

BIO-GEN®
TECHNICAL SHEET

BIO-GEN® Disposable sterile device	
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• **Description:** BIO-GEN bone grafts of equine origin.

• **Device constituents:**

BIO-GEN (all codes except those listed below): Cancellous and/or cortical bone of equine origin.

BIO-GEN MIX GEL: ratio 1:1 of cancellous and cortical bone, of equine origin, and inert water-based gel.

BIO-GEN PUTTY: Cancellous bone and type I collagen powder, both of equine origin.

• **Properties/Intended use:**

All BIO-GEN devices act as grafting material for bone regeneration procedures. As they are enzyme deantigenated, they feature a natural remodeling (resorption and substitution with vital bone of the patient) in physiological time by the activity of the cell elements involved in the regeneration process (osteoclasts and osteoblasts). Remodeling time is variable, and it depends by anatomical variables (ratio between vital bone surface and volume of the grafted material) and by individual factors which may 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.

BIO-GEN MIX GEL: Granules of cortical and cancellous bone, provided already hydrated into sterile syringes.

BIO-GEN PUTTY: Freeze-dried bone paste cylinder.

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

Specific indications of use for dental surgery and orthopedics are listed below:

Dental surgery:

BIO-GEN CORTICAL BONE GRANULES, BIO-GEN CANCELLOUS GRANULES, BIO-GEN MIX GRANULES and BIO-GEN 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 products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR). They are osteoconductors providing volumetric augmentation, favoring regeneration of newly formed bone and in case of implant/prosthesis in the same site, favoring their secondary stabilization.

BIO-GEN CANCELLOUS BONE WEDGE and BIO-GEN CANCELLOUS BONE 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 in the same site, favoring their secondary stabilization.

BIO-GEN PUTTY may be used in surgical procedures such as filling of defects after root resection, apicoectomy, and cystectomy; filling of extraction sockets to enhance preservation of the alveolar ridge. It is an osteoconductor, providing volumetric augmentation, favoring regeneration of newly formed bone and in case of implant/prosthesis in the same site, favoring their secondary stabilization.

Orthopedics surgery:

BIO-GEN PUTTY may be used in surgical procedures: - as a bone void filler to fill voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure; - in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. It is an osteoconductor, providing volumetric augmentation, favoring regeneration of newly formed 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 **BIO-GEN** 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 **BIO-GEN** 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 in non-containment defects or where the containment of the device by periosteal covering or the use of appropriate barriers (for example membranes) has not been maintained.

- **BIO-GEN BONE BLOCK** shall not to 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 upper jaw and 3 mm thick in the mandible. Do not use for volumetric "onlay" increments in the posterior mandible.

• Instructions for use:

- **BIO-GEN (all codes except those listed below):** Hydrate the device in a sterile physiological solution for 1-2 minutes. Proceed with the graft.

- **BIO-GEN PUTTY:** The device can be applied whether hydrated or dry. In the latter case the fluids present in the grafting site will hydrate the device, which will feature a mouldable consistency after a period variable between 1 and 3 minutes, accordingly to the device dimension (0.5-1 cc ≈ 1 minute; > 1 cc ≈ 3 minutes). Hydration can be performed applying sterile physiological solution drop by drop until the device will lose its original rigidity. Proceed with the graft.

- **CANCELLOUS BONE WEDGE and BIO-GEN CANCELLOUS BONE 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.

- **BIO-GEN MIX GEL:** The product is ready for use.

• **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 so as 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).

- **BIO-GEN CORTICAL BONE GRANULES, BIO-GEN CANCELLOUS GRANULES, BIO-GEN MIX GRANULES, BIO-GEN MIX GEL and BIO-GEN PUTTY:** 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 product during transport and does not entail variations in the properties of the product itself.

- **BIO-GEN CANCELLOUS BONE BLOCKS and WEDGES:** 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 8-12 months, 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.

• **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). Do not use after the expiration date shown on the label.

• **Packaging:**

- **BIO-GEN GRANULES (Cortical, Cancellous and Mix):** Glass bottle in single carton box. Alternatively, one glass bottle in single PETG blister pack or in single OPA-OPA or OPA-Aluminum pouch. Informative leaflet.

- **BIO-GEN PUTTY:** Glass bottle in single carton box. Alternatively, one glass bottle in single PETG blister pack or in single OPA-OPA or OPA-Aluminum pouch. Alternatively, one piece in double PETG blister pack (orthopedics formats only). Informative leaflet.

- **BIO-GEN MIX GEL:** PP or PETG syringe in PETG blister pack. Informative leaflet. Alternatively, PP or PETG syringe in an OPA-OPA or OPA-Aluminum pouch. Informative leaflet.

- **BIO-GEN CANCELLOUS BONE WEDGE and BIO-GEN CANCELLOUS BONE BLOCK:** One piece in double PETG blister pack. Informative leaflet. Alternatively, one piece enclosed in a double OPA-OPA / OPA-Aluminum pouch. Informative leaflet.

• **Patient labels and Implant card:**

Patient's labels contain all the data relative to the device tracking. The labels are placed inside the packaging or on the back of the blister/pouch in a suitable number of copies to be affixed to the medical record and on the back of the implant card to be delivered to the patient.

The implant card is printed inside this leaflet. At the end of the surgery, cut a copy of the implant card and fill it with the following information: name and surname of the patient, date of the surgery, name of the operator who performed the

surgery and address of the center where it was performed. Attach a copy of the patient's label to the back of the implant card and deliver the implant card properly filled to the patient.

• **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**

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-05	BIO-GEN Cortical Bone Granules	Cortical Granules - 6 btl / 0.5g 0.25-1mm
BGC-05s	BIO-GEN Cortical Bone Granules	Cortical Granules - 1 btl / 0.5g 0.25-1mm
BGM-05	BIO-GEN Mix Granules	Cancellous cortical mix granules - 6 btl / 0.5g 0.25-1mm
BGM-05n	BIO-GEN Mix Granules	Cancellous cortical mix granules - 1 btl / 0.5g 0.25-1mm
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 0.25-1mm
BGM-100	BIO-GEN Mix Granules	Cancellous cortical mix granules - 6 btl / 1g 0.25-1mm
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 0.25-1mm
BGM-GEL02n	BIO-GEN Mix Gel	Cancellous cortical mix gel - 1 syr / 0.25ml 0.25-1mm
BGM-GEL05	BIO-GEN Mix Gel	Cancellous cortical mix gel - 3 syr 0.5ml/syr 0.25-1mm
BGM-GEL05s	BIO-GEN Mix Gel	Cancellous cortical mix gel - 1 syr / 0.5ml 0.25-1mm
BGM-GEL1	BIO-GEN Mix Gel	Cancellous cortical mix gel - 3 syr 1ml/syr 0.25-1mm
BGM-GEL1s	BIO-GEN Mix Gel	Cancellous cortical mix gel - 1 syr / 1ml 0.25-1mm
BGP-01	BIO-GEN Putty	Cancellous Dry Paste Putty - 6 btl / 0.5 cc
BGP-01s	BIO-GEN Putty	Cancellous Dry Paste Putty - 1 btl / 0.5cc
BGP-02	BIO-GEN Putty	Cancellous Dry Paste Putty - 1 pc / 2 cc

BGP-03	BIO-GEN Putty	Cancellous Dry Paste Putty - 1 pc / 3 cc
BGP-05	BIO-GEN Putty	Cancellous Dry Paste Putty - 1 pc / 5 cc
BGS-05	BIO-GEN Cancellous Granules	Cancellous Granules - 6 btl / 0.5g 0.25-1mm
BGS-05n	BIO-GEN Cancellous Granules	Cancellous Granules - 1 btl / 0.5g 0.25-1mm
BGS-05s	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-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-20	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