OSTEOPLANT® Calcitos

TECHNICAL SHEET

CALCITOS® **Disposable sterile device**	CE 0477

• **Description:** **OSTEOPLANT CALCITOS** - bone grafts of equine origin.

• **Device constituents:**

OSTEOPLANT CALCITOS : cancellous bone of equine origin.

• **Properties/Intended use:**

OSTEOPLANT CALCITOS: Bone substitutes of the OSTEOPLANT CALCITOS line, act as grafting material for bone regeneration procedures. As they are thermally deantigenated, they are deprived of bone collagen and they feature a partial remodeling by osteoclastic/osteoblastic activity. Acting mainly as osteoconductive space keepers, they are suitable as bone grafts in bone regeneration surgery where a long-term substitute graft is required. Remodeling time is variable, and it depends by anatomical variables (ratio between vital bone surface and volume of the grafted material) and by individual factors which may vary from patient to patient.

• **Indications of use and clinical performances:**

OSTEOPLANT CALCITOS devices are indicated only for ***dental surgery***:

OSTEOPLANT CALCITOS may be used in dental surgical procedures such as augmentation or reconstructive treatment of the alveolar ridge; filling of defects after root resection, apicoectomy, and cystectomy; filling of extraction sockets to enhance preservation of the alveolar ridge; filling of infrabony periodontal defects; sinus lift; filling of periodontal and peri-implant defects in conjunction with devices intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR). It provides volumetric augmentation, favoring regeneration of newly formed bone and in case of implant/prosthesis implanted in the same site, favoring the secondary stabilization of them.

• **Restrictions on use /target population:**

The device is single use and single patient; it cannot be reused or re-sterilized. **All the OSTEOPLANT CALCITOS** devices must be used exclusively by experienced dentists and/or surgeons. The device has not been tested on pregnant patients. The device has not been tested on children who have not reached skeletal maturity.

• **Contraindications:**

- Do not use in the presence of infected wounds. Do not use to guarantee the primary stability of prosthetic elements or bone portions, do not use to support directly the functional load.

• **Instructions for use:**

- **OSTEOPLANT CALCITOS:** Hydrate the device in a sterile physiological solution for 1-2 minutes. Proceed with the graft.

• **Precautions:**

- Use of the device in direct combination with pharmaceutical products has not been tested. - The device may vary in color between white and ivory, due to the natural origin of bone tissue and the production process applied. Such coloring does not entail variations in the device's properties. - Any presence of a fraction of granules of a smaller dimension to that stated on the label may be due to partial fragmentation of the product during transport and does not entail variations in the properties of the product itself.

- The devices must be grafted exclusively into vital bone tissue. Make sure that the device is placed in direct contact with the vital bone tissue. Properly prepare the graft site, by eliminating any fibrous tissue residues and, if necessary, making some perforations of the receiving bone bed in order to favor the initial phases of bone regeneration.

- The use of components of autologous/homologous origin in combination with Bioteck devices is not contraindicated but has to be performed at the discretion of the surgeon and should be decided from patient to patient, based on the individual's medical condition. The combination with autologous/homologous component is not a standardized procedure (each human derivative acts differently accordingly to its source and to the procedure used for its collection and its combination with Bioteck devices), therefore it introduces additional variables to the surgery outcomes.

- When the restoration of the periosteal coverage is not possible or not certain, protect the graft site from epithelial invasion with a suitable membrane.

- In the following cases the device must be used with particular care: acute or chronic infections (e.g. osteomyelitis) of the surgical site; uncontrolled metabolic disorders, such as diabetes, osteomalacia, thyroid dysfunction, severe renal or hepatic diseases; long-lasting cortisone therapy; autoimmune diseases; radiotherapy; chemotherapy; use of bisphosphonates; chain smokers (> 10 cigarettes/day).

• **Adverse effects:** The device is biocompatible; no side effects attributable to the device have been clinically found. Latex free: the device contains no latex.

• Potential complications:
Possible complications that can arise in any surgical procedure include: swelling of the operated site, hemorrhage, local inflammation, serum leakage from the wound, reopening of the wound, local inflammation, bone loss, infection or pain.
• Sterilization and storage: The device is sterilized by beta radiation at 25 kGy. Store out of direct sunlight in a cool, dry place, at a maximum temperature of 25°C +2°C. The device can be stored/transported at temperatures up to 40°C for short periods (less than 6 continuative months). If stored correctly, the package seal and device sterility is guaranteed for 5 years as from date of manufacture (see expiry date on the external label).
• Packaging:
- **OSTEOPLANT CALCITOS**: Glass bottle in single carton box. Alternatively, one glass bottle in single PETG blister pack or in single OPA-OPA or OPA-Aluminum pouch. Informative leaflet.
• Patient labels and Implant card:
Patient's labels contain all the data relative to the device tracking. The labels are placed inside the packaging or on the back of the blister/pouch in a suitable number of copies to be affixed to the medical record and on the back of the implant card to be delivered to the patient.
The implant card is printed inside the leaflet. At the end of the surgery, cut a copy of the implant card and fill it with the following information: name and surname of the patient, date of the surgery, name of the operator who performed the surgery and address of the center where it was performed. Attach a copy of the patient's label to the back of the implant card and deliver the implant card properly filled to the patient.
• Breakage of casing and disposal of packaging: Do not use the device if the packaging is damaged. The materials used to make the packaging do not require special disposal.
• Manufacturer: Bioteck S.p.A., Via E. Fermi 49 - 36057 Arcugnano (VI), Italy. Produced in the plant at 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-029n	CALCITOS	Cancellous granules	- 1 btl / 0.25g 0.25-1mm
OMC-030	CALCITOS	Cancellous granules	- 6 btl / 0.5g 0.25-1mm
OMC-030n	CALCITOS	Cancellous granules	- 1 btl / 0.5g 0.25-1mm
OMC-031n	CALCITOS	Cancellous granules	- 1 btl / 1g 0.25-1mm