VITALITY BONE™

Particulate Allograft

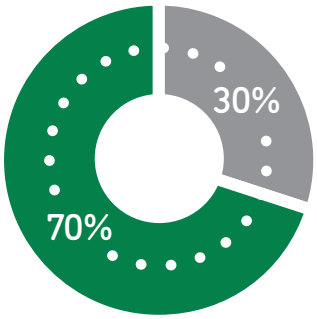
Benefits & Key Features

Processed by an AATB Accredited Tissue Bank

Vitality Bone™ Particulate Allograft is processed by an established, AATB accredited tissue bank with more than 30 years of experience providing oral surgeons, periodontists, and implantologists with high quality allograft products.

70/30 Cortical/Cancellous Mix

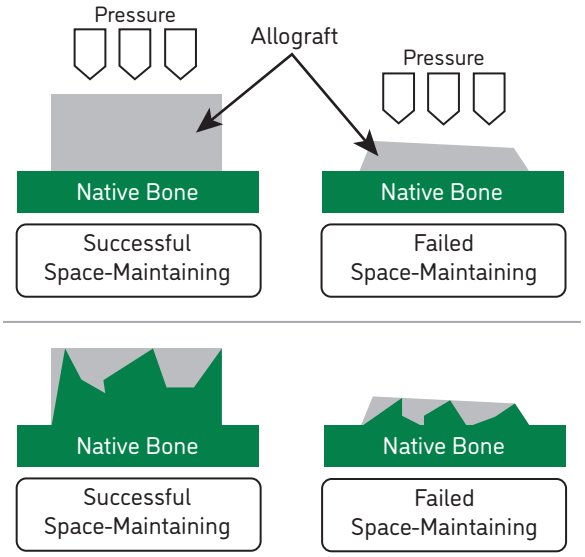
Due to its structural porosity, cancellous bone graft allows for a high concentration of osteoblasts and osteocytes, resulting in superior osteogenic potential. Additionally, its large trabecular surface area encourages vascularization and incorporation at the recipient site. Cortical bone particles provide structure and rigidity, which is particularly important for procedures involving horizontal and vertical augmentation of the alveolar ridge.[1,2] To capitalize on the benefits of both cancellous and cortical particles, each vial of Vitality Bone™ Particulate Allograft contains an ideal mixture of 70% cortical and 30% cancellous bone.



500-1000 Micron Particle Size

Compared with smaller particles, larger particles possess greater mechanical resistance, reducing the risk of premature chemical dissolution and improving space-maintaining capability. Allograft bone substitutes must be retained during bone formation in order to support osteoblast function. In instances where bone substitutes are not successfully retained, there is an elevated risk of defective, insufficient bone formation. Conversely, smaller particles possess greater shapeability and more rapid dissolution, reducing the overall time needed for bone formation.[3]

Vitality Bone™ Particulate Allograft consists of a 500-1000 micron particle size in order to maximize the quality of bone formation while maintaining a turnover period of approximately 4 months.



100% Mineralized Allograft

Mineralized freeze died bone allograft (FDBA) has several characteristics that make it an ideal scaffold for hard tissue engineering, including biocompatibility, biodegradability, and mechanical properties. FDBA provides a sturdy foundation for bone growth that does not inhibit the function nor migration of cells. It has an interconnected pore structure and high porosity, providing a natural scaffold architecture and site for stem cells to differentiate into osteoblasts, encouraging new bone growth. Indications for FDBA include socket preservation, guided bone regeration, ridge augmentation, maxillary sinus augmentation, and treatment of peri-implant defects.[4-6]

Instructions for Use

3-Step Application

Open package and transfer particulate to sterile field

Rehydrate particulate in sterile 0.9% saline solution (~1 min)

Transplant particulate into bony defect as needed

Precautions

Vitality Bone™ Particulate Allograft should always be used by a licensed clinical professional. Prior to clinical use, clinicians should be familiar with Vitality Bone™ Particulate Allograft as well as its associated IFU. Improper preparation of this product may adversely affect its handling properties.

All Vitality Bone™ Particulate Allograft products should be used with caution.

General Instructions

For use on a single patient only. Once the package has been opened, the product must be used for the current procedure or discarded. Please note that the exterior box is non-sterile and is used solely to protect the product during shipment and storage. Always use sterile technique for preparation and transplantation of Vitality Bone™ Particulate Allograft products. Do not attempt to re-sterilize previously opened products. Additional product should always be available in case of unexpected need during the procedure.

Always inspect packing and labeling materials carefully. Do not use if the product is past its expiration date, if there are discrepancies in the label information, or if the product/packaging is damaged.

Regulatory bodies, including but not limited to the U.S. Food and Drug Administration (FDA) and the American Association of Tissue Banks (AATB), require that allograft tissue be traceable from donor to recipient. The transplantation facility is responsible for traceability of the tissue post-transplantation. Always record the patient name (or identifying number), the tissue identification information, and any comments regarding the use of the tissue. Retain this information for your personal records.

Safety & Quality Assurance

Vitality Bone™ Particulate Allograft is produced by an AATB accredited tissue bank. By accepting AATB accreditation, tissue banks agree to comply with on-site inspections of processing facilities, annual audits, and other various AATB-prescribed safety regulations. All tissue is processed in certified ISO Class 1000 and Class 100 clean rooms. Pre-processing and post-processing quality assurance and quality control reviews are performed on all donated tissues. Each donor is approved by the tissue bank's Medical Director to ensure compliance with donor acceptance criteria prior to release. Policies and procedures for donor tracking, documentation, tissue processing, allograft packaging, and distribution activities are designed and executed in compliance with current FDA regulations. All donors are recovered and processed in the United States.

Ordering Information

Ordering Vitality Particulate Allograft

Volume	Item Code
0.5cc	AGCCC005
1.0cc	AGCCC010
2.0cc	AGCCC020

Contact us at 202-331-3061 or visit vitalitybone.com

References:

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[9] Salyer KE, Gendler E, Squier CA. Long-term outcome of extensive skull reconstruction using demineralized perforated bone in Siamese twins joined at the skull vertex. Plast Reconstr Surg. 1997;99:1721-6.

[10] Schwartz Z, Mellonig JT, Carnes DL Jr , et al. Ability of commercial demineralized freeze-dried bone allograft to induce new bone formation. J Periodontol. 1996;67:918–26

[11] Grover V, Kapoor A, Malhotra R, Sachdeva S. Bone allografts: A review of safety and efficacy. Indian Journal of Dental Research. 2011;22:496

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