Patient Information Leaflet

Chondro-Gide®

Name of material/device and available sizes

Chondro-Gide®

20 x 30 mm
30 x 40 mm
40 x 50 mm

The product illustration is exemplary for the product family

Intent and indications for using this material/device

Chondro-Gide® is a resorbable material that is surgically implanted to cover chondral or osteochondral defects treated with marrow stimulation techniques (e.g., AMIC® - autologous matrix induced chondrogenesis). The defects can be acute or chronic and be caused by a fall, accident or other traumatic events. The material gradually resorbs over several months (1 – 4 months) and is replaced by the patient's own tissues. Provided active infection is not present at the surgical site, this material can be safely used in most patients. However, there is no data available on use of this material during pregnancy and lactation, and in children. Until such time that additional data becomes available, it is recommended that Chondro-Gide® be avoided in pregnant and lactating women, and in children.

Patient-specific operating instructions

As Chondro-Gide® is an implantable material that degrades and disappears naturally over time (1 - 4 months), there are no patient-specific operating instructions or maintenance procedures required for this material. It is important that all post-operative instructions and precautions advised by the surgeon are followed and that any post-operative follow-up appointments are attended. This will help reduce the risk of any post-operative complications and maximise the likelihood of a successful clinical outcome. Please contact your surgeon immediately for advice if any signs of post-operative infection (i.e., increase in redness, excessive swelling, worsening pain, fever, malaise, etc.) or allergic reaction (i.e., wheezing, chest tightness, shortness of breath and a cough, and swollen lips/tongue/eyes/face) become evident. Please call an ambulance or attend the nearest hospital Emergency Department in the event of a life-threatening emergency.

How does Chondro-Gide® work?

Chondro-Gide® is a natural collagen material derived from veterinary-certified porcine (pig) tissue. It is carefully purified such that it becomes biocompatible with human tissues. No chemical additives or further cross-linking have been employed, and no residual components are present that can pose a threat to the patient.

The material has two distinct surfaces (i.e., bilayer); a) a smooth (dense) surface which is placed facing the joint space, and b) a rough (porous) surface which is placed against the cartilage

defect. Chondro-Gide® acts to stabilise the chondral tissue repair defects. The smooth (dense) layer facilitates a temporary barrier function; preventing the transplanted chondrocytes or stem-cell enriched blood coagulates from being flushed out of the cartilage defect. The rough (porous) layer supports ingrowth of cells and newly-formed tissues. Chondro-Gide® is hydrophilic and has a fibrous microstructure. When applied, the collagen fibres swell, resulting in an optimal fit onto the cartilage defect. The structural integrity is assured even when wet. Chondro-Gide® can be secured into place by fibrin glue or sutures. The degradation rate and lifetime of the material can be affected by a number of factors including features of the surgical site, blood flow to the site, and patient comorbidities. The material is sterilised by gamma sterilisation.

Potential side effects that can occur

Chondro-Gide® has been proven to be a safe and reliable material. It is derived from natural collagen that is carefully purified to minimise risk of immunological reactions. Nevertheless, any history of collagen or atypical allergies and/or inflammatory joint disease should be discussed with your surgeon prior to using this material (i.e., mammalian meat allergy). As with any surgical procedure, possible side effects that may occur includes swelling at the surgical site, flap sloughing, bleeding, local inflammation/tissue death, and infection. These side effects could lead to reduced tissue healing. Other surgery related disturbances that may appear include bone loss and pain. Increased pain and swelling after surgery for longer periods than expected may be indicative of malfunctioning or failure of the material. If such circumstances arise, immediately contact your surgeon for advice.

Chondro-Gide® is designed and processed in a way that ensures patient safety and avoids compromising the clinical condition of the patient. Although every effort is taken to minimise risks associated with the clinical use of this material, any potential risks and complications that could occur are addressed in this patient information leaflet.

Potential interaction(s) of Chondro-Gide® with other equipment and recommended precautions

Chondro-Gide® is a non-metallic material. It does not demonstrate magnetic behaviour or generate heat during magnetic resonance (MR) examination. Chondro-Gide® has not been specifically studied in the MR environment. In some circumstances, metal hardware may have been employed to secure Chondro-Gide® in position. Please consult with the radiologist/radiographer if this is the case or if you are unsure if metal hardware has been used. In such circumstances, the radiologist/radiographer may need to seek further information from your surgeon and/or consider other scanning methods; the risk of MR scanning in such situations could result in patient injury.

Notice regarding any serious incident that occurs in relation to these devices

Report any serious incident (e.g. serious deterioration of a patient's health) that occurs in relation to these devices to the manufacturer (Geistlich Pharma AG) and to the Therapeutics Goods Administration (TGA).

The Therapeutics Goods Administration (TGA) address and website

Therapeutic Goods Administration
PO Box 100
Woden ACT 2606
Australia
https://www.tga.gov.au/

The manufacturer address and website

Geistlich Pharma AG
Bahnhofstr. 40
6110 Wolhusen
Switzerland
www.geistlich-pharma.com

The distributor address and website (Australian sponsor)

Geistlich Pharma Australia Pty Ltd.
The Zenith – Tower A,
Level 21, Suite 21.02
821 Pacific Highway
Chatswood NSW 2067
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Phone +61-(1)-800 776 326
info@geistlich.com.au
www.geistlich.com.au

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