FAQ

requently asked uestions

maxgraft®

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biomaterials

What is the origin of maxgraft®?

Living donors femoral heads – maxgraft® granules

All cancellous maxgraft® products 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 cortical products (maxgraft® cortico, maxgraft® uni-cortical block) originate from organ and tissue donation, in accordance with European and national laws.

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.

If maxgraft® products are mainly derived from patients undergoing hip replacement surgery, isn't this bone of poor quality?

No, not necessarily.

The main indication for hip replacement surgery is a degenerative cartilage disease with no impact on bone quality.

After procurement, each femoral head is thoroughly inspected for adequate bone structure and tissue of impaired quality is discarded. Femoral heads from older patients usually show a more open porous structure which is an ideal scaffold for new bone formation.

Open porous structure of a cancellous maxgraft® block

Why should I use allografts instead of autografts?

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 quantities and availability, and the bone tissue obtained from the iliac crest is described to be subject to fast resorption[1]. Moreover, the harvesting of autologous bone often requires a second surgical site associated with an additional bone defect and potential donor site morbidity[2,3].

Several histological[4,5] and morphological[6] studies have demonstrated that there is no difference in the final stage of incorporation and new bone formation between allografts and autografts. Thus, the application of processed allogenic bone tissue is a reliable and predictable alternative.

Is maxgraft® a safe product?

maxgraft® products are safe to use without any reported case of disease transmission.

maxgraft® and its production process fulfill the European guidelines and safety regulations for human tissues and cells (2004/23EC, 2006/17EC, 2006/86EC). These set quality standards for donor selection, procurement, processing, quality control, storage, traceability, and distribution of human tissue and cells. Moreover, it is declared as a drug by law in Germany and therefore fulfills the highest safety and pharmaceutical standards according to national drug law requirements.

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

Which steps ensure the safety of maxgraft®?

The safety of maxgraft® is ensured by five measures, i.e., donor anamnesis, serum testing, chemical processing, lyophilization, and final gamma-irradiation.

The health status of the potential donor is assessed in the context of a donor anamnesis. Then, a series of serological testing is performed. All tissue donors are screened for infections according to the standards applicable for blood- and organ donation.

Only tissue that has been tested negative for HIV, Hepatitis B and C, and Syphilis are entering a validated, wet-chemical purification process (Allotec® process). During the chemical treatment, all non-collagenic proteins are either removed or denatured to eliminate potential antigenicity, potential viruses are inactivated, and bacteria are destroyed. Finally, the tissue undergoes lyophilization to preserve the structural integrity of the material. The final product is gamma-sterilized to ensure a pharmaceutical sterility assurance level of 10^{-6} (maximum 1 viable pathogen in 1.000.000 units) and stored in a double-sterile barrier packaging.

In general, every step of the production from explantation in the operation room to final gamma-irradiation is performed either in aseptic or cleanroom environment at pharmaceutical standard.

https://www.youtube.com/watch?v=RHa2neZZuLw

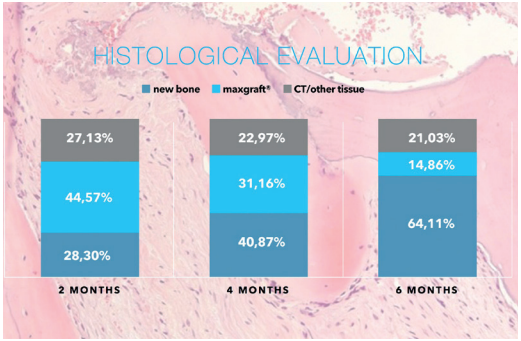
What happens with the material after implantation?

Due to the natural bone surface structure (micro- and macropores, rough surface) and the natural collagen, new bone formation starts early and is supported by direct cell/protein/growth factor binding to the surface.

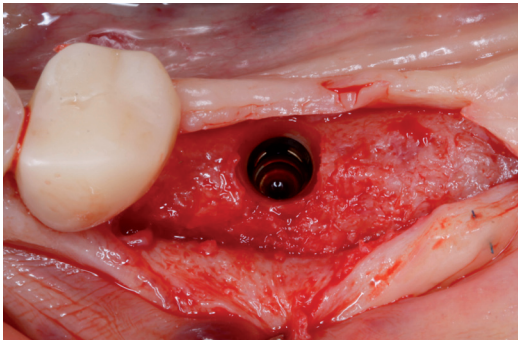
maxgraft® serves as a scaffold for blood vessels and bone-forming cells that migrate along with the grafting material and start with the formation of a new bone matrix. Thereby, the material will be progressively integrated into the newly formed bone and continuously remodeled into own bone. The time of complete remodeling is individual for each patient.

Histomorphometric analysis of biopsies harvested after two, four, and six months from maxgraft® granules augmented areas (ridge preservation) showed the gradual increase of newly formed bone while residual bone substitute material decreased[7].

After six months, 64% newly formed bone, 15% allograft material, and 21% connective tissue were detected. In the long term, maxgraft® has the potential to be fully replaced by the patient's own bone.



Histomorphometric analysis of biopsies harvested after two, four, and six months from maxgraft® granules augmented areas



Augmented area at the re-entry: optimal vital bone situation, Photo courtesy of A. Puisys, Lithuania

When should the re-entry/
implantation be performed
in case of a two-stage surgery?

Bone formation is dependent on many different factors. Based on literature about freeze-dried allografts and clinical feedback regarding maxgraft®, it will take about 3–4 months until the granules are completely incorporated into the newly formed bone matrix.

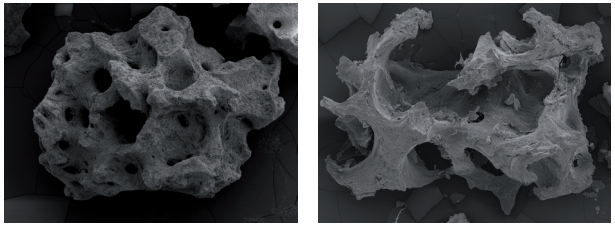
The full incorporation and vascularization of a bone block takes about six months (recommended before placing implants). Nevertheless, new bone formation continues after this period. Radiographical control before re-entry is recommended to assess the remodeling status.

What is the difference in properties between allografts and xenografts?

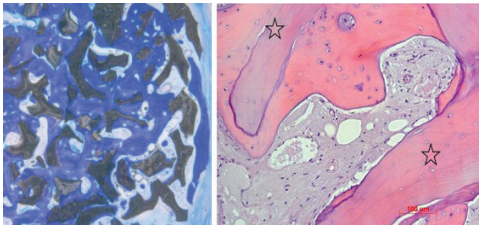
Due to the wet-chemical Allotec® process, the natural collagen is maintained. Therefore, maxgraft® products present excellent osteoconductive properties and full remodeling potential. Unlike xenografts, allografts contain human collagen that does not induce an immune reaction, which may be observed when using mineralized collagen of animal origin. Most bovine xenografts, such as cerabone®, are treated with high temperature that transfers the material into a non-resorbable, purely mineral hydroxyapatite. cerabone® granules osseointegrate into the newly formed bone matrix with only superficial resorption, whereas maxgraft® is first integrated and then continuously remodeled into the patient's bone.

Depending on the indication each material has its benefits.

While maxgraft® provides a fast and natural bone regeneration, cerabone® is characterized by long-term volume stability, even in case of missing mechanical load.



SEM picture of cerabone® (left) and maxgraft® (right). The contained human collagen is visible



Histology of a biopsy probe after an augmentation procedure with cerabone® (left) and maxgraft® (right)

Can I mix allograft (maxgraft®) with xenografts (cerabone®)?

Yes, you can.

Hereby, you would combine the advantages of both bone substitute materials: the fast remodeling capacity of maxgraft® due to the resemblance of autologous bone and the superior volume stability of cerabone®.
The mixture of both products is indeed regularly used by many clinicians in practice.

In which indications would you recommend the cancellous and in which one cortico-cancellous maxgraft® particles?

Clinically there is no significant difference regarding the performance of either cortico-cancellous or cancellous particles.

Cancellous granules demonstrate more resorption, whereas the cortical granules show more residual grafting material after healing of 18 weeks[3]. The ratio of cortical bone in maxgraft® cortico-cancellous granules is 15–30%. In grafting areas outside the bony envelope, the cortical fraction might reduce volume loss due to its decelerated resorption.

Literature:

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