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Renuva®
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.
Renuva® 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

Renuva 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. Renuva 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

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

CAUTIONS AND WARNNGS FOR USE

NOTE: Potential residues of processing agents/solutions may be present. No antibiotics were used during the processing of Renuva 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** Renuva Allograft Adipose Matrix tissue.
- **Do not sterilize** Renuva Allograft Adipose Matrix tissue.
- **Do not freeze** Renuva Allograft Adipose Matrix tissue.
- **Do not use** Renuva 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.
- Renuva Allograft Adipose Matrix tissue should be used within 2 hours following preparation of the product.
- Renuva 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 Renuva Allograft Adipose Matrix combined with autologous lipoaspirate has not been evaluated.
- The use of Renuva Allograft Adipose Matrix combined with local anesthetic agents, e.g. lidocaine, has not been evaluated.

Conditions that could potentially inhibit integration of Renuva 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 have 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 Renuva 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.

PACKAGING & LABELING

Renuva 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.

INSTRUCTIONS FOR USE

Note: Renuva Allograft Adipose Matrix must be rehydrated prior to use.

Recommended Rehydration Instructions for 1.5cc Package:

1. The Renuva 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 Lock connector for use in rehydration of 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 from the Accessory Kit packaging and depress the plunger fully to ensure that no air is within the chamber. **Using the empty syringe, take up a minimum 1.2 mL of sterile 0.9% saline and expel any trapped air.**
4. Attach the Luer Lock connector to the syringe containing the sterile saline.
5. Remove the syringe containing the Renuva Allograft Adipose Matrix tissue from its packaging. Draw back the plunger to the 1.5cc mark such that there is adequate space between the tissue and the plunger for unpacking the tissue.
6. **IMPORTANT: Unpack the tissue by tapping the syringe with a gloved finger for easier rehydration.**
7. Remove the end cap from the syringe. Attach the syringe containing the tissue to the Luer Lock connector on the saline syringe.
8. **Hold both syringes and exert equal pressure on each syringe plunger for approximately 15 seconds, allowing all the saline to enter the tissue-containing syringe but without transferring any tissue into the saline-filled syringe.**
9. Work the tissue and saline back and forth between the two syringes in small increments. Slowly increase the amount of tissue moving between the syringes until all of the mixture is visibly rehydrated and moves easily between the syringes.
10. **Pass the mixture an additional 10 times through each syringe**. If applicable, remove any additional air in the syringe containing the mixture prior to injection.
11. Remove the empty syringe and Luer Lock connector.
12. Attach the desired size needle or cannula to the syringe containing the tissue. Rehydrated Renuva 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.

Recommended Rehydration Instructions for 3cc or 5cc Package:

1. The Renuva Allograft Adipose Matrix 3cc and 5cc products each include 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 one empty 5mL plastic syringe, three 3mL plastic syringes and four Luer Lock connectors for use in rehydration of 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 5mL syringe from the Accessory Kit packaging and depress the plunger fully to ensure that no air is within the chamber. **For the 3cc product, use the empty 5cc syringe from the Kit and take up a minimum 2.4 mL of sterile 0.9% saline and expel any trapped air. For the 5cc product, use the empty 5cc syringe from the Kit and take up a minimum 3.8 mL of sterile 0.9% saline and expel any trapped air.**
4. Attach the Luer Lock connector to the syringe containing the sterile saline.
5. Remove the syringe containing the Renuva Allograft Adipose Matrix tissue from its packaging. Draw back the plunger to the 3cc mark such that there is adequate space between the tissue and the plunger for unpacking the tissue.
6. **IMPORTANT: Unpack the tissue by tapping the syringe with a gloved finger for easier rehydration.**
7. Remove the end cap from the syringe. Attach the syringe containing the tissue to the Luer Lock connector on the saline syringe.
8. **Hold both syringes and exert equal pressure on each syringe plunger for approximately 15 seconds, allowing the saline to enter the tissue-containing syringe but without transferring any tissue into the saline-filled syringe.**
9. Work the tissue and saline back and forth between the two syringes in small increments. Slowly increase the amount of tissue moving between the syringes until all of the mixture is visibly rehydrated and moves easily between the syringes.
10. **Pass the mixture an additional 10 times through each syringe**.
11. Remove the empty syringe and Luer Lock connector.
12. Divide the rehydrated Renuva Allograft Adipose Matrix tissue, per physician preference, using the three 3mL plastic syringes provided in the Accessory Kit. If applicable, remove any additional air in the 3mL syringes containing the mixture prior to injection. Dividing the tissue into smaller units allows for easier placement of the tissue.
13. Attach the desired size needle or cannula to the 3mL syringe(s) containing the tissue. Rehydrated Renuva 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.

Summary of Rehydration Ratios:

To rehydrate:	Mix with:
1.5cc tissue package	Min. 1.2mL of sterile 0.9% saline in 3mL syringe
3cc tissue package	Min. 2.4mL of sterile 0.9% saline in 5mL syringe
5cc tissue package	Min. 3.8mL of sterile 0.9% saline in 5mL syringe

STORAGE

Renuva 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.

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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

mtfbiologics®

Processed by: Musculoskeletal Transplant Foundation
125 May Street, Edison, NJ 08837, USA
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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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