

PRODUCTION AND QUALITY CONTROL.



Biotech® and its quality standards.

How is Calcitos® manufactured? Above all, which controls does it undergo? Quality controls, during its production, are many. They are being performed

on each production lot. Samples are routinely sent to GLP (Good Laboratory Practice)-certified labs for third-party independent results checking.

MANUFACTURING PROCESS

QUALITY CONTROLS

RAW MATTER (EQUINE FEMURS)

Equine femurs come from EEC-originated animals whose meat is destined to human consumption. Horses are subjected to all the veterinary controls required by European and Italian regulations. Bone tissues cannot transmit Spongiform Encephalopathies (European Regulation 2003/32/EEC).

ELIMINATION OF LIPIDS

Complete lipids and glucidic antigens elimination is checked by Gas Chromatography (GC-FID) and Visible Spectrometry (VIS).

ELIMINATION OF POLYSACCHARIDE ANTIGENS

Polysaccharides elimination is controlled by High Performance Liquid Chromatography (HPLC-RID) and through electrophoresis of glycoproteins coupled with fluorescence dye-staining.

ELIMINATION OF PROTEIN ANTIGENS

Protein elimination control is again performed by High Performance Liquid Chromatography (HPLC-DAD).

ELIMINATION OF CELL RESIDUALS BY OXIDATION

Cell elimination control is performed by quantifying nucleic acids through fluorometric measurements.

APATITE CRYSTAL CONTROLLED DECARBONATION THROUGH HEAT TREATMENT

Finally, proper decarbonation is checked by Fourier Transform Infrared Spectrometry (FT-IR).

25 KGY BETA RAYS STERILIZATION

The sterilization protocol is validated according to the very demanding ISO11137 standard.





BIOTECK® S.P.A.

Bioteck® is an Italian Company manufacturing bone substitutes and protective membranes for applications in the fields of Orthopedics, Neurosurgery, Oral and Maxillo-Facial surgery. Founded in 1995, the company grows steadily and is currently present in more than 50 Countries all over the world. Commitment to scientific research is at the basis of the innovative solutions Bioteck® proposes. Many research projects the Company collaborates to have given great impulse to base research and added novel knowledge in the field of Bone Biology.

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THE "OPEN DOORS" POLICY.

Customers deserve transparency.

Bioteck® applies for Calcitos® too, as for all the other clinical solution it produces, a thorough "Open Doors" policy. The new Production and R&D Center, in fact, may be visited any time someone requests to.

Bioteck® personnel will greet the visitor, who will be able to touch by hand all the steps of the manufacturing processes, and have his/her questions fully and thoroughly answered.

CALCITOS®

Long-lasting bone substitute.

Calcitos® is a registered trademark of Bioteck® S.p.A.





Calcitos[®]

The equine
clever alternative.

Long lasting
bone substitute.

BIOTECK[®]



STABLE BONE AUGMENTATION.

The clever choice springing from research.

Calcitos® is an equine space-keeping bone substitute. It may be successfully used whenever a long-lasting bone augmentation is desired. Therefore, it is indicated for all the application calling for volume stability over time.

A WINNING HEAT-BASED PROCESS.

A resorption-preventing treatment.

Calcitos® is manufactured by subjecting cancellous equine bone to a very high temperature. This aims to eliminate bone collagen and to achieve a controlled decarbonation of the apatite crystal. These two actions minimize the adhesion of osteoclasts, the bone remodeling cells, on Calcitos®, preserving its integrity in the grafted site.

CANCELLOUS GRANULES

OMC-030

Cancellous granules

0.5 - 1.0 mm

6 bottles 0.5 g \approx 1.0 cc

OMC-030n

Cancellous granules

0.5 - 1.0 mm

1 bottle 0.5 g \approx 1.0 cc

SAFETY AND BIOCOMPATIBILITY.

Confidence from testing.

Calcitos® passed all biocompatibility tests required by current regulations on implantable, class III medical devices. Any pathogen in the origin tissue, if present, is eliminated by the very same heat treatment and by the final sterilization with beta rays at 25 kGy.

PROVED EFFECTIVENESS.

A long history of success.

Bone substitutes manufactured by heat-treating animal bone have been widely known in oral and maxillo-facial surgery for years and hundreds of indexed clinical publications testify their effectiveness.



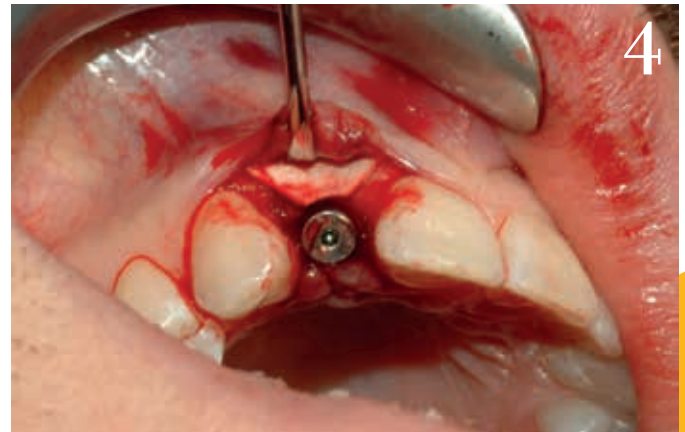
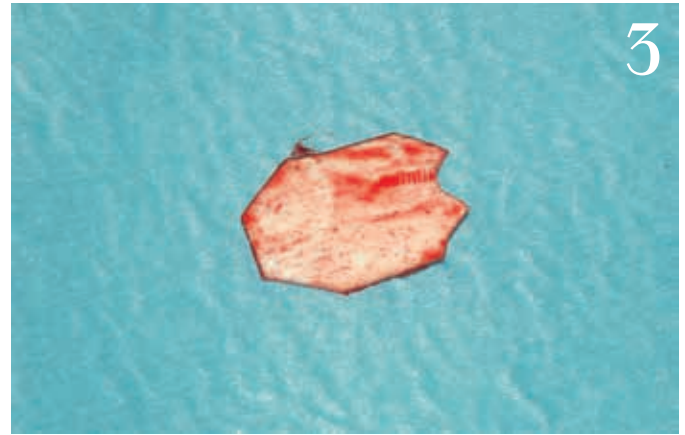
APPLICATIONS.

The main indications for use.

Calcitos® is the perfect choice for all the cases calling for the preservation of bone volume over time, and the prevention of the resorption that may be observed when other biomaterials are being grafted.

Some main indications are:

- Ridge augmentation, to increase volume stability over time.
- Extra-crestal or extra-alveolar immediate loading procedures.
- Sinus augmentation, mixing it to autogenous bone to prevent resorption.
- Socket preservation.
- GBR, mixing it to autogenous bone to prevent resorption.



Calcitos® being applied to correct a ridge profile (figure 1). A flexible cortical bone membrane is adapted to the ridge profile (figure 2), shaped (figure 3) and positioned on the vestibular side (figure 4) to

contain granules (figure 5). Suture follows (figure 6).

Courtesy Prof. Di Stefano, Milano, Italy.

FEATURES AND CHARACTERISTICS.

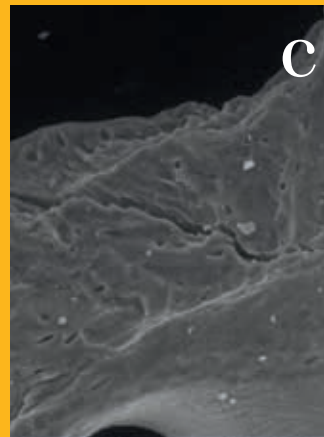
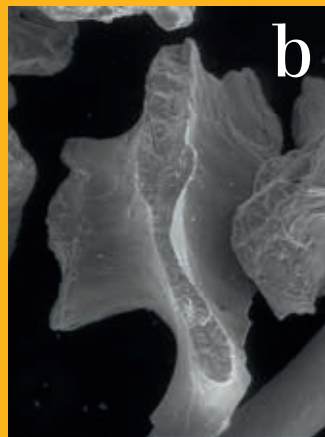
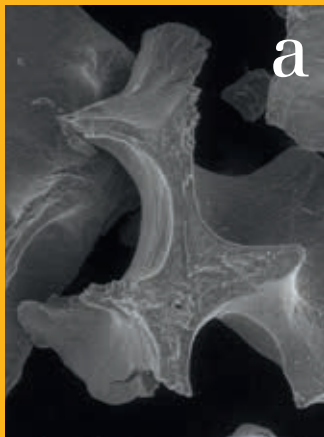
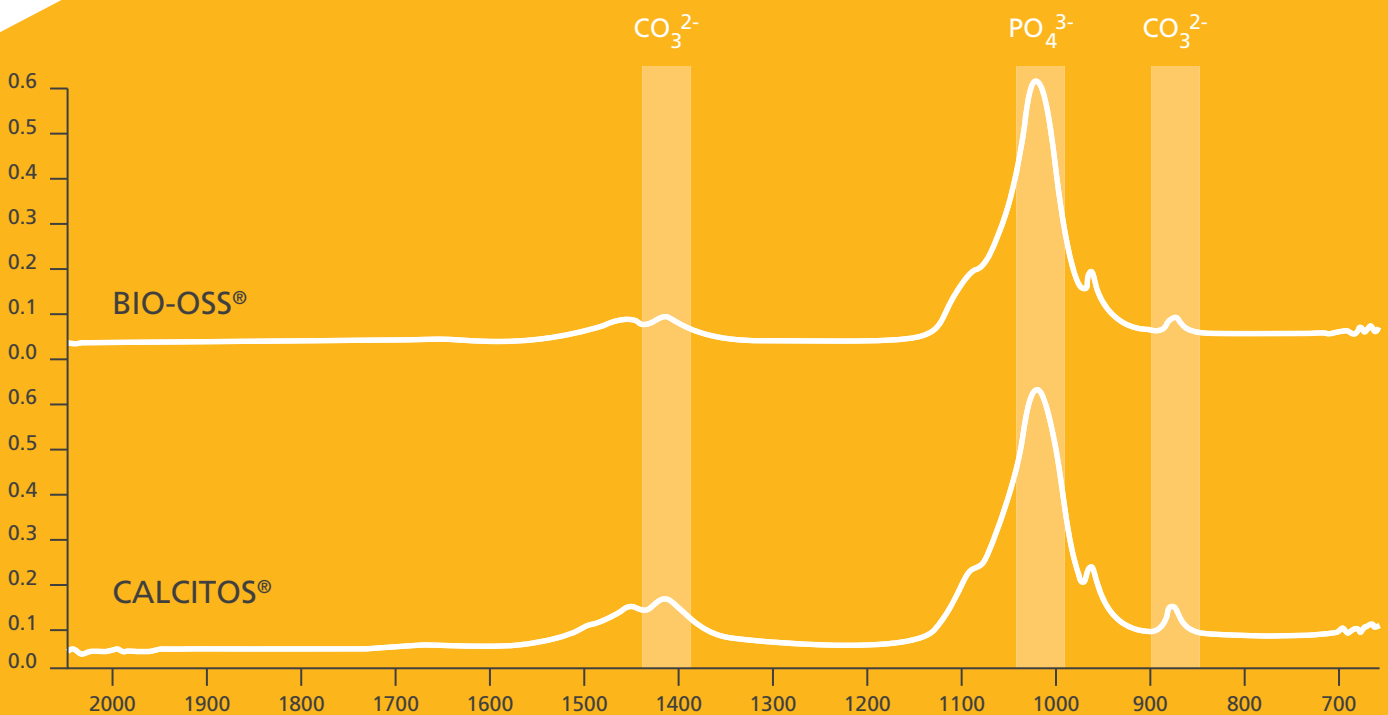
Analytic data, measurable properties.

Calcitos® displays the same physico-chemical properties of other bone substitutes manufactured by heat-treating animal bone.

Because of the thermal process bone undergoes some alterations that may be easily measured by applying the most up-to-date analysis techniques.

FT-IR spectra of Calcitos® and anorganic bovine bone are identical: IR absorbance wavelengths and the ratio between the molar attenuation coefficients are absolutely comparable.

Credits: Bioteck® R&D Lab.



Calcitos® and anorganic bovine bone are substantially identical when observed with Scanning Electron Microscopy (SEM), both a low (left) and high magnification (right).

a,c) Calcitos®; b,d) anorganic bovine bone.

Credits: Padua University, Italy – Electron Microscopy Service, CUGAS Center