Marketed By: ZIMMER BIOMET

Manufactured By: rti surgical®

PUROS® Allograft Bone Particles

Read this entire package insert carefully prior to use.

Single patient use only, on a single occasion.

Rx ONLY **Restricted to sale by or on the order of a physician.**

DESCRIPTION

Puros Allograft Bone Particles are sterile, dehydrated cortical and/or cancellous bone from donated human tissue. Puros Allograft Bone Particles are preserved by the Tutoplast® process which maintains the collagen matrix of native bone.

The implant is restricted to homologous use for the repair, replacement or reconstruction of skeletal defects. This would include filling bone voids or gaps of the skeletal system (e.g. dental intraosseous, oral and cranio-/ maxillofacial defects, defects of the extremities, pelvis and spine, interbody and posterolateral spine fusion procedures with appropriate stabilizing hardware, etc.). The implant is not intended to be used in load bearing applications without appropriate hardware.

DONOR SCREENING AND TESTING (SUMMARY OF RECORDS)

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.

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).

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

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 the following manufacturing residuals may remain after processing; acetic acid, acetone, hydrogen peroxide and sodium hydroxide.

STERILIZATION

The Tutoplast process is a validated, chemical sterilization process that includes meticulous cleaning and gentle solvent dehydration of tissue.

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

STORAGE AND SHIPPING

STORAGE CONDITIONS

Store in a clean, dry environment at the temperature range specified on the implant 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.

PRECAUTIONS

Prior to use, the surgeon must become familiar with the implant and the surgical procedure. The implant should be used with caution where an active infection is present in or around the surgical site. Appropriate placement and retention of the implant are critical for success of the surgical procedure.

It is important to read and understand the following instructions prior to clinical use. Improper preparation technique may adversely affect handling properties.

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 box is non-sterile and is used to protect the implant during shipping and storage.
- Additional implant should be available in case of unexpected need during the procedure.
- Remove the double-barrier packaged implant, the package insert, patient implant stickers and Tissue Utilization Record from the box.
- 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 packaging is damaged.
  - Do not use if there are discrepancies in label information.
  - Return all packages with flaws in the sterile barrier to RTI Surgical, Inc.
- To prevent contamination of the implant, use sterile technique for preparation and implantation.
- Do not re-sterilize the implant.
- Use standard practices for handling and disposal of human tissue.
- Promptly report all complaints and patient adverse events to Zimmer Biomet Dental (See Returns and Complaints section).

DIRECTIONS FOR IMPLANTATION

1. Open the package and pass the implant into the sterile field.
2. Rehydrate the implant before use by soaking in sterile 0.9% saline solution for 15 to 30 minutes.
   Note: Use promptly after rehydration.
3. Dispense into bone defect as needed.

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.

DEFINITION OF LABEL SYMBOLS		
		
Attention, see instructions for use	Expiration date	Storage temperature limits
		
Sterile by Gamma Irradiation	Single use only (Do not reuse)	Lot number (Donor ID)
	Rx ONLY	
Catalog number	Prescription Use Only	Serial Number (Tissue ID)

CUSTOMER RETURNS AND COMPLAINTS

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

Marketed in the U.S.A. by:	Imported and marketed in Canada by:
Zimmer Biomet Dental 4555 Riverside Drive Palm Beach Gardens, FL 33410 Tel: 1.561.776.6700 www.zimmerbiometdental.com	Zimmer Biomet Dental Canada Inc. 106 - 2345 Argentia Road Mississauga Ontario L5N 8K4 Tel: 1.800.363.1980 CTO Registration Number: 100086

Manufactured By:
RTI Surgical, Inc.
11621 Research Circle
Alachua, FL 32615 U.S.A.
Tel: 386-418-8888
CTO Registration number: 100053

This optional address section applies to implants that are manufactured outside of RTI Alachua facility.
Example format below:
Processor
Address
Contact Information