Royal Matrix HD® Allograft Dermis

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| 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. |

# Caution- see IFU Do not reuse IMPLANT DESCRIPTION

Royal Matrix HD® Allograft Dermis is dehydrated dermis from donated human tissue processed through the Tutoplast® tissue sterilization process.

# PROCESSING AND STERILIZATION

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.

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

# 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

* 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.

# 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.***

The implant is preserved by the Tutoplast® tissue sterilization Tutoplast® tissue sterilization process, low dose gamma irradiation is  Remove the packaged implant, package insert, implant

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 to be used by a qualified healthcare professional (e.g., physician) in homologous applications for the repair, replacement, reconstruction, or augmentation of soft tissue including acute and chronic, partial- and full-thickness wounds such as: diabetic, venous, arterial and pressure ulcers, burns, acute surgical, traumatic and dehisced surgical wounds.

# DONOR SCREENING AND TESTING

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:

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| **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 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 report (if performed).

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 AND SHIPPING

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. 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.

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 to the success of the surgical procedure.

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 Surgical, Inc. 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 Surgical (See Customer Returns and Complaints section).

# INSTRUCTIONS 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 for at least 30 seconds or until the implant becomes soft and flexible. Use promptly after rehydration.

*Note: 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.*

1. Size the implant according to the tissue defect and place securely to prevent displacement and to aid incorporation. Use the implant where it is under minor to moderate tension.
2. 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.

# TISSUE UTILIZATION RECORD (TUR)

Complete and return the enclosed Tissue Utilization Record (TUR) to RTI Surgical, Inc. 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.

# CUSTOMER COMPLAINTS AND RETURNS

Please contact RTI Surgical 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>

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| **DEFINITION OF LABEL SYMBOLS** |
| Caution, consult instructions for use | Use by YYYY-MM-DD Use-by date | temperature_limitation2 Storage temperature limits |
| SterileR2 Sterilized using Irradiation | Do not reuse Single use. Do not re-use | For prescription use only |
| Catalog number Catalogue Number | Serial number Serial Number (Tissue ID) | Lot Lot Number (Donor ID) |
| Manufacturer Manufacturer | Do not resterilize | Description: fig31 Do not use if package is damaged |

**Marketed By: Royal Biologics** (dba Royal Wound-X) 401 Hackensack Ave. Suite 604 | Hackensack, NJ 07601| USA TEL: 1.201.488.1549 | [www.royalbiologics.com](http://www.royalbiologics.com/)

# Manufacturer  Manufactured / Distributed By: RTI Surgical, Inc.

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