BIOTECK®

BIOCOLLAGEN®

TECHNICAL SHEET

BIOCOLLAGEN® **Disposable sterile device**	CE 0373

Description

BIOCOLLAGEN® Membrane/felt/gel/collagen paste.

Product constituents

BIOCOLLAGEN®/ BIOCOLLAGEN® MeRG/ BIOCOLLAGEN® Felt:

Type I equine collagen (from Achilles tendon).

BIOCOLLAGEN® GEL:

Type I equine collagen (from Achilles tendon), inert aqueous-base gel, enzyme deantigenised cancellous equine bone powder (< 0.4 mm).

BIOCOLLAGEN® CRUNCH:

Type I equine collagen (from Achilles tendon), inert aqueous-base gel, enzyme deantigenised cancellous equine bone powder (< 0.4 mm) and granules (0.4-2 mm).

Indications and expected results

BIOCOLLAGEN®/BIOCOLLAGEN® GEL:

BIOCOLLAGEN® it is to be used as epithelial anti-invasion membrane in bone regeneration operations through grafts. The barrier effect is exerted for 4-6 weeks, after which the product begins to be reabsorbed by the endogenous collagenases.

BIOCOLLAGEN® GEL is a collagen gel that, when positioned to cover a bone graft, stabilises it and protects it against invasion of soft tissue cells. In orthopaedics it is also used as a haemostatic and/or as a concentrated cellular carrier. In dentistry it can be used, in lieu of a traditional collagen membrane, to cover bone grafts in smaller sites (small peri-implant sites - with less than 3 exposed coils- or to protect bone grafts in small periodontal sites). It has no osteoconductive effect. The protection time is about 4 weeks.

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 stabilized by the collagen component is totally osteoclastically remodeled 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® Felt:

BIOCOLLAGEN® Felt acts as a hemostatic felt, thanks to the hemostasis effect induced by the collagen. It can also be used as a carrier for cell grafts, platelets derivatives 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 hemostatic 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® Felt:
As hemostatic: if necessary, shape the felt before use. Apply dry.
As carrier: first load the felt with the desired substance, according to the substance instructions for use. Apply to the site concerned.

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.
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. In the event of exposure and where there is no infection, intervene to restore the connective covering. The exposed membrane is in fact degraded by endogenous collagenase in a shorter time, resulting in less protection time. 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 hemostatic forceps. If also using fibrin glue, dilute to lengthen polymerization 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 vascularization 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® Felt:
This product cannot provide a barrier effect against epithelial cell invasion. Only use as described in this informative leaf let (hemostatic and/or carrier).

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.

Sterilization and storage

The product is sterilized 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® (membranes, excepted MeRG):
Boxed glass bottle, or glass bottle in individual PETG blister pack, or double PETG blister pack. Informative leaflet.
Alternatively, a glass bottle inserted in a OPA-Aluminium pouch or in a double OPA-OPA / OPA-Aluminium pouch. Informative leaflet.
BIOCOLLAGEN® (gel formats):
PET syringe in individual or in double PETG blister pack. Informative leaflet.
Alternatively, PET syringe in an OPA-Aluminium pouch or in a double OPA-OPA / OPA-Aluminium pouch. Informative leaflet.
BIOCOLLAGEN® (MeRG codes):
Membrane and elastomer template packaged individually in double PETG blister pack. Informative leaflet.
Alternatively, membranes and templates individually packaged in a double OPA-OPA / OPA-Aluminium pouch. Informative leaflet.
BIOCOLLAGEN® CRUNCH:
One PET bottle or one PET syringe in double PETG blister pack. Informative leaflet.
Alternatively, a PET bottle or a PET syringe in a double OPA-OPA / OPA-Aluminium pouch. Informative leaflet.
BIOCOLLAGEN® Felt:
One felt in double PETG blister pack. Informative leaflet.
Alternatively, a felt 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 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

BCG-01	BIOCOLLAGEN® Membrane	6 collagen membranes 25 x 25 x 0.2 mm.
BCG-01n	BIOCOLLAGEN® Membrane	1 collagen membrane 25 x 25 x 0.2 mm.
BCG-02	BIOCOLLAGEN® Membrane	6 collagen membranes 15 x 20 x 0.2 mm.
BCG-04	BIOCOLLAGEN® Membrane	1 collagen membrane 40 x 30 x 0.2 mm.
BCG-05	BIOCOLLAGEN® Membrane	1 collagen membrane 50 x 50 x 0.2 mm.
BCG-07	BIOCOLLAGEN® Membrane	1 collagen membrane 70 x 50 x 0.2 mm.
BCG-1008	BIOCOLLAGEN® Felt	1 collagen felt 100 x 80 x 8 mm.
BCG-255	BIOCOLLAGEN® Felt	1 collagen felt 25 x 50 x 8 mm.
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-CRU5	BIOCOLLAGEN® Crunch	Paste, 1 syringe, 5 ml.
BCG-GEL1	BIOCOLLAGEN® Gel	Collagen gel, 3 syringes, 1 ml each.
BCG-GEL10	BIOCOLLAGEN® Gel	Collagen gel, 1 syringe, 10 ml.
BCG-GEL15	BIOCOLLAGEN® Gel	Collagen gel, 1 syringe, 15 ml.
BCG-GEL1n	BIOCOLLAGEN® Gel	Collagen gel,1 syringe, 1 ml.
BCG-GEL2	BIOCOLLAGEN® Gel	Collagen gel, 1 syringe, 2 ml.
BCG-GEL20	BIOCOLLAGEN® Gel	Collagen gel, 1 syringe, 20 ml.
BCG-GEL430	BIOCOLLAGEN® Gel Hemostatic	Collagen gel,, 1 syringe, 4 ml.
BCG-GEL5	BIOCOLLAGEN® Gel	Collagen gel, 1 syringe, 5 ml.
BCG-merg	BIOCOLLAGEN® MeRG Membrane	1 collagen membrane 50 x 50 x 0.2 mm.
BCG-mergDisc	BIOCOLLAGEN® MeRG Disc Membrane	4 collagen membranes Ø12-14-16-18 mm.
BCG-mergK	BIOCOLLAGEN® MeRG Membrane	1 collagen membrane 30 x 30 x 0.2 mm.
BCG-mergS	BIOCOLLAGEN® MeRG Membrane	1 collagen membrane 50 x 50 x 0.4 mm.
BCG-XC10	BIOCOLLAGEN® XC COLLAGEN XENOMATRIX	Collagen tridimensional matrix, 2 patches, patch A: Ø 14 x 4mm, patch B: 20 x 10 x 4 mm.
BCG-XC30	BIOCOLLAGEN® XC COLLAGEN Membrane	1 collagen membrane 30 x 25 x 0.2 mm.
BCG-XC50	BIOCOLLAGEN® XC COLLAGEN XENOMATRIX	1 collagen tridimensional matrix, 15 x 30 x 4 mm.
BCG-XC60	BIOCOLLAGEN® XC COLLAGEN Membrane	1 collagen membrane 30 x 30 x 0.2 mm.