OROPRO™ CRYOPRESERVED UMBILICAL CORD ALLOGRAFT

OROPRO™

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

INSTRUCTIONS FOR USE

DONATED HUMAN TISSUE

THIS 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.**
- **Not intended for IV use.**

Description

OROPRO™ is a versatile product that is derived from donated human birth tissue. The allograft contains tissue elements that are inherent to an umbilical cord homogenate, which include but are not limited to collagen substrates and extracellular matrix. This allograft provides natural collagen scaffold to support replacement by endogenous tissue. The birth tissue is obtained with consent from cesarean section delivery from healthy mothers. **OROPRO™** is processed using aseptic techniques and stored under cryopreserved conditions and should NOT be sterilized.

Donor Screening and Testing

The donated human umbilical cord tissue was recovered by a regulated procurement agency after having obtained both informed consent and healthy screening results from mothers scheduled for elective Caesarean deliveries. 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 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, samples of the tissue are cultured 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 microorganisms 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)
- Trypanosoma 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 Aseptic 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 contamination at every step of the process. This allograft implant was aseptically processed in a 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 10% by volume DMSO as cryoprotectant.

Storage

OROPRO™ must be stored at ≤-130°C until time for use. It is the responsibility of the Tissue Dispensing Service, Tissue Dispensing Intermediary, and/or End-User Clinician to maintain the allograft in appropriate storage conditions prior to further distribution or use and to track expiration dates accordingly. Appropriate inventory control should be maintained so that the allograft with an earlier expiration date is preferentially used and expiration is avoided. 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 -40°C or colder. It 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

OROPRO™ is aseptically vialed (primary container), packaged in an outer vial (secondary container) and placed into a sealed pouch for distribution. Once a package seal has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

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

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

OROPRO™ 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

Potential medical/surgical conditions or complications that apply to any surgical procedure may occur during or following use 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 processing 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 **OROPRO™** 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 REFREEZE ONCE THAWED.**
- **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.**

Precautions

OROPRO™ 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 **OROPRO™** 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 outer vial containing the allograft vial from sealed pouch and inspect the packaging and labeling materials carefully.
3. Do not use if there are discrepancies in label information.
4. Photograph and document all packages with compromised sterile barrier, lacking allograft, wrong size or wrong labeling.
5. To prevent contamination of the allograft, use sterile technique for preparation and implantation.
6. Use standard practices for handling and disposal of human tissue.
7. Open outer vial, remove allograft vial, and hold upright.
8. Thaw allograft by holding the product vial in your hand, do not turn upside down or shake, thawing takes approximately 3 minutes.
9. Packaging is not sterile, if used in a surgical environment, use a sterile 23g needle to withdraw the allograft out of the vial into a sterile syringe.
10. Physician experience and knowledge are key to proper application and usage.
11. If unsure as to appropriate application do not use until fully informed as to protocol and technique from an experienced user.
12. Allograft may be diluted with preservative free saline, using aseptic technique.
13. 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.
14. 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, 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:

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FDA registration: 30133239405
AATB Accredited Member #00327
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	Read attached information on product use
	One time use on one recipient
	Serial number and lot number in bar code
	Manufacturing date and expiration date on product label