

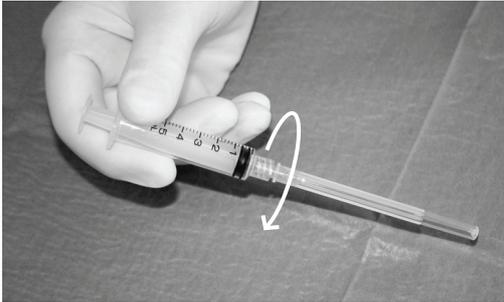
INSTRUCTIONS ON HOW TO PREPARE CHONDROGRID®



Extract the contents of both boxes

- 1 Sterile bottle of 4 mg lyophilized CHondroGrid®
- 1 Endotoxin free, sterile water 2 ml vial
- 1 Sterile 5 ml luer-lock syringe
- 2 Sterile 5 cm, 21 gauge needles

Open the **CHondroGrid®** Kit package



1. Attach the first needle to the syringe



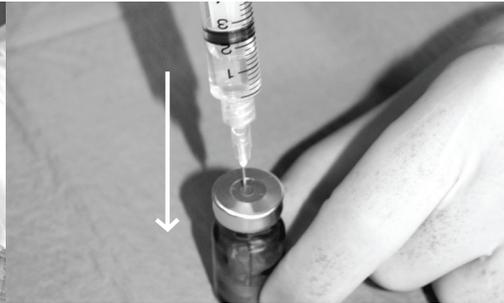
2. Open the 2ml vial of endotoxin free, sterile water injectable



3. Aspirate the entire contents of the vial into the syringe



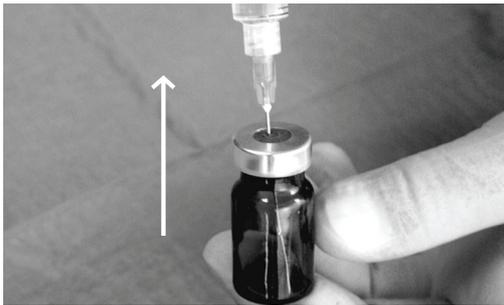
4. Hold the **CHondroGrid®** bottle and insert the needle in the middle of the rubber cap



5. Inject the 2 ml endotoxin free, sterile water into the **CHondroGrid®** bottle



6. Check carefully to ensure that lyophilized and endotoxin free, sterile water have blended perfectly



7. Keeping the bottle in the vertical position, aspirate the entire contents of the **CHondroGrid®** bottle back into the syringe



8. Remove the syringe and carefully detach the first sterile needle used to blend the preparation



9. Attach the second sterile needle to the syringe ready for the injection



10. **CHondroGrid®** 4mg/2ml is ready to be injected

Tips and recommendations

- Ensure that needles are firmly attached to the syringe body to avoid disconnection and/or spillage of the liquids.
- Check carefully that the lyophilized content is fully diluted and blended. Gently shaking the bottle and waiting a few seconds is recommended.
- It is strongly recommended that the entire procedure be carried out in sterile conditions.

CHONDROGRID®

Sterile, Single-Use Device.

DESCRIPTION

Lyophilized low molecular weight Collagen Hydrolysate for intra and peri-articular injection.

COMPOSITION

Bovine low molecular weight Collagen Hydrolysate.

INDICATIONS

CHondroGrid® is indicated for the treatment of pain symptoms and loss of functionality of the major joints (knee, shoulder, hip, wrist and ankle) and of their musculotendinous and ligamentous structures, caused by degenerative diseases or traumatic events or overload.

The most common indications for 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, overload and overwork to the above mentioned joints. **CHondroGrid®** is also indicated in cases of meniscopathy and as preparative and maintenance therapy before and following meniscectomy surgery, ligament reconstruction or cleaning and/or reconstruction of the articular cartilage. Application for these indications is performed through intra-articular injection.

In case of traumas and/or peri-articular lesions to musculotendinous and ligamentous structures the application is performed through peri-articular injection and infiltration of the involved structures.

MECHANISM OF ACTION

Intra-articular injection: low molecular weight Collagen Hydrolysate spreads onto articular surface reinforcing the cartilage matrix, which is made of a dense network of collagen fibers, deteriorated by the in-progress pathologic processes.

CHondroGrid® therefore acts as a direct mechanical reinforcement of weakened and/or damaged collagen matrix, improving mobility and helping to reduce painful symptoms affecting the joint.

Peri-articular injection: low molecular weight Collagen Hydrolysate acts as a direct reinforcement of damaged collagen scaffold of the peri-articular structures, such as tendons and or ligaments, contributing to pain reduction and a faster functional recovery.

THERAPY PROTOCOL

Intra-articular injection

The treatment is based on three injections: two performed at 15 days apart and the third at one month after the last injection.

Peri-articular injection

The treatment includes two injections 30 days apart from each other.

Infiltration in musculotendinous and ligamentous structures

Two injections with an interval of about 10 days each other.

Materials required for the use of the device (not included in the packaging)

One vial of sterile water for injection (2 ml or more)

One sterile syringe

Two sterile needles

INSTRUCTIONS FOR USE

ATTENTION: drain the joint fluid or the effusion before injecting **CHondroGrid®**.

1 - Open the vial of sterile water for injection.

2 - Draw 2 ml of sterile water for injection into the 5 ml syringe.

3 - Open the blister, remove the vial and inject the sterile water through the rubber cap.

4 - Stir until complete solubilization.

5 - Draw the resulting solution into the syringe.

6 - Replace the used needle with the second sterile one.

7 - Inject the product under proper aseptic conditions.

Intra-articular injection

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

Peri-articular infiltration of musculotendinous and ligamentous structures
Locate the point or points of maximum tenderness and if necessary mark them with a dermatographic-marker pen. The injection can be performed under instrumental guidance to locate the site of injury.

WARNING AND PRECAUTIONS

CHondroGrid® should be used only by qualified medical personnel, following strict aseptic procedures.

CHondroGrid® should not be used in combination with other injectable compounds. It is however indicated in patients previously treated with injections of hyaluronic acid or autologous PRP. If further supportive therapy to the cartilage is required, the use of **CHondroGrid®** may be associated with the oral intake of low molecular weight Collagen Hydrolysate food supplements, such as Chondrovita® or similar.

Do not load excessively the treated joint in the hours immediately following the infiltration.

Do not use **CHondroGrid®** if the package is opened or damaged.

Do not inject **CHondroGrid®** intravascularly.

Do not use after the expiration date. The expiration date refers to the product unopened and stored properly.

Keep out of the reach of children.

CONTRAINDICATIONS AND SIDE EFFECTS

Patients with known hypersensitivity to collagen. Articular or peri-articular infection, hemarthrosis, erythema and/or psoriatic spots in the area to infiltrate.

The intra- and peri-articular injection may occasionally cause transient pain, slight swelling, redness and superficial skin reaction due to the mechanical action of the needle. These reactions are usually short-lived and resolve spontaneously within few days with rest and application of ice.

PACKAGE CONTENTS AND PATIENT LABELS

A glass vial in a single PETG blister. Information leaflet. The label on the blister consists of six peel-off labels, which also serve for the application on medical records of the patient or other documentation.

STERILIZATION AND STORAGE

The product is sterilized by beta irradiation at 25 kGy. Store out of direct sunlight, in a cool and dry place, at a temperature between 4 and 40°C. In correct storage conditions the integrity of the package and therefore the sterility of the product are guaranteed for 2 years from the date of production (see expiration date on the external label).

MANUFACTURER

Bioteck SpA, Via E. Fermi 49, 36057 Arcugnano (VI), Italy.

Produced in the plant at no. 3 Via g. Agnelli - 10020 Riva presso Chieri (Turin), Italy.