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Nr.5



**Calcibon® materials have clinically proven efficacy:**  
(1) Data on file at Ceramisys  
(2) Pre-clinical studies on file at Ceramisys  
(3) Ceramisys clinical case - 08-GB-CS-07/13

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Document intended for health care professionals. Calcibon® is a range of CE marked medical devices of class III manufactured by the Ceramisys Ltd. company. The conformity assessment of class III devices was carried out by the Notified Body BSI N°2797. Calcibon® is a porous material in block and granular forms that is composed of nominally 60% hydroxyapatite and 40%  $\beta$ -tricalcium phosphate. Calcibon® is intended to be used as a scaffold to support the ingrowth of adjacent viable bone in defects that are not intrinsic to the stability of the bone structure. These defects may be located in the long bones, pelvis and extremities, and Calcibon® granules may also be used in spine surgery (spondylodesis). Before any surgical procedure, carefully read the instructions.

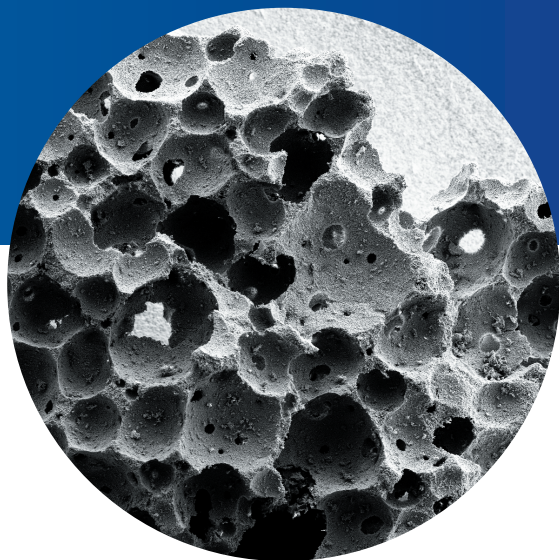
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Spine Biologics

# Calcibon Granules and Blocks

Resorbable, synthetic bone graft granules and blocks  
with a highly interconnected porous matrix

# CALCIBON GRANULES AND BLOCKS



## Ultra high porosity

Rapid bone ingrowth throughout an interconnected porous structure is driven by a porosity of 81%. Essential nutrients for bone growth are transferred, assisted by the microporosity of the HA/B-TCP structure. The product provides intended support without significantly limiting natural bone density.

## Osteoconductive

Early vascularisation and rapid bone regeneration, throughout the implant, as a result of an osteoconductive scaffold.

## Easy application

A cohesive mixture, easily handled, is formed when mixing Calcibon Granules with blood. To fit more closely bone defects, Blocks can be easily shaped.

## Indications

Calcibon Granules may also be used for the filling of spinal cages. Calcibon Granules and Blocks are indicated for the repair of non-load bearing aseptic osseous defects of the long bone, pelvis and extremities.

## Volume stable

Bone volume is maintained throughout the whole repair and regeneration process.

## Resorbable

Calcibon Granules and Blocks undergo complete resorption at a controlled rate due to its similar composition to the mineral component of human bone.

## Wide variety

Granules and Blocks available in a large range of convenient sizes.

## CLINICAL PERFORMANCE

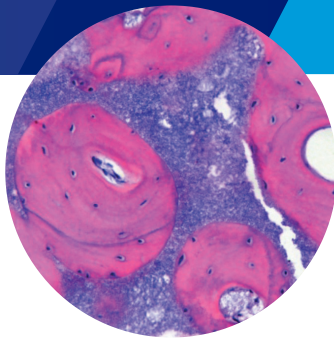
Studies show that Calcibon bone graft substitutes provide excellent osseointegration with rapid vascularisation and bone penetration through to the core of the implant.<sup>1</sup> Calcibon has proven biocompatibility.<sup>2</sup> Its performance as an osteoconductive biomaterial has been demonstrated over many years of successful clinical use.

### Osteoconduction

Osteoblasts migrate throughout the fully interconnected structure laying down new bone resulting in complete integration of the implant and the formation of a biocontinuous matrix. Biomolecules adsorb onto the porous surface supporting the regenerative process.

### Resorption

Calcibon resorbs over time during which bone remodeling and maturation occurs. Dissolution of Calcibon occurs releasing ions locally which provides a nurturing environment for osteoblasts and supports the deposition of new bone.



Calcibon surrounded by new bone is shown in a histological evaluation of human bone biopsy. Complete integration of the implant was observed.<sup>3</sup>

Osteokonduktinė medžiaga. Chirurginės rūšies trikalcio fosfato granulės. Porėtos struktūros 80% ± 10%, porų dydis 200-800 μm. Tūris xxx ml. Sterilioje pakuotėje. Turi būti galimybė maišyti su krauju, kaulų čiulpais.

## CALCIBON GRANULES AND BLOCKS: MATERIALS AND CHARACTERISTICS

- 60% HA + 40% β-TCP
- Porosity 81%
- Macro Porosity 200μm - 800μm
- Micro Porosity 1μm - 10μm
- Fully Interconnected Structure
- Gamma irradiated Sterile packaged
- 5 years Shelf Life

## ORDERING INFORMATION:



Part Number	Description and Size
ZB000050 Calcibon	Granules 1-4 mm 5cc
ZB000010 Calcibon	Granules 1-4 mm 10cc
ZB000015 Calcibon	Granules 1-4 mm 15cc
ZB000020 Calcibon	Granules 1-4 mm 20cc
ZB000025 Calcibon	Granules 1-4 mm 25cc
ZB000030 Calcibon	Granules 1-4 mm 30cc



Part Number	Description and Size
ZB101010	Calcibon Block 10x10x10 mm
ZB060640	Calcibon Block 40x6x6 mm
ZB051240	Calcibon Block 40x12x5 mm
ZB101040	Calcibon Block 40x10x10 mm
ZB122525	Calcibon Block 25x25x12 mm
ZB102050	Calcibon Block 50x20x10 mm
ZB123030	Calcibon Block 30x30x12 mm