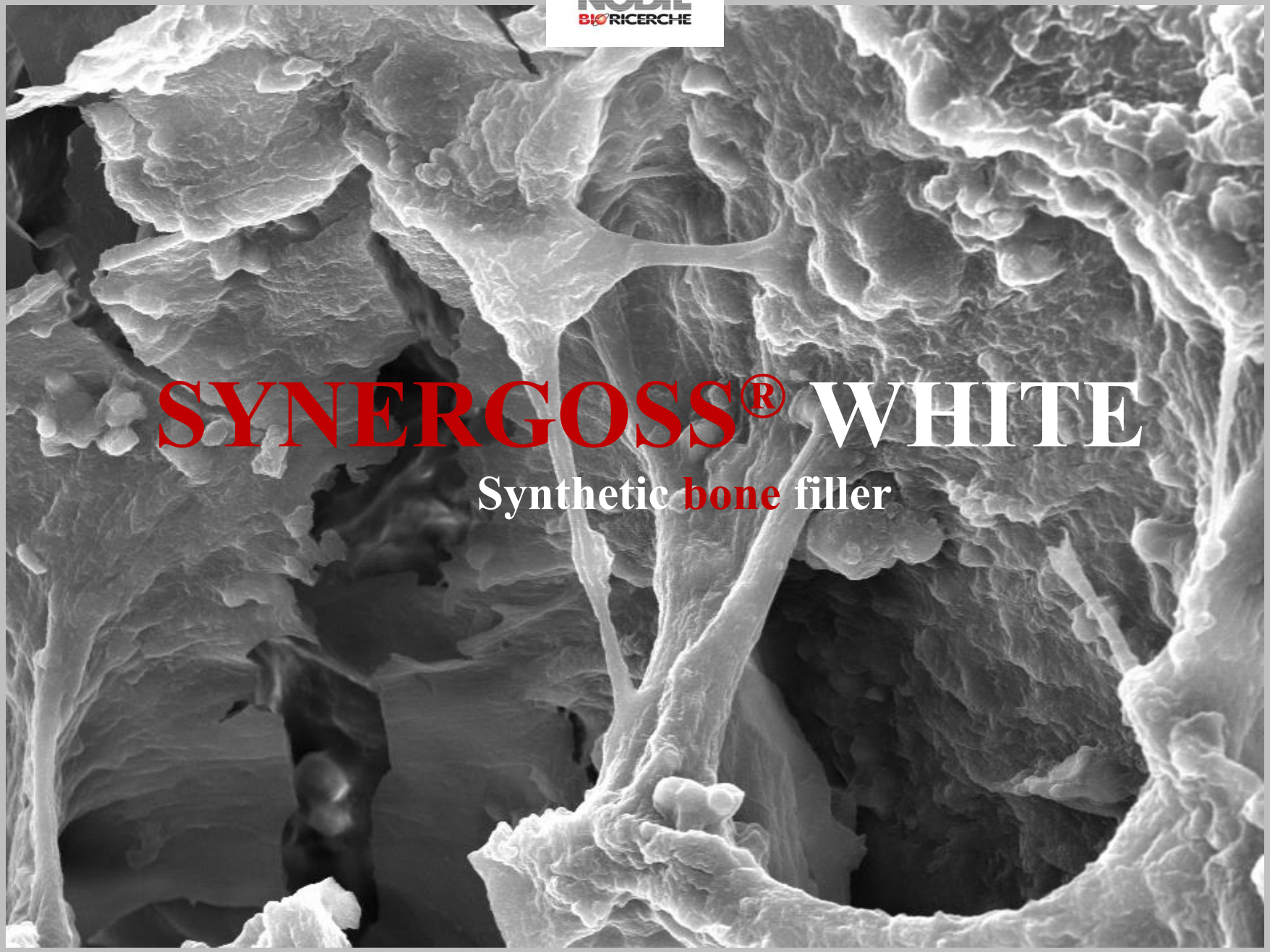

SYNERGOSS® WHITE
Synthetic bone filler

What is Synergoss® White?

Synergoss White is a synthetic bone filler composed of
80% β-tricalcium phosphate
and
20% hydroxyapatite,
which are well-known osteoconductive materials.

Why calcium phosphate-based materials?

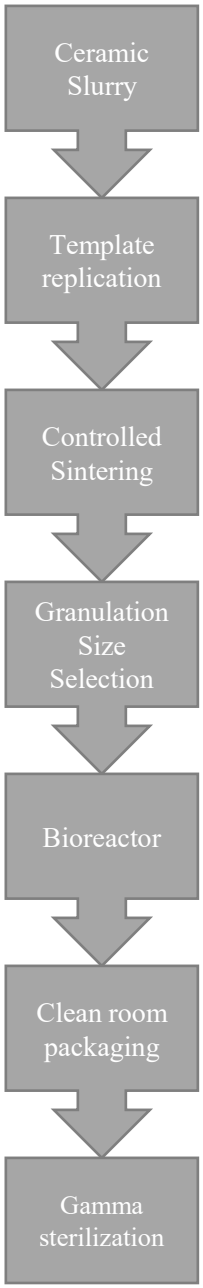
Calcium phosphates are the major inorganic component in native bone (around 65%), with excellent biocompatibility and mechanical properties.

Hydroxyapatite is the most stable calcium phosphate, do not cause inlfammation reaction and the surface act as a nucleating site for bone minerals in body fluid. β-tricalcium phosphate is less stable than hydroxyapatite with a higher resorption rate and is widely used to increase biocompatibility, promotes the proliferation of osteoprecursor cells and the initial bone formation.

The mixture of hydroxyapatite and β-tricalcium phosphate stimulates the osteogenic differentiaition of mesenchymal stem cells, increase cell adhesion, and enhance mechanical properties.

The release of calcium and phosphorus ions regulates the activation of osteoblast and osteoclast to facilitate bone regeneration.

How Synergoss® White is made?



High quality raw materials are used to prepare an initial ceramic slurry.

The slurry is used to replicated a engineered controlled porous structure, which is later one dried and sintered in a controlled environment. Thruogh the use of a property bioreactor the ceramic granules are finilized.

Synergoss® White is packed in a sterile sealed glass vial and blistered in a ISO 7 Clean Room and sterilized with Gamma irradiation (25 kGy).

The in-house developed process ensure no variations among the different batches (homogeneous and costant composition) and reproducible morphology, which make clinicians confident about the tissue response to Synergoss® White.

Which are the main characteristics of Synergoss® White?

Reproducibility: batch-to-batch reproducible morphology, micro- and macro-porosity and surface area

Safety: No risk of infection or disease trasmission

Biocompatibility: characterized by an excellent biocompatibility and similarity to the mineral phase of teeth

Sterility: is sterilized under gamma radiation at 25 kGy. No modification due to the irradiation

Controlled and predictable resorption: biphasic mixture allows to achieve an excellent mechanical resistance and a gradual and controlled resorption within 6 months

Optimized morphology: Synergoss® White is composed by granules with a macro-pores forming trabecular structure and a high interconnected micro-porosity inside each granule.

Easy handling: Synergoss® White can be easily mixed with blood, saline solution or used directly in the bone defect

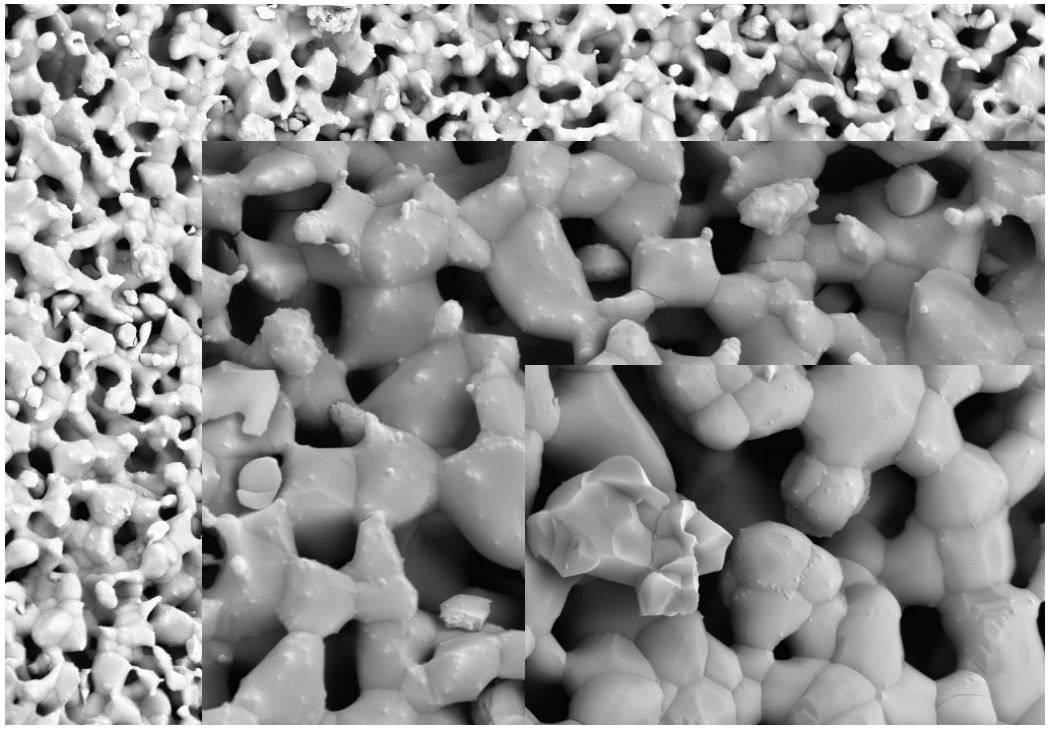
Synergoss® White microstructure can promote clot formation?

Synergoss® White granules is characterized by a porosity of 60% with a degree of open porosity equal to 98%. The pore size of Synergoss® White ranges from 100 to 1100 µm.

The granules immediatly take up blood and other liquids when getting into contact with them. Synergoss® White can be easily handled by the clinician and shows a good adherence to the instruments for the right and easy positioning.

Blood uptake and consequent clot formation is important to stimulate the overall healing process.

The microstructure of Synergoss® White promote clot formation, blood vessel infiltartion, high wettability (capillarity), nutrients transportaton and clot formation; which are fundamental to stimulate the overall healing process, besides allowing cell infiltration and new bone growth.



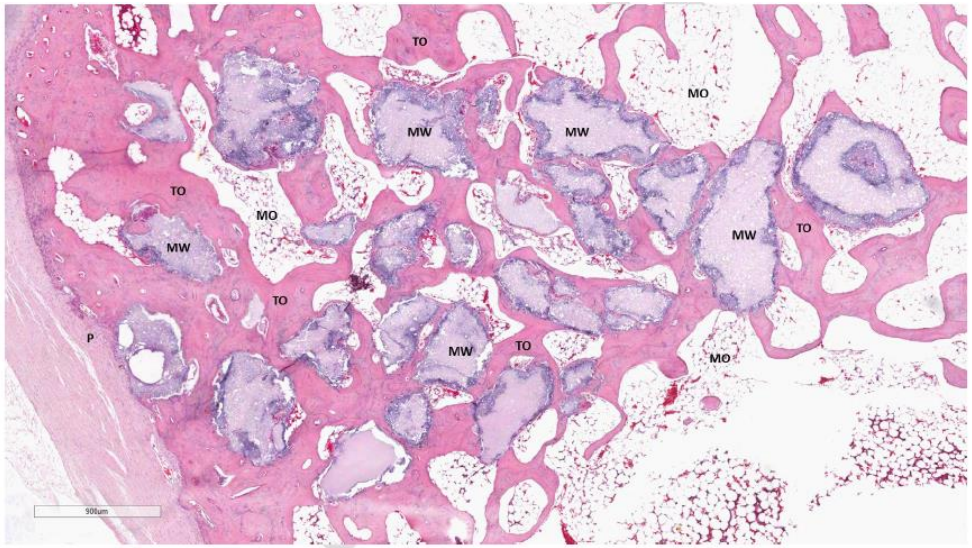
SEM images showing the microporous structure of Synergoss® White granules

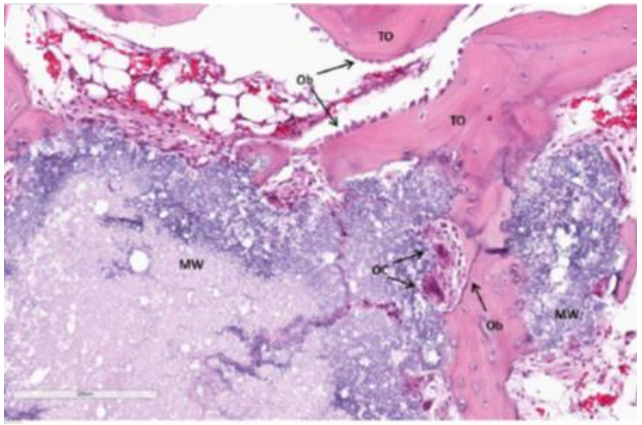
What happens with the Synergoss® White after implantation?

26 weeks after implantation, no inflammatory processes were found at the site of the implantation of the Synergoss® White.

The histological picture reveled a cell population charcateristic of a normal medullary tissue. Furthermore, new bone formation was found in the implantation site of Synergoss® White, intense activity of osteoblast at the level of newly formed bone trabeculae, presence of macrophages in the medullary component and osteoclast on the surface of the material.

Direct deposition of new bone tissue on the surface of Synergoss® White granules, which appeared osseointegrated and in close contact with the newly formed bone withour interposition of fibrous tissue.





Histology of a biopsy after 26 weeks after bone implantation in rabbit. MW: Synergoss® White residual. MO:Bone marrow. TO: New Bone. P: Periosteum. Ob: Osteoblast. OC: Osteoclast

Why use the synthetic bone filler
Synergoss® White
instead of a animal origin bone filler?

Synergoss® White can be a synthetic alternative to animal-derived bone filler.

- Controlled morphology and structure, designed to obtain ideal properties to stimulate healing process and new bone formation
- Biphasic calcium phosphte composition give a predictable resorption/remodeled time (6 months)
- Engineered surface structure which provide a rough and high hydrophilic surface area
- Synergoss® White is 100% synthetic; thus 100% safe with no risk of infection or disease trasmission
- No restriction by dietary or religious constrain

Synergoss® White will be resorbed and may be preferred by some clinicians compared with non remodeled animal-derived bone filler.

The overall outcomes depends on many other individual parameters for each singolar patient, such as health status, age, surgical procedure, hygiene.

In which clinical cases is Synergoss® White recommended?

Synergoss® White is recommended for:

- Socket and ridge preservation
- Horizontal and vertical augmentation
- Sinus lift
- Intraosseous defect

Synergoss® White is produced in two different size:

- 0,3/1 mm range granules are suggested to fill small to medium gaps; in particular in aesthetic region. Lower dimensional variability of granules ensure volume stability of small defect

- 0,3/2 mm range granules are suggested to fill large defectes (such as sinus lift), where the higher dimensinal varibility between granules create more space between single particles, promoting a better re-vascularization of larger defect.

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