ANU LIFE SCIENCE

Liquid For single patient

Processed by Anu Life Sciences, Inc.

DESCRIPTION AND STORAGE CONDITIONS

Read this entire package insert carefully prior to use.
Single patient use only, on a single visit.

Restricted to sale by or on the order of a physician. Only qualified licensed professionals should transport/transplant this donated human tissue.
Regen Anu Rheo is aseptic amnion placental tissue and fluid. Regen Anu Rheo is preserved using proprietary minimally manipulated system that retains the extracellular matrix and 3D collagen structure of its scaffold of the amniotic membrane combined with the associated amniotic fluid. This allograft provides natural collagen scaffold to support replacement by endogenous tissue. This allograft implant is restricted to homologous use for the repair, replacement, reconstruction, or augmentation of human tissue. This allograft is **processed aseptically and cannot be sterilized.** Anu Life Sciences, Inc. assumes no responsibility for the clinical use of this allograft tissue, the administering licensed professional determines route and method of use solely.

Donor Screening and Testing

The donated human placental tissue is recovered by a non-profit organ procurement agency, after informed consent, screening for healthy mothers scheduled for elective Caesarian deliveries. The donors consent to the collection of this tissue, provided that its collection does not cause any harm to their infants. The donors blood was tested for relevant communicable diseases in a laboratory certified under the Clinical Laboratory Improvement Amendments of the 1988 (CLIA) or equivalent and registered with the FDA for donor testing. The following test criteria were met for this donor:

Required donor Testing All results must be reported negative or non reactive to allow release	**Allograft Release Testing** All results must be reported negative or non-reactive to allow release
Blood Test	
Hiv-1/ Hiv-2 Antibody	Endotoxin
Hepatitis C Virus Antibody	BioBurden
Hepatitis B Surface Antigen	
Hepatitis B Core Antibody (total	
Syphilis	Note:Screening for exposure to other viruses or parasites may have been completed. A negative/nonreactive result is not required, all results are evaluated on a case by case basis by CMO/Medical director.
Human T-Cell Lymphotropic Virus 1 Antibody	Cytomegalovirus CMV-AB (IgG&IgM)
Human T-Cell lymphotropic Virus 2 antibody	Epstein Barr EBV Ab(IgG&IgM)
HiV-1 / HCV NAT-TMA	Toxoplasma gondii Toxoplasma Ab (IgG&IgM)
Zika antibody	Trypansoma cruzi T.Cruzi Ab (IgG&IgM)
At the time of procurement, cultures of the tissue are taken and sent out for evaluation. Donor tissue with cultures testing positive for the following microorganisms are deferred: • *Clostridium* • *Streptococcus pyogenes* (group. A strep.) • *Enterococcus* • Fungi (mold or yeast phase)	

Additionally: The donor, as a screening tool in addition to blood analysis, completed social and medical questions. A licensed physician has reviewed the results of testing and determined the donor has met all eligibility requirements. The physician utilized available relevant information which may have included, but was not limited to: Donor interview, medical/hospital records, donor physical assessment, infectious disease test results, radiology/pathology and other records if available and pertinent. Recipient records must be maintained for the purpose of tracing tissue post-transplant per JCAHO and FDA requirements.

Warranty

This biologic allograft processed and packaged for surgical implantation, is unique and does not constitute a product under liability laws. No implied warranties of merchantability or fitness for a particular purpose are applicable. No implied warranties exist as to defects in biologics, which cannot be detected, removed, or prevented by reasonable use of available scientific procedures or techniques. Furthermore, all warranties are disclaimed, whether expressed or implied by operation of law or otherwise including all implied warranties of merchantability or fitness for a particular purpose.

Processing

Donor tissue is recovered using the safest techniques and sterile equipment to minimize any bio-burden contamination. The donor tissue is procured via a network of qualified and trained recovery partners, using the most stringent screening and recovery protocols in a controlled environment, minimizing and limiting the risks of disease transmission at every step of the process. All allografts are processed aseptically eliminating the need for terminal sterilization. This allograft implant was processed in a controlled environment from a single donor. Microbial testing was performed, where appropriate, and results met documented acceptance criteria. The allograft implant was released for transplantation based on the donor eligibility determination and review of processing records.

This product is **not STERILE**, the vial and contents are ASEPTIC **not STERILE**. The product is meticulously processed in an aseptic environment, every precaution was taken and exercised to insure the absence of any bio-burden. Testing has been completed according to USP71 sampling on bioburden.

Storage and Shipping

Store optimally in a clean environment **at -80C temperature** ,

Temperature can range from -40c to -192c until time for use**.**

Do not let this product thaw until it is time to use. Once thawed this product must be used within 15 minutes or discarded, it cannot be re-frozen.

This product is shipped in a validated shipping container with dry ice or equivalent at -65c or colder, and must arrive within the validated time for the container. The product should be transferred to an appropriate cold storage location prior to the expiration of the shipping container.

HCT/P tracking

Per 21 CFR 1271.290,… enable tracking from the donor to the consignee or final disposition must be maintained. Joint Commission standard QC.5.310.7 requires that "the organization that receives tissue provide a system that fully complies with the completion and return of tissue usage information cards requested by source facilities." To comply with these requirements, a Tissue Tracking/Transplant Record (TTR) and pre-printed labels are provided with every allograft. Record the patient information, the transplant facility name and address, the allograft tissue

information (using stickers) and comments regarding tissue use on the TTR. Return the completed TTR to Anu Life Sciences, and retain a copy in the patient medical record. Even if the tissue has been discarded for any reason, a completed TTR with the allograft identification must be returned to Anu Life Sciences, Inc.

Warnings

Same and similar potential medical/surgical, conditions or complications that apply to any surgical procedure may occur during or following implantation of this allograft. The physician or surgeon is responsible for informing patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, the potential for transmission of infectious agents may exist.

A small number of patients may experience localized immunological reactions to the implant and/ or trace amounts of residual chemicals (DMSO) from processing.

Precautions

Prior to use, the surgeon must become familiar with the implant and the surgical procedure.

The implant should be used with considerable caution in surgical sites where an active infection is present, in necrotic sites or in sites with poor perfusion.

The implant should NOT be used under high tension or pressure. We do **NOT** recommend use into the spinal canal, disc, or epidural space

Appropriate placement of the allograft is critical for successful outcomes.

Instructions for use

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties.

General instructions

1. For use on a single visit/surgery/episode for a single patient, it can not be shared or stored after thawing.
2. Remove the tube containing vial from plastic bag, Inspect the packaging and labeling materials carefully:
3. Do not use past expiration date specified on the product label.
    a. Do not use if the implant or packaging is damaged.
    b. Do not use if there are discrepancies in label information
    c. Return all packages with flaws in the sterile barrier, or lacking allograft or wrong size or wrong labeling
    d. To prevent contamination of the implant use sterile technique for preparation and implantation.
    e. Do not sterilize or re-freeze
    f. Use standard practices for handling and disposal of human tissue
    g. Promptly report all complaints and patient adverse events to BPSR or Anu Life Sciences.
    h. Take photographs if possible to document any concerns.
4. Open outer vial, remove inner vial, hold upright.
5. Thaw allograft by holding the inner vial in your hand, do not turn upside down or shake, thawing takes approximately 3 minutes.
6. **Packaging is not sterile**, if used in a surgical environment, use a sterile 18g needle to withdraw the allograft out of the vial into a sterile syringe. The contents of the vial are aseptic, the outer vial was prepared in an aseptic environment but it is not sterile.
7. Physician experience and knowledge are key to proper application and usage.
8. If unsure as to appropriate application, do not use until fully informed as to protocol and technique from an experienced user.
9. Mix with preservative free Saline preferably, can be mixed with BMA, PRP, Patients Blood, or 1%preservative free xylocaine/bupivacaine
10. Fill out the Tissue Tracking Record card (even if the allograft is discarded) and return to Anu Life Sciences. This information is kept confidential and used only for implant tracking.
11. Follow your patient and inform Anu Life Sciences of any adverse events, concerns, or questions immediately.

Customer Returns and Complaints:

An RMA is required for any and all tissue returns. Take photographs to document any damage, defects, or deficiencies, send to Anu via email ASAP. Call number below to request RMA

Disclaimer: It is the responsibility of the Tissue Dispensing Service, Tissue Distribution Intermediary, and/or End-User clinician to maintain tissue intended for transplant in appropriate storage containers and temperatures. Recipient records must be maintained for the purpose of tracing tissue post-transplantation. Anu Life Sciences, Inc., will not be liable for any damages, whether direct or indirect, special, incidental, or consequential, resulting from improper use of this allograft. The instructions for use are specific, and Anu Life Sciences, Inc. waives all responsibility associated with mishandling, inappropriately storing, and/or not taking proper precautions with the allograft tissue included with this insert.

Questions or concerns contact:

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FDA registration 3013239405
Trademarks are on file.: Regen Anu Rheo
Anu Life Sciences Inc, - Manufacturer
General Surgical of Florida, Inc – Distributor

	Read attached information on product use
	To be used with prescription only
	One time use on one recipient
 	Serial number and lot number in bar code
 	mfg date and expiration date in bar code and on product label