CUSTOMERS RETURNS AND COMPLAINTS
For further information or to report a complaint or adverse event, please contact:

Marketed in the USA by:	Imported and marketed in Canada by:
Zimmer Biomet Dental 4555 Riverside Drive Palm Beach Gardens FL 33410, USA Tel: 1.561.776.6700	Zimmer Biomet Dental Canada Inc. 106 – 2345 Argentia Road Mississauga, Ontario Canada 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: 1.386.418.8888
Fax: 1.386.462.5533

CTO Registration Number: RTI Surgical, Inc. 100053

Processed by:
Tutogen Medical GmbH
Industriestrasse 6
91077 Neunkirchen am Brand
Germany
TEL: +49 9134 9988-0
FAX: +49 9134 9988-99

Definition of label symbols			
Consult instructions for use	Do not re-use	Do not resterilize	Temperature limit
Use-by date	Do not use if package is damaged	Sterilized using irradiation	Keep dry
Keep away from sunlight	REF	LOT	SN
	Catalogue number	Batch code (Donor ID)	Serial number
Rx ONLY			
Restricted to sale by or on the order of a physician	Caution		

1003775Rev03

PUROS® Allograft Customized Block

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 healthcare professional.

DESCRIPTION
The Puros® Allograft Customized Block is a cancellous bone implant, processed using the Tutoplast™ Process and terminally sterilized by gamma irradiation. The implant is customized to fill a bone defect of an individual patient using a Computer Aided Design (CAD) model. The implant is shaped by processing a cancellous bone block with a Computer Numerical Control (CNC) system to match the CAD model of the patient's bone defect.

The implant is restricted to homologous use for the repair, replacement or reconstruction of skeletal defects by a qualified healthcare professional (e.g. dentist). This would include filling bone voids or gaps of the skeletal system (e.g. dental intraosseous, oral and craniomaxillofacial defects). The implant is not intended to be used in load bearing applications without appropriate hardware.

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).

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.

Sterilization
Tutoplast is a validated, chemical sterilization process that includes meticulous cleaning and gentle solvent dehydration of tissue. Low dose gamma irradiation is applied terminally to the product 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 product 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 and/or trace amounts of the following residual chemicals from the manufacturing process; acetone and hydrogen peroxide.

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.
The type of fixation at thin areas of the graft must be chosen under careful consideration.

INSTRUCTIONS FOR USE
⚠ 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 product should be available in case of unexpected need during the procedure.
- This implant and all packaging materials used by RTI Surgical, Inc. are not made from natural latex rubber.
- Remove the double-barrier packaged product, the package insert, patient implant stickers and Tissue Utilization Record from the box.
- Inspect the product, including all packaging and labeling materials carefully:
  - Do not use past expiration date specified on the product 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
- Open the package and pass the implant into the sterile field.
- Rehydrate the implant before use by soaking in sterile 0.9% saline solution for up to 30 minutes to improve handling properties.
  Note: Use promptly after rehydration.
- Place into bone defect as needed.

TISSUE UTILIZATION RECORD (TUR CARD)
Complete the enclosed Tissue Utilization Record (TUR). This information is kept confidential and used only for implant tracking. The TUR card should be completed even if the implant was discarded. Refer to the enclosed TUR card for additional information.