BioGenix
BONE

Tissue Regeneration Corporation

biogenixbone.com

TRC (Tissue regeneration corporation) is a multi-facility institute specializing in the preparation of a wide range of grafts based on the science of tissue engineering. Tissue engineering is an emerging science that aims to regenerate existing biological tissue and create new tissue using biological cells and biomaterial. Our competitive edge is derived from a strong focus on improving patient outcomes. The TRC team consists of highly dedicated and motivated professionals who are committed to finding solutions in order to achieve the highest standards in our work.

STATE-OF-THE-ART PRODUCTION

Tissue Regeneration Corporation adheres to strict policies and procedures that were devised in line with the guidelines and standards of the FDA and UK codes of practice for productions of human derived therapeutic materials. All tissues are procured in a class 1000 environment and processed in sterile class 10-1000 clean rooms. The donor coordinator acquires the necessary consent for donation and interviews the family of each donor to obtain the donor's medical history. TRC will only supply tissue from donors where lawful consent has been established. Where consent has been obtained by TRC, the tissue preparation is undertaken by our highly trained team who are constantly assessed using our specifically developed competency assessment program.

Every donated tissue is tasted using several microbiologic and serologic testes such as HBs Ag, HBc Ab, HCV Ab, HIV Ab (1&2), HTLV Ab (I&II), RPR with ELISA method and complementary tests such as NAT (Nucleic Acid Test) method and FTA. Most of the donors are young, additionally our country has one of the lowest HIV infection rates in the world therefore we can provide some of the best quality tissues with minimal risk of AIDS transmission. All our bony grafts have both osteoinductive and osteoconductive properties confirmed by both in vitro and in vivo. Furthermore, the biomechanical properties of both the machined and large bones are routinely tested according to ASTM standards. Our work is consistent with the fundamentals of both national and international quality standards and ethical principles, specifically we obey all AATB and Euro-GTP rules in cellular and tissues-based products. The services and facilities (including pharmaceutical grade cleanrooms) are all consistent with the current good manufacturing practice (cGMP).

Freeze dried bone is lyophilized to measure Residual Water (RW) <5% eliminating the potential for microbial growth and minimizing autodegredative reactions. Irradiation is carried out to an established protocol ensuring a minimum dose of 15KGY is received by the tissue. Processed bone grafts are non-cytotoxic as per ISO 10993-5. Final product release is undertaken as an independent function by quality assurance specialist personnel.

QUALITY ASSURANCE

All microbiology testing is performed internally by accredited laboratories specializing in donation screening. Final donor assessment and selection is undertaken by our own clinical specialist in tissue donation under supervision of coroner specialists. Donations are tracked by barcode including automated test result transfer to the database (the same database used for blood donation, processing and supply). This database has automated controls to prevent release of non-conforming tissue. Processes are validated in-house by the tissue development laboratory. All critical physical/chemical parameters are continuously monitored using a sophisticated IT package with appropriate warning levels and alarm states. This package continuously monitors (where appropriate) temperatures (of rooms, deep freezers, liquid nitrogen tanks etc.), clean room pressures, air particles, oxygen levels, etc.

PRODUCTS BENEFITS

Tissues engineered products from allogenic sources are used in many surgical procedures because they are naturally biocompatible and can be remodeled to the patient's own bone. They simplify potential revision procedures, and they eliminate second site morbidity and pain that may result from autograft removal. They are easy to use, take little time to prepare and are available pre-shaped to exact specifications. the end result is a facility, which ranks amongst the best in the world. TRC is staffed with highly trained dedicated doctors, scientists, technicians, nurses and all levels of support staff. This combination of a motivated professional workforce within a state-of-the-art facility ensures our commitment to safety, quality and efficacy of all our tissue grafts.

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In general, bone products can be categorized into two main groups:

FDBA and DFDBA

1- FDBA
(FREEZE-DRIED BONE ALLOGRAFT)

Freeze-Dried Bone Allograft (FDBA) refers to a bone graft material that has undergone a freezedrying process to remove water content while preserving its structural and biological properties.
It is derived from allogenic (donor) bone tissue, processed to eliminate cells and antigens, and then freeze-dried to create a biocompatible and osteoconductive graft. Due to its preserved natural bone structure and collagen content, it serves as a scaffold for natural bone regeneration and has the potential of complete remodeling into patients' own bone.

2- DFDBA
(DEMINERALIZED FREEZE-DRIED BONE ALLOGRAFT)

DFDBA undergoes a demineralization process where mineral components, such as hydroxyapatite, are removed from the allograft bone. This exposes the organic matrix, which contains essential growth factors like bone morphogenetic proteins (BMPs), transforming growth factor-beta (TGF-β), and insulin-like growth factors (IGFs).
DFDBA stands out for its superior osteoinductive potential compared to Freeze-Dried Bone Allograft (FDBA). Osteoinduction refers to the material's ability to stimulate undifferentiated cells to transform into osteoblasts, thereby facilitating new bone formation. This property accelerates the remodeling process, leading to faster bone formation when compared to mineral-based products.

PRODUCTS LIST

Cortical cancellous powder (FDBA, DFDBA, PDFDBA)

The granules within this product exhibit a balanced combination of cortical and cancellous bone characteristics. The cortical component, a dense bone tissue, provides structural support and durability, while the cancellous component, with its open trabecular structure, promotes optimal cellular activity and facilitates rapid revascularization.
Cortical cancellous powder consists of particle sizes ranging from 150 to 2000 microns.

This product is available in three types: FDBA, DFDBA, PDFDBA

Demineralized powders, with their higher rates of remodeling and absorption compared to mineral powders, are recommended for application in small defects or contained areas where effective space preservation is crucial. For larger areas or non-contained regions with lower absorption rate requirements, a combination with mineral powders or the utilization of Partially Demineralized Freeze-Dried Bone Allograft (PDFDBA) products is recommended.

DFDBA

FDBA

PDFDBA

PDFDBA is the particulate bone grafting product combining mineralized and demineralized bone in a single vial. Already a popular combination among many specialists. PDFDBA 70/30 leverages the complementary benefits of space-maintaining mineralized cortical bone with osteoinductive demineralized matrix to optimize the environment for the regeneration of vital bone.

Product	Description	Volume (cc)	Code
Powder-FDBA (Mineralized Bone)	150-2000µm	0.5	29041
		1	29042
		2	29043
	150-1000µm	0.25	29000
		0.5	29001
		1	29002
		2	29003
	500-1000µm	0.25	29020
		0.5	29021
		1	29022
		2	29023
	150-500µm	0.5	29011
		1	29012
		2	29013
Powder-DFDBA (Demineralized Bone)	150-2000µm	0.5	29541
		1	29542
		2	29543
	150-1000µm	0.5	29501
		1	29502
		2	29503
	500-1000µm	0.5	29521
		1	29522
	150-500µm	0.5	29511
		1	29512

Product	Description	Volume (cc)	Code
Powder - Partial Demineralized FDBA & DFDBA (PDFDBA)	150-2000µm	0.5	29941
		1	29942
	150-1000µm	0.5	29901
		1	29902
Powder - Partial Demineralized FDBA & DFDBA (PDFDBA)	100-2000µm	0.5	29931
		1	29932

INDICATIONS

Cortical cancellous Powder (FDBA):

- Socket Preservation
- Ridge Augmentation (laterally /vertically)
- Dehiscence
- Fenestration
- Furca
- Fresh Socket
- Close sinus lift
- Open Sinus lift

Cortical cancellous Powder (DFDBA):

- Cysts
- Socket preservation
- Periodontal pocket
- Open Sinus Lift (Layer technique)

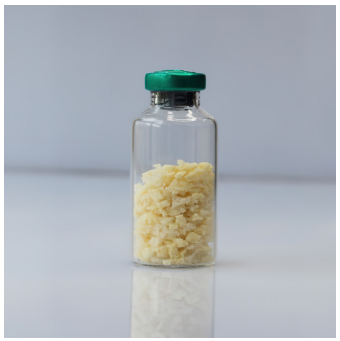
Cortical cancellous Powder (PDFDBA):

- Socket Preservation
- Dehiscence
- Fenestration
- Crater Defects
- Cysts
- Open Sinus lift/Close
- Fresh Socket

Cortico-Cancellous Crushed (FDBA, DFDBA):

The composition of Cortico-Cancellous Crushed, with its 30% cancellous and 70% cortical particle ratio, defines its unique characteristics. Its particle size ranges between 2 to 5 millimeters, enhances its versatility. The availability in both FDBA and DFDBA provides clinicians with options tailored to specific clinical requirements.

FDBA



DFDBA

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INDICATIONS:

DFDBA

- Extraction Sites
- Cysts
- Socket Preservation
- Open Sinus (Layer technique)
- Defects > 1cm

FDBA

- Open Sinus lift
- Ridge Augmentation
- Socket Grafting
- Defects > 1cm

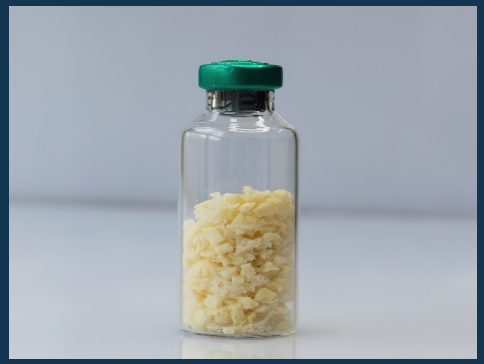
Product	Description	Volume (cc)	Code
Crushed-DFDBA (Demineralized Bone)	2-5mm	0.5	29552
Crushed-FDBA (Mineralized Bone)	2-5mm	1	29052

Cortico-Cancellous Chips (FDBA, DFDBA):

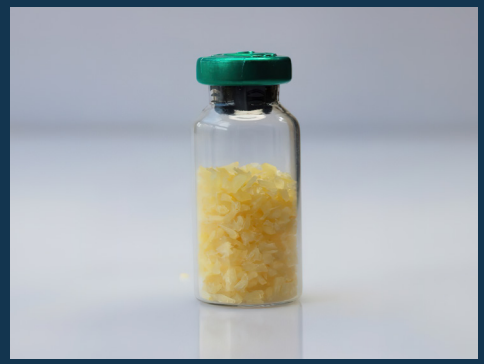
The composition of this product, with a predominant 60% cancellous and 40% cortical particle ratio, underscores its unique characteristics. The particle size ranges between 2 to 10 millimeter.

Product	Description	Volume (cc)	Code
Crushed-FDBA (Mineralized Bone)	2-10mm	1	29062
		2	29063
Crushed-DFDBA (Demineralized Bone)	2-10mm	1	29562
		2	29563

FDBA



DFDBA



Cancellous Cubes (FDBA, DFDBA)

Cancellous cubes, available in sizes of 5x5x5 mm and 10x10x10 mm, are composed of 100% cancellous bone which allows for space maintenance in the bone void and rapid remodeling thanks to its natural architecture. They can be fixed using standard bone screws and can be trimmed using standard instrumentation to fit the bone void. Cancellous cubes are ideal for craniofacial reconstructions and ridge maintenance procedures requiring either horizontal or vertical augmentation

Product	Description	Volume	Code
Cube-DFDBA (Demineralized Bone)	10*10*10mm	1 Piece	29582
	5*5*5*mm	1 Piece	29571
Cube-FDBA (Mineralized Bone)	10*10*10mm	1 Piece	29082
	5*5*5*mm	1 Piece	29071

INDICATIONS:

FDBA

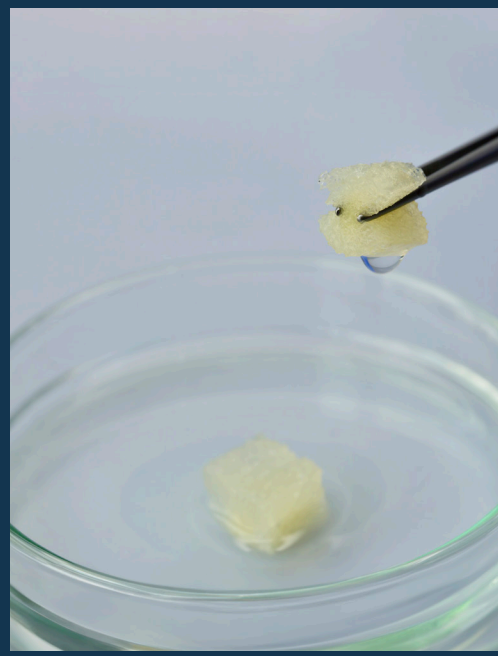
- Open Sinus Lift
- Ridge Augmentation
- Craniofacial Reconstruction
- Socket grafting

DFDBA

- Socket Grafting
- Ridge Augmentation
- Open Sinus Lift
- Tunnel Bone Grafting

FDBA

DFDBA (Flexible)



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Cancellous Matchstick (FDBA, DFDBA)

100% cancellous Bone derived from femoral/tibial epiphysis provide solid scaffold to encourage remodeling in a variety of dental bone void filling procedures available in size of 5*5*35 mm.

INDICATIONS:

FDBA

- Ridge Maintenance
(Horizontal & Vertical Augmentation)
- Craniofacial Reconstruction

DFDBA

- Ridge Augmentation
- Open Sinus Lift
- Tunnel Bone Grafting
- Craniofacial Reconstruction

DFDBA (Flexible)

FDBA

Strip Bone Block (FDBA)

CORTICO-CANCELLOUS STRIP:

Cortico-cancellous strips derived from ilium bone that consist of both cancellous and cortical bone. The cancellous bone creates an osteoconductive matrix for incorporation whilst the cortical face provides structural support, ideal for drilling and fixation with screw.
This product should be connected from the cancellous region to the patient's cortex, aiming to facilitate vascularization.

INDICATIONS:

- Lateral Augmentation
- Vertical and Horizontal Augmentation
- Craniofacial Reconstruction

BONE PUTTY (FDBA, DFDBA):

This product is composed of two main components: particulate bone and carrier known as hyaluronic acid. The combination of these two parts results in a uniform and paste-like product, facilitating ease of use for the surgeon.
The particles used in this product typically have a size ranging from 150 to 2000 micrometers.

INDICATIONS:

- Extraction sites
- Crater Defects
- Cysts
- Tunneling Tech
- Sinus Lift Close/Open

Cortical Strut Plate

Cortical Strut Plate is 100% cortical bone block derived from the diaphysis of the femoral bone, shaped into a thin rectangular sheet with an approximate thickness of one millimeter (0.7-1.2 mm). Similarly, to the autogenous bone, it can be used for the shell technique.
The concept of the shell technique is the preparation of a biological container, which creates the necessary space for the full incorporation of particulate bone graft material to rebuild new bone for dental implant placement. The technique is also published as cortical lamina technique or framework technique.
With excellent strength and a prolonged absorption time, Cortical Strut Plate acts as a robust barrier against any micromovements in the augmentation area, protecting the desired space for the growth of new bone in both horizontal and vertical dimensions. Additionally, due to its optimum thickness, it efficiently ensures blood supply to the Augmentation area.

INDICATIONS:

- Vertical Augmentation
- Horizontal Augmentation
- Complex three-dimensional augmentation
- Single tooth gap
- Fenestration defect

Cat. Code	Product	Dimensions	
29112	Cortical Strut Plate	10*20mm	0.7<T<1.2 mm
29113	Cortical Strut Plate	10*25mm	0.7<T<1.2 mm
29114	Cortical Strut Plate	10*40mm	0.7<T<1.2 mm

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BioGenix Membrane

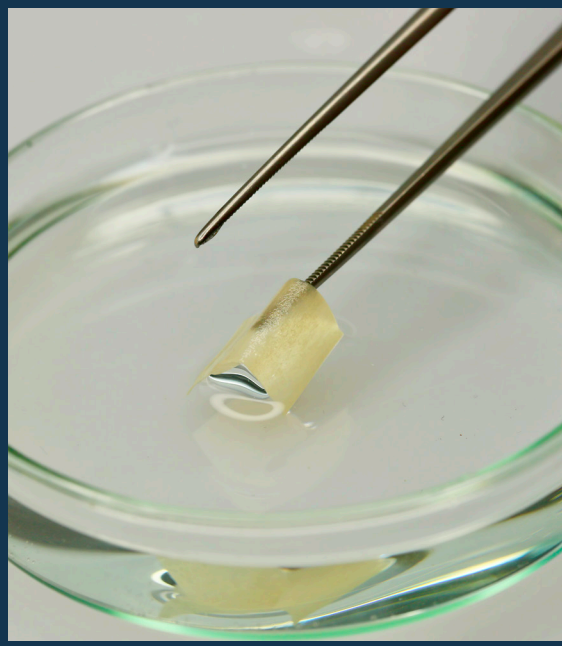
PRODUCTS LIST

Collagen Membrane:

The collagen membrane is derived from pericardium or fascia Lata with thicknesses of 0.2-0.6 and 0.6-0.9 mm. These products are utilized effectively as a barrier in various surgeries. The absorption time varies based on their thickness, ranging from 1.5 to 4 months.

INDICATIONS:

- Root Coverage
- Gingival Augmentation
- Guided Tissue Regeneration
- Guided Bone Regeneration
- Sausage Technique



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BioGenix Membrane

PRODUCTS LIST

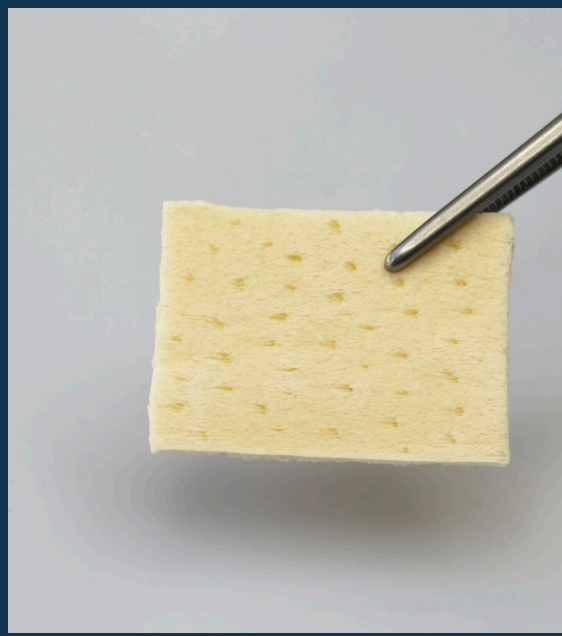
Derm:

This product is essentially an Acellular Dermal Matrix (ADM), comprising a combination of collagen, elastin, and fibrin.
Due to its exceptional tensile strength and firmness, especially in thicknesses below 1 millimeter, it can be used as a barrier in GBR (Guided Bone Regeneration) and Sausage technique surgeries. In thicknesses > 1mm, it can serve as an alternative to connective tissue grafts (CTG) for increasing gingival thickness or providing root surface coverage in Gingival Recession procedures.

Note: These products have two surfaces, smooth and porous. Typically, the smooth surface faces outward, and the porous surface adheres to the bonding material. Each surface possesses specific types of collagens. The smooth surface contains collagen types 1 and 5, enhancing cellular guidance, while the porous surface contains collagen types 2 and 4, promoting improved vascularization.

INDICATIONS:

- Root Coverage
- Gingival Augmentation
- Soft Tissue Ridge Augmentation
- Soft Tissue Augmentation Around Implants
- Sausage Technique
- Guided Tissue Regeneration
- Guided Bone Regeneration



Thank you

for putting your trust in us

At Tissue Regeneration Corporation, we are driven by innovation and grounded by our mission to save lives, restore health and give hope.

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TRC is staffed with highly trained dedicated doctors, scientists, technicians, nurses and all levels of support staff. This combination of a motivated professional workforce within a state-of-the-art facility ensures our commitment to safety, quality and efficacy of all our tissue grafts.