BIOTECK®

# BIOCOLLAGEN®

## TECHNICAL SHEET

| **BIOCOLLAGEN®**<br>***Disposable sterile device*** | CE 0373 |
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## Description

*BIOCOLLAGEN®* Membrane/fleece/collagen paste.

## Product constituents

***BIOCOLLAGEN®/ BIOCOLLAGEN® MeRG/ BIOCOLLAGEN® Fleece:***
Type I equine collagen (from Achilles tendon).
***BIOCOLLAGEN® GEL:***
Type I equine collagen (from Achilles tendon), inert aqueous-base gel, enzyme deantigenised spongy equine bone powder (< 0.4 mm).
***BIOCOLLAGEN® CRUNCH:***
Type I equine collagen (from Achilles tendon), inert aqueous-base gel, enzyme deantigenised spongy equine bone powder (< 0.4 mm) and granules (0.4-2 mm)..

## Indications and expected results

***BIOCOLLAGEN®/ BIOCOLLAGEN® GEL:***
BIOCOLLAGEN® and BIOCOLLAGEN® GEL should be used as an anti-invasion epithelial membrane in bone regeneration operations by grafting. The barrier effect works for 4-6 weeks, after which the two products begin being reabsorbed by the endogenous collagenase.
***BIOCOLLAGEN® MeRG:***
BIOCOLLAGEN® MeRG must be used as a tissue regeneration membrane together with the cartilage lesion treatment procedure using micro fractures according to Steadman, in order to avoid washing of mesenchymal cells from the bone marrow and to provide a scaffold for their implantation and proliferation, thereby facilitating the formation of filler fibro cartilaginous tissue. Membrane degradation is seen 60-90 days after grafting.
***BIOCOLLAGEN® CRUNCH:***
BIOCOLLAGEN® CRUNCH must be used as a bone graft. The osteoconductive component stabilised by the collagen component is totally osteoclastically remodelled and completely replaced with endogenous bone tissue 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.
***BIOCOLLAGEN® Fleece:***
BIOCOLLAGEN® Fleece acts as a haemostatic felt, thanks to the haemostasis effect induced by the collagen. It can also be used as a carrier for cell grafts, pharmaceuticals, plate derivates or other.

## Instructions for use

***BIOCOLLAGEN®:***
If necessary, shape the membrane before hydrating. Hydrate for 3-5 minutes in a sterile physiological solution. Alternatively, where there is significant bleeding, do not hydrate. Apply to cover the bone graft. Does not require fixing with osteosynthesis means.
***BIOCOLLAGEN® MeRG:***
BIOCOLLAGEN® MeRG must be used together with the cartilage lesion treatment procedure using micro fractures according to Steadman. Use together with fibrin glue is recommended. After having obtained arthroscopic access and curetted the lesion, proceed by mapping the lesion, inserting and shaping the elastomer template included. Trim the MeRG membrane 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 proceed to blow the $CO_2$. Carry out the micro fractures according to Steadman. Use non-traumatic forceps to introduce the membrane, positioning it near the lesion, with the rough part towards the flaw. Insert a needle, positioning it near the lesion, in the upper pole, ready to transport the fibrin glue into the flaw. Slightly retract the forceps to temporarily separate the membrane from the lesion and introduce the fibrin glue. Now apply gentle pressure to the membrane to improve adhesion, adding more fibrin glue to the edges if required. Wait 1-2 minutes. Block the flow of $CO_2$ and slowly introduce the irrigation solution into the joint. Check membrane stability with gentle flexion-extension of the joint. Release the haemostatic forceps to ensure that the membrane is imbued with blood.
***BIOCOLLAGEN® GEL:***

The gel is ready for use. Complete cover the bone graft with a layer no less than 1 mm thick.
***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:***
As haemostatic: if necessary, shape the fleece before use. Apply dry.
As carrier: first load the fleece with the desired substance, according to the substance instructions for use. Apply to the site concerned.

## Warnings and precautions

***BIOCOLLAGEN®/ BIOCOLLAGEN® GEL:***
BIOCOLLAGEN® (membrane) or BIOCOLLAGEN® GEL (gel) must be positioned in such a way as to cover *the entire graft surface*: any unprotected portions will be quickly invaded by epithelial and connective cells, causing partial or total failure of bone regeneration.
Suture the soft tissues without pulling taut, perfectly sealing the surgical site: any exposure of the product is at high risk of infection, and leads to a high risk of failure of the bone generation surgery. In the event of exposure and where there is no infection, intervene to restore the connective covering. In the event of exposure and infection, remove all the grafted material, subject the patient to an antibiotic treatment if appropriate, and repeat the bone regeneration operation at least four weeks later.
***BIOCOLLAGEN® MeRG:***
Carefully evaluate whether or not the patient is eligible for treatment, according to the extent and depth of the lesion. Consider any other pathologies that may coexist (such as varus, valgus, total meniscectomy, arthritis and ligament lesions). Handle the membrane carefully to avoid breaking or tearing. Ensure that the portal through which the membrane will pass is patent and sufficiently sized to introduce the membrane without damaging it. To obtain a more stable membrane result, it is advisable to under-dimension it slightly with regards to the flaw, in order to avoid possible separation due to the mechanical action of the surrounding structures. This operation must only be carried out using haemostatic forceps. If also using fibrin glue, dilute to lengthen polymerisation times.
***BIOCOLLAGEN® CRUNCH:***
Carefully evaluate whether or not the patient is eligible for guided bone regeneration surgery, considering age, general health, local anatomical and pathological conditions, individual habits and related risk factors. The most common causes for failure of guided bone regeneration surgery are due to lack of vascularisation or infection of the graft site. Avoid, therefore, any excessive compression of the product during filling, and correctly manage the detachment, release and suture of soft tissues, in order to avoid accidental reopening.
***BIOCOLLAGEN® Fleece:***
This product cannot provide a barrier effect against epithelial cell invasion. Only use as described in this informative leaflet (haemostatic and/or carrier).

## Side effects

The product is biocompatible. It does not cause side effects.
Latex free: the device is latex free.
Ensure that the patient shows no individual hypersensitivity to collagen of equine origin.
The product has not been tested on pregnant women.

## 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

***BIOCOLLAGEN® (Cod. BCG-01):***
Six glass bottles boxed separately. Informative leaflet.
***BIOCOLLAGEN® (Cod. BCG-04/05/07):***
One membrane in double PETG blister pack. Informative leaflet.
***BIOCOLLAGEN® (Cod. BCG-01n/XC30):***
One membrane in glass bottle in PETG blister pack. Informative leaflet.
***BIOCOLLAGEN® GEL (Cod. BCG-GEL X):***
Three (BCG-GEL1) or one syringe (other BCG-GELX codes) in PET in individual PETG blister packs. Informative leaflet.

***BIOCOLLAGEN® MeRG (Cod. BCG-merg; BCG-mergS)***
One 50 x 50 x 0.2 mm membrane (BCG-merg) or one 50 x 50x 0.4 mm (BCG-mergS) membrane; one elastomer template packaged separately in double PETG blister pack. Informative leaflet.
***BIOCOLLAGEN® MeRG (Cod. BCG-mergDisc)***
Four disc membranes, 0,2 mm thick, ∅12, 14, 16, 18 mm in double PETG blister pack, four elastomer templates ∅12, 14, 16, 18 mm in double PETG blister pack. Informative leaflet.
***BIOCOLLAGEN® CRUNCH (Cod. BCG-CRU XX):***
One PET jar or one PET syringe in double PETG blister pack. Informative leaflet..
***BIOCOLLAGEN® Fleece (Cod. BCG-XXXX):***
One fleece in double PETG blister pack. 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

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

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| **BCG-01** | BIOCOLLAGEN® Membrane | 6 membranes 25 x 25 x 0.2 mm. |
| **BCG-01n** | BIOCOLLAGEN® Membrane | 1 membrane 25 x 25 x 0.2 mm. |
| **BCG-04** | BIOCOLLAGEN® Membrane | 1 membrane 40 x 30 x 0.2 mm. |
| **BCG-05** | BIOCOLLAGEN® Membrane | 1 membrane 50 x 50 x 0.2 mm. |
| **BCG-07** | BIOCOLLAGEN® Membrane | 1 membrane 70 x 50 x 0.2 mm. |
| **BCG-255** | BIOCOLLAGEN® Fleece | 1 fleece 25 x 50 x 8 mm. |
| **BCG-508** | BIOCOLLAGEN® Fleece | 1 fleece 50 x 80 x 8 mm. |
| **BCG-1008** | BIOCOLLAGEN® Fleece | 1 fleece 100 x 80 x 8 mm. |
| **BCG-GEL1** | BIOCOLLAGEN® GEL | Gel, 3 syringes, 1 cc. each. |
| **BCG-GEL1n** | BIOCOLLAGEN® GEL | Gel, 1 syringe, 1 ml. |
| **BCG-GEL2** | BIOCOLLAGEN® GEL | Gel, 1 syringe, 2 ml. |
| **BCG-GEL5** | BIOCOLLAGEN® GEL | Gel, 1 syringe, 5 ml. |
| **BCG-GEL10** | BIOCOLLAGEN® GEL | Gel, 1 syringe, 10 ml. |
| **BCG-GEL15** | BIOCOLLAGEN® GEL | Gel, 1 syringe, 15 ml. |
| **BCG-GEL20** | BIOCOLLAGEN® GEL | Gel, 1 syringe, 20 ml. |
| **BCG-GEL430** | BIOCOLLAGEN® GEL HEMOSTATIC | Gel, 1 syringe, 4 ml. |
| **BCG-CRU5** | BIOCOLLAGEN® CRUNCH | Paste, 1 syringe, 5 ml. |
| **BCG-CRU10** | BIOCOLLAGEN® CRUNCH | Paste, 1 syringe, 10 ml. |
| **BCG-CRU10j** | BIOCOLLAGEN® CRUNCH | Paste, 1 jar, 10 cc. |
| **BCG-CRU15** | BIOCOLLAGEN® CRUNCH | Paste, 1 jar, 15 cc. |
| **BCG-merg** | BIOCOLLAGEN® MeRG Membrane | 1 membrane 50 x 50 x 0.2 mm. |
| **BCG-mergS** | BIOCOLLAGEN® MeRG Membrane | 1 membrane 50 x 50 x 0.4 mm. |
| **BCG-mergDisc** | BIOCOLLAGEN® MeRG Disc Membrane | 4 membranes, ∅12, 14, 16, 18 mm, thickness 0.2 mm. |
| **BCG-XC30** | BIOCOLLAGEN® X COLLAGEN Membrane | 1 membrane 30 x 25 x 0.2 mm. |