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European Orthopaedics

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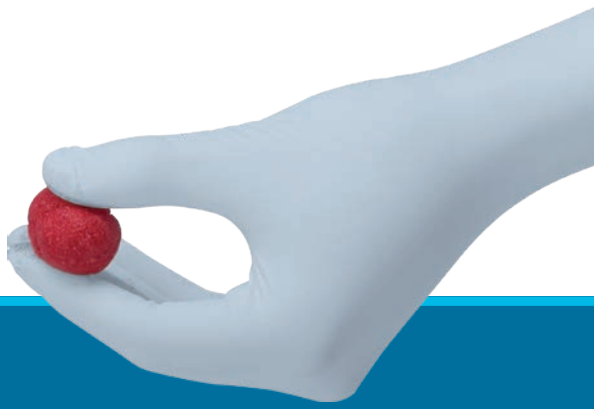
***Preservation** in motion*



Ceros TCP Putty

Kneadable bone substitute

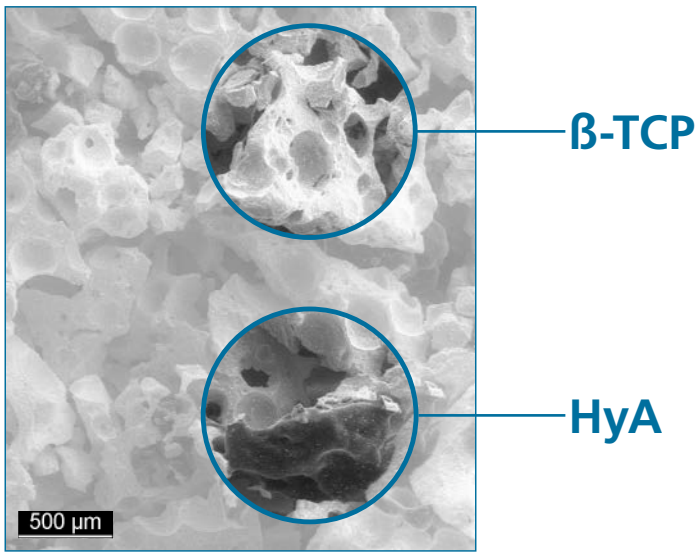
Product information

Our Ceros TCP Putty – Features & benefits

Chemical composition
Ceros TCP Putty is a sterile, osteoconductive, resorbable bone substitute offering kneadable properties. [1, 2, 3]

Ceros TCP Putty is made of synthetic, monophasic beta-tricalcium phosphate (β-TCP, beta-TCP, $[Ca_3(PO_4)_2]$) granules in a fermented, non-animal-derived sodium hyaluronate carrier in granular form. Ceros TCP Putty is delivered as dry powder mixture in a cup. The Ceros TCP Putty dry powder mixture consists of 92.5 % beta-TCP granules and 7.5 % sodium hyaluronate (dry w/w-%).

A kneadable Ceros TCP Putty paste is obtained by adding and mixing with a liquid component intra-operatively. The liquid component, which can consist of a sterile physiological salt solution, autologous blood or bone marrow or blood- or bone-marrow-derived cellular material, is not provided, but must be procured intra-operatively. The amount of liquid to be added to the respective powder mixture is listed in the instructions for use (Table 1, chapter 9.2) and on the product label.



Sterile Ceros TCP Putty in dry state: Ceros granules (β-TCP) and hyaluronic acid (HyA)

Synthetic ß-tricalcium phosphate (ASTM F 1088)

- Mathys Ltd Bettlach has more than 35 years of clinical experience with synthetic β-TCP
- Synthetic, biocompatible, osteoconductive and resorbable bone graft substitute [1, 2, 3]
- No risk of disease transmission

Fermented hyaluronic acid (EN ISO 22442 1-3)

- Non-animal derived hyaluronic acid in granular form, obtained by fermentation
- No risk of disease transmission
- Hyaluronic acid is naturally occurring in the body and one of the main components of the extracellular matrix

Remodeling into bone

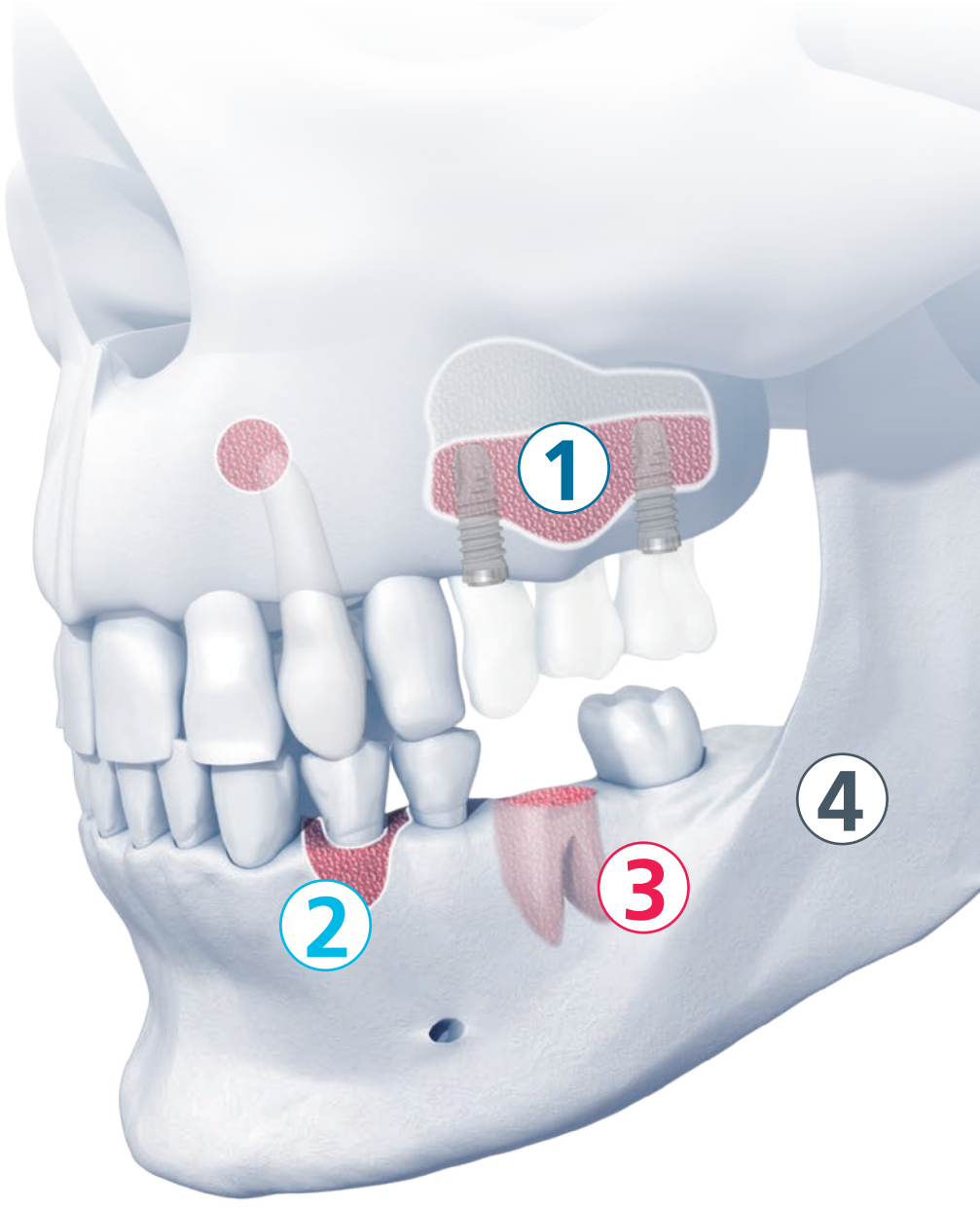
The monophasic beta-tricalcium phosphate granules have defined porosity and are remodeled by cellular activity and as a rule replaced by autologous bone in vivo within 6 – 18 months. The sodium hyaluronate is enzymatically metabolized in vivo. Depending on the patient's constitution (sex, metabolism, smoking status) and age, and the location and size of the bone defect or intended bony fusion, the remodeling time may vary. [1, 3]

Adding autologous blood or bone marrow or blood- or bone-marrow-derived cellular material or morselized bone to synthetic bone substitutes is state of the art to enhance their osteointegration. [4, 5, 6]

Performance and indication

Intended use and indications
Ceros TCP Putty is used in bone defect filling in periodontal, oral and maxillofacial surgery, including filling of extraction socket. It also is used to increase bone volume with bone augmentation on the sinus floor and/or alveolar ridges using the guided bone regeneration technique.

For detailed description of preparation and indications/contraindications please read the instructions for use.



Evidence from clinical studies

No.	Field of application	Product	Reference
1	Sinus Floor Augmentation	Ceros TCP Putty	Foitzik et al (2015) [1] Kluk (2013) [2] Knabe et al. (2017) [7]
2	Horizontal Augmentation, dehiscence, in combination with GBR	Ceros TCP granules* with autologous bone	Merli 2015_a [8]
	Periodontal defects in combination with GBR	Ceros TCP granules* with autogenous platelet concentrate	Moder 2012 [9]
	Lateral mandibular defect	Ceros TCP granules* with autologous bone	Merli 2013 [10]
3	Alveolar defect	Ceros TCP granules*, 0.7 – 1.4 mm	Markwalder 1987 [11]

*clinical data based on equivalence product Ceros TCP Granules

Evidence from animal studies

No.	Field of application	Product	Reference
4	Mandibular bone defect in minipigs	Ceros TCP granules*, 0.7 – 1.4 mm	Buser 1998 [12] Jensen 2005 [13]
	Mandibular bone defect in minipigs	Ceros TCP granules*, 0.7 – 1.4 mm with blood or platelet concentrate	Jensen 2006 [14]
	Mandibular bone defect in sheep	Ceros 82 granules*, 0.7 – 1.4 mm	Gatti 1990 [15]
	Mandibular ridge augmentation in combination with GBR in dog	Ceros TCP granules*, 0.7 – 1.4 mm	Von Arx 2001 [16]

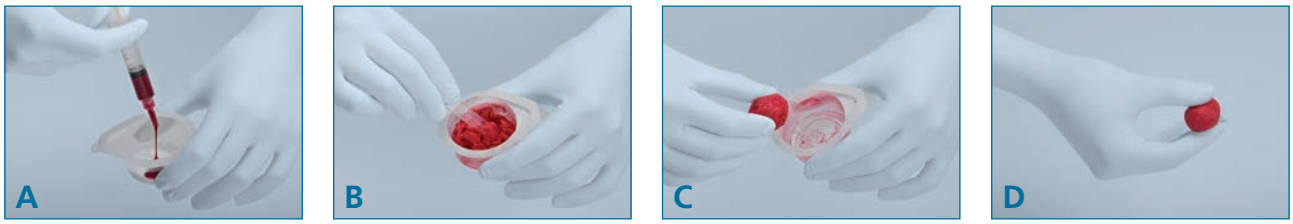
*clinical data based on equivalence product Ceros TCP Granules

Clinical application and order information

Clinical application

1) Open the cup containing the Ceros TCP Putty dry powder mixture.
2) Fill in complete amount of liquid into blister (**Fig. A**).
3) Mix liquid with powder during approximately 1 minute (**Fig. B**).
4) Wait after mixing for at least 1 minute. Do not wait longer than for 2 hours.
5) Take out Ceros TCP Putty using sterile gloves or using a sterile spatula or other sterile accessories (**Fig. C**).
6) Knead and shape Ceros TCP Putty between your fingers wearing sterile gloves.
7) Shape Ceros TCP Putty (**Fig. D**).
8) Apply pre-shaped Ceros TCP Putty onto the desired location.
9) Close bone defect using appropriate procedures.
10) No additional waiting time is required, as Ceros TCP Putty does not set in situ after implantation (no cement reaction).

For detailed information on the clinical application including the amount of liquid to be added to the respective powder mixture please read Instruction for Use.



Order information

Ceros TCP Putty

Item no.	Description
42.34.0101	Ceros TCP Putty, 0.5 cc
42.34.0102	Ceros TCP Putty, 1.0 cc
42.34.0103	Ceros TCP Putty, 2.5 cc
42.34.0104	Ceros TCP Putty, 5.0 cc

Material: β-tricalcium phosphate, non-animal derived sodium hyaluronate

To learn more about Ceros TCP Putty or the Ceros portfolio in general please contact your local Mathys representative directly.

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MATHYS
European Orthopaedics

Australia
Mathys Orthopaedics Pty Ltd
Lane Cove West, NSW 2066
Tel: +61 2 9417 9200
info.au@mathysmedical.com

Austria
Mathys Orthopädie GmbH
2351 Wiener Neudorf
Tel: +43 2236 860 999
info.at@mathysmedical.com

Belgium
Mathys Orthopaedics Belux N.V.-S.A.
3001 Leuven
Tel: +32 16 38 81 20
info.be@mathysmedical.com

France
Mathys Orthopédie S.A.S
63360 Gerzat
Tel: +33 4 73 23 95 95
info.fr@mathysmedical.com

Germany
Mathys Orthopädie GmbH
«Centre of Excellence Sales» Bochum
44809 Bochum
Tel: +49 234 588 59 0
sales.de@mathysmedical.com

«Centre of Excellence Ceramics» Mörsdorf
07646 Mörsdorf/Thür.
Tel: +49 364 284 94 0
info.de@mathysmedical.com

«Centre of Excellence Production» Hermsdorf
07629 Hermsdorf
Tel: +49 364 284 94 110
info.de@mathysmedical.com

Italy
Mathys Ortopedia S.r.l.
20141 Milan
Tel: +39 02 5354 2305
info.it@mathysmedical.com

Japan
Mathys KK
Tokyo 108-0075
Tel: +81 3 3474 6900
info.jp@mathysmedical.com

New Zealand
Mathys Ltd.
Auckland
Tel: +64 9 478 39 00
info.nz@mathysmedical.com

Netherlands
Mathys Orthopaedics B.V.
3001 Leuven
Tel: +31 88 1300 500
info.nl@mathysmedical.com

P. R. China
Mathys (Shanghai) Medical Device Trading Co., Ltd
Shanghai, 200041
Tel: +86 21 6170 2655
info.cn@mathysmedical.com

Switzerland
Mathys (Schweiz) GmbH
2544 Bettlach
Tel: +41 32 644 1 458
info@mathysmedical.com

United Kingdom
Mathys Orthopaedics Ltd
Alton, Hampshire GU34 2QL
Tel: +44 8450 580 938
info.uk@mathysmedical.com

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