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 environment and processed in sterile class 10-10000 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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BIOGENIX BONE

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 freeze- drying 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.

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

Product	Description	Volume (cc)	Code
Cortical Cancellous Powder	150-1000µm	5	29004
		10	29005
		15	29009
		30	29007
	500-1000µm	5	29014
		15	29019
		30	29017
	150-2000µm	5	29024
		10	29025
		15	29029
		30	29027
		5	29044
		15	29044
		30	29047

DEMINERALIZED (DFDBA)

Product	Description	Volume (cc)	Code
Cortical Cancellous Powder	150-1000µm	5	29004
		15	29009
		30	29007
	500-1000µm	15	29019
		30	29017
	150-2000µm	15	29029
		30	29027
		5	29044
		15	29049
		30	29047

PDFDBA

Product	Description	Volume (cc)	Code
Cortical Cancellous Powder	150-1000µm	15	29004
		30	29009
	1000-2000µm	15	29007
		30	29019
	150-2000µm	15	29017
		30	29029

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.

INDICATIONS:

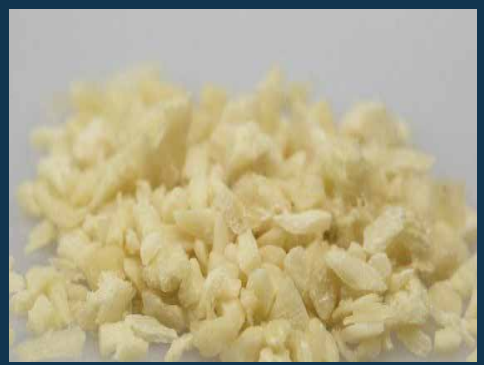
DFDBA

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

FDBA

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

FDBA



DFDBA

CRUSHED

Product	Description	Volume (cc)	Code
Cortical Cancellous Crushed	2 - 5 mm	15	29059
		30	29057
		15	29559
		30	29557

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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
Cortical Cancellous Chips	2 - 10 mm	5	29064
		10	29065
		15	29069
		30	29067
Demineralized Cortical Cancellous	2 - 10 mm	5	29564
		10	29565
		15	29569
		30	29567

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	Piece	Code
Cancellous Cube	5 × 5 × 5mm	5	29074
	5 × 5 × 5mm	15	29079
Demineralized Cancellous Cube	5 × 5 × 5mm	5	29574
	5 × 5 × 5mm	15	29579
Cancellous Cube	10 × 10 × 10mm	5	29084
	10 × 10 × 10mm	10	29085
Demineralized Cancellous Cube	10 × 10 × 10mm	5	29584
	10 × 10 × 10mm	10	29585

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

FDBA (Flexible)

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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

BioGenix Membrane

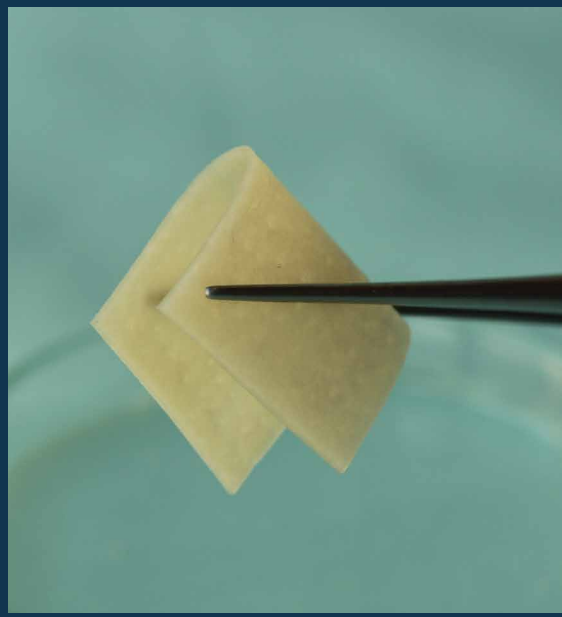
PRODUCTS LIST

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



BioGenix Membrane

PRODUCTS LIST

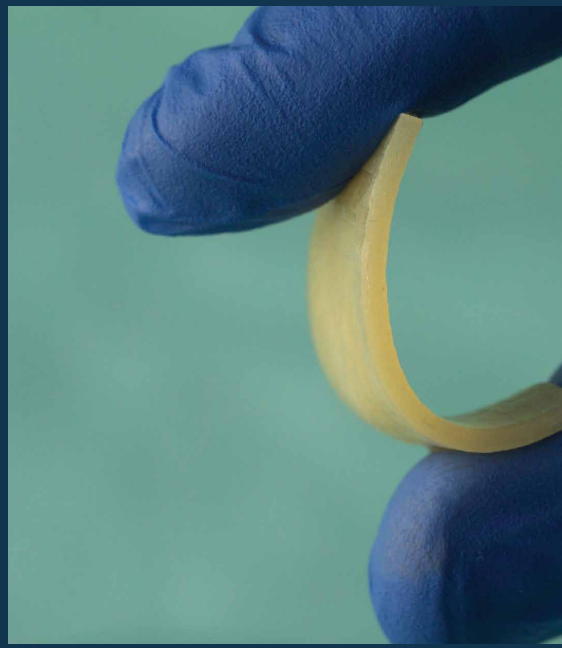
Derm:

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



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FIBULAR RING:

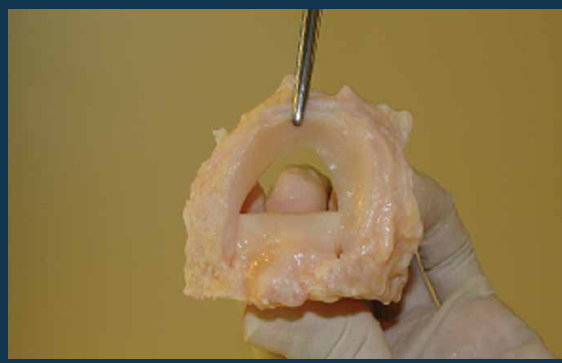
Febular Ring products are Cortico-Cancellous allografts which mostly consist of cortical bone. Febular Rings can be used for disk replacement in sipne surgeries, or for defects of relatively long bones.

HEMI FEMORAL SHAFT:

Hemi Femoral Shaft is a Cortico- Cancellous allograft bone shaft which mostly consists of a cortical plate. It is intended for use in bone defects, long bones, multilevel corpectomy in cervical spine and total hip repairs.

MENISCUS:

This product is designed for knee meniscus defects repair and replacement. I has a bone block which is located on the medial side and is capable of forming to desired shape by the surgeon.



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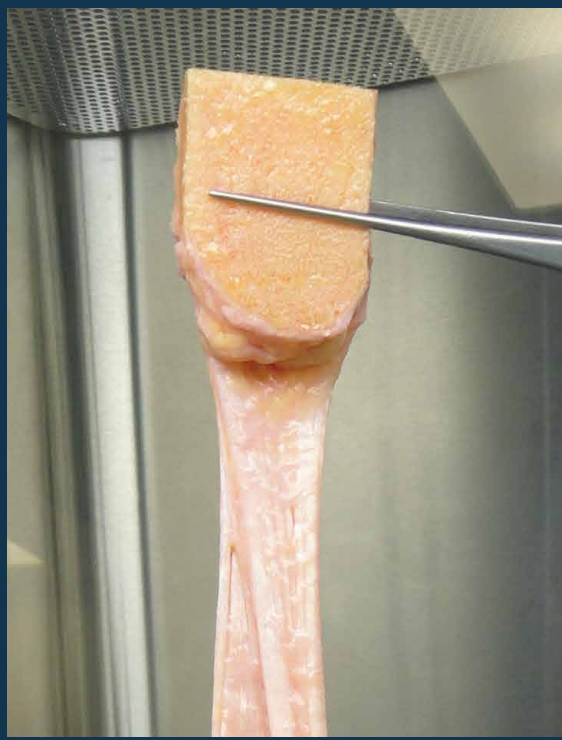
BIOGENIX ACHILLES TENDON WITH CALCANEUS:

This Product with a minnimum length of 25 cm and loop of 7-9 mm, is designed for repairing tendon defects like Acl and Pcl. It may be derived from tibialis anterior, tibialis posterior, Peroneus Longus and achilles. Achilles can be used to repair cuff labrum and tendon tears.



TRICORTICAL PATELLAR WEDGE:

Tricortical Patellar Wedge is a cortico-cancellous allograft which is manufactures as tricortical to provide more strength. This product can be used for correction of hand, foot and knee deformities.

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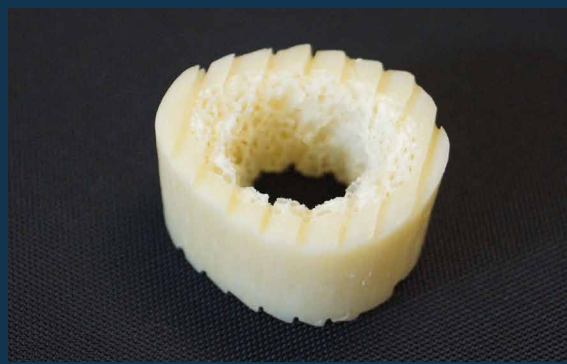
HUMOROUS CAGE:

Humerus Cage is a Cortico-Cancellous allografts which mostly consists of cortical bone. Humerus Cage can be used for disk replacement in spine surgeries or repairing defects of releatively long bones.

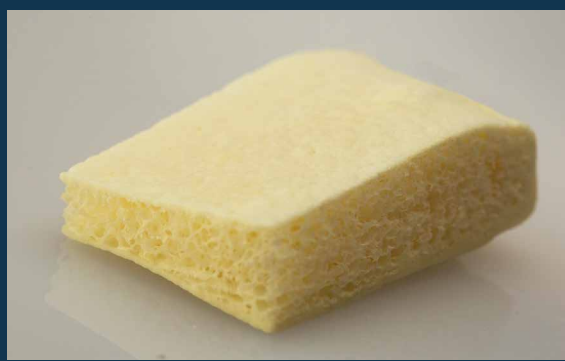
FEMORAL CROSS SECTION:

Femoral Cross Section (Parallel) products are Cortico-Cancellous allograft bone shafts which mostly consist of a cortical plate. They are used in bone defects, long bones and lumbar discectomy procedures.



TRICORTICAL ILLIAC CREST STRIP:

Tricortical Iliac Crest Strip products are Cortico-Cancellous allografts which are designed as plate, in such a way that one side is cortical and the other side is cancellous (Tricortical and medial part ofcancellous). Tricortical Iliac Crest Stripcan be used for for correction of hand, foot and knee deformities.



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FEMORTRICORTICAL ILLIAC CREST WEDGEAL CROSS SECTION:

Tricortical Iliac Crest Wedge products are Cortico-Cancellous allografts which are designed as tricortical for more strength. Tricortical Iliac Crest Wedge can be used for repairing deformities of hand, foot and knee.

TIBIAL WEDGE:

Tibial Wedge (HTO Wedge) is a Cortico-Cancellous allograft. HTO Wedge is designed tricortical for additional strength. It is intended for use in bone fractures or particularly in HTO.

TIBIAL SHAFT:

Tibial Shaft/Segment is a Cortico-Cancellous allograft bone shaft which mostly consists of a cortical plate. It isintended for use in bone defects, long bones, multilevel corpectomy in back spine and total hip repairs.

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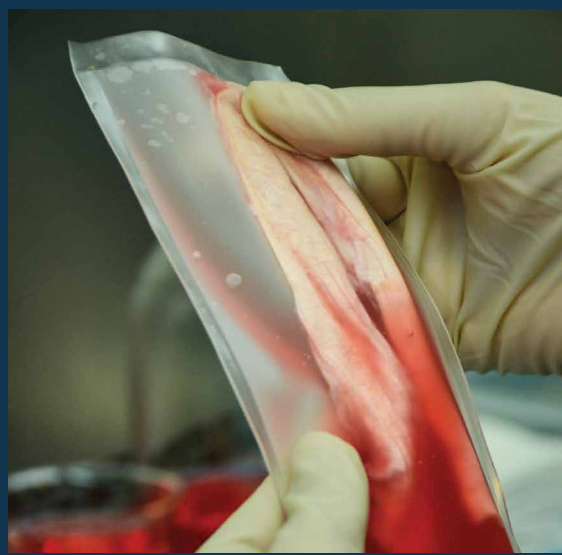
FEMORAL SHAFT SEGMENT:

Femoral Shafts/Segments products are Cortico-Cancellous allograft bone shafts which mostly consist of a cortical plate. They are used in bone defects, long bones and multilevel corpectomy in spine or total hip procedures.

BIOGENIX TENDON:

This Product with a minnimum length of 25 cm and loop of 7-9 mm, is designedfor repairing tendon defects like Acl and Pcl. It may be derived from tibialis anterior, tibialis posterior, Peroneus Longus and achilles. Achilles can be used to repair cuff labrum and tendon tears.



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.