"MeRG IMPROVES SURGICAL TECHNIQUE AND RESULTS"

MeRG

NON-ALLERGENIC RE-ABSORBABLE LYOPHILISED EQUINE COLLAGEN (BIOCOLLAGEN®)

COLLAGEN MEMBRANE FOR SCAFFOLD - GUIDED REGENERATION IN TREATING LESIONS TO THE CARTILAGE OF THE KNEE AND ANDKLE

Pack contains:

n° 1 Lyophilised Collagen Membrane
50x50x0,2 mm (S-version: 50x50x0.4 mm)

n° 1 Surgical template
50x50x0,2 mm

Code BCG-merg or BCG-mergS (Biocollagen®)

Technical data MeRG®- Biocollagen®

regeneration. (Biocollagen®)

Description:
Re-absorbable membrane for guided tissue regeneration, (Biocollagen®).

Composition:
Type I non-allergenic lyophilised collagen from equine Achilles' tendon (Type I >95%, Type III <5%).

Properties:
Microfibrillar collagen membrane. The peculiar arrangement of its fibers, given by the exclusive manufacturing process, gives the membrane resistance to torsion, pulling and tearing. The membrane features a smooth and a rough/fibrillar side. The rough side improves adhesion, and allows for fixation with fibrin glue. Adhesion increases if blood is present. The collagen the membrane is made of is achieved from equine Achilles' tendons (one of the principal sources of type I collagen). Equines can not transmit encephalopathies.
Collagen shows the chemical and structural features of a glycoprotein, capable of interacting with the fibroblasts' and platelets' receptors. It activates factors XII and VIII and constitutes the structural basis of connective tissues. Its interactions with platelets is fundamental for coagulation, since its bonding with the platelets integrins leads to platelet degranulation and to release the factors that activate coagulation. This creates the fibrin network that stops blood cells creating the clot. Finally fibroblasts migrate into the clot following chemotactic stimulation.

Therapeutic indications:
Chondral lesions treatment.

Contraindications:
Hypersensitivity to collagen.

Activity:
MeRG® carries out a "tent effect action" over mesenchymal cells, preventing their dispersion in the joint cavity. MeRG® is made of collagen fibres in a structure that favours cells adhesion. The three-dimensional structure of MeRG® enhances histological repair.
In-vivo tests have shown that during the repair process, fibroblasts attach to the collagen fibrils, proliferate and orientate in order to reshape the damaged tissue.
Collagen therefore supports tissue repair.

Degradation time:
MeRG® is physiologically degraded in 60/90 days. The fragments of collagen obtained by degradation are heat-sensitive and at a temperature of 37°C undergo a denaturation process, transforming into gelatine.

Product preparation:
Rehydrate the product with sterile physiological solution for 3-5 minutes after shaping it.

Sterilisation:
The product is supplied sterile by means of treatment with ß rays at 25 kG and cannot be re-sterilized.
Me.R.G.® is a medical device to be used under the supervision of a doctor-surgeon.

CE 0373 Biocollagen®

Tipo-lito ABALTI S.R. - Cremona (VI) - Cod. no. 20100_MERG_ENG

Manufactured by Bioteck S.p.A.
Arcugnano - Italy
vi@bioteck.com

BIOTECK
The science of bone tissue

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Pack contains:
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50x50x0.2 mm (S-version: 50x50x0.4 mm)
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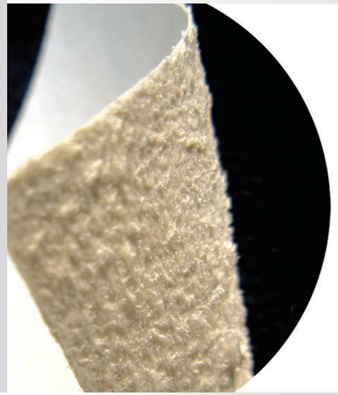
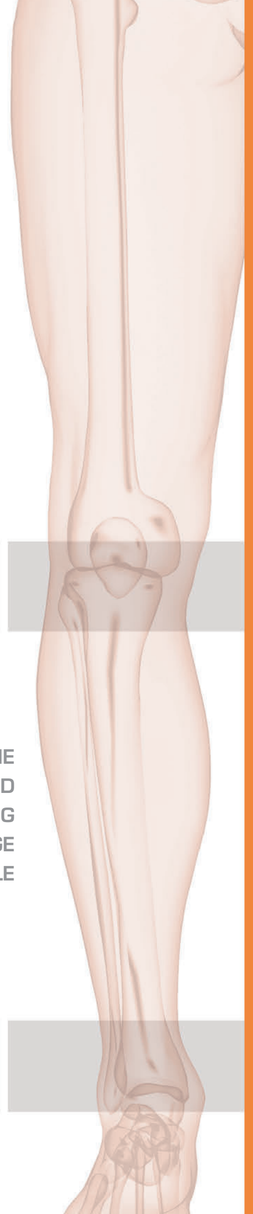
Distributed by:

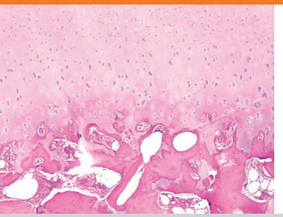
MeRG

Scaffold-Guided Regenerative Medicine

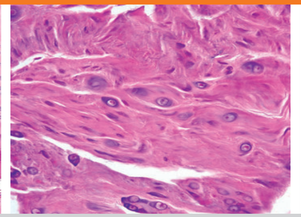


COLLAGEN MEMBRANE FOR SCAFFOLD - GUIDED REGENERATION IN TREATING LESIONS TO THE CARTILAGE OF THE KNEE AND ANKLE

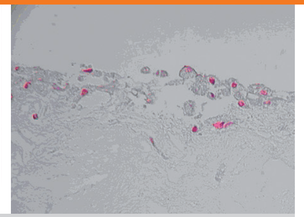




HYALINE CARTILAGE



FIBROUS CARTILAGE



CHONDROCYTE CULTURE ON MERG MEMBRANE

A safe, complete system

NON-ALLERGENIC RE-ABSORBABLE LYOPHILISED EQUINE COLLAGEN (BIOCOLLAGEN®)

TISSUE TRIAD

Cartilage regeneration techniques through the use of supports are today a focal point for the ortho-paedic scientific community within the scope of the applications of the so-called:

Scaffold-Guided Regenerative Medicine

This term represents a new treatment approach aimed at tissue regeneration rather than replacement. The **Tissue Triad** must, therefore, be re-created.

Scaffold
Fibrillar collagen
Membrane MeRG®

Cells
Adult MSCs
Micro-fractures

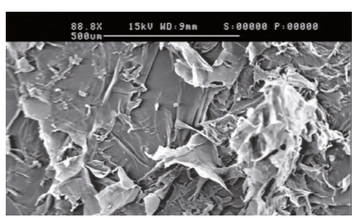
Signalling molecules
Growth factors
PRP Fibrin sealant

COLLAGEN

This is the basic substance of the extra-cellular matrix. There are at least 19 types of collagen, all with different structural and physical-chemical characteristics. The pure, non-denatured type I collagen retains the typical triple helix structure typical of all species of the animal world, and is recognised as belonging to the human organism. Collagen originating from equine Achilles' tendon is pure, and is today the preferred choice as equines have the added advantage of being free from the risk of B.S.E.. Type I collagen has a dual action mechanism, being both biologically active and plastic, thereby allowing for the protection of the lesion, maintaining an ideal environment and enabling the most important biological processes of tissue repair, stimulating new tissue formation.

The collagen membrane (MeRG®) acts as a three-dimensional structure for Scaffold-Guided Regenerative Medicine - (S.G.R.M.).

MICROSCOPIC PICTURE OF Merg HAND FIBRILLATION



MeRG

IMMEDIATE ACTIVATION OF PLATELET AGGREGATION

MeRG® containing type I native collagen, **stimulates platelet aggregation**, by interacting with the membrane integrins and thereby prompting **quicker coagulation**.

MeRG GUIDES TISSUE REPAIR

MeRG® acts directly over the stages of the histological repair process:

- **haemostasis**
- **inflammation**
- **fibroblast proliferation**
- **new tissue formation**

By acting as close-knit three-dimensional scaffold, it traps and holds mesenchymal stem cells (M.S.C.) and blood, including platelets, which release PDGF (Platelet Derived Growth Factor) growth factors.

(Platelet Derived Growth Factor).

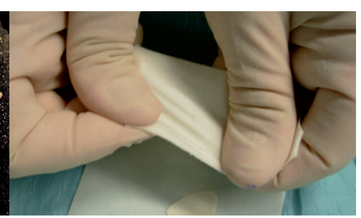
LOCALLY-APPLIED COLLAGEN MEMBRANE STIMULATES HISTOLOGICAL TISSUE REPAIR

MeRG® made of type I collagen, and interacting with the fibroblast receptors, chondroblasts involved in the synthesis of connective and cartilage tissue structures, becomes an **ideal substrate for histological repair** cells. Adhere to the superficial heterologous collagen fibres, proliferate and orientate in order to reshape the damaged tissue. The presence of the collagen membrane in the treated area therefore supports the **new autologous tissue formation**, thereby encouraging **efficient regeneration**.

TYPE I COLLAGEN IS AN EFFECTIVE INDUCER OF TISSUE REPAIR PROCESSES

MeRG® MEMBRANE AND SURGICAL TEMPLATE

HYDRATED MeRG® MEMBRANE



MeRG

TREATMENT OF CARTILAGE LESIONS WITH MINI-ARTHROTOMY AND/OR ARTHROSCOPY

The Steadman micro-fracture technique for the repair of chondral lesions of the knee has been practised for many years in therapeutic protocols.

This technique exploits **the regenerative potential of mesenchymal stem cells** (M.S.C., committed) and can be applied to grades III and IV cartilage defects, according to the Outerbridge classification, (damage, therefore, affecting also the subchondral bone), with dimensions in exceeding 2 cm^2 in size.

The new technique is based on proven biological concepts first demonstrated by Richard Steadman in the 1990s with micro-fractures.

The approach differs from micro-fractures alone, since **the use of a guided regeneration membrane MeRG®** is also involved.

It is applied over the defect, after performing the micro-fractures, with fibrin glue (Tissucol- Baxter). This covering entraps the very first milliliters that flow from the bone marrow and contain the highest concentration of mesenchymal cells. This helps the formation of the so-called "superclot" and prevents the dispersion of the cells in the joint cavity, which usually happens, instead, with the micro-fractures alone. The membrane, therefore, protects and shields the cells that, after differentiation, will form the new tissue.

The final repaired tissue achieved will be fibrous cartilage.

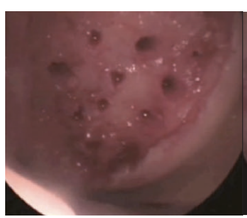
POST-OPERATIVE TREATMENT

According to the Steadman rehabilitation protocol suggested for micro-fractures:

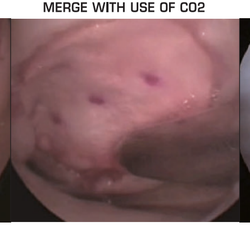
Clinical Orthopaedics and Related Research Number 391S-2001

Light touch-down weight bearing 1/6 weeks with crutches, gradual CPM 0/90. From the 6th week, gradual weight-bearing up to full weight-bearing over the next 2 weeks.

MICROFRACTURES SEC. STEADMAN



TECHNICAL ARTROSTOPICA APPLICATION MERGE WITH USE OF CO2



SECOND LOOK AT 7 MONTHS