



FAQ

requently

asked

questions

maxgraft® bonebuilder

botiss
biomaterials

What is the origin of
maxgraft[®] bonebuilder?



Living donors femoral heads – maxgraft® bonebuilder

maxgraft® bonebuilder is made of cancellous human bone blocks. These blocks originate from living donors by explantation of femoral heads (hip replacement) in certified procurement centers established, supervised, and managed by C+TBA (Cells+Tissuebank Austria). The C+TBA is a non-profit organization aiming to provide allografts for orthopedic and dental regeneration. As the biggest Austrian tissue bank in the area of musculoskeletal tissue, C+TBA is one of the few tissue banks that accompanies the whole process of its grafts, from tissue donation, procurement, and processing to distribution. Tissue donation will only be carried out after a donor's written consent.

What is the lead time?

Why is the lead time longer
than for other bottling products?

The lead time is about 4-5 weeks. The planning phase is dependent on the quality and complexity of the scan and the amount of additional information given during order submission.

Usually, the first design proposal is provided to the surgeon within one week. In the case of feedback loops and adaptations, this process might be prolonged. The design will be changed according to the surgeon's demands as often as necessary without additional charges. The final design confirmation needs to be provided by the responsible surgeon by submission of the written order form. Delivery time is approximately four to five weeks after receipt of the order form.

What is the maximum
size of maxgraft[®] bonebuilder?

The maximum size for each block is 23x13x13 mm. This is due to technical and biological reasons. Firstly, the maximum size of maxgraft® bonebuilder is dependent on the source of the material, the dimension, and the quality of the femoral heads. Secondly, the size is restricted due to the fixation method for milling of the blocks in the CNC milling machine. To avoid fractures during milling a maximum size was defined based on the experience of the producing tissue bank C+TBA.

In cases with multiple or larger defects, several blocks can be designed and used. The second and each additional block that is designed based on the same data set has a lower price. Please contact your local botiss distribution partner or write us to bonebuilder@botiss.com to get information about prices.

Is maxgraft[®] bonebuilder available
as a cortico-cancellous block?

No. As different articles show satisfying volume stability of purely cancellous bone blocks (which provide better revitalization) only cancellous blocks are used³.

The fact of only using cancellous bone also permits to have a high accuracy in the block production. This accuracy would be reduced if a cortical layer should be considered in the 3D planning and production of the block. The dimension of a cortical layer of a cortico-cancellous bone block is in most cases unpredictable and irregular. Moreover, the adaptation of the block to the ridge contour would be less precise.

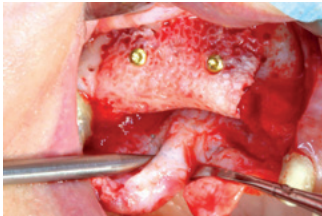
How much gain in width and height can be expected with maxgraft[®] bonebuilder?

The overall limits of the maxgraft® bonebuilder, technique are still unknown, and the overall outcome depends on many factors such as defect geometry and size (contained defect, etc.) and biological factors (vitality of the recipient site, etc.).

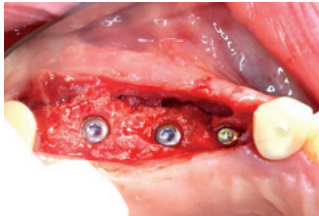
In the literature, one can find some reports on similar allogenic bone blocks where a reliable clinical outcome of 3-4 mm gain in vertical height is mentioned¹, whereas horizontally up to 5-6 mm were achieved.

How long does the
maxgraft[®] bonebuilder
take to integrate?

The healing time is approximately five to six months. This is dependent on the defect size and the individual healing process. maxgraft® bonebuilder serves as a scaffold for blood vessels and bone-forming cells that migrate along with the grafting material and start with the formation of a new bone matrix. Thereby, the material will be progressively integrated into the newly formed bone and continuously remodeled into own bone². The time of complete remodeling is individual for each patient.



maxgraft® bonebuilder fixation in maxilla

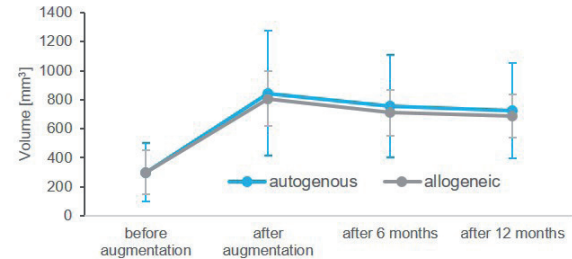


Augmented area at re-entry after six months: Vital bone situation, Photo courtesy of Dr. O. Blume, Germany

How much resorption is anticipated within six months after augmentation?

The volume loss after augmentation varies and is also dependent on the defect size and geometry. For horizontal single tooth reconstructions with cancellous maxgraft® blocks, minimal volume loss has been documented after six but also after 12 months³.

In summary, the volume loss was comparable to autologous bone blocks without the need of over contouring³. Other authors have published an average volume loss using cancellous allogeneic blocks of about 5-10% (approximately 0.5 mm)⁴.

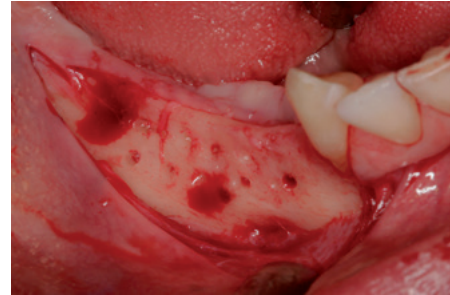


Comparison of the volume loss of autogenous and allogeneic bone blocks after horizontal reconstruction (diagram adapted from Kloss et al. 2018)

Is there a recommendation concerning the perforation of the cortical local bone at the augmentation site prior to fixation of maxgraft[®] bonebuilder?

No. To date, an improvement in osteogenesis due to perforation of the cortical layer of the recipient site has not been proven. However, perforation induces translocation of blood, cells, and growth factors into the augmentation site that might accelerate healing, especially in the mandible.

Care should be taken not to harm anatomical structures.



Perforation of the cortical layer in the mandible,
Photo courtesy of Dr. O. Yüksel, Germany

Should maxgraft[®] bonebuilder
be rehydrated?

Yes, maxgraft® bonebuilder should be rehydrated briefly before fixation by placing the block inside a disposable syringe filled with a sterile saline solution and creating a vacuum to remove excess air trapped within the block. By rehydrating the material, the adaptability of maxgraft® bonebuilder to the specific defect site can be enhanced.

<https://www.youtube.com/watch?v=0VpVWjfqqNQ>

If you are using platelet-rich fibrin (PRF) matrices on top of the augmented area, it is advisable to mix the saline solution with the exudate serum obtained from the preparation of PRF⁵.

How should maxgraft® bonebuilder be fixated?

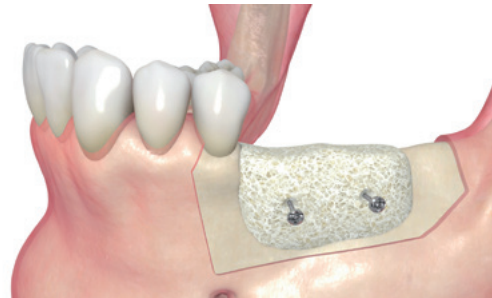
Which screws should be used?

maxgraft® bonebuilder should be fixated at the recipient site with osteosynthesis screws – preferably flat-headed screws to avoid perforation of the surrounding soft tissue. maxgraft® bonebuilder needs to be immobile for optimal contact between the local bone and allograft. No self-tapping screws should be used to prevent the breakage of the block. The application of excessive force might cause damage to the block graft.

Screw position and screw length can be estimated by the surgeon using the 3D PDF to perform measurements. For most defects, screws with a diameter of 1.2–1.5 mm and a length of 8–11 mm are suitable. Countersinking the bold head of the screw into the block is recommended as the head may irritate the soft tissue; a diamond bur can be used to create the countersink.

The allograft needs to be immobile for optimal contact between the local bone and the allograft and optimal graft integration. To prevent the perforation of the soft tissue, all sharp edges need to be removed; a diamond bur can be used for this process. It is essential to avoid any contact with saliva while handling the bone block to reduce the risk of contamination.

<https://www.youtube.com/watch?v=oGdLMh9su0I>



How fragile are maxgraft® bonebuilder blocks?

What should be
kept in mind for handling?

maxgraft® bonebuilder blocks are processed human cancellous bone blocks and should be handled with care.

Applying pressure on the material should be avoided. In order to prevent breakage while positioning the screws, no self-tapping screws should be used. In general, the material is quite flexible because of the Allotec® process (specific cleaning process of C+TBA), which retains the natural collagen and a residual moisture content of <10%.



Can the dental implant
be placed simultaneously
into maxgraft[®] bonebuilder?

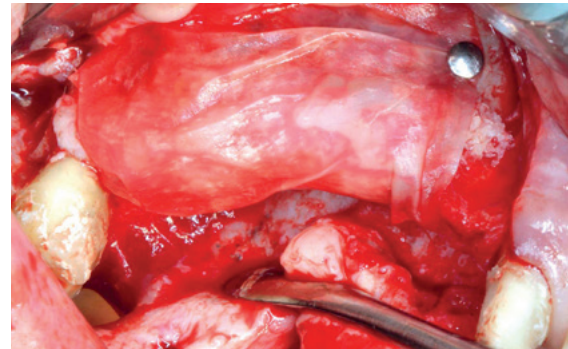
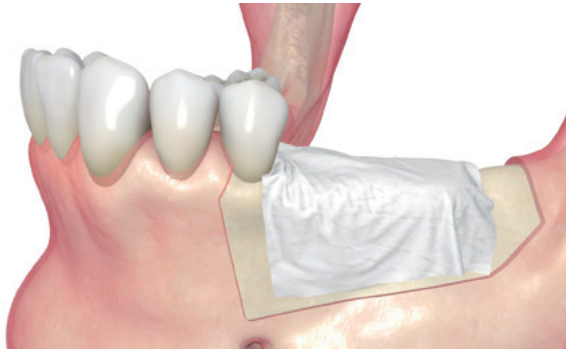
No, maxgraft® bonebuilder is indicated for two-stage alveolar ridge augmentation.

Depending on the location, type, and extent of the defect, the healing time is approximately six months.

Is there a recommendation
for the use of a membrane
to cover maxgraft[®] bonebuilder
in respect of GBR?

For GBR procedures, the use of barrier membranes (resorbable or non-resorbable) is of utmost importance.⁵

The membranes act as temporary barriers against ingrowth of fast proliferating fibroblasts and epithelium into the defect, maintaining the space for controlled bone regeneration. In combination with maxgraft® bonebuilder, Jason® membrane – a pericardium membrane that provides a naturally long barrier function – is often used.



Covering of the maxgraft® bonebuilder block with Jason® membrane,
Photo courtesy of Dr. O. Blume, Germany

Can maxgraft[®] bonebuilder
be used with additional
bone substitute materials?

Yes. Because of the good fit, often no additional bone substitute materials are needed to augment the defect site.

However, in case any residual volume needs to be filled, allogenic particulate material (e.g. maxgraft® granules), with its preserved human collagen provides excellent osteoconductive properties and is therefore the first choice.

Notwithstanding, other materials or mixtures of different materials (e.g., bovine or synthetic biomaterials) can also be used for defect contouring. The final decision depends on the defect morphology and preferences of the patient and surgeon.

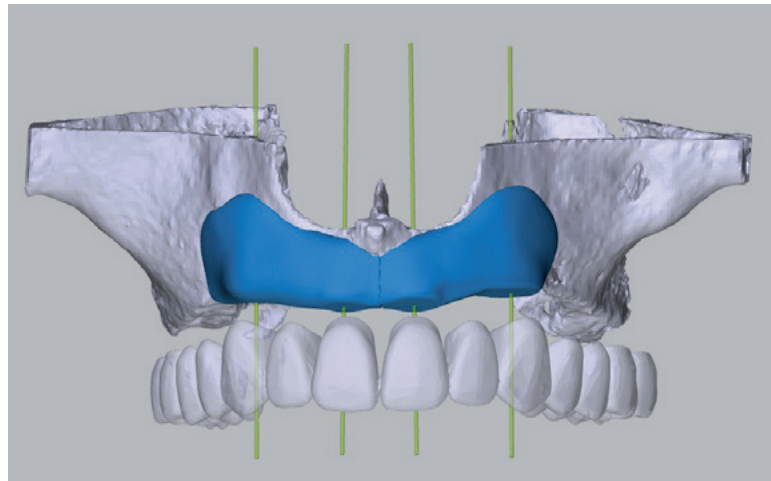
Should maxgraft[®] bonebuilder
be covered with a non-resorbable
particulate material in order
to prevent volume loss?

There is no general recommendation on that as there is no data regarding its benefits. The resorption during the remodeling and integration phase depends strongly on defect area as well as defect size and defect geometry.

Some clinical users prefer to do it based on their own experiences, but also many users who do not cover maxgraft® bonebuilder with any particulate material (and just use the block plus a membrane) experience good stable clinical outcomes.

What is the benefit of
maxgraft[®] bonebuilder?

maxgraft® bonebuilder is a patient customized allogenic bone block. It is easy to apply as it is ensuring maximal contact of the bone block to the recipient site. This reduces the need for manual adjustments and consequently saves surgical time. Moreover, the harvesting of autologous bone is not required and thus might reduce the patient's morbidity and discomfort. The individual design provides a precise fit between local bone and the allogenic bone block, enabling rapid revascularization and fast graft incorporation^{7,8}.



Designed bone blocks in the 3D planning software

I am interested in maxgraft[®]
bonebuilder, how can I send
you my case and which data
format is needed?

Please register on www.botiss-bonebuilder.com where you can upload your case. All data must be uploaded as a .zip or .rar file in unlinked single frame images in DICOM (.dcm) format.

Workflow

maxgraft® bonebuilder

1. Patient details

The clinician can upload patient CT/CBCT scans on

www.botiss-bonebuilder.com.

The 3D design at botiss requires single-frame data images in DICOM format. The botiss CAD designers support the upload via telephone:

+49 (0)30 20 60 73 96 -35 / -28 or via e-mail: bonebuilder@botiss.com

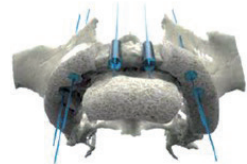


2. Block design

The botiss product specialists design the virtual customized bone block with a 3D planning software based on the radiographic data. This process is done in interactive exchange with the clinician.

3. Design check of the 3D planning

The computer designed bonebuilder block provided as 3D PDF is checked by the clinician who may request modifications. After the design is finalized the clinician approves the design.



PATIENT CUSTOMIZED allogenic 3D bone implant

5. Production of maxgraft® bonebuilder

The design data is transmitted to the Cells-Tissuebank Austria, the responsible tissue bank located in Krems. Each individual maxgraft® bonebuilder is milled from a processed allogenic cancellous block. After submission of the order form maxgraft bonebuilder is delivered in approximately 4 weeks.

4. Order of maxgraft® bonebuilder

After the release of the design production starts, botiss requires order placement via an order form which can be found on the botiss website.

https://www.botiss-dental.com/pdf/Instructions_CT_CBCT_and_data_export.pdf

A virtual implant planning has already been done elsewhere.

Can I submit it to botiss
for targeted construction
of maxgraft[®] bonebuilder?

Yes, in many cases this is possible.

Please contact the botiss CAD/CAM team for support:
bonebuilder@botiss.com or +49 30 20 60 73 98 30

Is it possible to discuss the feasibility of a case before starting the ordering process?

Yes, this is highly appreciated.

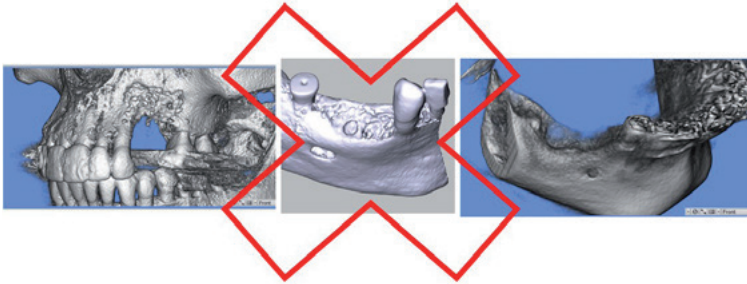
Please leave a comment in the comment section during upload and we will get back to you after reviewing your case.

Support/Contact:

bonebuilder@botiss.com or +49 30 20 60 73 98 30

Can teeth or implants, that need to be removed, be eliminated digitally for the planning of maxgraft[®] bonebuilder so that the block can later be placed in the fresh extraction site?

We do not recommend virtual removal of any parts of the data (bone substitute material, teeth, etc.). The bonebuilder principle is based on the clear definition of the bone structure of the recipient site to be able to design the optimal block surface. Any virtual removal during the 3D planning corresponds with a high probability of an unsuccessful clinical outcome of the procedure as the supposed planned surface can differ highly from the clinical defect surface. Consequently, poor fit of the block is highly likely which can result in problems regarding block revascularization and block healing. In case of a planned extraction we recommend to wait 3-4 months after extraction for tissue healing and then proceed with making a new scan of the defect for a reliable 3D planning.



(from left to right: bone substitute material in situ, fresh extraction sites with unclear definition of the bone structure)

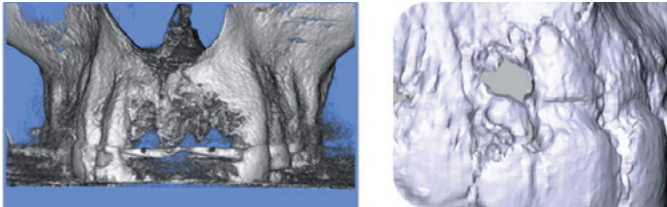
Is it possible to order
maxgraft[®] bonebuilder already
with the dental implant osteotomy?

No, it is not possible as maxgraft® bonebuilder is indicated for a two-stage procedure. The correct position and length of the implant needs to be judged and planned after integration and healing of maxgraft® bonebuilder (approx. 5–6 months) by the surgeon and cannot be planned beforehand.

maxgraft® bonebuilder is a customized product.
I expect 100% precise fit.

Is this possible?

Any individual planning is only as good as the data on which it is based. We do our best to generate a reliable 3D model of the defect and an optimal fitting bone block but there are many factors which can influence the fitting that are not 100% predictable. Factors that influence block fitting are for example: data quality, defect geometry, timeframe between scan date – planning and final surgery, and individual bone resorption/remodeling of the patient etc.



Examples of unsuitable CBCT (fresh extraction sites, low data quality)

Can you tell me the block thickness so I can order the right screws?

Is it possible to receive
maxgraft[®] bonebuilder already
with the holes for the screws?

We do not produce maxgraft® bonebuilder with already existing screw holes. The correct surgical screw position and screw length should be chosen by the surgeon based on the intraoperative clinical situation and position of anatomical features such as nerves and blood vessels. Characteristics such as block thickness and screw position can only be estimated by the responsible surgeon when using the 3D PDF. We do provide the option to get a 3D-printed plastic dummy of the patient's defect and the designed maxgraft® bonebuilder. With this in hand, the surgeon can estimate the best screw length and position.

Literature:

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2. Kloss FR, Offermanns V, Donkiewicz P, Kloss-Brandstätter A. Customized allogeneic bone grafts for maxillary horizontal augmentation: A 5-year follow-up radiographic and histologic evaluation. *Clin Case Rep.* 2020;00:1–8.
3. F. R. Kloss, V. Offermanns, and A. Kloss-Brandstätter, "Comparison of allogeneic and autogenous bone grafts for augmentation of alveolar ridge defects - a 12-month retrospective radiographic evaluation," *Clin. Oral Implants Res.*, no. February, pp. 1163–1175, 2018.
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