Distributed By:

Katena Products, Inc.
4 Middlebury Blvd., Unit 1, Randolph, NJ 07869, USA
Tel.: 800.225.1195 | 973.989.1600 | www.katena.com

TUTOPLAST® PROCESSED PERICARDIUM

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

Tutoplast Processed Pericardium is dehydrated, Tutoplast processed pericardium from donated human tissue. The implant is preserved by the Tutoplast tissue sterilization process which retains the three-dimensional collagen structure responsible for the multi-directional, mechanical properties of the original pericardium tissue.

Tutoplast Processed Pericardium is regulated as a 361 human cell and tissue product (HCT/P) 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. ophthalmologist). This includes grafting for horizontal and vertical soft tissue augmentation of thickness and length. 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 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 interview, medical/hospital records, donor physical assessment, infectious disease test results, radiology/pathology reports, death certificate and autopsy report (if performed).

PROCESSING

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

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.

Trace amounts of manufacturing residuals may remain after processing (acetic acid, acetone, hydrogen peroxide and sodium hydroxide).

STERILIZATION

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.

STERILE R 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) 10^{-6}.

STORAGE AND SHIPPING

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

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

Storage Conditions

Store implant in a clean, dry environment at the temperature range specified on the product 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, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant. Successful treatment is dependent upon the patient's host tissue 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 success of the surgical procedure.

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.***

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 double-barrier packaged product, the package insert, implant identification labels and Tissue Utilization Record from the box.
- Inspect the product, including all packaging and labeling materials carefully:
  - Do not use past expiration date specified on product label.
  - Do not use if the implant or packaging is damaged.
  - Do not use if there are discrepancies in label information.
- 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 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 product defects and patient adverse events to Katena Products, Inc. (See Complaints and Returns section).

DIRECTIONS FOR IMPLANTATION

1. Open outer pouch and pass inner pouch to sterile field.
2. Open sterile inner pouch and remove implant.
3. Re-hydrate the implant prior to use by soaking in sterile, room temperature saline solution for up to 30 minutes to improve suppleness and handling properties.

   Note: 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.
4. Size the implant according to the tissue defect.
5. Place the implant securely to prevent displacement and to aid incorporation. Implant so that the free edges do not protrude. Either absorbable or non-absorbable suture material may be used. Select the appropriate suture size for the surgical procedure. If absorbable sutures are used, it is recommended to select the longest lasting materials available. Place the stitches 2-3 mm from the edge of the implant. Use the implant where it is under minor to moderate tension.

TISSUE UTILIZATION RECORD (TUR)

Complete and return the enclosed Tissue Utilization Record (TUR) to RTI Surgical, Inc. This information is kept 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 Katena Products, Inc. for all complaints, returns or adverse reaction reporting.

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Definition of Label Symbols		
		
Consult instructions for use	Lot number (Donor ID)	Storage temperature limits
		
Sterile by Gamma Irradiation	Single use only Do not reuse	For prescription use only
		
Catalog Number	Serial Number	Manufacturer
		
Use-by date		

Manufactured by:

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