Tums Allograft

Iranian Tissue Bank

- Orthopedic & Spine Surgery
- Dentistry and Maxillofacial Surgery
- ENT and Plastic Surgery
- Cardiovascular Surgery

Research and Proparation Center

Iranian Tissue Bank (I.T.B) is the first and unique multi-facility tissue bank in country. I.T.B started its activity in 1994 with preparing of homograft heart valves. Then we expanded our activities and now I.T.B is a multi tissue bank. From 1994 to 2006 we have procured more than 2700 tissues from Cadaver donors.

The state-of-the-art technology and highly trained staff enable us to provide the widest range of tissue grafts available. Also I.T.B is an organ procurement organization that procures multi organs for transplantation. After donation legislation approval in 2000, we obtained informed consent from all of the donors (Donor Card).

I.T.B adheres to strict policies and procedures that were written according to guidelines and standards of EATB, AATB & FDA.

All of the tissues are procured under aseptic conditions. Tissue processing is performed in our GMP clean room facilities located in Imam Khomeini Hospital. The activity protocol and its special accessories are used in our clean room to make a class 10000 or better operating room and class 100 for tissue processing.

The Quality Control and Assurance Systems

- Donor selection according to AATB and WHO.
- Implementation of executive guidelines approved by the ministry of health.
- Obtaining iso 13485:2016 certification from KGS.
- GMP-compliant performance.
- Production and processing in a clean room equipped and supervised by the Iran Food and Drug Administration.
- Sterilization with gamma rays by the atomic energy organization.

Serology Tests	Microbial Tests	Biological Tests	Structural Tests
✓ HBc.Ab	✓ Aerobic	✓ Microbial Growth	✓ Moisture Limit
✓ HIV 1,2 Ag-Ab	✓ Anaerobic	✓ Bioburden	✓ Chemical Residue
✓ HCV.Ab	✓ Yeast	✓ Cellular Viability	✓ Biomechanical Strenght
✓ HBs.Ag	✓ Fungi	✓ Sterility	
✓ HTLV.Ab		✓ Sensitization	
✓ R.P.R		✓ Endotoxin	
		✓ Irratitation	

General Information

An Allograft is tissue that removed from a human donor which means the donor material comes from a member of the same species, but the donor is not genetically identical to the recipient. Over 1,000,000 allografts are performed in Iran annually. The use of musculoskeletal allograft is commonly used in reconstructive surgery of the hip, knee and long bones, as well as in cases of bone loss due to trauma or tumors. Using allograft tissue from another person can eliminate the need for a second operative site to remove autograft bone or tendon, reduce the risk of infection at a separate surgical site, and safeguard against pain and loss of function at or near the secondary site. Because of tissue processing, calls responsible for tissue rejection are removed or inactivated so after surgery, there is no need for immunosuppressive therapy.

Donor Selection

After cardiac and cerebral death the potential donor will be assessed by tissue procurement coordinator (a trained medical doctor). The Major exclusion criteria are:

- Any Communicable diseases
- Systemic infection or sepsis
- Malignancy (Except primary CNS tumors)
- Previous Use of human pituitary extracts or xenografts
- Past or present Nonmedical IV drug abuse
- Clinical or laboratory evidence of HIV, Hepatitis B or C infection
- Suspicious sexual history, recent prisoning and tattooing
- Long-term corticosteroid therapy
- Connective tissue disorders
- Unknown cause of death
- History of Long-term immobility
- History of Osteomyelitis/TB in donated bone
- History of Heavy metal intoxication
- Metal in situ

Recovery Procedures

I.T.B Procures tissue aseptically and processes it by strict adherence to surgical principles and clean room protocols. Following tissue recovery, the technologists reconstruct the donor to allow for normal funeral arrangements. Reconstruction will be done by using prosthesis and pads in donor site

Retrieval Time

Tissue retrieval is done within 36 hours of death if the body is refrigerated within 6 hours.
If the body is kept at room temperature, retrieval will occur within 12 hours of death.

Processing Methods

All allograft tissues are delivered to I.T.B's clean room facilities in a nutrient medium after recovery. The tissue is processed as soon as possible under clean condition room. A tissue technician cleans the bone from excess soft tissues and then removes the bone marrow with multiple washing and suctioning. After complete cleaning the tissue is cut into appropriate shapes and each piece packed separately. Multiple samples are taken from bone, attached soft tissues, bone surface swabbing and washing fluid for microbial cultures.
The processed tissue is transferred to ultra low temperature freezer (at -80°C) for later sterilization.

Note:
The tissue can be stored at -80°C for up to 3 years and in -40°C for 6 months

To minimize cell damage and promote normal function we use Cryoprotectant and controlled rate freezing machine with specific protocol for cardiovascular, osteoarticular and soft tissues.
we also use Leophylization (freeze-drying) procedure for some musculoskeletal tissues.
this procedure can increase tissue's shelf life.

Our Products

- **Cryopreserved Tendon**
- **Lyophilzed Bone**
- **Frozen Bone**
- **Lyophilized Acellular Dermis Membrane**
- **Glycerolized Acellular Dermis Membrane**
- **Lyophilized Fascia Lata**
- **Lyophilized Pericardium Membrane**
- **in-Alcohol Cartilage**
- **Lyophilzed Amniotic Membrane**
- **Cryopreserved Heart Valve**
- **DBM Putty**
- **Collagen Filler**

Benefits

- This product is non-hemolytic and is compatible with surrounding blood cells.
- It is pH balanced (identical pH to Human blood, 7.2) and is suitable for stem cells.
- Biocompatibility and no need for hypersensitivity reaction test before usage.
- Easy to use and quick preparation.
- Fast graft and traceable source of all human tissues for a long period of time.
- Easy to use and quick to prepare.
- Fast graft Incorporation and complete remodeling potential.
- Biocompatibility.
- Safe, sterilized by gamma irradiation.
- No antigenicity.
- No donor site morbidity.
- 5 years shelf life at room temperature (lyophilized products).

Prudoct Name	Type	Size (mm)
Tibialis Tendon	Anterior	23 - 30 cm
	Posterior	23 - 30 cm

Achilles Tendon	with Bone Block	23 - 30 cm
	with out Bone Block	23 - 30 cm

Bone Patellar Tendon Bone	----------	15 - 22 cm

Double Tendon	Semi - Tendinosus + Semi - Membranosus	15 - 30 cm

Meniscus	Whole	Right
	Whole	Left

Tendon allografts offer a valuable solution when a patient's tendon is teared or damaged. These allografts have revolutionized orthopedic practices, providing remarkable advantages in tendon reconstruction. Processed under aseptic conditions and preserved through cryopreservation at -80°C, these allografts exhibit exceptional structural integrity and possess the ability of tendon reconstruction.

The aseptic processing techniques employed during procurement and processing ensure the preservation of allograft quality, minimizing the risk of contamination. This products are as a great solution in sport medicine surgeries such as ACL,PCL and total and subtotal menisectomy.

Furthermore, in cases where native tissue is absent, allografts, such as patellar tendon allografts, are employed for reconstruction. These allograft tendons find applications not only in sports medicine but also in foot and ankle surgery, as well as trauma cases.

MBA Powder (FDBA)	150 - 1000 µm
	500 - 1000 µm
	150 - 2000 µm

DBM & MBA Powder (DFDBA & FDBA)	150 - 1000 µm
	500 - 1000 µm

MBA Granule (FDBA)	1000 - 2000 µm

DBM & MBA Granule (DFDBA & FDBA)	1000 - 2000 µm

MBA Crushed (FDBA)	1 - 3 mm

MBA Chips (FDBA)	2 - 8 mm

Particulated bone allografts, derived from human bone tissue, are biomaterials used to fill bone defects and promote bone regeneration. They come in various particle sizes, each offering unique properties and applications.

Powdered allografts, the smallest particles, possess high integration capabilities and are suitable for small defects. Granule and crushed allografts are larger in size, serving as a foundation for bone regeneration and can be used as fillers or for augmentation.

Chip allografts, the largest among particulated bone grafts, provide a bone scaffold, making them ideal for .larger defects or augmentation

Volumes (cc)	
0.3	5.0
0.5	10.0
1.0	15.0
2.0	20.0

MBA Bone Block
(FDBA)

MBA Cube
(FDBA)

MBA Matchsick
(FDBA)

DBM Matchstick
(DFDBA)

Bone grafting using Cube, Matchstick and Block forms has revolutionized orthopedic and maxillofacial surgeries, offering distinct advantages due to their unique compositions. Cube and Matchstick configurations consist solely of cancellous bone, while block formations comprise a core of cancellous bone enveloped by a cortical surface. These allograft are meticulously processed to decellularization and ensure sterilization. The resulting grafts provide essential structural support and seamlessly integrate with the recipient's bone, promoting the formation of new bone.

Cube and block bone allografts effectively address osseous deficiencies caused by various conditions, from post-traumatic injuries to degenerative diseases and reconstructive procedures. In dental implantology, they serve as a reliable scaffold for augmenting deficient mandible and maxilla structures and facilitating successful implant placement. Moreover, in reconstruction surgeries, these grafts significantly contribute to restoring maxillofascial and skeletal, enabling patients to regain both physical form and function.

Ongoing refinement of bone grafting techniques, along with continued research and innovation, will further enhance the applications and outcomes of cube and block bone allografts, elevating the standard of care in orthopedic and maxillofacial surgeries.

Available Sizes (mm)
5 x 5 x 12
5 x 5 x 25
10 x 10 x 10
20 x 10 x 5
20 x10 x10

Lyophilized Bone Section

Fibular Shaft Bone

Femoral Shaft Bone

Tibial Shaft Bone

Size (mm)
L=60 mm
L=80 mm
L=10 cm
L=12 cm
L≥15 cm

Allograft bone shafts are a valuable tool in orthopedic surgery, offering a unique and effective solution for a wide range of challenging conditions. These grafts provide a structural scaffold that seamlessly integrates into the recipient's bone, promoting bone formation with weight-bearing features.

These products epitomize the convergence of strength and versatility in orthopedic care. Their ability to provide immediate structural support, promote bone growth, and reduce infection risk makes them an essential tool in addressing a wide spectrum of challenging clinical scenarios. Whether repairing large bone defects, facilitating limb-sparing procedures, or promoting healing in nonunions, allograft bone shafts stand as a testament to the power of regenerative medicine in orthopedics.

Lyophilzed Bone Wedge

Tibial Wedge

Tri-Cortical Iliac Wedge

Patellar Wedge

Bone wedge allografts are typically composed of dense cancellous bone with either no cortical ridges or a single/multiple cortical ridges.

The cancellous bone provides a natural scaffold for bone ingrowth, while the cortical ridges provide additional structural support.

Edge Lenght	Height (mm)
E<30×30×30 mm	H<12 mm
	H= 12 - 15 mm
	H≥15 mm
E>30×30×30 mm	H<12 mm
	H= 12 - 15 mm
	H≥15 mm

Product Name
Femur Bone
Tibia Bone
Fibula Bone
Humeus Bone
Ulna Bone
Radius Bone
Iliac Crest Bone

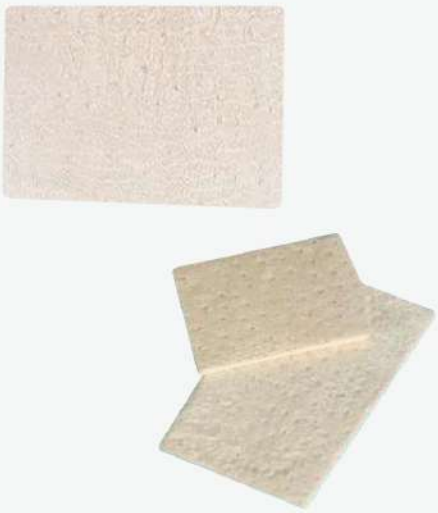
Lorem iFrozen bone allografts are invaluable in addressing various medical challenges, particularly in cases involving extensive tumors, orthopedic infections, and limb-sparing procedures. These allografts offer numerous advantages, including structural support, restoration of bone integrity, and the stimulation of cellular incorporation for healing. This underscores the versatility and effectiveness of fresh-frozen whole bone allografts.

By utilizing these allografts as an alternative to amputation in osteosarcoma cases, we make significant strides in preserving skeletal functionality and improving the overall quality of life for patients. To mitigate potential risks such as immune rejection and disease transmission, we employ a comprehensive understanding of the complexities associated with the use of whole bone allografts.

Our grafts are sterilized with high-dose gamma irradiation, reducing these risks. Moreover, we prioritize rigorous screening and testing procedures to align with best practices, ensuring patient safety is our topmost concern.

Size (mm)	Bone Section
L < 15 cm	Whole
L = 15 - 22 cm	Distal
L ≥ 23 cm	Shaft
	Proximal

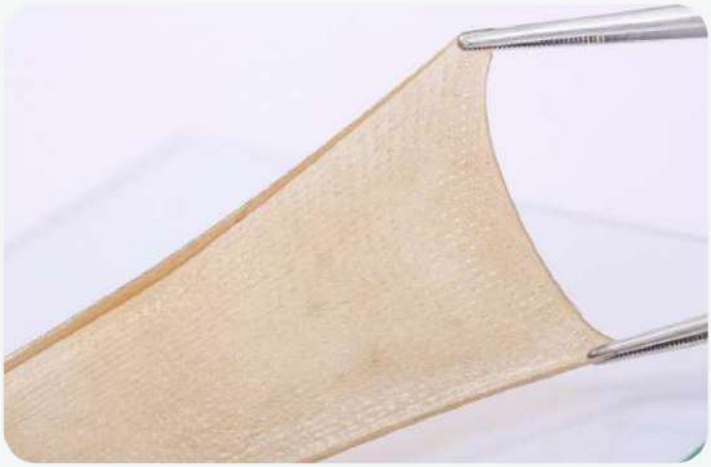
Lyophilized Acellular Dermis Membrane



The lyophilized acellular dermis membrane (ADM) contains basement membrane on one of its surfaces. It can provide a dense and impenetrable layer against microorganism and pathogen penetration into deeper layers. So the membrane surface can stay exposed in high-perfused tissue of the oral cavity.
The product origin is the collagen membrane (skin dermal layer), which consists of strong collagen type I and III fibres that strengthen the product, and also elastic fibres causing flexibility. This collagen membrane results in product's unique features.

Thickness (mm)	Size (mm)
0.3 ~ 0.4	10 x 15
0.4 ~ 0.6	15 x 20
0.6 ~ 1.0	20 x 30
1.0 ~ 1.8	20 x 40

Glycerolized Acellular Dermis Membrane



Glycerolized skin is processed from donated human skin and contains dermal collagen and elastic fibers. The product has become acellular using enzymatic and chemical treatment methods, so its antigenic properties are eliminated, while the natural structure of the collagen and elastic fibers, basal membrane, and the three-dimensional tissue structure are preserved.
Glycerolized Acellular Dermis Membrane is presented in a glycerolized form as a biologic dressing to treat burning, trauma, and other complicated ulcers in different sizes.

Thickness (mm)	Size (mm)
0.3 ~ 0.5	<100 cm^2
0.5 ~ 0.8	≥100 cm^2

The product is processed from human Fascia Lata and is available as lyophilized products in various sizes. Due to its flexibility, adhesiveness, and biocompatibility, it can easily be used at the operation site, causing volume enhancement and providing mechanical strength.

Fascia Lata is commonly used for ligament reconstruction, repair of craniotomy and dural defects, eyelid repair, and bladder suspension. This soft tissue graft is derived from the lateral surface of the thigh.

Fascia lata allograft membrane is particularly useful in ligament reconstruction, dural repair, eyelid repair, and bladder suspension. In ligament reconstruction, it provides structural support and helps to restore joint stability and function. For dural repair, it mends cerebrospinal fluid leaks and dural defects, preventing complications like meningitis and spinal fluid leakage. In eyelid repair surgeries, it offers valuable support and stability to the eyelid tissue, facilitating the restoration of its structural integrity and preventing complications like ectropion and entropion. Finally, in bladder suspension surgeries, it provides support to the bladder and helps to restore its normal position in cases of pelvic organ prolapse.

Thickness (mm)	Size (mm)
< 0.5	25 x 50
0.5 - 1.0	45 x 85
≥ 1.0	85 x 85

Lyophilized Pericardium Membrane

Thickness (mm)	Size (mm)
< 0.5	10 x 15
	15 x 20
≥ 0.5	20 x 30
	20 x 40
	10 x 15
	15 x 20
	20 x 30
	20 x 40

The pericardial membrane has two soft surfaces with approximate thicknesses of 0.3 to 0.8 mm. The product is presented to clients in a lyophilized form, after physical, chemical and anzymatic treatments and becoming acellular. It shows no immunologic or immunoreactive feature.

Pericardium is commonly used for pericardial defects, dura mater repair, and periodontal reconstruction in procedures such as GBR and GTR surgeries. These soft tissue grafts are derived from the pericardial sac.

Lyophilzed Amniotic Membrane

The product is processed from amniotic membrane and is available as a lyophilized product, in various sizes. This unique product shows high efficacy in wound healing, so it has abundant applications in wound healing in various surgeries.

The amniotic membrane consists of the epithelial cell layer, basal membrane, high-density collagen layer, fibroblast-like cell layer, and spongy layer.

Thickness (mm)	Size (mm)
0.2 ~ 0.5	100 x 100
	100 x 150

Our allogenous donated tissue Cartilages are derived from meticulously selected human costal cartilage or nasal septum sources. Through a rigorous processing procedure, these cartilages are transformed into high-quality slices that are soaked in alcohol and radiated. To ensure ease of use and optimal formability, our product is thoughtfully packaged in three-layered packages.

Costal Cartilage	Available Size (mm)	
	Slice	20 - 30 mm
		30 - 45 mm
	Block	45 - 60 mm
		20 - 30 mm
		30 - 45 mm
		45 - 60 mm

Nasal Septum	Available Size (mm)
	< 15×25 mm
	> 15×25 mm

Extensive research and a wealth of references consistently highlight the impressive durability of our allogenous radiated cartilage products. In fact, studies indicate that these products exhibit a remarkable durability rate of approximately 80%, surpassing even the durability of autografts. This outstanding durability is a testament to the meticulous processing methods employed during production.

This product offer a comprehensive solution for a wide range of surgical applications. Whether used in reconstructive procedures or as a support structure for grafting, our cartilages provide excellent structural integrity and longevity. Surgeons and medical professionals can rely on the high-quality and reliable performance of our cartilage products.

Aortic Heart Valve

Pulmonary Heart Valve

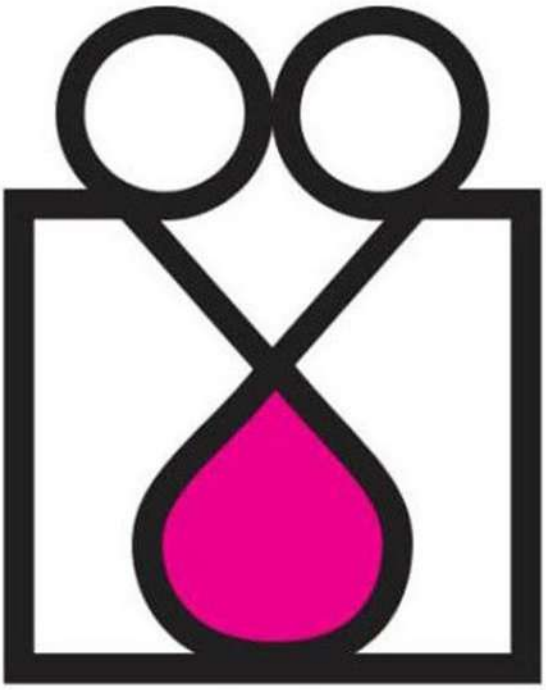
Our allograft heart valves undergo a meticulous and stringent screening and testing protocol to ensure the highest standards of safety. Each donor valve undergoes thorough evaluation and assessment. Following this, the valves are subjected to a comprehensive processing method, including treatment with an antibiotic solution aimed at mitigating potential biological risks.

The fixation process employed meticulously preserves the native tissue properties and microstructure of the valves, yielding allografts with exceptional durability and optimal hemodynamics. The resultant processed valves are ideally suited for deployment in cardiac and vascular surgeries, facilitating the repair of congenital defects and the effective treatment of valve insufficiency.

Our off-the-shelf allograft valves provide surgeons reliable options for various procedures. They can be implanted to address congenital issues, valve deficiencies, or deteriorating bioprosthetics. The goal is always to restore the patient's heart to a healthy state of function. Clinical studies show our allografts demonstrate excellent biocompatibility and low immunogenicity. The risk of structural degradation over time is also minimal.

As naturally derived human tissues, the allograft heart valves offer an advantageous alternative in some cases versus mechanical or xenograft substitutes. The allografts provide surgeons highly biocompatible materials for valve replacement or repair.

Thickness (mm)	Size (mm)
9 - 31	40 - 65



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itB
Iranian Tissue Bank

Phone: *021-66581520-21*

Website: *www. itbc.tums.ac.ir*

Email: *itbrc@sina.tums.ac.ir*

Address: *Tranplant Products Research and Bank Center- Dr Mirkhani Building- Imam Khomeini Hospital- Keshavarz Boulevard- Iran*