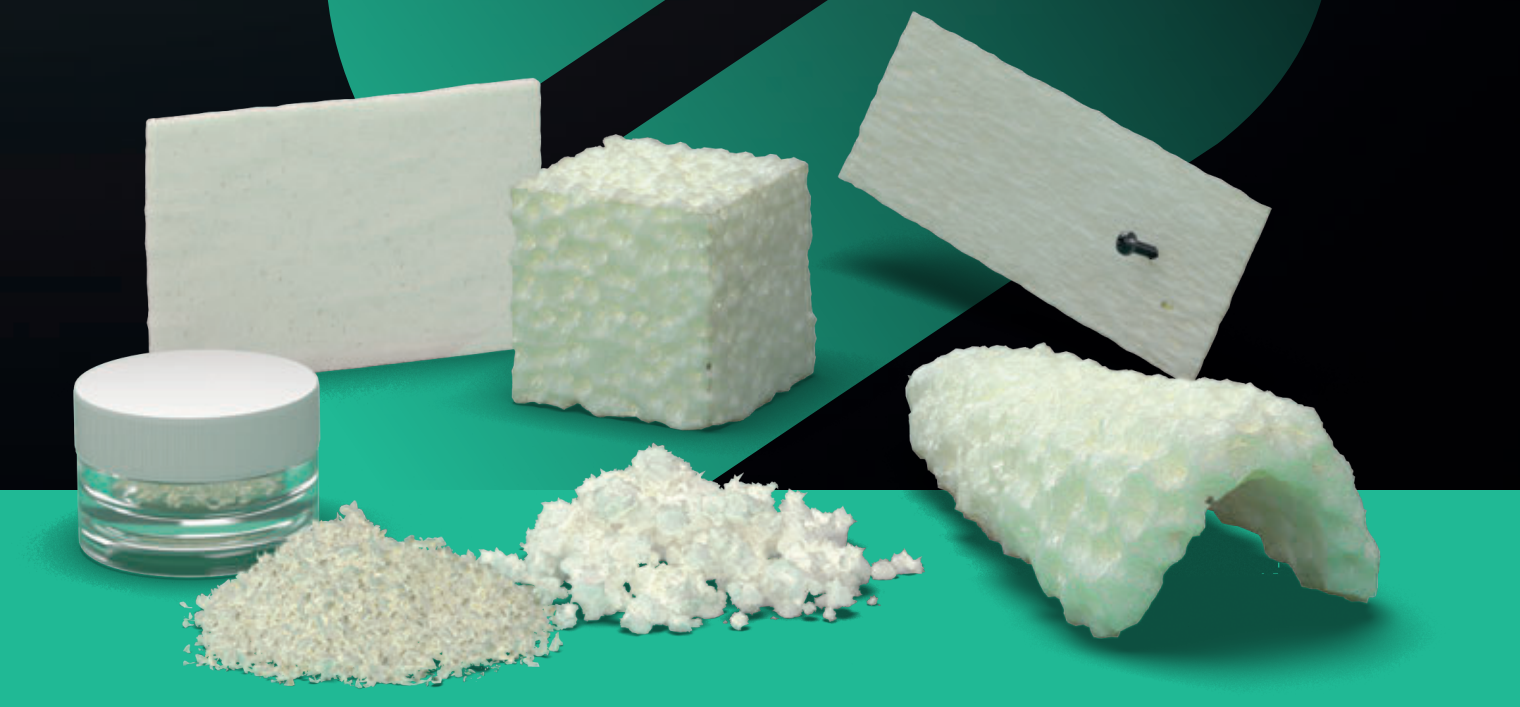
straumann

STRAUMANN®
ALLOGRAFTS

Mastering natural results.



Product overview

STRAUMANN® ALLOGRAFT PORTFOLIO

AN INDUSTRY LEADING PORTFOLIO OF ALLOGENIC BIOMATERIALS.

Human allografts are biologically active, safe and readily available alternatives to autologous grafts. Their properties, compositions and performance approximate the ones of autologous tissues without exposing patients to the risks and comorbidities of a second surgical harvesting site. With botiss® and LifeNet Health®, Straumann offers one of the industry's most comprehensive portfolios of clinically proven allogenic bone graft materials.

Straumann is teaming up with botiss® and LifeNet Health, the European and US industry leaders for human allografts. Donors, clinicians and, foremost, patients can expect very high pharmaceutical-like standards to apply to each delivery step, from donors to patients.

The proposition to our customers is straightforward, an innovative range of biologically performing, easy-to-handle, and readily available solutions from a single provider combined with our highest standards for service and support.

EXPECT MORE!

PROVEN EFFECTIVENESS

- → Scientifically and clinically proven biological performance, clinical effectiveness and safety
- → Documented to promote bone regeneration, structural support and volume preservation[1,2]

CONSISTENT PERFORMANCE & SAFETY

- → Processed and tested at high standards for consistent and predictable performance and safety

MATCHING CLINICAL NEEDS

- → Versatile regenerative potential and handling properties adapted to individual clinical needs
- → Broad indication spectrum including periodontal regeneration, socket preservation, ridge augmentation and sinus grafting

1 Eskow AJ, Mealey BL. Evaluation of healing following tooth extraction with ridge preservation using cortical versus cancellous freeze-dried bone allograft. J Periodontol. 2014 Apr;85(4):514-524.

2 Wood RA, Mealey BL. Histologic comparison of healing after tooth extraction with ridge preservation using mineralized versus demineralized freeze-dried bone allograft. J Periodontal. 2012 Mar;83(3):329-336.

EXPLORE THE DIVERSE TYPES OF ALLOGRAFTS!

Based on their mineral content, tissue origin, and application format, each allograft comes with unique properties to support natural regeneration, volume stability, and provide optimal handling.

MINERALIZED AND DEMINERALIZED ALLOGRAFTS

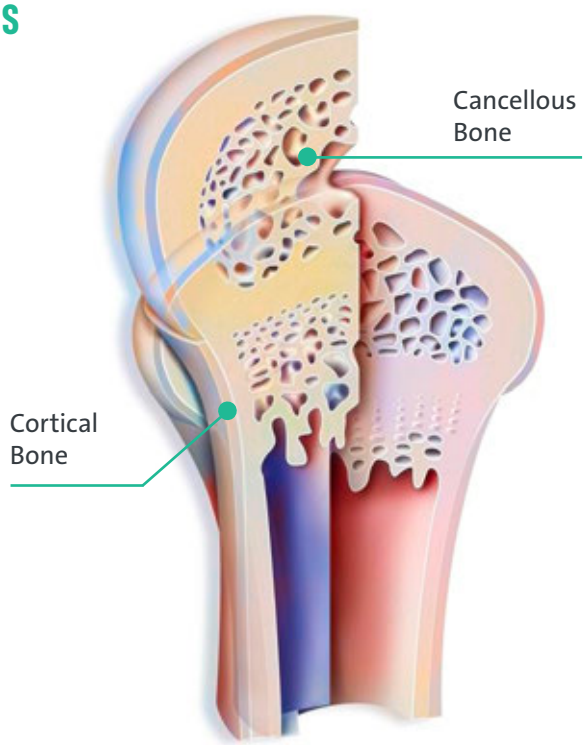
Mineralized Bone Allografts
Mineralized bone allografts were cleaned from remaining cells and non-collagenous components before sterilization. Their mineral phase (hydroxyapatite and collagen) remains in its native state.
Mineralized bone allografts *are radioopaque, osteoconductive and volume stable.*

Demineralized Bone Allografts
Compared to mineralized allografts, demineralized allografts undergo additional processing, removing 92%–99% of hydroxyapatite. Demineralized bone allografts mainly consist of an acellular collageneous matrix rendering them *osteoinductive, less volume stable and radiolucent.*

CANCELLOUS AND CORTICAL BONE ALLOGRAFTS

Cancellous Bone Allografts
Cancellous bone allografts are obtained by processing the inner trabecular component of donated bone. The trabecular porosity provides extra space for cell invasion, angiogenesis, matrix and bone formation. Cancellous allografts are often used in cases where rapid healing and new bone growth are desired.

Cortical Bone Allografts
Cortical bone allografts display a higher density and less surface area compared to cancellous bone allografts. Vascular in-growth and bone formation in this type of bone graft are channelled purely based on inter-particle spacing. As a result, cortical allografts remodel slowly and display the highest available long-term volume stability of all allograft types.



PARTICULATE, BLOCK AND PLATE BONE ALLOGRAFTS

Particulate Bone Allografts
Particulate allografts can be considered the first and most flexible treatment choice for smaller defects.

Block Bone Allografts
Block bone allografts have proven ideal for augmenting larger, e.g lateral alveolar defects. Adequate graft stabilization and intimate contact with the alveolar contours of the recipient site are essential.

Structural Bone Allografts
Structural bone allografts refer to a type of allografts that includes plates and customized block grafts. They are specifically designed to support procedures requiring space maintenance as part of advanced immediate and staged procedures.

THE STRAUMANN® ALLOGRAFT PORTFOLIO – SAFETY AT THE HIGHEST STANDARDS.

ALLOGRAFTS – AN OVERALL SAFE SOLUTION

The use of freeze-dried bone allografts can prevent patients from the risks and morbidities associated with autogenous harvesting. However, what about their safety?

Numerous immunologic, histologic and long-term survival studies have documented the safety of allogenic materials.[1–8]

This safety is based on rigorous testing and sophisticated processing methodologies, consistently ensuring the absence of any immunogenic residuals or pathogens.

Moreover, the safety and efficacy of allografts are directly tied to their providers' extensive experience, specialized know-how, and continuous innovation.

C⁺TBA/BOTISS® BIOMATERIALS AND LIFENET HEALTH®

C+TBA, the cells and tissue bank in Austria, through botiss biomaterials and Health, in U.S., are among the European and American industry-leading tissue banks. Both non-profit organisations control the complete process of allogenic graft materials sourcing and processing in their respective regions. Founded in 1982 and 2004, both providers apply safety standards at the highest possible levels, from voluntary donation and selection to processing up to final sterilization.

THE ALLOGRAFT PROCESS – STRINGENT CRITERIA, METICULOUS CONTROLS AND THOROUGH PROCESSING AT EACH STEP

Through highly elaborated proprietary and partly patented processes, C⁺TBA and LifeNet Health have collectively facilitated over 10 million allograft transplantations without a single incident of disease transmission.

WHICH ASPECTS ARE OF SPECIAL IMPORTANCE FOR THE SAFETY OF ALLOGRAFTS?

Donation and testing: Only tissues voluntarily donated and devoid of pathogens are considered for processing. This is achieved by applying cutting-edge microbiological and molecular diagnostic screening techniques to identify traces of potential pathogens at the molecular level.

Processing: Using validated inactivation processes for viral, bacterial, and fungal pathogens in a controlled and cleaned room environment, provides an extra layer of safety in ensuring pathogen-free end products.

Removing undesired cellular and non-collagenous components minimizes the likelihood of an immune response while preserving the natural regenerative capacity of the graft.

Sterilization: Meeting the highest standards with a Sterility Assurance Level (SAL) of 10^{-6} for a safe and ready-to-use application.

Sources: LifeNet Health documented the delivery of over 10 Mio transplants. CTB+A documented delivery of 100.000 transplants.
Sources: https://www.straumann.com/en/discover/youtooth/article/esthetics/2017/aneta-pecanov-schroder-allogenic-bone-grafts-same-safety-as-pharmaceutical-products html and LifeNet Health, internal data.

RESPECTFUL AND RESPONSIBLE SOURCING – QUALITY AND ETHICAL CONSIDERATIONS LEADING THE WAY

The sourcing, testing, processing, storage and distribution of Allograft products in the U.S. adhere to the code of federal regulations (CFR). Stringent requirements apply to testing laboratories, including registration and certification under applicable specific FDA programs and regulations. In the E.U., the corresponding aspects for Allografts are regulated by E.U. directives 2004/23/E.U. as transferred into national law.

The C+TBA is certified and regularly audited by the Austrian Ministry of Health and regulated by the Austrian Tissue Safety Act (GSG 2009).

LifeNetHealth and C+TBA are non-profit organizations that obtain Allograft tissues exclusively on a voluntary and non-remunerated

THE PROCESSES BEHIND THE PRODUCTS – LEAVING NO MARGIN FOR ERROR WHEN IT COMES TO PATIENT SAFETY

ALLOWASH XG®

Allowash XG® is LifeNet Health's patented allograft production process. The process removes >99 % of bone marrow and blood elements from the internal bone matrix. Low-temperature sterilization provides a Sterility Assurance Level (SAL) of 10^{-6} while preserving the mechanical properties and regenerative potential of the tissue[9]. Since 1995, over 10 million tissue grafts have been processed with Allowash XG® without a case of disease transmission.

PAD®

Demineralized allografts are produced by LifeNet Health's PAD® process. PAD® stands for precise demineralization and consistently ensures residual calcium levels of 1 to 4 % for optimal exposure of native osteoinductive growth factors.

PRESERVON®

LifeNet Health's patented and proprietary of the Preservon process, which allows preserving grafts pre-hydrated at room temperature[10]. By keeping the grafts moist, bone and dermis allografts can be stored at room temperature without drying out, eliminating waiting time for rehydration and preventing the product from becoming brittle over time.

MATRACELL®

Matracell® is LifeNet Health's proprietary production technology for dermal allografts. Unique combinations of detergent washing and endonuclease enzymatic treatments remove ≥97 % of the donor genetic material and cells while preserving the biomechanical strength and bio-activity regenerative potential of the original tissues. Terminal sterilization of the final packaged material ensures a Sterility Assurance Level of 10^{-6}.

ALLOTEC®

Maxgraft® allograft are produced by C+TBA's proprietary AlloTec® process. The process comprises mechanical washing steps, oxidative treatment, freeze-drying and moderate temperature sterilization with a Sterility Assurance Level (SAL) of 10^{-6}. Non-residual chemical cleaning with volatile reagents ensures the preservation of mechanical and biological regenerative properties while reducing the antigenicity and infection risk to a minimum.

AVAILABLE ALLOGRAFTS AND THEIR PROPERTIES

Graft Type	Product	Available Format	Properties
Mineralized Cancellous	**maxgraft®**	→ Granules → Blocks • Customized blocks (maxgraft® bonebuilder) • Preshaped (maxgraft® bonering)	→ Osteoconductive → Medium remodelling (4–6 months) → Volume stability*
Mineralized Cortical	**AlloGraft® Mineralized Cortical**	→ Granules (AlloGraft®) → Plates (maxgraft® cortico)	→ Osteoconductive → Slow remodeling (6+ months) → Long-term volume stability[1]
Mineralized Cortical/ Cancellous Mix	**maxgraft® Cortical/ Cancellous**	→ Granules	→ Osteoconductive → Medium to slow remodeling (4–6+ months) → Long-term volume stable
Demineralized / Mineralized Mixes	**AlloGraft® Demineralized / Mineralized Cortical** **AlloGraft® Demineralized Fibers and Cancellous Chips**	→ Granules	→ Osteoinductive → Fast remodeling (3–4 months) → Volume stable
Demineralized Cortical	**AlloGraft® Demineralized Cortical**	→ Granules	→ Osteoinductive[2–3] Fast remodeling (3–4 months) → Does not provide volume stability
Dermal Matrix	**AlloGraft® Dermal Matrix**	→ Soft Tissue substitute → Fleece	→ Fast soft tissue integrating → Remodeling within 4–6 months

MaxGraft® is a brand of botiss
AlloGraft® is a brand of LifeNet Health Inc.

1 Rummelhart JM et al. J Periodontol. A comparison of freeze-dried bone allograft and demineralized freeze-dried bone allograft in human periodontal osseous defects. J Periodontol. 1989;60(12):655-663.
2 Zhang M et al. Effect(s) of the demineralization process on the osteoinductivity of demineralized bone matrix. J Periodontol. 1997;68:1085-1092.
3 Herold RW et al. Effects of varying degrees of allograft decalcification on cultured porcine osteoclast cells. J Periodontol. 2002;73(2):213-219.

INDICATIONS AND ALLOGRAFT TYPE

Indications	Allograft Type
Periodontal Treatments	→ AlloGraft® Demineralized Cortical
Ridge Augmentation	→ maxgraft® blocks → maxgraft® bonebuilder → maxgraft® cotico
Lateral Window Sinus Augmentation	→ AlloGraft® Mineralized Cortical → maxgraft® blocks
Soft Tissue Augmentation	→ AlloGraft® Dermal Matrix
Fenestration Defect Treatments	→ AlloGraft® Demineralized Fibers and Cancellous Chips
Socket Preservation (for sockets with intact buccal wall as part of immediate or early implant placement ≤16 weeks post-augmentation	→ AlloGraft® Demineralized Cortical Granules → Alternative: AlloGraft® Mineralized Cortical/Cancellous Granules → Optional add-on: AlloGraft® Dermal Matrix
Socket Preservation (for sockets with intact buccal wall as part of immediate or early implant placement (>6 months post-augmentation) or in osteoporotic patients	→ AlloGraft® Mineralized Cortical Granules → Optional add-on: AlloGraft® Dermal Matrix
Socket Preservation (for sockets with buccal defects)	→ AlloGraft® Demineralized / Mineralized Cortical → AlloGraft® Demineralized Fibers and Cancellous Chips
Socket Preservation (with a missing buccal walls)	→ maxgraft® Mineralized Cancellous Granules → AlloGraft® Demineralized / Mineralized Cortical
Osteotome Sinus Floor Elevation (acc. to Summers)	→ AlloGraft® Demineralized / Mineralized Cortical → Alternative: maxgraft® Mineralized Cortical Granules

SUGGESTED VOLUME

Peridontal Defects	Suggested Volume (cc)
Incisors	0.5
Canine	0.5
Premolar	0.5
Molar	0.7–1.0

Extraction Sites	Suggested Volume (cc)
Central Incisor	0.7–1.0
Lateral Incisor	0.5
Canine	0.7–1.0
Premolar	0.7–1.0
Molar	1.2–2.0

Sinus Grafts	Suggested Volume per site (cc)
Each Sinus	2.5–5.0

MAXGRAFT® GRANULES/BLOCKS

Allograft

Cancellous granules and blockgrafts

maxgraft® allograft is the safe and established alternative to autologous bone. maxgraft® granules and cancellous blocks are 100 % derived from living donor bone processed under pharmaceutical conditions by the Cells and Tissue Bank Austria (C⁺TBA). Founded in 2004, C⁺TBA is one of the leading european tissue banks, recognized by numerous national authorities across the world and member of the European Association of Tissue Banks (EATB).

FEATURES AND BENEFITS

Safety and biocompatibility	The cleaning process (Allotec® process) of maxgraft® products preserves the natural structure of both the mineral phase and the organic phase (collagen).
Biofunctionality	High porosity and the physiologic content of human collagen account for the excellent osteoconductivity of maxgraft®. The natural bone structure allows complete integration of the implant due to the ingrowth of cells and blood vessels.
Hydrophilicity	Interconnected pores and rough surface morphology are fundamental to good hydrophilicity. Due to their excellent hydrophilicity, the maxgraft® products absorb liquid quickly. Adhesion of proteins and signaling molecules from the blood further improves the biological properties of maxgraft®.
Volume stability	Due to its close similarity to native bone, maxgraft® will be degraded by osteoclasts if not loaded after the healing period. Depending on the indication, the product can be mixed with a slow resorbable grafting material (deproteinized bovine bone minerals (DBBM)).
Patient comfort	maxgraft® is a safe and trusted bone regeneration solution most similar to patient's own bone. It is a true alternative to autologous bone, eliminating donor site complications such as morbidity, infection or postoperative pain.

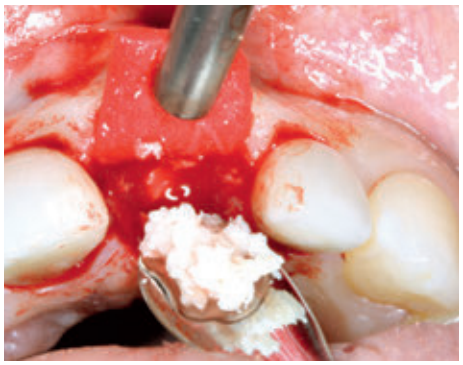
Available in the following sizes

Code	Description	Product
BO-30005	< 2 mm, 1×0.5 cc (ml)	maxgraft® cancellous granules
BO-30010	< 2 mm, 1×1.0 cc (ml)	
BO-30020	< 2 mm, 1×2.0 cc (ml)	
BO-30040	< 2 mm, 1×4.0 cc (ml)	
BO-32112	20×10×10 mm, 1×block	maxgraft® cancellous block
BO-32111	10×10×10 mm, 1×block	

Code	Description	Product
BO-31005	< 2 mm, 1×0.5 cc (ml)	maxgraft® cortico-cancellous granules
BO-31010	< 2 mm, 1×1.0 cc (ml)	
BO-31020	< 2 mm, 1×2.0 cc (ml)	
BO-31040	< 2 mm, 1×4.0 cc (ml)	

PROPERTIES

Attribute	Description
Origin	All products originate from femoral heads explanted from living donors (hip total endoprosthesis).
Composition	Natural mineralized collagen
Porosity	65–80 %
Pore size	600–900 µm
Degradation kinetics	Fast graft incorporation and complete remodeling potential to patients' own bone.
Healing/integration time	3–4 months with particles 5–6 months in block augmentation
Storage temperature	5–30 °C
Shelf life	5 years



Courtesy of Dr. Algirdas Puišys, Vilnius/Lithuania

APPLICATION AND HANDLING

Opening
maxgraft® is delivered sterile and must be used immediately after opening in an aseptic environment.

Rehydration
Rehydration of maxgraft® granules in blood from the defect site or saline solution is not necessary but facilitates handling and application. maxgraft® blocks do not need to be rehydrated. However, larger sized bone grafts may be rehydrated in a suitable physiological medium for at least 10 minutes (e.g. physiological saline).

Application of granules
- → Avoid compressing the particles during application. Non compacted particles leave space for blood vessel ingrowth and formation of new bone matrix.
- → Fill the defect as completely as possible.
- → Ensure maximum contact between the graft material and viable bone in a well vascularized area.

Application of blocks
- → Ensure maximum contact between the block and viable bone in a well vascularized area.
- → For fixation of the block, prepare a pilot hole carefully and fix the screw slowly without pressure.
- → Additional use of a granulated bone substitute may be recommended for achieving the aimed esthetic bony contour and for filling possible gaps.

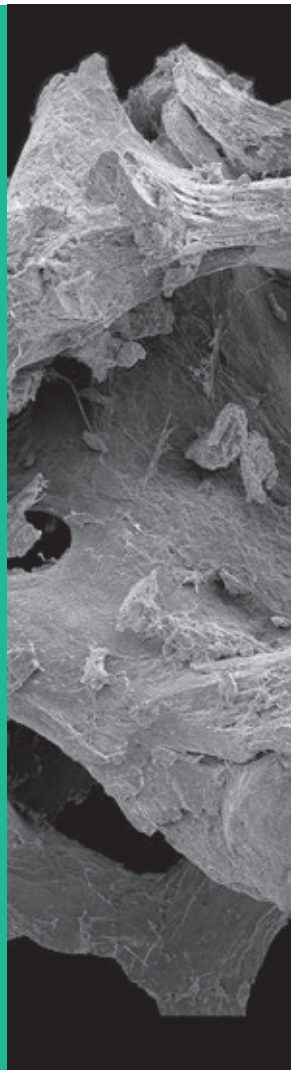
Covering
Always cover the augmentation site with a barrier membrane (e.g. Jason® membrane) to ensure undisturbed osseous regeneration and to prevent migration of the particles into the oral cavity.

Wound closure
Ensure that soft tissue coverage of the augmented site is complete and free of tension. Undisturbed vascularization of the augmented site is of utmost importance.

Healing time and re-entry
The appropriate healing time is patient- and site-dependent and has to be decided by the clinician based on the assessment of the patient's individual situation. Depending on the defect size, the graft will be incorporated stably within approx. 3–4 months (particles in socket preservation, smaller bone defects, periodontal defects) or approx. 5–6 months (block grafting in extensive defects).

Mixing with other bone substitutes
Mixing of maxgraft® granules with autologous bone adds a biological activity (osteoinductive and osteogenetic properties of autologous bone) and supports faster regeneration and formation of new bone.

Mixing of maxgraft® granules with xenogenic materials (Straumann® XenoGraft, cerabone®) combines the advantages of both materials: the biological potential of maxgraft® and the long-term volume stability of xenogenic materials lead to fast regeneration of strong vital bone.



botiss biomaterials GmbH
Hauptstr. 28, 15806 Zossen, Germany

Literature:
https://www.botiss-dental.com/pdf/maxgraft_LiteratureList.pdf

MAXGRAFT® BONEBUILDER

Allograft

3D shaped individualized, processed allogenic block

maxgraft® bonebuilder is an innovative, customized allogenic bone block which is individually designed and adjusted to the desired 3-dimensional bone contour. Based on CT/CBCT scans of the patient, the bone block is virtually designed by botiss biomaterials GmbH (Zossen, Germany) using the latest 3D-CAD technology. The final product is then milled from processed cancellous bone blocks directly in the clean room facility of the Cells and Tissue Bank Austria (C+TBA) prior to final irradiation.

FEATURES AND BENEFITS

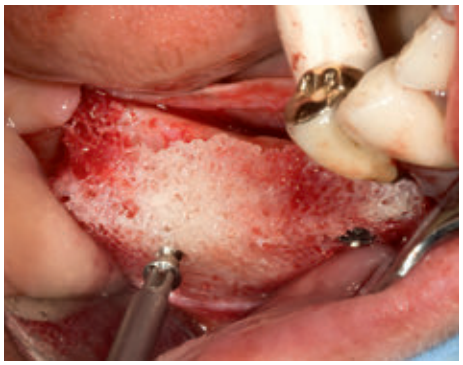
Easy to apply	The patient-individualized allogenic block is delivered sterile and → is ready to be applied in surgery → is designed to fit perfectly to the recipient site → reduces risk of infection compared to a bone block (because repetitive intra- and extraoral handling can be avoided) → saves chair-time compared to autologous blocks
Osteoconductivity	The natural structure and composition of maxgraft® provide an excellent scaffold for osseointegration: → High porosity and the physiological content of human collagen account for the excellent osteoconductivity → Maximum contact area between the graft and the bone supports fast vascularization and integration of the graft
Preservation of mineral and organic phase of the bone	The cleaning process (Allotec® process) of maxgraft® products preserves the natural structure of both the mineral phase and the organic phase (collagen). Collagen attracts endothelial cells and osteoblasts by chemotaxis. This ensures quick incorporation and natural remodeling.
Hydrophilicity	Interconnected pores and rough surface morphology are fundamental to good hydrophilicity. Due to the excellent hydrophilicity, the maxgraft® bonebuilder absorbs blood quickly. Adhesion of proteins and signaling molecules from the blood further improves the biological properties of maxgraft®.
Volume stability	Clinical experience shows that the maxgraft® bonebuilder has a high volume stability.

Available in the following sizes

Code	Description	Product
BO-PMla	Individualized allogenic bone graft, maximum dimensions 23×13×13 mm	maxgraft® bonebuilder

PROPERTIES

Attribute	Description
Origin	The maxgraft® bonebuilder is manufactured from cancellous blocks originating from femoral heads explanted from living donors (hip total endoprosthesis).
Composition	Natural mineralized collagen
Porosity	Natural porosity of human cancellous bone (65–80 %)
Degradation kinetics	Fast graft incorporation and complete remodeling potential into patients' own bone. Newly generated bone will degrade if not loaded after healing period.
Healing/integration time	Approx. 6 months
Storage temperature	5–30 °C
Shelf life	5 years



Courtesy of Dr. Michele Jacotti, Brescia/Italy

APPLICATION AND HANDLING

Indication
maxgraft® bonebuilder can be used in all stable situations in which an augmentation with a bone substitute material is indicated. It is especially beneficial in indications in which extensive horizontal and limited vertical augmentation (up to 4 mm) is desired, such as:

- → Block grafting in extensive horizontal/vertical defects where a predictable outcome cannot be achieved by application of bone substitute particles
- → Complex 3-dimensional reconstruction of large defects

Rehydration
Larger sized bone grafts, may be rehydrated in a suitable physiological medium for at least 10 minutes (e.g. physiological saline). However, excessive rehydration prior to transplantation may compromise the physical properties of maxgraft® bonebuilder and should therefore be avoided.

Preparation of the augmentation site prior to fixation of maxgraft® bonebuilder
Perforate the cortical layer of the bone prior to fixation of maxgraft® bonebuilder to induce bleeding, which leads to the translocation of blood and growth factors into the grafting area.

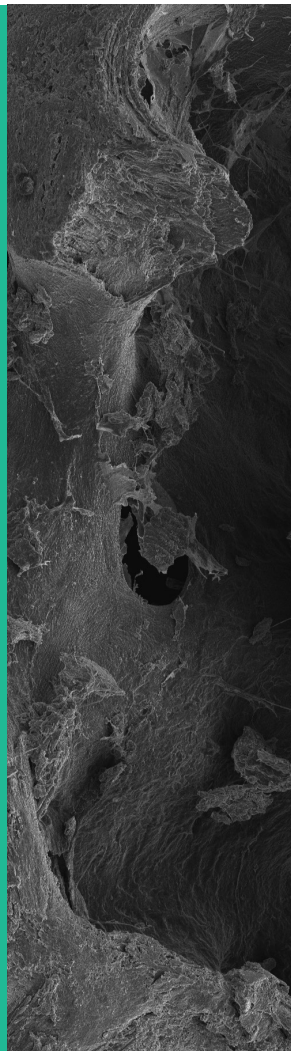
Combination with xenograft or synthetic bone graft
Additional void volume should be filled with particulate grafting material (e.g. Straumann® XenoGraft, cerabone® or Straumann® BoneCeramic) to improve the esthetic outcome and to protect the soft tissue.

Guided bone regeneration (GBR)
Cover the maxgraft® bonebuilder with a resorbable barrier membrane for GBR (e.g. Jason® membrane) to prevent ingrowth of soft tissue into the bone graft.

Fixation of the maxgraft® bonebuilder
Fix the maxgraft® bonebuilder with screws for osteosynthesis, preferably with flat-headed screws to avoid perforation of the surrounding soft tissue (such as the Straumann® Bone Block Fixation 1.5 mm). Application of excessive force may cause damage to the maxgraft® bonebuilder.

Volume stability
Due to its close similarity to native bone, maxgraft® will be degraded by osteoclasts if not loaded after the healing period.

Re-entry
Depending on the defect size, the graft will be steadily incorporated within 5–6 months.



For more information visit www.botiss-bonebuilder.com

botiss biomaterials GmbH
Hauptstr. 28, 15806 Zossen, Germany

Literature:
https://www.botiss-dental.com/pdf/maxgraft_LiteratureList.pdf

MAXGRAFT® BONERING

Allograft

Ringshaped cancellous blockgrafts

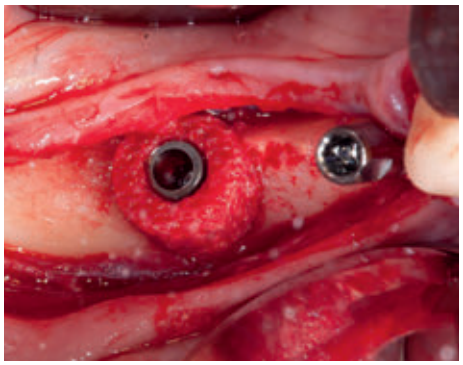
maxgraft® bonering is a pre-fabricated ring of processed allogenic donor bone, which is placed press-fit into a trephine drill-prepared ring bed.

FEATURES AND BENEFITS

Simultaneous bone augmentation and implant placement	The bone ring technique reduces the entire treatment time by several months when compared to bone blocks, enabling a shorter time-to-teeth and a reduction of the overall treatment costs.
Design	The ring design is ideally suited for the reconstruction of the anatomical shape of the jaw.
Osteoconductivity	The natural structure and composition of maxgraft® provide an excellent scaffold for osseointegration. High porosity and the physiologic content of human collagen account for the excellent osteoconductivity of maxgraft®. The natural bone structure allows complete integration of the implant due to the ingrowth of cells and blood vessels.
Biocompatibility	The cleaning process (Allotec® process) of maxgraft® products preserves the natural structure of both the mineral phase and the organic phase (collagen). Collagen attracts endothelial cells and osteoblasts by chemotaxis. This ensures quick incorporation and natural remodeling of the maxgraft® bonering.
Hydrophilicity	Interconnected pores and rough surface morphology are fundamental to good hydrophilicity. Due to their excellent hydrophilicity, the maxgraft® products absorb liquid quickly. Adhesion of proteins and signaling molecules from the blood further improves the biological properties of maxgraft®.
Volume stability	Clinical experience shows that the maxgraft® bonering has a high volume stability. (Publication in preparation)

PROPERTIES

Attribute	Description
Origin	The maxgraft® bonerings are manufactured from cancellous blocks originating from femoral heads explanted from living donors (hip total endoprosthesis).
Composition	Natural mineralized collagen
Porosity	Natural porosity of human cancellous bone (65–80 %)
Degradation kinetics	Fast graft incorporation and complete remodeling potential into patients' own bone. Newly generated bone will degrade if not loaded after healing period.
Healing/integration time	Approx. 6 months
Storage temperature	5–30 °C
Shelf life	5 years



Courtesy of Dr. Bernhard Giesenhagen, Kassel/Germany

APPLICATION AND HANDLING

Anatomical requirements for the use of maxgraft® bonering technique

A thin alveolar ridge (no matter in which area of the jaw) is a contraindication for the maxgraft® bonering technique. In this case, the quantity of bone is insufficient to anchor the implant. The maxgraft® bonering technique with simultaneous sinus floor elevation (SFE) and implant placement is indicated if the residual maxillary bone height is less than 4 mm, but not less than 1 mm. These measurements are guidelines. Always consider the quality of the residual bone when using this technique. The Straumann® BL or BLT Implant together with the Closure and Fixation Cap must have sufficient primary stability within the maxgraft® bonering and residual maxillary ridge. This is to ensure that these components remain firmly in place during the surgical procedure and healing phase.

Handling and rehydration of the maxgraft® bonering

maxgraft® bonering is processed from human cancellous bone and should be handled with care. Avoid applying pressure on the material. maxgraft® bonering does not need to be rehydrated. Excessive rehydration can result in a loss of structural integrity.

Preparation of the ring bed

Preparation of the ring bed using the AlloGraft Ring surgical kit ensures close contact of the maxgraft® bonering to vital bleeding bone. This leads to uptake of blood into the maxgraft® bonering and enables fast integration of both implant and bone graft.

Use of additional bone graft and a barrier membrane

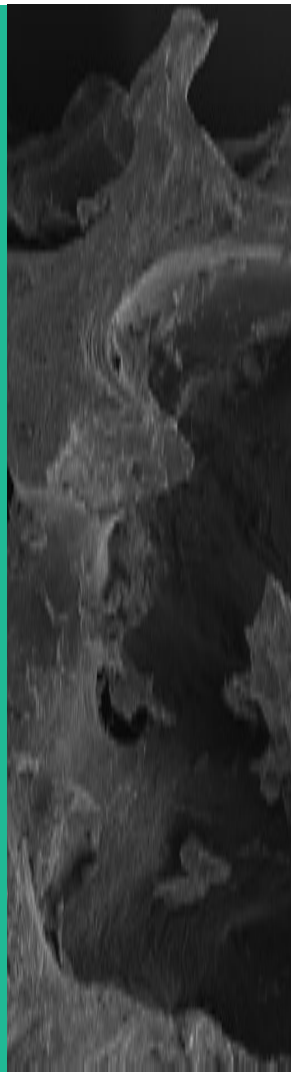
The combination with xenogenic materials (Straumann® XenoGraft, cerabone®) offers the advantages of both materials. The biological potential of the maxgraft® bonering supports fast incorporation of graft and implant. The volume-stable xenogenic material that is applied to fill void volumes and to overlay the graft acts as a barrier against resorption and improves the esthetic outcome.

Cover the entire augmentation area by a barrier membrane that has a long term barrier function (such as the Jason® membrane). Secure the membrane with pins to ensure positional stability.

Use of the Straumann® Bone Level and Bone Level Tapered Implants

To achieve sufficient primary stability, the implant should extend at least 3 mm into the residual alveolar bone ridge.

If the maxgraft® bonering technique is used with Bone Level Tapered Implants, the surgical procedure will depend not only on the bone quality but also on the residual bone. Insert the Straumann® BLT Implant at least 3 mm into the residual ridge through the maxgraft® bonering. This only applies for soft bone (type 3 or 4) and a residual bone height of 3 mm in an underprepared implant bed, so that primary stability can be achieved with the tapered apical section of the BLT Implant. If primary stability cannot be achieved with the BLT Implant, a switch to the Bone Level Implant is recommended.



botiss biomaterials GmbH
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Literature:
https://www.botiss-dental.com/pdf/maxgraft_LiteratureList.pdf

We strongly recommend to also read the more detailed instructions provided in our brochure *"Basic information for the surgical procedure – maxgraft® bonering with Straumann® BL and BLT implants"*.

Use of the Straumann® Bone Level and Bone Level Tapered Implants for sinus floor elevation (SFE)

The maxgraft® bonering technique with simultaneous SFE and implant placement is indicated if the residual maxillary bone height is less than 4 mm, but not less than 1 mm. These measurements are guidelines. Always consider the quality of the residual bone when using this technique. The BL or BLT Implant together with the Closure and Fixation Cap must have sufficient primary stability within the maxgraft® bonering and residual maxillary ridge. This is to ensure that these components remain firmly in place during the surgical procedure and healing phase.

Contraindications

The maxgraft® bonering technique with simultaneous SFE and implant placement is contraindicated when the residual maxillary bone height is less than 1 mm.

Use of the Closure and Fixation Cap

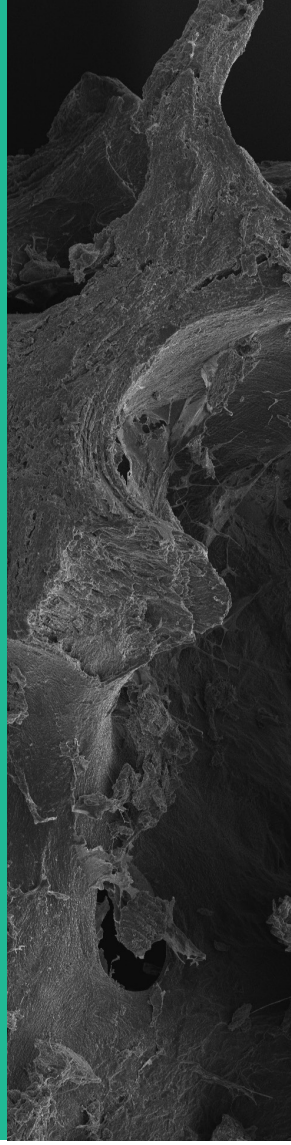
Secure the maxgraft® bonering using the Closure and Fixation Cap if the seating of the maxgraft® bonering is not sufficiently stable or the implant provides insufficient primary stability of the bone ring.

In the sinus floor elevation technique, the Closure and Fixation Cap is used for fixing the implant and maxgraft® bonering to the residual bone to provide primary stability during the healing phase.

Re-entry

The maxgraft® bonering is fixated directly with a suitable implant and provides excellent primary stability. Load the implants no earlier than 6 months after implantation to enable proper incorporation.

Please note that the regenerated bone is susceptible to natural remodeling. To avoid resorption of the bone graft caused by a lack of mechanical load, do not overly delay the final restoration.



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Literature:
https://www.botiss-dental.com/pdf/maxgraft_LiteratureList.pdf

INSTRUMENTS AVAILABLE AS SPARE PARTS

Product	Image	Description	Material	Code
Surgical Kit				
Allograft Ring surgical set		Instrument tray complete with all instruments for the Allograft Ring surgical technique	Stainless steel	BK-33000
Closure Caps***				
Sterile NC Closure and Fixation Cap		NC Closure and Fixation Cap, Ø 5.5 mm	Ti	024.2220S
Sterile RC Closure and Fixation Cap		RC Closure and Fixation Cap, Ø 5.5 mm		024.4220S
Instruments for Surgical Kit				
Pilot Drill Ø 2 mm		Outer-Ø 2 mm	Stainless steel	BK-33001
Trephine 6 mm		Outer-Ø 6 mm		BK-33002
Trephine 7 mm		Outer-Ø 7 mm		BK-33003
Planator 6 mm		Outer-Ø 6 mm		BK-33006
Planator 7 mm		Outer-Ø 7 mm		BK-33007
Diamond Tulip				BK-33004
Diamond Disc				BK-33005
bonering Fix				BK-33010
Instrument Tray and Rack				
Instrument Tray maxgraft® bonering		Tray for Allograft Ring instruments, empty, length 135 mm, width 177 mm, height 39 mm	Stainless steel	BK-33009
Instrument Rack		Rack for maxgraft® bonering instruments for 12 instruments with shaft, length 25 mm, height 51 mm, width 60 mm		**BK-33008**

Available in the following sizes

Code	Description	Product
BO-33160	maxgraft® bonering 3.3 L: 10 mm; D: 6 mm*	maxgraft® bonering
BO-33170	maxgraft® bonering 3.3 L: 10 mm; D: 7 mm*	
BO-33174	maxgraft® bonering 4.1 L: 10 mm; D: 7 mm**	

* Can be used with implants with an outer diameter of 3.3 mm to 3.6 mm

** Can be used for Straumann® Bone Level Implants with a diameter of 4.1 mm

*** Use the Closure and Fixation Cap if the maxgraft® bonering is not stable after implant insertion

MAXGRAFT®
CORTICO

Allograft

Cortical plates

maxgraft® cortico has the function of a stable, dense, and slowly resorbable barrier, protecting the augmented area from micro-movement for new bone growth in horizontal and vertical dimensions.

FEATURES AND BENEFITS

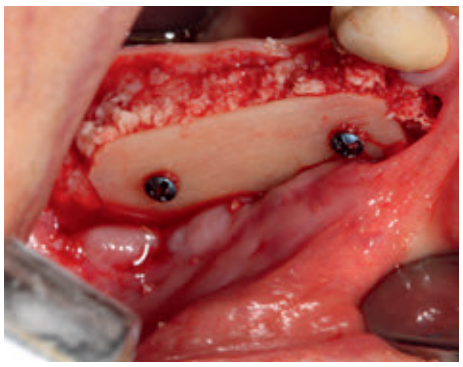
Safety and biocompatibility	The cleaning process (Allotec® process) of maxgraft® products preserves the natural structure of both the mineral phase and the organic phase (collagen). Collagen attracts endothelial cells and osteoblasts by chemotaxis. This ensures the reliable incorporation and natural remodeling over time. maxgraft® products are safe and have an impressive safety track record with no reported cases of disease transmission.
Biofunctionality	maxgraft® cortico is an avital cortical bone plate with full remodeling potential. Due to its slow remodeling it allows outstanding space maintenance for new bone growth in horizontal and vertical dimension. The physiologic content of human mineralized collagen as well as the overall structure most similar to patient's own bone allows excellent biocompatibility and predictable integration combined with long-term stability.
Easy handling; established technique	The convenience of the shelf availability, predictable size and thickness of maxgraft® cortico obviates the need for bone harvesting and allows a faster and easier treatment procedure. maxgraft® cortico is easy to stabilize with screws, therefore micro-movements of the augmented site are easily prevented, offering best possible conditions to support bone healing.
Patient comfort	maxgraft® is the safe and trusted bone regeneration solution most similar to patient's own bone. It is a true alternative to autologous bone, eliminating donor site complications such as morbidity, infection or postoperative pain. It improves patient comfort by reducing the number of surgical intervention sites and/or decreases invasiveness.

Available in the following sizes

Code	Description	Product
BO-31251	25 × 10 × 1 mm cortical bone plate	maxgraft® cortico

PROPERTIES

Attribute	Description
Origin	Donors are only accepted from selected central European countries that have successfully transferred Directive 2004/23/EU into national law. maxgraft® products are produced at the Cells+Tissuebank Austria (C+TBA), a non-profit organization aiming to provide allogenic transplants for orthopedic and dental regeneration. C+TBA is certified and audited by the Austrian Ministry of Health in accordance with the European Directives and regulated by the Austrian Tissue Safety Act (GSG 2009).
Composition	Cortical bone from human donors
Healing/ integration time	5–6 months
Storage temperature	5–30 °C
Shelf life	5 years



Courtesy of Dr. med. dent. Kai Höckl, Bad Krozingen, Germany

APPLICATION AND HANDLING

Shell technique with maxgraft® cortico

The concept of the shell technique is the preparation of a biological container which creates the necessary space for full incorporation of the particulated bone graft material. The maxgraft® cortico bone plate functions as a stable, avital and potentially resorbable barrier. It enables a safe and motion-free protection of the augmented area and helps creating the needed environment for new bone growth.

Trimming

maxgraft® cortico can be trimmed extraorally using a diamond disk to match the required size.

Rehydration

maxgraft® cortico does not need to be hydrated. However, rehydration in sterile saline for approximately 10 minutes has been shown to increase breaking strength and the flexibility of the plate.

Application of maxgraft® cortico

The plate is positioned with a distance by predrilling through the plate and the local bone. Osteosynthesis screws are used to create an immobile compartment.

To prevent perforations of the soft tissue, sharp edges need to be removed, e.g. by using a diamond ball.

Additional use of a granulated bone substitute is recommended for filling the created gap between host bone and maxgraft® cortico. The use of autologous and/or allogeneic granulated bone grafting material (maxgraft® granules) is recommended for maximum regeneration potential.

Covering

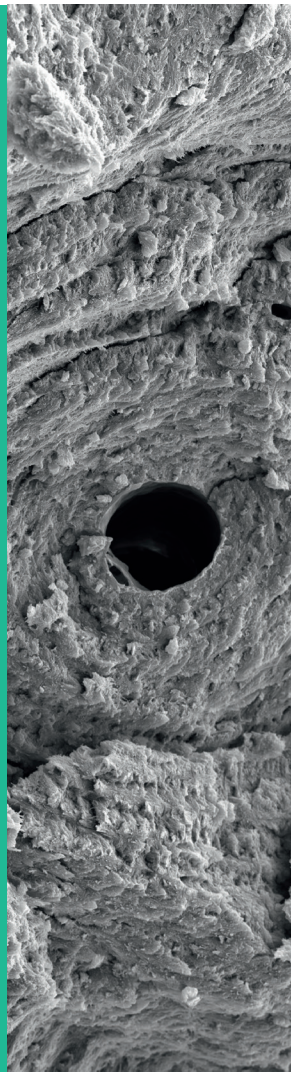
Always cover the augmentation site with a barrier membrane (e.g. Jason® membrane) to ensure undisturbed osseous regeneration, and to prevent migration of particles into the oral cavity.

Wound closure

Ensure that soft tissue coverage of the augmented site is complete and free of tension. Undisturbed vascularization of the augmented site is of utmost importance.

Healing time and re-entry

The appropriate healing time is patient- and site-dependent and has to be decided by the clinician based on the assessment of the patient's individual situation and the particulated material used.



botiss biomaterials GmbH
Hauptstr. 28, 15806 Zossen, Germany

Literature:
https://www.botiss-dental.com/pdf/maxgraft_LiteratureList.pdf

ALLOGRAFT®

Allograft

Mineralized Cortical Granules

Mineralized Cortical Granules are osteoconductive and remodel slowly. These properties render them ideal for indications requiring long-term volume stability.

FEATURES AND BENEFITS

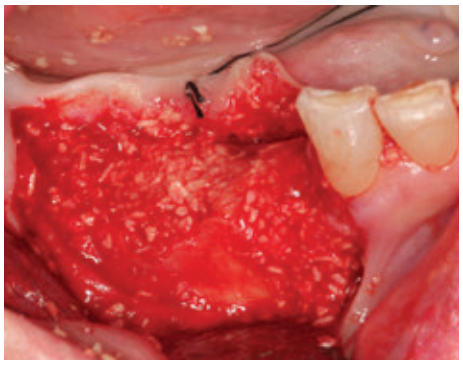
Osteoconductive	→ Osteoconductive to promote integration with host bone[1, 8] → Reported to result in increased amounts of newly formed bone compared to other bone graft materials (xenografts or synthetic materials)[9]
Volume stable	→ Slower resorption compared to cancellous allograft[1] → Improved ridge height stability compared to cancellous allograft[1] → Slowly **remodels** to vital bone (+ 6 months) for high volume stability[8, 10]
Clinically versatile	→ Can be used in immediate and delayed dental implant placement procedures[2, 6, 7, 8]
Safety and biocompatibility	→ Processed using LifeNet Health's patented Allowash XG® **cleaning and disinfection** technology for enhanced safety[11] → Sterility Assurance Level (SAL) standards of 10^{-6} [3, 4]

Available in the following sizes

AlloGraft Mineralized Cortical Granules	
070.206	250–710 µm, 0.5.cc
070.207	250–710 µm 1.0.cc
070.208	250–710 µm 2.0.cc
070.218	250–1000 µm 0.25 cc
070.219	250–1000 µm 0.5 cc
070.220	250–1000 µm 1.0 cc
070.221	250–1000 µm 2.0 cc
070.230	250–1000 µm 2.5 cc

PROPERTIES

Attribute	Description
Origin	All donors have been recovered, screened, tested, processed, stored, and distributed in accordance with current U.S. federal regulations and in accordance with distributed territory regulations. All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of1988 (CUA) and 42 CFR 493.
Composition	Mineralized cortical granular bone
Healing / integration time	Aprox. 6 months
Storage temperature	Ambient temperature (2°C to 37°C, with excursions of less than 24 hours up to 40°C)
Shelf life	4 years



Grafting with AlloGraft Cortical granules.
Photo courtesy of Robert Miller, DMD,
Fort Lauderdale, FL

APPLICATION AND HANDLING

OPENING INSTRUCTIONS

1. Non-Sterile Team Member:
Peel open outer tray foil lidstock and present inner contents to the Sterile Team Member.

2. Sterile Team Member:

a. If the bio-implant is packaged in a plastic tray, firmly grasp the "Peel Here" tab and remove from outer tray. If rehydration is preferred by the physician, place the bio-material in a sterile basin and follow the appropriate preparations for use below.

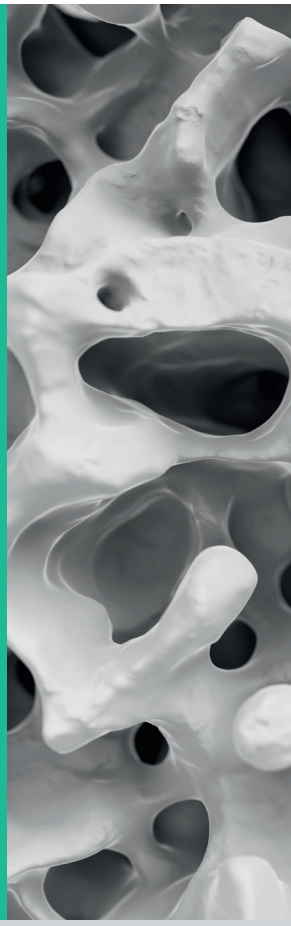
b. If the bio-implant is packaged in a jar, firmly grasp the jar and remove from outer tray. If rehydration is preferred by the physician, keep the bio-implant in the jar and follow the appropriate preparations for use below.

PREPARATIONS FOR USE

3a. Preservon:
It is recommended to rinse the bio-implant in sterile irrigan per doctor preference.

3b. Freeze-dried:
If rehydrating, refer to the table below for the recommended rehydration instructions. Hydrating media may include antibiotic solution, sterile saline, I.V. fluids, blood, plasma, bone marrow, or other specific blood components.

Rehydration Instructions: All Other Allograft Bio-Implants (Freeze-Dried): Rehydrate until required consistency and handling are achieved as per physician preference.



Recommended for
Mineralized Cortical Granules are recommended/indicated for:
→ Sinus Augmentation
→ Ridge Preservation
→ Extraction Socket Preservation
→ Bone Void Filling

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1864 Concert Drive Virginia Beach, VA 23453, USA

ALLOGRAFT®

Allograft

Demineralized Cortical Granules

This granular allograft consists of a demineralized Bone Matrix (DBM) fostering rapid cell invasion, proliferation and optimal healing. The resulting osteoinducitve properties render it ideal for indications requiring periodontal regeneration[12, 13] and new bone formation.[14]

FEATURES AND BENEFITS

Osteoinductive	→ Comprised of demineralized bone matrix (DBM) with osteoinductive potential to promote healing and remodeling into vital bone[14] → PAD® demineralization technology is used to maintain optimal osteoinductive potential through targeting an optimal residual calcium level of 1–4% exposing native growth factors
Promotes vital bone formation and periodontal regeneration	**For Periodontal Regeneration:**[15–26] → Supports periodontal tissue formation (bone, ligament and cementum)[22–24] → Improves bone fill and reduces crestal resorption when combined with enamel matrix derivative (EMD) compared to EMD alone[15, 17] → Supports significant periodontal ligament fibroblasts (PDLF) attachment when compared to xenografts and synthetic materials[26] **For Socket Preservation**[27] → Promotes new alveolar bone formation as early as 20 weeks after tooth extraction (Wood RA, see above)
Safety and biocompatibility[28]	→ Processed using LifeNet Health's patented Allowash XG® cleaning and disinfection technology for enhanced safety and biocompatibility → Meeting high Sterility Assurance Level (SAL) standards of 10^{-6} for a safe product that is ready-to-use for the most common dental grafting applications → More than 10 million grafts distributed without any incidence of disease transmission

Available in the following sizes

AlloGraft Demineralized Cortical Granules	
070.222	250–1000 microns, 0.25 cc
070.223	250–1000 microns, 0.5 cc
070.224	250–1000 microns, 1.0 cc
070.225	250–1000 microns, 2.0 cc

PROPERTIES

Attribute	Description
Origin	All donors have been recovered, screened, tested, processed, stored, and distributed in accordance with current U.S. federal regulations and in accordance with distributed territory regulations. All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of1988 (CUA) and 42 CFR 493.
Composition	Comprised of demineralized Bone Matrix (DBM) from cortical bone
Healing / integration time	3–4 months
Storage temperature	Ambient temperature (2°C to 37°C with excursions of less than 24 hours up to 40°C)
Shelf life	4 years

APPLICATION AND HANDLING

OPENING INSTRUCTIONS

1. Non-Sterile Team Member:
Peel open outer tray foil lidstock and present inner contents to the Sterile Team Member.

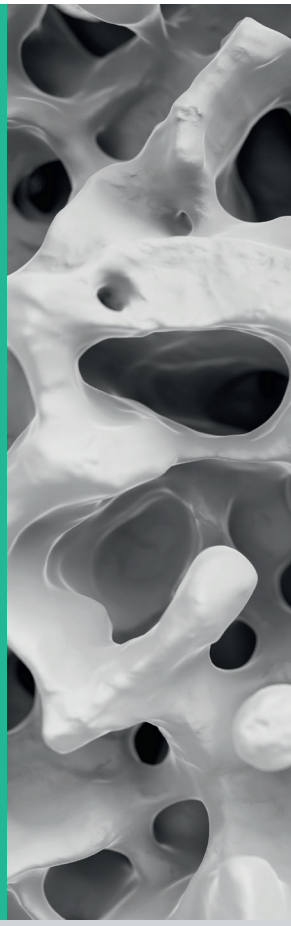
2. Sterile Team Member:
a. If the bio-implant is packaged in a plastic tray, firmly grasp the "Peel Here" tab and remove from outer tray. If rehydration is preferred by the physician, place the bio-material in a sterile basin and follow the appropriate preparations for use below.

b. If the bio-implant is packaged in a jar, firmly grasp the jar and remove from outer tray. If rehydration is preferred by the physician, keep the bio-implant in the jar and follow the appropriate preparations for use below.

PREPARATIONS FOR USE

3. Freeze-dried:
If rehydrating, refer to the table below for the recommended rehydration instructions. Hydrating media may include antibiotic solution, sterile saline, I.V. fluids, blood, plasma, bone marrow, or other specific blood components

Rehydration Instructions: All Other allograft Bio-Implants (Freeze-Dried): Rehydrate until required consistency and handling are achieved as per physician preference.



Recommended for

Demineralized Cortical Granules are recommended/indicated for:

→ Periodontal Defects
→ Sinus Augmentation
→ Ridge Preservation
→ Extraction Socket Maintenance
→ Bone Void Filling

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BONE GRAFTS

ALLOGRAFT®

Allograft

Demineralized/Mineralized Cortical Granules

The blend of 80% mineralized and 20% demineralized ground cortical bone provides volume stability combined with osteoinductive potential. It is ideal for indications requiring bone formation (3–4 months) and optimal healing.[29]

FEATURES AND BENEFITS

Convenient	→ Ready-to-use 80/20 mix eliminates the requirement to blend grafts chair-side and reduces the number of graft types in inventory
Osteoconductive[33]	→ Natural bone matrix facilitates cell attachment and proliferation as well as vascular in-growth[30]
Osteoinductive[35, 37]	→ Contains demineralized bone matrix (DBM) to promote rapid healing and remodelling into vital bone[29] → PAD® demineralization technology is used to maintain optimal osteoinductive potential through targeting an optimal residual calcium level of 1–4% exposing native growth factors[31]
Promotes vital bone formation and volume stability[32–37, 40–50]	→ Supports vital alveolar bone formation and dimensional stability[44, 45] → Alternative to Xenograft or Autograft[46]
Safety and biocompatibility[38, 39, 53]	→ Processed using LifeNet Health's patented Allowash XG® cleaning and disinfection technology for enhanced safety and biocompatibility → Meeting high Sterility Assurance Level (SAL) standards of 10^{-6} for a safe product that is ready-to-use for the most common dental grafting applications → Long-term evidence of safety based on > 10 million successfully implanted grafts

Available in the following sizes

AlloGraft Demineralized/Mineralized Cortical Granules	
070.234	250–1000 microns, 0.5 cc
070.235	250–1000 microns, 1.0 cc
070.236	250–1000 microns, 2.0 cc
070.237	250–1000 microns, 2.5 cc

PROPERTIES

Attribute	Description
Origin	All donors have been recovered, screened, tested, processed, stored, and distributed in accordance with current U.S. federal regulations and in accordance with distributed territory regulations. All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of1988 (CUA) and 42 CFR 493.
Composition	80% mineralized ground cortical with 20% demineralized ground cortical in a single graft
Healing / integration time	3–4 months
Storage temperature	Ambient temperature (2°C to 37°C with excursions of less than 24 hours up to 40°C)
Shelf life	4 years

APPLICATION AND HANDLING

OPENING INSTRUCTIONS

1. Non-Sterile Team Member:
Peel open outer tray foil lidstock and present inner contents to the Sterile Team Member.

2. Sterile Team Member:

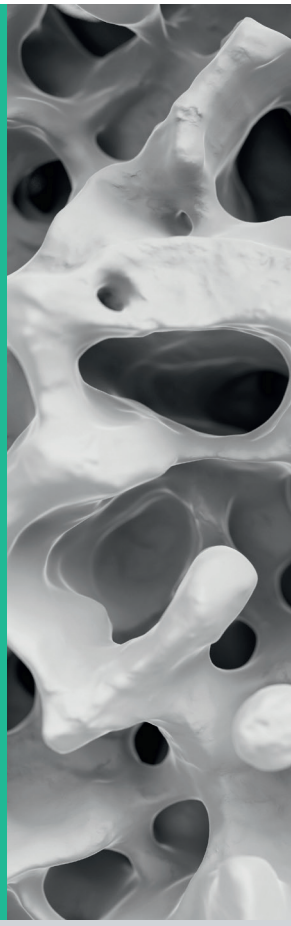
a. If the bio-implant is packaged in a plastic tray, firmly grasp the "Peel Here" tab and remove from outer tray. If rehydration is preferred by the physician, place the bio-material in a sterile basin and follow the appropriate preparations for use below.

b. If the bio-implant is packaged in a jar, firmly grasp the jar and remove from outer tray. If rehydration is preferred by the physician, keep the bio-implant in the jar and follow the appropriate preparations for use below.

PREPARATIONS FOR USE

3. Freeze-dried:
If rehydrating, refer to the table below for the recommended rehydration instructions. Hydrating media may include antibiotic solution, sterile saline, I.V. fluids, blood, plasma, bone marrow, or other specific blood components.

Rehydration Instructions: All Other allograft Bio-Implants (Freeze-Dried): Rehydrate until required consistency and handling are achieved as per physician preference.



Recommended for
Demineralized/Mineralized Cortical Granules are recommended/indicated for:
→ Periodontal Defects
→ Sinus Augmentation
→ Ridge Preservation
→ Extraction Socket Maintenance
→ Bone Void Filling

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ALLOGRAFT®

Allograft

Demineralized Fibers and Cancellous Chips

This graft consists of a mixture of demineralized bone fibers and mineralized cancellous chips (250–1000 microns).
This combination renders it volume stable, osteoinductive, and moldable upon rehydration.

FEATURES AND BENEFITS

Convenient[63, 70]	→ Ready-to-use mix avoids the requirement to blend grafts chair-side and reduces the number of graft types in inventory. → Contains no fillers or carriers commonly used in other bone putties and gels.
Versatile[63, 70]	→ Moldable upon rehydration to conform to the surgical site → Interlocking fibers allow the graft to remain intact and in place for versatile and straightforward applications in various indications[54]
Designed to provide vital bone volume stability [55–59, 62, 68, 72]	→ 50/50 mix of osteoinductive demineralized fibers and space-maintaining natural cancellous chips → Designed to encourage bone formation and healing with improved space maintenance
Osteoconductive[64–66, 69, 71]	→ Cancellous chips provide a natural osteoconductive matrix to encouage bone healing and provide volume stability → Demineralized cortical fibers provide an increased surface area for cellular attachment and proliferation
Osteoinductive[61, 62, 70]	→ The cortical fibers are demineralized using LifeNet Health's patented PAD technology, ensuring optimal residual calcium levels of 1–4% to preserve the tissue's inherent osteoinductive potential
Safety and biocompatibility[38, 39, 53, 73]	→ Processed using LifeNet Health's patented Allowash XG® cleaning and disinfection technology for enhanced safety and biocompatibility → Meeting high Sterility Assurance Level (SAL) standards of 10^{-6} for a safe product that is ready-to-use for the most common dental grafting applications → Long-term evidence of safety based on > 10 million successfully implanted grafts

Available in the following sizes

AlloGraft Demineralized Fibers and Cancellous Chips	
070.248	0.5 cc
070.249	1.0 c
070.250	2.5 cc

PROPERTIES

Attribute	Description
Origin	All donors have been recovered, screened, tested, processed, stored, and distributed in accordance with current U.S. federal regulations and in accordance with distributed territory regulations. All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of1988 (CUA) and 42 CFR 493.
Composition	Demineralized bone fibers (50%) and cancellous bone (50%)
Healing / integration time	4–6 months
Storage temperature	Ambient temperature (2°C to 37°C with excursions of less than 24 hours up to 40°C)
Shelf life	4 years

APPLICATION AND HANDLING

OPENING INSTRUCTIONS

1. Non-Sterile Team Member:
Peel open outer tray foil lidstock and present inner contents to the Sterile Team Member.

2. Sterile Team Member:

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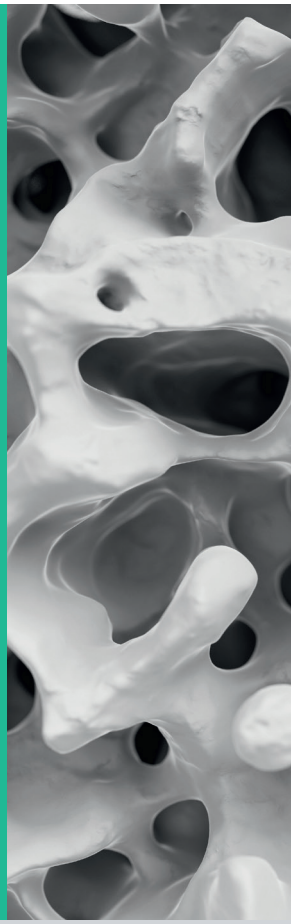
b. If the bio-implant is packaged in a jar, firmly grasp the jar and remove from outer tray. If rehydration is preferred by the physician, keep the bio-implant in the jar and follow the appropriate preparations for use below.

PREPARATIONS FOR USE

3. Freeze-dried:
If rehydrating, refer to the table below for the recommended rehydration instructions. Hydrating media may include antibiotic solution, sterile saline, I.V. fluids, blood, plasma, bone marrow, or other specific blood components.

Rehydration Instructions: All Other allograft Bio-Implants (Freeze-Dried): Rehydrate until required consistency and handling are achieved as per physician preference.



Recommended for
Demineralized Fiber and Chips is recommended/indicated for:
→ Surgical procedures requiring a bone void filler

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DERMIS

ALLOGRAFT

Allograft

Dermal Matrix

This decellularized dermal matrix is a soft tissue substitute that is fully hydrated, ready to use and can be stored at room temperature. It can be used for the treatment of gingival recessions/root coverage; also used for thin gingiva around teeth or implants in conjunction with bone grafting material; graft can also be used in conjunction with Enamel Matrix Derivative (EMD).

FEATURES AND BENEFITS

Promotes tissue integration and healing[77–79, 86, 87, 92]	→ Improved cellular infiltration and revascularization capacity compared to porcine collagen matrices[86, 87, 92] → Histologically shown to promote fibroblast infiltration, vascularization and remodeling[74, 77–79]
Proven clinically effective[83]	→ Equivalent outcomes to Connective Tissue Graft (CTG) for Miller Class II, III defects[76] → Equivalent performance in Alveolar ridge augmentation and socket preservation compared to PTFE[85] and in combination with particulate allograft[83]
Combinable with Emdogain® [82, 83, 88, 90]	→ In combination with Enamel Matrix Derivative (EMD) significantly enhances cell adhesion capacity[89] → Demonstrated effectiveness with Emdogain® for the treatment of Class I and II Recession[83]
Convenient and reliable[92]	→ Preserved using LifeNet Health's proprietary Preservon® process[92] → Supplied pre-hydrated, ready-to-use to minimize chair-time → Room temperature stable and storable without becoming brittle
Biocompatible[74–76, 89]	→ Processed using LifeNet Health's proprietary Matracell® production technology, retaining natural growth factors, collagen and elastin[84]
Safe[80–82, 85, 86, 91]	→ MatraCell® technology is designed to inactivate viruses, reducing the risk of disease transmission[80] → Terminally sterilized to achieve medical device level of sterility, Sterility Assurance Level (SAL) of 10^{-6} [91] → The Matracell® decellularization technology removes 97% of donor DNA, minimizing the risk of an immune response[73, 85, 88]

PROPERTIES

Attribute	Description
Origin	All donors have been recovered, screened, tested, processed, stored, and distributed in accordance with current U.S. federal regulations and in accordance with distributed territory regulations. All donors are tested for relevant infectious diseases. Testing is performed by laboratories that are registered with the U.S. Food and Drug Administration (FDA) and certified under the Clinical Laboratory Improvement Amendments of 1988 (CUA) and 42 CFR 493.
Composition	Acellular dermal matrix, human origin
Healing / integration time	4–6 months
Storage temperature	Room temperature (15˚C to 30˚C), with excursion of: - up to 37°C for 3 months or less - down to -100°C for 30 days
Shelf life	3 years

Available in the following sizes

AlloGraft Dermal Matrix	
DM-150	0.76–1.25 mm, 1.0 × 1.0 cm
DM-100	0.76–1.25 mm, 1.5 × 2.0 cm
DM-151	0.76–1.25 mm, 1.0 × 4.0 cm
DM-101	0.76–1.25 mm, 2.0 × 4.0 cm
DM-250	1.26–1.75 mm, 1.0 × 1.0 cm
DM-200	1.26–1.75 mm, 1.5 × 2.0 cm
DM-251	1.26–1.75 mm, 1.0 × 4.0 cm
DM-201	1.26–1.75 mm, 2.0 × 4.0 cm

Recommended for

Dermal Matrix is recommended/indicated for:

→ Periodontal Defects
→ Sinus Augmentation
→ Ridge Preservation
→ Extraction Socket Maintenance
→ Bone Void Filling

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