Bone Substitute Materials
Overview
What can patients and surgeons expect from us? Reliable products, and expertise, which ensures secure application. Moreover, developments needed in the future.

Biomet is one of the leading orthopaedic companies worldwide. We develop and produce products for orthopaedic and trauma surgery. Our predominant competence enables us to accompany our clients continuously in clinical surgeries.

This vicinity has an impact: We take impulses in, and our own Research and Development Department is a direct contact partner for new ideas. Here we connect the clinically documented quality of our implants with the future orientated possibilities of bioactive materials. Through this we become an innovation force and are able to face the continuous developments in our markets more flexibly.

The results are products and performances, that aid the surgeons’ community, to support the healing process of their patients in a medically optimal, scientifically proven, and cost-effective manner.
Time-tested Products
Autologous graft, bone bank or bone substitute material? The first criterion when treating a bone defect is always a rapid recovery process, without as few complications for the patient as possible. Moreover economical and technical aspects are essential. The treatment with bone substitutes proves to be well suited for the treatment of bone defects with respect to availability, duration of surgery and incurred costs, linked with excellent compatibility and documented treatment achievements.

Quality and Unlimited Quantity
Biomet developed a portfolio of bone substitute materials (based on mainly hydroxyapatite calcium phosphates). Unlike autologous material, they have the advantage to have a rapid availability in constant quality and unlimited quantity. Furthermore, the application of bone substitute materials avoids a second surgery for harvesting autologous material: The duration of the surgery and the anesthesia are reduced and patients are not faced with possible complications and pain at the donor site.
Bone substitute materials have advantages in comparison to bone bank materials: There are no logistics issues in providing the materials for surgery and they are available in adequate quantity.

A Solution for Each Indication
Not all bone substitute materials are the same: For each separate indication, suitable bone substitute materials were thoroughly researched and developed. Particularly the utilisation of different substances with specific characteristics and functionalities supports the healing process in the long run. Biomet’s bone substitute materials have proven to be of high quality for a number of years already. Their excellent biocompatibility and their clinical success are documented extensively. Praxis-orientated trainings and consulting services aid to support surgeons and their personnel in order to ensure consistent successful application.
A precondition for successful clinical use of bone substitutes are the exact indication and the correct application. They are suitable for non-infected, metaphyseal, cancellous bone defects. Bone substitutes should only be implanted into a vital bony bed. When utilizing bone substitute materials, it is always vital to carry out a correct reposition and an adequate osteosynthesis.

<table>
<thead>
<tr>
<th>Product</th>
<th>Endobon</th>
<th>Calcibon</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Blocks, Cylinder, Granules</td>
<td>Paste (liquid &amp; powder)</td>
</tr>
<tr>
<td>Basic Material</td>
<td>Hydroxyapatite (ceramic)</td>
<td>Calciumdeficient hydroxyapatite</td>
</tr>
<tr>
<td>Material Properties</td>
<td>Biological Stable osseous integration</td>
<td>Synthetic Stable osseous integration</td>
</tr>
<tr>
<td></td>
<td>Ready-to-use</td>
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<tr>
<td></td>
<td>Augmentable</td>
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<tr>
<td></td>
<td>Porous</td>
<td></td>
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<tr>
<td>Characteristics</td>
<td>Osteoconductive</td>
<td>Osteoconductive</td>
</tr>
<tr>
<td></td>
<td>Biodegradable</td>
<td>Biodegradable</td>
</tr>
<tr>
<td>Indications</td>
<td>1. Tibia plateau fractures</td>
<td>1. Distal radius fractures</td>
</tr>
<tr>
<td></td>
<td>2. Osteotomies</td>
<td>2. Calcanus fractures</td>
</tr>
<tr>
<td></td>
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<td>3. Tibia plateau fractures</td>
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</tbody>
</table>
## Calcibon Granules

**Granules**

Calcium deficient hydroxyapatite

**Synthetic**
- Stable osseous integration
- Ready-to-use
- Augmentable
- Porous

**Osteoconductive**
- Biodegradable

1. Mixing with spongiosa
2. Large bone defects, e.g. hip revision
Endobon is a natural hydroxyapatite ceramic (HA ceramic), which is particularly suitable as a bone graft substitute. It is of biological origin and osteoconductive. The newly formed bone can grow directly onto the ceramic surface and into the implant. The interconnecting pore system of Endobon allows the new bone to grow through the whole implant.

**Indications**
Endobon is an excellent bone substitute material for impression fractures close to the joint, like tibia and radius fractures, for fractures of the calcaneus and for osteotomies.

**Material Properties**
Endobon is a primary stable hydroxyapatite ceramic. The inner structure with its interconnecting system of macro and micro pores with pore sizes of 100 to 1,500 μm allows the newly formed bone to grow through the whole implant. This finally leads to a stable osseous integration of the Endobon implant.

Endobon has a porosity of 45-85 Vol.% and a density of 0.4 to 1.6 g/cm³ resembling the values of natural bone.

**Quality and Production**
Endobon is manufactured in a two-stage high-temperature process:
- 1. Pyrolysis above 900°C
- 2. Sintering above 1,200°C
This leads to a complete combustion and ablation of all bacteria, viruses, and prions from the original material. Endobon has been successfully used in clinical applications for more than 15 years.

**Usage**
Endobon is available in the form of blocks, cylinders, or granules of different sizes. The latter are especially suited for augmentation of autologous bone chips.
All forms are easily and rapidly usable during surgery.
The blocks and cylinders are especially suitable for fractures below load bearing joints, e.g. tibia plateau fractures. The granules should be used for filling irregularly formed defects.
6 Weeks Post-operatively
6 weeks after the implantation of Endobon, integration of the implant with the surrounding vital bony bed can be seen on the microscopic analysis.

3 Months Post-operatively
After 3 months, the microscopic analysis shows a nearly complete osseous integration of the implant.

6 Months Post-operatively
After 6 months, the histological slide shows direct contact of the newly formed bone (1) and the ceramic surface (2).
Calcibon is a synthetic, biodegradable bone substitute material. It belongs to the family of calcium phosphates, a group of osteoconductive bone substitutes. The cured Calcibon material is a micro-crystalline, calcium-deficient hydroxyapatite. The chemical composition and the crystalline structure of the cured material mimic the mineral part of natural bone.

**Material Properties**
Calcibon powder is synthesized from calcium and phosphate salts. Its different components are Tri-calcium-phosphate, calcium-hydrogen-phosphate and calciumcarbonate.

**The Biodegradability**
Calcibon has the potential to be biodegraded by the surrounding vital bony bed through remodelling. Calcibon is thereby broken down by osteoclasts and the new bone is reconstructed by osteoblasts.
The remodelling process depends on the individual and the environment where Calcibon is implanted. A vital bony bed, close contact with the surrounding bone, and a functional stimulation improve the rate of the remodelling.
Calcibon – Two Products: Paste or Granules

The synthetic calcium-phosphate material Calcibon is available in two different forms: as a paste, mixed from a liquid and a powder component, or ready-to-use as granules.

Despite identical origins the two products, Calcibon and Calcibon Granules differ in their properties regarding further processing. Both products are introduced in more detail on the following pages.
Calcibon consists of two components: Calcibon liquid and Calcibon powder. Mixing these two components results in a smooth and malleable paste ideal for filling bone defects. The paste hardens at body temperature in-situ and reaches a very high compressive strength.

**Processing**

The Calcibon paste is mixed directly before application. Calcibon liquid is an aqueous di-sodium-hydrogen-phosphate solution, which initiates the curing process within the paste.

The processing cycle of Calcibon has been optimized in consideration of the Operating Room environment:

- Short mixing time: 1 minute
- Sufficient application time: 4 minutes
- Acceptable final setting time: 5 minutes

Overall required time: 10 minutes

**The Compressive Strength**

One of the outstanding properties of Calcibon is its extremely high compressive strength. In-vitro testing shows that after 6 hours, the cured final material shows a compressive strength of approximately 15 MPa, already in the range of the strength of cancellous bone (10-20 MPa). This compressive strength continues to increase over time and results in a final strength of up to 45 MPa after 3 days. Thus, the compressive strength is in the area of cortical bone (25-100 MPa).

**Compressive strength versus time**

After 6 hours the compressive strength of Calcibon is comparable to that of cancellous bone. After 3 days the final compressive strength of up to 45 MPa is reached.
**Indications**

Calcibon is indicated for refilling of noninfected, metaphyseal, cancellous bone defects caused either by trauma, benign tumour, surgery, or congenital. Calcibon may also be used to refill cavities created in connection with kyphoplasty, if classified as fracture type A1 (according to Magerl classification).

The most common indications for the clinical use of Calcibon are distal radius fractures, tibia plateau fractures, and calcaneus fractures.

**Usage**

The cohesion time of Calcibon is extremely short. Already after mixing, the binding forces inside the paste are high enough to ensure the form stability of the material, even in an aqueous environment.

Even though Calcibon should be implanted into a dry and blood-free environment, the short cohesion time allows an implantation into a wet bony bed, where the material will keep its form and harden adequately.
Calcibon Granules are a line extension of the existing Calcibon product range. Like the paste, the granules are also manufactured synthetically, are biodegradable and biocompatible. The main differences: The granules are ready-to-use, however, due to their porosity the compressive strength is reduced. In addition they are highly suitable to be used for augmentation in combination with other materials.

Material Properties
The production process of Calcibon Granules is at first glance identical to the one of the Calcibon powder. Nevertheless, the mixing of the two components already takes place during production. The granules are hence a completely hardened material. Due to a special manufacturing technique porous granules with micro and macro pores are produced.

The porous Calcibon Granules have macro pores of 150-550 µm. These allow cells, e.g., osteoclasts and osteoblasts, to migrate into the granules. The activities of these cells enable the cellular biodegradation of the Calcibon Granules and the formation of new autologous bone.

The macro pores are separated from each other by thin walls, which in turn consist of a micro porous network. These micro pores allow the cells involved in the remodelling process to be supplied with nutrients.
**Indications**

Generally, Calcibon Granules are intended for filling and reconstructing large, non-infected, metaphyseal, cancellous bone defects. The origin of these defects can vary greatly; from *e.g.*, trauma, benign tumour, surgery, to congenital.

Calcibon Granules can be used as filling material for revision hip surgery, *e.g.*, for the reconstruction of the acetabulum and to fill the shaft. Moreover, the granules can be used as filling material for cages in spinal surgery.

**Use**

Calcibon Granules are ready-to-use. No mixing time has to be taken into account.

Calcibon Granules can be applied directly to the aseptic bone bed or augmented with other material, such as bone marrow, bone grafts, blood, and PRP (Platelet-Rich-Plasma, extracted with the GPS III System).
## Ordering Information

### Calcibon Synthetic calcium-phosphate

<table>
<thead>
<tr>
<th>Product</th>
<th>Description</th>
<th>Quantity</th>
<th>Art. Nr.</th>
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<tbody>
<tr>
<td>Calcibon 5 g</td>
<td>circa 4 ml paste</td>
<td>30 3005 0001</td>
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<tr>
<td>Calcibon 10 g</td>
<td>circa 8 ml paste</td>
<td>30 3010 0001</td>
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<td>Calcibon 20 g</td>
<td>circa 16 ml paste</td>
<td>30 3020 0001</td>
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<tr>
<td>Calcibon Granules 10</td>
<td>10 ml Granules</td>
<td>30 3210 0001</td>
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<tr>
<td>Calcibon Granules 20</td>
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<tr>
<td>Calcibon Granules 50</td>
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<td>30 3250 0001</td>
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### Endobon Hydroxyapatite

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<thead>
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<tbody>
<tr>
<td>Block 5</td>
<td>5.0 x 5.0 x 10.0 mm</td>
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<td>Block 12.5</td>
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<td>30 2030 0001</td>
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<tr>
<td>Block 20</td>
<td>20 x 20 x 10.0 mm</td>
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<tr>
<td>Cylinder 9</td>
<td>Ø 8.50 x 20 mm</td>
<td>30 2022 0001</td>
<td></td>
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<tr>
<td>Cylinder 10</td>
<td>Ø 9.55 x 20 mm</td>
<td>30 2023 0001</td>
<td></td>
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<tr>
<td>Cylinder 11</td>
<td>Ø 10.60 x 20 mm</td>
<td>30 2024 0001</td>
<td></td>
</tr>
<tr>
<td>Cylinder 12</td>
<td>Ø 11.70 x 20 mm</td>
<td>30 2025 0001</td>
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</table>

### Granules size

<table>
<thead>
<tr>
<th>Product</th>
<th>Granules size</th>
<th>Art. Nr.</th>
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<tbody>
<tr>
<td>Granules I</td>
<td>1.5 - 2.8 mm</td>
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<tr>
<td>Granules II 5 ml</td>
<td>2.8 - 5.6 mm</td>
<td>30 2035 0001</td>
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<tr>
<td>Granules II 10 ml</td>
<td>2.8 - 5.6 mm</td>
<td>30 2069 0001</td>
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</table>
References

Endobon


Calcibon and Calcibon Granules


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