BIOTECK®

BIOCOLLAGEN®

TECHNICAL SHEET

BIOCOLLAGEN® **Disposable sterile device**	CE 0477

• **Description:** BIOCOLLAGEN Membrane/fleece/collagen paste.

• **Device constituents:** **BIOCOLLAGEN MEMBRANE, BIOCOLLAGEN FLEECE and BIOCOLLAGEN MERG MEMBRANE** *:* Type I collagen from equine tendon.

BIOCOLLAGEN CRUNCH*:* Type I collagen from equine tendon, water-based inert gel, powder (<0.4 mm) and granules (0.4-2 mm) of cancellous equine bone deantigenated by enzymes.

• **Properties/Inteded use:**

BIOCOLLAGEN MEMBRANE: Resorbable membrane to be used as protective barrier in bone regeneration operations.

BIOCOLLAGEN FLEECE*:* it acts biological carrier thanks to the hydrophilic feature of collagen.

BIOCOLLAGEN MERG MEMBRANE: Tissue regeneration membrane to be applied together with the cartilage lesion treatment procedure using micro fractures according to Steadman. Membrane degradation is seen 60-90 days after grafting.

BIOCOLLAGEN CRUNCH*:* It acts as grafting material for bone regeneration procedures. The osteoconductive component stabilized by the collagen component is physiologically remodeled and replaced with endogenous bone tissue by the action of osteoclasts and osteoblasts. The remodeling will occur in a period that varies from 4 to 8 months depending on the initial ratio between residual patient vital bone surface and the bone volume to be regenerated.

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

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

Dental surgery:

- **BIOCOLLAGEN MEMBRANE** may be used in surgical procedures alone or in combination with suitable augmentation materials for immediate or delayed guided tissue and bone regeneration: 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; elevation of maxillary sinus floor (protection of the Schneider membrane and closure of the lateral antrostomy); filling of peri-implants defects in conjunction with devices intended for Guided Bone Regeneration (GBR); in case of surgical bone defects and bone wall defects; in the context of maxillary ridge reconstruction for prosthetic treatment; in the context of fenestration defects; in case of periodontal bone defects (3 wall defects) and furcation defects (class I and II); in case of dehiscence defects; in case of Immediate or delayed augmentation around implants in extraction sockets. It provides protection of the grafting site from invasion by soft tissues/epithelial cells. The barrier effect is exerted for 4-6 weeks, after which the device begins to be reabsorbed by the endogenous collagenases.

It provides containment and stabilization of the grafting material and/or coagulum inside the grafting site and it favors the bone regeneration inside the grafting site.

Orthopedics surgery

- **BIOCOLLAGEN MEMBRANE** may be used in surgical procedures such as filling of voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. It can also be used in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. It provides protection of the grafting site from invasion by soft tissues/epithelial cells. The barrier effect is exerted for 4-6 weeks, after which the device begins to be reabsorbed by the endogenous collagenases.

It provides containment and stabilization of the grafting material and/or coagulum inside the grafting site and it favors the bone regeneration inside the grafting site.

- **BIOCOLLAGEN FLEECE** may be used in surgical procedures such as filling of voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. It can also be used in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. It acts as a carrier for cell grafts, plate derivatives or other autologous derivatives and it favors the bone regeneration inside the grafting site.

- **BIOCOLLAGEN CRUNCH** may be used in surgical procedures such as filling of voids or gaps of the skeletal system in the extremities, spine, and pelvis not intrinsic to the stability of the bony structure. It can also be used in the treatment of surgically treated osseous defects or osseous defects created from traumatic injury to the bone. It favors the formation of newly formed bone inside the grafting site; it provides a volumetric augmentation inside the grafting site and in case of implant/prosthesis implanted in the same site, favoring the secondary stabilization of them.

- **BIOCOLLAGEN MERG MEMBRANE** may be used in surgical procedures as tissue regeneration membrane together with the cartilage lesion treatment procedure using micro fractures according to Steadman. They avoid washing of mesenchymal cells from the bone marrow

and they provide a scaffold for their implantation and proliferation, thereby facilitating the formation of new cartilaginous tissue.

• Restrictions on use /target population:

All BIOCOLLAGEN devices must only be used 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. The device is single use and single patient; it cannot be reused or re-sterilized.

• Contraindications:

- **BIOCOLLAGEN 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.

- **BIOCOLLAGEN MEMBRANE AND BIOCOLLAGEN FLEECE** shall not be fixed with stitches or osteosynthesis means applying tension on the membrane or fleece.

- **BIOCOLLAGEN MERG MEMBRANE** shall not be fixed with stitches or osteosynthesis means applying tension on the membrane. They shall not to be used in the treatment of related cartilage defects (kissing lesions). Do not use in patients affected by hemophilia.

- **BIOCOLLAGEN CRUNCH** shall not to be used in non-containment defects or where the containment of the device has not been maintained through the use of appropriate barriers (for example membranes). Do not hydrate. Do not apply under irrigation.

• Instructions for use:

- **BIOCOLLAGEN MEMBRANE*:*** If necessary, shape the membrane before hydrating. Hydrate for 1-2 minutes in a sterile physiological solution. Do not hydrate where there is significant bleeding. Apply to cover the bone graft. Does not require affixing with osteosynthesis means.

- **BIOCOLLAGEN MERG MEMBRANE*:*** they must be used together with the cartilage lesion treatment procedure using micro fractures according to Steadman. Use together with tourniquet. Use together with fibrin glue is recommended. They must be applied through mini-arthrotomy or by arthroscopy with the use of CO_2. For the latter technique the procedure is as it follows: after having obtained arthroscopic access and curetted the lesion, proceed by mapping the lesion, inserting and shaping the elastomer template in the package. Trim the MeRG membrane when dry, superimposing the shaped elastomer template. Hydrate the membrane with the sterile physiological solution for 1-2 minutes. Empty the joint of liquid content and inject the CO_2. Create the micro fractures according to Steadman. Use non-traumatic forceps to introduce the membrane, positioning it on the lesion, with the rough part facing the defect. Insert a needle, positioning it near the lesion, in the upper region, ready to transport the fibrin glue on the edges of the membrane. Once the membrane has been positioned on the defect, apply the fibrin glue on the edges of the membrane, covering partially the cartilage surrounding the membrane and apply gentle pressure to the membrane to improve adhesion. Wait 1-2 minutes for the polymerization of the fibrin glue (please read carefully the fibrin glue instruction for the correct polymerization time). Block the flow of CO_2 and slowly introduce the irrigation solution into the joint. Check the membrane stability with by slightly flexing the appendage. Release the tourniquet to ensure that the membrane is imbued with blood.

- **BIOCOLLAGEN CRUNCH:** The paste is ready for use. Position to fill the bone defect. Cover the graft site with an anti-invasion epithelial membrane.

- **BIOCOLLAGEN FLEECE*:*** If necessary, shape the fleece before combination with the autologous derivative to be carried by the fleece. Imbibe the fleece with the autologous derivative for 2-3 minutes (or accordingly to the autologous derivative IFU, if present) and apply to the grafting site.

• Precautions:

- Use of any **BIOCOLLAGEN** devices in direct combination with pharmaceutical products has not been tested. - 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. - In the following cases the devices 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).

- **BIOCOLLAGEN MEMBRANE:** Position the membrane so as to cover the entire surface of the graft: any unprotected portions would be rapidly invaded by epithelial and connective cells, causing partial or total failure of bone regeneration.

Suture the soft tissues without tension by perfectly sealing the surgical site. In the event of exposure and in the absence of infection, intervene to restore the integrity of the connective cover. The exposed membrane is in fact degraded by endogenous collagenases more quickly, with a

consequent reduction in protection time. In the event of exposure and infection, completely remove the grafted material, subject the patient to a suitable antibiotic treatment and repeat the bone regeneration operation at least four weeks after the end of therapy.

- **BIOCOLLAGEN MERG MEMBRANE:** Evaluate carefully if the patient is eligible for treatment depending on the extent and depth of the lesion. Consider any concomitant pathologies (such as varus, valgus, total meniscectomies, arthrosis and ligament injuries). Handle the membrane carefully to avoid breakage or tearing. Make sure that the portal through which the membrane will pass is patent and wide enough to introduce the membrane without damaging it. To obtain a better stability result of the membrane it is advisable to slightly undersize it with respect to the defect, to avoid possible detachments due to the mechanical action of the surrounding structures. This operation must be performed exclusively using the tourniquet. In the case of concomitant use of fibrin glue, dilute it to lengthen the polymerization time.

- **BIOCOLLAGEN CRUNCH:** In order to allow the regeneration of bone tissue, it 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 grafting 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. When the restoration of the periosteal coverage is not possible or not certain, protect the graft site from epithelial invasion with a suitable membrane.

- **BIOCOLLAGEN FLEECE:** this device cannot serve as a barrier against epithelial cell invasion. Only use as carrier of autologous derivatives.

• **Adverse effects:** The device is biocompatible; no side effects attributable to the device have been clinically found. Latex free: the device does not contain 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). If stored correctly, the package seal and device sterility is guaranteed for 5 years as from date of manufacture (see expiry date on the external label).

• **Packaging:**

- BIOCOLLAGEN MEMBRANE:

Boxed glass bottle, or glass bottle in an individual PETG blister pack, or one membrane in double PETG blister pack. Informative leaflet. Alternatively, a glass bottle inserted in an OPA-Aluminum pouch or in a double OPA-OPA / OPA-Aluminum pouch. Alternatively, one membrane in a double OPA-OPA / OPA-Aluminum pouch. Informative leaflet.

- **BIOCOLLAGEN MERG MEMBRANE:** Membrane and elastomer template (the latter present only in the MeRG REF codes which include the template) packaged individually in a double PETG blister pack. Informative leaflet. Alternatively, membranes and templates individually packaged in a double OPA-OPA / OPA-Aluminum pouch. Informative leaflet.

- **BIOCOLLAGEN CRUNCH***:* One PP or PETG syringe in a double PETG blister pack. Informative leaflet. Alternatively, a PP or PETG syringe in an OPA-OPA / OPA-Aluminum pouch. Informative leaflet.

- **BIOCOLLAGEN FLEECE***:* One fleece in a double PETG blister pack. Informative leaflet. Alternatively, one fleece 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 the 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

BCG-01	BIOCOLLAGEN Membrane	Collagen membrane	- 6 pc 25 x 25 x 0.2 mm
BCG-01n	BIOCOLLAGEN Membrane	Collagen membrane	- 1 pc 25 x 25 x 0.2 mm
BCG-01s	BIOCOLLAGEN Membrane	Collagen membrane	- 1 pc 25 x 25 x 0.2 mm
BCG-02	BIOCOLLAGEN Membrane	Collagen membrane	- 6 pc 15 x 20 x 0.2 mm
BCG-02s	BIOCOLLAGEN Membrane	Collagen membrane	- 1 pc 15 x 20 x 0.2 mm
BCG-04	BIOCOLLAGEN Membrane	Collagen membrane	- 1 pc 40 x 30 x 0.2 mm
BCG-05	BIOCOLLAGEN Membrane	Collagen membrane	- 1 pc 50 x 50 x 0.2 mm
BCG-07	BIOCOLLAGEN Membrane	Collagen membrane	- 1 pc 70 x 50 x 0.2 mm
BCG-1008	BIOCOLLAGEN Fleece	Collagen Fleece	- 1 pc 100 x 80 x 8 mm
BCG-200	BIOCOLLAGEN Fleece	Collagen Fleece	- 1 pc 25 x 50 x 8 mm
BCG-255	BIOCOLLAGEN Fleece	Collagen Fleece	- 1 pc 25 x 50 x 8 mm
BCG-300	BIOCOLLAGEN Fleece	Collagen Fleece	- 1 pc Ø 30-32 x 6-8 mm
BCG-CRU10	BIOCOLLAGEN Crunch	Mouldable paste	- 1 syr / 10 ml
BCG-CRU5	BIOCOLLAGEN Crunch	Mouldable paste	- 1 syr / 5 ml
BCG-merg	BIOCOLLAGEN MeRG Membrane	Collagen membrane	- 1 pc 50 x 50 x 0.2 mm
BCG-mergK	BIOCOLLAGEN MeRG Membrane	Collagen membrane	- 1 pc 30 x 30 x 0.2 mm
BCG-mergQ	BIOCOLLAGEN MeRG Membrane	Collagen membrane	- 1 pc 30 x 30 x 0.2 mm
BCG-mergW	BIOCOLLAGEN MeRG Membrane	Collagen membrane	- 1 pc 30 x 30 x 0.2 mm
BCG-01	BIOCOLLAGEN Membrane	Collagen membrane	- 6 pc 25 x 25 x 0.2 mm