Ceros® TCP Granules

Synthetic β-TCP bone substitute material
Bone substitute materials play an important role in oral surgery and implantology in order to assure the best possible patient care.

Treatment with autologous bone is the so-called “gold standard” because of its osteoconductive, osteoinductive and osteogenic properties. Despite these advantages, the clinical use of autologous bone is limited due to the need for a second application, possible complications, as well as its limited availability.

Therefore, bone graft substitutes serve a very important function. They can be used to fill defects and/or extend the volume of autologous bone and serve as a scaffold for guided bone regeneration.

Bone substitute materials consisting of beta-tricalcium phosphate (β-TCP) have a longstanding clinically proven history. These synthetic bone replacement materials are characterized by their high biocompatibility. They are resorbed and completely transformed into vital bone.

Advantages at a glance

100 % synthetic
- Provides high biocompatibility, preventing any risk of pathogen transmission.
- Unlike autologous bone and xenografts, there are no limitations with regard to quantity and/or quality.

Osteoconductive
- Their porous structure makes Ceros® TCP Granules an optimal matrix for the infiltration of bone cells and blood vessels, thus ideal for the remodeling into vital bone.

Complete remodelling into vital bone
- Ceros® TCP Granules are remodeled into new vital bone within 6–18 months.
Ceros® TCP Granules are a fully synthetic and resorbable bone graft substitute made of pure beta-tricalcium phosphate (β-TCP) with an overall porosity of 60%.

Ceros® TCP Granules consist of macropores distributed mainly within a range of 100–500 μm and micropores smaller than 10 μm.\(^6,7\)

The size and distribution of the macropores (A) has been proven to promote the new formation of blood vessels and vital bone.\(^20\)

The porous structure (B) facilitates the transport of blood, blood components and bone marrow into the core of the bone substitute to ensure cell nutrition during resorption and bone formation.\(^22,25\)

Micropores smaller than 10 μm (C) increase the surface area of the bone substitute and thus are promoting the resorption by osteoclast activity.\(^7,22\)
Ceros® TCP is completely remodeled into vital bone

A substance can be resorbed if the Ca:P ratio is < 1.6. If this ratio is > 1.6, as in hydroxyapatite, the bone substitute is not resorbed.\(^{13}\)

Ceros® TCP Granules are resorbable since the Ca:P ratio is 1.5. Osteoclastic resorption of Ceros® TCP Granules therefore ensures extensive resorption and remodeling into vital bone.

The progression of the remodeling process over time depends on different factors (vitality of the bone bed, localization, etc.). It lasts approximately 6 to 18 months.

In a study investigating jaw defects in minipigs, Buser et al. showed that Ceros® TCP Granules were almost completely remodeled into a bone matrix within 24 weeks. The percentage of Ceros® TCP Granules was reduced over the investigation period of 4 to 24 weeks from 19\% to 6\%, while the bone matrix increased from 23\% to 68\%.\(^{18}\)

Clinical Experience

Since 1982, Ceros® TCP Granules have proved their worth in traumatologic, spinal and orthopaedic surgery and in dental surgery for filling endosseous defects and augmenting volume in cases with an insufficient quantity of autologous cancellous bone.\(^{2, 3, 5, 10, 11, 15-17, 19, 23, 26}\)

Ceros® TCP Granules long-term clinical results and studies show good clinical results, excellent biologic compatibility as well as a complete bony integration and substitution with natural bone.\(^{2, 3, 4, 7-10, 14-19, 21, 23, 24, 25, 26, 27}\)
Ceros® TCP Granules are indicated for use as a bone void filler in non-load-bearing regions requiring cancellous rather than cortical bone material.

For example, Ceros® TCP Granules may be used to:
- supplement autologous cancellous bone
- act as a support and stabiliser for guided bone regeneration, “GBR”
- fill bone defects after hemisection of teeth, bone removal, osteotomy, tumour resection, root apex resection, tooth extraction or cystectomy
- fill bone defects resulting from traumatic or pathological origin
- augment an atrophied mandibular ridge (only in conjunction with the “GBR” membrane technique)
- prepare the implant bed (e.g. sinus lift)
- fill bone defects around dental implant after immediate placement into extraction sockets
- minor bone deficits such as fenestration defects on implants and periodontal defects can be made to heal well with Ceros® TCP Granules, possibly in combination with a membrane as part of Guided Bone Regeneration (GBR).

In general, the larger the number of bone walls at bone defects and the more favourable the morphology of the defect-covering soft tissue, the more predictable is the success of the intervention.

**Examples of dental defects**

- Root apex resection (about 1.0 g)
- Sinus lift (about 2.0-3.0 g)
- Periodontal defect (about 1.0-2.0 g)
- Alveolar defect (about 2.0-3.0 g)
Important considerations for application

- Mixture of the Ceros® TCP Granules with the patient’s own blood, including cancellous bone or bone marrow if available, makes insertion into the defect easier, since the granules become incorporated into the coagulate.
- For good bony integration of Ceros® TCP Granules, a mechanically stable situation as well as an appropriate defect configuration are most important. Ceros® TCP Granules must always be applied by endosseous or subperiosteal implantation, i.e., in direct contact with the vital bone.
- For preparation of the implant bed, inflamed and necrotic tissue must be removed and the bone freshly exposed.
- The quantity of bone graft substitute to be used depends on the size of the bone defect and the prospectively desired jaw contour. The appropriate granule size is determined by the size of the bone defect, the extent of the bleeding, the size of the spongiosa chips if used, etc. Care should be taken to ensure an adequate packing density.
- The bone defect must be filled completely with granules. However, to ensure tension-free wound closure, it is essential to avoid overfilling.
- The regions of the endosseous vessel and nerve cords should be kept clear to avoid pressure sores.
- Dislodged granules must be removed from the soft tissue.
- It is important to ensure that the wound is closed free of tension and made saliva-tight.
- Coverage of granule-filled defects with a membrane is recommended, especially in augmented regions that are exposed to mastication forces or facial muscle movements.
- Under certain circumstances it may be advisable to place a layer of autologous spongy bone on labial and buccal applications of Ceros® TCP Granules and cover it with the periosteum or a membrane.
- As a general recommendation when placing implants using a staged approach, it is suggested to wait 4–6 months between bone augmentation and implant placement for defect-filling cases, and 6–12 months for sinus lift cases.
- Due to their composition, Ceros® TCP Granules are radiopaque. Therefore, it is possible to monitor the resorption and remodelling of the bone around the implant or implant site.

Mixture
Ceros® TCP Granules can be mixed with sterile physiologic solution, patient blood, bone (cancellous bone) or bone marrow.

Note
In large defects and labial/buccal augmentations, the use of a mixture with autologous cancellous bone is recommended.
Ceros® TCP Granules, Porosity 60%, sterile

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<th>Package unit</th>
<th>Volume</th>
<th>Grain size</th>
<th>Reference Code</th>
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**References**
