

Puros[®] Allograft Customized Block

Product information

The Custom Approach For Complex Defects



Puros Allograft Customized Block



Patients with severe atrophy of the mandible or maxilla who have elected for an implant-supported restoration may benefit from customized treatment. Allogenic (human) blocks as well as autologous blocks are the choice materials for the bone graft required for these cases. The success or failure of the grafting procedure may be determined by how well the block conforms to the defect.

Puros Allograft Customized Blocks are a crucial developmental step in block grafting. A custom block is produced using CAD/CAM technology based on a CBCT/CT scan of the defect area. This makes the procedure more comfortable for your patient by reducing surgery time and minimizing the risk of complications.¹

Your Benefits

Tutoplast® Process

- Retains osteoconductive properties due to the preservation of the natural bone matrix collagen and mineral composition, trabecular pattern and original porosity.^{2,3}
- Sterilized and preserved using the proprietary Tutoplast Process, customized allogenic blocks are a high-quality option for successful bone regeneration procedures.⁴
- In more than 40 years, over 5 million grafts have been sterilized using the Tutoplast Process without a single case of graft-related infection reported.⁵

Congruent In Shape

- Customized block fits precisely to defect.
- Large contact surface area improves ingrowth of blood vessels and revascularization.⁶

Reduced Surgery Time

- Additional manual adjustment of the defect and of the customized block is seldom required, allowing for reduced surgery time and reduced morbidity.⁷

1. Schlee M, Rothamel D. Ridge augmentation using customized allogenic bone blocks: proof of concept and histological findings. *Implant Dent.* (2013) 22:212-8.

2. Keith JD Jr, Petrungaro P, Leonetti JA, Elwell CW, Zeren KJ, Caputo C et al. Clinical and histologic evaluation of a mineralized block allograft: results from the developmental period (2001-2004). *Int J Periodontics Restorative Dent.* 2006;26:321-327.

3. Leonetti JA, Koup R. Localized maxillary ridge augmentation with a block allograft for dental implant placement: case reports. *Implant Dent.* 2003;12:217-226.

4. Würzler KK, Will F, Berger S. Herstellung und Anwendung CAD/CAM-gefräster, patientenspezifischer Knochenblöcke. *Implantologie Journal* (2015) 5:30-36.

5. Data on file with RTI Surgical, Inc

6. McAllister, B. S. Bone augmentation techniques *Journal of Periodontology* 2007;78:377-396

7. Parthasarathy, J., 3D modeling, custom implants and its future perspectives in craniofacial surgery. *Annals of Maxillofacial Surgery* 2014;4:9-18.

Please Note The Following Information



Imaging

Preparation Of Patient

- Remove temporaries and metal restorations, where possible.
- Position patient in stable position.

Imaging Requirements

- In general, all CT/CBCT devices are suitable.
- Recommended slice thickness: 0.2 to 0.6 mm.
- Gantry angle: 0°.
- Please ensure that high-contrast imaging is achieved, particularly in the case of cancellous structures and thin residual bone (e.g. thin sinus floor).

Scan Data

- Do not use data compression.
- Data must be provided in DICOM format only (.dicom or .dcm)*.
- Copy the DICOM data to a storage medium (CD, DVD, USB stick) and send it to your local Zimmer Biomet Dental office or contact our Customer Service Department for more information.

Planning And Design

Design Draft

- Zimmer Biomet Dental will e-mail you a 3D-PDF file of the drafted customized block consisting of the block and the defect site.
- To open the PDF file, you need Adobe Acrobat Reader.
- Adjustments can be made at any time before final approval.

Surgery

- Despite precise planning, the block may not fit as expected and minor manual adjustments may be required.
- Ensure you have the appropriate instruments (e.g., Luer, milling, piezo) available for any required manual adjustments.

Ordering Information

Catalog Number	Description
67217	Puros Allograft Customized Block Standard, 27 x 15 x 15 mm max
67218	Puros Allograft Customized Block Large, 27,1 x 15,1 x 15,1 mm min - 60 x 30 x 30 mm max

* Please contact your radiologist or device manufacturer if you have any questions on DICOM export.

Design And Order Process



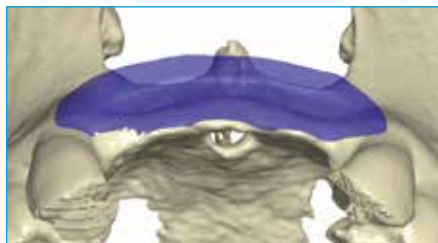
1. Data Submission

Fill-in the order form (ZB0516). Send the form together with CT/CBCT data (required in DICOM format) to Zimmer Biomet Dental.



2. Design Of The Customized Block

Zimmer Biomet Dental designs the Customized Block according to the requirements written on the order form and e-mails you a 3D-PDF draft for review. Adjustments can be made to the design at any time prior to final approval.



3. Approval

Once the design is finalized, your approval is required to release the block for milling.



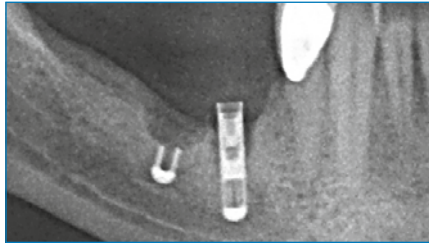
4. Milling Of Customized Block

Puros Allograft Customized Blocks are milled from Tutoplast-processed, allogenic cancellous bone. The final block has been gamma sterilized and is provided in double-pouched, sterile packaging.

5. Shipment

On the order form you can order the customized block alone or together with a collagen membrane and Puros Allograft Cancellous Particles (0,25–1 mm, 0,5 cc). Once the final design has been approved (step 3), the customized block will be released from manufacturing after approximately 4–6 weeks. The expected delivery date will be confirmed to allow you to schedule surgery accordingly.

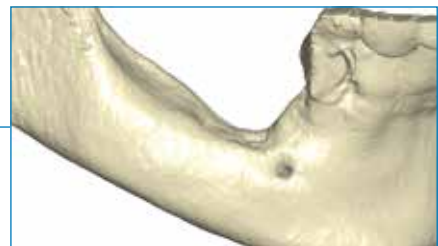
Case



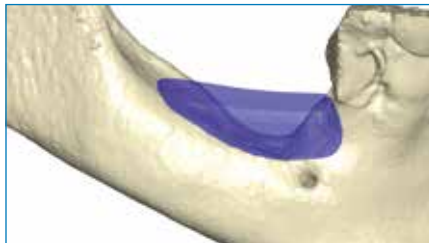
Right mandible defect, failed implants need to be removed, lateral view.

1

2



Three-dimensional model of the defect site, lateral view.



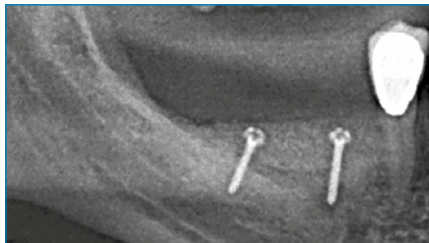
Designed block, lateral view.

3

4



Puros Allograft Customized Block.



Radiograph taken after block augmentation, block fixed with osteosynthesis screws.

5

6



Implant placement after 6-month healing period.



Prosthetic restoration.

7

8



1 year follow-up.



Contact us at 1-800-342-5454 or visit zimmerbiometdental.com

Zimmer Biomet Dental
Global Headquarters
4555 Riverside Drive
Palm Beach Gardens, FL 33410
Phone: +1-561-776-6700
Fax: +1-561-776-1272

Name of the medicinal product: PUROS® ALLOGRAFT | **Composition:** Human cancellous tissue (with cortical component in the Puros® Allograft Blend version), preserved using the Tutoplast® Process, sterilised by gamma irradiation. | **Therapeutic indications:** To cover or fill bone defects or to create bony structures in maxillofacial surgery. Therapeutic indications for which positive experience has been reported include the following: Regeneration of periodontal bone defects; Regeneration of furcation defects; Regeneration following cyst resection and apicoectomy; Regeneration of extraction sockets; Regeneration of gaps between the alveolar wall and dental implants; Regeneration of defects following block removal; Regeneration of gaps around block grafts; Horizontal alveolar ridge augmentation (particles); Sinus augmentation; Three-dimensional (horizontal and/or vertical) alveolar ridge augmentation (block augmentation). Further applications have been described in other surgical specialties. | **Contraindications:** None known. | **Undesirable effects** (frequency cannot be estimated from the available data): Graft rejection, implant site reaction, graft failure. As with every surgical procedure, there is the possibility of infection due to the procedure itself. | **Warnings:** Store dry, sunlight protected and not over 30 °C. Do not freeze. Discard any unused material; do not resterilise! See also instruction for use. Keep out of reach of children. | **General classification for supply:** Prescription only. | **Further information:** see package leaflet; | **Date of revision of the text:** 02.2018 „11“. | **Pharmaceutical Entrepreneur:** Tutogen Medical GmbH, Industriestraße 6, 91077 Neunkirchen am Brand, Germany | **Co-distributor:** Zimmer Dental GmbH, Wilhelm-Wagenfeld-Str. 28, D - 80807 München.

Unless otherwise indicated, as referenced herein, all trademarks are the property of Zimmer Biomet; and all products are manufactured by one or more of the dental subsidiaries of Zimmer Biomet Holdings, Inc., and distributed and marketed by Zimmer Biomet Dental (and, in the case of distribution and marketing, its authorized marketing partners). Puros products are manufactured by RTI Surgical, Inc. Tutoplast is a U.S. registered trademark owned by Tutogen Medical GmbH. For additional product information, please refer to the individual product labeling or instructions for use. Product clearance and availability may be limited to certain countries/regions. This material is intended for clinicians only and does not comprise medical advice or recommendations. This material may not be copied or reprinted without the express written consent of Zimmer Biomet Dental. ZBINST0018DE_EN REV A 04/18 ©2018 Zimmer Biomet. All rights reserved.

