Bone tissue augmentation

BIOHORIZONS® biologics

MinerOss™ A
An allograft that offers an alternative treatment option to autologous graft.

Valid from May 2021

Inspiring excellence in oral reconstruction

biohorizons camlog

Safety aspects

Serological testing

Virus	Test	Specification
Hepatitis B virus (HBV)	HBsAg, HBcAb*, NAT	negative
Hepatitis C virus (HCV)	Ab, NAT	negative
Human immunodeficiency virus	Ab, NAT	negative
Human T-Lymphotropic virus (HTLV 1/2)	Ab, NAT	negative

Bacteria	Test	Specification
Treponema pallidum (Lues)	CMIA, TP Ab	negative

Only tissue of donors who have been tested negative enters the Allotec® process.
* negative for active infection (in case of positive HBcAb C+TBA performs further investigations)

The Allotec® process

Independent validation of the critical viral inactivation steps of the process

Step 1
After crude removal of surrounding soft tissue, fat and cartilage, the donor tissue is brought into its final shape.

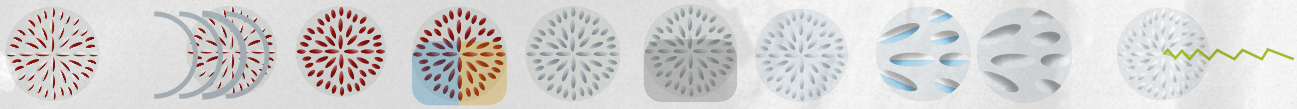
Step 2
The defatting of the donor tissue allows moderate penetration of solvents during subsequent processing.

Step 3
A treatment with alternating durations of diethyl ether and ethanol leaches out cellular components and denatures non-collagenic proteins, thereby inactivating potential viruses.

Step 4
An oxidative treatment further denatures persisting soluble proteins, thereby eliminating potential antigenicity.

Step 5
Freeze-drying preserves the natural structure of the tissue and maintains a residual moisture of <10 %, allowing quick rehydration and easy handling.

Step 6
Double packing and final sterilization by gamma-irradiation guarantees a 5-year shelf-life at 5–30 °C.



Manufacturing process of MinerOss™ A

High safety standards

After thorough donor anamnesis, maximum safety is assured via a series of strict serological testing combined with C+TBA's Allotec® purification procedure and radiological sterilization.

First, serology and nucleic acid tests (NAT) are performed to identify infections before antibodies are detected in the blood. Potential viruses are inactivated, and bacteria destroyed during Allotec® purification procedure where non-collagenic proteins are denatured.

An oxidative treatment is then used to denature persisting soluble proteins and eliminate potential antigenicity. Finally, the tissue undergoes dehydration via a lyophilization technique that facilitates the sublimation of frozen water from solid phase to gas phase. This stage preserves the material's structural integrity.

The lyophilization process is an accepted and well document procedure that preserves structural properties while improving graft incorporation. [7, 8]

The microscopic pores within the material ensure rapid rehydration of the tissue. The final sterilization by gamma irradiation guarantees a sterility assurance level (SAL) of 10^{-6} while ensuring structural and functional integrity of the product and its packaging.

The success factors of the manufacturing process

The Allotec® process

Explantation from femoral heads (patients undergoing hip surgery) or diaphysis (post-mortem donors)

- **Written consent**
- **Donor screening (risk analysis)**
- **Serological testing (Ab screening and NAT test)**

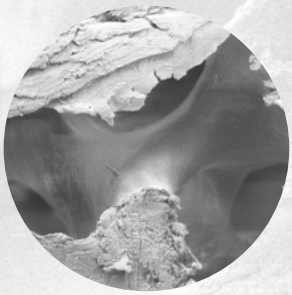
Wet chemical by Allotec® processing of the granules, blocks and struts

- **Ultrasound bath**
- **Purification with volatile reagents**
- **Oxidative treatment**

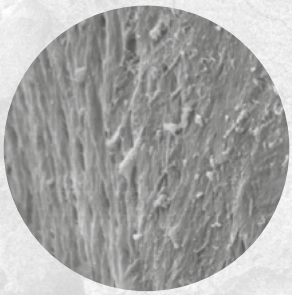
Lyophilization and gamma-sterilization

- **5-years shelf-life at 5–30 °C**

High safety standards



SEM picture of MinerOss™ A at 100-fold magnification showing macroporous structure.



SEM picture of MinerOss™ A at 500-fold magnification showing microporous structure.

MinerOss™ A human bone substitute

Fast graft incorporation and complete remodeling potential [1–5]

The scientific evidence shows that allografts are the second best option to patient's own bone compared to other bone substitutes. [1]

MinerOss™ A is a processed allogenic bone tissue that offers proven, reliable, and predictable surgical outcomes comparable to autologous bone harvested from intra-oral donor sites.

MinerOss™ A is an allograft predominantly derived from human donor femoral heads post hip replacement surgery. The donor tissue is thoroughly inspected and undergoes a strict serological screening protocol.

Thanks to its natural bone composition consisting of mineralised human collagen, MinerOss™ A shows a high biologic regeneration capability in combination with natural remodelling. Therefore MinerOss™ A is an excellent alternative to autologous bone, meaning that there is no need for an intraoral surgical donor site, which reduces morbidity for the patient.

MinerOss™ A undergoes high safety standards in its production process and guarantees a 5-year shelf life at room temperature (5–30 °C).

Post-mortem donor – diaphysis:
MinerOss™ A Cortico-cancellous Block and
MinerOss™ A Cortical Strut

Living donors – femoral heads:
MinerOss™ A Cancellous Granulate,
MinerOss™ A Cortico-cancellous Granulate and
MinerOss™ A Cancellous Block

Product characteristics of MinerOss™ A

Proprietary tissue processing maintains tissue integrity

- Bone from human donors
  (living donors: femoral heads, post-mortem donors: diaphysis)
- Natural bone composition – mineralized human collagen
- High biologic regeneration capability and natural remodeling [4]
- High safety standards
- 5 years shelf-life at room temperature (5–30 °C)

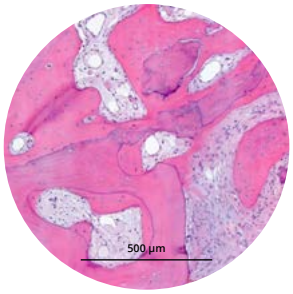
Strut
(25x10x1 mm)

Blocks
(10x10x20 mm and 10x10x10 mm)

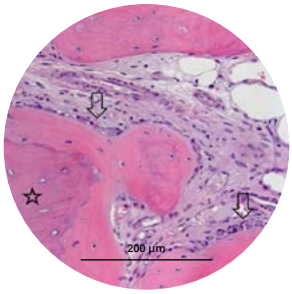
Granulates

Histological structure of MinerOss™ A

Histology of biopsy harvested 7 months after block augmentation [3, 5, 6]



The allogenic bone can be recognized by the empty cavities of the osteocytes and is embedded in newly formed bone matrix.



Allogenic bone (asterisk) embedded in newly formed bone.
New bonematrix is lined by osteoblast (arrows) showing ongoing bone formation.

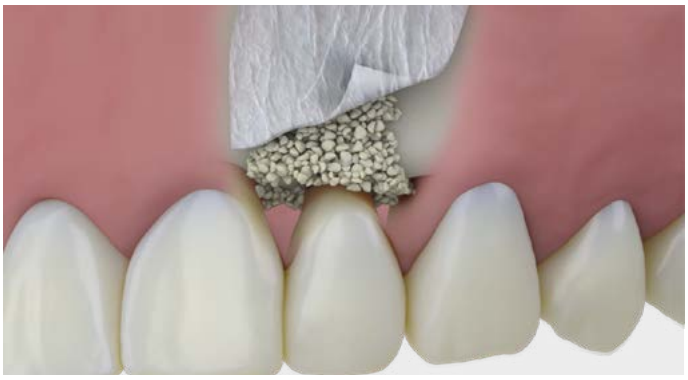
Ideal for following indications

Regeneration and augmentation

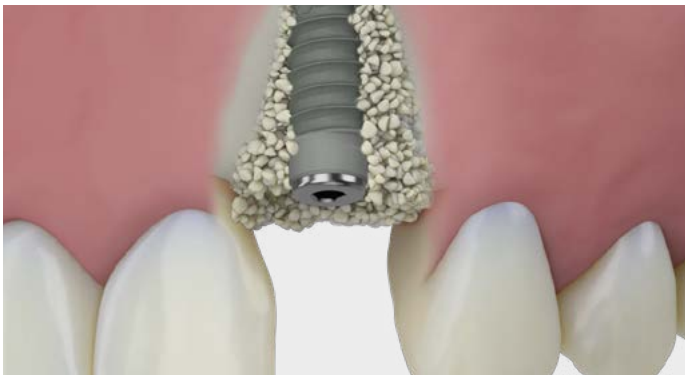
Large bone defects where one bone wall is maintained can be restored to replace missing or inadequate bone tissue, or for filling or stabilizing bone defects by using MinerOss™ A in combination with collagen membrane.

- Regeneration of periodontal osseous defects
- Regeneration after cyst and root tip resections
- Regeneration of extraction sockets
- Regeneration of gaps between alveolar wall and dental implants
- Sinus augmentation
- Regeneration of gaps around block grafts
- Horizontal augmentation of alveolar ridges
- Three dimensional (horizontal and/or vertical) augmentation of alveolar ridges

Regeneration of extraction sockets
Filling the socket with MinerOss™ A in combination with collagen membrane regenerates bone and so retains the volume and shape of the bone over time.



Regeneration of periodontal osseous defects
A tooth with a good prognosis can be retained by regenerating lost bone, with the support of biomaterials such as MinerOss™ A in combination with collagen membrane.



Regeneration of gaps between alveolar wall and dental implants
MinerOss™ A is applied to the defect to support bone regeneration.

The alternative bone-tissue graft

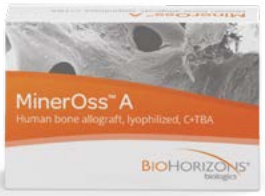
High patient acceptance – shorter treatment times

- **Shorter surgery time**
  The ready-to-use allograft shortens surgery time by eliminating the need for a donor site.
- **Lower patient morbidity and less pain for the patient**
  Avoiding a donor site eliminates the postoperative pain associated with a second procedure.
- **Unlimited availability**
  It is predominantly derived from human donor femoral heads post hip replacement surgery.
- **No clinical difference in final incorporation compared to autologous bone [3, 5, 6]**

The scientific evidence shows that allografts are the second best option to patient‘s own bone compared to other bone substitutes [1]

Ordering information

MinerOss™ A



MinerOss™ A Cancellous Granulate

Art. No.	Volume	Particle size
BM1007.1005	0.5 cm^3	250–1000 µm
BM1007.1010	1.0 cm^3	250–1000 µm
BM1007.1020	2.0 cm^3	250–1000 µm
BM1007.1040	4.0 cm^3	250–1000 µm

MinerOss™ A Cortico-cancellous Granulate

Art. No.	Volume	Particle size
BM1008.1005	0.5 cm^3	250–1000 µm
BM1008.1010	1.0 cm^3	250–1000 µm
BM1008.1020	2.0 cm^3	250–1000 µm
BM1008.1040	4.0 cm^3	250–1000 µm

MinerOss™ A Cancellous Block

Art. No.	Product size
BM1010.1010	10x10x10 mm
BM1010.1020	10x10x20 mm

MinerOss™ A Cortico-cancellous Block

Art. No.	Product size
BM1009.1010	10x10x10 mm
BM1009.1020	10x10x20 mm

MinerOss™ A Cortical Strut

Art. No.	Product size
BM1010.1000	25x10x1 mm

25 x 10 mm (Cortical)

Responsible tissue bank
Cells+Tissuebank Austria gGmbH | Magnesitstr. 1 | 3500 Krems an der Donau | Austria
Phone +43 2732 76954 0 | Fax +43 2732 76954 40 | vigilanz@ctba.at

References

[1] Schmitt et al. Clin Oral Implants Res. 2013, 24, 576.
[2] Solakoglu et al. Clin Implant Dent Relat Res. 2019, 21, 1002-1016.
[3] Kloss et al. Clin Case Rep. 2020, 8, 5.
[4] Wen et al. J. Periodont. 2019, 1, 734.
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[6] Tunkel et al. Clinical Case Reports 2020, 00:1-13.
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[8] Barbeck et al. Materials 2019, 12, 3234.

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