



**OSTEOPLANT<sup>®</sup>**  
**TECHNICAL SHEET**

**OSTEOPLANT®**  
 Disposable sterile device



## 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.

### **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 a sterile physiological solution for 3-5 minutes. Proceed with 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.

### **OSTEOPLANT® ACTIVAGEN:**

The product is ready for use. 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.

### **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.

### **Granular formats (bone conductors) - OSTEOPLANT® Chips or spongy 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).

### **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 bone wedge/block, OSTEOPLANT® Femoral hemi-head,**

### **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).

### **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.

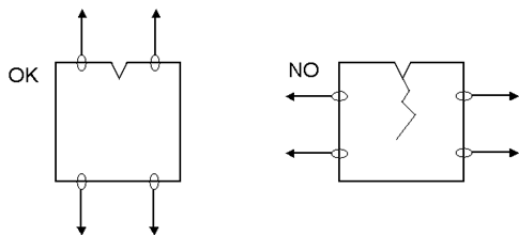
### **Flexible formats - OSTEOPLANT® FLEX SPONGY/ CORTICAL**

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 syringe in double PETG blister pack. Informative leaflet.

Alternatively, PET syringe in a double OPA-OPA / OPA-Aluminium pouch. Informative leaflet.

### Patient labels

For blister packs: six copies are included on the external blister pack; these can be removed and placed on the clinical file. For all other packaging types, patient labels are included inside the package.

### Breakage of casing and disposal of packaging

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.

### 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

<b>OB-01-05</b>	OSTEOPLANT Cancellous Chips	4-6 mm chips, 5 cc.
<b>OB-01-10</b>	OSTEOPLANT Cancellous Chips	4-6 mm chips, 10 cc.
<b>OB-01-10A</b>	OSTEOPLANT Cancellous Chips	2-4 mm chips, 10 cc.
<b>OB-01-100</b>	OSTEOPLANT Cancellous Chips	4-6 mm chips, 100 cc.
<b>OB-01-20</b>	OSTEOPLANT Cancellous Chips	4-6 mm chips, 20 cc.
<b>OB-01-20A</b>	OSTEOPLANT Cancellous Chips	2-4 mm chips, 20 cc.
<b>OB-01-30</b>	OSTEOPLANT Cancellous Chips	4-6 mm chips, 30 cc.
<b>OB-01-30A</b>	OSTEOPLANT Cancellous Chips	2-4 mm chips, 30 cc.
<b>OB-01-50</b>	OSTEOPLANT Cancellous Chips	4-6 mm chips, 50 cc.
<b>OB-01-90</b>	OSTEOPLANT Cancellous Chips	4-6 mm chips, 90 cc.
<b>OB-02-01</b>	OSTEOPLANT Cancellous Cortical Chips	4-6 mm chips, 70% cancellous, 30% cortical, 10 cc.
<b>OB-02-02</b>	OSTEOPLANT Cancellous Cortical Chips	4-6 mm chips, 70% cancellous, 30% cortical, 15 cc.
<b>OB-02-03</b>	OSTEOPLANT Cancellous Cortical Chips	4-6 mm chips, 70% cancellous, 30% cortical, 20 cc.
<b>OB-02-04</b>	OSTEOPLANT Cancellous Cortical Chips	4-6 mm chips, 70% cancellous, 30% cortical, 30 cc.
<b>OB-02-08</b>	OSTEOPLANT Cancellous Chips	2-4 mm chips, 8 cc..
<b>OB-02-10</b>	OSTEOPLANT Cancellous Chips	4-6 mm chips, 2 cc..
<b>OB-02-20</b>	OSTEOPLANT Cancellous Chips	2-4 mm chips, 20 cc.
<b>OGM-GEL10</b>	OSTEOPLANT Mix Gel	Granules (50% cortical, 50% cancellous) in gel, 1 syringe, 10 ml, granules size 0.5-1 mm.
<b>OGM-GEL15</b>	OSTEOPLANT Mix Gel	Granules (50% cortical, 50% cancellous) in gel, 1 syringe, 15 ml, granules size 0.5-1 mm.
<b>OGM-GEL2</b>	OSTEOPLANT Mix Gel	Granules (50% cortical, 50% cancellous) in gel, 1 syringes, 2 ml, granules size 0.5-1 mm
<b>OGM-GEL5</b>	OSTEOPLANT Mix Gel	Granules (50% cortical, 50% cancellous) in gel, 1 syringes, 5 ml, granules size 0.5-1 mm.
<b>OGS-03A</b>	OSTEOPLANT Cancellous Granules	Granules, 1 bottle, 3 gr., granules size 0.5-1mm.
<b>OGS-05A</b>	OSTEOPLANT Cancellous Granules	Granules, 1 bottle, 5 gr., granules size 0.5-1 mm.
<b>OGS-AC10</b>	OSTEOPLANT Activagen	DBM granules, 1 bottle 1 cc.
<b>OGS-AC20</b>	OSTEOPLANT Activagen	DBM granules, 1 bottle 2 cc.
<b>OGS-AC25</b>	OSTEOPLANT Activagen Implant	DBM granules, 3 pieces, 0.5 cc. each
<b>OGS-AC5</b>	OSTEOPLANT Activagen	DBM granules, 3 bottles, 0.5 cc. each.
<b>OGS-ACI10</b>	OSTEOPLANT Activagen Injectable Paste	DBM paste, 1 syringe, 10 cc.
<b>OGS-ACI2</b>	OSTEOPLANT Activagen Injectable Paste	DBM paste, 1 syringe, 2 cc.
<b>OGS-ACI5</b>	OSTEOPLANT Activagen Injectable Paste	DBM paste, 1 syringe, 5 cc.
<b>OGS-ACI500</b>	OSTEOPLANT Activabone Precise	DBM gel, 1 syringe, 0.5 ml
<b>OGS-ACM1</b>	OSTEOPLANT Activagen Mouldable Paste	DBM paste, 1 syringe 1 cc.
<b>OGS-ACM10</b>	OSTEOPLANT Activagen Mouldable Paste	DBM paste, 1 syringe 10 cc.
<b>OGS-ACM2</b>	OSTEOPLANT Activagen Mouldable Paste	DBM paste, 1 syringe 2 cc.
<b>OGS-ACM40</b>	OSTEOPLANT Activagen Mouldable Paste	DBM paste, 1 syringe 0.5 cc.
<b>OGS-ACM5</b>	OSTEOPLANT Activagen Mouldable Paste	DBM paste, 1 syringe, 5 cc.
<b>OGS-ACM500</b>	OSTEOPLANT Activagen Mouldable Paste	DBM paste, 3 syringes, 0.5 cc. each.
<b>OGS-ACM5c</b>	OSTEOPLANT Activagen Mouldable Paste	DBM paste, 1 syringe, 5 cc. with straw extrusion
<b>OGS-ACM600</b>	OSTEOPLANT Activagen Mouldable Paste	DBM paste, 3 syringes, 1 cc. each.
<b>OGS-GEL1</b>	OSTEOPLANT Angiostad	DBM gel, 3 syringes 1 ml. each.
<b>OGS-GEL2</b>	OSTEOPLANT Angiostad	DBM gel, 1 syringe 2 ml.
<b>OMC-03</b>	OSTEOPLANT Cancellous Dowel	1 cancellous dowel Ø 12 x 20 mm.
<b>OMC-04</b>	OSTEOPLANT Cancellous Dowel	1 cancellous dowel Ø 14 x 20 mm.

<b>OMC-05</b>	OSTEOPLANT Cancellous Dowel	1 cancellous dowel Ø 16 x 20 mm.
<b>OMC-05S</b>	OSTEOPLANT Flex Cancellous Disk	1 flexible cancellous disk Ø 16 x 5 mm.
<b>OMC-12S</b>	OSTEOPLANT Flex Cancellous Dowel	1 flexible cancellous dowel Ø 12 x 12 mm.
<b>OMC-50b</b>	OSTEOPLANT Cancellous Block	2 blocks 30 x 20 x 12 mm.
<b>OMC-50b1</b>	OSTEOPLANT Cancellous Block	1 block, 30 x 20 x 12 mm.
<b>OMC-5011</b>	OSTEOPLANT APF Cortical-Cancellous Dense Block	1 dense block – h 11 mm.
<b>OMC-5012</b>	OSTEOPLANT APF Cortical-Cancellous Dense Block	1 dense block – h 12 mm.
<b>OMC-AR14</b>	OSTEOPLANT A-RACHIDE Cancellous Dense Block	1 dense block
<b>OMC-E1</b>	OSTEOPLANT Cancellous Trapezium	1 trapezium 10 x 10 x 15 mm.
<b>OMC-E2</b>	OSTEOPLANT Cancellous Trapezium	1 trapezium 10 x 15 x 20 mm.
<b>OSP-01</b>	OSTEOPLANT Cancellous Block	1 block 20 x 20 x 10 mm.
<b>OSP-010P</b>	OSTEOPLANT Cancellous Wedge (plate)	1 wedge 50 x 40 x 10 mm.
<b>OSP-0125P</b>	OSTEOPLANT Cancellous Wedge (plate)	1 wedge 50 x 40 x 12,5 mm.
<b>OSP-01A</b>	OSTEOPLANT Cancellous Block	1 block 10 x 10 x 10 mm.
<b>OSP-01B</b>	OSTEOPLANT Cancellous Block	1 block 10 x 10 x 20 mm.
<b>OSP-01B2</b>	OSTEOPLANT Cancellous Block	2 blocks 10 x 10 x 20 mm.
<b>OSP-02</b>	OSTEOPLANT Cancellous Block	1 block 50 x 40 x 5 mm.
<b>OSP-02B</b>	OSTEOPLANT Cancellous Block	1 block 40 x 30 x 10 mm.
<b>OSP-03</b>	OSTEOPLANT Cancellous Block	1 block 50 x 40 x 10 mm.
<b>OSP-04</b>	OSTEOPLANT Hemi Femoral-Head	1 hemi femoral-head Ø 60 x 20 mm.
<b>OSP-0452</b>	OSTEOPLANT Cancellous Cup	1 cup Ø 52 x 24 mm.
<b>OSP-0452A</b>	OSTEOPLANT Cancellous Half Cup	1 half cup Ø 52 x 24 mm.
<b>OSP-0456</b>	OSTEOPLANT Cancellous Cup	1 cup Ø 56 x 24 mm.
<b>OSP-0456A</b>	OSTEOPLANT Cancellous Half Cup	1 half cup Ø 56 x 24 mm.
<b>OSP-0460</b>	OSTEOPLANT Cancellous Cup	1 cup Ø 60 x 24 mm.
<b>OSP-0460A</b>	OSTEOPLANT Cancellous Half Cup	1 half cup Ø 60 x 24 mm.
<b>OSP-05</b>	OSTEOPLANT Cancellous Wedge	1 wedge 40 x 30 x 10 Final 2mm.
<b>OSP-05B</b>	OSTEOPLANT Cancellous Wedge	1 wedge 40 x 30 x 15 Final 2 mm.
<b>OSP-06</b>	OSTEOPLANT Cancellous Wedge	1 wedge 50 x 40 x 10 Final 2mm.
<b>OSP-06B</b>	OSTEOPLANT Cancellous Wedge	1 wedge 50 x 40 x 15 Final 2 mm
<b>OSP-07</b>	OSTEOPLANT Cancellous Wedge	1 wedge 50 x 20 x 20 Final 2 mm.
<b>OSP-070</b>	OSTEOPLANT Flex Acetabular Mat	1 flexible acetabular mat Ø 70 x 5-7 mm.
<b>OSP-075P</b>	OSTEOPLANT Cancellous Wedge (plate)	1 wedge 50 x 40 x 7.5 mm.
<b>OSP-07A</b>	OSTEOPLANT Cancellous Dihedron	1 dihedron 50 x 20 x 10 mm.
<b>OSP-08</b>	OSTEOPLANT Cortical Rod	1 rod 80 x 20 x 6 mm.
<b>OSP-09</b>	OSTEOPLANT Cortical Rod	1 rod 100 x 20 x 6 mm.
<b>OSP-10</b>	OSTEOPLANT Cortical Rod	1 rod 120 x 20 x 6 mm.
<b>OSP-11</b>	OSTEOPLANT Cancellous Wedge	1 wedge 10 x 15 x 8 Final 1 mm
<b>OSP-12</b>	OSTEOPLANT Cancellous Wedge	1 wedge 20 x 20 x 12 Final 1 mm
<b>OSP-20B</b>	OSTEOPLANT Cancellous Cortical Stick	2 sticks 50 x 8 x 5 mm.
<b>OSP-30</b>	OSTEOPLANT Cancellous Cortical Stick	2 sticks 100 x 8 x 5 mm.
<b>OSP-40</b>	OSTEOPLANT Cancellous Cortical Stick	1 stick 60 x 5 x 8 mm.
<b>OSP-FIX2</b>	OSTEOPLANT Cortical Pin	1 pin 2 x 2 x 40 mm.
<b>OSP-FIX3</b>	OSTEOPLANT Cortical Pin	1 pin 3 x 3 x 50 mm.
<b>OTC-C1</b>	OSTEOPLANT Cortical Flex	1 flexible cortical sheet 25 x 25 x 2-2.5 mm.
<b>OTC-C4</b>	OSTEOPLANT Cortical Flex	1 flexible cortical sheet 40 x 40 x 1-2.5 mm.
<b>OTC-C5</b>	OSTEOPLANT Cortical Flex	1 flexible cortical sheet 40 x 40 x 2-2.5 mm.

<b>OTC-C7</b>	OSTEOPLANT Cortical Flex	1 flexible cortical sheet 50 x 50 x 1-2.5 mm.
<b>OTC-C8</b>	OSTEOPLANT Cortical Flex	1 flexible cortical sheet 70 x 70 x 1-2.5 mm.
<b>OTC-C9</b>	OSTEOPLANT Cortical Flex	1 flexible cortical sheet 40 x 40 x 0.7 mm.
<b>OTC-CE</b>	OSTEOPLANT Cortical Membrane	1 cortical membrane 25 x 25 x 0.2 mm.
<b>OTC-CE2</b>	OSTEOPLANT Cortical Membrane	1 cortical membrane 50 x 25 x 0.2 mm.
<b>OTC-S1</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous sheet 25 x 25 x 3 mm.
<b>OTC-S10</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous block 50 x 20 x 15 mm.
<b>OTC-S12</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous dowel Ø 12 x 30 mm.
<b>OTC-S12f</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous drilled dowel Ø 12 x 30 mm.
<b>OTC-S15</b>	OSTEOPLANT Cancellous Flex	2 flexible cancellous strips 100 x 12 x 3 mm.
<b>OTC-S19</b>	OSTEOPLANT Cancellous Flex	1 flexible dual drilled dowel Ø 17/12 x 30 mm.
<b>OTC-S3</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous dowel 30 x 20 x 3 mm.
<b>OTC-S4</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous sheet 50 x 25 x 3 mm.
<b>OTC-S5</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous sheet 50 x 50 x 3 mm.
<b>OTC-S7</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous sheet 60 x 30 x 3 mm.
<b>OTC-S8</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous sheet 60 x 50 x 3 mm.
<b>OTC-S9</b>	OSTEOPLANT Cancellous Flex	2 flexible cancellous strips 100 x 10 x 8 mm.
<b>OTC-S9A</b>	OSTEOPLANT Cancellous Flex	1 flexible cancellous dowel 100 x 10 x 8 mm.