



BIO-GEN[®]
TECHNICAL SHEET

Description

BIO-GEN® Equine origin bone substitute with total osteoclastic remodelling.

Product constituents

BIO-GEN® (all codes except those listed hereto):

Spongy and/or cortical bone of equine origin, fully enzyme deantigenised.

BIO-GEN® MIX GEL:

Spongy and cortical bone of equine origin, fully enzyme deantigenised, inert, aqueous-based gel.

BIO-GEN® PUTTY:

Fully enzyme deantigenised spongy bone and type I collagen powder, both of equine origin.

Indications and expected results

The *BIO-GEN®* range of bone substitutes act as osteoconductive materials to be used in bone regeneration surgery. 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.

Instructions for use

BIO-GEN® (all codes except BIO-GEN® MIX GEL):

Hydrate the product in a sterile physiological solution for 3-5 minutes. Proceed with the graft.

BIO-GEN® MIX 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.

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 and paste formats - BIO-GEN® Spongy granular/Cortical granular/MIX/PUTTY:

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).

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.

Block or wedge format - BIO-GEN® Spongy wedge/block:

Shape the block or wedge 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 block or wedge and the vital patient bone).

If the device 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.

Gel formats - BIO-GEN® MIX GEL:

No particular precautions are necessary.

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.

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**BIO-GEN[®] (gel formats):**

PET or PP syringe in PETG blister or in in double PETG blister pack. Informative leaflet.
Alternatively, PET or PP syringe in an OPA-Aluminium pouch or in a double OPA-OPA / OPA-Aluminium pouch.
Informative leaflet.

BIO-GEN[®] PUTTY:

Boxed glass bottle or double PETG blister pack. Informative leaflet.
Alternatively, a glass bottle inserted in a OPA-Aluminium pouch. Informative leaflet.

BIO-GEN[®] (granular formats):

Boxed glass bottle. Informative leaflet.

BIO-GEN[®] (wedge/block):

One piece in double PETG blister pack. Informative leaflet.
Alternatively, one piece enclosed 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

BGB-11	BIO-GEN Cancellous Bone Block	Cancellous Block - 1 pc 10 x 10 x 10 mm
BGB-12	BIO-GEN Cancellous Bone Block	Cancellous Block - 1 pc 10 x 10 x 20 mm
BGB-30	BIO-GEN Cancellous Bone Wedge	Cancellous Wedge - 1 pc 25 x 10 x 5 mm
BGC-04	BIO-GEN Cortical Bone Granules	Cortical Granules - 1 btl / 0.5g 0.25-1mm
BGC-05	BIO-GEN Cortical Bone Granules	Cortical Granules - 6 btl / 0.5g 0.5-1mm
BGC-05n	BIO-GEN Cortical Bone Granules	Cortical Granules - 1 btl / 0.5g 0.5-1mm
BGC-05s	BIO-GEN Cortical Bone Granules	Cortical Granules - 1 btl / 0.5g 0.25-1mm
BGC-10s	BIO-GEN Cortical Bone Granules	Cortical Granules - 1 btl / 1g 0.25-1mm
BGC-20s	BIO-GEN Cortical Bone Granules	Cortical Granules - 1 btl / 2g 0.25-1mm
BGM-05	BIO-GEN Mix Granules	Cancellous Cortical Mix Granules - 6 btl / 0.5g 0.5-1mm
BGM-05n	BIO-GEN Mix Granules	Cancellous Cortical Mix Granules - 1 btl / 0.5g 0.5-1mm
BGM-05s	BIO-GEN Mix Granules	Cancellous Cortical Mix Granules - 1 btl / 0.5g 0.25-1mm
BGM-10	BIO-GEN Mix Granules	Cancellous Cortical Mix Granules - 6 btl / 0.25g 0.5-1mm
BGM-100	BIO-GEN Mix Granules	Cancellous Cortical Mix Granules - 6 btl / 1g 0.5-1mm
BGM-100s	BIO-GEN Mix Granules	Cancellous Cortical Mix Granules - 1 btl / 1g 0.25-1mm
BGM-10s	BIO-GEN Mix Granules	Cancellous Cortical Mix Granules - 1 btl / 0.25g 0.25-1mm
BGM-20	BIO-GEN Mix Granules	Cancellous Cortical Mix Granules - 1 btl / 2g 0.5-1mm
BGM-30	BIO-GEN Mix Granules	Cancellous Cortical Granules - 1 btl / 0.25g 0.25-1mm
BGM-35	BIO-GEN Mix Granules	Cancellous Cortical Granules - 1 btl / 0.5g 0.25-1mm
BGM-40	BIO-GEN Mix Granules	Cancellous Cortical Granules - 1 btl / 1g 0.25-1mm
BGM-50	BIO-GEN Mix Granules	Cancellous Cortical Mix Granules - 1 btl / 2g 0.25-1mm
BGM-GEL05	BIO-GEN Mix Gel	Cancellous Cortical Mix Gel - 3 syr 0.5ml/syr 0.5-1mm
BGM-GEL05n	BIO-GEN Mix Gel	Cancellous Cortical Mix Gel - 1 syr / 0.5ml 0.5-1mm
BGM-GEL1	BIO-GEN Mix Gel	Cancellous Cortical Mix Gel - 3 syr 1ml/syr 0.5-1mm
BGM-GEL1n	BIO-GEN Mix Gel	Cancellous Cortical Mix Gel - 1 syr / 1ml 0.5-1mm
BGM-GEL2	BIO-GEN Mix Gel	Cancellous Cortical Mix Gel - 1 syr / 2 ml
BGP-01	BIO-GEN Putty	Cancellous Dry Paste - 6 btl / 0.5 cc
BGP-01n	BIO-GEN Putty	Cancellous Dry Paste - 1 btl / 0.5cc
BGP-01s	BIO-GEN Putty	Cancellous Dry Paste - 1 btl / 0.5cc
BGP-02	BIO-GEN Putty	Cancellous Dry Paste - 1 pc / 2 cc
BGP-03	BIO-GEN Putty	Cancellous Dry Paste - 1 pc / 3 cc
BGP-05	BIO-GEN Putty	Cancellous Dry Paste - 1 pc / 5 cc
BGP-06	BIO-GEN Putty	Cancellous Dry Paste - 1 pc / 0.5 cc
BGS-05	BIO-GEN Cancellous Granules	Cancellous Granules - 6 btl / 0.5g 0.5-1mm
BGS-05n	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 0.5-1mm
BGS-05s	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 0.25-1mm
BGS-08	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 0.25-1mm
BGS-09	BIO-GEN Cancellous Granules	Cancellous Granules - 6 btl / 0.5g 1-2mm
BGS-09s	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 1-2mm
BGS-10	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 1-2mm
BGS-11	BIO-GEN Cancellous Granules	Cancellous Granules - 6 btl / 1g 1-2mm
BGS-11s	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 1g 1-2mm
BGS-15	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 0.25-1mm
BGS-20	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 2g 0.5-1mm
BGS-21	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 2g 0.25-1mm
BGS-22	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 2g 1-2mm

BGS-23	BIO-GEN Cancellous Granules	Cancellous Granules - 6 btl / 1g 2-3mm
BGS-23s	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 1g 2-3mm
BGS-24	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 1-2mm
BGS-25	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 1g 1-2mm
BGS-30	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 1g 2-3mm
BGS-40	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 2g 0.25-1mm