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READ BEFORE USING

MOTYS™
Placental Tissues
DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY. Aseptically Processed. MOTYS Is Terminally Sterilized. Do Not Resterilize.

THIS TISSUE WAS RECOVERED FROM A DONOR FROM WHOM LEGAL AUTHORIZATION OR CONSENT HAS BEEN OBTAINED. THIS RECOVERY WAS PERFORMED USING ASEPTIC TECHNIQUES. PROCESSING AND PACKAGING WERE PERFORMED UNDER ASEPTIC CONDITIONS. TISSUE IS TERMINALLY STERILIZED

DESCRIPTION AND INDICATIONS FOR USE

MOTYS is a sterile allograft derived from human placental tissue matrix to supplement damaged or inadequate tissue. MOTYS is an aseptically processed and terminally sterilized, dehydrated powder mixture consisting of amnion, chorion, and umbilical cord tissue. MOTYS is provided in a stoppered and sealed 10 mL glass vial with a sterile vial adapter, the powder may be reconstituted at the time of use with sterile saline.

CAUTIONS AND WARNINGS FOR USE

Do not resterilize. Do not freeze. Potential residues of processing agents / solutions may be present. No antibiotics or cryopreservation agents were used during the processing of MOTYS.

Extensive medical screening procedures have been used in the selection of all tissue donors for MTF (please see Donor Screening & Testing Section). Transmission of infectious diseases may occur despite careful donor selection and laboratory testing, including serology and nucleic acid testing (NAT). Bacterial infection at the site of grafting may occur.

PRECAUTIONS

Conditions that could potentially inhibit the effect of MOTYS:

- Low vascularity of the surrounding tissue
- Local or systemic infection
- Inability to cooperate with and/or comprehend post-operative instructions

ADVERSE EFFECTS

Possible adverse effects of using MOTYS include but are not limited to:

- Local or systemic infection
- Failure of integration into the surrounding tissue
- Specific or non-specific immune response to some component of the graft

Within the United States: **Adverse outcomes attributable to the tissue must be promptly reported to Bioventus LLC.**

ALLOGRAFT INFORMATION

MOTYS is a terminally sterilized, dehydrated powder mixture consisting of amnion, chorion, and umbilical cord tissues. After tissue processing and packaging this allograft was terminally sterilized via electron beam (E-Beam) sterilization. In addition, the allograft was tested and met an MTF standard for an acceptable Endotoxin limit. **Do not subject allograft to additional sterilization procedures.**

Dispose of excess or unused tissue and all packaging that has been in contact with the tissue in accordance with recognized procedures for discarding regulated medical waste materials.

INSTRUCTIONS FOR USE

MOTYS is packaged in a stoppered and sealed glass vial and foil pouch with a sterile vial adapter and is designed to be passed directly into the sterile field.

Employ best practices with aseptic “no touch” technique when handling MOTYS including minimizing direct handling of MOTYS until ready to use and ensuring frequent glove changes. MOTYS may be reconstituted at the time of use with sterile saline. Recommended steps for reconstitution are listed below:

1. Peel back the foil pouch and remove the glass vial.
2. Gently tap the glass vial on a padded surface until all of the powder is moving freely and any powder is dislodged from the stopper at the top of the vial.
3. Pull back the flip top seal from the top of the glass vial to expose the rubber stopper and remove the crimp cap.
4. Wipe the top of the rubber stopper with an alcohol pad.
5. Peel back the lid on the vial adapter packaging.
6. To maintain sterility, leave the vial adapter in its package and place the vial adapter on top of the rubber stopper on the vial by holding the outside of the packaging..
7. Break the vacuum inside the vial by gently attaching the vial adapter by pushing down until it is securely in place. An audible click will be heard and the powder will become dispersed in the vial.
8. Withdraw 4 mL of sterile saline into a sterile syringe and then remove the needle from the syringe.
9. Lay the vial with the attached vial adapter horizontally so that all tissue is spread evenly on the side wall of the vial.
10. With the vial still in the horizontal position, attach the syringe to the vial adapter via the Luer Lock connection and slowly transfer the entire volume of saline from the syringe to the vial.
11. With the syringe still attached, immediately stand the vial upright and then hold at a 45° angle. While holding the syringe, begin to tap the vial and swirl the solution while simultaneously rotating the vial.
12. If there is any particulate adhered to the side wall of the vial or the bottom edge of the vial, position that part so that it is facing up and tap the vial to have it dislodged and fall into solution. Do not shake the vial in order to avoid bubble formation.
13. Once tissue is fully suspended, depress the plunger of the syringe all the way down, invert the vial and slowly withdraw the suspension through the vial adapter and into the syringe.
14. MOTYS is now ready for use and should be used immediately. If the contents have settled, gently swirl the syringe until a uniform suspension is created.

STORAGE

MOTYS should be stored at ambient temperature. No refrigeration or freezing is required. It is the responsibility of the clinician to maintain the tissue intended for transplantation in the appropriate recommended conditions prior to use.

DONOR SCREENING & TESTING

Prior to donation the donor’s medical/social history is screened for medical conditions or disease processes that would contraindicate the donation of tissue in accordance with current policies and procedures approved by the MTF Medical Board of Trustees.

Donor blood samples taken at the time of recovery were tested by a facility that is CLIA certified and registered with the FDA. The donor blood samples were tested for:

- Hepatitis B virus (HBV) surface antigen
- HBV core antibody
- Hepatitis C virus (HCV) antibody
- HIV-1/2 antibody
- Syphilis
- HIV-1 NAT
- HCV NAT
- HBV NAT

Additional testing of SARS-CoV-2 virus, HTLV I & II and/or West Nile Virus (as applicable) may also have been performed. All infectious disease test

results passed acceptability for screening. This allograft tissue has been determined to be suitable for transplantation.

The infectious disease test results, authorization, current donor medical history interview, physical assessment, available relevant medical records to include previous medical history, laboratory test results, autopsy and coroner reports, if performed, and information obtained from any source or records which may pertain to donor suitability, have been evaluated by an MTF physician and are sufficient to indicate that donor suitability criteria current at the time of procurement, have been met. This tissue is suitable for transplantation. The donor suitability criteria used to screen this donor are in compliance with the FDA regulations published in 21 CFR Part 1271 Human Cells, Tissues, and Cellular and Tissue Based Products, as applicable. All procedures for donor screening meet or exceed current standards established by the American Association of Tissue Banks.

PACKAGING & LABELING

MOTYS is aseptically packaged in a stoppered and sealed glass vial and hermetically sealed foiled pouch that is terminally sterilized by irradiation. The foil pouch containing MOTYS is labeled and then placed inside a unit carton with a sterile vial adapter with protective insert. This allograft must not be used under any of the following circumstances:

- If the pouch seal is damaged or not intact or has any physical damage;
- If the pouch label or identifying bar code is severely damaged, not legible or is missing; or
- If the expiration date shown on the pouch label has passed.

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

PATIENT RECORD

Tissue recipient records must be maintained by the consignee and clinic for tracing tissue post transplantation. A TissueTrace® Tracking Form and peel-off stickers have been included with each package of tissue. Please record the patient ID, name and address of the clinic, allograft tissue information (using the peel-off stickers), and comment regarding the use of the tissue on the TissueTrace Tracking Form. Alternately, a system for electronic submission may be used and sent to MTFTTC@Sceris.com. ***Within the United States:*** Once completed, the bottom page of the form should be returned to MTF using the self-addressed mailer. Copies of this information should be retained by the transplant facility and by the hospital for future reference.

Reference: Current MTF policies and procedures are in compliance with current FDA, AATB and other regulatory requirements.

Note: Not available for International distribution.

Definitions of Label Symbols

 **Consult instructions for use**

 **Do Not Reuse**

Terminally Sterilized

Processed by: Musculoskeletal Transplant Foundation
125 May Street, Edison, NJ 08837, USA
Within the United States: 800.433.6576
Outside of the United States: +1.732.661.0202
All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

CAUTION: Restricted to use by a physician and/or podiatrist.

For customer service inquires:

Bioventus LLC
4721 Emperor Blvd., Suite 100
Durham, NC 27703 USA
1-800-396-4325
BioventusGlobal.com