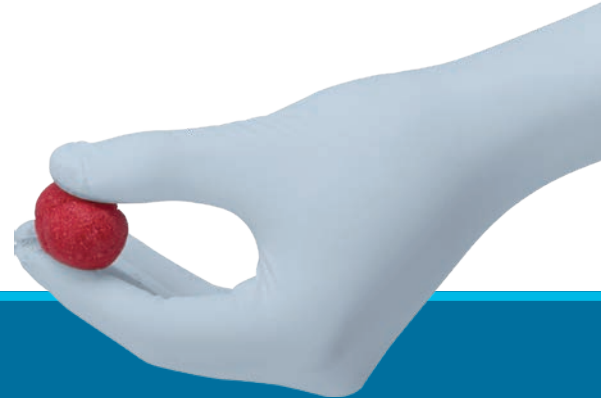




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Preservation in motion



cyclOS Putty
Kneadable bone substitute
Product information

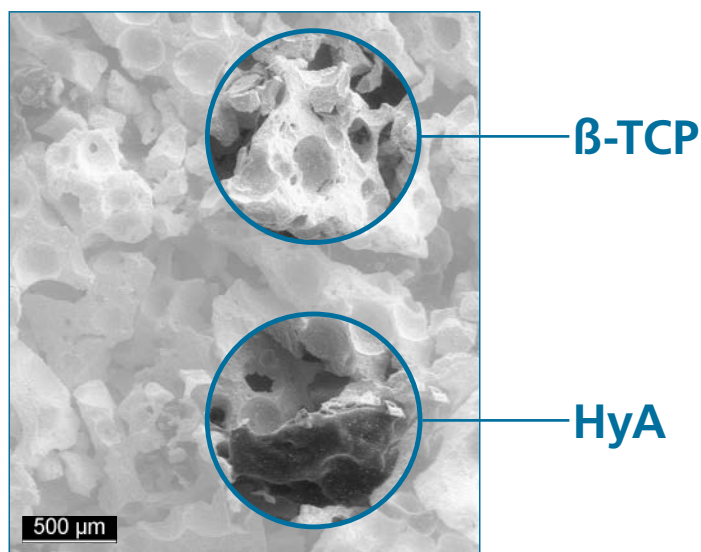
Our cyclOS Putty – Features & Benefits

Chemical composition

cyclOS Putty is a sterile, osteoconductive, resorbable bone substitute offering kneadable properties. ^{1, 2, 3}

cyclOS Putty is made of synthetic, monophasic beta-tricalcium phosphate (β -TCP, beta-TCP, $[\text{Ca}_3(\text{PO}_4)_2]$) granules in a fermented, non-animal-derived sodium hyaluronate carrier in granular form. cyclOS Putty is delivered as dry powder mixture in a cup. The cyclOS dry powder mixture consists of 92.5 % beta-TCP granules and 7.5 % sodium hyaluronate (dry w/w-%).

A kneadable cyclOS 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 cyclOS Putty in dry state: beta-TCP granules (β -TCP) and hyaluronic acid (HyA)

Synthetic β -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

cyclOS Putty is a bone substitute intended to be used as filling material for bone defects, as augmentation material, and bone substitute for bony fusion in skeletally mature patients.

Indications include bone defect fillings or bony fusion of the skeletal system.

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



Clinical application and order information

Clinical application

- 1) Open the cup containing the cyclOS Putty dry powder mixture. The sterile cyclOS Putty dry powder mixture in the cup may contain agglomerates.
- 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 cyclOS Putty using sterile gloves (wearing two pairs of gloves is recommended) or using a sterile spatula or other sterile accessories (**Fig. C**).
- 6) Knead and shape cyclOS Putty between your fingers wearing sterile gloves (wearing two pairs of gloves is recommended).
- 7) Shape cyclOS Putty. cyclOS Putty may be portioned but not be used for a second patient (**Fig. D**).
- 8) Apply pre-shaped cyclOS Putty onto the desired location.
- 9) Close bone defect using appropriate procedures.
- 10) No additional waiting time is required, as cyclOS 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

cyclOS Putty

Item no.	Description
59.37.2429	cyclOS Putty, 0.5 cc
59.37.2425	cyclOS Putty, 1.0 cc
59.37.2428	cyclOS Putty, 2.5 cc
59.37.2426	cyclOS Putty, 5.0 cc
59.37.2427	cyclOS Putty, 10.0 cc

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

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

References

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