

Dentistry, Periodontology, Oral & Maxillofacial surgery



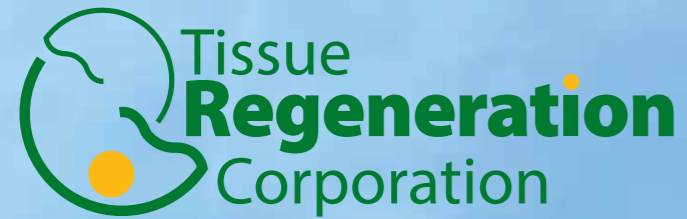
**Tissue
Regeneration
Corporation**



ISO13485:2003
MD 558259



ISO9001:2008
FM 553061



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 tested 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 PCR 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 FDA 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 <0.5 aW (water activity) eliminating the potential for microbial growth and minimizing autodegradative reactions. Irradiation is carried out to an established protocol ensuring a minimum dose of 25KGY 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.

SHIPPING AND INSTRUCTION TO USE



All shipping arrangements are made and handed on an individual basis. The product is usually delivered by either TRC transport or via the express special mail as special delivery in a padded envelope usually direct to the point of use e.g. theatre. More urgent delivery e.g. same day or by specified time can be arranged at additional cost. Where an operation is graft critical, the patient must not be taken to theatre before the graft has arrived and its condition checked. Deep freeze products will be sent packed in dry ice (-70°C). Vapor phase LN2 shipper (-130°C) is also available in the event of extended transport durations. These products should be stored in -60°C or lower temperature freezers as soon as they are received by the client. They should fully thaw prior to transplantation. Thawing protocols are attached to all frozen products. On the other hand, freeze-dried products should be transported and stored at room temperature until they are used. Such grafts should be stored away from direct sunlight at ambient temperature. They must be re-hydrated with a physiologic solution or the recipient's own blood prior to implantation for at least 30 minutes.

ORDERING



Extensive inventories are available for allograft tissues by Tissue Regeneration Corporation. Please contact us up to 2 weeks before the required time and specify both the type and specification of your desired product. Our staff will contact you as soon as possible and will send you the specifications along with digital photographs of the mentioned tissues and delivery options. We have a strict "Surgeon OK" program before your request is dispatched. In cases of urgency and special "rush orders", we can arrange the shipment of tissues to the client in less than 48 hours.

PRODUCTS LIST

Dentistry, Periodontology, Oral & Maxillofacial surgery



Note: Tissues listed below don't reflect the complete stock of our products, merely a representation of the types and sample size available in Tissue Regeneration Corporation. Please contact your representative for information pertaining to items not listed below.

CenoBone

Indication: Extraction socket preservation, Ridge augmentation and other periodontal, oral & maxillofacial applications. Bone powders are used as space filler for lost or insufficient bone tissue for tumor resectomy, traumas, bone cysts repair, prosthetics implants augmentation etc.



Cortical Cancellous Powder

Code	Description	Volume
29001	150-1000 µm	0.5 cc
29002	150-1000 µm	1 cc
29003	150-1000 µm	2 cc
29031	1000-2000 µm	0.5 cc
29032	1000-2000 µm	1 cc
29033	1000-2000 µm	2 cc
29041	150-2000 µm	0.5 cc
29042	150-2000 µm	1 cc
29043	150-2000 µm	2 cc



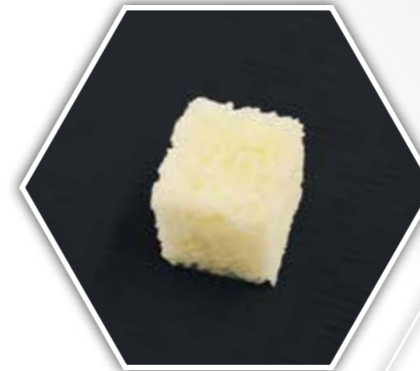
Cortical Cancellous Crushed

Code	Description	Volume
29052	2-5 mm	1 cc
29053	2-5 mm	2 cc
29054	2-5 mm	5 cc



Cortical Cancellous Chips

Code	Description	Volume
29062	2-10mm	1 cc
29063	2-10mm	2 cc
29064	2-10mm	5 cc



Cancellous Cube

Code	Description	Quantity
29071	5 × 5 × 5mm	1 Piece
29082	10 × 10 × 10mm	1 Piece



Cancellous Matchstick

Code	Description	Quantity
29091	5x35 mm	1 Piece



Cortico-Cancellous Strip

Code	Description	Quantity	Thickness
29180	10 × 10mm	1 Piece	(T) ≥ 4mm
29181	10 × 20mm	1 Piece	(T) ≥ 4mm
29182	10 × 40mm	1 Piece	(T) ≥ 4mm
29183	20 × 40mm	1 Piece	(T) ≥ 4mm





Ilium Bicortical Strip

Code	Description	Quantity	Thickness
28190	10 × 10mm	1 Piece	(T)=8-16 mm
28191	10 × 20mm	1 Piece	(T)=8-16 mm
28192	20 × 20mm	1 Piece	(T)=8-16 mm
28193	20 × 40mm	1 Piece	(T)=8-16 mm



Partial Demineralized Cortical Cancellous Powder

Code	Description	Volume
29901	150-1000 µm	0.5 cc
29902	150-1000 µm	1 cc
29931	1000-2000 µm	0.5 cc
29932	1000-2000 µm	1 cc
29941	150-2000 µm	0.5 cc
29942	150-2000 µm	1 cc



DBM Gel

Code	Volume
29610	0.25 cc
29611	0.5 cc
29612	1 cc



DBM Putty

Code	Volume
29621	0.5 cc
29622	1 cc



Demineralized Cortical Cancellous Powder

Code	Description	Volume
29501	150-1000 µm	0.5 cc
29502	150-1000 µm	1 cc
29503	150-1000 µm	2 cc
29531	1000-2000 µm	0.5 cc
29532	1000-2000 µm	1 cc
29533	1000-2000 µm	2 cc
29541	150-2000 µm	0.5 cc
29542	150-2000 µm	1 cc
29543	150-2000 µm	2 cc



Demineralized Cortical Cancellous Crushed

Code	Description	Volume
29552	2-5 mm	1 cc
29553	2-5 mm	2 cc
29554	2-5 mm	5 cc



Demineralized Cortical Cancellous Chips

Code	Description	Volume
29562	2 - 10 mm	1 cc
29563	2 - 10 mm	2 cc
29564	2 - 10 mm	5 cc



Demineralized Cancellous Cube

Code	Description	Quantity
29571	5 × 5 × 5mm	1 Piece
29582	10 × 10 × 10mm	1 Piece



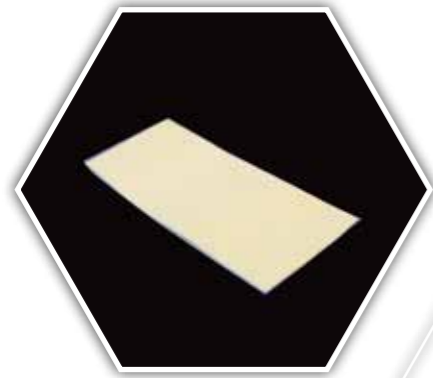


Demineralized Cancellous Matchstick

Code	Description	Quantity
29591	5×35mm	1 Piece

CenoMembrane

Indication: periodontal and oral applications for gingival soft tissue repair procedures, flap extensions over bone grafts, repair of recession defects or donor biopsy sites, GBR and GTR.

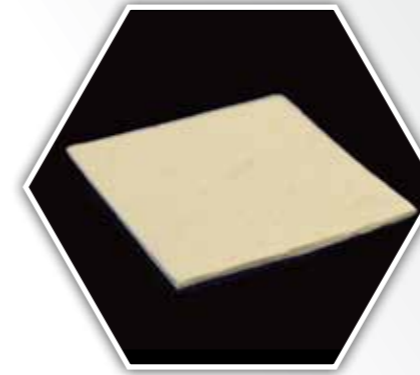


CenoMembrane

Code	Description	Quantity	Thickness
42810	10 × 10mm	1 Piece	T=0.2 - 0.6 mm
42811	10 × 20 mm	1 Piece	T=0.2 - 0.6 mm
42812	20 × 20mm	1 Piece	T=0.2 - 0.6 mm
42813	20 × 30 mm	1 Piece	T=0.2 - 0.6 mm
42814	20 × 40 mm	1 Piece	T=0.2 - 0.6 mm
42815	15 × 20 mm	1 Piece	T=0.2 - 0.6 mm
42820	10 × 10mm	1 Piece	T=0.6 - 0.9 mm
42821	10 × 20 mm	1 Piece	T=0.6 - 0.9 mm
42822	20 × 20mm	1 Piece	T=0.6 - 0.9 mm
42823	20 × 30 mm	1 Piece	T=0.6 - 0.9 mm
42824	20 × 40 mm	1 Piece	T=0.6 - 0.9 mm
42825	15 × 20 mm	1 Piece	T=0.6 - 0.9 mm
42830	10 × 10mm	1 Piece	T=1 - 1.4 mm
42831	10 × 20 mm	1 Piece	T=1 - 1.4 mm
42832	20 × 20mm	1 Piece	T=1 - 1.4 mm
42833	20 × 30 mm	1 Piece	T=1 - 1.4 mm
42834	20 × 40 mm	1 Piece	T=1 - 1.4 mm
42835	15 × 20 mm	1 Piece	T=1 - 1.4 mm

CenoDerm

Indication: periodontal and oral applications for gingival soft tissue repair procedures, flap extensions over bone grafts, repair of recession defects or donor biopsy sites, GBR and GTR.



CenoDerm

Code	Description	Quantity	Thickness
51810	10 × 10mm	1 Piece	T=0.2 - 0.6 mm
51811	10 × 20 mm	1 Piece	T=0.2 - 0.6 mm
51812	20 × 20mm	1 Piece	T=0.2 - 0.6 mm
51813	20 × 30 mm	1 Piece	T=0.2 - 0.6 mm
51814	20 × 40 mm	1 Piece	T=0.2 - 0.6 mm
51815	15 × 20 mm	1 Piece	T=0.2 - 0.6 mm
51820	10 × 10mm	1 Piece	T=0.6 - 0.9 mm
51821	10 × 20 mm	1 Piece	T=0.6 - 0.9 mm
51822	20 × 20mm	1 Piece	T=0.6 - 0.9 mm
51823	20 × 30 mm	1 Piece	T=0.6 - 0.9 mm
51824	20 × 40 mm	1 Piece	T=0.6 - 0.9 mm
51825	15 × 20 mm	1 Piece	T=0.6 - 0.9 mm
51830	10 × 10mm	1 Piece	T=1 - 1.4 mm
51831	10 × 20 mm	1 Piece	T=1 - 1.4 mm
51832	20 × 20mm	1 Piece	T=1 - 1.4 mm
51833	20 × 30 mm	1 Piece	T=1 - 1.4 mm
51834	20 × 40 mm	1 Piece	T=1 - 1.4 mm
51835	15 × 20 mm	1 Piece	T=1 - 1.4 mm
51840	10 × 10mm	1 Piece	T> 1.4mm
51841	10 × 20 mm	1 Piece	T> 1.4mm
51842	20 × 20mm	1 Piece	T> 1.4mm
51843	20 × 30 mm	1 Piece	T> 1.4mm
51844	20 × 40 mm	1 Piece	T> 1.4mm
51845	15 × 20 mm	1 Piece	T> 1.4mm



**Tissue
Regeneration
Corporation**

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