Adipose Matrix is comprised of dehydrated adipose tissue. Discoloration of the skin may occur if injected superficially. Mechanical trauma:

Renuva Allograft Adipose Matrix tissue.

NOT:

Syphilis

Specific or non-specific immune response to some component of the allograft.

Do not re-use:

Outside of the United States

HIV-1/2 antibody

Do not combine

Local or systemic infection

Hepatitis B core antibody

Do not subject

HIV-1 (NAT)

Do not use

Syphilis

HBV (NAT)

Dehydration of the tissue may result in degradation or contamination of the product. Components are perforated or torn. A damaged pouch containing the allograft to additional sterilization procedures.

CONTRAINDICATIONS

All infectious disease tests were negative. This allograft 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, serologic and microbiologic testing meet or exceed current standards established by the American Association of Tissue Banks.

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.

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 rehydrating the tissue. The Accessory Kit is packaged in a double Tyvek

DESCRIPTION AND INDICATIONS FOR USE

Renuva Allograft Adipose Matrix is comprised of dehydrated adipose tissue which is intended for the replacement of damaged or inadequate integumental adipose tissue matrix. 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 including, but not limited to, lips and breast tissue.

WARNINGS

- Do not re-use Renuva Allograft Adipose Matrix tissue.
- Do not sterilize Renuva Allograft Adipose Matrix tissue.
- Do not combine with autologous liposapirate.
- 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.

NOTE: 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 such as HIV or hepatitis, as well as a theoretical risk of the Creutzfeldt-Jakob (CJD) agent, may occur in spite of careful donor selection and serological testing.

PRECAUTIONS

- Aseptic technique must be adhered to throughout the procedure.
- Renuva Allograft Adipose Matrix tissue should be used within 2 hours following rehydration.
- 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.
- Failure to follow rehydration instructions may lead to sub-optimal results.

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

- Fever
- Uncontrolled diabetes
- Pregnancy
- 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-operative instructions
- Infection at the injection site

ADVERSE EFFECTS

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

- Local or systemic infection
- Specific or non-specific immune response to some component of the graft
- Discoloration of the skin may occur if injected superficially

As with any injectable procedure, there is potential for swelling, tenderness, redness, bruising, pain or irritation at the injection site during the immediate post-operative period.

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. 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.
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 and one Luer-Lok 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 1.2mL of sterile 0.9% saline and expel any trapped air.
4. Attach the Luer-Lok 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-Lok 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-Lok connector.

Summary of Rehydration Ratios:

<table>
<thead>
<tr>
<th>To rehydrate:</th>
<th>Mix with:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.5cc tissue package</td>
<td>1.2mL of sterile 0.9% saline in 3mL syringe</td>
</tr>
<tr>
<td>3cc tissue package</td>
<td>2.4mL of sterile 0.9% saline in 5mL syringe</td>
</tr>
<tr>
<td>5cc tissue package</td>
<td>3.8mL of sterile 0.9% saline in 5mL syringe</td>
</tr>
</tbody>
</table>

PATIENT RECORD

Tissue recipient records must be maintained by the consignee and transplant facility for the purpose of tracking tissue post transplantation. A Tissue Trace® 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 Tissue Trace Tracking Form. Alternatively, use a system for electronic submission may be used and sent to MTFDDC@Scrier.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.

Definitions of Label Symbols

- Consult instructions for use
- Processed By: Musculoskeletal Transplant Foundation
- Do Not Reuse

125 May Street, Edison, NJ 08817, USA
Processed By: Musculoskeletal Transplant Foundation
Outside of the United States: +1.732.661.0202

All recovery, processing and distribution costs were paid for by MTF, a non-profit organization.

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