RHEO - Cryopreserved Amniotic Fluid, ECM Liquid

Processed by BioStem Life Sciences, Inc.

For single patient use only, on a single visit

DESCRIPTION AND STORAGE CONDITIONS

Read this entire package insert carefully prior to use.
Restricted to sale by or on the order of a physician. Only qualified licensed professionals should transport/transplant this donated human tissue.
RHEO is aseptic amnion placental tissue. RHEO is preserved using proprietary minimally manipulated system that retains the extracellular matrix and 3d collagen structure of its scaffold within the 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.** BioStem Life Sciences, 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 was recovered by a regulated procurement agency, after informed consent and screening for healthy mothers scheduled for elective Caesarian deliveries. The donor consents to the collection of this tissue, provided that its collection does not cause any harm to their infants. The donor's 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 US 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
Blood Test
HIV-1/ HIV-2 Antibody
Hepatitis C Virus Antibody
Hepatitis B Surface Antigen/ HBV NAT
Hepatitis B Core Antibody (total)
CMV with negative/nonreactive IgM antibody required
Syphilis
Human T-Cell Lymphotropic Virus 1 Antibody
Human T-Cell lymphotropic Virus 2 Antibody
HIV-1 / HCV NAT-TMA
West Nile Virus (WNV)
At the time of procurement, cultures of the tissue are taken and grown 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)

Allograft Release Testing For release testing on final product, Bioburden testing must present with "No Growth" results along with Endotoxin results ≤ 0.5 EU/ml.
NOTE: Screening for exposure to other viruses or parasites may have been completed. A negative / non-reactive result is not required, all results are evaluated by Medical Director: Cytomegalovirus CMV-AB (IgG&IgM) Epstein Barr EBV Ab (IgG-IgM) Toxoplasma gondii Toxoplasma Ab (IgG-igM) Trypansoma Cruzi T.Cruzi Ab (IgG-IgM), Lyme.

As a screening tool in addition to blood analysis, the donor completed a social and medical questionnaire. 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. **BioStem Life Sciences is cGMP, practices cGTP, is FDA registered and inspected** and follows national tissue bank, FDA, and other regulatory requirements. 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 by BioStem Life Sciences.

This product is **NOT STERILE**, the vial and contents are ASEPTIC **NOT STERILE**. This allograft implant was aseptically processed in a controlled environment from a single donor. Testing has been completed according to USP71 sampling on bioburden. The allograft contains less than 5% DMSO as cryoprotectant.

Storage and Shipping

Store in a clean environment **at -80C temperature**, temperature can range from **-65C 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. 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, 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 BioStem 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 BioStem 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.

Localized immunological response, injection site tenderness potentially can occur due to technique, allograft or less than 5% DMSO as cryoprotectant 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. BioStem Life Sciences does **NOT** recommend use in 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, this product cannot 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. Photograph and document all packages with compromised sterile barrier, lacking allograft, 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 BioStem 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 outside of the 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 (PREFERRED), can be mixed with BMA, PRP, Patients blood, or preservative free xylocaine/bupivacaine.
10. Fill out the Tissue Tracking Record card (even if the allograft is discarded) and return to BioStem Life Sciences. This information is kept confidential and used only for implant tracking.
11. Follow your patient, inform BioStem Life Sciences of any adverse events, concerns or questions immediately.

Customer Returns and Complaints:

BioStem Life Sciences, Inc. does not accept returns. If product is unusable please document why, take photographs of any damage, defects, or deficiencies and forward this information to info@biostemlife.com.

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. BioStem 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 BioStem 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:

BioStem Life Sciences Inc.
2836 Center Port Circle
Pompano Beach, FL 33064
877-940-8372 main
Email: info@biostemlife.com
www.biostemtech.com

FDA registration 3013239405
BioStem Life Sciences, Inc., Pompano Beach, Florida Manufacturer/Processor

	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 on product label