BIOTECK®

OSTEOPLANT® Calcitos

TECHNICAL SHEET

CALCITOS® **Disposable sterile device**	CE 0373

Description
OSTEOPLANT® Calcitos Long-lasting equine origin osteoconductive bone substitute

Product constituents
Cancellous bone of equine origin.

Indications and expected results
The bone substitutes of the OSTEOPLANT® Calcitos series act as osteoconductive s and are therefore suitable as bone grafts in bone regeneration surgery where a long-term substitute graft is required.

Instructions for use
Hydrate the product in a sterile physiological solution for 3-5 minutes. Proceed with the graft.

Warnings and precautions
The device is disposable and for use on one patient only; it cannot be reused or resterilised.
The use of the product in direct combination with drugs has not been tested.
Preparation of receiving site:
Prepare the graft site appropriately, eliminating any fibrous tissue residues and, if necessary, perforating the receiving bone bed in order to help encourage the initial phases of bone regeneration.
Hydration:
For the purpose of enrichment with cells and growth factors it is possible to add biological fluids of autologous origin to the product, such as: whole bone marrow, concentrated bone marrow, blood, PRP.
Graft:
Arrange the granules in the graft site without applying excessive compression (if the granules are too compressed, the space between one granule and the next is reduced and the blood vessels forming cannot permeate the graft).
Protection of graft site:
When it is not possible, or you are not sure of restoring the periosteal covering, protect the graft site from epithelial invasion with a suitable membrane.

Side effects
The product is biocompatible. It does not cause side effects.
Latex free: the device is latex free.
The product has not been tested on pregnant women.

Sterilisation and storage
The product is sterilised by beta radiation at 25 kGy. Store out of direct sunlight in a cool, dry place at a temperature of between 4°C and 40°C. If stored correctly, the package remains sealed and therefore product sterility is guaranteed for 5 years as from date of manufacture (see expiry date on external label).

Package
One blister-packed bottle. Three or six bottles boxed separately. Informative leaflet.
Alternatively, a bottle inserted in a OPA-Aluminium pouch. Informative leaflet.

Patient labels
For the blister/pouch formats: on the outer blister/pouch in six copies, which can be removed in order to be affixed on the medical record. For all other packaging types, patient labels are included inside the package.

Breakage of casing and disposal of packaging
Do not use the product if the packaging is damaged.
The materials used to make the packaging do not require any particular disposal conditions.

Manufacturer

Bioteck S.p.A., Via E. Fermi 49, 36057 Arcugnano (Vicenza), Italy.
Produced in the plant at no. 26 Strada Buttigliera (now no. 3 Via g. Agnelli), 10020 Riva presso Chieri (Turin), Italy

Risk Class

The risk class of this device, according to current EEC regulations is III (three).

Codes

OMC-030	OSTEOPLANT® Calcitos	Granules, 6 bottles, 0.5 g each, granules size 0.5-1 mm
OMC-030n	OSTEOPLANT® Calcitos	Granules, 1 bottle 0.5 g, granules size 0.5-1 mm