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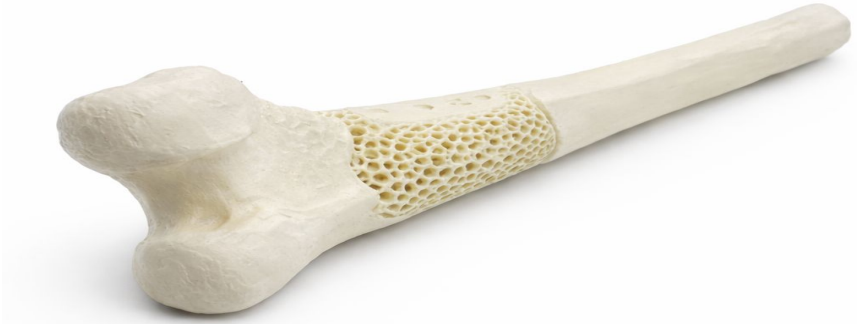

Scan or click to watch

biodrook: Advanced Bone Regeneration

biodrook develops and manufactures customized 3D-printed bone implants in Ukraine.

- Production facility operational
- ISO 13485 quality system implemented
- First product certified (Ukraine)
- Commercial sales initiated
- Two products in certification (2026 launch)

ResorBone

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ResorBone™ is a medical device certified in Ukraine for surgical use in bone tissue regeneration.

Key Characteristics and Clinical Indications:

- **Intended for filling bone defects** resulting from trauma, surgical interventions, resections, or post-extraction procedures.
- The material exhibits **both osteoconductive and osteoinductive properties:** it provides a structural scaffold for bone matrix formation while actively stimulating new bone growth.
- **Fully bioresorbable with a controlled degradation rate**, allowing gradual replacement by newly formed bone tissue (bone regenerate).
- **Certification in Ukraine** confirms compliance with safety requirements and applicable regulatory standards for medical use.

Key Advantages:

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Expertise

Developed by a team of specialists with clinical experience in surgery and biomaterials.

Speed

Production within 5 days from receiving the patient's CT data to delivery of a surgery-ready implant.

Access

Access to a portfolio of biopolymers from leading global biomaterial manufacturers.

Safety

Biocompatible and sterile materials that do not cause toxic or adverse immune reactions.

Bioresorbable materials

Eliminate the need for secondary surgery to remove the implant.

The biodrook team ensures rapid production launch, controlled certification processes, development of informative before-and-after case portfolios, collaboration with surgeons and patients, and financial support facilitation through charitable foundations.

Our Biomaterials:

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Non-resorbable materials:

- PEEK (polyetheretherketone)

In development:

- TPU (thermoplastic polyurethane)
- PP (polypropylene)
- Silicone

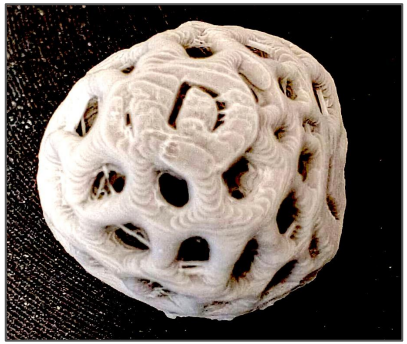
Used for: cranial plates (PEEK), hernia meshes (PP), facial reconstruction (TPU).

Resorbable materials:

- PLLA (poly-L-lactide),
- Hydroxyapatite

In development:

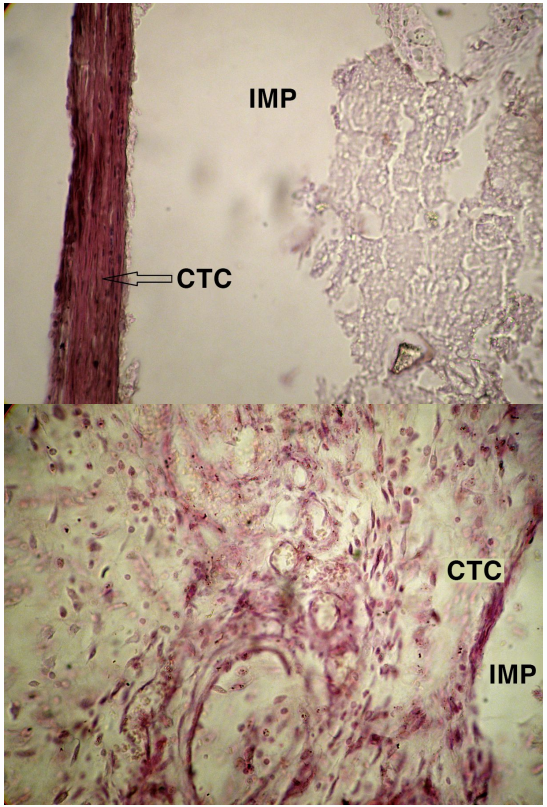
- PLA (polylactide),
- PCL (polycaprolactone),
- PLGA (polylactide-co-glycolide)



Used for: bone defect filling, arthrodesis, intervertebral fusion, bone volume reconstruction.

How the Implant Works:

- The implant is composed of a bioresorbable polymer matrix combined with a mineral filler closely resembling the native bone mineral composition.
- After implantation, osteoclasts attach to the surface of mineral particles and begin resorption, simultaneously releasing signaling peptides that attract osteoblasts.
- Mesenchymal cells release growth factors, initiating early vascularization of the implant followed by angiogenesis.
- As the polymer gradually degrades, new mineral particles are exposed, continuously serving as structural guidance for native bone formation within the lattice scaffold.



CTC: Connective Tissue Capsule
IMP: Anatomically Adapted Bioresorbable Bone Filler

Degradation and Material Modifications:

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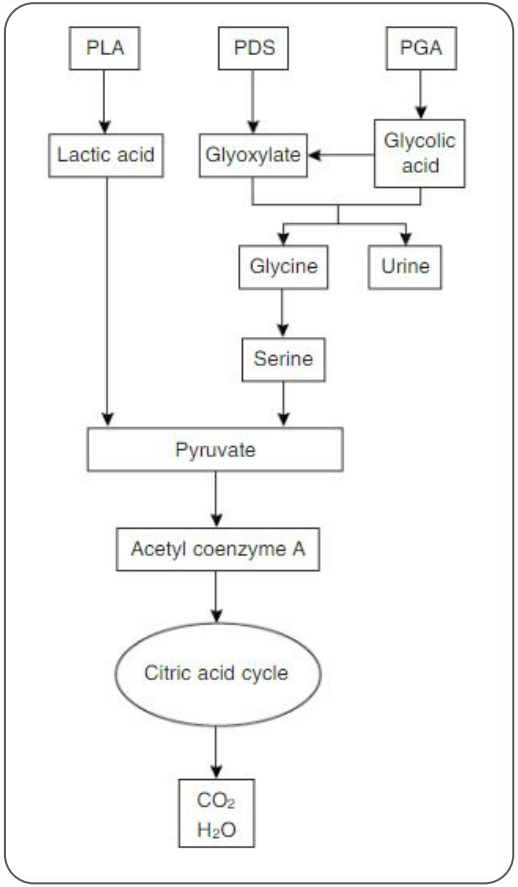
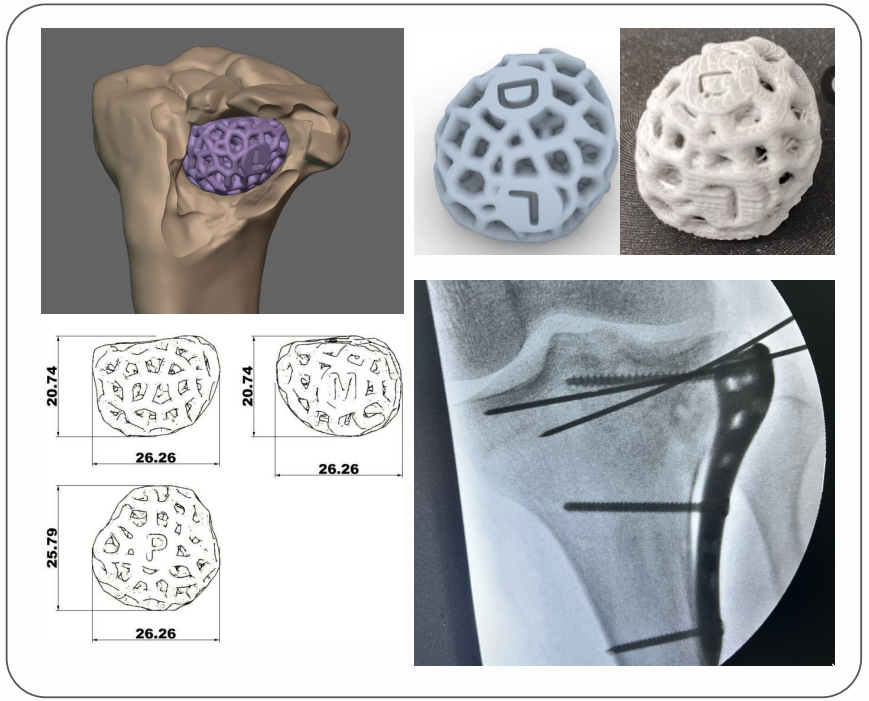
- The mechanical properties of the implant gradually decrease as the polymer molecular weight declines during degradation. Different polymers exhibit distinct degradation timelines as specified by manufacturers; actual in vivo degradation may vary from reference data.
- Our supplier portfolio enables the selection of materials with degradation periods ranging from 3 months to 2 years.
- The biopolymer (PLA) degrade via hydrolysis, producing no toxic byproducts.
- Polymer fillers demonstrate antibacterial properties, including bioactive glass 45S5, calcium phosphates (CaP), and β-tricalcium phosphate (β-TCP).



How to work with the implant:

- The implant is supplied sterile and ready for use.
- The implantation procedure requires prior planning. The surgeon independently selects the internal fixation methods to be used and provides this information to the modeler during the implant development stage.
- The designer develops elements such as tabs, connectors, and fixation meshes strictly according to the surgeon’s instructions.
- Screws, wires, adhesives, and surgical instruments are not supplied directly by the implant manufacturer, but can be additionally provided by other manufacturers if necessary, in accordance with the surgeon’s standard practices.



Production Process and Participation of Doctors:

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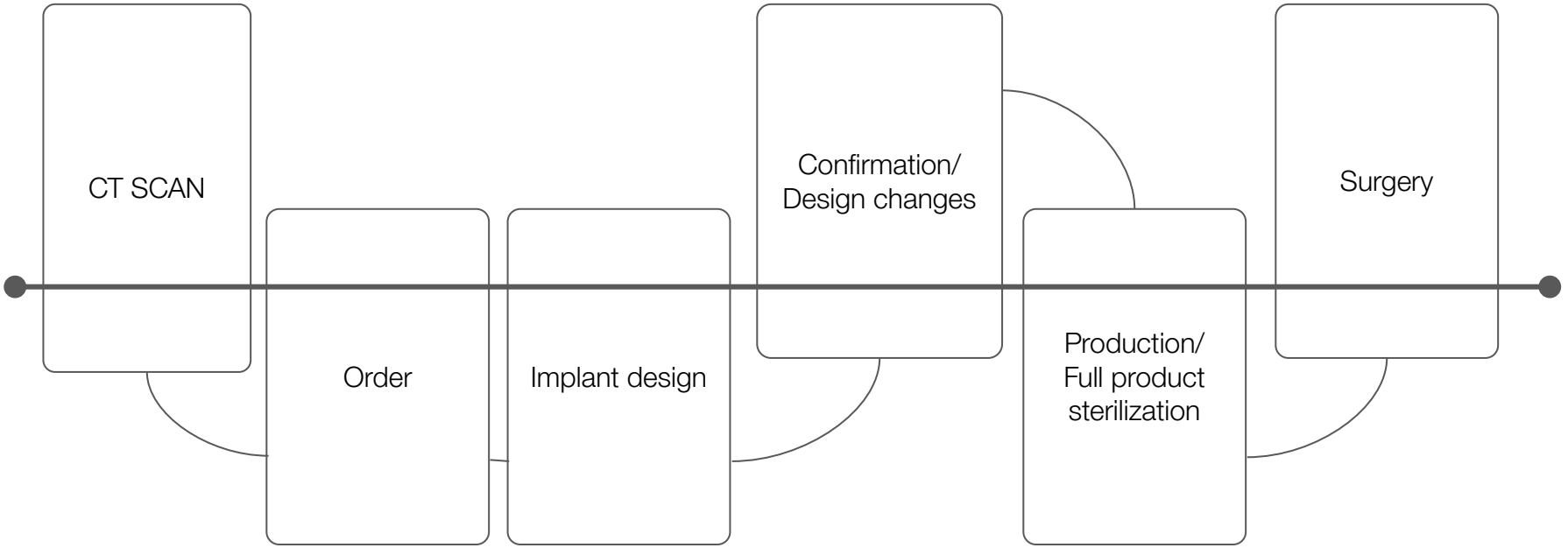
Responsibility of the doctor



Manufacturer's responsibility

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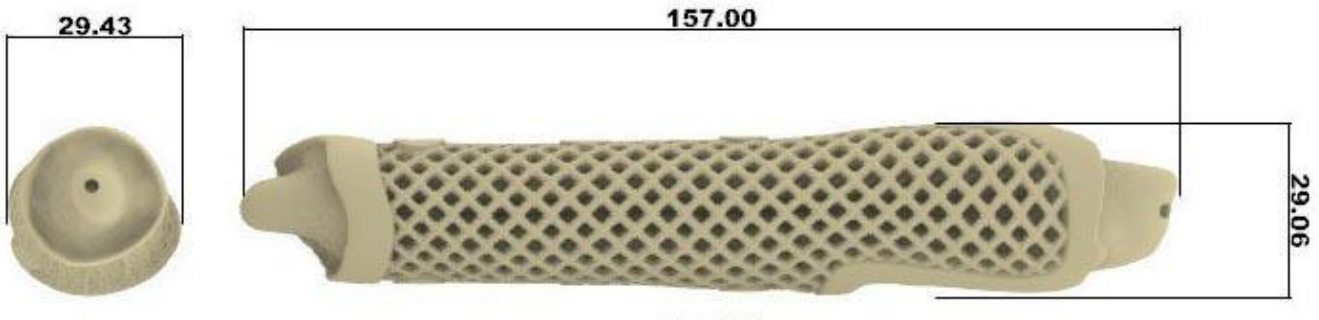
Implant Design Development Process



Step 1: Order Form & Clinical Data Collection

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Structured order form collects technical specifications and clinical requirements for implant design.

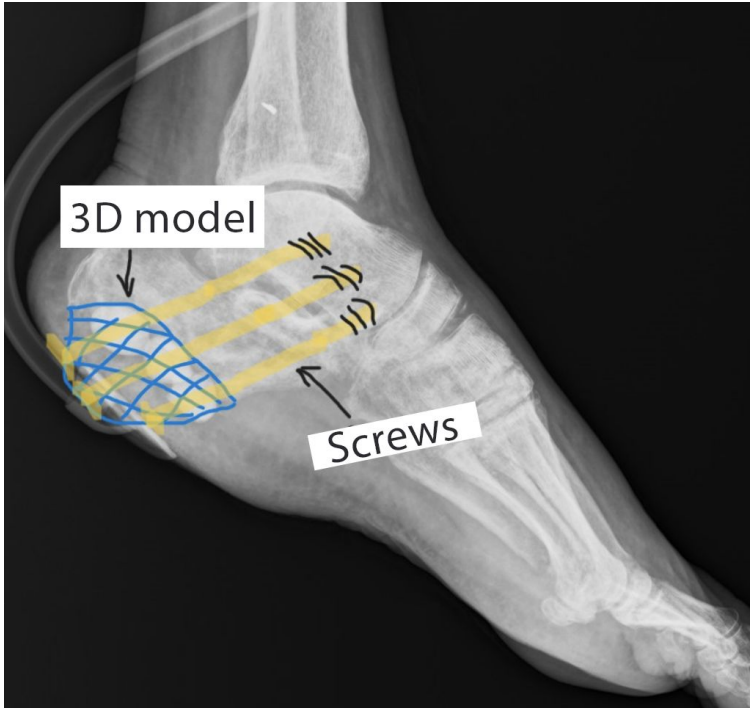
Key inputs include:

- Indication for implantation
- Defect geometry (location, size, direction, volume)
- Desired fixation method
- Anatomical implantation site

Visual input: 3D sketches provided by the surgeon to clarify spatial positioning and fixation strategy.

Collaborative VR session: The surgeon creates a volumetric sketch using a virtual reality headset, supported by short guided training.

All supplementary case data are securely stored on a restricted-access corporate drive for traceability.

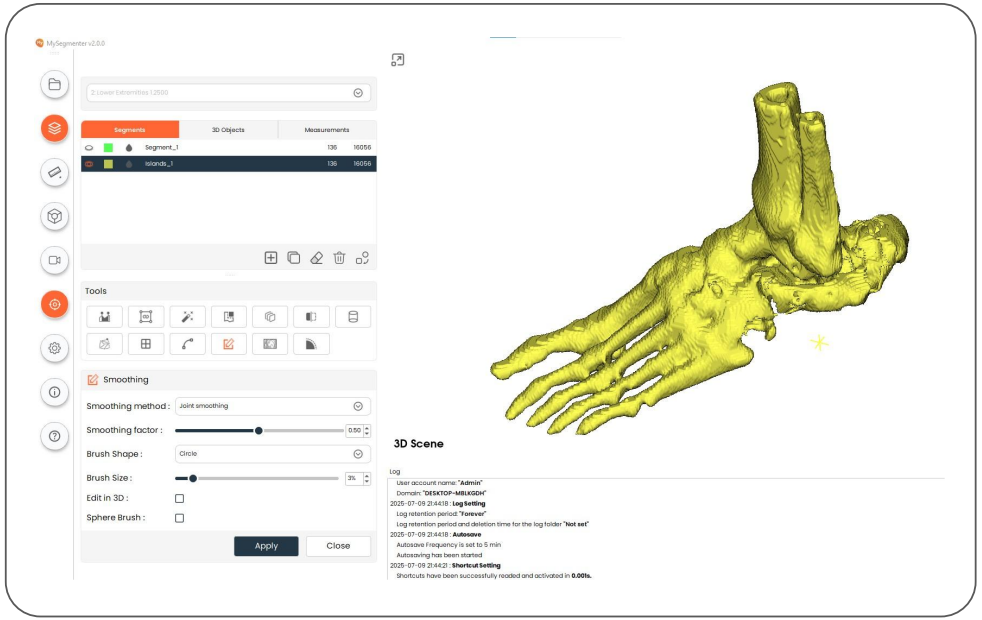


Step 2: Bone Defect Segmentation

A critical step in the development of the 3D implant model is segmentation of the bone defect.

Segmentation is performed using the patient's CT scan provided by the surgeon.

Specialized software is used to convert CT imaging data into a precise 3D model of the bone defect.



Step 3: Post-Processing & Surgeon Validation

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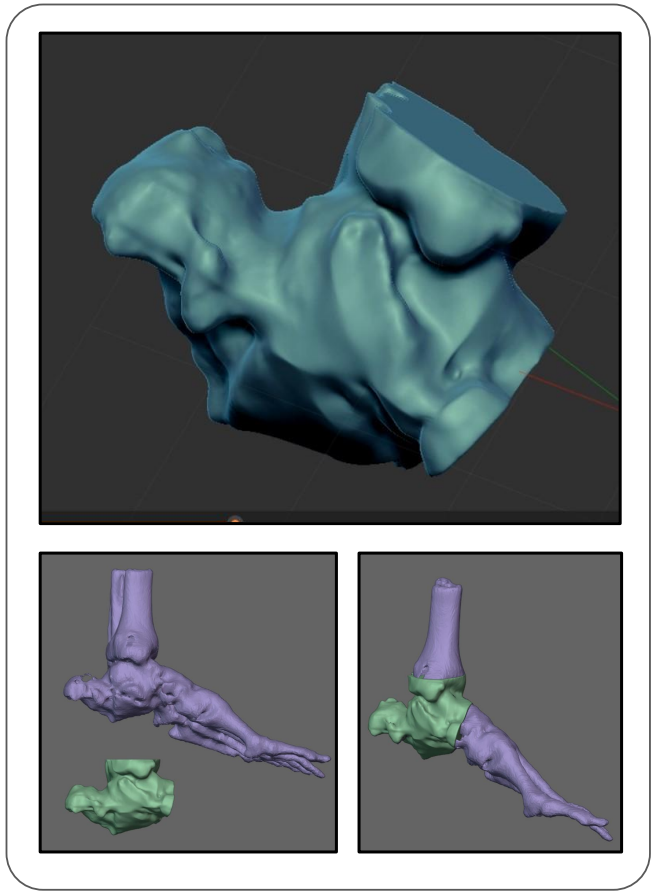
After converting the patient's CT into a 3D model, the segmentation is refined through:

- Isolating the target bone fragment containing the defect
- Removing external fixation hardware and any irrelevant elements (if present)
- Improving surface clarity and separating bone fragments for better defect assessment

Surgeon review & approval:
The finalized segmentation is sent to the surgeon for verification against the original CT. Files are shared as a 3D file, video, or images, and the surgeon confirms/approves the segmentation before proceeding.



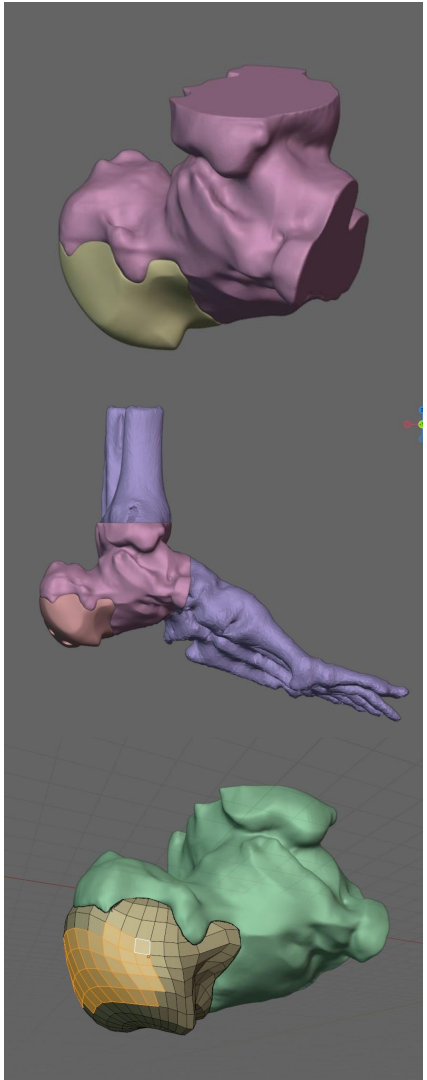
Step 4: 3D Implant Design

Implant modeling begins after the surgeon approves the segmented 3D model as consistent with the patient's CT scan.

During the design process:

- The anatomical shape is carefully reconstructed to match native bone geometry
- All clinical requirements and technical specifications are incorporated
- The augment is designed to precisely fill the defect and restore structural integrity

All design revisions are coordinated at multiple stages and formally approved by the surgeon before finalization.



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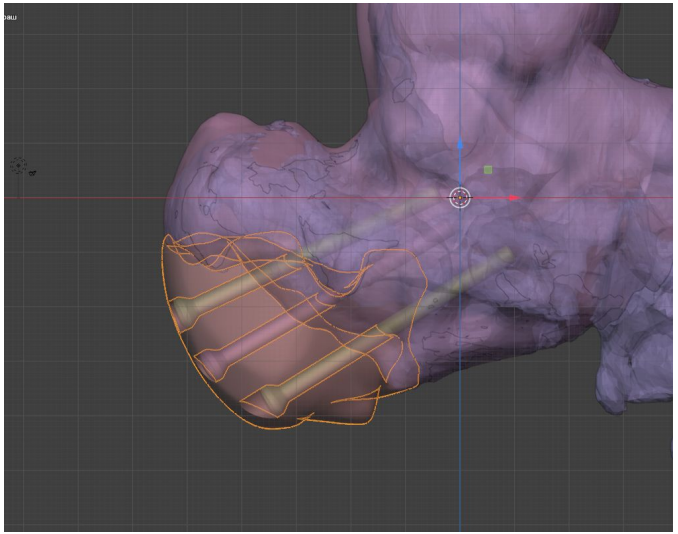
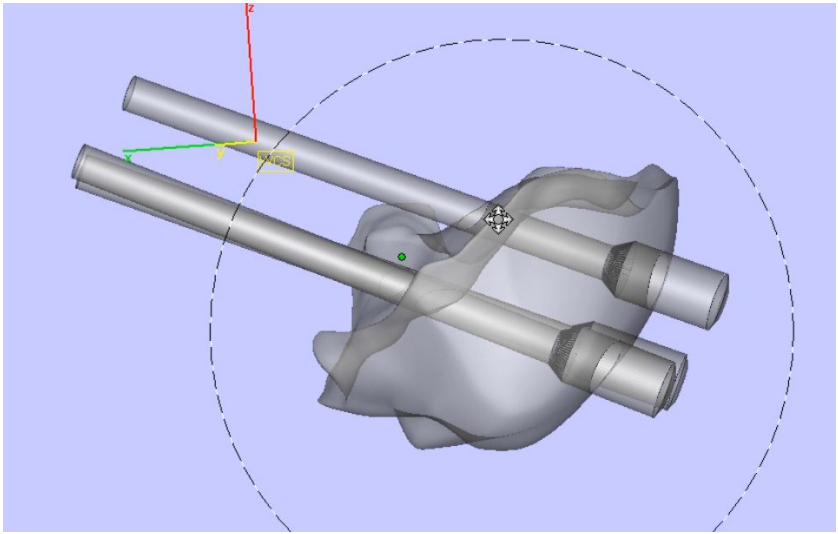
It is important to note that accurate anatomical shape and design are not the only critical aspects of the implant model. Proper planning of fixation is equally essential to ensure structural stability.

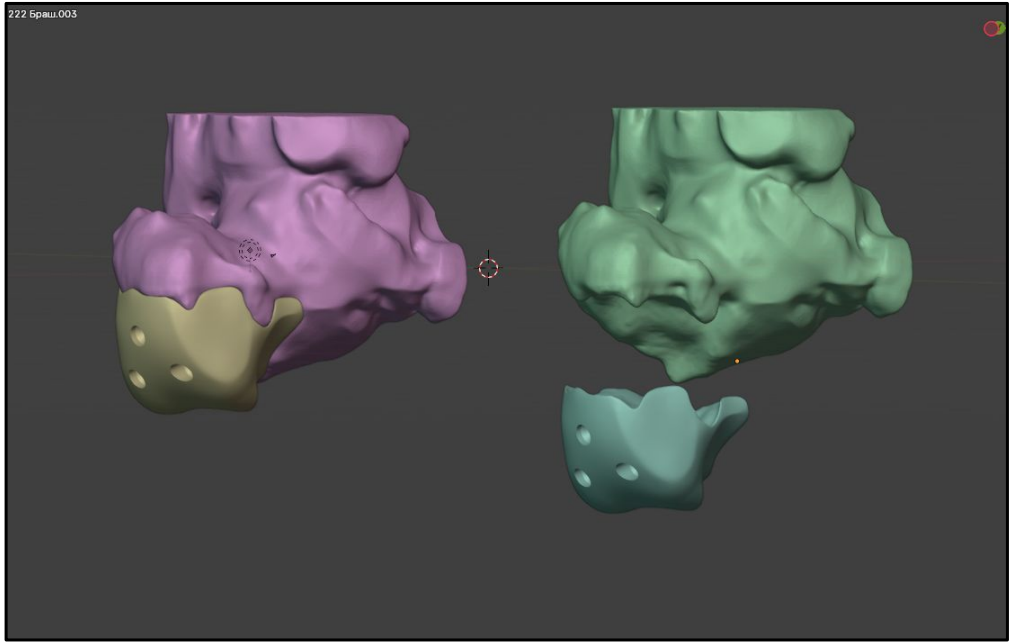
Therefore, all fixation parameters, including screw positioning, angulation, and direction are carefully coordinated and validated with the surgeon during the design process.



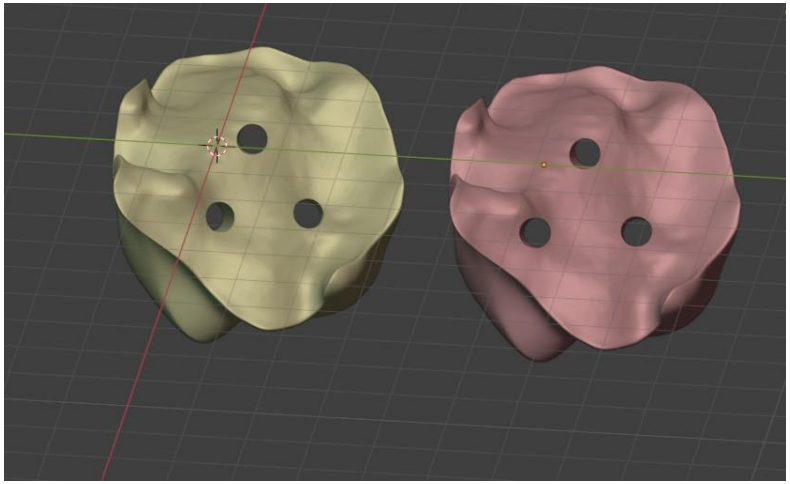


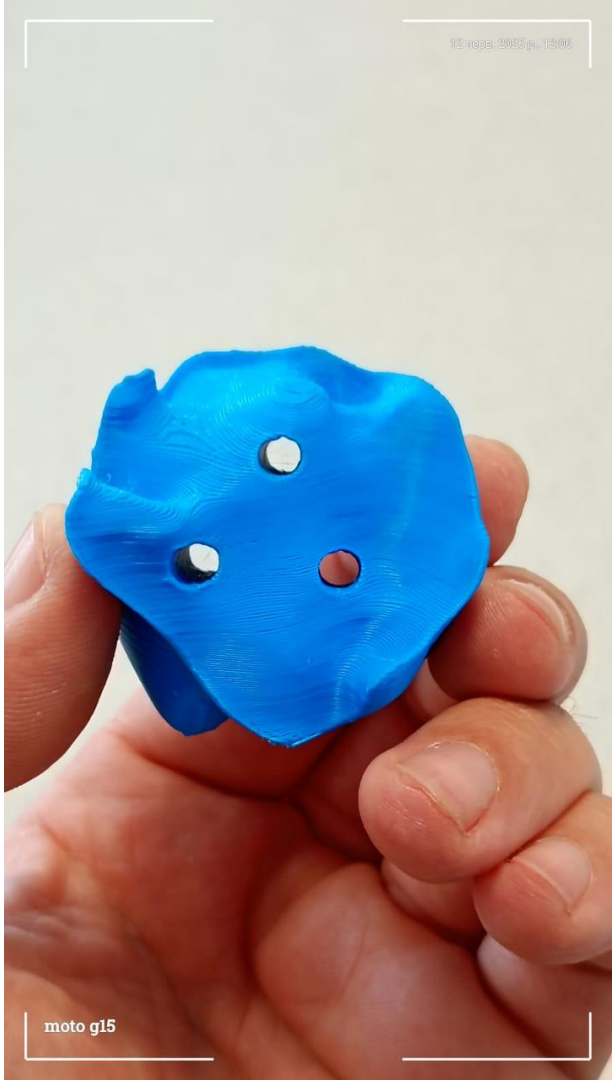
Upon completion of the design process, the 3D model is delivered to the surgeon as a 3D file, with additional images and video materials provided if required.

The surgeon is able to review the implant design in full detail prior to final approval.



For enhanced evaluation of shape, proportions, thickness, and implant conformity to the 3D bone defect segmentation, a physical prototype of the implant and a surgical bone model are printed using technical-grade polylactide (PLA).





Modeling is simple and fast

If surgical prototype printing is not required, the surgeon may approve manufacturing based solely on digital modeling and virtual reality (VR) planning results.

The use of VR enables:

- Evaluation of anatomical conformity of the implant
- Verification of spatial positioning and fixation parameters
- Analysis of shape, thickness, and volume
- Final design approval without the need for physical prototyping

This approach optimizes preparation time and provides flexibility in the clinical planning process.

VR glasses are provided by the manufacturer.

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Версія: ЗРАЗОК
Дата останнього перегляду 01.07.2025

ПАСПОРТ МЕДИЧНОГО ВИРОБУ

Загальна інформація:
Код продукту:
Назва виробу: Пацієнт-специфічний біорезорбуючий заповнювач кісткових дефектів
Клас виробу: Клас III (хірургічно інвазивний, резорбуючий)
Дата виготовлення: 01/07/2025
Використати до: 01/10/2025

Унікальні ідентифікаційні дані виробу:
Код виробу / серійний номер: XX - YY- 01/01/2025-00
Номер замовлення:

Виробник:
ТОВ "3Д-біодрук", 09100, Київська обл., Біла Церква, вул. Київська, 37В
email: info@biodrook.com /

Опис виробу:
Індивідуальний медичний виріб - імплант, що резорбує у біологічних тканинах людини протягом 36 місяців. Виготовляється з біорезорбуючої полімерно-мінеральної композиції за технологією 3D друку.

Склад та характеристика:
Виріб виготовлено з полімерно-мінеральної композиції RESOMER Composite L 210 S HA, що складається з 75% полі(L-лактиду) та 25% гідроксиапатиту.
Виріб має макро- і мікропористу структуру, що сприяє остеокондукції та васкуляризації.
Розміри та форма виробу визначені індивідуально за КТ пацієнта та індивідуального припису медичного фахівця.
Повна резорбція: до 36 місяців

Безпечність виробу:
Безпека виробу підтверджена випробуваннями біологічної безпеки згідно з вимогами стандарту ISO 10993.
Стерилізація виробу проводиться озоном, забезпечуючи рівень гарантії стерильності (SAL) ≤ 10^{-6}.
Рекомендується проводити рентгенологічний контроль біодеградації виробу через 3, 6 та 12 місяців після імплантації.
Виріб призначений для одноразового використання. Повторна стерилізація заборонена.

Передбачене застосування / Показання до застосування / Протипоказання:

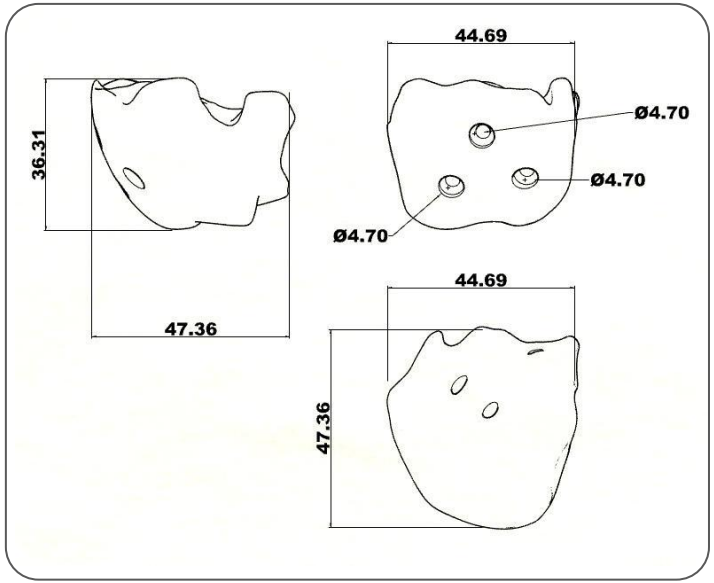
Згідно інформації у інструкції із застосування медичного виробу

Комплектація:
Пацієнт-специфічний біорезорбуючий заповнювач кісткових дефектів, модель дефекту, не специфічний заповнювач кісткових дефектів, інструкція із застосування, паспорт медичного виробу.

Маркування:
Зразок маркувальної етикетки наведено у Додатку 1 Паспорту медичного виробу.

Умови зберігання:
Виріб слід зберігати у оригінальному пакуванні.в сухих, чистих приміщеннях при температурі нижче 35 °C та відносній вологості не більше 75%

Умови транспортування:
Відповідають умовам зберігання



Each implant is delivered with a Medical Device Passport that includes comprehensive technical and identification data.

Example of the use of bioresorbable implants in the treatment of a gunshot wound.

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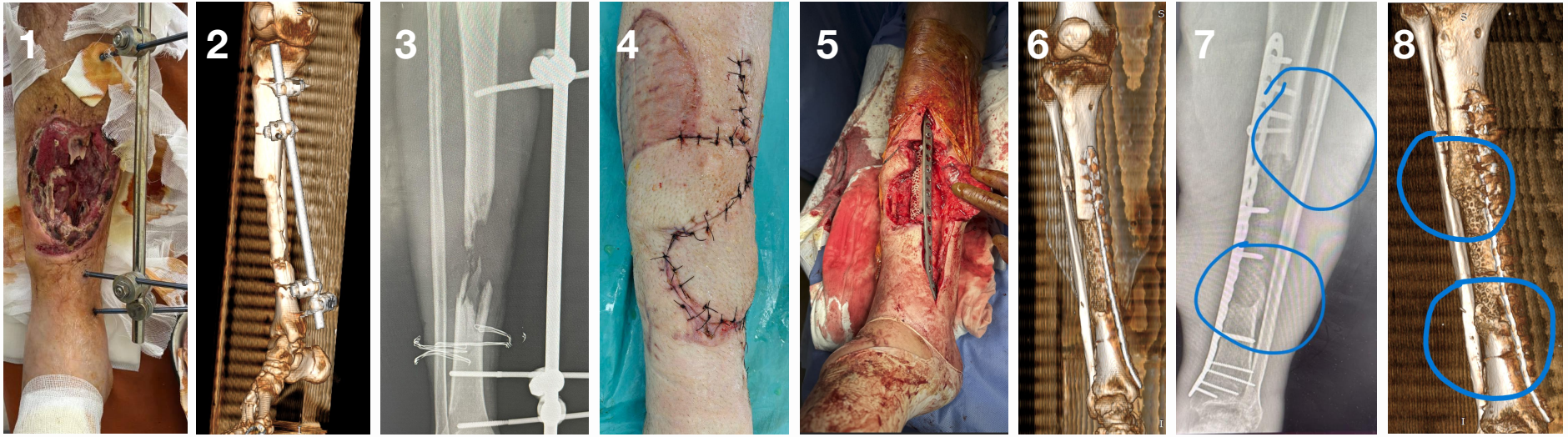
A gunshot defect of the diaphysis of the right tibia (up to 25 cm^3) (Fig. 1–3) was sustained on August 26, 2025, during combat operations in eastern Ukraine. Primary surgical debridement was performed and an external fixation device was applied. The next stage (Fig. 4) involved soft tissue reconstruction using skin–muscle flaps to close the defect, along with the placement of an antibiotic-loaded cement spacer.



The following procedure was performed (Fig. 5–6): open reduction, removal of the cement spacer, and defect reconstruction using a 3D implant (biodrook ResorBone). The fixation method was converted from external fixation to an LCP plate with screws. Figures 7–8 show that signs of bone union appeared at month 4, with the formation of periosteal callus. In the middle third, a change in the density of the implant is observed.

CLINICAL CASE 1

Patient: 38-year-old female, domestic trauma (fall from ~2 m height)
Diagnosis: Comminuted impaction fracture of the distal epimetaphysis of the left tibia with fragment displacement.

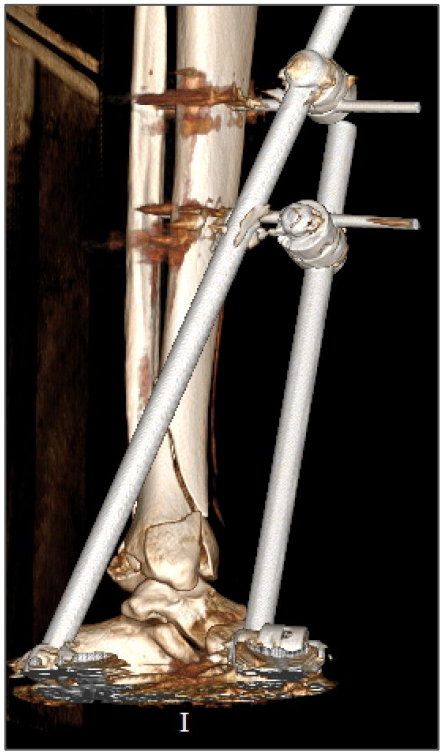
CT-Based Defect Dimensions:
- Height (Z): 50.49 mm
- Width (X): 17.50 mm
- Width (Y): 17.42 mm
- Volume: 4.575 cm^3

Indications for 3D Implantation:
- Significant impaction defect >4 cm^3
- Risk of secondary depression of the articular surface
- Need for anatomical restoration of the load-bearing zone

Surgical Treatment:
- Open reduction of fracture fragments
- Defect reconstruction using a patient-specific 3D bioresorbable implant

Implant material: Resomer® L210 S HA
Fixation: LCP plate and screws

Results:
Complete anatomical restoration of the affected segment achieved and stabilized with an LCP plate and screws.
No early complications observed.
Radiographic remodeling expected over an extended healing period.



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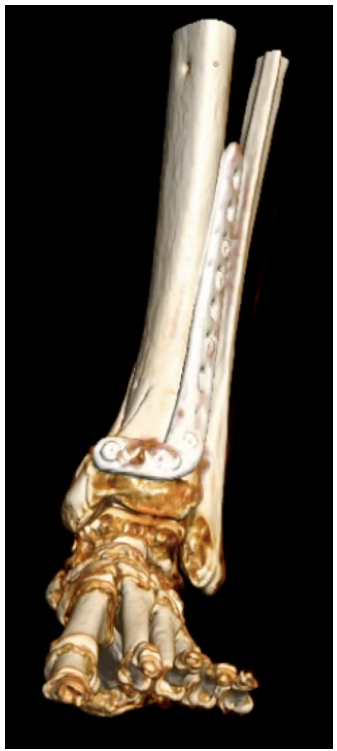


after

CLINICAL CASE 2

Patient: 49-year-old male, gunshot injury sustained during combat
Clinical History: Two prior cement spacer reconstructions due to infection.
Diagnosis: Chronic osteomyelitis of the proximal epimetaphysis of the left tibia with a defect of the lateral condyle and central intercondylar region. Status post cement spacer placement.

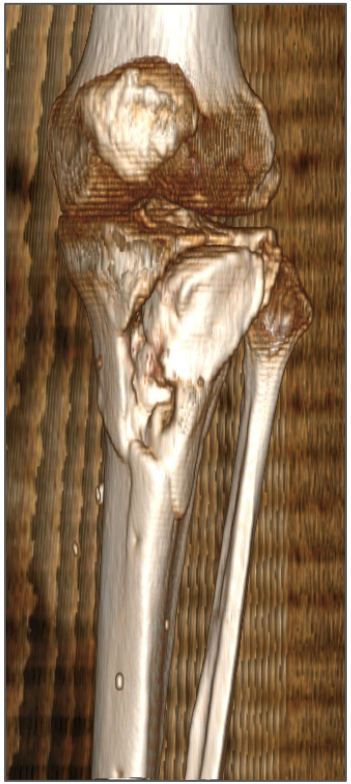
CT-Based Defect Dimensions:
- Height (Z): 77.8 mm
- Width (X): 60.23 mm
- Width (Y): 41 mm
- Volume: 62.45 cm^3

Indications for 3D Implantation:
- Extensive bone defect following infectious complications
- Ineffectiveness of cement spacers
- Need to restore the load-bearing articular zone of the knee

Surgical Treatment:
- Removal of the cement spacer
- Reconstruction using a patient-specific 3D bioresorbable implant

Implant material: Resomer® L210 S HA
Fixation: LCP plate and screws

Results: Complete defect reconstruction achieved. Full passive limb function restored. No complications observed.



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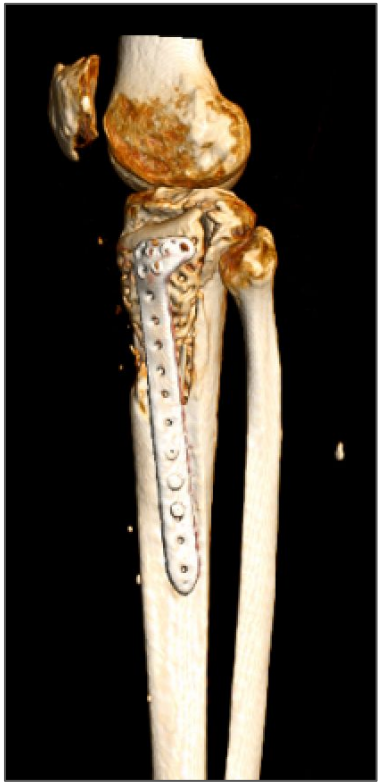


after

CLINICAL CASE 3

Patient: 36-year-old male, domestic trauma (jump from ~1.5 m height)
Clinical History: Type 2 diabetes mellitus (compensated since 10/2025); insulin therapy 16 IU/day; blood glucose ≤9 mmol/L.
Diagnosis: Impaction fracture of the lateral condyle of the left tibia with fragment displacement.

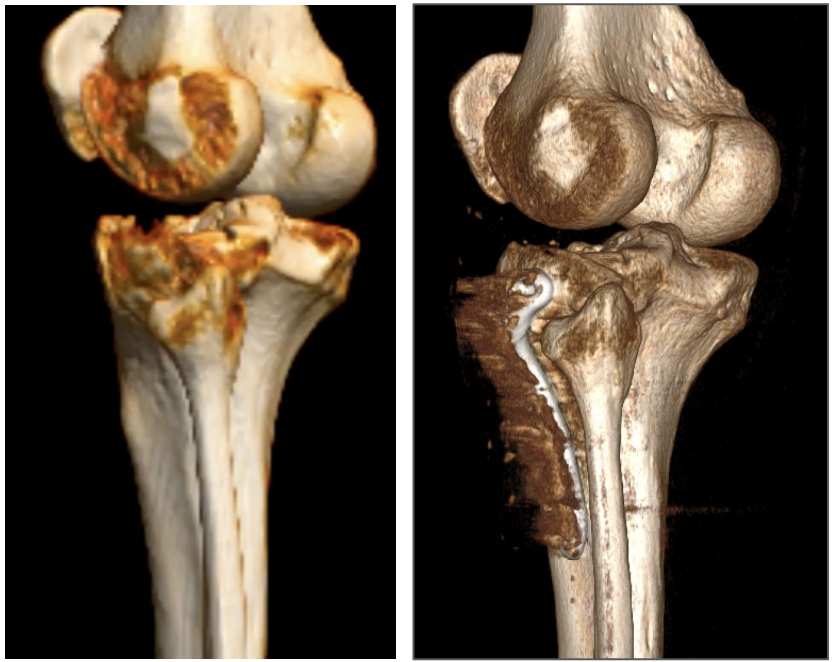
CT-Based Defect Dimensions:
- Volume: ~6 cm^3

Indications for 3D Implantation:
- Significant impaction defect
- Need to restore the load-bearing articular zone
- Concomitant diabetes mellitus (increased risk of infectious complications)
- Avoidance of autologous bone graft harvesting

Surgical Treatment:
- Open reduction of fracture fragments
- Angle-stable fixation using LCP plate and screws
- Reconstruction with a patient-specific 3D bioresorbable implant

Implant material: Resomer® L210 S HA

Results: Complete anatomical defect reconstruction achieved. Stable fixation with LCP plate. Passive flexion: 90°; pain score 4/10. No infectious complications observed.



before after

Team

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Denys Gurak

Founder of biodrook.
Serial entrepreneur and investor in the technology sector.
Former Director of the GMP Center and Deputy Director General of the “Ukrainian Defense Industry”.

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.

Serhii Horbenko

Chief Medical Officer, Surgeon
Former military medic, retired major.

Yulia Shapovalova

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

biodrook

Open to clinical and research collaboration.

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Chief Technical Officer:
Mykhailo Pluzhnyk

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