



Ceros[®] TCP
Granules and Putty

THOMMEN
Medical

Introduction

Bone graft substitutes play an important role in dental surgery/implantology in order to assure optimal management of the patient.

Treatment with autogenous bone is the so-called "golden standard" because of its osteoconductive, osteoinductive and osteogenic properties. Despite these advantages, the clinical use of the procedure is limited by the need for a second intervention and possible attendant complications as well as the limited availability.

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

Synthetic graft substitute is available in unlimited supply and offers the significant advantage that there is no risk of pathogen transmission related to the source of the material or process technology. Moreover, the material has uniform product properties (e.g. interconnected porosity) owing to its reproducible production processes.

**Thommen Medical supplements its product portfolio with
Ceros® TCP Putty, a new innovative bone graft substitute**

Mathys AG Bettlach has granted Thommen Medical worldwide exclusive distribution rights for Ceros® TCP Granules and the new and innovative kneadable Ceros® TCP Putty for dental applications. Both products have already been registered in the European markets and approval in the important US market is expected shortly.

Mathys has been developing, manufacturing, and distributing products for artificial joint replacement (hip, knee, shoulder, finger) for more than 45 years and is one of the pioneers in the research and development of synthetic bone graft substitutes around the world. The first biomaterials were launched into the market as early as in 1980. Accordingly, there are more than 25 years of clinical experience with the application of Ceros®.

Ceros® TCP

more than 25 years of clinical experience

Ceros® TCP is a fully synthetic bone graft substitute made of pure beta-tricalcium phosphate. Its porous and interconnected structure makes the material an ideal osteoconductive scaffold facilitating new bone formation.

Ceros® TCP is one of the few bone graft substitute whose clinical benefit and safety in orthopaedics, trauma, spine and oral surgery have been proven for more than 25 years.

Indications

For use as bone void filler in no load-bearing regions requiring cancellous rather than cortical bone material. This includes the filling of bone defects and reconstitution of resected or damaged bone areas.*

* For a detailed description of indications please refer to the respective instructions for use.

Advantages at a glance

100% synthetic

- Provides high biocompatibility and preeminent safety, preventing any risk of pathogen transmission.
 - Unlike autogenous bone, there are no limitations with regard to quantity and quality.
-

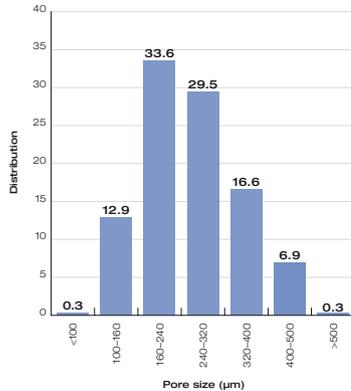
Resorbable

- Converts into new vital bone within 3–18 months.
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Osteoconductive

- Facilitates perfect formation of new blood vessels due to an optimized interconnected pore distribution. This produces ideal conditions for cell adherence and the ensuing resorption process.

Ceros® TCP Granules



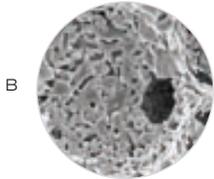
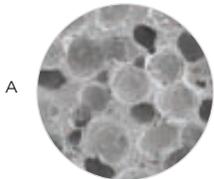
Ceros® TCP Granules are an osteoconductive bone graft substitute with a pore size of 100–500 µm (macroporosity) and a fraction of micropores (1–10 µm). See pore size distribution graph at right.

The size and distribution of the interconnected macro pores (A, B) has been proven to promote the new formation of blood vessels and vital bone.^{1,2} The microporosity (C) enlarges the surface area and promotes adherence of the cells to the implant surface.

Ceros® TCP Granules are particularly well-suited for filling easily accessible bone defects.

Ceros® TCP Granules can be mixed with bone material and enriched with patient blood. Mixing with blood (until coagulation) simplifies the handling. For prophylactic, anti-infection treatment, it can also be mixed with common water-soluble antibiotics.

Ceros® TCP Granules (porosity 60%) are available in grain sizes of 0.5–0.7 mm and 0.7–1.4 mm.



1 Lu et al. 1999

2 Bohner et al. 2004, Doernberg et al. 2006

Advantages at a glance

Defined macro- and microporosity with interconnecting pores

- Optimizes the ingrowth of blood vessels and therefore supports the formation of vital bone.
- The micropores increase the surface area and thus ensure optimal distribution of nutrients during the bone conversion process.

Extending the volume

- Ceros® TCP Granules are particularly well-suited for extending the volume of autogeneous spongy bone and for filling easily accessible bone defects.



Ceros® TCP Putty

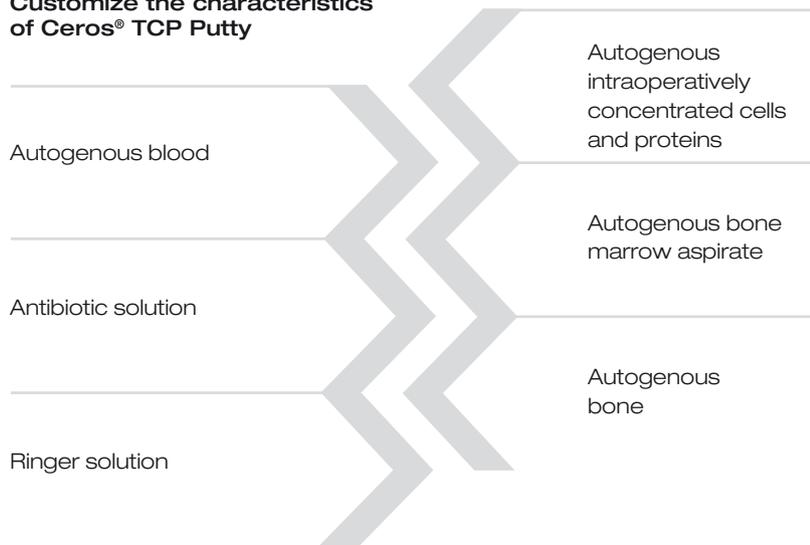


1 Ceros® TCP Putty is a kneadable, bone graft substitute made of pure, synthetic beta-tricalcium phosphate in a hydrogel made of fermented sodium hyaluronate carrier.

The Ceros® TCP Putty dry powder can be mixed with Ringer solution, autogenous blood or its derivatives, bone marrow aspirate or antibiotic solutions.

The modular structure and user convenience of Ceros® TCP Putty allow for individualized and optimal management of each patient.

Individualized patient solution. Customize the characteristics of Ceros® TCP Putty



Advantages at a glance

Enrichment properties

- Enrichment of osteoconductive material has a positive influence on the formation of new bone (osseinductive effect) and, if used with antibiotics, an antibacterial effect.
-

Robust texture

- Saves time and prevents loss of material, since
 - defect can be filled easily,
 - Ceros® TCP Putty remains inside the bone defect even during rinsing or major blood flow.
-

Volume stability

- Due to optimized packing density no structural collapse at defect site.

Product Overview

Ceros® TCP Granules

Porosity 60%, sterile



Package unit	Grain size	
0.5 g*		
1.0 g*		
2.5 g (5×0.5 g)	0.5–0.7 mm	7.03.540
2.5 g (5×0.5 g)	0.7–1.4 mm	7.03.542

Ceros® TCP Putty*

sterile



0.5 cc	59.35.0100
1.0 cc	59.35.0101
5.0 cc	59.35.0102

* Available autumn 2009.

TCP = beta-tricalcium phosphate

Local distributor



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