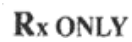
Definition of Label Symbols		
 Caution, consult instructions for use	 Sterile by using irradiation	 Use-by date
 Catalogue number	 Lot number (Donor ID)	 For prescription use only
 Do not reuse Single use	 Serial Number (Tissue ID)	 Do not use if package is damaged
 Storage temperature limits	 Manufacturer	 Do not resterilize

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

Derm-Maxx
DERMAL MATRIX

Instructions for Use

STERILE R Rx ONLY 37°C 1°C

Marketed By:
ROYAL BIOLOGICS
401 Hackensack Ave. Suite 604
Hackensack, NJ 07601 USA
Tel: 1.201.488.1549
Website: www.royalbiologics.com

IMPLANT DESCRIPTION

Derm-Maxx™ Dermal Matrix is dehydrated dermis from donated human tissue processed through the Tutoplast® tissue sterilization process. The implant is preserved by the Tutoplast® tissue sterilization process which retains the three-dimensional collagen structure responsible for the multidirectional, mechanical properties of the original dermal tissue.

The implant is regulated as 361 human cell and tissue product (HCT/Ps) as defined in USFDA 21 CFR 1271 and is restricted to homologous use for the repair, replacement, reconstruction, or augmentation of soft tissue by a qualified healthcare professional (e.g., physician). The implant is provided sterile and requires rehydration prior to use.

DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

LOT This symbol on the outer label indicates the unique identification 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 Surgical, Inc. 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 interviews, medical/hospital records, donor physical assessments, infectious disease test results, radiology/pathology reports, death certificate and autopsy reports (if performed).

WARRANTY STATEMENT

This biologic graft, processed and packaged for surgical implantation, is unique and does not constitute a product under liability laws in most states. 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.***

PROCESSING AND STERILIZATION

The 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.

The Tutoplast® tissue sterilization process includes meticulous cleaning and gentle solvent dehydration of tissue. The process inactivates or removes potential pathogens, gently removes unwanted materials, such as cells, antigens and viruses and allows the implant to be stored at room temperature. As part of the Tutoplast® tissue sterilization process, low dose gamma irradiation is applied terminally to the dry implant to achieve a minimum sterility assurance level (SAL) of 10^{-6}. Trace amounts of manufacturing residuals may remain after processing (acetic acid, acetone, hydrogen peroxide and sodium hydroxide).

STORAGE & SHIPPING

Storage Conditions

Store in a clean, dry environment at the temperature range specified on the implant label. 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, it is not possible to guarantee freedom from transmission of infectious agents or other adverse reactions such as hypersensitivity, allergic or immune response.

PRECAUTIONS

Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant, as such conditions may compromise outcomes.

The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determines that the clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken. Appropriate placement and fixation of the implant are critical to the success of the surgical procedure.

INSTRUCTIONS FOR USE

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect the success of the surgical procedure.

GENERAL INSTRUCTIONS FOR IMPLANT HANDLING

- 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.
- Remove the packaged implant, the package insert, the implant identification labels and Tissue Utilization Record (TUR) card from the outermost packaging.
- Inspect the implant, packaging, and labels carefully:
  - Do not use past expiration date specified on implant label.
  - Do not use if there are discrepancies in label information.
  - Do not use if the implant or packaging is damaged.

  The implant's sterile barrier is comprised of two sealed pouches to prevent contamination of the implant, use sterile technique for preparation and implantation.
- Additional implants should be available in case of an unexpected need during the procedure.
- Do not re-sterilize the implant.
- The implant and all packaging materials used by RTI Surgical, Inc. are latex-free.
- Use standard practices for handling and disposal of human tissue.
- Promptly report all implant defects, complaints, and patient adverse events to RTI Surgical, Inc. (See Customer Complaints and Returns section).

DIRECTIONS FOR PREPARING THE IMPLANT

1. Open outer pouch and pass inner pouch to sterile field.
2. Open sterile inner pouch and remove implant.
3. Rehydrate the implant in a sterile basin containing room temperature sterile saline for at least 30 seconds or until the implant becomes soft and flexible. Keep the implant in room temperature sterile saline until ready for implantation.
   Note: It is recommended to hydrate one implant at a time.
4. Pharmaceutical antibiotics or other antimicrobial agents prescribed by the surgeon as a precaution against incidental infection may be added to the soaking solution. The prescribing surgeon is responsible for selecting a suitable antibiotic or other antimicrobial agent at the appropriate concentration.
   Note: The surgeon may prefer to position the implant with the deep dermal side against the vascular supply. Use the table and (a) below to identify the implant surfaces.

Implant Surfaces	Characteristics
Deep Dermal side	Rough, dull, no visible pattern
Basement Membrane	Dotted pattern, shiny, visible pores

   a) Post hydration, to discern the deep dermal side of the implant from the basement membrane side, note that the deep dermal side of the graft is rough and dull. With the implant at the surgical site, add a drop of blood to each side of the implant. After 2-3 seconds, rinse with sterile saline. The deep dermal side of the implant will absorb the blood drop, but the blood drop will rinse off the basement membrane side.
5. Size the implant according to the tissue defect and trim per surgeon preference.
   Note: For abdominal wall repair procedures, the surgeon should plan to close or minimize the defect during the procedure. The edges of the implant should extend a minimum of 3-5cm beyond the perimeter of the defect on all sides.
6. The surgeon should select the appropriate suture and needle for the surgical procedure. If absorbable sutures are used, it is recommended to select the longest lasting materials available.
7. Place the implant securely to prevent displacement and to aid incorporation. Use the implant where it is under minor to moderate tension.

TISSUE UTILIZATION RECORD (TUR)

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

CUSTOMER COMPLAINTS AND RETURNS

Please contact RTI Surgical, Inc. for all complaints, returns or adverse reaction reporting.

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