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2024

Team.





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

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



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



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



Tamir HaroshBusiness development advisorProfessional advisor, head ofbusiness development, negotiationand 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Bone Implantation: Trapped in outdated practices





Non-custom Metal Implant

Transplantation of your own bone

Transplantation of cadaveric tissue



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3D-printed implants: Superior Tech, Slow Adoption MORE THAN 202 150 199 First 3D-printed implant First on-site manufacturing companies transplanted implant engaged in 3D bioprinting manufacturing lab

A turnkey solution for 3D-printed implants



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The production process and the participation of doctors:

Responsibility of the doctor



Manufacturer's responsibility

Key advantages



Expertise	Speed	Access	FDM technology	Bioresorbent materials
4+ years of experience in implementation, industrial partnership, QMS	start in Ukraine. A loyal regulator, an organic need due to the war	to the portfolio of biopolymers of the world's best biomaterials manufacturers	printing makes it easy to scale production due to the availability and mass production of printers	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.

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- 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

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Applications

Our biomaterials

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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.

Examples of the use of bioresorbable implants

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

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





Reconstruction using a PCL scaffold

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

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

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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



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



Postoperative CT scan



3 months after surgery, no complications

Examples of the use of bioresorbable implants:

16-week Histological Analysis PCL-BMP-Imp Gel-BMP Gel-BMP-Imp PCL-BMP Implant esorption lacunae 100µm 100µm Postoperative results of lower jaw reconstruction (cancer):

Resorption of polycaprolactone implants in dental surgery

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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.

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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:

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- 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 phosphatecoated 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.



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Infrastructure and portfolio development: next steps



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

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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:

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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 protective 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

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



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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!

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