# Puros® Customized Block Allograft Product information

## The custom approach for complex defects.

zimmer | dental

# Puros Customized Block Allograft

Patients with severe atrophy of the mandibular ridge who have elected for an implant-supported restoration will always require customized treatment. Allogenic (human) blocks as well as autologous blocks are the materials of choice for the bone graft required in numerous cases. The success or failure of the grafting procedure may be determined by how well the block approximates to the bed.

Puros Customized Block Allografts are a crucial developmental step in block grafting. A custom block is produced using CAD/CAM technology based on three-dimensional X-ray data of the defect area. This makes the procedure more comfortable for your patient by reducing operating time and minimizing the risk of complications.[1]

Puros Customized Block Allografts are authorised pharmaceutical products (Marketing Authorization no.: PEI.H.04761.01.1).

# 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.[2,3,4]
- Sterilized and preserved using the proprietary Tutoplast Process, customized, allogenic blocks are a high-quality option for successful bone regeneration procedures.[5]
- In 43 years over 3 million grafts have been sterilized using the Tutoplast Process without a single known case of graft-related infection reported.[6]

## Congruence Of Form

- Block fits precisely to local bone.
- Large surface contact areas supports ingrowth of blood vessels and revascularization.[7]

## Reduced Surgery Time

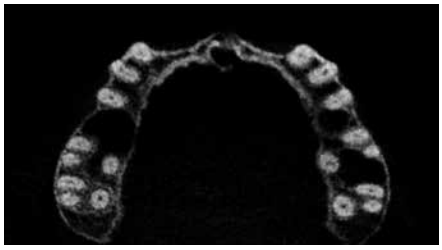
- Additional manual adjustment of the bone bed and of the customized graft is unnecessary in most cases, leading to reduced operating time and reduced morbidity.[8]

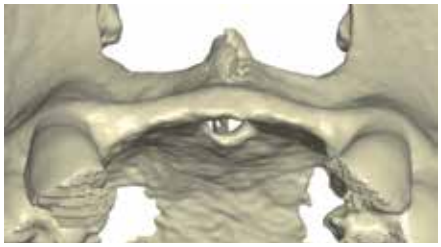

1. *Schlee M, Rothamel D. Ridge augmentation using customized allogenic bone blocks: proof of concept and histological findings. Implant Dent. (2013) 22:212-8.*
2 *Keith JD Jr, Petrungaro P, Leonetti JA, Elwell CW, Zeren KJ, Caputo C et al. Clinical and histologic evaluation of a mineralized block allograft: 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 *Schoepf C. Allograft safety: efficacy of the Tutoplast® process. International Magazine of Oral Implantology. 2006;1:10-15.*
5 *Würzler KK, Will F, Berger S. Herstellung und Anwendung CAD/CAM-gefräster, patientenspezifischer Knochenblöcke. Implantologie Journal (2015) 5:30-36.*
6 *Data on file at Tutogen Medical GmbH*
7 *McAllister, B. S. Bone augmentation techniques Journal of Periodontology 2007;78:377-396*
8 *Parthasarathy, J., 3D modeling, custom implants and its future perspectives in craniofacial surgery. Annals of Maxillofacial Surgery 2014;4:9-18.*

# Design And Order Process

## 1. Providing Data

Fill out the order form in full. Send the form together with a disk containing the CT/CBCT scan data required in DICOM format to Zimmer Dental.



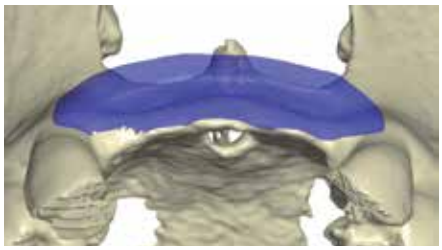


## 2. Design Of The Customized Block

Zimmer Dental designs the Customized Block according to the requirements written on the order form and e-mails you a three-dimensional draft for review. The maximum length of a block is limited to 40 mm. Adjustments can be made to the design at any time.

## 3. Approval

Once the design is finalized, you sign to confirm your approval for manufacture.



## 4. Manufacture Of Customized Block

Puros Customized Block Allografts are manufactured from Tutoplast-processed, allogenic donor bone and provided in double-barrier sterile packaging. The final block consists of 100% cancellous bone.

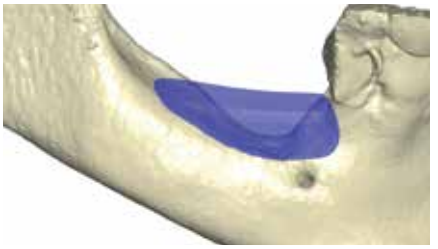
## 5. Delivery

The delivery comprises the Customized Block, a collagen membrane (CopiOs® Pericardium Membrane) and Puros®-Cancellous Particulate Allograft (particle size 0.25 – 1 mm). Once the plan is approved (step 3) the Customized Block is produced and will be normally available after 4 – 6 weeks. **We will inform you of the definitive delivery date in good time.**

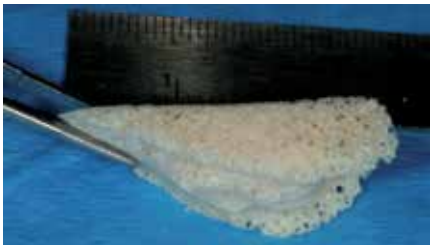
# Case

1 Initial situation, right mandible

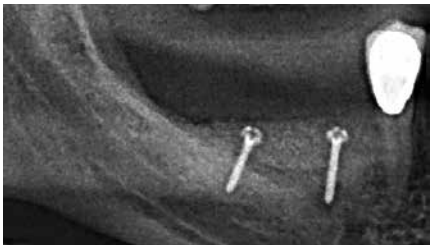
2 Three-dimensional reconstruction of defect, lateral view



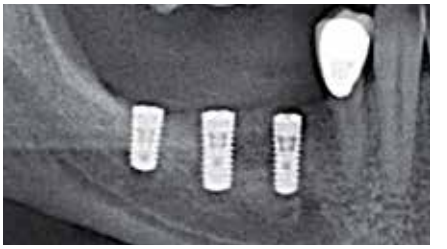
3 Designed graft, lateral view



4 Puros Customized Block Allograft

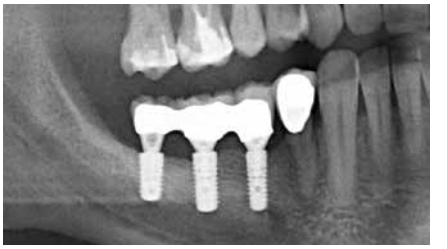


5 X-ray after augmentation procedure, graft fixed with osteosynthesis screws



6 X-ray after implant placement after 6-month healing period

7 Prosthetic restoration



8 1 year follow up

*Diagrams and clinical photographs courtesy of Dr. Dr. K. K. Würzler, individual results may vary.*

# Please Note The Following Information

## Imaging

**Preparation of patient**

- Remove temporaries and metal restorations as completely as possible.
- Stable positioning of patient.

**Imaging requirements**

- In general, all CT/CBCT devices are suitable
- Recommended slice thickness: 0.2 to 0.6mm.
- 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 maxillary sinus floor).

**Data preparation/export**

- Do not use data compression.
- Data must be provided in DICOM format only (.dicom or .dcm)*.
- Copy the DICOM data to a data carrier (CD, DVD, USB stick) and send it to Zimmer Dental, or upload the data at www.zimmerdental.de/upload.

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

## Planning And Design

**Design draft**

- Zimmer Dental will e-mail you a PDF file with the three-dimensional view of the designed draft consisting of the block and the defect site.
- To open the PDF file you need the current, free of charge Adobe Acrobat Reader: http://get.adobe.com/de/reader/.
- Adjustments or design changes can be made at any time.

## Operation

- However meticulous the planning, it may happen that the block does not fit 100%, and so minor manual adjustments may be required.
- Make sure you have the right instruments (e.g., Luer, milling, piezo) ready for the manual adjustment.

***Name of the medicinal product:*** *PUROS® ALLOGRAFT*

***Qualitative and quantitative composition:*** *Human cancellous tissue, preserved using the Tutoplast® process, sterilised by gamma irradiation The pack contains a mould or the quantity of ground substance stated on the outer packaging.*

***Pharmaceutical form:*** *Tissue graft. Bone graft in the form of cancellous particles, patient customized block, blocks and dowels. The grafts are usually whitish in colour.*

***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*

***Adverse reactions:*** *The following frequency conventions are used in the rating of adverse reactions:*
*Very common (>1/10)*
*Common (>1/100 to <1/10)*
*Uncommon (>1/1,000 to <1/100)*
*Rare (>1/10,000 to <1/1,000)*
*Very rare (<1/10,000)*
*Not known (cannot be estimated from the available data).*

| System Organ Class | Frequency | Adverse reaction |
|---|---|---|
| Immune system disorders | Not known | Transplant rejection |
| General disorders and administration site conditions | Not known | Implant site reaction |
| Injury, poisoning and procedural complications | Not known | Transplant failure |

As with every surgical procedure, there is the possibility of infection due to the procedure itself.

**Special warnings and precautions for use**
- *Prior to insertion of the graft, the therapeutic indication must be carefully established in the following cases:*
  - *Implantation in a necrotic host site*
  - *Implantation in a hypoperfused area*
  - *Implantation in a host site with active or latent infection*
  - *In the event of disturbances or diseases that negatively affect the healing rate.*
- *The graft remains sterile provided that the packaging is undamaged. If the sterile packaging is damaged, the product may not be resterilised and must be discarded. In the event of contamination during the surgical procedure, the graft must be discarded.*
- *When using the graft, please bear in mind that mechanical stress can vary depending on the application site and the product's physical stability must be able to withstand such conditions.*
- *When preparing the graft for the individual patient, avoid damage due to heat generation. The graft's structural integrity should be maintained.*
- *The graft must be inserted (preferably using a "press-fit" technique) and secured in such a way that it remains in place and its incorporation is facilitated.*
- *It is essential to avoid stresses that exceed the physical stability of the graft when implanting moulds, in order to maintain the graft's structural integrity.*
- *PUROS® ALLOGRAFT is intended for single use only. Any unused material should be discarded.*

***Marketing authorisation number:*** *PEI.H.04761.01.1*

***General classification for supply:*** *Medicinal product subject to medical prescription*

***Further information:*** *see package leaflet; Marketing Authorization Number PEI.H.04761.01.1;*
*Date of revision of the text: 11/2015 „07"*
*Tutoplast® is a registered trademark of Tutogen Medical GmbH.*
*Puros® is a registered trademark of Zimmer Dental Inc.*
***Pharmaceutical Entrepreneur:*** *Tutogen Medical GmbH, Industriestraße 6, 91077 Neunkirchen am Brand, Germany*

***Co-distributor:*** *Zimmer Dental GmbH, Wentzingerstraße 21, 79106 Freiburg*
*Tel.: 0800-2 33 22 30, Fax: 0800-2 33 22 32, e-mail: kundenservice.dental@zimmer.com*

**For more information on our products,**
**continuing professional education programs and training packages:**

Zimmer Dental GmbH
Wilhelm-Wagenfeld-Str. 28
80807 München
Deutschland

Free of charge service numbers for Germany:

| | |
|---|---|
| Customer service | 0800-101-64-20 |
| Fax order number | 0800-313-11-11 |

**If you would like to receive a regular copy of our eNews, visit us at**
**www.zimmerdental.com**



zimmer | dental