RHEO™

INSTRUCTIONS FOR USE

DONATED HUMAN TISSUE

THIS RHEO™ TISSUE HAS BEEN DETERMINED TO BE SUITABLE FOR TRANSPLANTATION

Read this entire package insert carefully prior to use.
For 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 tissue.
Not intended for veterinary use.

Distributed By:
BioStem Technologies, Inc.
2836 Center Port Circle
Pompano Beach, Fl. 33064

Processed By:
BioStem Life Sciences
2836 Center Port Circle
Pompano Beach, Fl. 33064

Description

RHEO™ is an aseptic amnion placental tissue allograft. **RHEO™** is preserved using a proprietary, minimally manipulated system which retains the extracellular matrix and three-dimensional collagenic structure of the scaffold within the amniotic fluid. This allograft provides natural collagen scaffolding 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 for this allograft.

Donor Screening and Testing

The donated human placental tissue and amniotic fluid was recovered by a regulated procurement agency, who, after having obtained both informed consent and healthy screening results for mothers scheduled for elective Caesarean deliveries, provided the donor tissue and amniotic fluid. The tissue 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 U.S. Food and Drug Administration (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:

- HIV-1/HIV-2 Antibody
- Hepatitis C Virus Antibody
- Hepatitis B Surface Antigen/ HBV NAT
- CMV with negative/nonreactive IgM antibody
- Hepatitis B Core Antibody (total)
- 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)

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 the Medical Director of BioStem Life Sciences:

- 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

The Medical Director (or licensed physician designee) of BioStem Life Sciences has reviewed the results of testing and determined the donor has met all eligibility requirements; as an additional screening tool to the blood analysis, the donor completed a social and medical questionnaire. Available relevant information for donor screening 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 tracing tissue post-transplant per the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), FDA and the American Association of Tissue Banks (AATB) requirements.

Processing

Donor tissue is recovered using current Good Tissue Practice (cGTP) and Sterile Technique that is designed to minimize bio-burden contamination. The donor tissue is procured via a network of qualified and trained recovery partners, using stringent screening and recovery protocols in a controlled environment, minimizing and limiting the risks of potential disease transmission at every step of the process. This allograft implant was aseptically processed in a sterile controlled environment from a single donor. Microbial testing was performed, where appropriate, and results of those tests met established and documented acceptance criteria. The allograft implant was released for transplantation based on the donor eligibility, independent third-party testing, and review and release of processing records related to this allograft.

This product is NOT STERILE, the vial and contents are ASEPTIC NOT STERILE. Third-party bioburden and endotoxicity testing of this allograft was performed in a laboratory certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) or equivalent and registered with the U.S. Food and Drug Administration (FDA) for donor tissue testing. Testing has been completed according to USP<71> sampling protocol on bioburden. The allograft contains 5% by volume DMSO as cryoprotectant.

Storage

RHEO™ allografts should be stored 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..

Packaging & Handling

RHEO™ is aseptically packaged and placed in a vial tube. The inner product vial containing the allograft is closed from the top of the vial.
This allograft must NOT be used under any of the following circumstances:

- If the packaged container is damaged or not intact.
- If the package label or identifying bar code is severely damaged, not legible or is missing; or
- If the expiration date shown on the package label has passed.

Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

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 or equivalent regulations require 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.

Contraindications

RHEO™ should not be used on: (1) areas with active or latent infection; and/or (2) into a patient with a disorder that would create an unacceptable risk of postoperative complications.

Warnings

Same and similar potential medical/surgical, conditions or complications that apply to any surgical procedure may occur during or following implantation or application of this allograft. The licensed medical professional performing medical or surgical application or implantation of the allograft is responsible for informing patient of the risks associated with their treatment and the possibility of complications or adverse reactions. While proprietary proccessing and validated sterilization methods are employed by BioStem Life Sciences to eliminate potential deleterious components of the allograft, as with all biological allografts, the possibility of rejection or immunologic response exists.

As with any human tissue allograft, the potential for transmission of infectious agents exists with use of **RHEO™** allografts.

Any adverse reactions, including the suspected transmission of disease attributable to this allograft, should be immediately reported to BioStem Life Sciences.

- **OUTER PACKAGING IS NOT STERILE.**
- **DO NOT STERILIZE OR AUTOCLAVE THE PRODUCT BEFORE USE.**
- **DO NOT FREEZE.**
- **FOR USE ON A SINGLE VISIT/SURGERY/EPISODE FOR A SINGLE PATIENT; IT CANNOT BE SHARED OR REUSED AFTER OPENING.**
- **DO NOT USE PAST EXPIRATION DATE SPECIFIED ON THE PRODUCT LABEL.**
- **DO NOT USE IF THE VIAL OR PACKAGING IS DAMAGED.**
- **DO NOT USE IF THERE ARE DISCREPANCIES IN LABEL INFORMATION.**
- **DO NOT FREEZE.**

Precautions

RHEO™ is intended for single-patient use only. Discard all unused material according to standard practices for handling and disposal of human tissue.

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

General Instructions

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

- Once the allograft container has been opened, the allograft shall be transplanted, or otherwise discarded.
- Once removed from packaging and thawed the allograft must be used within 15 minutes.
- DO NOT USE THE ALLOGRAFT if the packaging integrity has been compromised.
- To prevent contamination of the vial, use sterile technique for preparation and implantation.

Use standard clinical practices for handling and disposal of human tissue. Prior to application, carefully follow the RHEO™ allograft preparation steps below using aseptic technique:

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.
4. Do not use if the implant or packaging is damaged.
5. Do not use if there are discrepancies in label information
6. Photograph and document all packages with compromised sterile barrier, lacking allograft, wrong size or wrong labeling
7. To prevent contamination of the implant, use sterile technique for preparation and implantation.
8. Do not sterilize or re-freeze
9. Use standard practices for handling and disposal of human tissue
10. Promptly report all complaints and patient adverse events to BioStem Life Sciences.
11. Take photographs if possible, to document any concerns. Open outer vial, remove inner vial, hold upright.
12. Thaw allograft by holding the inner vial in your hand, do not turn upside down or shake, thawing takes approximately 3 minutes.
13. 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.
14. Physician experience and knowledge are key to proper application and usage.
15. If unsure as to appropriate application do not use until fully informed as to protocol and technique from an experienced user.
16. Mix with preservative free Saline (PREFERRED)
17. 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.
18. Follow your patient, inform BioStem Life Sciences of any adverse events, concerns or questions immediately.

Customer Returns and Concerns

BioStem Life Sciences does not accept any returns. If product is unusable, please document the reason 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 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 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
http://biostemtechnologies.com
quality@biostemlife.com

FDA registration: 30133239405
AATB Accredited Member #00327
Trademarks are on file
BioStem Life Sciences, Inc., Pompano Beach, Florida
Manufacturer/Processor

	Read attached information on product use
	One time use on one recipient
	Serial number and lot number in bar code
	Manufacturing date and expiry date on product label