CHondroGrid

CHG-004
Sterile lyophillzed
CHondroGrid®
4 mg bottle

Accessory kit for CHondroGrid® application (not included)

1. **Sterile water for injection 2 ml vial**
1. **Sterile 5 ml luer-lock syringe**
2. **Sterile 5 cm, 21 Gauge needles**

APPLICATIVE PROTOCOL

INTRA-ARTICULAR INJECTION
Three injections administered over a period of 45 days:
first at day 1, second at day 15, third at day 45.

Inject the solution into the articular space, if necessary under instrumental guidance, such as echography, especially when treating hip and shoulder.

Injectable Hydrolyzed Collagen

Code CHG-004
Injectable Collagen
Hydrolysate - 1 btl 4 mg

CE
0477

codeY_CHG_CAT_ENG rev. 20200303

CHondroGrid® is manufactured by:

BIOTECK®

BIOTECK S.p.A.

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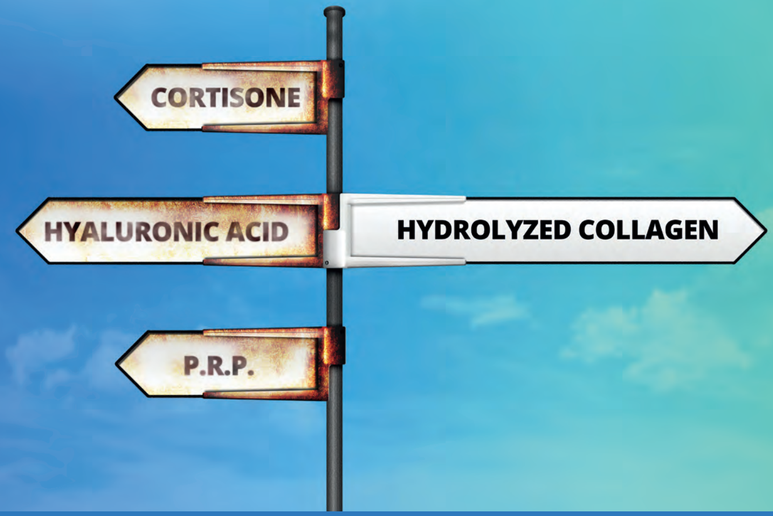
BIOTECK®

CHondroGrid

The new **collagen way**

The most innovative and advanced method of treating chondropathies



HYDROLYZED COLLAGEN LOW MOLECULAR WEIGHT PEPTIDES FOR INTRA-ARTICULAR INJECTION

CHondroGrid

A new approach and a new therapeutic opportunity

CHondroGrid® is a locally-acting medical device that makes hydrolyzed collagen low-molecular weight peptides immediately available at the site of interest, and allows effective treatment of pain and loss of functionality caused by articular affections.

HYDROLYZED COLLAGEN

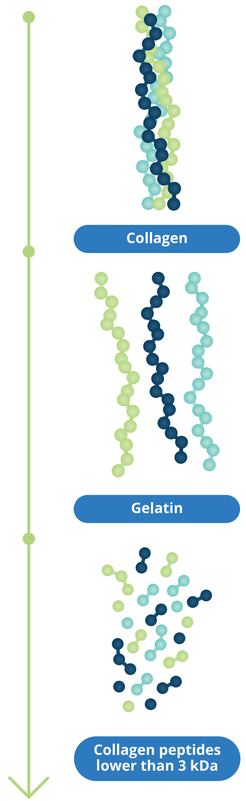
Collagen is the main component of all intra-articular structures. Therefore, when joints are injected with **hydrolyzed collagen, a mixture of low-molecular weight peptides**, these small molecules actively prompt the reparation and reinforcement of the articular matrix and **they also help the recovery and preservation of the native trophic** state of all the joint compartment.

CHondroGrid® consists of 4 mg of lyophilized peptides with a molecular weight lower than **3kDa.** After being suspended in injectable water, and consequently delivered to the patient by intra-articular injection, they **spread rapidly all over the articular surface.**

CHondroGrid® targets directly the suffering site, delivering small **collagen-specific amino acid chains that will support the structural** and functional recovery of the intra-articular components. As a consequence, articular pain and function improve. **CHondroGrid®**, therefore, may help reducing analgesics and NSAIDs.

Scientific investigations have shown that low molecular collagen peptides are a natural byproduct of physiologic or pathologic collagen degradation. When present, these small molecules are ready to be incorporated again into **newly-generated collagen chains.**

CHONDROGRID® IS THE INNOVATIVE SOLUTION TO TREAT PAINFUL, DYSFUNCTIONAL AND DEGENERATIVE ARTICULAR DISORDERS.



EXTRACELLULAR
MATRIX REINFORCEMENT

NEW COLLAGEN
SYNTHESIS

INFLAMMATION
REDUCTION

PAIN
RELIEF

ACTION

Cartilage and the surrounding articular structures (the ligaments and the synovial membrane) consist primarily of **collagen fibers.** After the intra-articular injection, **the numerous low-molecular weight peptide chains CHondroGrid®** consists of, diffuse into the synovial liquid and spread over the synovia and the articular cartilage, **reinforcing and repairing** its damaged or worn extracellular matrix. The joint recovers its function, and pain symptoms are alleviated.

INDICATIONS

The most common indications for the use of **CHondroGrid®** are the symptoms, management and functional treatment of: osteoarthritis, acute or chronic arthrosynovitis secondary to osteoarthritis or rheumatoid arthritis, traumas or injuries, articular overload and overwork.

CHondroGrid® is also indicated in cases of degenerative meniscopathies, prior to and following meniscectomy surgery, or cleaning and/or reconstructing the articular cartilage.

EFFECTIVENESS

Hydrolyzed collagen is absolutely non cytotoxic. Instead, in vitro experiments show it increases all parameters measuring cell vitality [1], [4]. No immunogenic effects have ever been observed in vivo [5]. It has been shown to be effective on degenerative articular disorders both in pre-clinical and clinical studies published in international, peer-reviewed journals [3], [4], [6], [7]. Such studies include double-blind randomized clinical trials on patients affected by knee osteoarthrosis [8], [9].

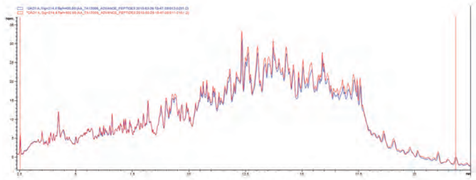
SAFETY AND PERFORMANCE

TSE-related Safety

CHondroGrid® is manufactured starting from pharma-grade highly purified bovine collagen. The extraction process applied to purify the CHondroGrid® bovine collagen has been certified safe by the European Directorate for the Quality of Medicines (**EDQM**) as far as the **TSE** (Transmissible Spongiform Encephalopathies) risk is concerned. During its production, **Bioteck** further checks the raw material for the absence of prions using biomolecular assays, such as Western Blot Test and HPLC chromatography. Safety and performance assessments performed on the **CHondroGrid®** device have been validated by all the Member States of the European Community.

Microbiological Safety

Bioteck performs strict microbiological tests on each product batch and monitors, along the entire production line, all the environments where the device is manufactured and packaged. After packaging, the product is sterilized by **beta irradiation at a 25 kGy** dose. The irradiation preserves all the qualitative and quantitative features of the peptide profile, causing no decay of the device performance. HPLC data recorded before and after sterilization show that the chromatographic peaks fully overlap, as shown in the plot that follows.



The **CHondroGrid®** 214 nm chromatograms before (blue) and after (red) 25 kGy beta ray-sterilization, showing complete overlapping.

Scientific references

1. Oesser, S. & Seifert, J. Stimulation of type II collagen biosynthesis and secretion in bovine chondrocytes cultured with degraded collagen. Cell Tissue Res. 311, 393–399 (2003).

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