

Regen
ALLOGRAFT



Iranian Tissue Product Co.

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



Iranian Tissue Product Company

The Iranian Tissue Product Company, a privately established entity in 2012, originated from the Tehran University of Medical Sciences (TUMS) and has achieved remarkable success in producing allograft products in Iran. Our endeavors are endorsed by esteemed faculty members and specialists.

Our journey began with a focus on allograft products, leveraging modern sciences and adhering to international standards.

Our products stand as the preferred choice and gold standard for human body tissue lesion reconstructions, spanning soft tissue and bone. Operating as versatile scaffolds, volumizing agents, and biologic dressings, our offerings seamlessly integrate into diverse medical fields, consistently yielding exceptional results.

Adhering to the American Association of Tissue Banks (AATB) standards and protocols, our commitment to quality, effectiveness, and safety is unwavering. Continuous regulatory oversight by competent bodies, coupled with rigorous quality control and assurance measures, ensures that our products consistently meet the highest standards.

Choose the Iranian Tissue Product Company for cutting-edge solutions that redefine tissue regeneration and reconstruction, setting a new benchmark in healthcare excellence. For further inquiries or information, feel free to reach out to us.

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 |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------|
| <ul style="list-style-type: none"> ✓ HBc.Ab ✓ HIV 1,2 Ag-Ab ✓ HCV.Ab ✓ HBs.Ag ✓ HTLV.Ab ✓ R.P.R | <ul style="list-style-type: none"> ✓ Aerobic ✓ Anaerobic ✓ Yeast ✓ Fungi | <ul style="list-style-type: none"> ✓ Microbial Growth ✓ Bioburden ✓ Cellular Viability ✓ Sterility ✓ Sensitization ✓ Endotoxin ✓ Irratitation | <ul style="list-style-type: none"> ✓ Moisture Limit ✓ Chemical Residue ✓ Biomechanical Strenght |

Our Products

- Cryopreserved Tendon
- Lyophilized Bone
- Frozen Bone
- Lyophilized Acellular Dermis Membrane
- Glycerolized Acellular Dermis Membrane
- Lyophilized Fascia Lata
- Lyophilized Pericardium Membrane
- in-Alcohol Cartilage
- Lyophilized 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).

Cryopreserved Tendon



| Product 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 torn 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.

Lyophilized Particulated Bone



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 |

Lyophilized Shaped Bone



MBA Bone Block
(FDDB)



MBA Cube
(FDDB)



MBA Matchstick
(FDDB)



DBM Matchstick
(DFDB)

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 allografts 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 maxillofacial 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

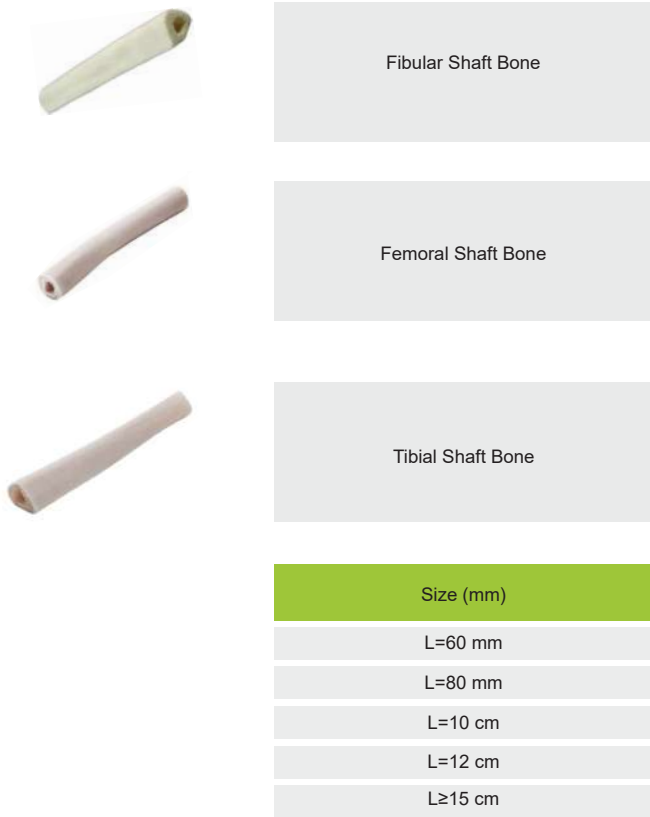
5 x 5 x 25

10 x 10 x 10

20 x 10 x 5

20 x 10 x 10

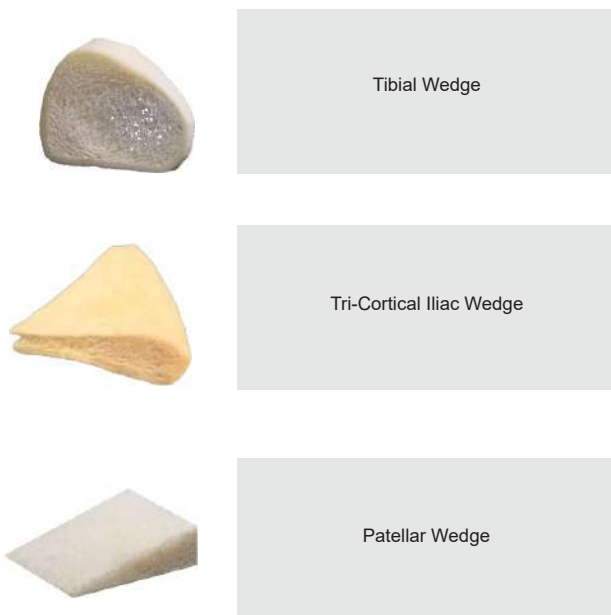
Lyophilized Bone Section



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.

Lyophilized Bone 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 Length | 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



Humerus Bone



Ulna Bone



Radius Bone



Iliac Crest Bone

Frozen 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 |

Lyophilized Fascia Lata



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 enzymatic 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.

Lyophilized 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 |

Costal Cartilage

Our allogeneous 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 |



Extensive research and a wealth of references consistently highlight the impressive durability of our allogeneous 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.

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





Aortic 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.



Pulmonary Heart Valve

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 |



Demineralized bone matrix (DBM) putty is a highly specialized bone graft material that has emerged as a valuable tool in the surgical management of bone defects. Derived from human or animal bone that has been processed to remove its mineral components, DBM putty presents a soft, malleable scaffold richly endowed with osteoconductive and osteoinductive properties. These properties enable DBM putty to serve as a platform for bone cell attachment, proliferation, and differentiation, fostering the regeneration of new bone tissue.

DBM putty offers a range of advantages over traditional autografts (bone grafts harvested from the patient's own body) and allografts (bone grafts sourced from cadavers). Its osteoconductive nature allows it to seamlessly integrate with the surrounding bone, while its osteoinductive capacity stimulates the production of bone-forming proteins, accelerating the healing process.

The biocompatible carrier in which DBM putty is incorporated plays a crucial role in its moldable and easy-to-form nature. This carrier, typically a combination of collagen and alginate, provides the putty with its desired consistency, allowing surgeons to precisely shape and contour it to fill bone voids of various sizes and configurations. The carrier also contributes to the overall bioactivity of DBM putty, enhancing its ability to promote bone regeneration.

| Volume (cc) |
|-------------|
| 0.5 |
| 0.1 |
| 2.0 |
| 5.0 |



Allogeneic collagen gel is typically formulated in a hyaluronic acid carrier, which acts as a delivery system for the collagen particles. The hyaluronic acid carrier is a naturally occurring substance in the skin that provides hydration and plumpness. By incorporating hyaluronic acid, the collagen gel can achieve a smoother, more natural-looking result.

In addition to its hyaluronic acid carrier, allogeneic collagen gel also benefits from a specific cross-linking process that enhances its durability. This process involves chemically bonding the collagen fibers together, making them more resistant to breakdown by enzymes. As a result, allogeneic collagen gel can provide a longer-lasting result compared to some other types of dermal fillers. This makes it a popular choice for patients seeking a more sustainable solution for wrinkle reduction and volume enhancement.

Collagen gel is a filler made from allogeneic collagen tissue sources, and it is provided in a cross-linked form. The product durability is higher than that of available collagen gels because the primary source of this filler is the collagen obtained from the human skin dermal layer, and it consists of type I and III high-density collagen fibers strengthened through the specific cross-linking process.

Collagen is a natural protein that gives the skin its strength and elasticity. Allogeneic collagen gel is used to reduce the appearance of wrinkles and folds, and to restore volume to nas. It is a popular option for dermal fillers because it is relatively safe and effective, and it is also relatively affordable compared to other types of dermal fillers.

| Volum (cc) |
|------------|
| 1.0 |
| 5.0 |

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