rti surgical™
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# Allograft Bone

**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

This implant is composed of donated human bone that was processed through the BioCleanse® sterilization process and terminally sterilized.

This implant 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 repair, replacement or reconstruction of bony defects by a qualified healthcare professional (e.g., physician). The implant is provided sterile.

## 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 |
| Syphilis | Negative/ Non-Reactive |
| Human T-Cell Lymphotropic Virus I/ II Antibody | Negative/ Non-Reactive |
| HIV-1/ HCV NAT-TMA | Negative/ Non-Reactive |

If additional testing was performed (e.g., West Nile Virus and HBV NAT-TMA), 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: family/next-of-kin interview, medical/hospital records, donor physical assessment, infectious disease test results, radiology/pathology reports, death certificate 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. IN ADDITION, ALL CONSEQUENTIAL DAMAGES, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THESE GRAFTS ARE HEREBY DISCLAIMED.***

## PROCESSING

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

The processing and/ or sterilization method used during the manufacturing process for the implant will be indicated on the label. 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.

Trace amounts of the following manufacturing residuals may remain after processing; ascorbic acid, detergents, hydrogen peroxide, isopropyl alcohol and povidone-iodine.

## STERILIZATION

BIOCLEANSE TISSUE STERILIZATION PROCESS The *BioCleanse* process is a validated sterilization process that inactivates or removes potential pathogens through a complex, proprietary combination of chemical treatments and mechanical processes.

The terminal sterilization method is indicated on the implant label. This implant was terminally sterilized using one of the following methods:

STERILE R Low dose gamma irradiation is applied terminally to the product to achieve a sterility assurance level (SAL) of $10^{-6}$.

STERILE Gas plasma is applied terminally to the product to achieve a sterility assurance level (SAL) of $10^{-6}$.

## STORAGE & 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.

***Room Temperature Implants***
Store in a clean, dry environment at the temperature range specified on the label.

***Frozen Implants***
Store at the temperature range specified on the label. Transfer to long-term storage conditions as soon as possible after receipt.

***Shipping Conditions***
Room temperature implants are shipped at ambient temperature via expedited shipping methods.

Frozen implants are shipped via expedited shipping methods in insulated containers validated to maintain the required environmental conditions during the shipping process.

## WARNINGS

The same 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. Resorption of the implant and commensurate substitution with functional host tissue is required to restore function. Fragmentation, displacement and/or disintegration of the implant at the surgical site may compromise its integrity and/or function.

## PRECAUTIONS

Prior to use, the surgeon must become familiar with the implant and surgical procedure. Where provided, use surgical instrumentation, accessories, and surgical technique guide with this implant.

To avoid implant failure, do not manipulate, shape or otherwise alter the implant.

Rehydrate freeze-dried implants prior to implantation to avoid implant damage.

Do not implant a partially or fully frozen implant as it may cause damage to surrounding tissue. Inadequate thawing or rehydration can result in implant damage. Furthermore, frozen implants may have different handling properties.

## GENERAL INSTRUCTIONS

⚠ **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.**

- Use on a single occasion for a single patient only. Once 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.
- The sterile barrier packaging is comprised of two or more sealed pouches. To prevent contamination of the implant, use sterile technique for preparation and implantation.
- Remove the packaged implant, the package insert, the implant identification labels and Tissue Utilization Record from the outermost packaging.
- Inspect the implant, including all packaging and labeling materials carefully:
  - Do not use past expiration date specified on the implant label.
  - Do not use if the implant or inner packaging is damaged.
  - Do not use if there are discrepancies in label information.
- This implant and all packaging materials used by RTI Surgical, Inc. are latex free.
- Additional implant should be available in case of an unexpected need during the procedure.
- Do not sterilize or re-sterilize the implant.
- Use standard practices for handling and disposal of human tissue.
- Promptly report all implant defects and patient adverse reactions to RTI Surgical, Inc. (See Customer Returns & Complaints Section).

## DIRECTIONS FOR PREPARING FREEZE-DRIED IMPLANT:

**1.** Pass innermost package onto sterile field.
**2.** Open innermost package within sterile field.
**3.** Place implant into sterile container and cover with sterile saline, sterile water or the patient's blood.
**4.** Rehydrate for at least 30 seconds.

## DIRECTIONS FOR PREPARING FROZEN IMPLANT:

1. Pass innermost package onto sterile field.
2. Open innermost package within sterile field.
3. Place implant into sterile container and cover with thawing fluid that is between room and body temperature (18.0 to 37.0°C or 64.4 to 98.6°F). If using more than one implant, place each in a separate sterile container.
   *Note: Do not use thawing fluid warmer than 37.0°C (98.6°F).*
4. Thaw for 15-60 minutes.
5. Change fluid every 10 minutes.
6. Discard any thawed implant not used in the surgical procedure.
7. Do not refreeze thawed implants.

## TISSUE UTILIZATION RECORD (TUR CARD)

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 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 RETURNS & COMPLAINTS

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

**RTI Surgical, Inc.**
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| DEFINITION OF LABEL SYMBOLS | | | |
|---|---|---|---|
|  |  |  | |
| See instructions for use | Use by date | Storage temperature limits | |
| STERILE R | STERILE |  | |
| Sterile by Gamma Irradiation | Sterile by Gas Plasma | Do not reuse Single patient use | |
| REF | LOT | SN | |
| Catalog number | Lot number (Donor number) | Serial Number (Tissue ID) | |
|  | Rx only | FD | FZ |
| Manufacturer | For prescription use only | Freeze Dried | Frozen |