1000441

Manufacturer: RTI Biologics
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Matrix HD®
Matrix HD® Fenestrated
3mm, 5mm, and 6mm Matrix HD®

Read this entire package insert carefully prior to use.

Single patient use only, on a single occasion.

Restricted to sale by or on the order of a physician.

Description

The sterile and dehydrated Matrix HD, Matrix HD Fenestrated and 3mm, 5mm, and 6mm Matrix HD dermis implants are processed from donated human tissue. The dermis is preserved by the Tutoplast® Tissue Sterilization Process which retains the original three dimensional collagen structures responsible for the multidirectional, mechanical properties of dermal tissue.
The implants are to be used in homologous applications such as repair or replacement of damaged or inadequate integument tissue and as supplemental support, protection, reinforcement or covering of soft tissue. The implants provide a natural scaffold to support the body's regenerative processes.

Donor Screening and Testing

LOT — This symbol on the outer label indicates the unique number assigned to the tissue donor.

The donated human tissue utilized for this implant was recovered from a donor screened for risk factors associated with infectious diseases and medical conditions that rule out donation. The donor's blood was tested for relevant communicable diseases 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 testing. The following test criteria were met for this donor:

REQUIRED INFECTIOUS DISEASE TESTING	
BLOOD TEST	**ACCEPTABLE RESULT**
HIV-1 / HIV-2 Antibody	Negative/ Non-Reactive
Hepatitis C Virus Antibody	Negative/ Non-Reactive
Hepatitis B Surface Antigen	Negative/ Non-Reactive
Hepatitis B Core Antibody (Total)	Negative/ Non-Reactive
Treponema Pallidum (Syphilis)	Negative/ Non-Reactive
Human T-Cell Lymphotropic Virus I / II Antibody	Negative/ Non-Reactive
HIV-1 / HCV / HBV* NAT-TMA	Negative/ Non-Reactive

*For donors received after January 01, 2014.

If additional testing was performed (e.g., West Nile Virus), all available test results were reviewed as part of the donor eligibility determination. A licensed physician for RTI Biologics determined that the donor met eligibility requirements. The physician utilized available relevant information which may have included, but was not limited to: donor risk assessment interview, medical/hospital records, donor physical assessment, infectious disease test results, radiology/pathology reports, death certificate and autopsy report (if performed).

Processing and Sterilization

SN — This symbol on the outer label indicates a unique serial number used for traceability.

This implant was processed in a controlled environment from a single donor. Microbial testing was performed, where appropriate, and results met a documented acceptance criterion. The implant was released for transplantation based on the donor eligibility determination and a review of processing records.

Trace amounts of the following manufacturing residuals may remain after processing; acetic acid, acetone, hydrogen peroxide and sodium hydroxide.

This implant was processed using the following methods:

Tutoplast® Process — The Tutoplast process is validated to sterilize and preserve tissue through meticulous cleaning, gentle solvent dehydration and gamma irradiation.

STERILE R — Low dose gamma irradiation applied terminally as part of the Tutoplast process achieves a sterility assurance level (SAL) of 10^{-6}.

Storage and Shipping

This symbol on the outer label indicates the storage temperature range for the product.

This symbol on the outer label indicates the expiration date of the product.

STORAGE CONDITIONS
Store in a clean, dry environment at the temperature range specified on the labeling. Keep away from sunlight.

SHIPPING CONDITIONS
Implant is shipped at ambient temperature via expedited shipping methods.

Warnings

The same potential medical/ surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant.

Precautions

Prior to use, the surgeon must become familiar with the implant and the surgical procedure.

The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. The implant should be used with caution in surgical procedures where it is under moderate to high tension.

Appropriate placement and fixation of the implant are critical for success of the surgical procedure.

General Instructions for Use

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties.

GENERAL INSTRUCTIONS

- Use on a single occasion for a single patient only. Once the package is opened, the implant must be used for the current procedure or discarded.
- The outermost packaging is non-sterile and is used to protect the implant during shipping and storage.
- Additional product should be available in case of unexpected need during the procedure.
- Remove the double-barrier packaged product, the package insert, implant identification labels and Tissue Utilization Record (TUR) from the outermost package.
- Inspect the implant, packaging and labeling materials carefully:
  - Do not use past expiration date specified on the labeling.
  - Do not use if the implant or packaging is damaged.
  - Do not use if there are discrepancies in label information.
- To prevent contamination of the implant, use sterile technique for preparation and implantation.
- The implant and all packaging materials used by RTI Biologics are latex-free.
- Do not re-sterilize the implant.
- Use standard practices for handling and disposal of human tissue.
- Promptly report all product defects, complaints and patient adverse reactions to RTI Biologics (See Customer Returns and Complaints section).

Directions for Implant Preparation

1. Open the package and pass the implant into the sterile field.
2. Rehydrate the implant before use by soaking in sterile, endotoxin-free, room temperature, physiological saline as defined in the table below or until the implant becomes soft and flexible. Use promptly after rehydration.

IMPLANT TYPE	REHYDRATION TIME
Matrix HD, Matrix HD Fenestrated	At least 30 seconds
3mm, 5mm, and 6mm Matrix HD	At least 5 minutes

Antibiotic agents prescribed by the surgeon may be added to the soaking solution as a precaution against incidental infection. The prescribing surgeon is responsible for selecting an appropriate antibiotic agent at a suitable concentration.

3. Size the graft according to the tissue defect and place securely to prevent displacement and to aid incorporation. Implant the graft so that free edges do not protrude.
4. Use absorbable or non-absorbable suture material with a round atraumatic needle. Select the appropriate suture size for the surgical procedure. Place the stitches 2-3 mm from the edge of the implant, where possible. Use the implant where it is under minor to moderate tension. At suture sites under moderate to high tension, double the implant section if appropriate for surgical technique.

Tissue Utilization Record (TUR)

Complete and return the enclosed Tissue Utilization Record (TUR) to RTI Biologics. This information is considered confidential and used only for implant traceability. The TUR should be filled out and returned for all implants, even if the implant was discarded. Refer to the TUR packaged with the implant for additional information.

Warranty Statement

This biologic graft, processed and packaged for surgical implantation, is unique and does not constitute a product under liability laws. No implied warranties of merchantability or fitness for a particular purpose are applicable. No implied warranties exist as to defects in biologics which cannot be detected, removed, or prevented by reasonable use of available scientific procedures or techniques. Furthermore, ***ALL WARRANTIES ARE DISCLAIMED, WHETHER EXPRESSED OR IMPLIED BY OPERATION OF LAW OR OTHERWISE INCLUDING ALL IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN ADDITION, ALL CONSEQUENTIAL DAMAGES, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THESE GRAFTS ARE HEREBY DISCLAIMED.***

Customer Returns and Complaints

Please contact RTI Biologics at the numbers listed below for all complaints, returns or adverse reaction reporting.

A complete symbols glossary is located at
http://www.rtix.com/en_us/healthcare-professionals/labeling

DEFINITION OF LABEL SYMBOLS		
Caution, consult instructions for use	Use-by date	Storage temperature limits
Sterilized using Irradiation	Single use. Do not re-use	For prescription use only
Catalogue number	Serial number	Lot number (Donor ID)
Manufacturer		

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