

The logo for BiOTECK features the word "BiOTECK" in a dark blue, serif font. The letter "i" is stylized, with a vertical bar to its left and a dot above it, all contained within a grey, rounded rectangular shape.

OSTEOPLANT[®]
TECHNICAL SHEET

BIOTECK [®]	File: M_181009_ST_OSTEOPLANT_EN	Date: 09.10.2018 Revision: 181009	Pag.
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OSTEOPLANT [®] Disposable sterile device	CE 0373
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Description

OSTEOPLANT[®] Equine origin collagenated bone conductors/bone promoters.

Product constituents:

OSTEOPLANT[®] (all formats except those listed hereto):

Equine origin cortical and spongy bone with preserved collagen component (type I bone collagen).

OSTEOPLANT[®] MIX GEL Equine origin cortical and spongy bone with preserved collagen component (type I bone collagen). Inert aqueous-based gel.

OSTEOPLANT[®] ACTIVAGEN Type I equine origin bone collagen. Inert aqueous-based gel.

OSTEOPLANT[®] ANGIOSTAD: Type I equine origin bone collagen, inert aqueous-based gel.

OSTEOPLANT[®] Activagen Injectable Paste: Type I equine origin bone collagen, type I collagen from equine Achilles tendon, inert aqueous-based gel, micro granules of equine spongy bone.

OSTEOPLANT[®] Activagen Mouldable Paste: Type I equine origin bone collagen, type I collagen from equine Achilles tendon, inert aqueous-based gel, micro granules of equine spongy bone, chips of equine spongy bone diameter 1-2 mm.

Indications and expected results:

Collagenated osteoconductive materials or total osteoclastic remodelling – (all formats except for those listed hereto): With the exception of the cases specified below, the OSTEOPLANT[®] 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 (ratio 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. The bone substitutes indicated with the term 'FLEX' have the same biological properties as the OSTEOPLANT[®] 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 - OSTEOPLANT[®] Cortical Membrane:

OSTEOPLANT[®] Cortical Membrane is a cortical membrane with osteoclastic remodelling to be positioned to protect bone grafts. Exerts a tent effect and protects from the invasion of epithelial cells. Its remodelling only takes place by means of the osteoclasts from the graft site below. It is therefore a long-lasting membrane that must not be removed. Total remodelling time depends on the conditions of the graft site (indicatively: from 6 to 12 months). **Bone promoters - OSTEOPLANT[®] ACTIVAGEN/ ANGIOSTAD** These are formulations based on type I bone collagen (demineralised bone matrix) stimulating morphogenesis (OSTEOPLANT[®] ACTIVAGEN) or angiogenesis (OSTEOPLANT[®] ANGIOSTAD), to be used together with other osteoconductive products to facilitate bone regeneration. **Bone promoters in bone paste - OSTEOPLANT[®] Activagen Injectable/Mouldable Paste.** These are bone paste bone promoters based on type I bone collagen (demineralised bone matrix) acting as bone promoters stimulating morphogenesis and bone conduction, to be used as bone grafts, facilitating bone regeneration.

Instructions for use: OSTEOPLANT[®] (all formats except those listed hereto): Hydrate the product in sterile saline solution for at least 5 minutes. Perform the graft. **OSTEOPLANT[®] Cortical Membrane:** If necessary, shape the membrane before hydrating. Hydrate in sterile saline for 3-5 minutes. Position in such a way that 1) the entire graft is covered and 2) there is an overlap of at least 3 mm between the membrane and the patient's bone, all around the graft site. Secure the membrane to the patient's bone by means of osteosynthesis.

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OSTEOPLANT® ACTIVAGEN: Before hydrating, mix with an osteoconductive product in granules, at a ratio of 1:1 (in weight). Hydrate the mix in a sterile physiological solution for 3-5 minutes. Proceed with the graft.

OSTEOPLANT® 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.

OSTEOPLANT® MIX GEL/ OSTEOPLANT® Activagen Injectable Paste/ OSTEOPLANT® Activagen Mouldable Paste: 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. The product may vary in colour between white and ivory, due to the natural origin of bone tissue and the production process applied. Such colouring does not entail variations in the product's properties.

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.

Combination with autologous/homologous components: The use of components of autologous/homologous origin in combination with Bioteck's biomaterials, although not contraindicated, has not been tested. The use of components of autologous/homologous origin is at the discretion of the surgeon and should be decided from patient to patient, based on the individual's medical condition.

Granular formats (bone conductors) - OSTEOPLANT® Chips or spongy and/or cortical bone granules: Arrange the chips or 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). 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.

Granular formats (bone promoters) - OSTEOPLANT® ACTIVAGEN: The product does not act as a bone conductor, but only as a bone promoter, and must therefore always be mixed, in the proportions given in the paragraph 'Instructions for use', with a osteoconductive graft material.

Formats in block, wedge, rod - OSTEOPLANT® Spongy or cortical/spongy bone block/wedge, OSTEOPLANT® Femoral hemi-head, OSTEOPLANT® Cup or Half Cup, OSTEOPLANT® Cortical rod: Shape the graft using sterile tools in order to 1) adapt the form to the graft site as far as possible, guaranteeing maximum contact between graft surface and vital patient bone, and 2) eliminate sharp corners that could damage the soft tissues. Ensure that primary graft stability is guaranteed, using osteosynthesis means if appropriate (lack of mutual movements between graft and the vital patient bone). If the device, in the form of cortical/spongy or spongy block, should be 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.

Paste formats (osteoconductive bone substitute or bone promoters in bone paste) - OSTEOPLANT® MIX GEL, OSTEOPLANT® Activagen Injectable Paste, OSTEOPLANT® Activagen Mouldable Paste: No particular precautions are necessary.

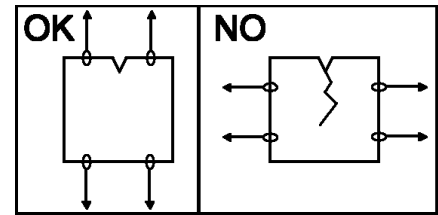
Gel formats (bone promoters) - OSTEOPLANT® ANGIOSTAD: The product does not act as an osteoconductive bone substitute, but only as a bone promoter, and must therefore always be used together with a bone conductor graft material.

Flexible formats - OSTEOPLANT® FLEX SPONGY/ CORTICAL To minimise 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 graft and the vital patient bone). In the event of a graft of OSTEOPLANT® 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 OSTEOPLANT® 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.

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

Ensure that the patient shows no individual hypersensitivity to collagen of equine origin. The product has not been tested on pregnant women. Latex-free: the device contains no latex.

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: OSTEOPLANT® (all formats except those listed hereto):

One piece in double PETG blister pack. Informative leaflet. Alternatively, one piece enclosed in a double OPA-OPA / OPA-Aluminium pouch. Informative leaflet.

OSTEOPLANT® (Paste/gel formats): PET or PP syringe in double PETG blister pack. Informative leaflet. Alternatively, PET or PP syringe in a double OPA-OPA / 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

OB-01-05	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc / 5cc 4-6mm
OB-01-10	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc / 10cc 4-6mm
OB-01-10A	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc / 10cc 2-4mm
OB-01-20	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc / 20cc 4-6mm
OB-01-20A	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc/ 20cc 2-4mm
OB-01-30	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc / 30cc 4-6mm
OB-01-30A	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc / 30cc 2-4mm
OB-01-50	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc / 50cc 4-6mm
OB-01-90	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc / 90cc 4-6mm
OB-02-01	OSTEOPLANT Cancellous Cortical Chips	Cancellous Cortical Chips - 1 pc / 10cc 4-6mm
OB-02-02	OSTEOPLANT Cancellous Cortical Chips	Cancellous Cortical Chips - 1 pc / 15cc 4-6mm
OB-02-03	OSTEOPLANT Cancellous Cortical Chips	Cancellous Cortical Chips - 1 pc / 20cc 4-6mm
OB-02-04	OSTEOPLANT Cancellous Cortical Chips	Cancellous Cortical Chips - 1 pc / 30cc 4-6mm
OB-02-08	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 pc / 8cc 2-4mm
OB-02-10	OSTEOPLANT Cancellous Chips	Cancellous Chips - 1 btl / 2cc 4-6mm
OGS-03A	OSTEOPLANT Cancellous Granules	Cancellous Granules - 1 btl / 3g 0.5-1mm
OGS-05A	OSTEOPLANT Cancellous Granules	Cancellous Granules - 1 jr / 5g 0.5-1mm
OGS-AC10	OSTEOPLANT Activagen	DBM Granules - 1 btl / 1 cc
OGS-AC20	OSTEOPLANT Activagen	DBM Granules - 1 btl / 2 cc
OGS-AC5	OSTEOPLANT Activagen	DBM Granules - 3 btl / 0.5 cc
OGS-ACI10	OSTEOPLANT Activagen Injectable Paste	DBM Injectable Paste - 1 syr / 10 cc
OGS-ACI2	OSTEOPLANT Activagen Injectable Paste	DBM Injectable Paste - 1 syr / 2 cc
OGS-ACI5	OSTEOPLANT Activagen Injectable Paste	DBM Injectable Paste - 1 syr / 5 cc
OGS-ACM1	OSTEOPLANT Activagen Mouldable Paste	DBM Mouldable Paste - 1 syr / 1 cc
OGS-ACM10	OSTEOPLANT Activagen Mouldable Paste	DBM Mouldable Paste - 1 syr / 10 cc
OGS-ACM2	OSTEOPLANT Activagen Mouldable Paste	DBM Mouldable Paste - 1 syr / 2 cc
OGS-ACM40	OSTEOPLANT Activagen Mouldable Paste	DBM Mouldable Paste - 1 syr / 0.5 cc
OGS-ACM5	OSTEOPLANT Activagen Mouldable Paste	DBM Mouldable Paste - 1 syr / 5 cc
OGS-ACM500	OSTEOPLANT Activagen Mouldable Paste	DBM Mouldable Paste - 3 syr / 0.5 cc
OGS-ACM600	OSTEOPLANT Activagen Mouldable Paste	DBM Mouldable Paste - 3 syr / 1 cc
OGS-GEL1	OSTEOPLANT Angiostad	DBM Gel - 3 syr 1ml/syr 0.5-1mm
OGS-GEL2	OSTEOPLANT Angiostad	DBM Gel - 1 syr / 2 ml
OMC-03	OSTEOPLANT Cancellous Dowel	Cancellous Dowel - 1 pc Ø 12 x 20 mm
OMC-04	OSTEOPLANT Cancellous Dowel	Cancellous Dowel - 1 pc Ø 14 x 20 mm
OMC-05	OSTEOPLANT Cancellous Dowel	Cancellous Dowel - 1 pc Ø 16 x 20 mm
OMC-05S	OSTEOPLANT Flex Cancellous Disk	Cancellous Disc - 1 pc Ø 16 x 5 mm
OMC-15d	OSTEOPLANT Cancellous Dowel dense	Cancellous Dowel - 1 pc Ø 15 x 40 mm
OMC-50b	OSTEOPLANT Cancellous Block dense	Cancellous Block - 2 pc 30 x 20 x 12 mm
OMC-50b1	OSTEOPLANT Cancellous Block dense	Cancellous Block - 1 pc 30 x 20 x 12 mm
OMC-80	OSTEOPLANT	Bone Block - 1 pc 22 x 8 x 9 mm
OSP-01	OSTEOPLANT Cancellous Block	Cancellous Block - 1 pc 20 x 20 x 10 mm
OSP-010P	OSTEOPLANT Cancellous Wedge for Plate	Cancellous Wedge - 1 pc 50 x 40 x 10 mm
OSP-0125P	OSTEOPLANT Cancellous Wedge for Plate	Cancellous Wedge - 1 pc 50 x 40 x 12.5 mm
OSP-01A	OSTEOPLANT Cancellous Block	Cancellous Block - 1 pc 10 x 10 x 10 mm
OSP-01B	OSTEOPLANT Cancellous Block	Cancellous Block - 1 pc 10 x 10 x 20 mm
OSP-01B2	OSTEOPLANT Cancellous Block	Cancellous Block - 2 pc 10 x 10 x 20 mm

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OSP-02	OSTEOPLANT Cancellous Block	Cancellous Block - 1 pc 50 x 40 x 5 mm
OSP-02B	OSTEOPLANT Cancellous Block	Cancellous Block - 1 pc 40 x 30 x 10 mm
OSP-03	OSTEOPLANT Cancellous Block	Cancellous Block - 1 pc 50 x 40 x 10 mm
OSP-04	OSTEOPLANT Hemi Femoral-Head	Hemi Femoral-Head - 1 pc Ø 60 x 20 mm
OSP-0452	OSTEOPLANT Cup	Cancellous Cup - 1 pc Ø 52 x 24 mm
OSP-0452A	OSTEOPLANT Half Cup	Cancellous Half Cup - 1 pc Ø 52 x 24 mm
OSP-0456	OSTEOPLANT Cup	Cancellous Cup - 1 pc Ø 56 x 24 mm
OSP-0456A	OSTEOPLANT Half Cup	Cancellous Half Cup - 1 pc Ø 56 x 24 mm
OSP-0460	OSTEOPLANT Cup	Cancellous Cup - 1 pc Ø 60 x 24 mm
OSP-0460A	OSTEOPLANT Half Cup	Cancellous Half Cup - 1 pc Ø 60 x 24 mm
OSP-05	OSTEOPLANT Cancellous Wedge	Cancellous Wedge - 1 pc 40 x 30 x 10 mm
OSP-05B	OSTEOPLANT Cancellous Wedge	Cancellous Wedge - 1 pc 40 x 30 x 15 mm
OSP-06	OSTEOPLANT Cancellous Wedge	Cancellous Wedge - 1 pc 50 x 40 x 10 mm
OSP-06B	OSTEOPLANT Cancellous Wedge	Cancellous Wedge - 1 pc 50 x 40 x 15 mm
OSP-07	OSTEOPLANT Cancellous Wedge	Cancellous Wedge - 1 pc 50 x 20 x 20 mm
OSP-070	OSTEOPLANT Flex Acetabular Mat	Cancellous Acetabular Mat - 1 pc Ø 70 x 5-7 mm
OSP-075P	OSTEOPLANT Cancellous Wedge for Plate	Cancellous Wedge - 1 pc 50 x 40 x 7.5 mm
OSP-07A	OSTEOPLANT Cancellous Dihedron	Cancellous Dihedron - 1 pc 50 x 20 x 10 mm
OSP-08	OSTEOPLANT Cortical Rod	Cortical Rod - 1 pc 80 x 20 x 6 mm
OSP-09	OSTEOPLANT Cortical Rod	Cortical Rod - 1 pc 100 x 20 x 6 mm
OSP-10	OSTEOPLANT Cortical Rod	Cortical Rod - 1 pc 120 x 20 x 6 mm
OSP-20B	OSTEOPLANT Cancellous Cortical Stick	Cancellous Cortical Stick - 2 pc 50 x 8 x 5 mm
OSP-30	OSTEOPLANT Cancellous Cortical Stick	Cancellous Cortical Stick - 2 pc 100 x 8 x 5 mm
OSP-FIX6	OSTEOPLANT Cortical Pin	Cortical Pin - 6 pcs Ø 4,8 - 5 x 8 mm
OTC-C1	OSTEOPLANT Cortical Flex	Cortical Sheet - 1 pc 25 x 25 x 2-2.5 mm
OTC-C4	OSTEOPLANT Cortical Flex	Cortical Sheet - 1 pc 40 x 40 x 1-2.5 mm
OTC-C7	OSTEOPLANT Cortical Flex	Cortical Sheet - 1 pc 50 x 50 x 1-2.5 mm
OTC-C8	OSTEOPLANT Cortical Flex	Cortical Sheet - 1 pc 70 x 70 x 1-2.5 mm
OTC-C9	OSTEOPLANT Cortical Flex	Cortical Sheet - 1 pc 40 x 40 x 0.7 mm
OTC-CE	OSTEOPLANT Flex Cortical Membrane	Cortical Membrane - 1 pc 25 x 25 x 0.2 mm
OTC-CE2	OSTEOPLANT Flex Cortical Membrane	Cortical Membrane - 1 pc 50 x 25 x 0.2 mm
OTC-S1	OSTEOPLANT Cancellous Flex	Cancellous Sheet - 1 pc 25 x 25 x 3 mm
OTC-S10	OSTEOPLANT Cancellous Flex	Cancellous Block - 1 pc 50 x 20 x 15 mm
OTC-S12	OSTEOPLANT Cancellous Flex	Cancellous Dowel - 1 pc Ø 12 x 30 mm
OTC-S19	OSTEOPLANT Cancellous Double Dowel Flex	Cancellous Drilled Dowel - 1 pc Ø 15/12 x 30mm
OTC-S2	OSTEOPLANT Cancellous Flex	Cancellous Sheet - 1 pc 40 x 40 x 3 mm
OTC-S3	OSTEOPLANT Cancellous Flex	Cancellous Sheet - 1 pc 30 x 20 x 3 mm
OTC-S4	OSTEOPLANT Cancellous Flex	Cancellous Sheet - 1 pc 50 x 25 x 3 mm
OTC-S5	OSTEOPLANT Cancellous Flex	Cancellous Sheet - 1 pc 50 x 50 x 3 mm
OTC-S7	OSTEOPLANT Cancellous Flex	Cancellous Sheet - 1 pc 60 x 30 x 3 mm
OTC-S8	OSTEOPLANT Cancellous Flex	Cancellous Sheet - 1 pc 60 x 50 x 3 mm
OTC-S9	OSTEOPLANT Cancellous Flex	Cancellous Strip - 2 pc 100 x 10 x 8 mm
OTC-S9A	OSTEOPLANT Cancellous Flex	Cancellous Strip - 1 pc 100 x 10 x 8 mm