biodrook

2024

Team.

biodrook

Denys Gurak

Founder of biodrook.
Serial entrepreneur and investor in the technology sector.
Former Director of the GMP Center and Deputy Director General of UkrOboronProm.

Mykhailo Pluzhnyk

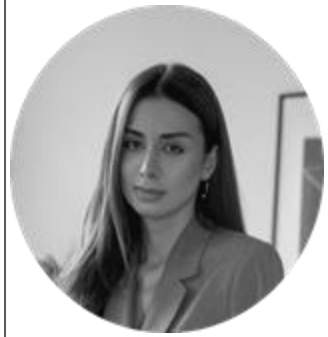
Chief Technical Officer
Engineer specializing in additive manufacturing, material chemistry, and project management.

Kateryna Osetrova

Director
Head of business development in Ukraine.
Management of the production of biotech products, cord blood bank, and medical center.

Carlton J. Savory, MD

First Command Surgeon of the U.S. Joint Special Operations Command, former Assistant Chief of Orthopedics at Walter Reed.



Yuliia Shapovalova

First advisor to the founder, legal counsel
Head of consulting companies, startup manager of IT, fintech, and investment (AMC, CIF) projects.

Advisory Board

Anthony Tether, Ph.
Chief scientific consultant
Former DARPA director, expert on innovative research and development

Alexander Gamota
Business development advisor
30+ years of experience as an executive and founder in consulting and project management with over $4 billion in value

Anson Ma
Chief Technology Advisor
Associate Professor at the University of Connecticut, Director of SHAP3D, expert in complex fluids and 3D printing

Daniel Edmonds-Waters
Strategic advisor
Chairman of the Griffith Leadership Center at the University of Michigan, former CEO of Kaiser Permanente

Ambassador Piet Hoekstra
Chief Advisor on Government Relations
Former US Ambassador to the Netherlands, political advisor

Philip Karber, PhD
Chief Strategy Advisor
President of the Potomac Foundation, former Chief Strategy Officer of the US Department of Defense, Strategic Advisor to NATO

Tamir Harosh
Business development advisor
Professional advisor, head of business development, negotiation and consulting teams for clients

Denis Burykin
Digital Strategy Advisor
Entrepreneur with leadership and management positions in ICT and technology-oriented organizations

Christopher Harvin
Chief International Advisor
Global strategic communications expert and political advisor

Bone Implantation:
Trapped in outdated practices

biodrook

- Non-custom Metal Implant
- Transplantation of your own bone
- Transplantation of cadaveric tissue

Expensive

Long Production & Delivery

Painful Recovery

3D-printed implants:
Superior Tech, Slow Adoption

1999

First 3D-printed implant transplanted

2022

First on-site implant manufacturing lab

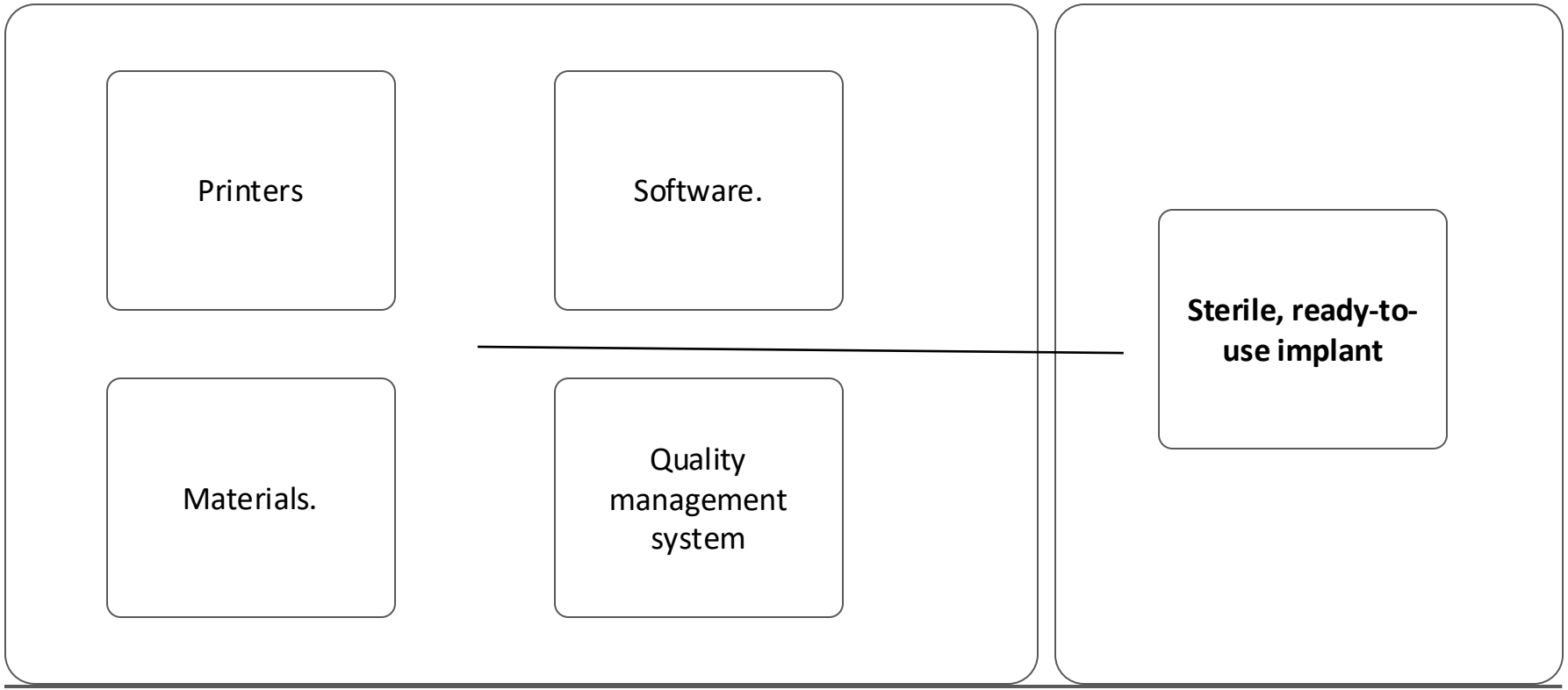
MORE THAN

150

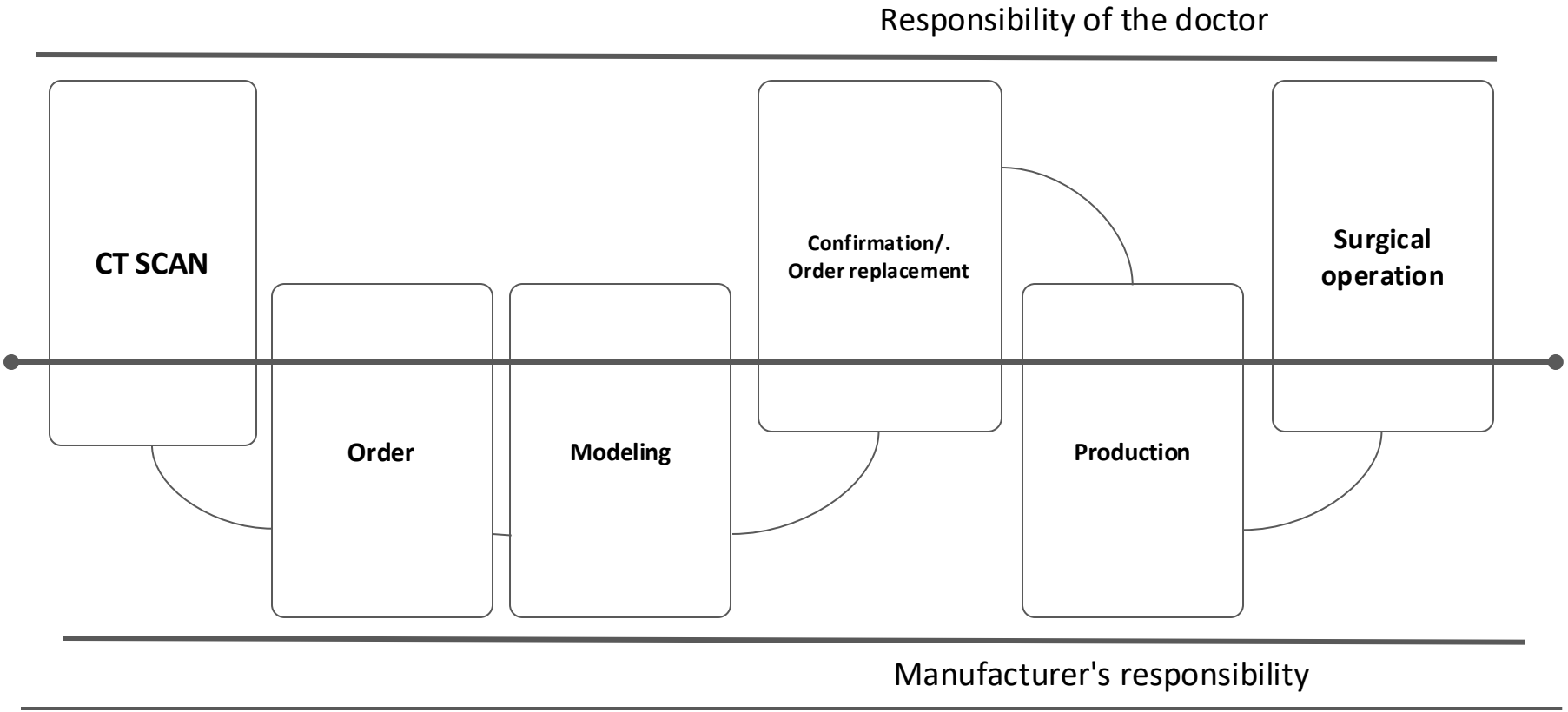
manufacturing companies engaged in 3D bioprinting

A turnkey solution for 3D-printed implants

biodrook



The production process and the participation of doctors:



Key advantages

biodrook

Expertise

4+ years of experience in implementation, industrial partnership, QMS

Speed

start in Ukraine. A loyal regulator, an organic need due to the war

Access

to the portfolio of biopolymers of the world's best biomaterials manufacturers

FDM technology

printing makes it easy to scale production due to the availability and mass production of printers

Bioresorbent materials

avoid repeated operations to remove implants

The biodrook team ensures a quick launch of production, controlled certification, creation of an informative portfolio of before and after cases, and work with surgeons and patients to ensure financial support for the implementation of surgical interventions from charitable foundations.

Advantages over existing solutions

biodrook

- production speed
- lower product price
- without need in a second operation
- no trauma to the patient for bone marrow autoplasty
- stimulation of osteogenesis
- suitable for use in the maxillofacial surgery
- non-allergenic, non-toxic, without teratogenic properties
- maximally adaptive, unlimited in form

biodrook

Applications

Our biomaterials

biodrook

Non-resorbent materials:

- PEEK (polyetheretherketone)
- PEKK (polyetheretherketone ketone)
- PP (polypropylene)
- TPU (thermopolyurethane)

Used for: cranial plates (PEEK), hernia mesh (PP), facial reconstruction (TPU).

Resorbent materials:

- PLDLA (poly D-co-L lactide)
- PLA (polylactide)
- PCL (polycaprolactone)
- PLGA (polylactide-co-glycolide)
- Bioglass 45S5

They are used for: filling bone defects, arthrodesis, intervertebral fusion, bone volume reconstruction.

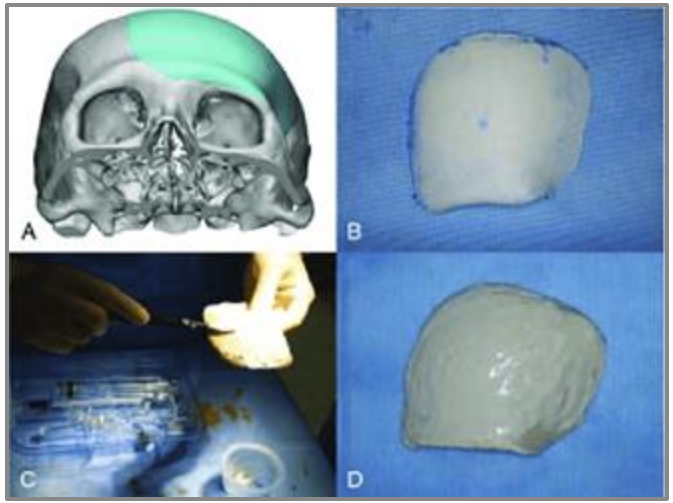
The Evonik Resomer polymer portfolio as an example of variations in resorption times

biodrook

Polymer name	Inherent viscosity (dl/g)	Composition	Degradation timeframe*	End group
RESOMER® C 209	0.8 - 1.0	Poly(caprolactone)	> 2 years	Ester
RESOMER® G 205 S	1.05 - 1.25	Poly(glycolide)	< 5 weeks	Ester
RESOMER® L 206 S	0.8 - 1.2	Poly(L-lactide)	> 3 years	Ester
RESOMER® Composite L 210 S HA	3.0 - 4.0	Poly(L-lactide) with 25 % Hydroxyapatite	< 3 years	Ester
RESOMER® Composite LG 855 S β-TCP	2.0 - 3.5	Poly(L-lactide-co-glycolide) with 30% β-tricalcium phosphate	< 1.5 years	Ester
RESOMER® Composite LR 706 S β-TCP	2.8 - 4.2	Poly(L-lactide-co-D,L-lactide) with 30% β-tricalcium phosphate	< 2 years	Ester
RESOMER® LRP t 7016	3.3 - 4.2	Poly(L-lactide-co-D,L-lactide-co-PEG) triblock	< 9 months	Acid
RESOMER® X 206 S	1.5 - 2.2*	Polydioxanone	< 6 months	Ester

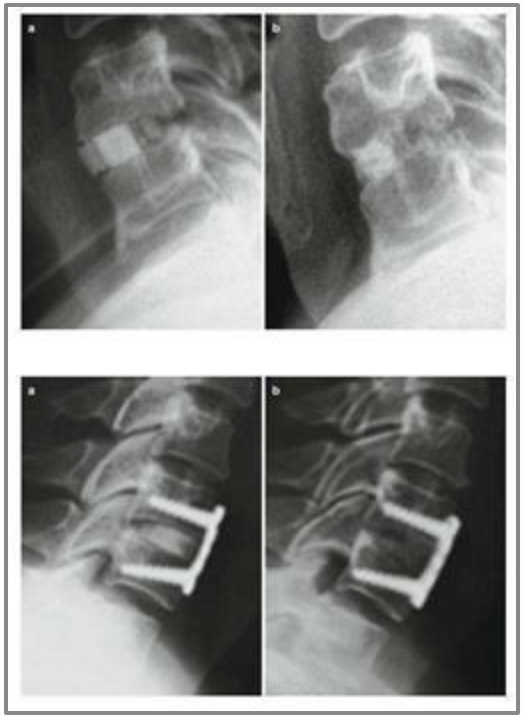
* The approximate degradation time is intended for polymer selection. The actual resorption time depends on the process and application and must be determined empirically.

Examples of the use of bioresorbable implants



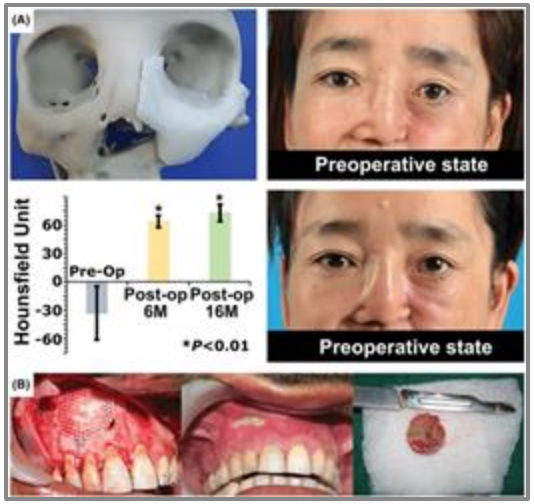
Surgical procedure of cranioplasty based on PCL/ß-TCP implants:

a) preoperative modeling of the implant structure.
(b) Three-dimensional printed PCL/ß-TCP implant. (C, D) Hydroxyapatite paste was applied to the implant surface. PCL - polycaprolactone; ß-TCP - beta-tricalcium phosphate.



Duocage osteoconductive cage made of PLLA/b-TCP:

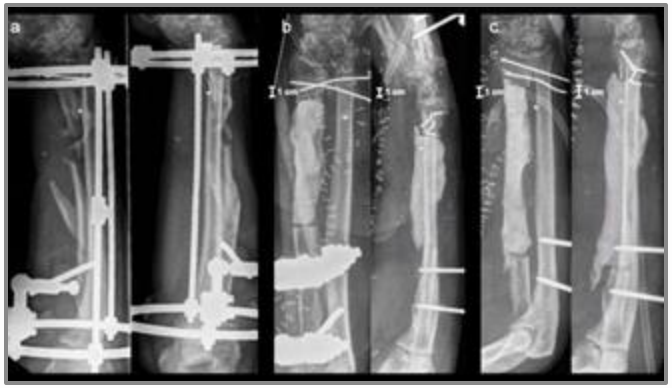
a) postoperative period
b) 32 months, complete osseointegration of the product and vertebral growth can be observed



Reconstruction using a PCL scaffold

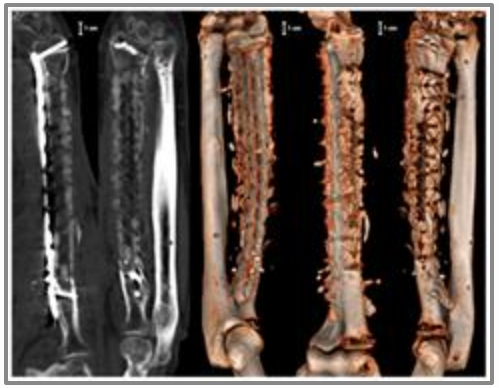
An example of the use of bioresorbable implants in case of a gunshot wound

biodrook

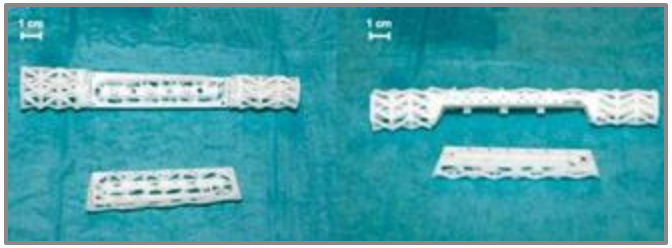


Radiographs (in direct projection and lateral projection) of the right forearm:

(a) at the time of hospitalization; (b) after the 1st surgery; (c) before bone reconstruction surgery



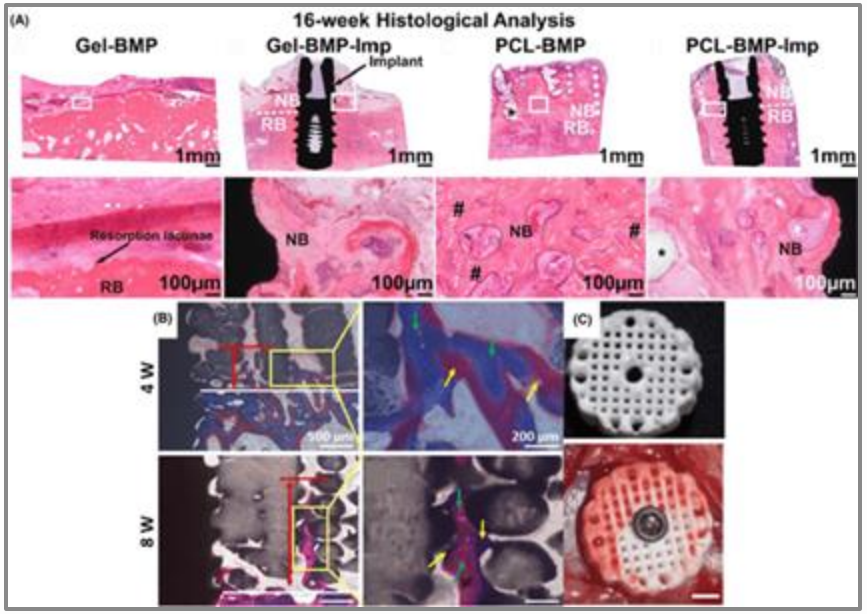
Postoperative CT scan



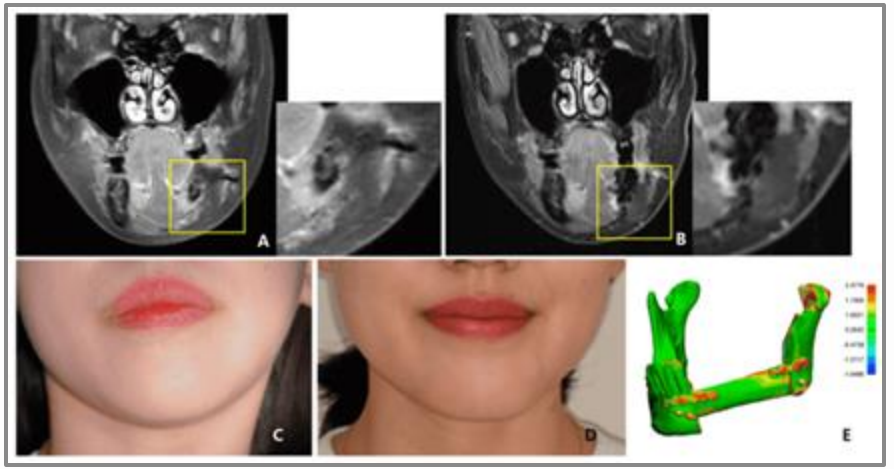
Printed scaffold for reconstruction, polycaprolactone material, resorption time 18-24 months

3 months after surgery, no complications

Examples of the use of bioresorbable implants:



Resorption of polycaprolactone implants in dental surgery



Postoperative results of lower jaw reconstruction (cancer):

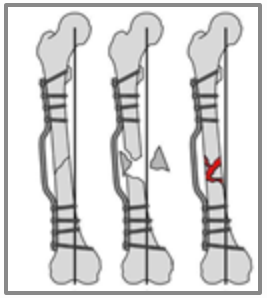
a) PCL lattice pattern clearly visible on coronary MRI 11 months after surgery

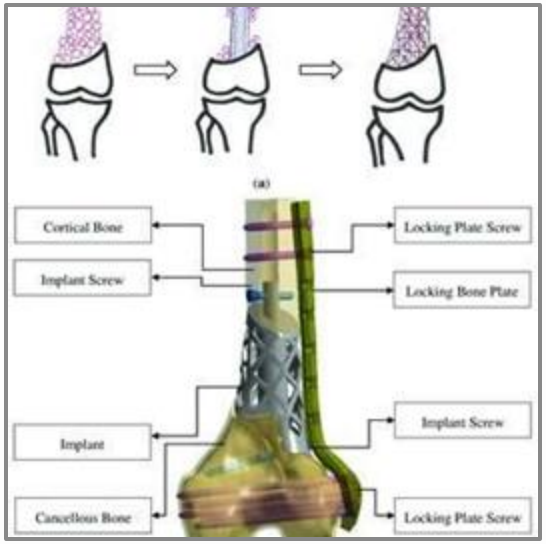
b) The implant pattern is not visible on MRI 40 months after surgery. The yellow box shows the area containing the PCL implant, which was magnified and displayed in the adjacent image. As shown in (c) preoperative photographs and (d) photographs 6 years after surgery, the patient's mandibular volume was maintained symmetrically

e) As a result of comparative mapping by overlaying the virtual plan and postoperative CT data, an error of 1 mm was detected.

How to work with the implant:

- The implant is delivered sterile and ready for use.
- The placement procedure requires preliminary planning. The surgeon chooses which internal fixation devices will be used and transmits this information to the modeler at the stage of implant development.
- The designer develops elements such as eyelets, spigots, and meshes for fastening solely on the surgeon's instructions.
- Screws, spokes, glue, and instruments are not supplied directly by the implant manufacturer, but can be additionally supplied by other manufacturers if necessary, according to the surgeon's usual practices.

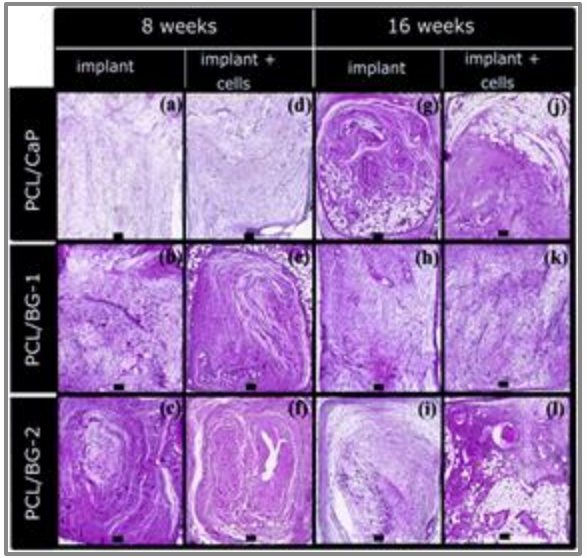




How the implant works:

biodrook

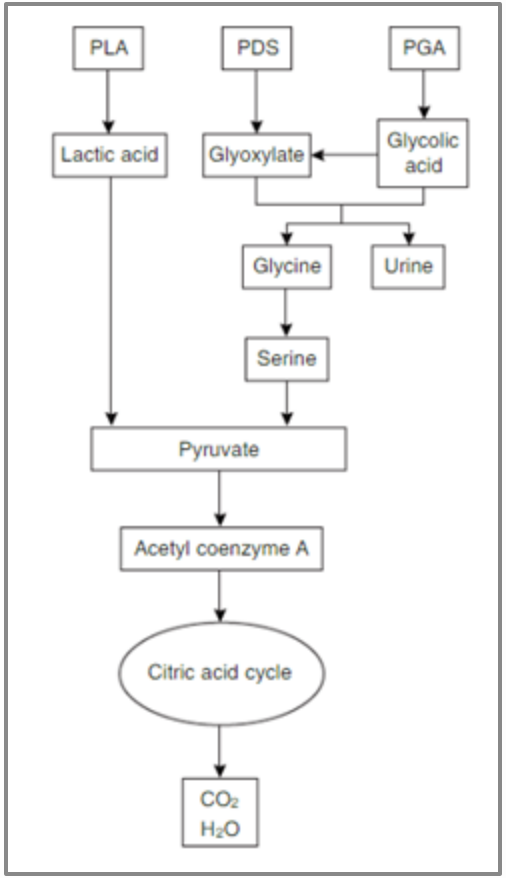
- The implant consists of a bioresorbable polymer and a mineral filler that is similar in composition to the mineral composition of the native bone
- After implantation, the osteoclasts attach to the surface of the mineral filler particles and begin to absorb it, while simultaneously releasing signal peptides that attract osteoblasts
- The mesenchymal cells secrete the appropriate set of factors and the primary vascularization of the implant and later angiogenesis begins
- As the polymer degrades, new mineral filler particles are released and continue to serve as a structural cue for the formation of new native bone based on the lattice scaffold



In vitro and in vivo bone formation potential of surface calcium phosphate-coated polycaprolactone and polycaprolactone/bioactive glass composite scaffolds. Patrina S P Poh, et al., 2015

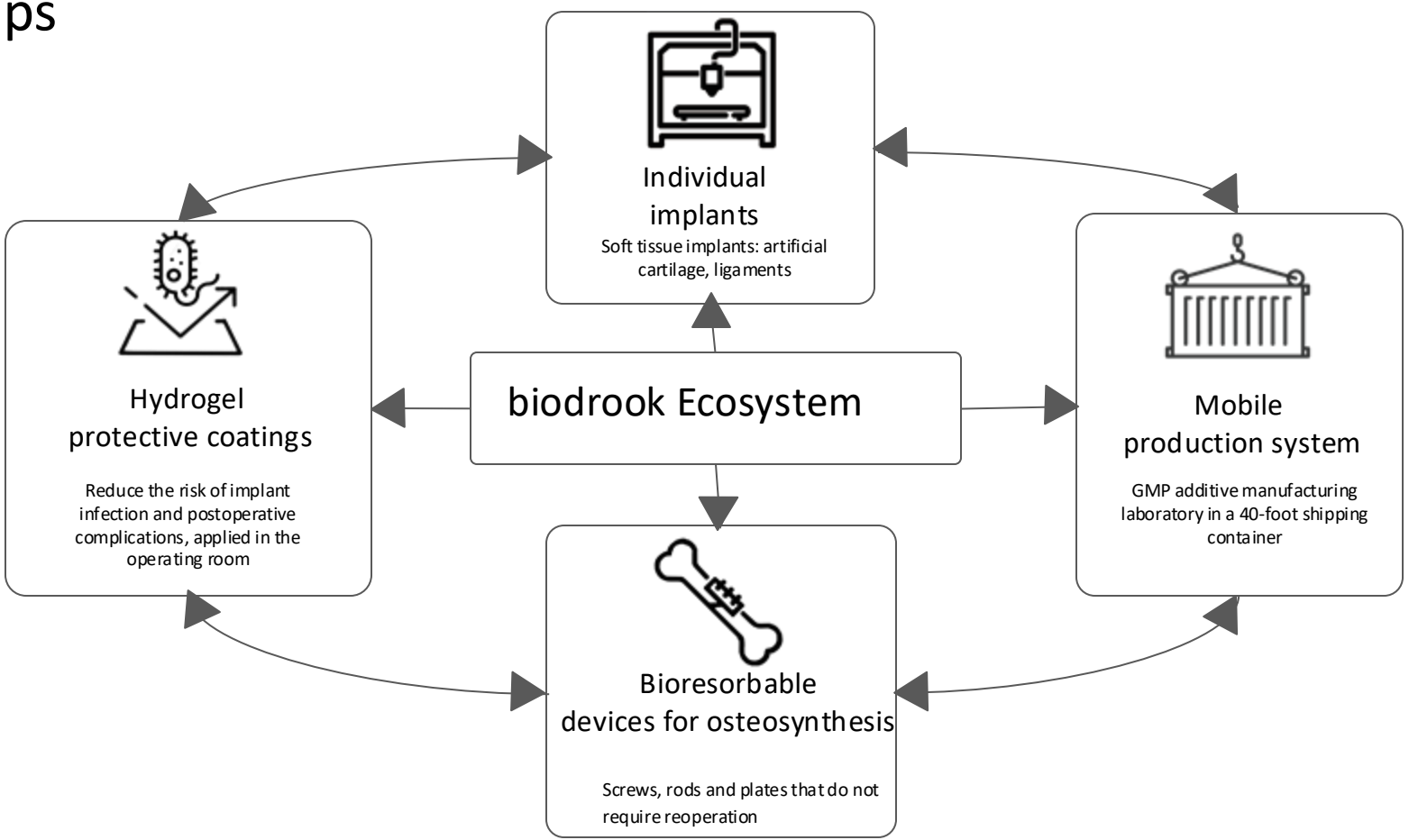
Degradation and modification:

- The mechanical properties of the implant gradually deteriorate as the molecular weight of the polymer decreases. Different polymers have different degradation periods specified by polymer manufacturers. The actual degradation periods may differ from the table.
- The portfolio of our suppliers allows us to use products with a degradation period of 3 months to 2 years
- The degradation of biopolymers in our portfolio (PLA, PLGA, PCL) is hydrolyzed and has no toxic degradation products
- Polymer fillers have antibacterial properties (45S5 bioglass, CaP, b-TCP)
- The production scheme allows potential modification of the polymeric component of the product with different antibiotics at the time of production, which will allow the release of APIs for a long time. This reduces the risk of infectious postoperative complications.



Infrastructure and portfolio development: next steps

biodrook



Production system in a shipping container: Mobile Medical Device Production Unit (MoMDPU)

biodrook

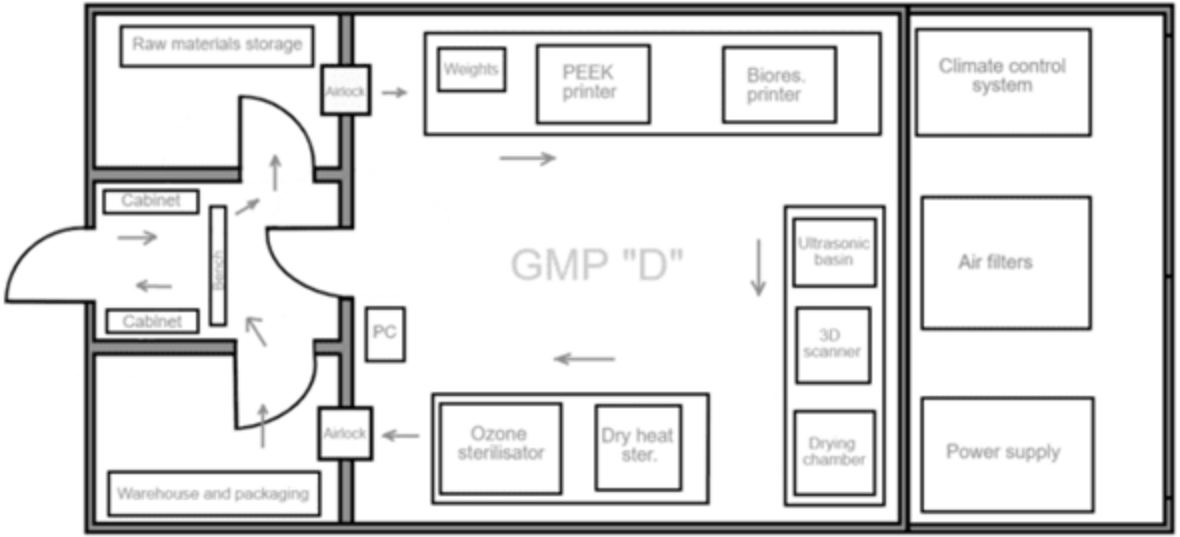
Production system:

- 3D printing from biocompatible polymers (PEEK, PLA, PLDLA, PCL, PP)
- cycle from granular polymer to packaged sterile product
- implant production from 4 to 48 hours
- deployment of production in 1 business day
- certification of the QMS according to ISO 13485
- in the future: soft tissue implants, large blood vessels, cartilage, skin
- operator training
- devices: cranial plates, reconstruction in the SCL, trauma plates, frames, resorbable bone defect fillers, resorbable screws, etc.

The military hospital receives its own production module that can meet the hospital's needs for customized and, partially, traditional bone implants.
Dual purpose: the module can also be used for civilian hospitals.

What's inside the container:

The diagram shows the additive manufacturing of implants under GMP class D conditions.



- At the entrance - certified raw materials in the form of powder/granulate
- The result is a sterile implant
- The container prototype is scheduled for release in 2026

Hydrogel protective coatings for implants

- The rapidly degradable hydrogel is applied to the sterile implant intraoperatively, before placement, and acts as a protectiv barrier to prevent the formation of biofilm on the implant surface.
- The hydrogel can be loaded with an antibiotic.
- Will be supplied with a pre-filled syringe/tube and mixing system
- Planned market launch: end of 2025

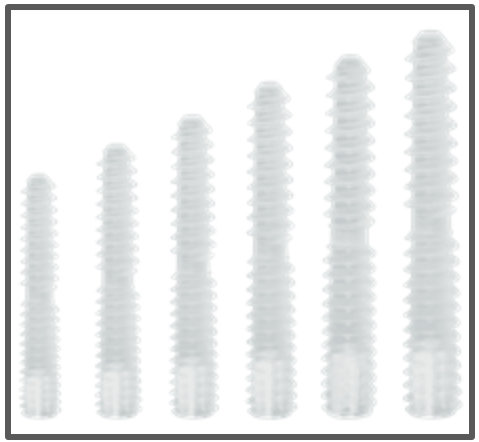
An example of a similar DAC (Defensive Antibacterial Coating) product filled with vancomycin

Example of a similar DAC product, clean

Bioresorbable screws and plates for osteosynthesis

biodrook

Our expertise in biopolymers allows us to create a product line that logically complements our core product.



The screws are manufactured using traditional extrusion technology into a metal mold, reproducing established and familiar shapes, repeating a convenient set of sizes and tools.

The resorbable trauma plates are made of PLGA and biodegrade up to 24 months, providing reliable osteofixation in the first 6-9 months.

The products are scheduled for release in late 2025

You can become an early adopter of our products and gain advantages in the healthcare market using our innovations

We are open for cooperation!

Contacts:
info@biodrook.com

Executive Director:
Kateryna Osetrova

k.osetrova@biodrook.com

Chief Technological officer:
Pluzhnyk-Hladyr Mykhailo

mpluzhnyk@biodrook.com