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RenuvaHD®
ALLOGRAFT ADIPOSE MATRIX

INSTRUCTIONS FOR USE
READ BEFORE USING
DONATED HUMAN TISSUE

CAUTION: TISSUE IS FOR SINGLE PATIENT USE ONLY.
Aseptically Processed. Passes USP <71> Sterility Tests.
RenuvaHD® Allograft Adipose Matrix Is Not Terminally Sterilized.
Do Not Sterilize.

THIS TISSUE WAS RECOVERED FROM A DECEASED 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. TERMINAL STERILIZATION AGENTS WERE NOT USED IN THE PROCESS.

DESCRIPTION AND INDICATIONS FOR USE

RenuvaHD Allograft Adipose Matrix is comprised of adipose tissue which is intended for the replacement of damaged or inadequate integumental adipose tissue matrix in areas of the body where native fat would exist. RenuvaHD Allograft Adipose Matrix may also be used for the reinforcement or supplemental support in underlying adipose tissue matrix as the result of damage or naturally occurring defects. The process utilized preserves the extracellular matrix of the allograft adipose. The resulting allograft serves as a framework to support the cellular repopulation and vascularization at the surgical site.

CONTRAINDICATIONS

- RenuvaHD Allograft Adipose Matrix should not be placed in an area where native adipose does not normally exist.
- RenuvaHD Allograft Adipose Matrix is contraindicated for patients with significant allergies manifested by a history of anaphylaxis or severe allergen sensitivity.

CAUTIONS AND WARNINGS FOR USE

NOTE: Potential residues of processing agents/solutions may be present, including peracetic acid, ethanol, propylene glycol, acetic acid, hydrogen peroxide, sodium deoxycholate, 1-propanol and chlorhexidine. No antibiotics were used during the processing of RenuvaHD Allograft Adipose Matrix.

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.

- **Do not re-use** RenuvaHD Allograft Adipose Matrix tissue.
- **Do not sterilize** RenuvaHD Allograft Adipose Matrix tissue.
- **Do not freeze** RenuvaHD Allograft Adipose Matrix tissue.
- **Do not use** RenuvaHD Allograft Adipose Matrix if any of the packaging components are perforated or torn. A damaged pouch containing the tissue may result in degradation or contamination of the product.

PRECAUTIONS

- Aseptic technique must be adhered to throughout the procedure.
- If the tissue matrix is prepared in advance of the injection procedure, ensure that a cap, needle or cannula is affixed to the tissue-containing syringe(s) in order to prevent drying.
- RenuvaHD Allograft Adipose Matrix has been formulated to be used with a 20G needle or larger bore needle/cannula. The use of a smaller bore needle may result in clogging.
- The use of RenuvaHD Allograft Adipose Matrix combined with autologous lipoaspirate has not been evaluated.
- The use of RenuvaHD Allograft Adipose Matrix combined with local anesthetic agents, e.g. lidocaine, has not been evaluated.

Conditions that could potentially inhibit integration of RenuvaHD Allograft Adipose Matrix include, but are not limited to:

- Immune response of non-infectious cause, including fever
- Low vascularity and/or ischemia of the surrounding tissue
- Local or systemic infection
- Mechanical trauma
- Poor nutrition or poor general medical condition
- Inability to cooperate with and/or comprehend post-procedure instructions
- Infection at the procedure site

ADVERSE EFFECTS

Possible adverse effects using human adipose include, but are not limited to:

- Anaphylaxis or other allergic response (e.g., urticaria)
- Local or systemic infection
- Specific or non-specific immune response to some component of the graft
- Discoloration of the skin may occur at the procedure site

As with any procedure, there is potential for swelling, tenderness, redness, bruising, pain or irritation at the procedure site during the immediate post-procedure period. In addition rare allergic reaction has been reported.

***Within the United States*: Adverse outcomes attributable to the tissue must be promptly reported to MTF. *Outside of the United States*: Adverse outcomes attributable to the tissue must be promptly reported to your local representative.**

ALLOGRAFT INFORMATION

During tissue processing and packaging of RenuvaHD Allograft Adipose Matrix, this allograft was tested and showed no evidence of microbial growth, complying with the requirements of USP <71> Sterility Tests. 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

Note: RenuvaHD Allograft Adipose Matrix must be prepared prior to implantation using the following procedures to ensure that the tissue can be adequately extruded using the recommended needle size.

Preparation Instructions for the 1.5cc Package:

1. The RenuvaHD Allograft Adipose Matrix 1.5cc product includes two double layer packages. One package consists of a 3mL plastic syringe that is pre-loaded with the allograft adipose tissue. The other package is an Accessory Kit that consists of one empty 3mL plastic syringe and one luer winged adapter for use in preparing the tissue.
2. Open the outer pouch of each double layer configuration and pass the inner pouches into the procedure area. Note that the outer surfaces of the outer pouches are not sterile.
3. Remove the empty 3mL syringe and luer winged adapter from the Accessory Kit packaging and attach the adapter to the empty syringe.
4. Remove the syringe containing the RenuvaHD Allograft Adipose Matrix tissue from its packaging.
5. Remove the end cap from the tissue syringe and discard any tissue which may be protruding from the syringe. Attach the syringe containing the tissue to the luer winged adapter on the empty syringe. The luer winged adapter is used to disrupt any potential aggregates for smoother transfer.
6. Beginning with small increments, work the tissue back and forth between the two syringes. Once all tissue is able to be passed from one syringe to the other, complete a minimum of 10 full passes through the luer winged adapter.
7. Remove the empty syringe and luer winged adapter.
8. Attach the desired size needle or cannula to the syringe containing the tissue. RenuvaHD Allograft Adipose Matrix has been formulated to be used with a 20G needle or larger bore needle/cannula. The use of a smaller bore needle may result in clogging.

Preparation Instructions for the 3cc Package:

1. The RenuvaHD Allograft Adipose Matrix 3cc product includes two double layer packages. One package consists of a 5mL plastic syringe that is pre-loaded with the allograft adipose tissue. The other package is an Accessory Kit that consists of three 3mL plastic syringes, one Luer Lock connector, and one luer winged adapter for use in preparing the tissue.
2. Open the outer pouch of each double layer configuration and pass the inner pouches into the sterile field or procedure area. Note that the outer surfaces of the outer pouches are not sterile.
3. Remove the empty 3mL syringes, Luer Lock connector and luer winged adapter from the Accessory Kit packaging.
4. Attach the Luer Lock connector to an empty 3mL syringe.
5. Remove the syringe containing the RenuvaHD Allograft Adipose Matrix tissue from its packaging.
6. Remove the end cap from the tissue syringe and discard any tissue which may be protruding from the syringe. Attach the 5mL syringe containing the tissue to the Luer Lock connector on the empty 3mL syringe.
7. Aliquot roughly 1.5cc of tissue matrix into the empty 3mL syringe.
8. Disconnect the 3mL tissue-containing syringe and affix a second empty 3mL syringe to the Luer Lock connector.
9. Aliquot the remaining tissue matrix into the empty 3mL syringe.
10. Disconnect the Luer Lock connector and 5mL syringe.
11. Affix a luer winged adapter to the third empty 3mL syringe.

12. Affix a tissue-containing 3mL syringe to the luer winged adapter. The luer winged adapter is used to disrupt any potential aggregates for smoother transfer.
13. Beginning with small increments, work the tissue back and forth between the two syringes. Once all tissue is able to be passed from one syringe to the other, complete a minimum of 10 full passes through the luer winged adapter.
14. Disconnect the syringe containing the prepared tissue matrix.
15. Repeat steps 12 through 14 for the remaining tissue-containing 3mL syringe.
16. Divide the RenuvaHD Allograft Adipose Matrix tissue, per physician preference, using the luer winged adapter and 3mL plastic syringes provided in the Accessory Kit. Once completed, remove the luer winged adapter.
17. Attach the desired size needle or cannula to the 3mL syringe(s) containing the tissue. RenuvaHD Allograft Adipose Matrix has been formulated to be used with a 20G needle or larger bore needle/cannula. The use of a smaller bore needle may result in clogging of the needle.

Luer Lock Connector

Luer Winged Adapter

STORAGE

RenuvaHD Allograft Adipose Matrix should be stored at ambient temperature. No refrigeration or freezing is required. It is the responsibility of the transplant facility or clinician to maintain the tissue intended for transplantation in the appropriate recommended storage conditions prior to transplant.

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 tissues 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 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, including laboratory testing, meet or exceed current standards established by the American Association of Tissue Banks.

PACKAGING & LABELING

RenuvaHD Allograft Adipose Matrix is aseptically packaged in a sterilized hermetically sealed foil pouch. The foil pouch containing the adipose matrix is inside a sealed Tyvek® pouch. The Tyvek pouch is labeled and contained within a carton. The carton also contains a sterile Accessory Kit for use in preparing the tissue. The Accessory Kit is packaged in a double Tyvek pouch configuration. This allograft must not be used under any of the following circumstances:

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

Once a container 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 transplant facility for the purpose of 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 transplant facility, allograft tissue information (using the peel-off stickers), and comments regarding the use of the tissue on the TissueTrace Tracking Form. Alternatively, 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 for future reference. ***Outside of the United States*:** Once completed, the bottom page of the form should be returned to the local allograft representative or provider. Copies of this information should be retained 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 all tissue forms are available for International distribution.

Definitions of Label Symbols

Consult instructions for use

Do Not Reuse

For Translation of Instructions for Use

www.mtfbiologics.org

Processed by: Musculoskeletal Transplant Foundation
125 May Street, Edison, NJ 08837, USA
Within the United States: 800.433.6576
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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.

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