OSTEOPLANT® osteOXenon

TECHNICAL SHEET

OX (osteOXenon®) **Disposable sterile device**	CE 0373

Description

OSTEOPLANT® OsteoXenon Equine origin collagenated bone conductors/bone promoters.

Product constituents

OsteoXenon (all formats except those listed hereto):
Equine origin cortical and/or spongy bone with preserved collagen component (type I bone collagen).
OsteoXenon MIX GEL:
Equine origin cortical and spongy bone with preserved collagen component (type I bone collagen), inert aqueous-based gel.
OsteoXenon COLLAGEN GEL:
Type I equine bone collagen (powder), equine Achilles tendon collagen (powder), inert aqueous-based gel.
OsteoXenon ACTIVAGEN:
Type I equine origin bone collagen.
OsteoXenon ANGIOSTAD:
Type I equine origin bone collagen, inert aqueous-based gel.

Indications and expected results

Collagenated bone conductors for total osteoclastic remodelling – (all formats except for those listed hereto):
With the exception of the cases specified below, the *OsteOXenon* range of bone substitutes act as bone conductors to be used as grafts in bone regeneration surgery.
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, thereby facilitating bone regeneration.
As they are enzyme deantigenised, they fully remodel and are replaced by patient endogenous tissue. The time required for complete replacement depends on anatomical variables (relationship between vital bone surface and graft site volume) and on individual factors that vary from patient to patient. Average remodelling time takes 4-6 months for spongy bone grafts, and 8-12 months for cortical bone grafts.
Flexible collagenated bone conductors with total osteoclastic remodelling - OsteOXenon FLEX SPONGY/CORTICAL/CORTICAL-SPONGY
The bone substitutes *OsteOXenon FLEX* have the same biological properties as the *OsteOXenon* substitutes (presence of type I bone collagen, same remodelling times). In addition, they have undergone partial demineralisation, making them flexible and therefore easily adaptable to curved surfaces and profiles.
Flexible cortical membrane with total osteoclastic remodelling – OsteOXenon Cortical Membrane:
OsteOXenon Cortical Membrane is a cortical membrane with osteoclastic remodelling to be positioned to protect bone grafts. Its effect protects against epithelial cell invasion. Its remodelling only takes place by means of the osteoclasts from the graft site below. It is therefore a long-lasting membrane that need not be removed. Total remodelling time depends on the conditions of the graft site (indicatively: from 6 to 12 months).
Collagen gel to stabilise and protect - OSTEOXENON COLLAGEN GEL: OSTEOXENON COLLAGEN GEL is a collagen gel that, when positioned to cover a bone graft with a bone conducting material, stabilises it and protects against invasion of soft tissue cells. It can be used, in lieu of a traditional collagen membrane, to cover bone grafts in smaller sites (small peri-implant sites - with less than 3 exposed coils- or to protect bone grafts in small periodontal sites). No bone conducting effect. Protection time is around 4 weeks.
Bone promoters - OsteOXenon ANGIOSTAD/ ACTIVAGEN:
These are formulations based on type I bone collagen (demineralised bone matrix) stimulating angiogenesis (*OsteOXenon ANGIOSTAD*) or morphogenesis (*OsteOXenon ACTIVAGEN*), to be used together with other osteoconductors to facilitate bone regeneration.

Instructions for use

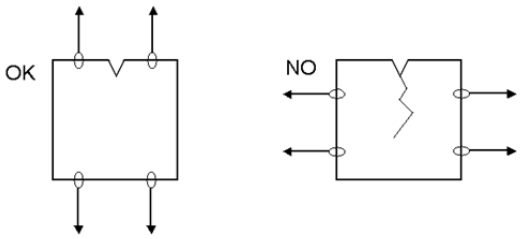
OsteoXenon (all formats except those listed hereto):
Hydrate the product in a sterile physiological solution for 3-5 minutes. Proceed with the graft.
OsteoXenon Cortical Membrane:
If necessary, shape the membrane before hydrating. Hydrate in a sterile physiological solution for 3-5 minutes. Position in such a way that 1) the entire graft is covered and 2) there is a superimposition of at least 3 mm between membrane and patient bone, all around the graft site. Fix the membrane to the patient bone by means of osteosynthesis.
OsteoXenon ANGIOSTAD:
The product is ready for use. Spread a layer of product, no thicker than one millimetre, over the vital bone surface of the area to be grafted (previously prepared), and proceed to graft the desired osteoconductive material. Alternatively, the product can be spread on the graft surface or surfaces (e.g.: block, wedge, sheet, etc.) in contact with the vital bone surface of the area to be grafted.
OsteoXenon ACTIVAGEN:
The product is ready for use. Mix in proportion of 1:1 (volume) with an osteoconductive product in granular form. Hydrate the mix in a sterile physiological solution for 3-5 minutes. Proceed with the graft.
OsteoXenon MIX GEL/OsteoXenon COLLAGEN GEL:
The product is ready for use.

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.

Patient conditions:
There are conditions linked both to the general health (e.g. metabolic diseases) and specific to the oral cavity (e.g. parodontal disease present), as well as to the patient's lifestyle (e.g.: cigarette smoking) that can significantly affect the success of bone regeneration. Before scheduling surgery, ensure that you have taken a careful, full patient history, have given the patient appropriate instructions, and have informed them as to the probabilities of success or failure of the surgery.
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 (products not ready for use):
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 stability:
Ensure, using osteosynthesis means if necessary, that the graft is stable with regards to the receiving bone bed (there must be no movement or micro movements that would destroy the newly-formed vessel network).
Protection of graft site:
When it is not possible, or you are not sure of restoring the periosteal covering, the graft site must be protected from epithelial invasion with a suitable membrane.
Granular formats (osteoconductive bone substitute) - OsteoXenon SPONGY/ MIX:
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).
Granular formats (bone promoters) - OsteoXenon ACTIVAGEN:
The product does not act as an osteoconductive bone substitute, but only as a bone promoter, and must therefore always be mixed, in the proportions given in the paragraph ‘Instructions for use’, with osteoconductive graft material.
Gel or paste formats (osteoconductive bone substitute) - OsteoXenon MIX GEL:
No particular precautions are necessary.
Gel formats (bone promoters) - OsteoXenon ANGIOSTAD:
The product does not act as an osteoconductive bone substitute, but only as a bone promoter, and must therefore always be used together with osteoconductive graft material.
Flexible formats - OsteoXenon FLEX SPONGY/CORTICAL/CORTICAL-SPONGY, OsteoXenon Cortical Membrane: To minimise the probability of graft breakage, shape with sterile tools as required before hydrating. In the event of a graft of *OsteoXenon FLEX CORTICAL*, the graft itself acts as an anti-epithelial invasion membrane, and there is therefore no need to protect the site with a membrane.

The flexible cortical membrane *OsteoXenon Cortical Membrane* has a *compulsory traction direction indicated by the indenting on one of the sides. Apply any traction force parallel to this direction (see drawing).*
The membrane must ALWAYS BE STABILISED, using appropriate osteosynthesis means where necessary.



Important note: As flexible formats are partially demineralised, they are almost entirely radiotransparent (radiotransparency has been seen up to 3 months after graft).

Side effects

The product is biocompatible. It does not cause side effects. Latex free: the device contains no latex.
Ensure that the patient shows no individual hypersensitivity to collagen of equine origin (only for BIO-GEN® PUTTY). 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

OsteOXenon (blocks, membranes and flex formats):
One piece in double PETG blister pack. Informative leaflet.
Alternatively, one piece enclosed in a double OPA-OPA / OPA-Aluminium pouch. Informative leaflet.
OsteOXenon (paste/gel formats):
PET syringe in single PETG blister pack. Informative leaflet.
Alternatively, PET syringe in an OPA-Aluminium pouch. Informative leaflet.
OsteOXenon (granular formats):
Glass bottle in single PETG blister pack. Informative leaflet.
Alternatively, a glass 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. 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	1 cancellous flexible sheet, 25 x 25 x 3 mm.
OSP-OX02	osteOXenon Cortical Flex	1 cortical flexible sheet, 25 x 25 x 2-2,5 mm.
OSP-OX02A	osteOXenon Cortical Flex	2 cortical flexible sheets, 12 x 25 x 2-2,5 mm.
OSP-OX03	osteOXenon Flex Cortical Membrane	1 cortical flexible membrane, 25 x 25 x 0,2 mm.
OSP-OX04	osteOXenon Flex Cortical Membrane	1 cortical flexible membrane, 50 x 25 x 0,2 mm.
OSP-OX05R	osteOXenon Cancellous Cortical Block	1 cancellous/cortical block, 15 x 30 x 5-6 mm.
OSP-OX06	osteOXenon Collagen Gel	Gel, 2 syringes, 0,25 ml each.
OSP-OX07	osteOXenon Collagen Gel	Gel, 2 syringes, 0,5 ml each.
OSP-OX11	osteOXenon Angiostad	DBM in Gel, 2 syringes, 0,5 ml each.
OSP-OX14	osteOXenon Activagen	DBM in Granules - 1 bottle, 0,5 cc.
OSP-OX21	osteOXenon Mix Gel	Granules (50% cortical, 50% cancellous) in gel, 2 syringes, 0,25 ml each, granules size 0,5-1 mm.
OSP-OX22	osteOXenon Mix Gel	Granules (50% cortical, 50% cancellous) in gel, 2 syringes, 0,5 ml each, granules size 0.5-1 mm.
OSP-OX23	osteOXenon Mix Gel	Granules (50% cortical, 50% cancellous) in gel, 1 syringe 1 ml, granules size 0,5-1 mm.
OSP-OX30	osteOXenon Cancellous Granules	Granules, 1 bottle, 0,5 g., 1cc. granules size 0,5-1 mm.
OSP-OX31	osteOXenon Mix Granules	Granules (50% cortical, 50% cancellous), 1 bottle, 0,5 g., 1cc. granules size 0,5-1 mm.
OSP-OX32	osteOXenon Mix Granules	Granules (50% cortical, 50% cancellous), 1 bottle, 1 g., 2 cc. granules size 0,5-1 mm.
OSP-OX33	osteOXenon Cancellous Granules	Granules, 1 bottle, 1 g., 2 cc. granules size 2-3 mm.
OSP-OX34	osteOXenon Cancellous Granules	Granules, 1 bottle, 1 g., 2 cc. granules size 2-4 mm.
OSP-OX35	osteOXenon Mix Granules	Granules (50% cortical, 50% cancellous), 1 bottle, 0,25 g., 0.5 cc. granules size 0,5-1 mm.
OSP-OX36	osteOXenon Cancellous Granules	Granules, 1 bottle, 1 g., 2 cc. granules size 0,5-1 mm.
OSP-OX37	osteOXenon Cancellous Granules	Granules, 1 bottle, 0.25 g., 0.5cc. granules size 0,5-1 mm.
OSP-OX38	osteOXenon Cancellous Granules	Granules, 1 bottle, 2 g., 4cc. granules size 0,5-1mm.
OSP-OX39	osteOXenon Cancellous Granules	Granules, 1 bottle,2 g., 4cc. granules size 2-3mm.
OSP-OX39A	osteOXenon Cancellous Granules	Granules, 1 bottle, 2 g., 4cc. granules size 2-3mm.
OSP-OX40	osteOXenon Cortical Granules	Granules, 1 bottle, 0,5 g.,1cc. granules size 0,5-1 mm.
OSP-OX41	osteOXenon Mix Granules	Granules (50% cortical, 50% cancellous), 1 bottle, 2 g., 4cc. granules size 0,5-1 mm.
OSP-OX51	osteOXenon Cancellous Block	1 block 10 x 10 x 10 mm.
OSP-OX52	osteOXenon Cancellous Block	1 block 10 x 10 x 20 mm.
OSP-OX54	osteOXenon Cancellous Block	2 blocks 10 x 20 x 3 mm.
OSP-OX55	osteOXenon Cancellous Block	2 blocks 10 x 20 x 5 mm.