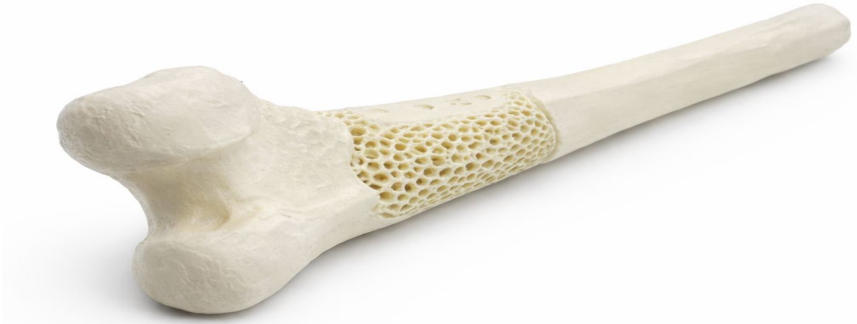
biodrook



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

biodrook

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:

biodrook

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:

biodrook

Non-resorbable materials:

- PEEK (polyetheretherketone)

In development:

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

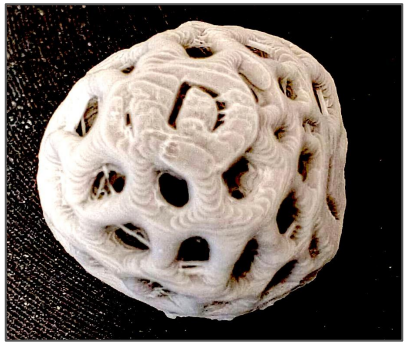
Used for: cranial plates (PEEK), hernia meshes (PP), facial reconstruction (TPU).

Resorbable materials:

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

In development:

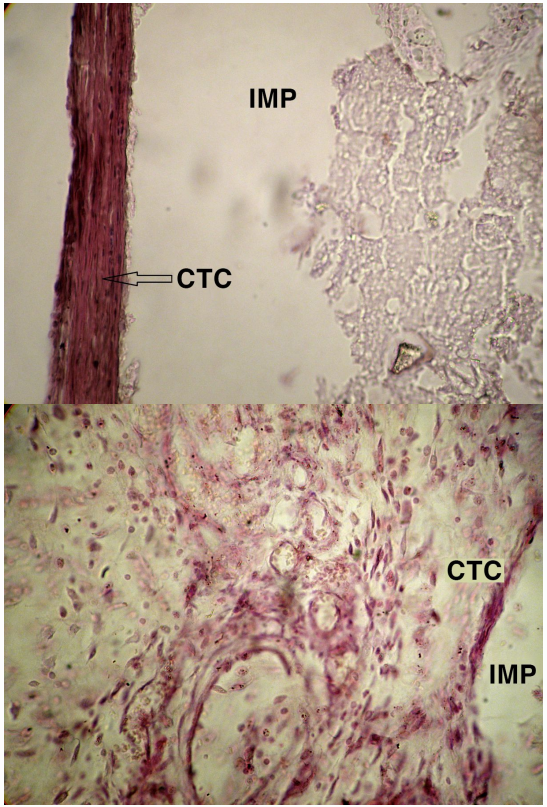
- PLA (polylactide),
- PCL (polycaprolactone),
- PLGA (polylactide-co-glycolide)



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.

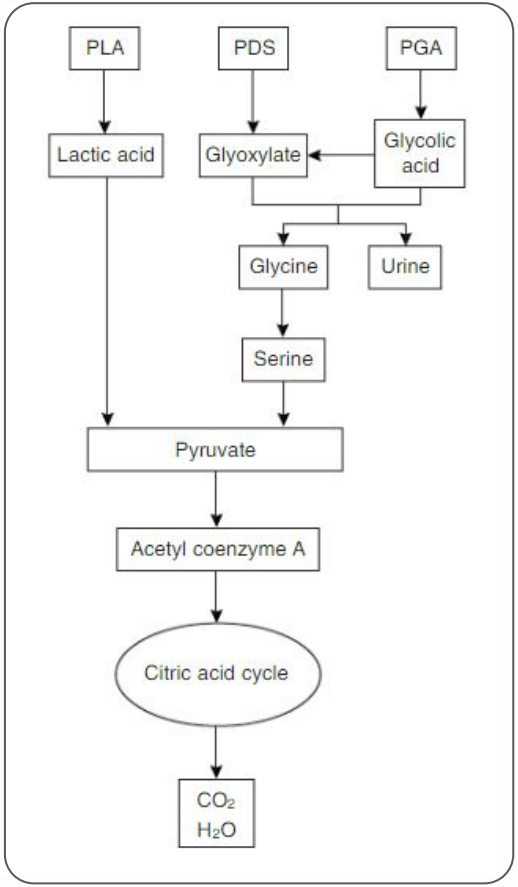


CTC: Connective Tissue Capsule
IMP: Anatomically Adapted Bioresorbable Bone Filler

Degradation and Material Modifications:

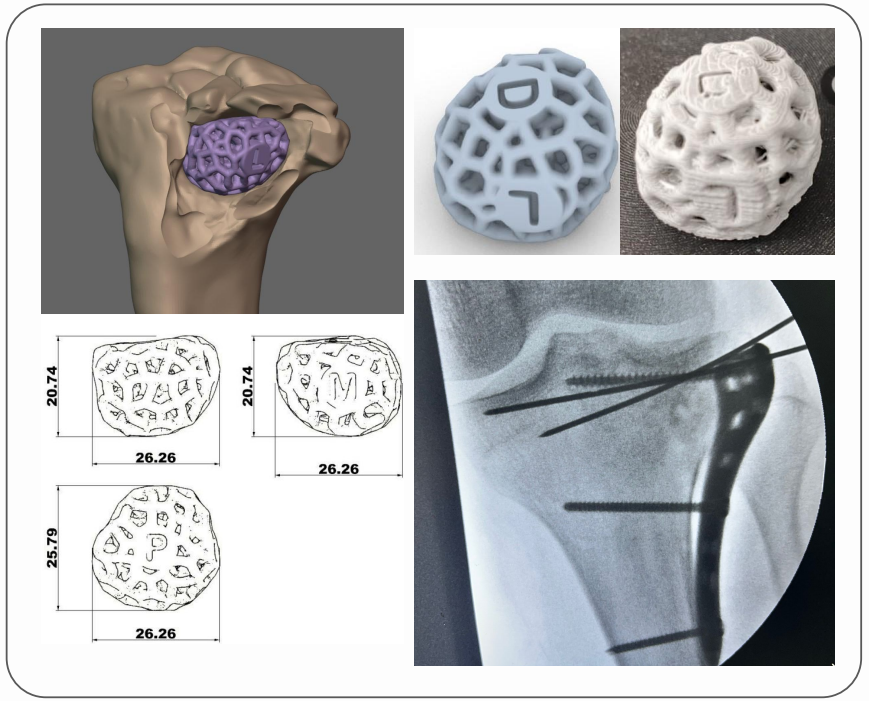
biodrook

- 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:

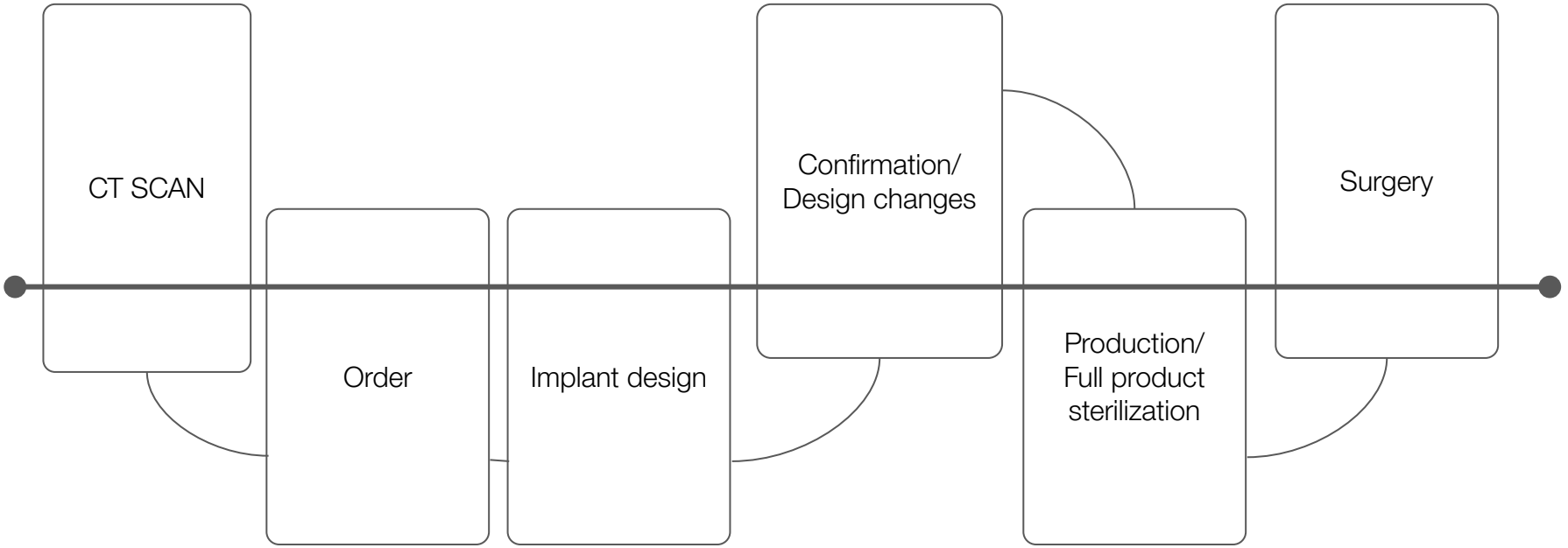
- The implant is supplied sterile and ready for use.
- The implantation procedure requires prior planning. The surgeon independently selects the internal fixation methods to be used and provides this information to the modeler during the implant development stage.
- The designer develops elements such 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:

biodrook

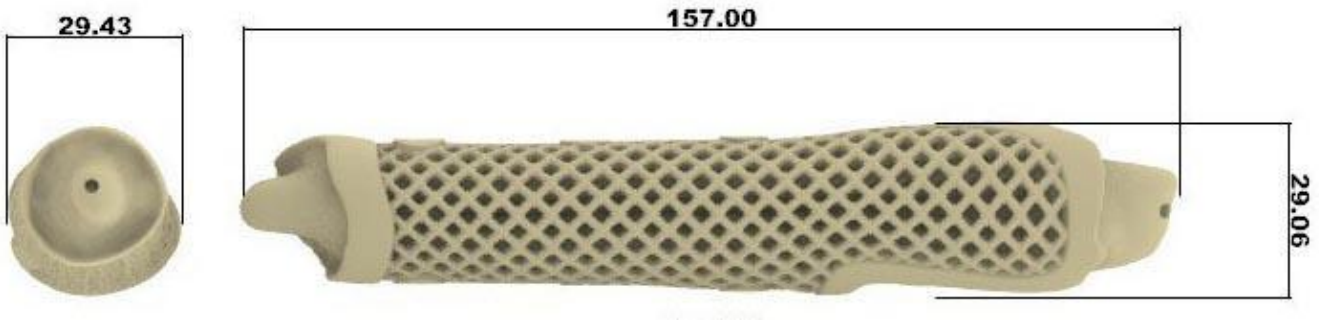
Responsibility of the doctor



Manufacturer's responsibility

biodrook

Implant Design Development Process



Step 1: Order Form & Clinical Data Collection

biodrook

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

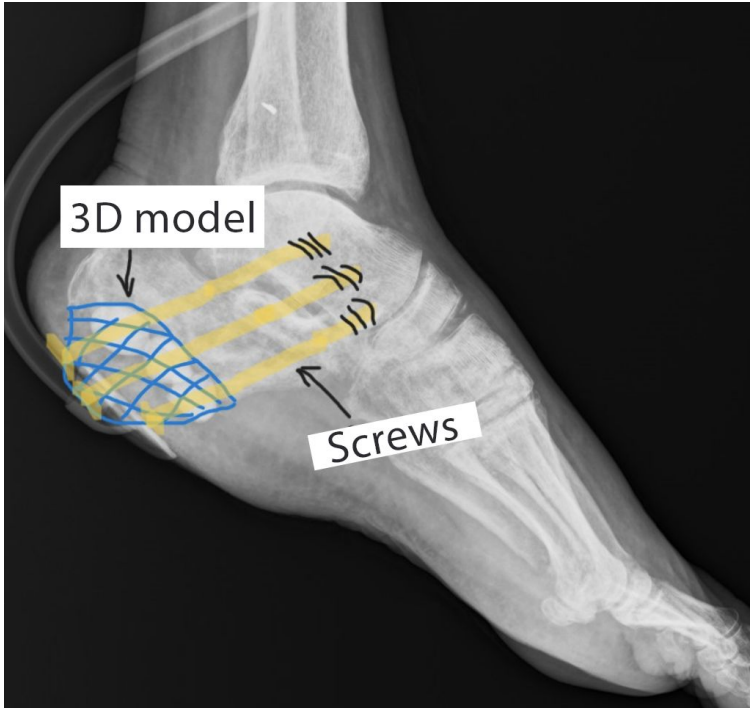
Key inputs include:

- 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.

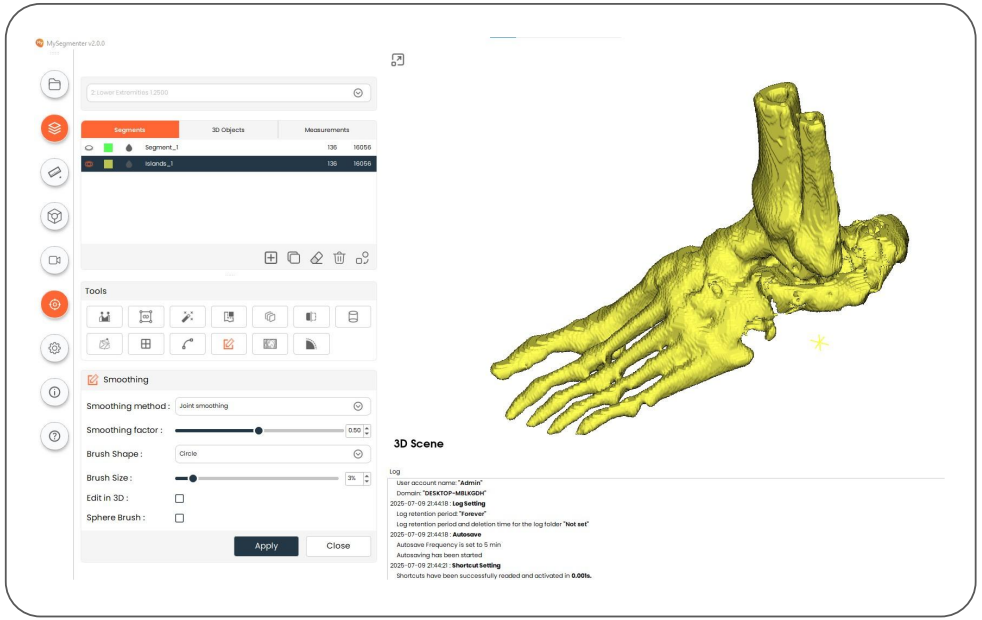


Step 2: Bone Defect Segmentation

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.



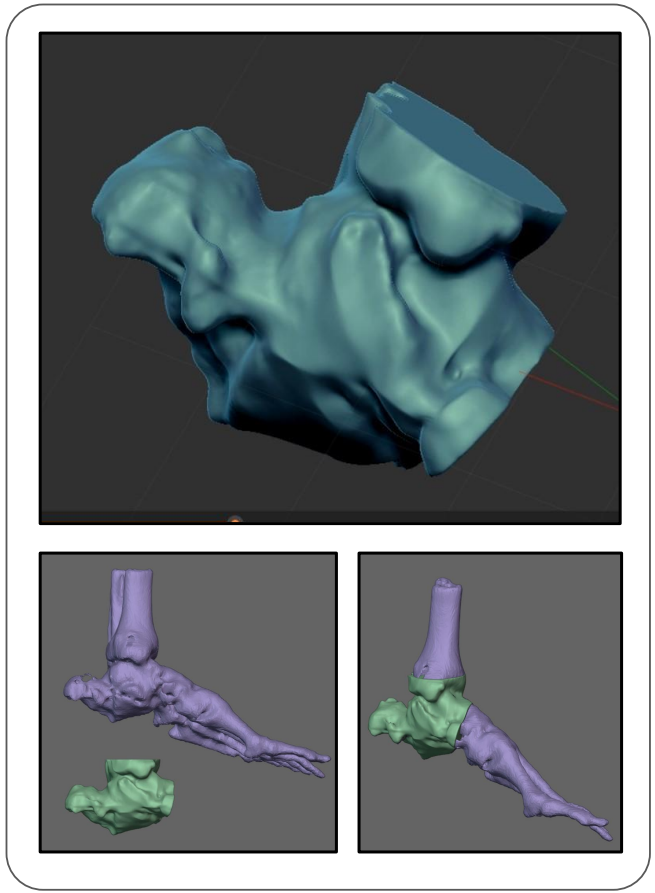
Step 3: Post-Processing & Surgeon Validation

biodrook

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.



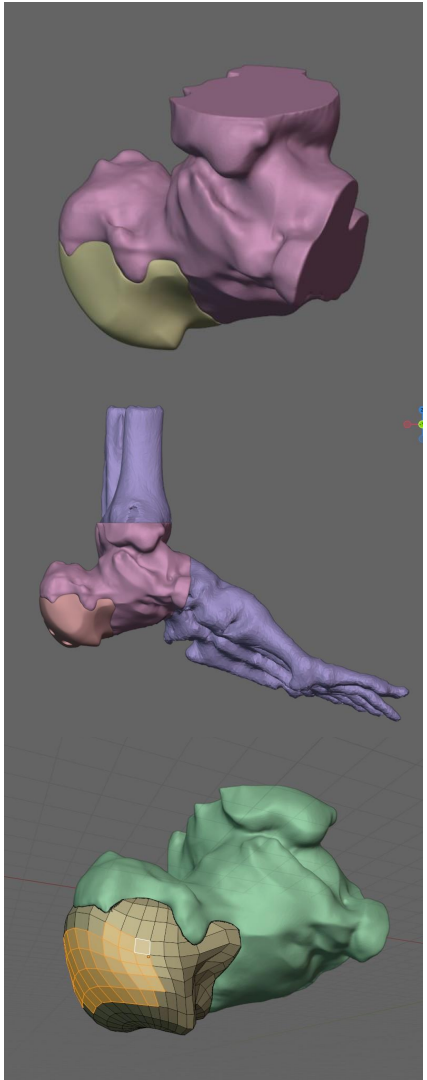
Step 4: 3D Implant Design

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

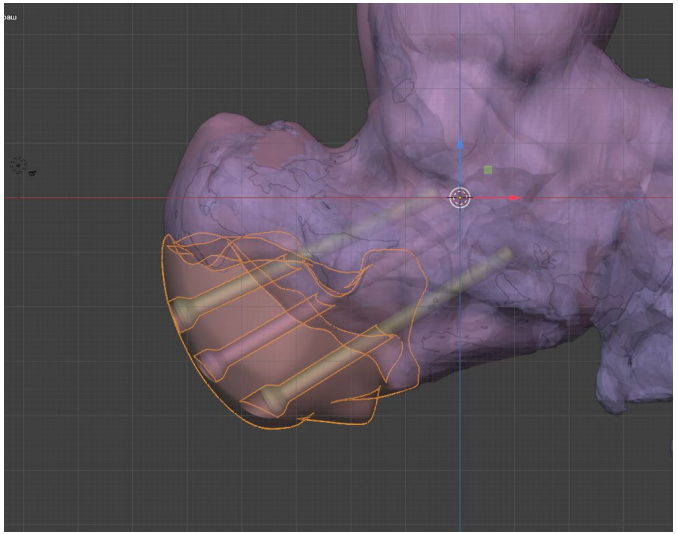
All design revisions are coordinated at multiple stages and formally approved by the surgeon before finalization.

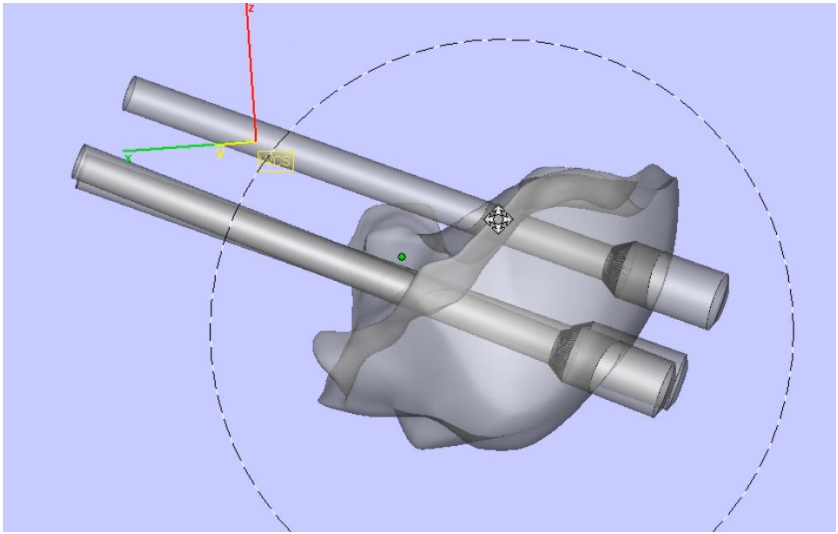


biodrook

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.

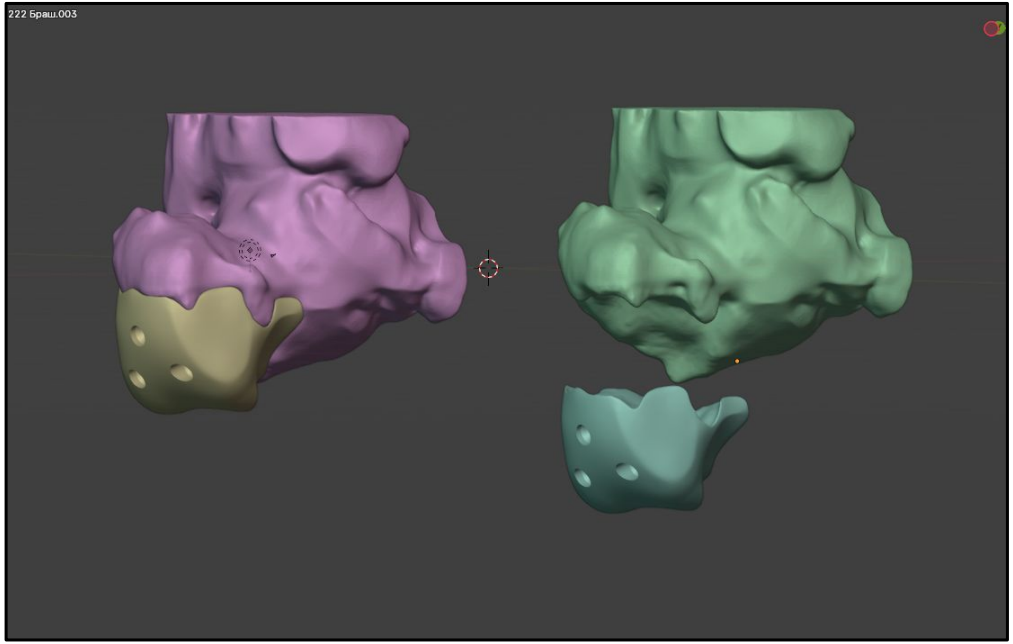
Therefore, all fixation parameters, including screw positioning, angulation, and direction are carefully coordinated and validated with the surgeon during the design process.



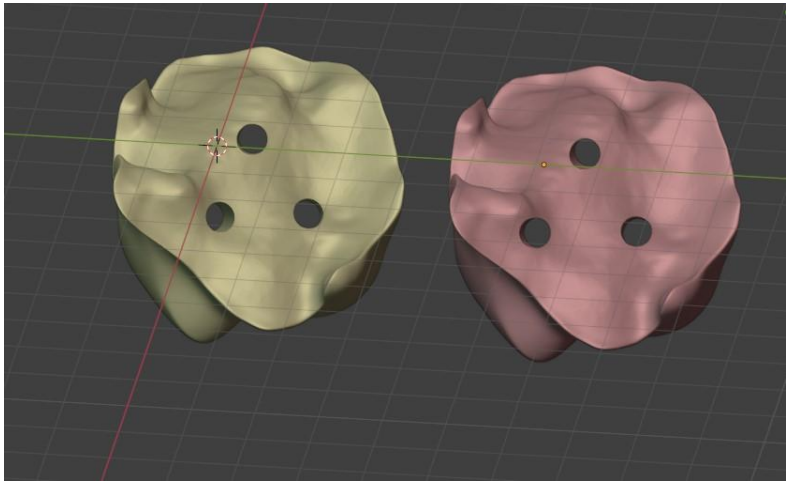


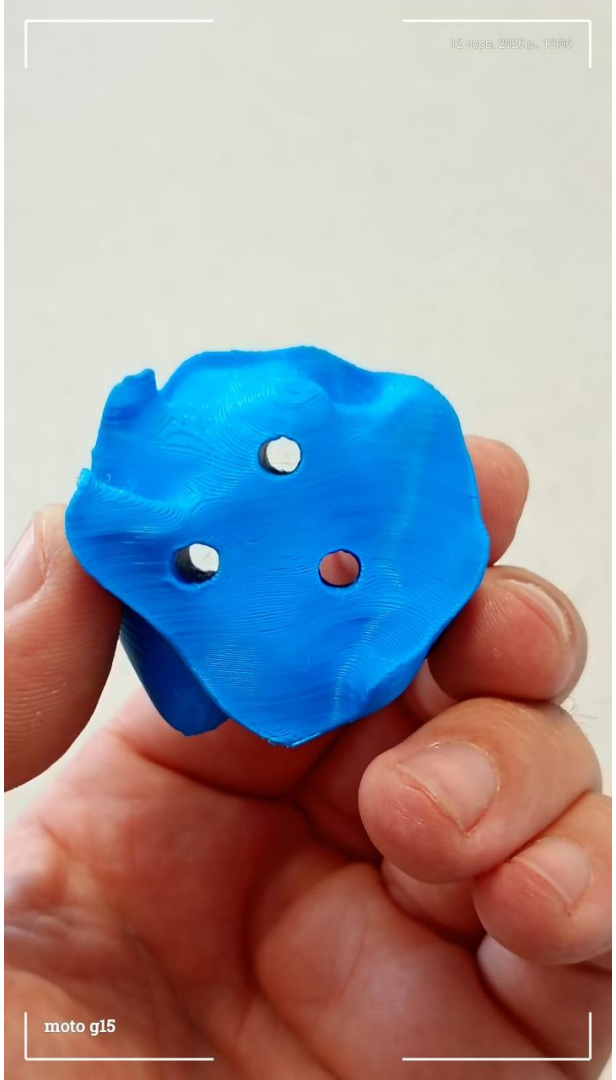
Upon completion of the design process, the 3D model is delivered to the surgeon as a 3D file, with additional images and video materials provided if required.

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.

biodrook

biodrook
www.biodrook.com

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:

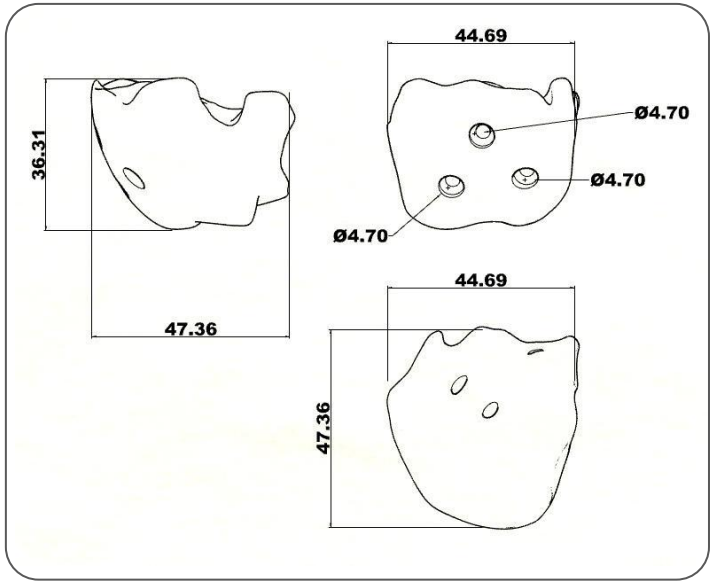
Згідно інформації у інструкції із застосування медичного виробу

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

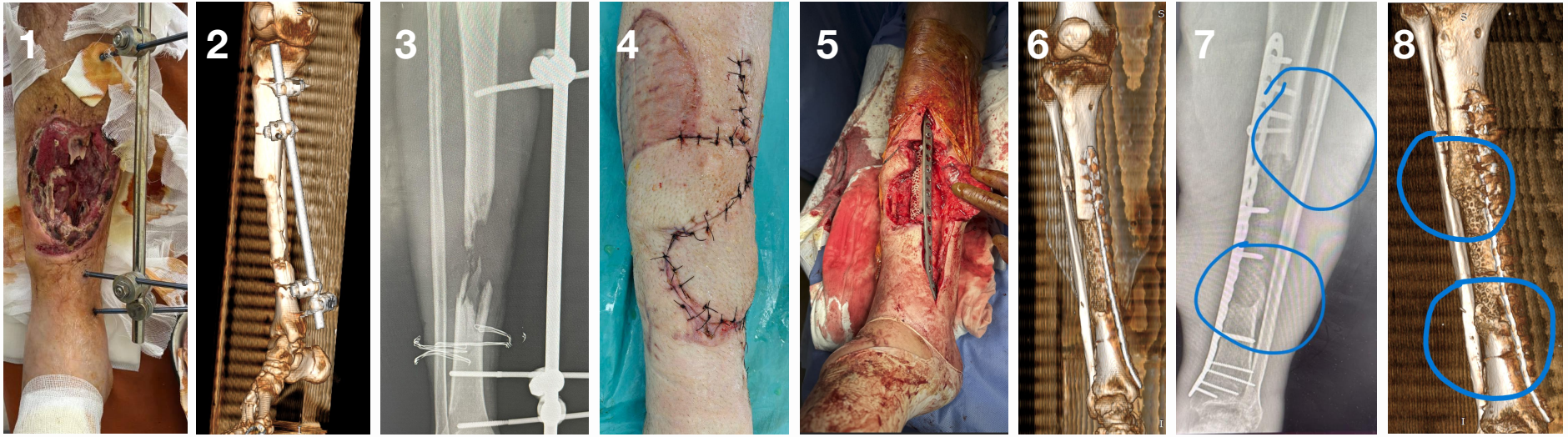


Each implant is delivered with a Medical Device Passport that includes comprehensive technical and identification data.

Example (*Clinical Case 4*) of the use of bioresorbable implants in the treatment of a gunshot wound.

biodrook

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 RATIONALE FOR USING THE RESORBONE IMPLANT (CASE 4)

biodrook

Large defect volume:
A segmental defect of approximately 14 cm would typically require prolonged external fixation with gradual bone regeneration over years.
A patient-specific implant enabled immediate restoration of segment geometry.

Challenging biological environment:
Prior flap reconstruction and loss of cortical bone significantly compromised local biology.
High mechanical stability was required to ensure successful healing under demanding conditions.

Accelerated bone healing:
Follow-up imaging demonstrated periosteal callus formation, cortical thickening, and early signs of union at 4 months.
This represents a significantly faster timeline compared to staged distraction osteogenesis.

Mechanical stability:
The combination of a patient-specific 3D implant and LCP plate provided a stable structural framework to support bone regeneration.

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.

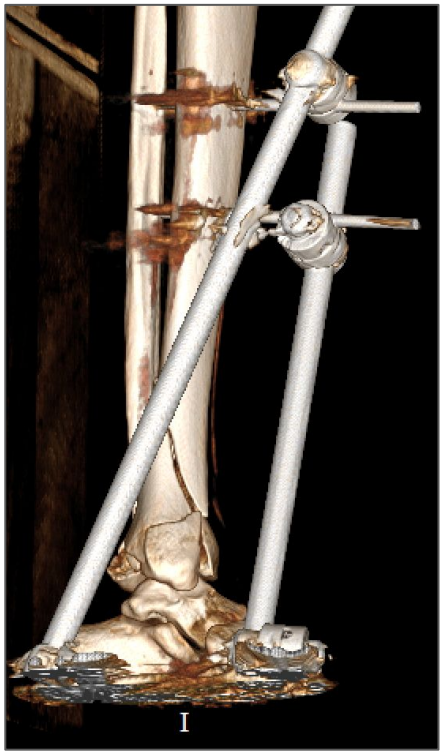
CT-Based Defect Dimensions:
- Height (Z): 50.49 mm
- Width (X): 17.50 mm
- Width (Y): 17.42 mm
- Volume: 4.575 cm^3

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

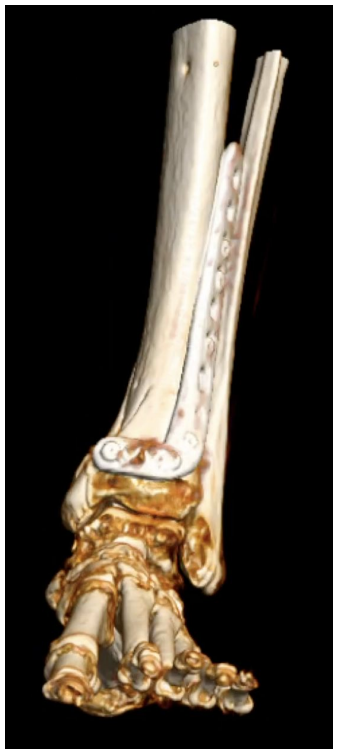
Surgical Treatment:
- Open reduction of fracture fragments
- Defect reconstruction using a patient-specific 3D bioresorbable implant

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.



before



after

CLINICAL RATIONALE FOR USING THE RESORBONE IMPLANT (CASE 1)

biodrook

Complex fracture with cancellous bone defect:
Requires structural support to restore the subchondral segment and maintain joint congruity.

Reduction in operative time:
Eliminates the need for autograft harvesting and intraoperative shaping, reducing overall procedure duration by approximately 1.5 hours.

Avoidance of donor site morbidity:
No additional surgical site, minimizing postoperative pain and complications associated with autograft harvesting.

Anatomically matched geometry:
The implant is designed to precisely fit the defect, ensuring controlled and reproducible placement.

Risk profile compared to autograft:
In cases of incomplete integration, resorption, or osteolysis in the subchondral zone, there is a risk of structural collapse, secondary instability of fixation, and the need for revision to address the defect.

Infection considerations:
Synthetic resorbable materials are generally less prone to act as a nidus for infection compared to biological grafts, although the risk is not eliminated.

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.

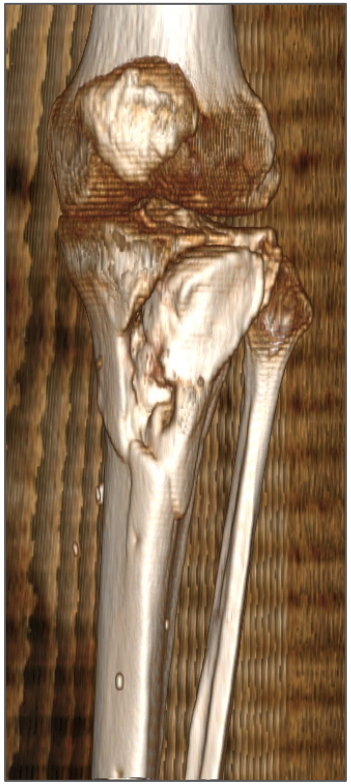
CT-Based Defect Dimensions:
- Height (Z): 77.8 mm
- Width (X): 60.23 mm
- Width (Y): 41 mm
- Volume: 62.45 cm^3

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

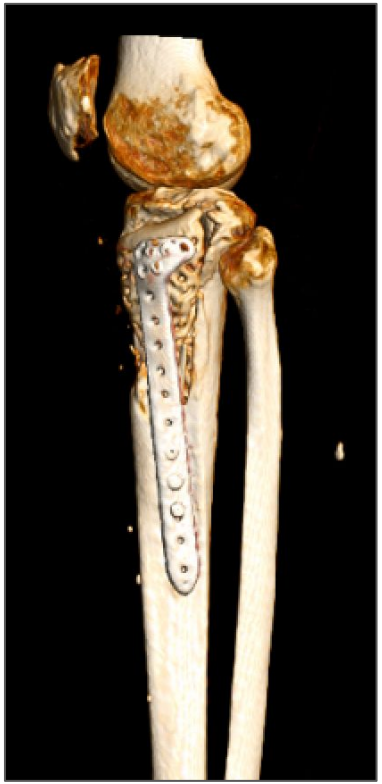
Surgical Treatment:
- Removal of the cement spacer
- Reconstruction using a patient-specific 3D bioresorbable implant

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

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



before



after

CLINICAL RATIONALE FOR USING THE RESORBONE IMPLANT (CASE 2)

biodrook

Critical defect volume:
62.5 cm^3 represents a critical-size defect. Even with bilateral autograft harvesting, the available volume would be insufficient. The use of bioglass or allograft at this scale is technically challenging and economically impractical, leaving no viable alternative for reconstruction.

Complex geometry:
The defect involves the lateral condyle and the central intercondylar region, with a multiplanar shape and variable depth. The implant incorporates a complex internal architecture that would be significantly more difficult to achieve using titanium.

Intraoperative adjustability:
Following debridement to viable tissue, defect boundaries may change. The implant material allows precise intraoperative modification through cutting and shaping, enabling accurate adaptation to the actual defect geometry.

Mechanical properties:
Provides sufficient structural strength to support partial load-bearing. The patient loads the limb at approximately 35% of body weight (total body weight ~100 kg).

CLINICAL CASE 6

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.

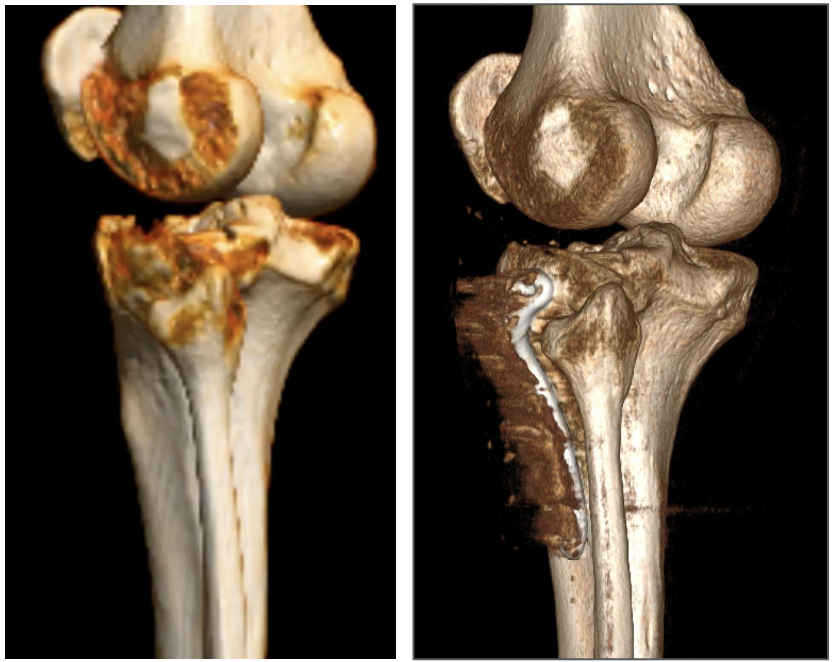
CT-Based Defect Dimensions:
- Volume: ~6 cm^3

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

CLINICAL RATIONALE FOR USING THE RESORBONE IMPLANT (CASE 6)

biodrook

Diabetes and microangiopathy:
The patient presents with microvascular impairment. In the setting of diabetic angiopathy, autograft is associated with a high risk of incomplete revascularization, resorption, central void formation within the defect, and nonunion with potential failure of fixation. The expected time to union in such fractures is approximately 16–17 months and may extend beyond 30 months in case of complications.

Complex geometry:
The defect extends from the lateral condyle to the central tibial plateau, including the region of cruciate ligament attachment.
A patient-specific implant enabled precise anatomical restoration, provided structural support of the articular surface, and avoided uncontrolled placement of autograft material.

Reduction of surgical trauma:
No graft harvesting was performed, eliminating the need for an additional surgical site.
This is particularly important in patients with diabetes due to impaired healing capacity and increased risk of complications.

Reduction in operative time:
The procedure was completed in under 1.5 hours.
Shorter operative time is associated with a reduced risk of postoperative infection.

CLINICAL CASE 7

Patient: 55-year-old male, right scaphoid fracture (2019), screw fixation.
Clinical History: Progressive wrist pain, swelling, and functional limitation.
Diagnosis: Post-traumatic deforming osteoarthritis of the wrist (Grade IV).

CT-Based Defect Dimensions:
- Height (Z): 5.70 mm
- Width (X): 26.97 mm
- Width (Y): 20.17 mm
- Volume: 1.93 cm^3

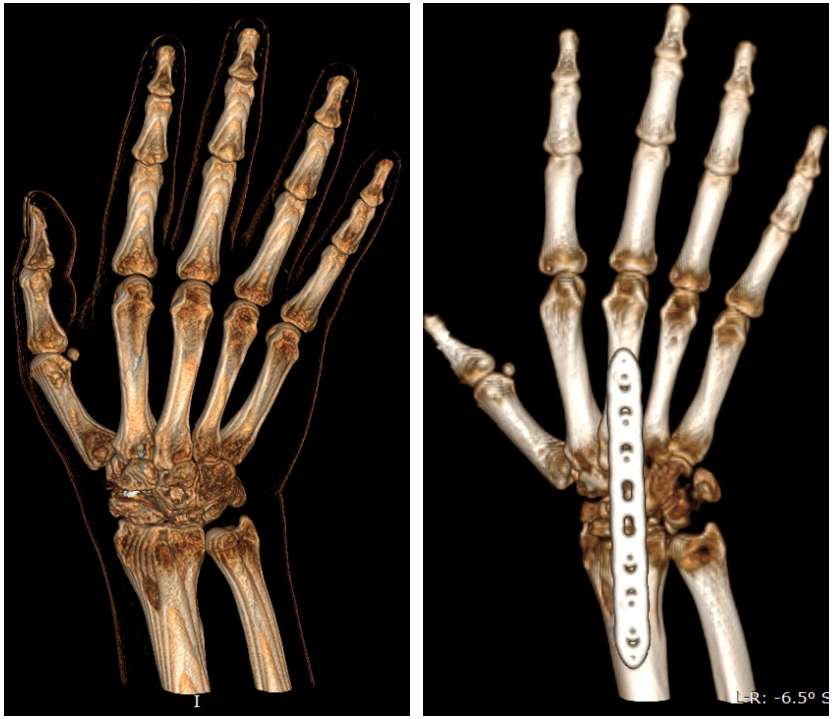
Indications for 3D Implantation:
- Significant structural defect following carpal bone resection
- Advanced degenerative changes with loss of joint congruity
- Need for precise anatomical reconstruction and stable fusion

Surgical Treatment:
- Removal of hardware
- Resection of destroyed articular surfaces
- Preparation of fusion surfaces
- Fixation with a titanium LCP plate with angular stability and screws

Implant material: Resomer® L210 S HA

Results: Stable fixation was achieved with adequate restoration of alignment and wrist length, without intraoperative complications.

biodrook



CLINICAL RATIONALE FOR USING THE RESORBONE IMPLANT (CASE 7)

biodrook

Restoration of geometry and length:
Carpal resection resulted in a complex 3D defect.
Autograft use may lead to wrist shortening, malalignment, and uneven fusion surfaces.
A patient-specific implant enables restoration of anatomical length, alignment, and provides a stable fusion construct.

Reduced operative time:
Procedure duration was 72 minutes.
Preoperative 3D planning and implant design eliminated the need for graft preparation and additional intraoperative adjustments, reducing infection risk.

Reduced surgical trauma:
No iliac crest graft harvesting was performed, avoiding donor site morbidity.

Revision setting:
Secondary procedure after long-standing pathology with compromised tissue quality.
A patient-specific implant offers more predictable outcomes compared to manual graft reconstruction.

CLINICAL CASE 14

Patient: 48-year-old male, military, smoker.
Clinical History: Bilateral distal mandibular defects with bone deficiency extending into the retromolar region, associated with mild post-traumatic deformity of the alveolar ridge.
Diagnosis: Post-traumatic and secondary mandibular alveolar atrophy.

CT-Based Defect Dimensions:
- Right: ~0.47 cm^3
- Left: ~0.55 cm^3

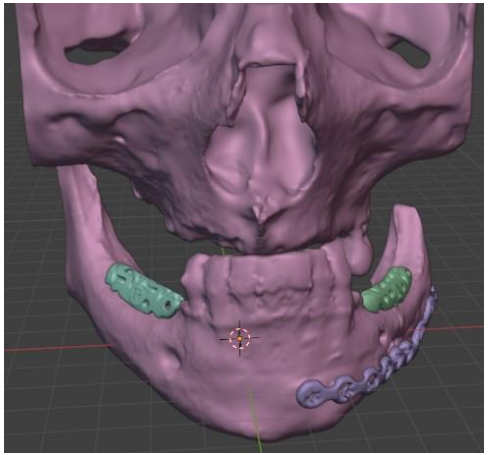
Indications for 3D Implantation:
- Bilateral alveolar defects with insufficient bone volume
- Need for precise anatomical reconstruction of the alveolar ridge
- Limitations of conventional grafting techniques
- Requirement for stable support for future functional rehabilitation

Surgical Treatment:
- Bilateral mandibular defect reconstruction
- Intraoral surgical approach
- Fixation with titanium screws
- Removal of previous hardware
- Operative time: ~90 minutes

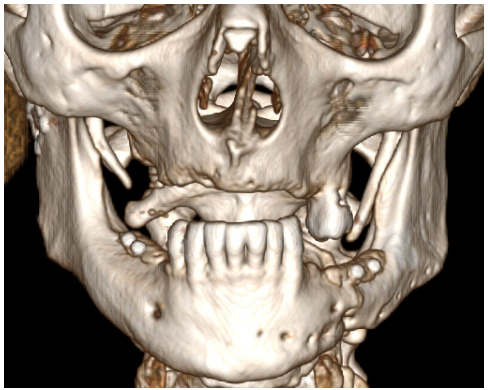
Implant material: Resomer® L210 S HA

Results: Implants were positioned correctly with good CT visualization and no signs of pain, inflammation, or systemic complications; no postoperative complications were observed.

biodrook



before



after

CLINICAL RATIONALE FOR USING THE RESORBONE IMPLANT (CASE 14)

biodrook

Restoration of anatomy:
Bilateral alveolar defects with irregular geometry required precise reconstruction. Conventional grafting may result in unpredictable contour and volume loss. A patient-specific implant enables accurate restoration of alveolar anatomy on both sides.

Limitations of grafting techniques:
Autograft volume is limited and associated with donor site morbidity, while allografts and substitutes may show variable resorption and integration.
In bilateral defects, these limitations become more pronounced.
A patient-specific implant provides a controlled and reproducible solution.

Reduced surgical trauma:
No bone graft harvesting was performed, avoiding additional surgical sites.
This reduces overall surgical trauma, particularly relevant in patients with risk factors such as smoking.

Optimized integration:
The Resomer® L210 S HA material supports bone regeneration and gradual resorption, eliminating the need for secondary removal procedures.

Surgical efficiency:
Preoperative 3D planning and implant design allowed for an intraoral approach and straightforward fixation, reducing operative complexity and time.

Case No.	Patient Age	Gender	Type of Defect	Defect Size	Degree of Resorption
1	38	Female	Impaction fracture (Pilon-2)	~4.6 cm^3	~40–45%
2	49	Male	Gunshot defect (epimetaphysis)	~62.5 cm^3	Dropped out
3	45	Male	Nonunion (pseudoarthrosis)	~6 cm^3	No data
4	41	Male	Gunshot defect (diaphysis)	~25 cm^3	Initial
5	35	Female	Impaction fracture of condyle	~6 cm^3	Expected
6	36	Male	Impaction fracture + diabetes mellitus	~6–7.6 cm^3	Minimal (~10%)
7	45	Male	Arthrodesis (arthrosis stage IV)	~3.5 cm^3	Expected
8	42	Male	Arthrodesis (old fracture)	~3.0 cm^3	Expected
9	52	Female	Congenital dysplasia of the left hip joint	~13.0 cm^3	Expected
10	40	Male	Bone defect	~10.6 cm^3	Expected
14	48	Male	Post-traumatic and secondary mandibular alveolar atrophy	~0.55 cm^3	Expected

biodrook

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 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.

Contact Information:
info@biodrook.com

Executive Director:
Kateryna Osetrova

k.osetrova@biodrook.com

Chief Technical Officer:
Mykhailo Pluzhnyk

mpluzhnyk@biodrook.com