Articular cartilage treatment with CartiFill™

Patient Information Leaflet

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CartiFill™ is imported by **RMS Innovations UK Ltd** (Hertfordshire, UK) and manufactured by Sewon Cellontech (Seoul, South Korea)

If your surgeon has found this treatment to be appropriate for your condition, you will receive a copy of this Patient Information Leaflet along with an Informed Consent Form. Please ensure that you are satisfied with your level of knowledge for this treatment before consenting.

What is CartiFill?

CartiFill is a highly purified porcine-derived collagen that has been modified to virtually eliminate the risk of rejection from your body. The collagen is supplemented with nutrients to help your cartilage tissue grow. CartiFill will be prepared with special biological 'glue' which mimics the body's natural healing conditions and allows the mixture to set in the wound area.

The Logic

Your body struggles to repair damaged cartilage due to the lack of blood supply. This can result in cartilage which progressively degenerates.

CartiFill is applied following a Microfracture procedure, whereby your bone marrow cells, including your own stem cells, are released into the wound site. CartiFill acts as a structural scaffold for cells, fixing them to a 3-dimensional network where they can grow. Collagen is used for this purpose as its presence encourages the growth and development of the cartilage.

The released cells multiply in numbers and form their own natural network over time, forming healthy cartilage, after which the CartiFill is safely broken down and removed by the body.

Your Treatment

The surgery can be summarised by 3 key stages:

1. **Debridement or ablation.**
   This removes undesirable loose and fibrous tissue to prepare the wound area for CartiFill. This also helps to decrease pain from the rubbing of tissues.
2. **Microfracture or Microdrilling.**
   Small holes are made at the wound site to allow bone marrow

cells, including stem cells, to be released into the site to help repair the area.

3. **Application of CartiFill.** CartiFill will be prepared in theatre prior to its use. CartiFill is applied over the wound area and it fixes to the surrounding tissue.

Your surgeon may perform the treatment through key-hole surgery, leaving two very small marks where the medical instruments were inserted. In this case the knee will *not* be surgically opened and the patient *may* have the opportunity to return home the same day. The alternative is a 'mini-open' procedure, whereby a small opening on the knee is made to expose the area for treatment.

Both treatment methods have their own benefits and risks. **Please consult your surgeon for their advice on which is the most appropriate treatment for you.**

Rehabilitation and Follow-up Visits

Your assigned physiotherapist will plan an appropriate rehabilitation programme for you following your surgery.

Who qualifies for this treatment?

This treatment will typically be given to patients with isolated regions of damaged cartilage in joints.

This treatment may be inappropriate for people who have a family history of autoimmune disease, have ever suffered an anaphylactic shock, have ever experienced hypersensitivity to an implant, or have a history of allergy to porcine or bovine protein. *Your surgeon will advise you of your best course of treatment*.

The risks

CartiFill is a CE-marked medical device and meets all of the requirements set out by the relevant European legislation (EC MDD 93/42/EEC; amended by 2007/47/EC).

The surgery risks should be explained to you in more detail by your surgeon. These include infection, post-operative pain, bleeding, injury to nerves, numbness, joint stiffness, and swelling of the joint. Your medical history may

also result in additional risks. Please consult your surgeon for more information.

The application of CartiFill has some associated possible side effects. These include fever, nightsweats, weight loss, loss of strength, pricking pain, numbness, visual disorders, flu-like symptoms, headache and, though rare, anaphylactic shock.

Allergic reaction may occur if you suffer from a porcine allergy and should notify your surgeon. The 'fibrin glue' used by the hospital will carry its own risks. Please consult your surgeon about these.

The healing process will vary from patient to patient. Some may have cartilage under-growth, while others may have over-growth; some patients may have a higher quality of tissue than others; and some patients may heal faster than others [note: smokers tend to heal slower].

There may be unforeseen risks. If you notice any new or unusual symptoms following the surgery, please notify your surgeon for assessment.

Confidentiality and Privacy

In this Patient Information Leaflet, RMS has endeavoured to raise your awareness to the potential risks related to this CartiFill procedure. We encourage the reporting of any side effects you encounter. Any that are made known to us will be shared with the regulatory authorities to be assessed. This will be done under the applicable EU privacy and data protection legislation by the criteria set in accordance with EU law. Information from your medical records may also be included under the same terms of confidentiality and privacy.

Key Messages

- A network of collagen fibres secure bone marrow cells to the damaged area.
- Your own cartilage is encouraged to grow and repair the damage.
- As with any medical procedure, there are associated risks.

Please contact your surgeon with any questions you have. Should they need any further information from RMS, they will contact them directly.