Marketed By:	Manufactured By:
ZIMMER BIOMET	rti surgical®

Puros® Demineralized Bone Matrix

DESCRIPTION
This package contains donated human allograft tissue intended for transplantation. Puros Demineralized Bone Matrix (DBM) combines human DBM with a carrier that is developed using DBM from the same donor. Puros DBM Putty with Chips contains cortical cancellous chips from the same donor as the DBM and carrier. This implant can be stored at room temperature (15º-25ºC) and is ready for immediate use without extra implant preparation (no mixing, no warming, etc.). The implants are sterilized with low dose, low temperature gamma irradiation.

This implant is restricted to homologous use for the repair, replacement or reconstruction of musculoskeletal defects by or on the order of a licensed practitioner. 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.). This implant is not intended to be used in load bearing applications without appropriate hardware.

GRAFT COMPOSITION			
DESCRIPTION	**DBM**	**CCC**	**Sterile Water**
Puros DBM Putty	X		X
Puros DBM Putty with Chips	X	X	X
DBM = Demineralized Bone Matrix CCC = Cortical Cancellous Chips			

DONOR SCREENING AND TESTING
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
The implant was processed in a controlled environment from a single donor. Microbial testing was performed, where appropriate, and results met documented acceptance criterion. The graft 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, hydrochloric acid, hydrogen peroxide, isopropyl alcohol, povidone iodine, sodium hydroxide, sodium phosphate buffer.

Sterilization:

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

Because the low temperature, low dose gamma irradiation part of the Cancelle SP process is applied terminally to this implant, a sterility assurance level (SAL) of 10^{-6} is achieved.

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.

This implant does not possess sufficient mechanical strength to support a defect prior to soft and hard tissue ingrowths.

PRECAUTIONS
Prior to use, the surgeon must become familiar with the implant and surgical procedure.
Do not use this implant in load-bearing applications without appropriate stabilizing hardware.
The implant should not be used when an active infection is present at the surgical site.

STORAGE
Implants are shipped at ambient temperature via expedited shipping methods. Store at the temperature range specified on the label.

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

GENERAL INFORMATION
- 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 outermost packaging 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.
- The implant's sterile barrier packaging is comprised of two sealed pouches. 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 latex free.
- 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 implant defects and patient adverse reactions to Zimmer Biomet Dental (See Customer Returns and Complaints section).

DIRECTIONS FOR USE:

1. Remove the double packaged implant, the package insert and Tissue Utilization Record from the box.
2. Compare the labeling identification number on the pouch with the number on the outer box.
3. Use standard sterile technique to open the outer package and pass inner package to sterile field.
4. In the sterile field, open inner package, and lay out the contents.
5. Keep dispenser capped when implant is not in use.
6. Remove cap from dispenser and dispense implant as needed.
7. Discard any unused implant and single use items in accordance with standard hospital or clinic practice for disposal of human tissue.

WARRANTY STATEMENT

This biologic graft, processed and packaged for surgical implantation, is unique and does not constitute a product under liability laws in most states. 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.***

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 AND COMPLAINTS

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

In the U.S.A.	**In Canada**
Zimmer Biomet Dental 4555 Riverside Drive Palm Beach Gardens, FL 33410 Tel: 1.561.776.6700 www.zimmerbiometdental.com	Zimmer Biomet Dental Canada Inc. 2323 Argentia Road Mississauga, Ontario, L5N 5N3 Canada Tel: 1.800.265.0968 Fax: 1.905.567.2076 CTO Registration Number: 100086

Puros® is a registered trademark of Zimmer Biomet or its affiliates.

DEFINITION OF LABEL SYMBOLS		
		
See instructions for use	Expiration date	Storage temperature limits
		
Sterile by Gamma Irradiation	Do not reuse Single patient use	Manufacturer
		
Catalogue number	Serial Number (Tissue number)	Lot number (Donor number)
Rx ONLY		
For prescription use only		

Manufactured By:
RTI Surgical, Inc.
11621 Research Circle | Alachua, FL 32615 | U.S.A
Tel: 386.418.8888 | Fax: 386.462.5533
CTO Registration Number: 100053