7 Pirkimo dalis
Besirezorbuojanti dvisluoksnė membrana

LEADING REGENERATION

Geistlich

Patient Information Leaflet

Chondro-Gide®

7.1.
Besirezorbuojanti

Name of material/device and available sizes

Chondro-Gide®
√ 20 x 30 mm 7.1.
30 x 40 mm
40 x 50 mm

7.1. su specialiu folijos šablonu.

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

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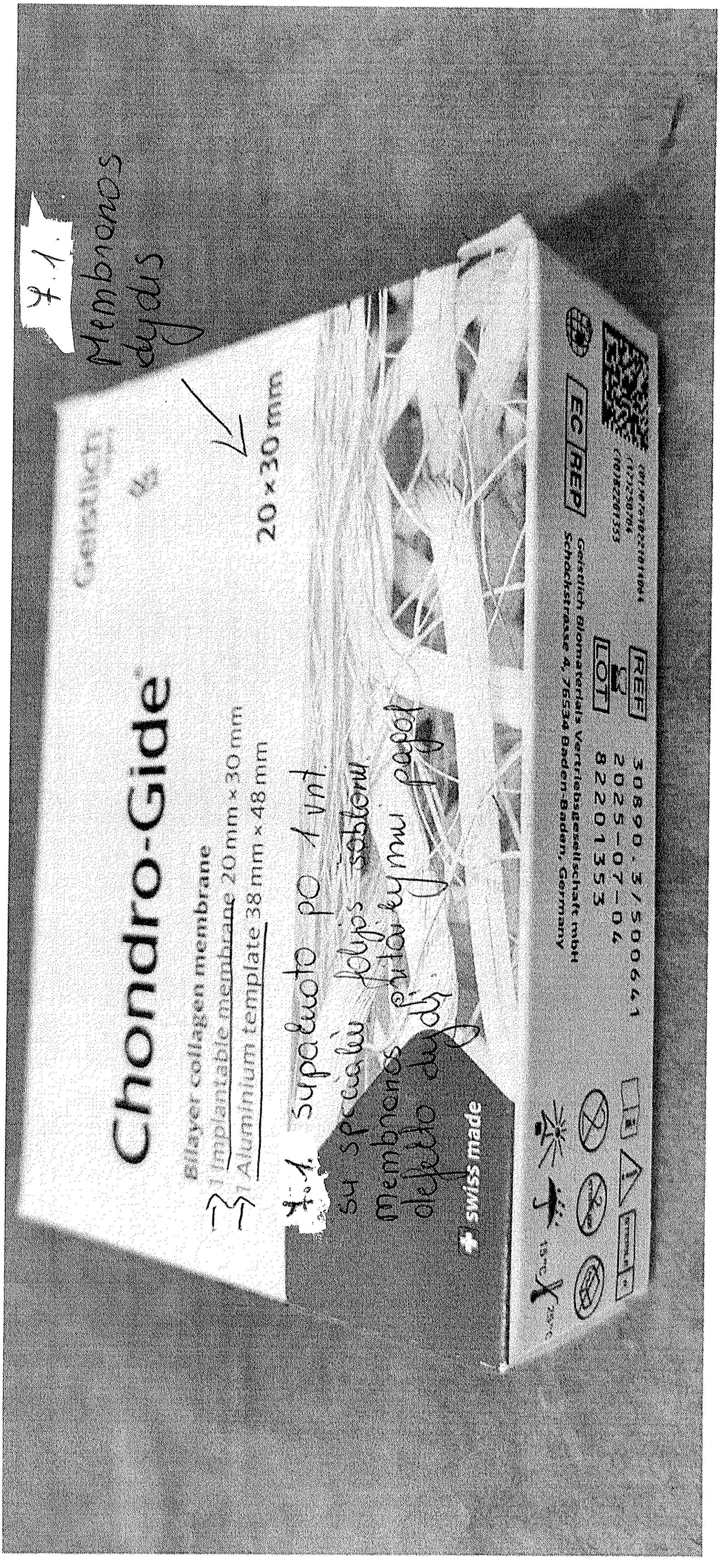
Chondro-Gide®
Geistlich
Bilayer collagen membrane
1 Implantable membrane 20 mm × 30 mm
1 Aluminium template 38 mm × 48 mm
20 × 30 mm
swiss made
Geistlich Biomaterials Vertriebsgesellschaft mbH
Schöckstrasse 4, 76534 Baden-Baden, Germany
EC REP
REF 30890.3/500641
2025-07-04
LOT 82201353
7.1.
Membranos dydis
7.1. supakuoto po 1 vnt.
su specialiu folijos šablonu
membranos pritaikymui pagal
defekto dydį

7.1.

Pakuote sterili

7.1.

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Geistlich
Surgery
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland
www.geistlich-pharma.com
Made in
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ifu.geistlich-pharma.com

7.1.

Chondro Gide - Dvisluoksnė kolageno membrana

Chondro-Gide® – Bilayer Collagen Matrix

Specifications of Chondro-Gide®

I ir III tipo

Collagen is the main structural protein of connective tissue and an important component of articular cartilage. Chondro-Gide® is comprised of collagen type I and III. It is manufactured in a patented process which results in a unique bilayer matrix (Image 1) with a compact and a porous side.

besirezorb. tipo kolageno membrane, skirta ortopedijai

The compact layer (Image 2) consists of a compact, cell occlusive surface, preventing the mesenchymal stem cells from diffusing into the joint space and protecting them from mechanical stress. The porous layer (Image 3) of the matrix is composed of loose collagen fibres that support cell invasion and attachment. The arrangement of the fibres provides high tensile strength and resistance to tearing. Chondro-Gide® can therefore be held in position by glue, sutures or pins.

biologiškai suderinama su žmogaus audiniais, natūraliai

Chondro-Gide® is produced from porcine collagen, which is naturally resorbed. Collagenases, gelatinases and proteinases are responsible for its breakdown into oligopeptides and finally single amino acids.

rezorbuojasi.

Safety and Quality

The proprietary manufacturing process of Chondro-Gide® involves several steps before the unique bilayer design is achieved. Standardised processes under clean room conditions, rigorous in-process and end control guarantee a high quality natural product. Thorough biocompatibility safety testing according to international standards proves that all elements possibly causing an undesirable local or systemic response are removed during the manufacturing process. The immunogenic potential of the matrix is reduced to a minimum.

Chondro-Gide® is a CE-marked product to cover articular cartilage defects that are either treated with autologous chondrocyte implantation (ACI) or with bone marrow stimulation techniques (AMIC®).

Image 1: Unique bilayer structure of Chondro-Gide® (100x)

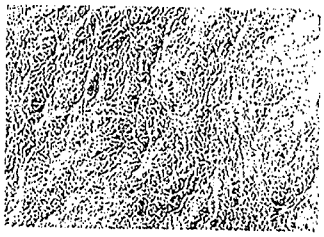

Image 2: Compact, cell occlusive surface (SEM ISCO)

Image 3: Porous, cell adhesive surface (SEM ISCO)

The AMIC® procedure is an easy to handle, cost effective method with good clinical results [3] and is particularly suitable for treating osteochondral and retropatellar defects [4].

Developed to Support Regeneration: Chondro-Gide®

Geistlich Surgery is a leader in the field of regenerative orthopedics, which leverages the body's own ability to repair bone and cartilage.

A Better Alternative to Standard MFx

MFx is commonly used in cartilage repair surgeries to recruit cells and other key bone marrow components to the site of the defect to support the regeneration of cartilage tissue. In larger lesions[8], the blood clot resulting from MFx is not stable enough to withstand shear forces in the joint.

AMIC® Chondro-Gide addresses this problem by combining BMS techniques with the use of a collagen membrane, which covers and protects not only the super clot but also the newly formed repair tissue.[9]

Chondro-Gide is a biocompatible and fully resorbable porcine collagen membrane. It was developed by Geistlich for use in AMIC Chondro-Gide, a minimally-invasive 1-step treatment to treat procedure to treat chondral lesions that is backed by more than 10 years of clinical experience.

Chondro-Gide Features[10]

- **Bio-derived, bilayer Collagen I/III membrane[10]**
- **Biocompatible and naturally resorbed[10]**
- **Easy to handle: supple and tear-resistant[10]**
- **Can be glued[10]**
- **Compatible with a range of tissue regeneration techniques[11]**
- **1-step procedure[10]**

Bioengineered to Leverage the Body's Own Healing Potential

A Smooth, Compact Top Layer

A Barrier to Prevent Cell Diffusion

Flexible and Strong, to Protect New Cartilage

A Rough, Porous Bottom Layer

A Bio-Derived Collagen Membrane

Ideal Conditions for Cell Attachment and Growth

Safety and Quality

A Stable Environment for Regeneration

Reduced Microfracturing and Chondrocyte Effective and Cost-Effective

A Proven Track Record of Success for AMIC® with Chondro-Gide®

Geistlich Chondro-Gide®

Regulatory approvals for Geistlich Chondro-Gide vary by country.

To learn more about product availability please visit www.geistlich-surgery.com or contact the Geistlich distributor in your region.

Sterilus pakuotėje po 1 vnt. su specialiu šablonu membranos pritvirtinimui.

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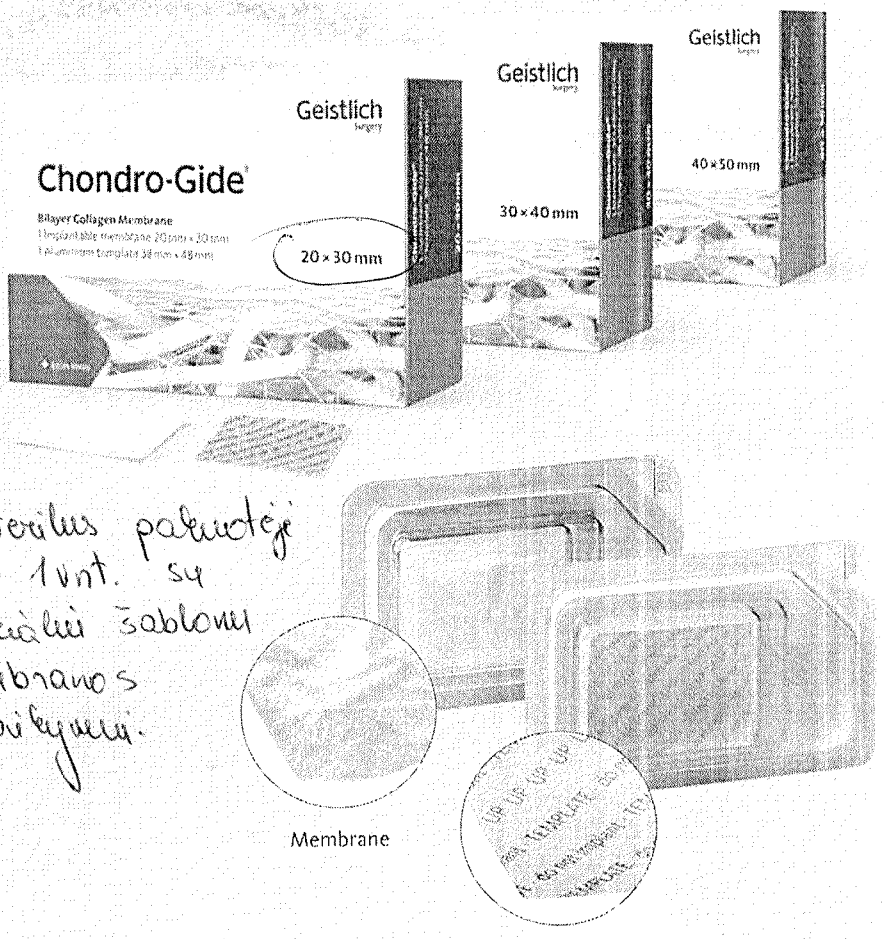

Template, do not implant

1 HJELLE, K., et al. Articular cartilage defects in 1,000 knee arthroscopies. Arthroscopy, Sep 2002, 18(7), 730-734. (Clinical study)

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14 Geistlich Pharma AG data on file (Bench test)

15 KRAMER, J., et al. In vivo matrix-guided human mesenchymal stem cells. Cell Mol Life Sci, Mar 2006, 63(5), 616-626. (Clinical study)

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33 STEINWACHS, M., et al., Scientific Evidence Base for Cartilage Injury and Repair in the Athlete, Cartilage, 2012, 3(Suppl. 1) 11S–17S, DOI: 10.1177/1947603511415841 (Review of clinical studies)

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Baxter

United States

TISSEEL [Fibrin Sealant] Kit (Freeze Dried) with DUPLOJECT System - 2 mL

For Topical Use Only

SKU: 1504514

Provides all components for reconstitution and delivery of fibrin sealant. Each TISSEEL [Fibrin Sealant] Kit with DUPLOJECT System contains 1 DUPLOJECT applicator, 2 joining pieces, 4 application cannula tips, 4 syringes, 4 needles, and the TISSEEL package insert. Topical Use Only - Do Not Inject. Available in 3 sizes. Single use. Sterile and non-pyrogenic.

Product Characteristics

Latex:	Not Made with Natural Rubber Latex
Concentration:	Rx Only
Package Insert Link:	baxterpi.com/pi-pdf/Tisse(..)

Carton

Pack Factor:	1

Website Links

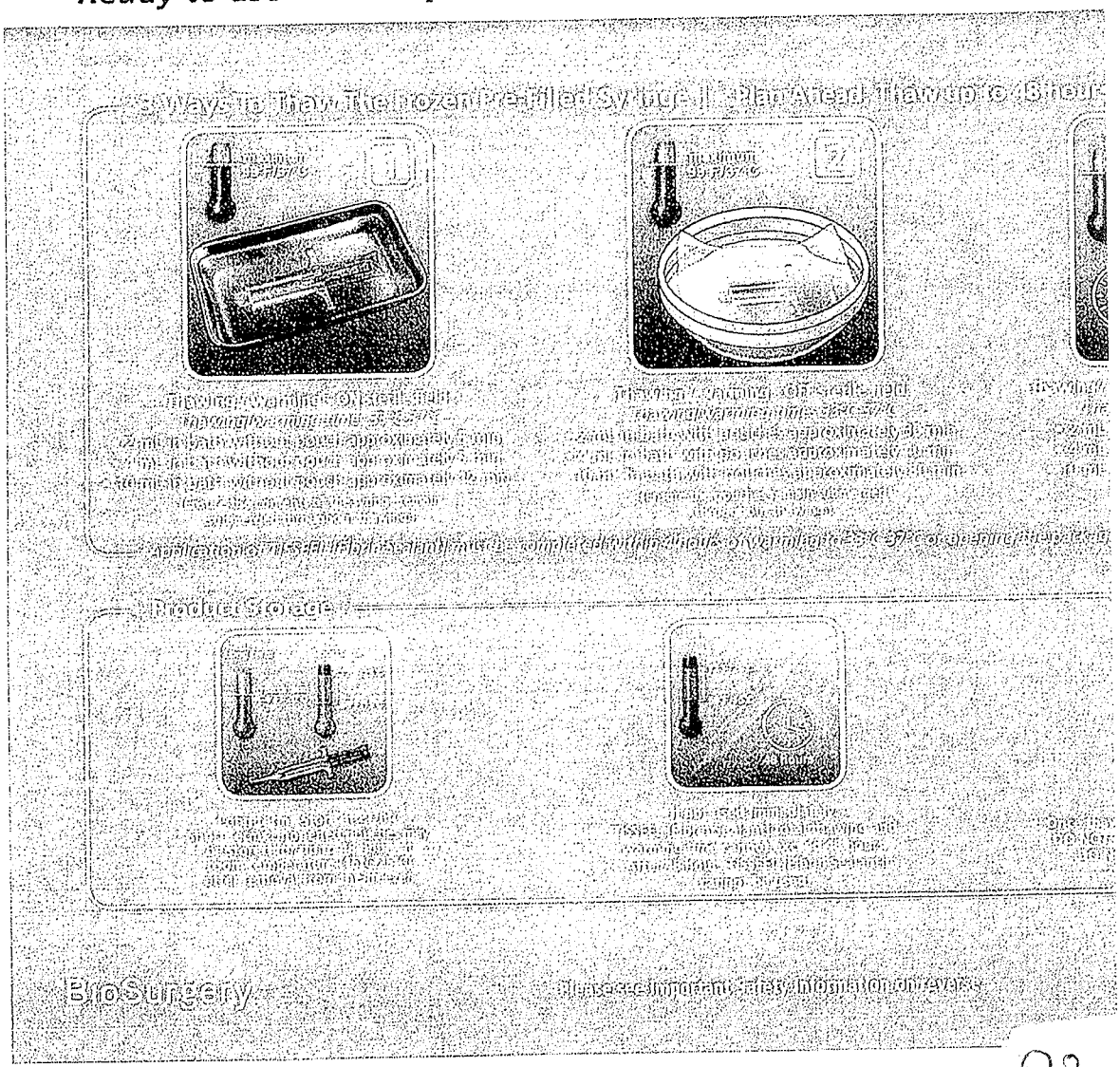
	www.tisseel.com
	baxterpi.com/pi-pdf/Tisse(..)

Ordering information

Baxter Product Code:	1504514
UPN/GTIN CS Unit:	60309444301028
UPN/GTIN EA Unit:	00303384301023
National Drug Code:	0944430102
Unit of Measure:	Each

TISSEEL
[Fibrin Sealant]

Ready to use TISSEEL [Fibrin Sealant] - Quick Reference Guide*



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