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Preservation in motion

cyclOS granules and preforms
Synthetic bone substitute

Product information

Features & benefits

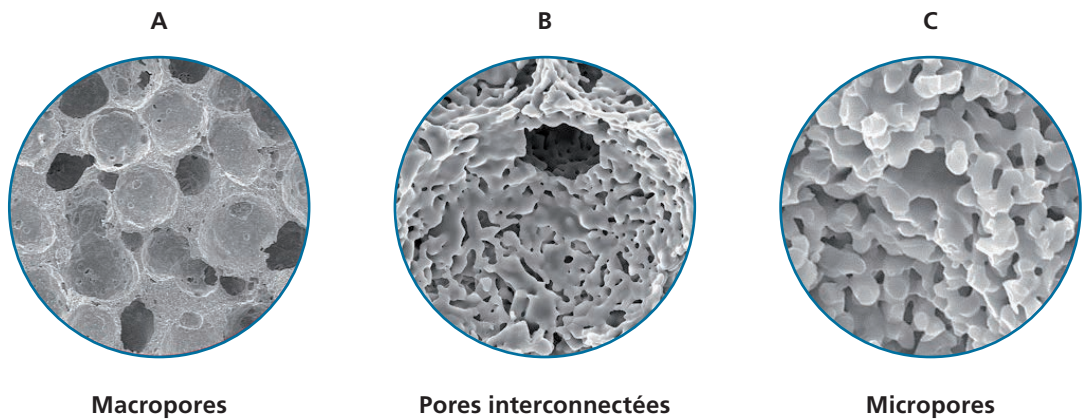
Chemical composition

The biological behaviour of bone substitutes is influenced by many factors, such as chemical composition, porosity, pore sizes and interconnections, vascularization and cell and bone infiltration of the scaffold.^{1, 2, 3} cyclOS granules and preforms have been developed to mimic the porous structure, chemical composition and remodeling behavior of cancellous bone.

cyclOS granules and preforms are synthetic, osteoconductive, resorbable and biocompatible bone substitutes consisting of β -tricalcium phosphate (β -TCP, $[\text{Ca}_3(\text{PO}_4)_2]$) complying with the standards ASTM F 1088 and ISO 13175-3. The solubility and Ca/P molar ratio of β -TCP are close to those of bone mineral. As a result, β -TCP is remodeled into bone by cellular processes. cyclOS granules and preforms are initially radio-opaque. As the bone remodeling process progresses the radio-opacity will resemble the one of autologous bone.

Porous structure

cyclOS granules and preforms have a total porosity (**A**) of 60 % and 70 % respectively, both with interconnecting macropores (**B**) of 100–500 μm in diameter, allowing vascularisation and bone tissue ingrowth.¹ The microporosity (**C**) (1–10 μm) enlarges the surface area of the pores and increases the interface between bone and bone substitute.



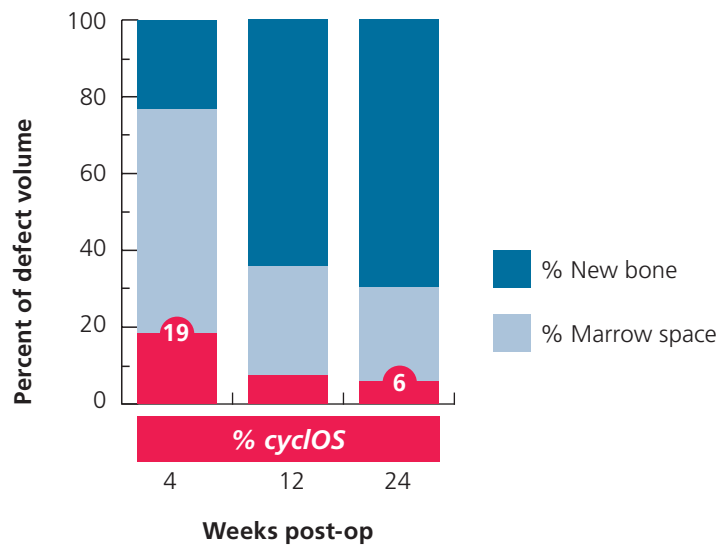
Remodeling into bone

Bone is a dynamic tissue which undergoes a continuous remodeling process. The complex process requires interaction between different cell types which are regulated by a variety of factors. Osteoclasts are the bone-crushing cells, whereas osteoblasts are the bone-building cells.

The chemical composition and porous structure of cyclOS granules and preforms allow for adaptation to the continuous remodeling cycle of healthy bone. Depending on the patient's constitution and age, (e.g. sex, metabolism) and the location and size of the bone defect, cyclOS granules are completely remodeled into vital bone within 6–18 months.^{4, 5, 6, 7, 8, 9, 10}

cyclOS granules inserted in a defined mandibular defect in minipigs transformed almost completely into homogenous bone structure within 24 weeks (from 19% to 6%), see figure.⁴

Remodelling⁴ of cyclOS



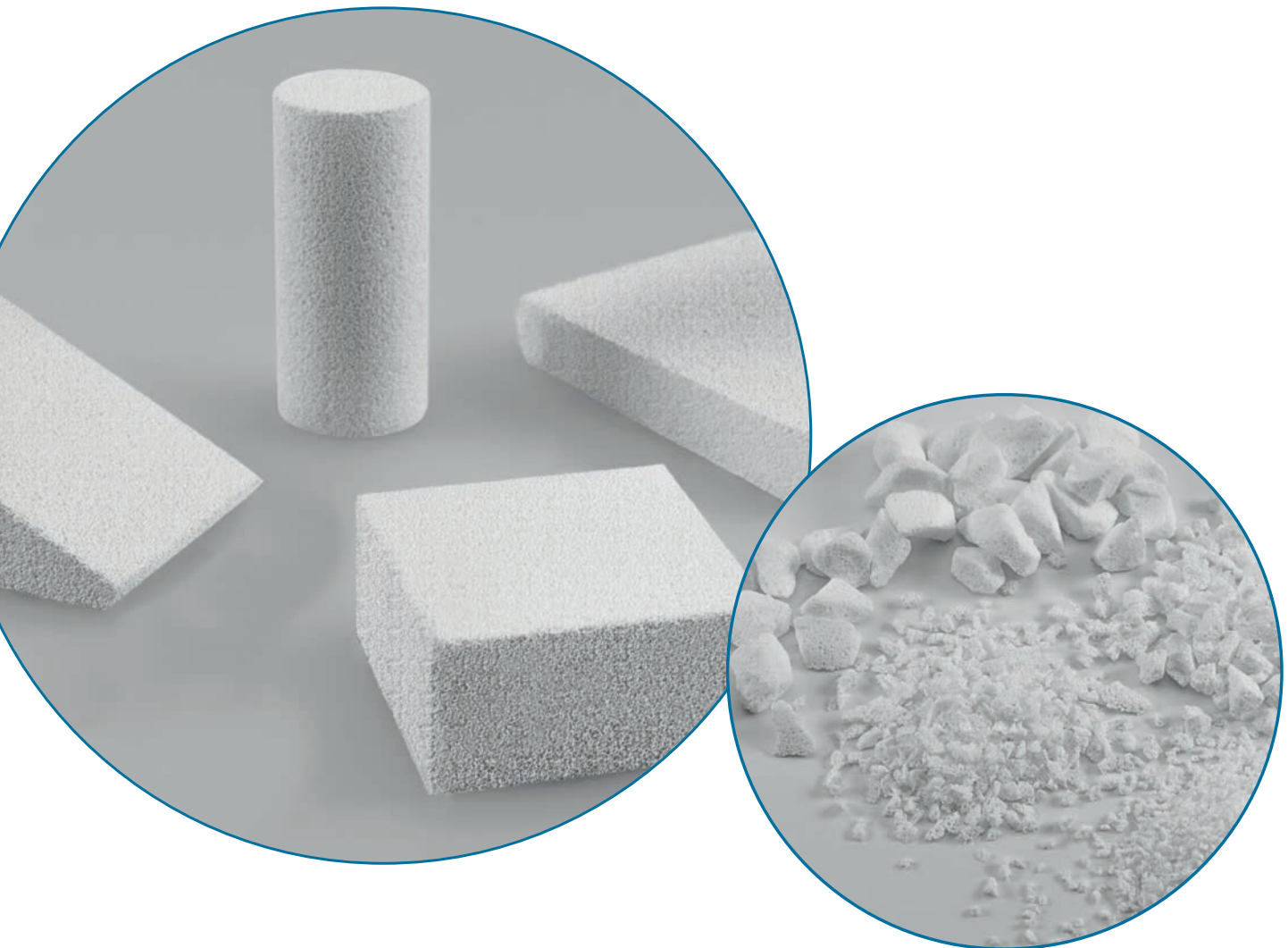
Performance and indication

Intended use and indications

cyclOS granules and preforms are synthetic bone substitutes intended to be used as filling material for bone defects, as augmentation material, and as 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

Maximum mechanical stability in the bone defect packing with cyclOS granules and preforms is a prerequisite for good osseous incorporation. In case of instability of the bone defect, the operating area must first be stabilized with appropriate osteosynthesis and or instrumentation procedures.

Always apply cyclOS granules and preforms by endosseous or subperiosteal implantation, ensuring direct contact with the vital bone without any intermediate connective tissue layer.

To prepare the implant site, remove all inflamed or necrotic tissue and bone fragments, and debride the bone until bleeding. The amount of implant material required depends on the size of the bone defect. The localization, nature and extent of the bone defect determines the operative procedure.

Fill the bone defect completely with cyclOS granules or preforms (press-fit) but overfilling and impaction grafting must be avoided to ensure a tension-free bone defect closure. Use cyclOS granules for the filling of irregular bone defects. cyclOS preforms may be used in their given form or be intra-operatively shaped to a desirable size using a sterile scalpel. Use a sterile spatula, a sterile surgical spoon or other appropriate, sterile instruments to apply cyclOS granules and preforms into the bone defect.

cyclOS granules and preforms can be mixed with autologous blood or bone marrow or blood- or bone-marrow-derived cellular material or morselized bone or allogenic bone material. Osseointegration of cyclOS preforms can further be enhanced by perfusion in autologous blood or bone marrow aspirate

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 granules

Item no.	Description
59.37.1137	cyclOS granules, 0.5–0.7 mm, 5.0 cc
59.37.1138	cyclOS granules, 0.5–0.7 mm, 10.0 cc
59.37.1139	cyclOS granules, 0.5–0.7 mm, 20.0 cc
59.37.1147	cyclOS granules, 0.7–1.4 mm, 5.0 cc
59.37.1148	cyclOS granules, 0.7–1.4 mm, 10.0 cc
59.37.1149	cyclOS granules, 0.7–1.4 mm, 20.0 cc
59.37.1157	cyclOS granules, 1.4–2.8 mm, 5.0 cc
59.37.1158	cyclOS granules, 1.4–2.8 mm, 10.0 cc
59.37.1159	cyclOS granules, 1.4–2.8 mm, 20.0 cc
59.37.1167	cyclOS granules, 2.8–5.6 mm, 5.0 cc
59.37.1168	cyclOS granules, 2.8–5.6 mm, 10.0 cc
59.37.1169	cyclOS granules, 2.8–5.6 mm, 20.0 cc

Material: β -tricalcium phosphate, 60 % porosity

cyclOS preforms

Item no.	Description
59.37.2105	cyclOS block, 20x20x10 mm
59.37.2110	cyclOS block, 30x20x10 mm
59.37.2407	cyclOS wedge, semicircular, 7°
59.37.2410	cyclOS wedge, semicircular, 10°
59.37.2413	cyclOS wedge, semicircular, 13°
59.37.2420	cyclOS wedge, 10°
59.37.2421	cyclOS wedge, 14°
59.37.2422	cyclOS wedge, 18°
59.37.2423	cyclOS wedge, 22°
59.37.2424	cyclOS wedge, 26°
42.34.2201	cyclOS cylinder, 11.3x25 mm

Material: β -tricalcium phosphate, 70 % porosity

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

References

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