


Distributor:

(866) 284-9690 □ www.exac.com

Manufacturer:

(386) 418-8888 □ (800) 624-7238 □ www.rtx.com

## CORTICAL BONE PINS

### Instructions for Use

#### DESCRIPTION

This package contains donated human tissue intended for transplantation. The implant was manufactured from cortical human bone that has been through the BioCleanse® process, freeze-dried and terminally sterilized. This implant is restricted to homologous use for the repair, replacement or reconstruction of musculoskeletal defects by a qualified healthcare professional (i.e., physician). This product is latex free.

#### DONOR SCREENING AND TESTING

After consent for donation was obtained, the donor was screened for risk factors associated with infectious diseases and medical conditions that would rule out donation. Human tissue utilized for this implant was recovered using aseptic technique from an eligible donor. The donor's blood was tested in a CLIA-certified or \*other licensed laboratory. FDA-licensed, approved or cleared test kits were used for all donor screening and for cadaveric blood testing, when applicable and available. The following test criteria were met for this donor:

Required Infectious Disease Tests and Acceptable Results	
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
Syphilis	Negative / Non-Reactive
Human T-Cell Lymphotropic Virus I / II Antibody	Negative / Non-Reactive
HIV-1 / HCV NAT-TMA	Negative / Non-Reactive

\*Laboratories may be licensed by a CLIA-recognized authorizing body.

The final determination of donor eligibility and release for transplantation was made by a licensed physician for RTI Biologics, Inc. The physician utilized all available relevant information which included, but was not limited to: family/next-of-kin interviews, medical/hospital records evaluation, donor physical assessment, infectious disease test results and autopsy report (if performed).

#### 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.*

#### PROCESSING

This implant was manufactured in a controlled environment from a single donor. Microbial testing was performed where appropriate and test results met documented acceptance criteria based on AATB and FDA requirements. This implant has been deemed suitable for transplantation based on donor eligibility and processing records.

#### BIOCLEANSÉ<sup>®</sup> TISSUE STERILIZATION PROCESS

Implants labeled with the BioCleanse® logo have been through the BioCleanse® process, a low temperature chemical sterilization process validated to kill viruses, fungi, bacteria and spores.

#### STERILIZATION

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

**STERILE** labeled products are terminally sterilized by gas plasma through a validated\* process.

\* 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.

#### RECEIPT INSPECTION

Verify that the product ordered matches the product received. Should you receive an incorrect order or find that the shipping container or implant packaging integrity is compromised, immediately notify your distributor.

#### STORAGE and EXPIRATION

Store product in a clean, dry environment within the specified temperature range to ensure integrity is maintained until the expiration date. Storage temperature and product expiration are stated on the outer label. Storage conditions should be documented.

Room temperature products are shipped via expedited shipping methods at ambient temperature based on distribution validation studies.

#### WARNINGS

The same medical/surgical conditions that may complicate any surgical procedure may occur during or following the transplantation of an allograft. Prior to use, the surgeon should be familiar with the implant and surgical procedure. The surgeon must ensure the patient is aware of general risks associated with their treatment and the possibility of the complications and adverse effects.

Fragmentation, displacement or disintegration of the implant may compromise its integrity or function.

A small number of patients may experience localized immunological reaction to the implant or trace amounts of these residual chemicals from the manufacturing process: detergent, hydrochloric acid, hydrogen peroxide, isopropyl alcohol, phosphate buffered saline, povidone-iodine.

Although the donor was tested and screened for selected human pathogens and the implant manufactured under aseptic conditions, transmission of infectious agents including but not limited to HIV, Hepatitis B Virus, Hepatitis C Virus and *Treponema pallidum* (Syphilis) may occur.

## **GENERAL PRECAUTIONS**

- Adhere to directions and warnings stated in the package insert.
- 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 product's sterile barrier packaging is comprised of two pouches. To prevent contamination of the implant, use sterile technique for preparation and implantation.
- Do not re-sterilize the implant.
- Inspect the product, including all packaging and labeling materials carefully:
  - Do not use past expiration date.
  - Do not use if the implant or packaging is damaged.
  - Do not use if there are discrepancies in label information.
- Additional implants should be accessible in case of an unexpected need during the procedure.
- Inadequate hydration may result in implant damage.

## **DIRECTIONS FOR TISSUE PREPARATION:**

1. Remove implant from non-sterile dust barrier and remove contents (TUR Card, labels etc.).
2. Pass sterile innermost package onto sterile field.
3. Place implant into sterile bowl containing sterile water, sterile saline or patient's own blood.
4. Hydrate for a minimum of 30 seconds before use.
5. Discard any unused implant in accordance with standard practice for disposal of human tissue.

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













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

## **CUSTOMER RETURNS AND COMPLAINTS**

For further information or to report a complaint or adverse event, please contact:

### **Exactech, Inc.**

2320 NW 66<sup>th</sup> Court  
Gainesville, Florida 32653-1630, USA.  
TEL: (866) 284-9690  
FAX: (800) 329-3922  
www.exac.com

<b>Definition of Label Symbols</b>		
 See instructions for use	 <b>EXP</b> or Expiration date	 Storage temperature limits
 For prescription use only	 Single patient use (Do not reuse)	 Manufacturer
 Catalog number	 Serial Number (Tissue number)	 Lot number (Donor number)
 Sterile by Gamma Irradiation	 Sterile by Gas Plasma	 Freeze Dried



### **RTI Biologics, Inc.**

11621 Research Circle | Alachua, FL 32615 | USA  
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Email: cs@rtix.com

RTI Biologics, Inc.: CTO Registration Number 100053

BioCleanse<sup>®</sup> is a registered trademark of RTI Biologics, Inc.