarely reimbursed in Poland.

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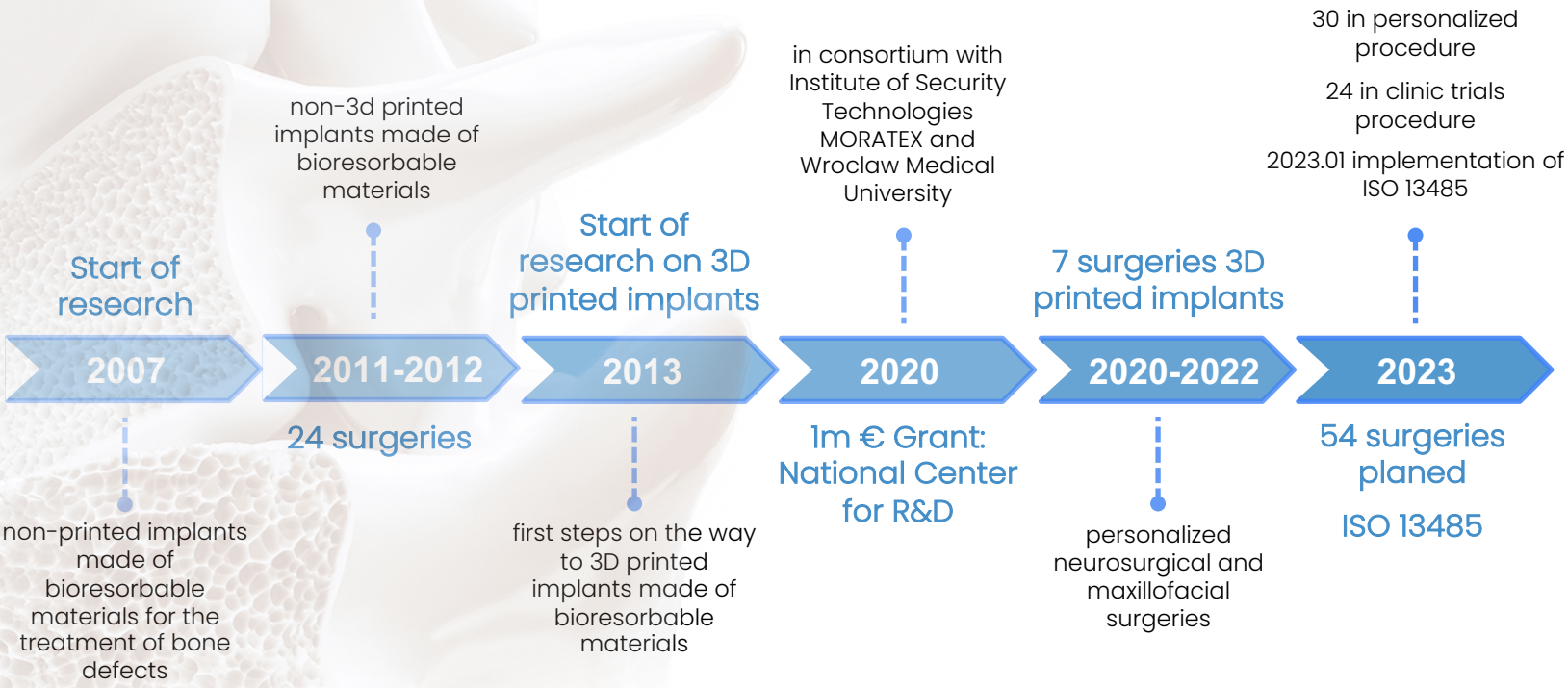
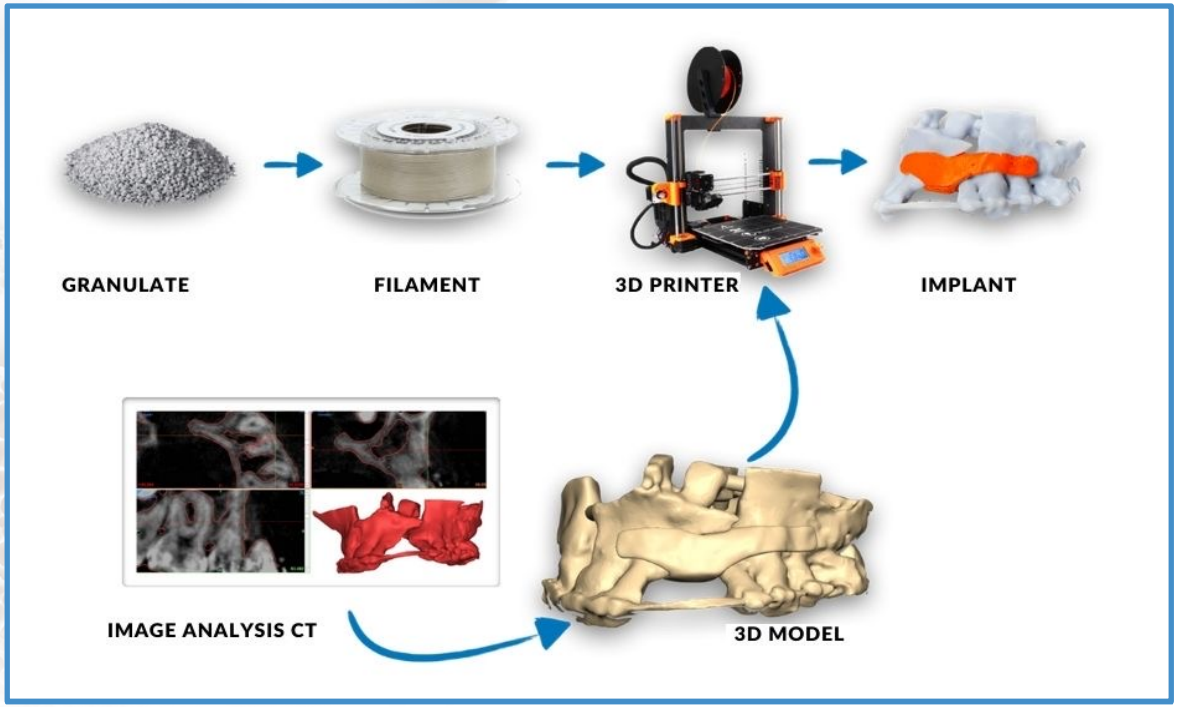
Timeline



We work together with scientists/engineers from leading Polish universities, European institutes, and well known orthopedic clinics

cyberbone

Cyberbone technology process



Our bone-forming Cyberbone filament

Material details:

- Matrix: PLDLLA
- Filler: Hydroxyapatite/TCP
- FDA approved/GMP

Material features:

- Biocompatible/bioresorbable
- Osteoinductive/osteoconductive

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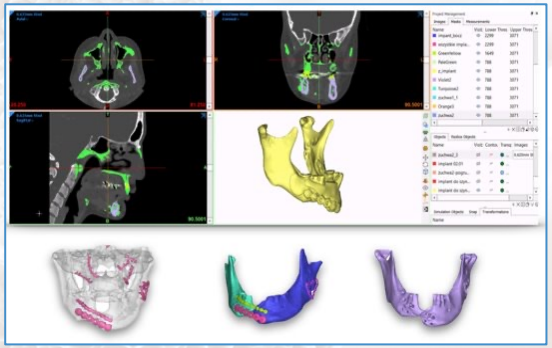
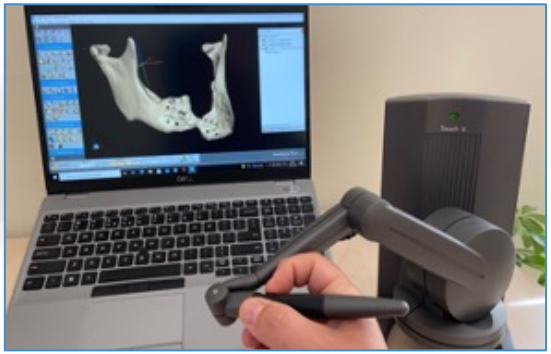
Modeling methodology

Medical imaging



Mimics system — generated model of jaw

Voxel modeling (CE)



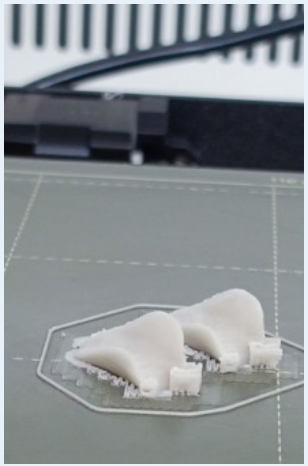
Voxel modeling using haptics — an example of the use of the Freeform Plus system to create a 3D model of an implant

FINAL MODEL

cyberbone

3D Printing process of bone-forming Cyberbone implants

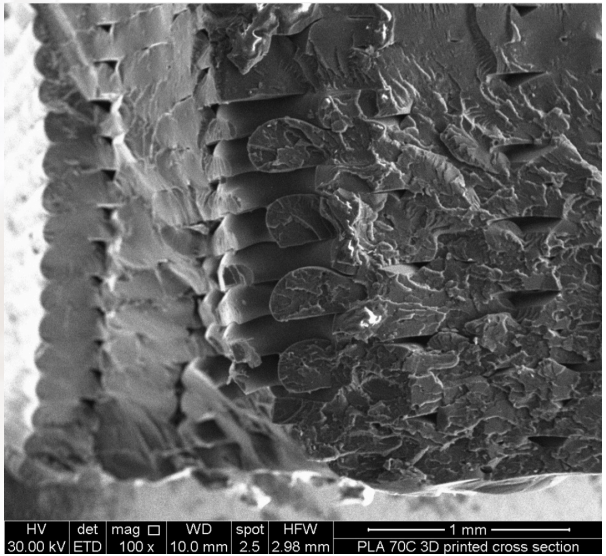
3D printing of personalized implants in a laminar chamber (class 3 purity as per ISO 14644-1). Good quality and affordable 3D printers that allow the technology to be popularized everywhere.



cyberbone

Microporosity

The FDM printing technique provides the required microporosity of implants for bone tissue regeneration.



Sterilization process of personalized Cyberbone implants

Standard sterilization process: radiation via accelerated electron beam.

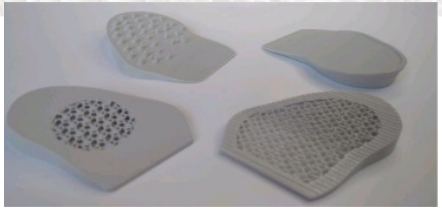
In progress: low-temperature plasma in the proces of validation as a sterilization method for dental and maxillofacial implants.

Three levels of Cyberbone implants personalization

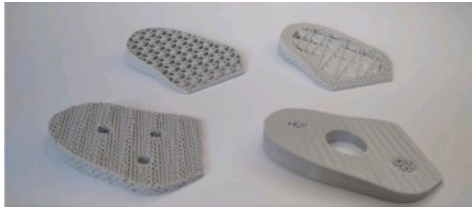
1. Personalization of the shape that optimally fits the bone defect.

2. Personalization of the composition filament (variable proportions of matrix and fillers).

3. Internal structure of the implant corresponding to the planned course of regeneration.



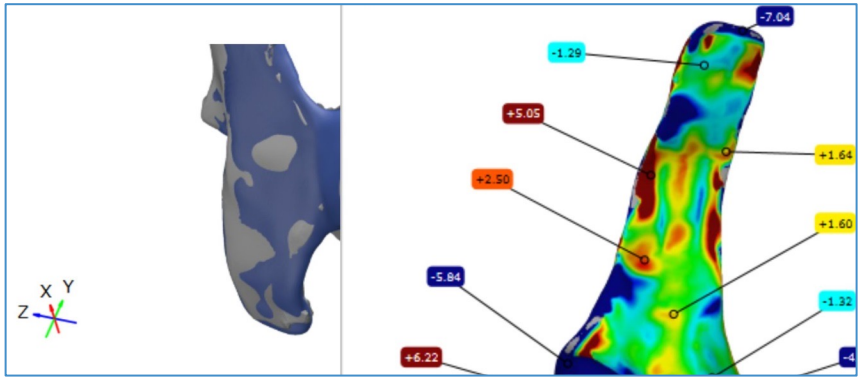




Quality management system for Cyberbone implants

Selected points

Personalization of implants requires control over the precision of 3D printing compared to STL design. In the Cyberbone project, we use the most precise methods for comparing such data.



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Quality management system for Cyberbone implants

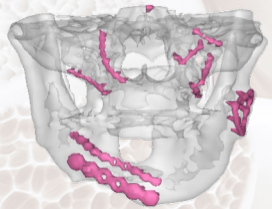
Selected points

They concern antimicrobial activity - this is the antimicrobial potential of the implant (material - PLDLLA+HAp) against microorganisms that cause intraoperative infections and secondary infections.

Cyberbone implants show antimicrobial properties against pathogenic microorganisms, including both clinical isolates and reference strains, especially against Streptococcus mutans, Enterobacter aurogenes and Pseudomonas aeruginosa.

Craniofacial reconstruction after a car accident

1



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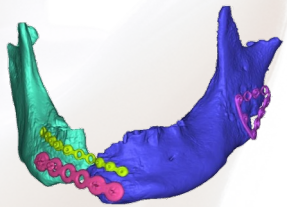

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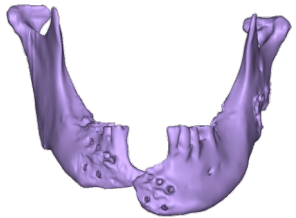

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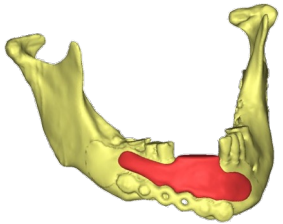
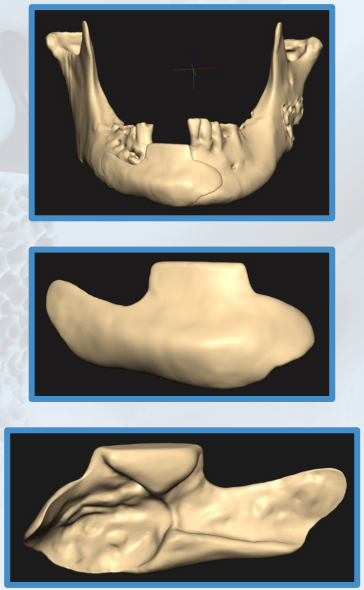


cyberbone

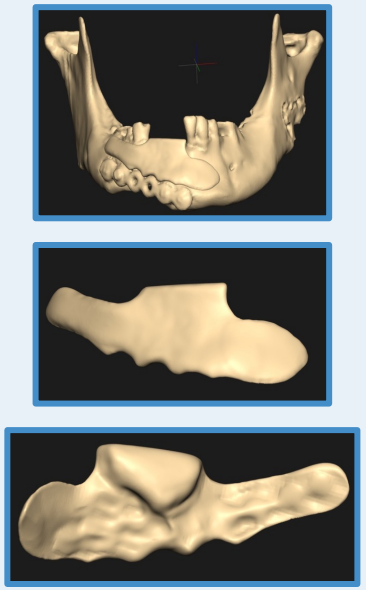
Craniofacial reconstruction after a car accident

Comparison of different implant versions

Version A



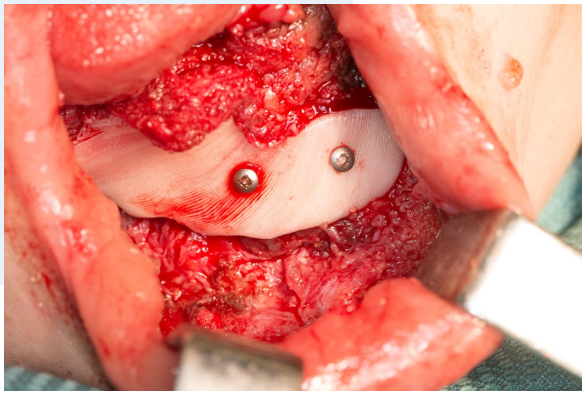
Version B



cyberbone

Craniofacial reconstruction after a car accident

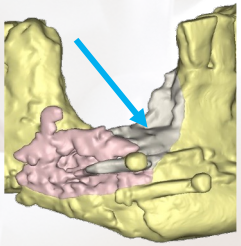
Printed implant

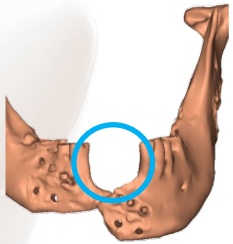


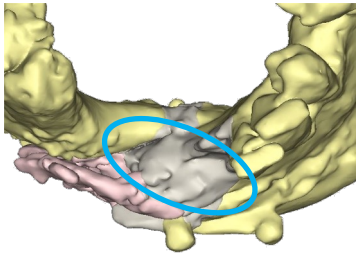
Successful surgery - implant placement

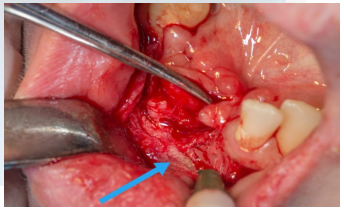
Process of regeneration

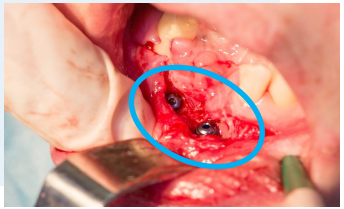
Due to exposure through the soft tissues, the implant became partially fractured and destabilized after about 50 days. About 70% of the implant remained in the implant site. After 12 months, the implant was found to induce anatomical bone remodeling, allowing the application of dental implant screws.











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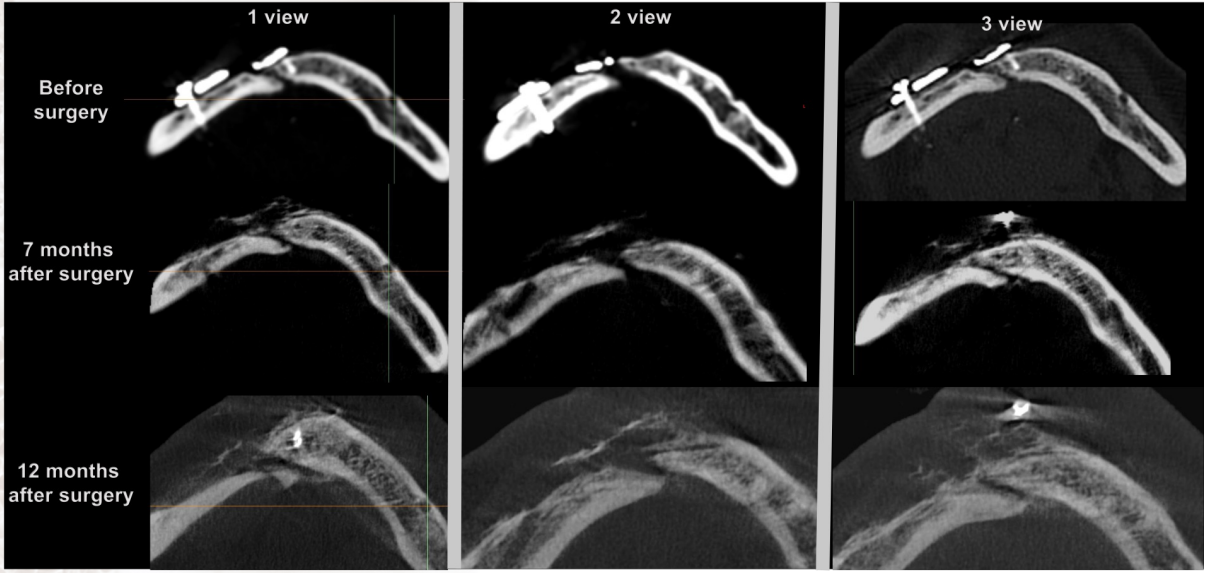
Process of regeneration



cyberbone

Success

After 14 months of the implant application, the patient had dental implants installed.

Before surgery

After 14 months

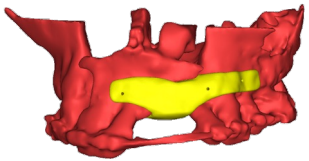
Cleft palate

The patient underwent jawbone reconstruction surgery, with implantation of autogenous bone taken from the hip plate.
Unfortunately, the biological material was completely resorbed, failing to initiate jawbone growth.

1

2

3



Cleft palate

Printed implant

Successful surgery - implant placement

Process of regeneration

1st medical check

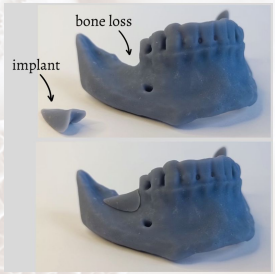
2nd medical check

3rd medical check

The path from manufacturing to the effect of surgery

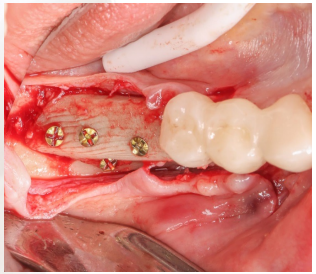
Patient with anatomical mandibular bone loss. Necessary scaffold for bone reconstruction for future orthodontic-implant treatment. A personalized 3D bioresorbable implant was prepared for the patient.

1



Printed implant

2



Successful surgery - implant placement

3

The effect of the surgery

cyberbone

TEAM

About 20 engineers – scientists - doctors from several institutions, universities, and companies cooperate with us.

Prof. **Zbigniew Rybak** MD, PhD, DSc

Prof. **Krzysztof Ficek** MD, PhD, DSc

areas of activity: implementations in applied orthopedic/plastic surgery and technological development

Prof. **Marcin H. Struszczyk** BEng, PhD, DSc

Scientists from the ITB Moratex Łódź

Monika Dobrzyńska-Mizera BEng, PhD

Monika Knitter BEng, PhD

Jacek Andrzejewski BEng, PhD, DSc

Scientists from the Poznań University Of Technology

areas of activity: polymer chemistry, implant-filament production, 3D printing of implants, post-production testing

Marcin Wątrobiński
Founder, CEO

Jan Szczygieł
CFO

Bogdan Czapiga MD, PhD, DSc

Maciej Stagraczyński MD, PhD

4th Military Clinical Hospital and Polyclinic in Wrocław

Michał Mikulski DDS

areas of activity: implementations in neurosurgery and maxillofacial surgery and technological development

Prof. **Marek Wyleżoł** BEng, PhD, DSc

Małgorzata Muzalewska BEng, PhD

Silesian University of Technology

areas of activity: designing 3D implants from CT images

Anna Ostrowska

QMS Manager

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