maxgraft®
maxgraft® bonering
maxgraft® bonebuilder
maxgraft® cortico

Processed human allograft
botiss regeneration system

Development / Production / Distribution

botiss academy

Processed human allograft

Introduction

New bone formation after grafting with allogenic bone tissue begins with an acute inflammatory response, within which granulation tissue gradually accumulates, and by activation of osteoclasts. Subsequently the incorporation process begins with the vascularisation of the allograft. By activation of osteoclasts the immune system facilitates the remodeling of the graft. These large cells completely degrade medullary bone, thereby allowing its substitution by osteoblasts. The immunological compatibility of processed allogenic bone is not different from autologous tissue. No circulating antibodies could be detected in blood samples from patients that underwent allograft surgery. Moreover, several histological and morphological studies have well documented that there was no clinical or radiological difference between patients that received autogenous and allogenic bone grafts. Therefore, allogenic bone represents a suitable alternative.

Yet, the autologous bone from intra-oral donor sites is of restricted quantity and availability. The bone tissue obtained from the iliac crest is described to be subject to fast resorption. Moreover, the harvesting of autologous bone requires a second surgical site associated with an additional bone defect and potential donor site morbidity. Thus, application of processed allogenic bone tissue represents a suitable alternative.

Classification

Autologous:
- Patient’s own bone, mostly harvested intra-orally or from the iliac crest
- No risk of disease transmission
- Local tissue reaction
- Intrinsic biological activity
- Long-term volume stability
- Bone from human donors (multi-organ donors or femoral heads of living donors)

Allogenic:
- Bone from tissue donors
- Intrinsic biological activity

Xenogenic:
- From other organisms, mainly bovine origin
- Long-term volume stability
- Synthetically produced, preferably calcium phosphate ceramics
- No risk of disease transmission
- No risk of disease transmission

Classification

Alloplastic:
- Inorganic or organic materials
- Synthetic bone substitute
- No biological activity
- No risk of disease transmission

Allogenic:
- Bone from human donors
- Intrinsic biological activity
- Long-term volume stability
- Synthetically produced, preferably calcium phosphate ceramics
- No risk of disease transmission

Xenogenic:
- Bone from animal donors
- Intrinsic biological activity
- Long-term volume stability
- Synthetically produced, preferably calcium phosphate ceramics
- No risk of disease transmission

C+TBA is a non-profit organization aiming to maintain continuous medical supply of allografts under pharmaceutical conditions. Serving as a platform for the definition of safety standards and assurance of compliance with defined product qualities, C+TBA focuses on the specifications of human bone tissue as required in a large number of diseases that are associated with the loss of bone tissue.

The quality standards for donor selection, procurement, processing, quality control, storage and distribution of human tissue and cells are mandatory committed in the European Directives 2004/23/EC and 2006/17/EC. In addition, at the national level, the legal requirements are defined by the Austrian Tissue Safety Act (GSG, 2009).

To meet and comply with both European and national requirements, C+TBA has implemented a quality assurance system at pharmaceutical level, which is regularly audited by the competent national authority, the Austrian Federal Office for Safety in Health Care (BASG / AGES).

The C+TBA is certified as a tissue bank according to §19 and §22 of the Austrian Tissue Safety Act.

Tissue donation and procurement

maxgraft® products are predominantly produced from living donor femoral heads after hip replacement surgery. Only cortico-cancellous blocks and cortical struts are produced from multi-organ donors.

The procurement, standardized by a predefined protocol, is carried out by certified procurement centers according to the European Directives. Tissue donations will only be carried out after the donor’s written consent. In addition, the health status of the potential donor is assessed in the context of a risk analysis and the donor is then selected on the basis of strict exclusion criteria. For all multi-organ donors the highest ethical and safety-related requirements are met.

After donor acceptance a series of serological testing is performed. In addition to antibody screening (Ab), nucleic acid tests (NAT) are performed. By using this method infections can be identified before antibodies are detected in the blood.

**Serological testing**

<table>
<thead>
<tr>
<th>Virus</th>
<th>Test</th>
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<tr>
<td>Hepatitis B Virus (HBV)</td>
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<td>Hepatitis C Virus (HCV)</td>
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<tr>
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Maxgraft® is only approved for processing after having passed a thorough inspection including a strict serological screening protocol.

Blood samples are taken simultaneously to tissue explantation during total hip replacement surgery or within 24h post mortem in case of multi-organ donation.
Safety and quality

Thorough donor anamnesis and serological testing combined with chemical and radiological sterilization offer maximal safety.

Reference samples

Samples are stored one year after the expiration date of the products, in order to be able to exclude maxgraft® as a source of transmission in case of a doubt. Despite worldwide monitoring, there is no single case of the transmission of a disease, caused by allografts used in dental medicine.

Virus inactivation

The critical viral inactivation steps of the process – dynamic immersion in ethanol, hydrogen peroxide and gamma irradiation – have been validated for reliability and reproducibility by an independent test facility. Suspensions of model viruses for non-enveloped and enveloped DNA viruses (HBV), and non-enveloped (HAV) and enveloped RNA viruses (HIV, HCV, HTLV) have been applied. The process shows an overall efficacy in inactivating all test viruses globally > 6 logs (reference value for efficient viral inactivation > 4 logs) and therefore can be considered effective in removing potential viral contaminants.

Biomechanical properties have recently been analyzed by the Institute of Material Science of the Technical University of Vienna, Austria. After the determination of E-modulus and pressure resistance no significant alterations were detected in irradiated products (post rad.) compared to non-irradiated ones (post proc.).

In an extensive experimental setting virus inactivating capacity of the process was validated and considered effective.

The C+TBA cleaning process

After shaping and crude cleaning, the donor tissue undergoes ultrasonication to remove blood, cells and tissue components, but mainly to promote the removal of fat from the cancellous structure of the bone, improving the penetration of subsequent substances.

During a chemical treatment non-collagenic proteins are denatured, potential viruses are inactivated and bacteria are destroyed.

In the subsequent oxidative treatment, persisting soluble proteins are denatured and potential antigenicity is eliminated.

Finally, the tissue undergoes lyophilization, a dehydration technique which facilitates the sublimation of frozen tissue water from solid phase to gas phase, thereby preserving the structural integrity of the material.

The tissue can be reconstituted rapidly due to microscopic pores within the material, which were created by the sublimating ice crystals during lyophilization. It has been well established that the lyophilization process preserves structural properties that improve graft incorporation.

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.

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

Step 2:
The detaileding of the donor tissue allows penetration of substances 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 by lyophilization preserves the natural structure of the tissue and maintains a residual moisture of < 5%, allowing quick rehydration and easy handling.

Step 6:
Double packing and final sterilization by gamma-irradiation guarantees a 5-year shelf-life at room temperature.

Step 7: Double packing and final sterilization by gamma-irradiation guarantees a 5-year shelf-life at room temperature.

© TBA’s allograft products provide a stable scaffold for revascularization and osteoblastic migration. Simultaneously, due to the preserved collagen content, the graft presents high flexibility supporting physiological bone formation and remodelling.

maxgraft®
Processed human allograft

maxgraft® is a sterile, high-safety allograft product, derived from human donor bone, processed by the Cell-Tissuebank Austria.

For experienced oral and maxillofacial surgeons, allograft bone blocks for block augmentation are the only real alternative to harvesting patients’ bone. A second surgical site to harvest autologous bone and the associated risk of infection, donor-site morbidity, postoperative pain and loss of bone stability can be avoided. The excellent biological regeneration capability of maxgraft® results in a predictable clinical outcome.

Properties
- Preserved biomechanical properties
- Sterile without antigenic effects
- Storable at room temperature for five years
- Osteoconductive properties supporting natural and controlled tissue remodeling

Indications:
Implantology, Periodontology and Oral and CMF Surgery

Granules
- Localized augmentation of the ridge for future implant placement
- Reconstruction of the ridge for prosthetic therapy
- Filling of osseous defects, such as extraction sockets
- Elevation of maxillary sinus floor
- Repair of intrabony periodontal defects

Blocks
- A predictable and highly effective alternative to traditional block grafting
- Ridge augmentation

The macroscopic structure of maxgraft® cancellous granules affirms the physiological constitution of the graft.

Structure and tissue composition

Mineralized collagen
The thermogravimetric analysis shows the mass reduction following heating and helps to determine the content of water and organic components like collagen. Heating from room temperature up to 1000°C resulted in a staged mass reduction. The first reduction of 34.64% can be attributed to the vaporization of water and the combustion of collagen, the second (3.88%) to the vaporization of carbon dioxide.

Surface
SEM pictures of maxgraft® illustrate the structure of the processed bone. Processing does not affect structural features and with its interconnecting macroporosity, maxgraft® is natural human bone matrix. Because of the special production process without sintering, maxgraft® retains its collagen matrix. At a higher magnification the structure of the mineralized collagen fibers can be recognized.

SEM pictures of maxgraft® at a 100-fold and 5000-fold magnification, showing the macroporous structure and surface of the mineralized collagen matrix.
maxgraft® bonering
Processed allogenic bone ring

maxgraft® bonering is a pre-fabricated cancellous ring of human donor bone, which is placed press-fit into a trephine drill-prepared ring bed. At the same time, an implant is inserted into the ring. The bony integration of both, maxgraft® bonering and the implant, occurs via the surrounding vital bone.

Preparation of ring bed

After determination of the position of the implant by the planator tip and the pilot drill, the ring bed is prepared with the trephine. Subsequently, the planator allows even paving of the local bone for optimal contact with maxgraft® bonering and in addition, removes the cortical layer for improved graft revascularization.

The maxgraft® bonering technique allows bone augmentation and implantation in a one-stage procedure. The technique is applicable for almost all indications, including sinus lift with limited maxillary bone height.

Indications:
Implantology
- Vertical augmentation (in combination with horizontal augmentation)
- Single tooth gap
- Edentulous space
- Sinus lift

Advantages
- Simultaneous implant placement and bone augmentation
- No second surgical procedure
- Significant reduction of treatment time

One-stage bone augmentation and implant placement

maxgraft® bonering surgical kit

With this surgical kit, botiss provides all necessary instruments to apply the maxgraft® bonering technique. The kit includes two convenient sizes of trephines, which precisely fit together with the maxgraft® bonering diameters.

The planators allow paving of the local bone to create a congruent and fresh contact surface of the implant area. The diamond disc and the diamond tulip help to shape the maxgraft® bonering for excellent adjustment to the local bone and for improved soft tissue healing. Altogether, these instruments allow optimal preconditions for the bony ingrowth of maxgraft® bonering.

All instruments are made of high quality surgical steel.

Soft tissue management

The height of maxgraft® bonering is adjustable to the defect

The maxgraft® bonering technique enables vertical bone augmentation and direct implantation

Immediate implant insertion through maxgraft® bonering ensures primary stability of implant and graft

Compared to the classical, two-stage augmentation with i.e. bone blocks, this technique reduces the entire treatment period by several months and saves the re-entry.

maxgraft® bonering surgical kit

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<th>Product Specifications</th>
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maxgraft® bonering 4.1

| Height 10 mm, recommended for implant diameters from 4.1 mm |
| Product Code |
| Art.-No. | Dimension | Content |
| 33174 | cancellous ring, Ø 7 mm | 1 x |
| 33030 | maxgraft® bonering surgical kit | 1 set |
| 33010 | bonering fix | 1 x |
maxgraft® bonebuilder
Customized allogenic bone block

maxgraft® bonebuilder is a customized allogenic bone transplant, which is individually adjusted to the bone defect. With maxgraft® bonebuilder, harvesting of autologous bone and manual adjustment of the obtained transplant is no longer required for the treatment of extensive defects. Donor site morbidity, operation time and costs can be significantly reduced.

The maxgraft® bonebuilder technology

In-house planning
botiss virtually designs the patient customized allogenic bone transplant based on the CT/DVT-scan of the bone defect. The design of the bone transplant undergoes a final inspection by the clinical user and, if required, is individually adjusted and released for production. The botiss partner Cells+Tissuebank Austria receives a *.stl milling file and the patient matched allogenic bone transplant is produced under cleanroom conditions. The resulting bone block is ready for insertion into the defect with only minor adjustments.

Indications
- Extensive bone defects
- Atrophic maxilla/mandible
- Horizontal/vertical augmentation

Advantages
- Individualized allogenic bone transplant
- Significantly reduced operation time
- Improved wound healing

After placement, the maxgraft® bonebuilder block is fixed with osteosynthesis screws. Residual defect volume should be filled with bone regeneration material and the augmentation site should be covered with a collagen membrane.

The strong capillary action of the three-dimensional, porous trabecular bone network enables fast and efficient penetration of nutrients and blood, resulting in excellent handling, as well as reliable and predictable outcomes.

The customized maxgraft® bonebuilder block allows precise horizontal and vertical reconstruction of the atrophic ridge.

1. Upload of CT/DVT-data on www.botiss-bonebuilder.com
After registration, CT/DVT-data of the patient can be uploaded on the botiss server. All radiological data have to single-frame data images. The only data type suitable for 3D planning is DICOM (*.dcm).

2. Block design
botiss designers create a three-dimensional model of the radiological images and design a virtual bone transplant in consultation with the clinical user.

3. Design quality check
The clinical user receives a 3D PDF file containing the virtually constructed maxgraft® bonebuilder block and has to confirm its design.

4. Individual order
The production of the block starts after the clinical user fills in the patient based order form for the bone block to the attention of botiss biomaterials.

5. Production of the individual bone block
At C+TBA the *.stl data of the design is imported into a milling machine and a block of maximally 23 x 13 x 13 mm is produced.

Product Specifications
maxgraft® bonebuilder
Art.-No. Content
PMIa Individual planning and production of a bone transplant max. dimensions 23 x 13 x 13 mm
PMIa 2 additional block(s) for this patient

www.botiss-bonebuilder.com
maxgraft® cortico

Shell technique with allogenic bone plates

maxgraft® cortico is a prefabricated plate made of processed allogenic bone. Similarly to the autogenous bone, it can be used for the shell technique.

maxgraft® cortico was developed to avoid the donor-site morbidity and to prevent the time-consuming harvesting and splitting of autologous cortico-cancellous bone blocks.

Preparation of the augmentation area

The proper size of the plate is estimated after the elevation of the mucosal flap or preoperatively using a digital planning software. Using a diamond disc, the plate is then cut extraorally.

Fixation and adaption

The plate is positioned within a certain distance by predrilling through the plate and local bone; fixation is performed with osteosynthesis screws to create a fixed compartment. To prevent the perforation of the soft tissue, the sharp edges has to be removed, e.g., by using a diamond ball.

Indications:
- Vertical augmentation
- Horizontal augmentation
- Complex three-dimensional augmentations
- Single tooth gaps
- Fenestration defects

Properties
- Osteoconductive
- Natural and controlled remodelling
- Conserved biomechanical parameters
- Sterile, no antigenic effect
- Five-year shelf life

The shell technique with maxgraft® cortico

The space between local bone and cortical plate can be filled with a variety of different particulated bone grafting materials. Then, the augmentation area needs to be covered with a barrier membrane (Jason® membrane, colp Protect® membrane) and a tension-free and saliva-proof closure must be applied.

Advantages
- Established augmentation technique with new material
- Significant reduction of operation time
- No donor-site morbidity
- No limitation of augmentation material

Filling and wound closure

Six months after transplantation, a superficial resorption of the plate can be seen; the stability, however, is maintained.

Product Specifications

maxgraft® cortico

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cortico trimmer

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Natural bone regeneration

To facilitate osteogenesis, allogenic particles can be used to fill the defect. The preserved human collagen provides an excellent osteoconductivity and enables a complete remodelling. Mixing with autologous chips or particulated PRF matrices can support the ossification.
Clinical application

Clinical case by Dr. Fernando Rojas-Vizcaya, Castellón, Spain

Socket preservation with maxgraft® granules

Antibiotics

When performing hard tissue augmentation, the patient should be treated with a sufficient dose of antibiotics to minimize the risk of infection and related possible graft loss. A potential treatment plan could include starting the antibiotic one day prior or at least one hour before surgery by ingestion of a full daily dose. In case of extensive jaw reconstruction a bacteriological screening (saliva sample) should be considered.

GBR/GTR

Resorbable collagen membranes act as a temporary barrier against ingrowth of fast proliferating fibroblasts and epithelium into the defect, and maintain the space for controlled regeneration of bone. The Jason® membrane is a pericardium membrane providing a long-lasting barrier function for -three to six months. mucoderm®, a three-dimensional collagen matrix, supports revascularization and fast soft tissue integration and thus, is a valid alternative to patients’ own connective tissue. When applying mucoderm® simultaneously with a bone graft material please assure adequate mobilization of the surrounding soft tissue.

Clinical application

Clinical case by Dr. Damir Jelušić, Opatija, Croatia

Ridge augmentation with maxgraft® cancellous blocks

After immediate loading protocol: Prosthesis will guide soft tissue during healing process
Clinical application

Clinical case by
Dres. Bernhard Giesenhagen and
Orcan Yüksel, Frankfurt, Germany

Part I: Vertical augmentation with maxgraft® bonering

Vertical augmentation with maxgraft® bonering
For the reconstruction in an atrophic jaw a vertical augmentation of up to 3 mm above local bone level can easily be achieved. If more vertical height is desired, enhancing additives such as bone morphogenic proteins (BMP) or growth factors are in discussion to be beneficial. For vertical and horizontal augmentation of a severely atrophic mandibular, the width of the ridge (in case of parallel-walled ridge) has to be at least 4 mm for successful application of maxgraft® bonering.
The maxgraft® bonering allows for direct implant insertion during sinus lift by providing the necessary primary stability. The sinus cavity should be filled with an additional grafting material (e.g. cerabone®, maxresorb® or maxresorb® inject).

Part II: Sinus lift with maxgraft® bonering

Preparation of the defect with a trephine
Press-fit placement of maxgraft® bonering into the defect
Direct implantation in the cancellous ring
Tension-free suturing after placement of Jason® membrane

Clinical situation in the second quadrant: Vertical and horizontal defect in the maxillary ridge; sinus cavity is filled with cerabone®

X-ray nine months post-operative: Full integration of maxgraft® bonering and implants and proceeding remodeling of the grafts
Clinical application

Clinical case by
Dr. Darius Pocebutas, Kaunas, Lithuania

Horizontal augmentation in a single tooth gap with maxgraft® bonering

Graft exposure
Wound dehiscence and graft exposure can be complications of block augmentation. After removal of necrotic soft tissue and infected hard tissue (use rotating instruments if necessary) the augmented area should be rinsed with chlorhexidine. Subsequently, the graft has to be covered again, if necessary, by harvesting a palatal soft tissue transplant.

Clinical application

Clinical case by
Dr. Anke Isser, Frankfurt, Germany

Ridge augmentation with maxgraft® bonebuilder

Design quality check
The design of maxgraft® bonebuilder has to be checked very carefully before it is released for production. Only the surgeon himself can assess the patients’ soft tissue situation and therefore, the required dimensions of the block. The botiss construction team will adjust the design of the block until it perfectly meets the expectations of the clinician.
Clinical application

Clinical case by
Dr. Michele Jacotti, Brescia, Italy

Ridge augmentation with maxgraft® bonebuilder

- Virtual planning of the block
- Patient matched maxgraft® bonebuilder
- Situation after mucosal flap preparation and perforation of the cortical layer
- Exact positioning of the maxgraft® bonebuilder block
- Fixation of the block with screws for osteosynthesis
- Careful wound closure
- Clinical situation at re-entry five months post-operative
- Full bony ingrowth of the block

- 3D implant positioning
- Stable implant insertion
- Abutment placement after ingrowth of the implants
- Final prosthesis

Fixation
maxgraft® blocks are fixed with screws for osteosynthesis, preferably with flat-headed screws to avoid perforation of the surrounding soft tissue.

Clinical application

Clinical case by
Dr. Viktor Kalenchuk, Chernivtsi, Ukraine

Ridge augmentation with maxgraft® bonebuilder

- Clinical situation before augmentation
- CT scan of region 36, 37 before surgery
- Situation after tooth extraction and mobilization of mucosal flap
- maxgraft® bonebuilder
- Immediate implant insertion in regio 34, 35; positioning and fixation of maxgraft® bonebuilder
- Filling of residual volume with cerabone®
- Covering the augmentation site with collprotect® membrane
- Wound closure and suturing
- CT scan of region 36, 37 after surgery
Clinical case Jan Kielhorn, Oehringen, Germany

Frontal defect treated with maxgraft® cortico

Rehydration
The processing of the C-TBA products preserves the natural collagen and maintains a residual moisture of <5%. According to our clinical users rehydration is not necessary and the products are ready for immediate use.

Clinical case Dr. Krzysztof Chmielewski, Gdansk, Poland

Single tooth restauration with maxgraft® cortico

Fixation with osteosynthesis screws

Covering with Jason® membrane and saliva-proof wound closure

Serious atrophy in the esthetic region

Preparation of the defect

maxgraft® cortico in preparation

Covering with a PRF matrix for improved soft tissue healing

Severe atrophy in the esthetic region

Preparation of the defect

maxgraft® cortico in preparation

Fixation with osteosynthesis screws

Augmentation with cerabone®

Covering with Jason® membrane and saliva-proof wound closure

Clinical application

www.botiss-webinars.com

Find more on:

Jan Kielhorn
Cortical struts and computer aided bone augmentation

Krzysztof Chmielewski
GBR in my daily practice: tent technique, cortical struts, maxgraft® bonebuilder, xenograft, PRF and more - selection of materials and techniques to achieve best results

Bernhard Giesenhagen
The bone ring technique - new perspectives in augmentation

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www.indication-matrix.com

CLINICAL SUCCESS
with the right regeneration concept

+ +

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# maxgraft® bonebuilder

**Product Specifications**

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# maxgraft® bonering surgical kit

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# Product Specifications

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# maxgraft® bonebuilder dummy

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# maxgraft® cortico

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# cortico trimmer

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