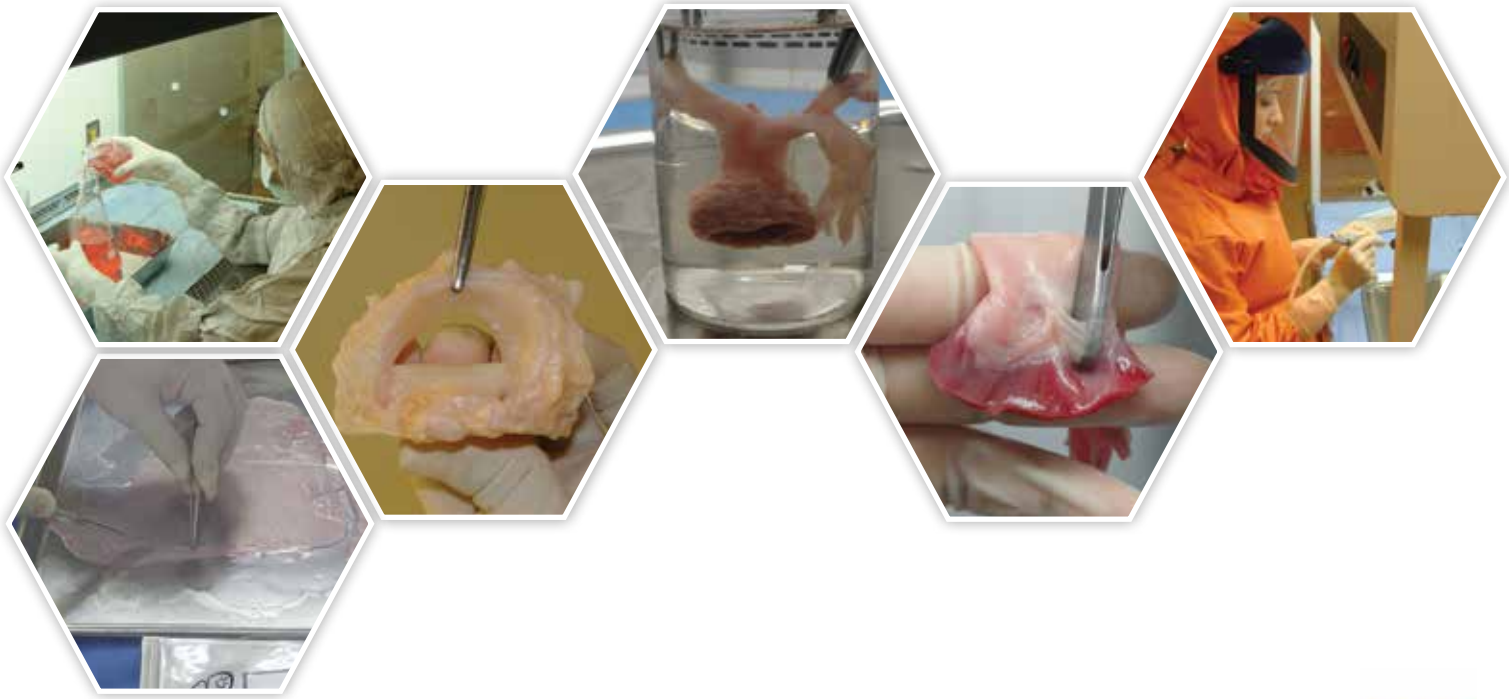
Tissue Engineering For Regenerating Life

Cryopreserved Products



Tissue Regeneration Corporation

BSI British Standards

ISO13485:2003 MD 558259

ISO9001:2008 FM 563061

Tissue Regeneration Corporation

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.

BSI British Standards

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STATE-OF-THE-ART PRODUCTION

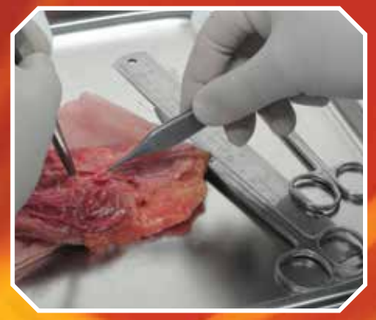
Tissue Regeneration Corporation adheres to strict policies and procedures that were devised in line with the guidelines and standards of the FDA and UK codes of practice for productions of human derived therapeutic materials. All tissues are procured in a class 1000 environment and processed in sterile 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 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 autodegredative 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

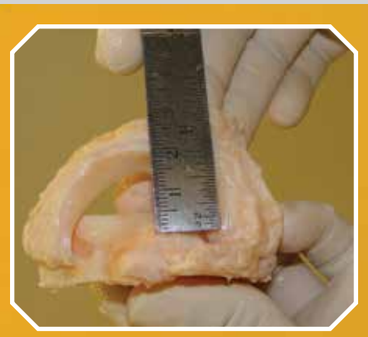


Tissues engineered products from allogenic sources are used in many surgical procedures because they are naturally biocompatible and can be remodeled to the patient's own bone. They simplify potential revision procedures, and they eliminate second site morbidity and pain that may result from autograft 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.

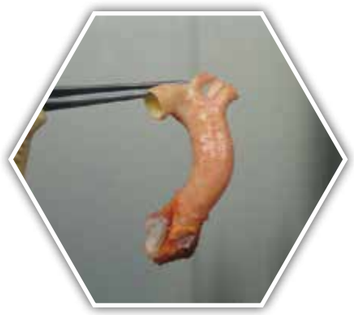
PRODUCTS LIST

Cryopreserved Products

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.

CenoValve

Indication: Allograft bio-implants for cardiac and vascular procedures. Suitable for a wide variety of complex congenital heart defects and adults with extensive valvular disease as well as for managing vascular reconstruction including aortic stenosis or atresia, hypoplastic left heart, repair of RVOTs (Right Ventricular Outflow Tract), pulmonary atresia, truncus arteriosus, Ross procedure, single ventricle/double outlet (Fontan), hypoplastic left heart (modified Fontan), tetralogy of Fallot, RVOT/ root enlargement procedures, ASD/VSD repair, transposition of great vessels, Peripheral Vascular Disease (PVD), Infected Synthentic Graft Replacement etc.

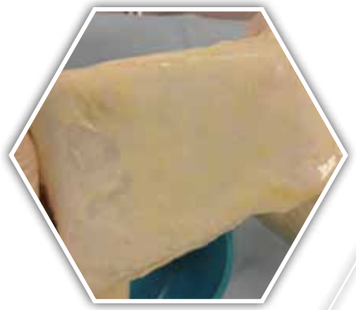


CenoValve

Code	Item	Size
703109	Aortic heart valve	D: 9mm
703111	Aortic heart valve	D: 11mm
703113	Aortic heart valve	D: 13mm
703115	Aortic heart valve	D: 15mm
703117	Aortic heart valve	D: 17mm
703119	Aortic heart valve	D: 19mm
703121	Aortic heart valve	D: 21mm
703123	Aortic heart valve	D: 23mm
703125	Aortic heart valve	D: 25mm
703127	Aortic heart valve	D: 27mm
703129	Aortic heart valve	D: 29mm
703131	Aortic heart valve	D: 31mm

CenoValve (Continue)

Code	Item	Size
713109	Pulmonary heart valve	D: 9mm
713111	Pulmonary heart valve	D: 11mm
713113	Pulmonary heart valve	D: 13mm
713115	Pulmonary heart valve	D: 15mm
713117	Pulmonary heart valve	D: 17mm
713119	Pulmonary heart valve	D: 19mm
713121	Pulmonary heart valve	D: 21mm
713123	Pulmonary heart valve	D: 23mm
713125	Pulmonary heart valve	D: 25mm
713127	Pulmonary heart valve	D: 27mm
713129	Pulmonary heart valve	D: 29mm
713131	Pulmonary heart valve	D: 31mm
703409-31	Aortic conduit	D: 9-31mm
713409-31	Pulmonary conduit	D: 9-31mm
713301	Hemi-pulmonary artery	L=20-80mm
713201	Mono cusp patch	W/L varies
713501	Pulmonary patch	20*20
713502	Pulmonary patch	30*30
713503	Pulmonary patch	20*40
713504	Pulmonary patch	20*60
753401	Femoral artery	L<50mm D: 5-15mm
753402	Femoral artery	L=50-100mm D: 5-15mm
753403	Femoral artery	L>100mm D: 5-15mm
743401	Saphenous vein	L<40cm D: 2-4mm
743402	Saphenous vein	L=40-80cm D: 2-4mm
743403	Saphenous vein	L>80cm D: 2-4mm
423501	Pericardial patch	20*20
423502	Pericardial patch	30*30

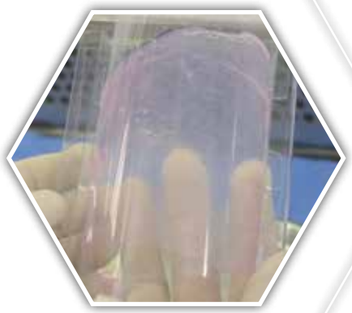


CenoValve (Continue)

Code	Item	Size
423503	Pericardial patch	40*40
423504	Pericardial patch	50*50
423505	Pericardial patch	60*60
423506	Pericardial patch	70*70
423507	Pericardial patch	80*80
423508	Pericardial patch	90*90
423509	Pericardial patch	100*100

AmniPatch

Indication: In ophthalmology, where it is used to proceed reepithelialization for a variety of procedures in conjunctival and corneal problems; in dermatology, where it is used to treat and protect skin burns or help heal the torpid ulcers; in general surgery, where it prevents post- surgery adhesions; in neurosurgery for brain operations and for the reconstruction of urinary and genital apparatus.

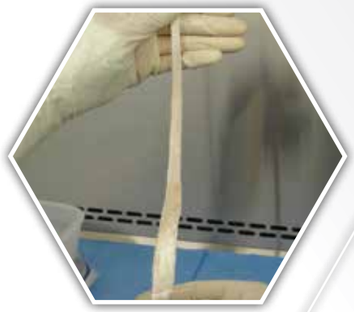


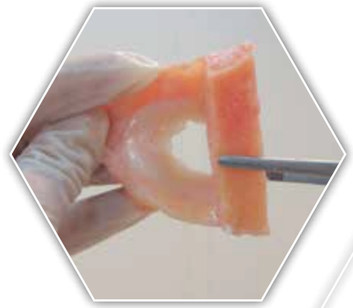
AmniPatch

Code	Item	Size
41411	Antibiotic Impregnated Amniotic Membrane	20*20
41412	Antibiotic Impregnated Amniotic Membrane	30*30
41413	Antibiotic Impregnated Amniotic Membrane	40*40
41414	Antibiotic Impregnated Amniotic Membrane	50*50
41415	Antibiotic Impregnated Amniotic Membrane	60*60
41416	Antibiotic Impregnated Amniotic Membrane	70*70
41417	Antibiotic Impregnated Amniotic Membrane	80*80
41418	Antibiotic Impregnated Amniotic Membrane	90*90
41419	Antibiotic Impregnated Amniotic Membrane	100*100

CenoTendon

Indication: Anterior Cruciate Ligament (ACL) reconstruction, Posterior Cruciate Ligament (PCL) reconstruction, Achilles tendon repair, Reconstruction or augmentation of the rotator cuff and any other tendon soft tissue augmentation or repair.





CenoTendon

Code	Item	Description	Size
31462	Patellar Bone + Patellar Tendon + Tibial Bone(BTB)	Pre-shaped	(W)=17-13 mm (L)=150-80 mm
32471	Achilles Tendon with Calcaneus	Whole	(W)=20-10 mm (L)=300-160 mm
32462	Achilles tendon with Calcaneus	Hemi	(W)=12-6 mm (L)=300-160 mm
32481	Achilles Tendon without Calcaneus	Whole	(W)=20-10 mm (L)=300-160 mm
32482	Achilles tendon without Calcaneus	Hemi	(W)=12-6 mm (L)=300-160 mm
33483	Proneus Longus Tendon	Whole	(Folded Diameter)=12-6 mm (L)=380-220 mm
34483	Posterior Tibialis Tendon	Whole	(Folded Diameter)=12-6 mm (L)=380-220 mm
35483	Anterior Tibialis Tendon	Whole	(Folded Diameter)=12-6 mm (L)=380-220 mm
36483	Semitendinosus Tendon	Whole	(W)=10-3 mm (L)=380-220 mm
37483	Gracilis Tendon	Whole	(W)=10-3 mm (L)=380-220 mm
38461	Medial Meniscus	with Tibial Plateau Bone Block	W/L varies
38462	Lateral Meniscus	with Tibial Plateau Bone Block	W/L varies

Instructions for thawing contents and dilution of cryoprotectant

1.Two sterile 500 ml basins and one sterile 5000 ml basin are needed.

2.Pour approximately 3000 ml of 40ºc sterile saline into large basin.

3.Pour 300 ml 4-10ºc RPMI or M199 sterile tissue culture medium into one of the 500 ml basins.
Note: you can use sterile isotonic fluid instead of culture medium (without adding recipient blood) but if there is more than 5 hours between thawing and implantation time, we recommend using culture medium or adding heparinized recipient blood to your isotonic fluid in thawing process.

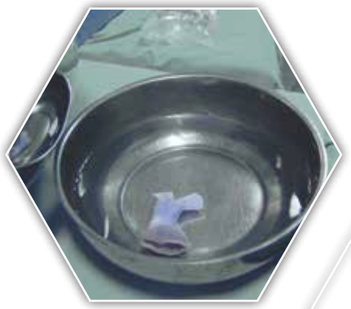
4.Remove the cryopreserved CenoValve/CenoTendon pouch form the cryotransport container and dry the outer surface of the pouch thoroughly.

5.Scrub the opening site using proper disinfectants. Circulating nurse then opens the pouch with sterile scissors.
Note: Be careful not to contaminate the inner part of the sterile pouch.

6.Contents are presented to the scrubbing nurse who retrieves the inner sterile pouch with a kocher clamp.

7.Place inner pouch in the large basin and gently agitate the pouch for 3-4 minutes.

8.Add 1000 ml of warmed saline to a large basin and gently agitate the pouch for additional 3-4 minutes.



9.Glycerol is not toxic in 37ºc therefore allow medium to completely thaw. Open the pouches with sterile scissors and pour their content into the empty sterile small basin.

10.Add 50 ml of tissue culture medium from its basin to the CenoValve/CenoTendon containing basin. Gently agitate for 2 minutes.

11. Add another 150 ml of tissue culture medium from it's basin to the CenoValve /CenoTendon containing basin. Gently agitate for 2 minutes.
Note: use sterile 50 cc syringes for adding medium.

12. The CenoValve/CenoTendon should be removed by the surgeon in sterile condition. Inspect for cracks or any damage and then place CenoValve/CenoTendon in another sterile 100 ml medium containing basin (100 ml remaining). Gently agitate for 2 minutes.
Note: Don't use CenoValve/CenoTendon if there is any crack or damage throughout thawing process.

13. Maintain the CenoValve/CenoTendon completely immersed within this basin until needed for implantation. We recommend obtaining approximately 50 ml of recipient's heparinized blood and Add to CenoValve/CenoTendon containing basin.

14. If the prepared CenoValve/CenoTendon is not soon implanted, place the basin of CenoValve/CenoTendon on ice until needed.

15. A sample of the CenoValve /CenoTendon may be obtained for culturing, at surgeons discretion, to ensure sterility.
Note: please report any adverse reactions due to CenoValve/CenoTendon to TRC (Tissue Regeneration Corporation).

Tissue Engineering For Regenerating Life

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