maxgraft®
maxgraft® bonering
maxgraft® bonebuilder
maxgraft® cortico
Processed human allograft

safe
biologic
successful

hard tissue
botiss regeneration system

Development / Production / Distribution

hard tissue

Fast Degeneration

Preservation

Augmentation

botiss academy

soft tissue

Bone & tissue days

Process human allograft

Introduction

Various bone graft materials are available to replace and regenerate bone matrix lost by tooth extraction, cystectomy or bone atrophy followed by loss of teeth or inflammatory processes.

Of all grafting options autologous bone is considered the „gold standard“, because of its biological activity due to vital cells and growth factors.

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.

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 vascularization 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 difference in the final stage of incorporation between allograft and autologous graft.

Classification

Autologous:
- Patient’s own bone, mostly harvested intra-orally or from the iliac crest
- Natural bone composition and structure

Allogenic:
- Bone from human donors (multi-organ donors or femoral heads of living donors)
- Long-term volume stability

Xenogenic:
- From other organisms, mainly bovine origin

Alloplastic:
- Synthetically produced, preferably calcium phosphate ceramics
- No risk of disease transmission

References

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).

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

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.

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

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.

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.

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

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 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.).

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


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

Step 2:
The detailing of the donor tissue allows 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:
Pressuring by lyophilization preserves the natural structure of the tissue and maintains a residual moisture of <0.5%, 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.
maxgraft®
Processed human allograft

maxgraft® is a sterile, high-safety allograft product, derived from human donor bone, processed by the Celle-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

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.
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.

Preparation of the implant bed is achieved by planator and trephine. The height of maxgraft® bonering is adjustable to the defect. The maxgraft® bonering technique ensures primary stability of implant and graft.

Comparing 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.

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

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

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.

Soft tissue management

Sharp edges should be smoothened to avoid soft tissue perforation and to support wound healing. Moreover, maxgraft® bonering should be covered with a slowly resorbable bone regeneration material (e.g. cerabone®) to fill the residual defect volume and to avoid potential adaption resorption of the graft.

After covering of the graft with a collagen membrane (Jason® membrane) a tension-free suturing of the operation area must be assured to avoid tissue perforation and graft exposure.

One-stage bone augmentation and implant placement

Soft tissue management

botiss-dental.com/products/maxgraft-bonering

Product Specifications

maxgraft® bonering 3.3
(height 10 mm, recommended for implant diameters from 3.3 - 3.6 mm)

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maxgraft® bonering 4.1
(height 10 mm, recommended for implant diameters from 4.1 mm)

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maxgraft® bonering surgical kit

maxgraft® bonering surgical kit 1 set

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 customised allogenic bone transplant based on the CT/DVF-scan of the bone defect. The design of the bone transplant undergoes a final inspection by the clinical user and is, by individual order, 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

Based on this model, Botiss designs a virtual block, which matches the surface structure of the defect and allows stable implant insertion after augmentation.

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.

The maxgraft® bonebuilder technology

1. Upload of CT/DVF-data on www.botiss-bonebuilder.com
After registration, CT/DVF-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 max. dimensions 23 x 13 x 13 mm is produced.

Product Specifications
maxgraft® bonebuilder

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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

Fixation and adaptation Advantages

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

Filing and wound closure

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, collprotect® membrane) and a tension-free and saliva-proof closure must be applied.

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

Clinical situation in the maxilla before extraction

Situation after tooth extraction and mobilization of mucosal flap

Augmentation of the maxillary ridge and filling of extraction sockets with maxgraft® granules. Placement of mucoderm® to improve soft tissue situation and Jason® membrane to cover surgical site

Mobilization and pre-fixation of the surrounding soft tissue

Clinical situation four months post-operative

Maxillary ridge in situ after preparation of mucosal flap

Tension-free wound closure

Four months post-operative: Bone is at the level of the planned crowns

Clinical situation four months post-operative

Maxillary ridge in situ after preparation of mucosal flap

Insertion of four implants

Placement of abutments

Positioning of prosthesis

Closure of mucosal flap

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.

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

Clinical application

Clinical case by
Dr. Damir Jelušić, Opatija, Croatia

Ridge augmentation with maxgraft® cancellous blocks

X-ray and CAD/CAM-based 3D image of maxillary ridge before surgery

X-ray and CAD/CAM-based 3D image of maxillary ridge before surgery

Manual adjustment of maxgraft® blocks on a CAD/CAM-based model

Clinical situation

Atrophic maxillary ridge after preparation of mucosal flap

Fixation of the prepared maxgraft® blocks

Filling of residual gaps with cerabone® and covering with Jason® membrane

Tension-free closure of mucosal flap

X-ray five months post-operative

X-ray and CAD/CAM-based 3D image three days post-operative

Clinical situation five months post-operative

CAD/CAM-based 3D image three days post-operative

Clinical situation five months post-operative

Insertion of three implants and gingiva formers

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.

Six months after re-entry: Patient is ready for final prosthesis

GBR/GTR
Clinical application

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

Part I: Vertical augmentation with maxgraft® bonering

Preparation of the ring bed in an atrophic mandible (third quadrant)
Vertical augmentation by placing a maxgraft® bonering
Simultaneous horizontal augmentation
Stable implant insertion
Insertion of second maxgraft® bonering and implant
Filling of the residual defect volume with cerabone® and covering the operation site with a Jason® membrane
Tension-free soft tissue management

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 mandible, 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).
Clinical application

Clinical case by Dr. Darius Pocebutas, Kaunas, Lithuania

Horizontal augmentation in a single tooth gap with maxgraft® bonering

Clinical situation pre-operative
Pilot drill in the recipient site
Preparation of the ring bed with the trephine
Paving of the local bone using the planator from maxgraft® bonering surgical kit

Measurement of the defect
Adjustment of maxgraft® bonering to desired height
Placement of the ring into the ring bed
Due to its structure the ring is instantly soaked with blood

Implant insertion in maxgraft® bonering; the shape of the ring mimics the anatomic structure of the ridge

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)

Gaps are filled with cerabone® and the augmentation site is covered with a Jason® membrane

Graft exposure
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.

Tension-free wound closure

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. Anke Isser, Frankfurt, Germany

Ridge augmentation with maxgraft® bonebuilder

Clinical situation pre-operative
Midcrestal incision line
Lingual mobilization and cortical perforation

Perfect fit of maxgraft® bonebuilder
Fixation of the blocks with screws for osteosynthesis
Contouring with cerabone®

Covering of the block with Jason® membrane
Horizontal mattress suture and tension-free wound closure

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

Clinical situation before augmentation

Clinical situation after mucosal flap preparation and perforation of the cortical layer

Clinical case by Dr. Viktor Kalenchuk, Chernivtsi, Ukraine

Ridge augmentation with maxgraft® bonebuilder

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

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 Jan Kielhorn, Oehringen, Germany

Frontal defect treated with maxgraft® cortico

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

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

Single tooth defect with severely resorbed vestibular wall
Fixation of maxgraft® cortico using an osteosynthesis screw
Augmentation with maxgraft®, granules mixed with particulated PRF matrices and fixation of a second maxgraft® cortico
Covering of the augmentation area with Jason® membrane
Covering with a PRF matrix for improved soft tissue healing
Tension-free wound closure
Situation after a healing period of four and a half months
Stable implantation

Clinical application

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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

Find more on:
www.botiss-webinars.com

Clinical success with the right regeneration concept

360°

www.indication-matrix.com
### maxgraft® cancellous granules

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### maxgraft® cortico-cancellous granules

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### maxgraft® blocks

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### maxgraft® bonering surgical kit

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Innovation.
Regeneration.
Aesthetics.

botiss biomaterials GmbH
Hauptstr. 28
15806 Zossen / Germany

Tel.: +49 33769 / 88 41 985
Fax: +49 33769 / 88 41 986

contact@botiss.com
www.botiss.com
www.botiss-dental.com