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Manufactured by:



386.418.8888 • 800.624.7238 • www.rti.com

## PERICARDIUM ALLOGRAFT HUMAN TISSUE FOR TRANSPLANT

### DESCRIPTION

This package contains donated human allograft tissue intended for transplantation. This product is restricted to homologous use for the repair, replacement or reconstruction of musculoskeletal defects by a qualified healthcare professional (i.e., physician).

### DONOR SCREENING AND TESTING

This donated human tissue was recovered using aseptic technique from a donor determined to be eligible for tissue donation. After consent for donation is obtained, tissue donors are screened for risk factors associated with infectious diseases and medical conditions that would rule-out donation. This screening includes, but is not limited to: Family/next-of-kin interview, medical/hospital record evaluation, donor physical assessment and autopsy report (if performed). The final determination of donor eligibility is made by a licensed physician utilizing all available, relevant information.

The donor's blood is tested by a CLIA certified laboratory utilizing test kits approved by the FDA for donor screening and cadaveric blood testing where applicable. The following test criteria were met for this donor:

**Table 1:** Required infectious disease tests and acceptable result

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
RPR for Syphilis	Negative / Non-Reactive
Human T-Cell Lymphotropic Virus I / II Antibody	Negative / Non-Reactive
HIV-1 / HCV NAT-TMA (tested after March 2005)	Negative / Non-Reactive
HIV-1 DNA by PCR (tested prior to March 2005)	Negative / Non-Reactive

### PROCESSING

Tissues are processed into their final forms in controlled environments. Microbial testing is performed where appropriate and results meet a documented acceptance criterion that is based on AATB and FDA requirements.

### Sterilization:

**STERILE R** labeled grafts are terminally sterilized by gamma irradiation with a validated\* dose.

\* All references to "validated" sterilization processes indicate that the tissue meets or exceeds requirements for product sterilization, based on a SAL of 10<sup>-6</sup> per AAMI and ISO Standards.

### ADVERSE REACTION

Because donor screening methods are limited, certain diseases may not be detected. The following complications of tissue transplantation may occur:

- Transmission of known infectious agents including, but not limited to, HIV, Hepatitis B, Hepatitis C, syphilis and bacteria;
- Loss of function and/or integrity of transplanted tissue due to resorption, fragmentation, and/or disintegration including, but not limited to, associated loss of continuity, displacement, bending and/or fracture.
- Immune rejection of transplanted grafts or allergic reactions to residual chemicals.

This product may contain trace amounts of the following processing chemicals: ascorbic acid, povidone-iodine.

The same medical/surgical conditions that may complicate any surgical procedure may occur during or following the transplantation of an allograft.

Exactech and RTI, their affiliates, distributors and agents disclaim all implied warranties concerning this tissue including any warranty of merchantability or fitness for particular purpose. Please promptly report complaints and possible adverse events as instructed in the Complaints section of this insert.

### RECEIPT INSPECTION

Upon arrival, unpack and inspect the graft. Verify that you have received the correct graft type and that the expiration date has not elapsed. Should you receive the incorrect order or find that the shipping container and graft packaging integrity is compromised, immediately notify Exactech at 866.284.9690 or 352.377.1140.

### STORAGE

Allografts must be stored as listed in the Table 2 below. Storage conditions are also stated on the package label. It is the responsibility of the end-user to maintain grafts intended for transplantation at appropriate storage conditions. Storage conditions should be documented.

**Table 2:** Storage

Storage Method	Temperature (Celsius/Fahrenheit)
Freeze Dried	(1-37 °C) ( 33-98°F)

### SPECIAL INSTRUCTIONS AND WARNINGS

- This product is for single patient use only.
- Once opened, the graft must be used for the current procedure or discarded.
- Do not use expired or damaged product.
- This graft may not be sterilized or re-sterilized.
- Adhere to instructions provided on surgical techniques and use of instrumentation.
- Additional RTI grafts of varying types and sizes should be accessible in case of an unexpected need.
- This allograft and all packaging materials used by RTI are latex free.
- The box or clear plastic outside packaging acts as a dust cover and is used to protect the allograft during shipping and storage.
- The surgeon should be familiar with the graft, surgical procedure and any instruments prior to use of this graft or subsequent products.

## **DIRECTIONS FOR TISSUE**

### **Directions for Freeze-Dried Tissue in Peel Packs:**

1. Remove dust cover or box and set TUR card aside; (Save packaging to use peel off labels).
2. Pass sterile inner package into sterile field.
3. Open inner peel pack on back table; peel or use sterile scissors.
4. Using sterile scissors open inner most packaging.
5. Place tissue into sterile bowl containing reconstituting fluid if required.
6. Rehydration takes approximately 15 minutes.

### **Directions for Freeze-Dried Tissue in a Bottle:**

1. Remove dust cover or box and set TUR card aside.
2. Using aseptic technique, remove tamper-resistant seal and cap.
3. Place a 22-gauge or smaller sterile needle on a 20-60cc syringe containing sterile rehydration fluid (for example, physiologic saline).
4. Disinfect the rubber stopper and top edges of the bottle with an aseptic wipe down with alcohol or another appropriate disinfecting agent.
5. Puncture the center of the rubber stopper; the plunger should fall. If not, replace the needle and repeat the process.
6. If the plunger still does not fall, the vacuum may not be present. Do not use the tissue.
7. Once the vacuum is confirmed and the graft is covered with rehydration fluid, allow for rehydration time of 15 minutes. (Tissue under partial vacuum rehydrates in less time than tissue not under partial vacuum.)
8. After the allowed time for rehydration, remove rubber stopper using aseptic technique. Pass contents of the bottle into sterile field.

An alternate method is to first confirm presence of vacuum in bottle. Then, using aseptic technique, deposit contents of bottle onto sterile field, cover with sterile reconstitution fluid, rehydrate at atmospheric pressure, and allow a minimum of 15 minutes or until graft is soft and pliable throughout.

Use of freeze-dried tissue prior to complete hydration may dramatically affect its mechanical and handling characteristics. Do not assume that the tissue will rehydrate in-situ since the physiologic response of the body may "seal" the outer surfaces of the tissue and prevent complete rehydration.

If more than one tissue is used at the same time, have separate sterile fluids and containers for each piece of tissue. Destroy any rehydrated freeze-dried tissues not used within 48 hours of complete hydration.

## **TISSUE UTILIZATION RECORD (TUR CARD)**

The TUR card is designed for tracking implanted grafts. All information provided is kept confidential and used for product tracking only. This card must be completed by the operating room staff or clinician after the surgery. For further instructions please see those listed on the TUR card. Return completed copy to RTI to address or fax provided on TUR card.










## **CUSTOMER RETURNS AND COMPLAINTS**


Please contact Exactech at the numbers listed below for all complaints, returns or adverse event reporting.

### Customer Service

Exactech, Inc.  
Gainesville, Florida, 32653, USA.  
TEL: 352.377.1140, 866.284.9690 (or)  
FAX: 352.378.2617  
www.exac.com

**Table 3:** Definitions of label symbols:

 See instructions for use	 Sterile by gamma irradiation	 Expiration Date (month/day/year)
 Catalogue number	 Lot number (Donor number)	 Serial Number (Tissue number)
 Storage temperature limits	 Do not reuse (Single patient)	 Manufacturer

 RTI Biologics, Inc.  
11621 Research Circle  
Alachua, FL 32615  
U.S.A