

BONE SUBST.

OSTIBONE®

**Injectable bone substitute for rapid bone reconstruction
resulting from nanotechnology**

Hydroxyapatite nanocrystals

Surface area for exchange
between HAP and liquid of
100 meters square per gram
(100m²/g)



Documentation



FH ORTHOPEDICS

OSTIBONE®



OSTIBONE® is an entirely synthetic bone substitute that contains no organic phase. It is a non granular, homogeneous, white gel, ready to use, that makes for quality bone reconstruction.

DESCRIPTION

Function

OSTIBONE® is a bone substitute filler providing rapid, very good quality bone reconstruction.

Unlike ceramic substitutes, OSTIBONE® adapts perfectly to the sites to be filled.

Owing to its very close contact with the bone it is involved in the steps for remodelling bone tissue, thus providing remarkable integration and osteogenesis.

Chemical composition

OSTIBONE® comes as a gel composed of water (70%) and hydroxyapatite nanocrystals (30%).

These nanocrystals are acicular; the gel has a very large specific surface area, of about 100m²/g, and its viscosity is ideal for easy injection.



Packaging

OSTIBONE® comes as a gel in a ready-to-use syringe, protected by sterile double packaging.

It is available in 3 volumes: 1ml, 2ml and 5 ml.



PROPERTIES

Biocompatibility

The chemical components of OSTIBONE® (water and hydroxyapatite) are acknowledged as being substances which are very well tolerated by the body.

Hydroxyapatite is a phosphate of calcium the chemical structure and pH of which are very close to that of the mineral phase of bone tissue.

Osteoconduction

As a result of its form and its hydroxyapatite nanoparticles, OSTIBONE® has a large contact surface area.

Its reactive capacity is greater than that of phosphocalcic bone substitutes, which therefore assists bone reconstruction.

The product is rapidly colonized by blood vessels and bone cells, so that the osteoclasts and osteoblasts proliferate rapidly, activating remodelling of the bone.

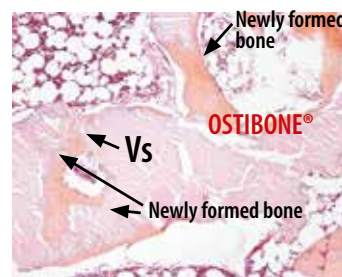
Resorption

Hydroxyapatite nanoparticles are readily resorbable.

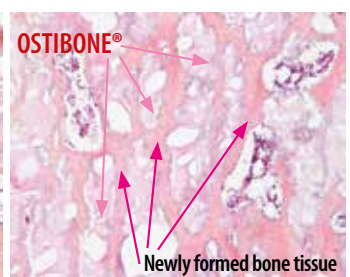
Human histological studies have demonstrated rapid cell invasion and considerable bone remodelling activity a short time after implanting.

There are three processes involved in resorption:

- Elimination by macrophages and osteoclasts;
- Integration of the crystals into the newly formed bone during remodelling (ossification process);
- Resorption by biodegradation, making room for the newly formed bone.



Newly formed, vascularized bone (Vs), delimiting portions of OSTIBONE® (pale pink)



Multiple spans of newly formed bone (dark pink) crossing remains of OSTIBONE® (pale pink)

EXAMPLES OF USE

>> Open wedge tibial osteotomy



>> Benign tumour



Mechanical properties

OSTIBONE® is a gel with absolutely no mechanical properties. It retains its initial form and does not evolve into any hardened phase. It can be used for any type of filling, sites with mechanical stresses should be stabilized by osteosynthesis.

In these cases, OSTIBONE® only fill.

Its form is stable: once in place in the bone site to be filled, it retains its appearance and body fluids do not eliminate it.

USE

Method of use

OSTIBONE® can be used without any preparation. It comes in a pre-filled syringe, ready to use.

It can be injected by a minimally invasive route using a needle, or be inserted directly into an open site requiring to be filled.

Fracture sites or sites requiring mechanical stability must be firmly fixed by solid osteosynthesis for best result.

Implanting sites must be alive and vascularized, so that the substitute can be colonized by cells and blood vessels. Tissue activity then ensures better bone reconstruction.

OSTIBONE® can be mixed with bone marrow or fragments of bone, if the surgeon wishes.

It can be used with solid phosphocalcic bone substitutes, such as Eurocer 400 and/or 200+.

INDICATIONS

In orthopaedics, trauma surgery or spinal surgery, OSTIBONE® can be used as a filler, either combined with an osteosynthesis system or when the bone has retained adequate mechanical resistance.

See the table of detailed indications on the back.





INDICATIONS (DETAILED TABLE)

ORTHOPAEDICS
Benign tumours without fracture
Open wedge osteotomy
Arthrodesis of the foot and ankle
Pseudarthrosis
Basic acetabulum reconstructions
Revision of loosened femoral shafts

TRAUMATOLOGY
Metaphyseal fractures with compression of cancellous bone
Fractures after implanting a hip or knee prosthesis

SPINAL SURGERY
Compression fractures
Vertebral arthrodesis
For filling vertebral cages.

REFERENCE

REFERENCE	PRODUCT
253 431	Dose of 5 ml

www.fhorthopedics.com

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ANALYSIS OF APPLICATIONS IN HUMANS

In 2006, the André Hermann Evaluation Centre (CEAH) conducted a continuous, multicentre, prospective trial, in order to check the short-term results of using the substitute. Owing to the series of 69 cases described after a minimum period of 6 months, the substitute was approved in France by the National Authority for Health (HAS), including its reimbursement.

The indications approved were as follows:

- Arthrodesis of the foot and ankle
- Open wedge osteotomy irrespective of the site
- Metaphyseal fractures with cancellous compression irrespective of the site
- Benign bone tumours (any location accepted)
- Cortical fractures on a hip femoral stem and spinal arthrodesis.

The only complication encountered at the start of the series in 3 cases (local inflammation and delayed healing) was not reproduced once the recommendations for implanting the bone substitute, of avoiding contact with the skin, were applied. Associating this bone substitute with osteosynthesis in the indications requiring this contributed to the filling sought.

Users appreciated the ease of use of the substitute and consider it a prime alternative in the therapeutic arsenal in orthopaedic surgery.

The results of the multicenter study are available from the CEAH.

>>> www.ceah.org



The bone substitutes : OSTIBONE®, EURO CER et EURO BONE 2 are in constant evaluation by Probiomateria GEICO's Group

>> www.geico-medical.org