



Tissue Engineering For Regenerating Life

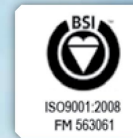


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TRC (Tissue regeneration corporation) is a multi-facility institute specializing in the preparation of a wide range of grafts based on the science of tissue engineering. Tissue engineering is an emerging science that aims to regenerate existing biological 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, HBe 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

Orthopedic and Spine surgeries



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: Augmentation of internal fixation and hip revision surgeries, in corpectomy and spinal fusions, for structural applications involving bone loss and joint revision surgeries. Bone filler products are used as space filler for lost or insufficient bone tissue for tumor resections, traumas, bone cysts repairs, prosthetics implants augmentation etc. Also they are used in fractures and large skeletal defects repairs.



Cortical Cancellous Powder

Code	Description	Volume
29044	150-2000 µm	5 CC
29045	150-2000 µm	10 CC
29046	150-2000 µm	20 CC
29047	150-2000 µm	30 CC



Cortical Cancellous Crushed

Code	Description	Volume
29054	2-5 mm	5 CC
29055	2-5 mm	10 CC
29056	2-5 mm	20 CC
29057	2-5 mm	30 CC



Cortical Cancellous Chips

Code	Description	Volume
29064	2-10mm	5CC
29065	2-10mm	10 CC
29066	2-10mm	20 CC
29067	2-10mm	30 CC



Cancellous Cubes

Code	Description	Quantity
29074	5 × 5 × 5mm	5 CC
29075	5 × 5 × 5mm	10 CC
29076	5 × 5 × 5mm	20 CC
29084	10 × 10 × 10mm	5 CC
29085	10 × 10 × 10mm	10 CC
29086	10 × 10 × 10mm	20 CC



Cancellous Matchsticks

Code	Description	Quantity
29092	5x35 mm	5 Pieces
29093	5x35 mm	10 Pieces



Cortical Strut

Code	Description	Quantity
29101	5 × 40 mm	1 Piece
29104	10 × 40 mm	1 Piece
29105	5 × 100 mm	1 Piece
29106	10 × 100 mm	1 Piece
29107	15 × 100 mm	1 Piece



Cortico-Cancellous Strip

Code	Description	Quantity	Thickness
29183	20 × 40 mm	1 Piece	(T) ≥ 4mm
29184	20 × 60 mm	1 Piece	(T) ≥ 4mm



Cancellous Block

Code	Description	Quantity
29211	15 × 15 × 30 mm	1 Piece
29212	20 × 20 × 30 mm	1 Piece



Demineralized Cortical Cancellous Powder

Code	Description	Volume
29544	150-2000 µm	5 CC
29545	150-2000 µm	10 CC
29546	150-2000 µm	20 CC



Demineralized Cortical Cancellous Crushed

Code	Description	Volume
29554	2-5 mm	5 CC
29555	2-5 mm	10 CC
29556	2-5 mm	20 CC



Demineralized Cortical Cancellous Chips

Code	Description	Volume
29564	2-10mm	5 CC
29565	2-10mm	10 CC
29566	2-10mm	20 CC



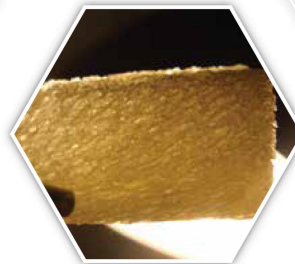
Demineralized Cancellous Cubes

Code	Description	Volume
29574	5 × 5 × 5mm	5 CC
29575	5 × 5 × 5 mm	10 CC
29576	5 × 5 × 5mm	20 CC
29584	10 × 10 × 10mm	5 CC
29585	10 × 10 × 10mm	10 CC
29586	10 × 10 × 10mm	20 CC



Demineralized Cancellous Matchsticks

Code	Description	Quantity
29592	5 x 35 mm	5 Pieces
29593	5 x 35 mm	10 Pieces



Demineralized Cancellous Block

Code	Description	Quantity
29711	15 × 15 × 30 mm	1 Piece
29712	20 × 20 × 30 mm	1 Piece



DBM Putty

Code	Volume
29623	2 cc
29624	5 cc



Femoral Shaft / Segment

Code	Description	Quantity
20131	H: 20 mm	1 Piece
20132	H: 40 mm	1 Piece
20133	H: 60 mm	1 Piece
20134	H: 80 mm	1 Piece
20135	H: 100 mm	1 Piece



Femoral Cross Section (Parallel)

Code	Description	Quantity
20113	H:10 mm	1 Piece
20114	H: 12 mm	1 Piece
20115	H: 14 mm	1 Piece
20116	H: 16 mm	1 Piece
20117	H: 18 mm	1 Piece
20118	H: 20 mm	1 Piece



Tibial Shaft / Segment

Code	Description	Quantity
22131	H: 20 mm	1 Piece
22132	H: 40 mm	1 Piece
22133	H: 60 mm	1 Piece
22134	H: 80 mm	1 Piece
22135	H: 100 mm	1 Piece



Fibular Shaft / Segment

Code	Description	Quantity
23131	H: 20 mm	1 Piece
23132	H: 40 mm	1 Piece
23133	H: 60 mm	1 Piece
23134	H: 80 mm	1 Piece
23135	H: 100 mm	1 Piece



Fibular Ring (Parallel)

Code	Description	Quantity
23162	H: 6 mm	1 Piece
23164	H: 8 mm	1 Piece
23166	H: 10 mm	1 Piece
23167	H: 12 mm	1 Piece
23168	H: 14 mm	1 Piece



Ilium Bicortical Strip

Code	Description	Quantity	Thickness
28193	20 x 40 mm	1 Piece	(T)=8-16 mm
28194	20 x 60 mm	1 Piece	(T)=8-16 mm



Tricortical Iliac Crest Wedge

Code	Description	Quantity	Length
28203	H=10mm	1 Piece	L: 22-40 mm
28204	H=12mm	1 Piece	L: 22-40 mm
28205	H=14mm	1 Piece	L: 22-40 mm
28206	H=16mm	1 Piece	L: 22-40 mm
28207	H=18mm	1 Piece	L: 22-40 mm
28208	H=20mm	1 Piece	L: 22-40mm



Tricortical Iliac Crest Strip

Code	Description	Quantity	Thickness
28211	10 × 20 mm	1 Piece	(T)=8-30 mm
28212	10 × 30 mm	1 Piece	(T)=8-30 mm
28213	20 × 40 mm	1 Piece	(T)=8-30 mm
28214	20 × 60 mm	1 Piece	(T)=8-30 mm



Tricortical Patellar Wedge

Code	Description	Quantity	Length
30203	H=10mm	1 Piece	L: 22-40 mm
30204	H=12mm	1 Piece	L: 22-40 mm
30205	H=14mm	1 Piece	L: 22-40 mm
30206	H=16mm	1 Piece	L: 22-40 mm
30207	H=18mm	1 Piece	L: 22-40 mm
30208	H=20mm	1 Piece	L: 22-40 mm

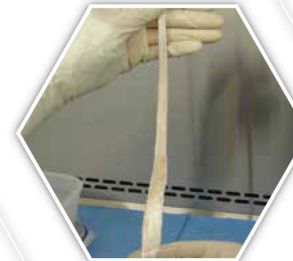


Tibial Wedge

Code	Description	Quantity	Length
22143	H=10mm	1 Piece	L: 22-60 mm
22144	H=12mm	1 Piece	L: 22-60 mm
22145	H=14mm	1 Piece	L: 22-60 mm
22146	H=16mm	1 Piece	L: 22-60 mm
22147	H=18mm	1 Piece	L: 22-60 mm
22148	H=20mm	1 Piece	L: 22-60 mm

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
31482	Patellar Bone + Patellar Tendon + Tibial Bone(BTB)	Pre-shaped	(W)=13-17 mm (L)=80-150 mm
32481	Achilles Tendon with Calcaneus	Whole	(W)=10-20 mm (L)=160-300 mm
32482	Achilles tendon with Calcaneus	Hemi	(W)=6-12 mm (L)=160-300 mm
32483	Achilles Tendon without Calcaneus	Whole	(W)=10-20 mm (L)=160-300 mm
32484	Achilles tendon without Calcaneus	Hemi	(W)=6-12 mm (L)=160-300 mm
33483	Proneus Longus Tendon	Whole	(Folded Diameter)=6-12 mm (L)=220-380 mm
34483	Posterior Tibialis Tendon	Whole	(Folded Diameter)=6-12 mm (L)=220-380 mm
35483	Anterior Tibialis Tendon	Whole	(Folded Diameter)=6-12 mm (L)=220-380 mm
36483	Semitendinosus Tendon	Whole	(W)=3-10 mm (L)=220-380 mm
37483	Gracilis Tendon	Whole	(W)=3-10 mm (L)=220-380 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 40°C sterile saline into large basin.

3. Pour 300 ml 4-10°C 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 CenoTendon pouch from 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 37°C 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 CenoTendon containing basin. Gently agitate for 2 minutes.

11. Add another 150 ml of tissue culture medium from its basin to the CenoTendon containing basin. Gently agitate for 2 minutes.

Note: use sterile 50 cc syringes for adding medium.

12. The CenoTendon should be removed by the surgeon in sterile condition. Inspect for cracks or any damage and then place CenoTendon in another sterile 100 ml medium containing basin (100 ml remaining). Gently agitate for 2 minutes.

Note: Don't use CenoTendon if there is any crack or damage throughout thawing process.

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

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

15. A sample of the CenoTendon may be obtained for culturing, at surgeon's discretion, to ensure sterility.

Note: please report any adverse reactions due to CenoTendon to TRC (Tissue Regeneration Corporation).





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