OSTEOPLANT® osteOXenon

TECHNICAL SHEET

OX (osteOXenon®) **Disposable sterile device**	CE 0477

• **Description:** OSTEOXENON bone grafts of equine origin.

• **Device constituents:**

OSTEOXENON (all codes except those listed below): Cortical and/or cancellous bone of equine origin with a preserved collagenic component (type I bone collagen). **OSTEOXENON MIX GEL:** ratio 1:1 of cancellous and cortical bone of equine origin with a preserved collagenic component (type I bone collagen), and inert water-based gel.

• **Properties/Intended use:**

OSTEOXENON (all codes except those listed below): act as grafting material for bone regeneration procedures. The preservation of the collagen component (type I bone collagen) allows the grafted material to respond physiologically to the action of the cell elements involved in the regeneration process (osteoclasts and osteoblasts), thereby facilitating bone regeneration. As they are enzyme deantigenated, they fully remodel and are replaced by the patient's endogenous tissue. The time required for complete replacement depends on anatomical variables (ratio between vital bone surface and graft site volume) and individual factors that vary from patient to patient. The average remodeling period is 4-6 months for cancellous bone grafts, and 8-12 months for cortical bone grafts. The formats indicated with the term "FLEX" have been subjected to an additional treatment of partial demineralization, making them flexible and easily adaptable to curved surfaces and profiles.

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

OSTEOXENON devices are indicated only for ***dental surgery***:

- **OSTEOXENON CANCELLOUS GRANULES, OSTEOXENON CORTICAL GRANULES, OSTEOXENON MIX GRANULES AND OSTEOXENON MIX GEL** may be used in 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). They provide 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.
- **OSTEOXENON CANCELLOUS BLOCK** may be used in surgical procedures such as augmentation or reconstructive treatment of the alveolar ridge. They are osteoconductors providing 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.
- **OSTEOXENON FLEX CORTICAL MEMBRANE** is an osteoconductor and bone membrane. It provides protection of the grafting site from invasion by soft tissues/epithelial cells, containment and stabilization of the grafting material and/or coagulum inside the grafting site and it favors the bone regeneration inside the grafting site. The barrier effect is exerted for at least 6 months, after which the device loses its occlusivity because of the osteoclastic resorption. It may be used in surgical procedures alone or in combination with suitable augmentation materials for immediate or delayed Guided Tissue and Bone Regeneration; in the augmentation or reconstructive treatment of the alveolar ridge; in case of surgical bone defects and bone wall defects; in the context of maxillary ridge reconstruction for prosthetic treatment; in the context of fenestration defects; in case of immediate or delayed augmentation around implants in extraction sockets; in sinus lift procedure for protecting the Schneider membrane or to close the lateral antrostomy.
- **OSTEOXENON CORTICAL FLEX** may be used for sinus lift, to protect the Schneider membrane mimicking Tulasne technique; for augmentation or reconstructive treatment of the alveolar ridge in combination with granular grafting material; in vertical ridge augmentation with concomitant implant placement. It provides bone volumetric augmentation, favoring the formation of new bone and in case of implant/prosthesis implanted in the same site, favoring the secondary stabilization of them. It acts also as contenitive barrier in confining grafting material inside a bone defect.
- **OSTEOXENON CANCELLOUS FLEX** may be used in surgical procedures for sinus lift, to protect the Schneider membrane mimicking Tulasne technique; for filling of extraction sockets to enhance preservation of the alveolar ridge; for augmentation or reconstructive treatment of the alveolar ridge. It provides volumetric augmentation, favoring the formation of new bone and in case of implant/prosthesis in the same site, favoring their secondary stabilization.

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

The device is single use and single patient; it cannot be reused or re-sterilized.
All **OSTEOXENON** 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:

- All **OSTEOXENON devices** must not to be used in patients who present individual hypersensitivity to collagen of equine origin. 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 directly support the functional load.
- The following devices shall not be used in non-containment defects or where the containment of the device has not been maintained through the use of appropriate barriers (for example membranes): **OSTEOXENON CANCELLOUS GRANULES, OSTEOXENON CORTICAL GRANULES, OSTEOXENON MIX GRANULES AND OSTEOXENON MIX GEL.**
- **OSTEOXENON CANCELLOUS BLOCK** shall not be used if a correct release of the flaps is not possible in order to guarantee a tension-free closure of the flaps. If used with the "onlay" technique, do not make volume increases greater than 5 mm thick in the jaw and 3 mm thick in the mandible. Do not use for volumetric "onlay" increments in the posterior mandible.

• Instructions for use:

- **OSTEOXENON (all codes except those listed below):** Hydrate the device in sterile physiological solution for 1-2 minutes. Proceed with the graft.
- **OSTEOXENON MIX GEL:** the device is ready for use.
- **OSTEOXENON CANCELLOUS BLOCK:** Hydrate the product in a sterile physiological solution for 3-5 minutes. Shape the graft with sterile tools in order to 1) adapt the form to the graft site as much as possible, guaranteeing maximum contact between the graft surface and vital patient bone and 2) eliminate sharp corners that could damage soft tissue. Proceed with the graft.
- **OSTEOXENON FLEX CORTICAL MEMBRANE:** If necessary, shape the membrane before hydrating. Hydrate in a sterile physiological solution for 1-2 minutes. Position in such a way that 1) the entire graft is covered and 2) there is a superimposition of at least 3 mm between the membrane and the patient's bone all around the graft site. Fix the membrane to the patient's bone by means of osteosynthesis.
- **OSTEOXENON CORTICAL FLEX:** shape the graft without hydrating it (sterile scissors are sufficient). Eliminate the sharp edges of the graft with a rotating burr. Place the graft and, if not used inside the maxillary sinus by the Tulasne technique, fix it by means of osteosynthesis. Graft the volume below the cortical graft with, for example, bone granules.
- **OSTEOXENON CANCELLOUS FLEX:** Hydrate the graft for 1-2 minutes with sterile physiologic solution. Place the graft and, if not used inside the maxillary sinus by the Tulasne technique, fix it by means of osteosynthesis. Protect the grafted site with a suitable membrane (such as Heart pericardium membrane).

• Precautions:

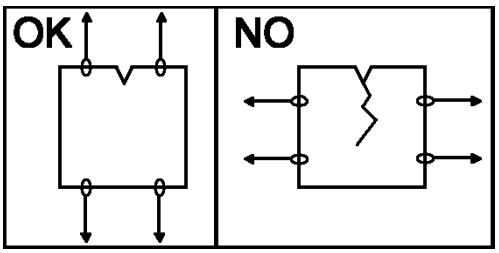
- Use of the device in direct combination with pharmaceutical products has not been tested. - The device may vary in color between white and ivory, due to the natural origin of bone tissue and the production process applied. Such coloring does not entail variations in the device's properties.
- The devices 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).-
- **OSTEOXENON GRANULES OF CANCELLOUS AND/OR CORTICAL BONE:** Arrange the granules on 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 forming blood vessels cannot permeate the graft). 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 device during transport and does not entail variations in the properties of the device itself.

- **OSTEOXENON CANCELLOUS BLOCK:** In case of small gaps still present between the graft and the receiving bone, use granular grafts to fill them. Ensure that primary graft stability is guaranteed, using osteosynthesis means if appropriate (lack of mutual movements between the graft and the vital patient bone). If the device, in the form of cancellous block, is used for vertical and/or horizontal increases of the jaw, we recommend not exceeding a 5 mm increase in the jaw and 3 mm increase in the mandible; we also recommend using a long-lasting or non-resorbable membrane and programming implant placement not before 8-9 months from the grafting, depending on the size of the increase and the biological conditions of the graft site, after imaging evaluation of the degree of integration/remodeling of the graft.

- **OSTEOXENON FLEX CANCELLOUS/ CORTICAL (any format):** To minimize the probability of graft breakage, shape with sterile tools as required before hydrating. Ensure that primary graft stability is guaranteed, using osteosynthesis means if appropriate (lack of mutual movements between the graft and the vital patient bone). For grafts with OSTEOXENON FLEX Cortical, the graft itself acts as an epithelial anti-invasion membrane, thus there is no need to protect the site with a membrane.

- **OSTEOXENON FLEX CORTICAL MEMBRANE** has a compulsory direction of traction, as indicated by indentation on one side. Apply any traction force parallel to this direction (see drawing). The membrane must ALWAYS BE STABILISED, using appropriate osteosynthesis means.



Important note: As they are partially demineralized, flexible formats are almost completely radiolucent (radiolucency has been observed up to 3 months from grafting).

• **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:**

- **OSTEOXENON CANCELLOUS BLOCK, OSTEOXENON FLEX CORTICAL MEMBRANE, OSTEOXENON FLEX CANCELLOUS/ CORTICAL (any format):** One piece in double PETG blister pack. Informative leaflet. Alternatively, one piece enclosed in a double OPA-OPA / OPA-Aluminum pouch. Informative leaflet.

OSTEOXENON GRANULES OF CANCELLOUS AND/OR CORTICAL BONE: Glass bottle in single PETG blister pack. Informative leaflet. Alternatively, a glass bottle inserted in an OPA-Aluminum or OPA-OPA pouch. Informative leaflet.

OSTEOXENON MIX GEL: One PP or PETG syringe in single or double PETG blister pack. Informative leaflet. Alternatively, one PP or PETG syringe in a double OPA-OPA / OPA-Aluminum pouch or in an OPA-Aluminum or OPA-OPA pouch. Informative leaflet.

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

• **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

OSP-OX01	OSTEOXENON Cancellous Flex	Cancellous Flex - 1 pc. 25 x 25 x 3 mm.
OSP-OX02	OSTEOXENON Cortical Flex	Cortical Flex - 1 pc. 25 x 25 x 2-2.5 mm.
OSP-OX03	OSTEOXENON FLex Cortical Membrane	Cortical Membrane - 1 pc. 25 x 25 x 0.2 mm.
OSP-OX04	OSTEOXENON Flex Cortical Membrane	Cortical Membrane - 1 pc. 50 x 25 x 0.2 mm.
OSP-OX08	OSTEOXENON Cortical Flex	Cortical Sheet- 1 pc 20-25 x 30-35 x 0.9 mm
OSP-OX21	OSTEOXENON Mix Gel	Cancellous Cortical Gel - 2 syr. / 0.25 ml.
OSP-OX21n	OSTEOXENON Mix Gel	Cancellous Cortical Gel - 1 syr / 0.25 ml
OSP-OX22	OSTEOXENON Mix Gel	Cancellous Cortical Gel - 2 syrs. / 0.5 ml.
OSP-OX22n	OSTEOXENON Mix Gel	Cancellous Cortical Gel - 1 syr / 0.5 ml
OSP-OX23	OSTEOXENON Mix Gel	Cancellous Cortical Gel - 1 syr. / 1 ml.
OSP-OX30	OSTEOXENON Cancellous Granules	Cancellous Granules - 1 btl / 0.5g ~1cc 0.25-1mm
OSP-OX31	OSTEOXENON Mix Granules	Cancellous Cortical Granules - 1 btl / 0.5g ~1cc 0.25-1mm
OSP-OX32	OSTEOXENON Mix Granules	Cancellous Cortical Granules - 1 btl / 1g ~2cc 0.25-1mm
OSP-OX33	OSTEOXENON Cancellous Granules	Cancellous Granules - 1 btl./2cc. 2-3mm.
OSP-OX34	OSTEOXENON Cancellous Granules	Cancellous Granules - 1 btl./ 1g. ~2cc. 2-4mm.
OSP-OX35	OSTEOXENON Mix Granules	Cancellous Cortical Granules - 1 btl / 0.25g ~0.5cc 0.25-1 mm
OSP-OX36	OSTEOXENON Cancellous Granules	Cancellous Granules - 1 btl / 1g ~2cc 0.25-1mm
OSP-OX37	OSTEOXENON Cancellous Granules	Cancellous Granules - 1 btl / 0.25g ~0.5cc 0.25-1 mm
OSP-OX38	OSTEOXENON Cancellous Granules	Cancellous Granules - 1 btl / 2g ~4cc 0.25-1mm
OSP-OX39	OSTEOXENON Cancellous Granules	Cancellous Granules - 1 btl./4cc. 2-3mm.
OSP-OX40	OSTEOXENON Cortical Granules	Cortical Granules - 1 btl / 0.5g ~1cc. 0.25-1 mm
OSP-OX41	OSTEOXENON Mix Granules	Cancellous Cortical Granules - 1 btl./2g. ~4cc. 0.25-1 mm.
OSP-OX50	OSTEOXENON Cancellous Granules	Cancellous Granules - 1 btl / 0.5g ~1cc 1-2mm
OSP-OX51	OSTEOXENON Cancellous Block	Cancellous Block - 1 pc. 10 x 10 x 10 mm.
OSP-OX52	OSTEOXENON Cancellous Block	Cancellous Block - 1 pc. 10 x 10 x 20 mm.
OSP-OX54	OSTEOXENON Cancellous Block	Cancellous Block - 2 pc. 10 x 20 x 3 mm.
OSP-OX54n	OSTEOXENON Cancellous Block	Cancellous Block - 1 pc 10 x 20 x 3 mm
OSP-OX55	OSTEOXENON Cancellous Block	Cancellous Block - 2 pc. 10 x 20 x 5 mm.
OSP-OX55n	OSTEOXENON Cancellous Block	Cancellous Block - 1 pc 10 x 20 x 5 mm
OSP-OX66	OSTEOXENON Cancellous Granules	Cancellous Granules - 1 btl / 1g ~2cc 1-2mm