Marketed by:

ZIMMER BIOMET

Puros® Ci Particulate Allograft

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

Puros Ci Particulate Allograft combines Tutoplast™ processed cortico-cancellous bone particulate with Cancelle SP® processed demineralized bone matrix (DBM) from the same human tissue donor. The Tutoplast process preserves the native collagen matrix of cortico-cancellous bone. DBM from each lot is tested for osteoinductive* potential. Only DBM with verified osteoinductive potential is released to processing.

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 the repair, replacement or reconstruction of skeletal defects. This includes filling bone voids or gaps of the skeletal system. The implant is not intended to be used in load bearing applications.

The implant is provided sterile and requires rehydration prior to use.

*DBM is evaluated for bone formation utilizing an in vivo athymic rat model. Findings from an animal model are not necessarily predictive of human clinical results.

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 AND STERILIZATION

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

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: acetone, ascorbic acid, hydrochloric acid, hydrogen peroxide, isopropyl alcohol, povidone iodine, sodium hydroxide, and sodium phosphate buffer.

This implant was processed using the following methods:

CANCELLE SP DBM STERILIZATION PROCESS — The Cancelle SP® process is a validated bone matrix sterilization process that inactivates potential pathogens through a combination of chemical treatments and gamma irradiation.

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

Tutoplast — The Tutoplast process is a validated tissue sterilization process that 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.

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.

Implants are shipped at ambient temperature via expedited shipping methods. Store at the temperature range specified on the label. Keep away from sunlight.

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. Resorption of the implant and commensurate substitution with functional host tissue is required to restore function.

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.

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.***

GENERAL INSTRUCTIONS

It is important to read and understand the following instructions and precautions 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 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.
- Remove the double-barrier packaged implant, the package insert, implant identification labels and Tissue Utilization Record (TUR) Card from the outermost package.
- Inspect the implant, packaging and label 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.
- This implant and all packaging materials used by RTI Surgical, Inc. are not made from natural latex rubber.
- Additional implants should be available in case of an unexpected need during the procedure.
- Do not re-sterilize the implant.
- Use standard practices for handling and disposal of human tissue.
- Promptly report all product defects, complaints, and patient adverse reactions to Zimmer Biomet Dental or Zimmer Biomet Dental Canada, Inc. (*See Customer Returns and Complaints* section).

DIRECTIONS FOR IMPLANT PREPARATION:

1. Open the tray package and pass the implant jar into the sterile field.
2. Open the jar and rehydrate the implant before use with sterile 0.9% saline solution. Let implant sit in saline solution for 5 to 30 minutes.

   Note: Use promptly after hydration.
3. Dispense into bone defect as needed.

TISSUE UTILIZATION RECORD (TUR) CARD

Complete the enclosed Tissue Utilization Record (TUR) per the instructions on the card for all implants, even if the implant was discarded. This information is kept confidential and used only for implant tracking.

CUSTOMER RETURNS AND COMPLAINTS

Please contact Zimmer Biomet Dental at the numbers listed below for all complaints, returns and adverse event reporting.

Marketed in the USA by:	Imported and marketed in Canada by:
Zimmer Biomet Dental 4555 Riverside Drive Palm Beach Gardens FL 33410 U.S.A. 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

Manufacturer:
RTI Surgical, Inc.
11621 Research Circle
Alachua, FL 32615
Tel: 386-418-8888
Web: www.rtisurgical.com
CTO Registration Number: 100053

DEFINITION OF LABEL SYMBOLS		
Caution (consult instructions for use)	Use-by date	(Storage) temperature limit
STERILE R		
Sterilized using irradiation	Do not re-use (Single patient use)	Manufacturer
REF	SN	LOT
Catalogue number	Serial Number (Implant ID)	Lot number (Donor number)
Rx only		
For prescription use only	Date of Manufacture	