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**Calcibon® Inject**

Injectable bone matrix

## Materials and characteristics

Calcibon Inject consists of :

- 83.5% nanostructured hydroxyapatite in paste form
- 16.5% granules (0.5-1.0 mm in size)

The granules are composed of hydroxyapatite and beta-tricalcium phosphate. The synthesis of 60% hydroxyapatite, which is resorbed slowly, and 40% beta-tricalcium phosphate, results in a fully homogenous composition with two different active phases of the different minerals (fig. 01 and 02).

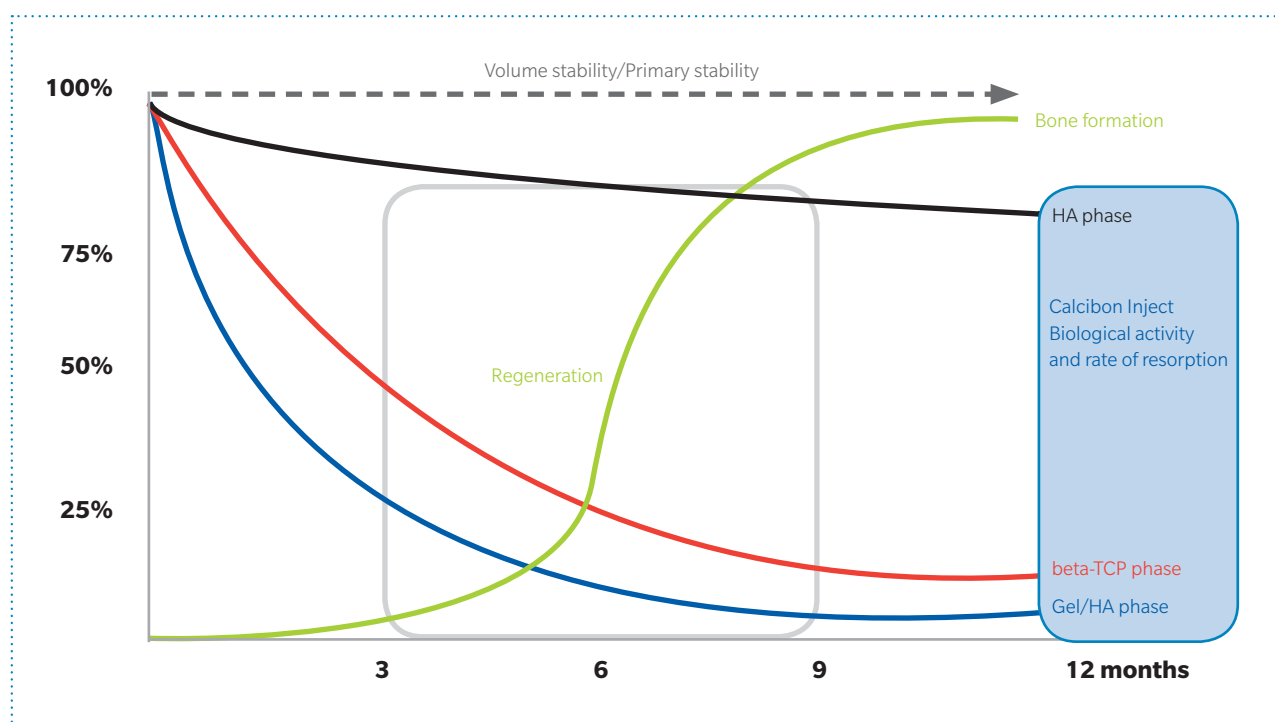
Calcibon Inject has an osteoconductive effect. As compared to pure pastes, Calcibon Inject shows additional mechanical and volume stability due to its hydroxyapatite/tri-calcium phosphate granules (fig. 02).

However, its viscosity enables a form-fit application in close contact with the bone bed during application.

### The four active phases of Calcibon Inject (schematic)



Fig. 01: The four active phases of Calcibon Inject

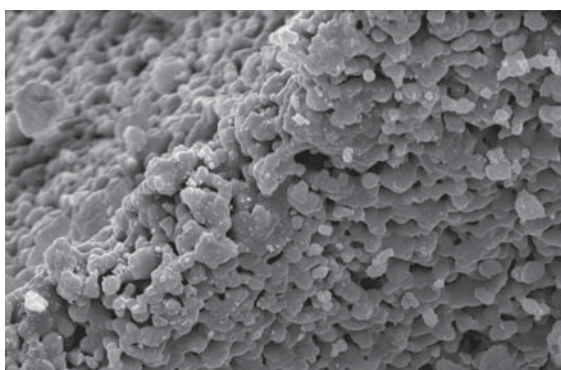


**Fig. 02:** Different rates of resorption of HA, beta-TCP and gel/HA and resulting bone formation

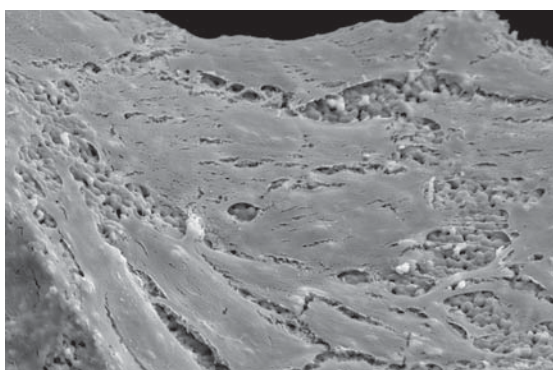
## Histology

The macroporosity of Calcibon Inject is achieved through an optimized matrix design with interconnecting pores (up to 80% porosity and pore sizes of 200-800  $\mu\text{m}$ ).

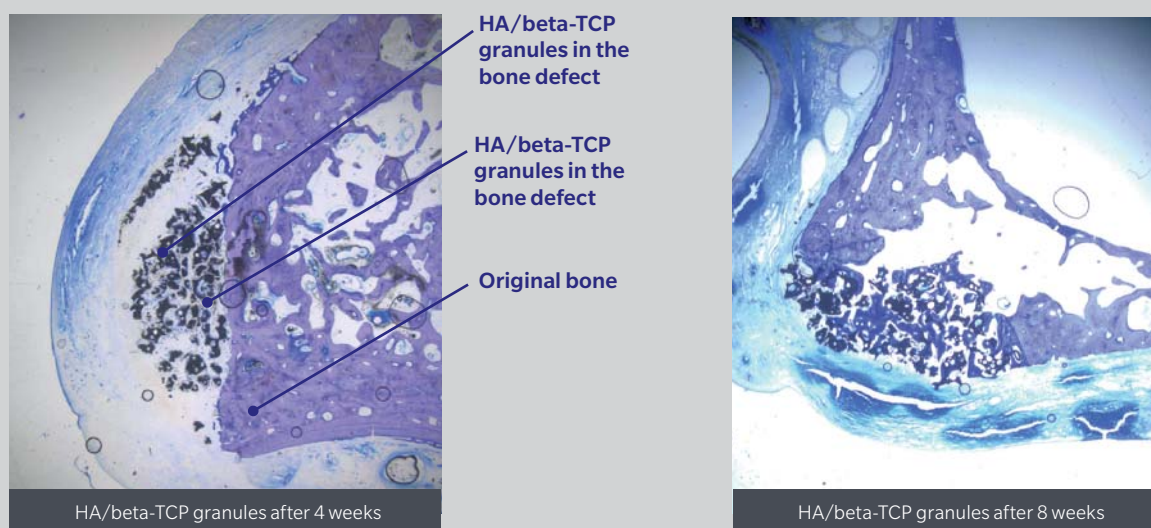
This provides ideal conditions for cellular ingrowth into the granules (e.g. migration of osteoclasts and osteoblasts), thus inducing osteogenesis and maximum regeneration of vital bone. Its porosity allows protein supply and the migration of cells for the necessary vascularization.



**Fig. 03a:** HA/beta-TCP granules without cells



**Fig. 03b:** HA/beta-TCP granules with cells



**Fig. 04:** Typical histology of the defect site after refilling with Calcibon Inject in an animal experiment (dog)

## Application and instructions for use

### Application

Due to its simple and safe application, Calcibon Inject is especially suitable for minimally-invasive treatment of small bone defects. The material can be injected directly into the non-infected bone defect. Where necessary, it may also be used in combination with autogenic or allogenic materials, e.g. to fill cages used in spinal surgery.

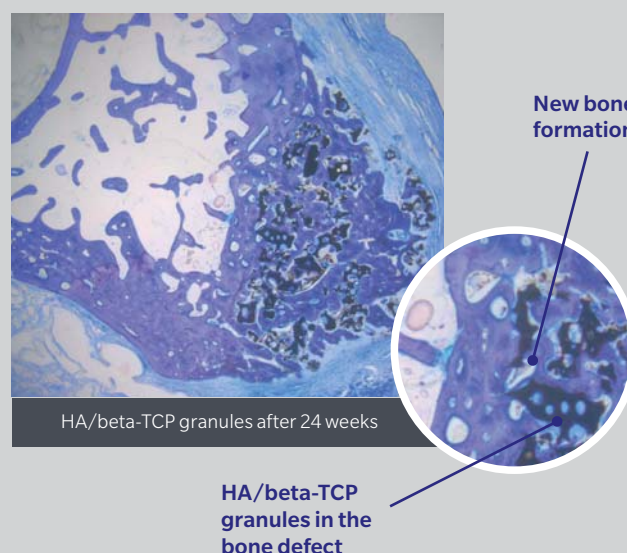
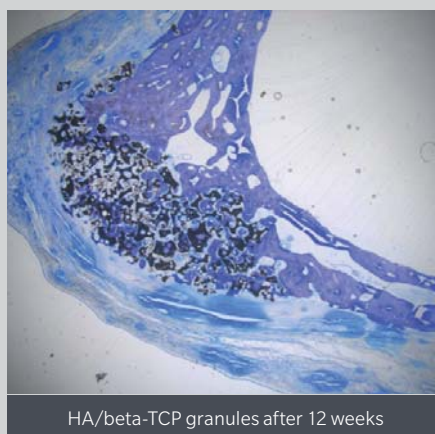
The Calcibon Inject syringe is removed from its double sterile pack and the syringe content is injected directly into the bone defect.

### Indications include, among others


- Bone defect filling
- Cyst filling
- Corrective osteotomy
- Distal radius fracture
- Calcaneal fracture
- Impression fracture of the tibial plateau
- Enchondroma
- Cage filling (spondylodesis)

### Indications for combination with autogenic/allogenic cancellous bone graft

- Acetabular reconstruction
- Defect filling in pseudarthrosis
- Defect filling in comminuted fractures
- Defect filling in revision hip or knee arthroplasty cases



Ordering information

PRODUCT	DESCRIPTION AND SIZE	PART NUMBER
	Calcibon Inject 1.0 cc (ml), one syringe	30 4001 0001
	Calcibon Inject 2.5 cc (ml), one syringe	30 4002 0001
	Calcibon Inject 5.0 cc (ml), one syringe	30 4005 0001

References:

1. Rothamel D., Neugebauer D., Lingohr T., Dreiseidler T., Ritter L., Zöller J.: "Surface Structure, biocompatibility and hard tissue regeneration of a nanostructured biphasic bone substitute material. An in vitro and animal experimentation pilot study". Submitted for publication.

2. Rothamel D., Ferrari D.: "Bone regeneration following socket preservation using different bone substitute materials. A pilot study in dogs". Submitted for publication.

## Notes

[illegible]



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Document intended for the exclusive use of healthcare professionals. Calcibon® Inject is a range of CE marked medical devices of class III manufactured by the Ceramisisys Ltd. company. The conformity assessment of class III devices was carried out by the Notified Body BSI N°0086. Calcibon® Inject is a synthetic osteoconductive bone paste intended to be used for filling and supporting the ingrowth of adjacent viable bone in bone defects that are not intrinsic to the stability of the bone structure. Defects may be located in the extremities, pelvis, spine, or dental, periodontal or mandibular areas. Before any surgical procedure, read carefully the instructions.