8 Pirkimo dalis
Besirezorbuojanti dvisluoksnė membrana

LEADING REGENERATION

Geistlich

# Patient Information Leaflet

Chondro-Gide®

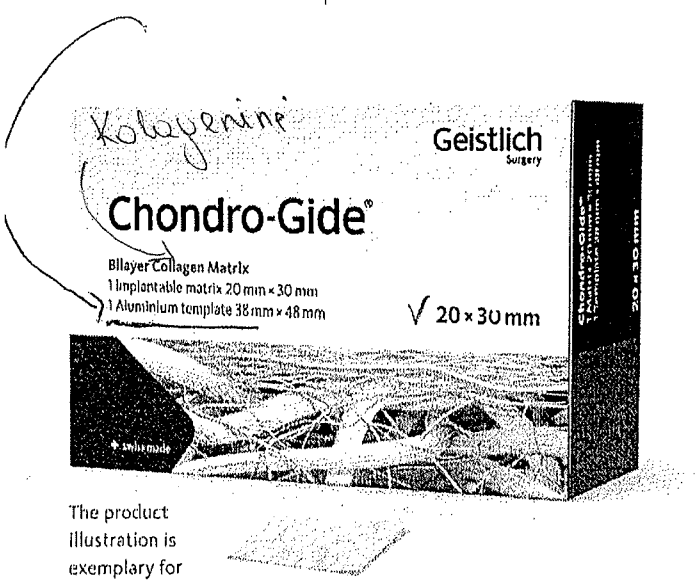
8.6.
Besirezorbuojanti

## Name of material/device and available sizes

Chondro-Gide®

20 x 30 mm
30 x 40 mm
√40 x 50 mm 8.6. Membranos dydis

8.4. 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



1

8.4 Su specialiu kolagas šablonu membranos pritaikymui papil. alveolio didyn.

supabrėžta PO vnt.

8.6. Neuloranos dydis

Geistlich

# Chondro-Gide®

**Bilayer collagen membrane**

1 Implantable membrane 40 mm × 50 mm

1 Aluminium template 38 mm × 48 mm

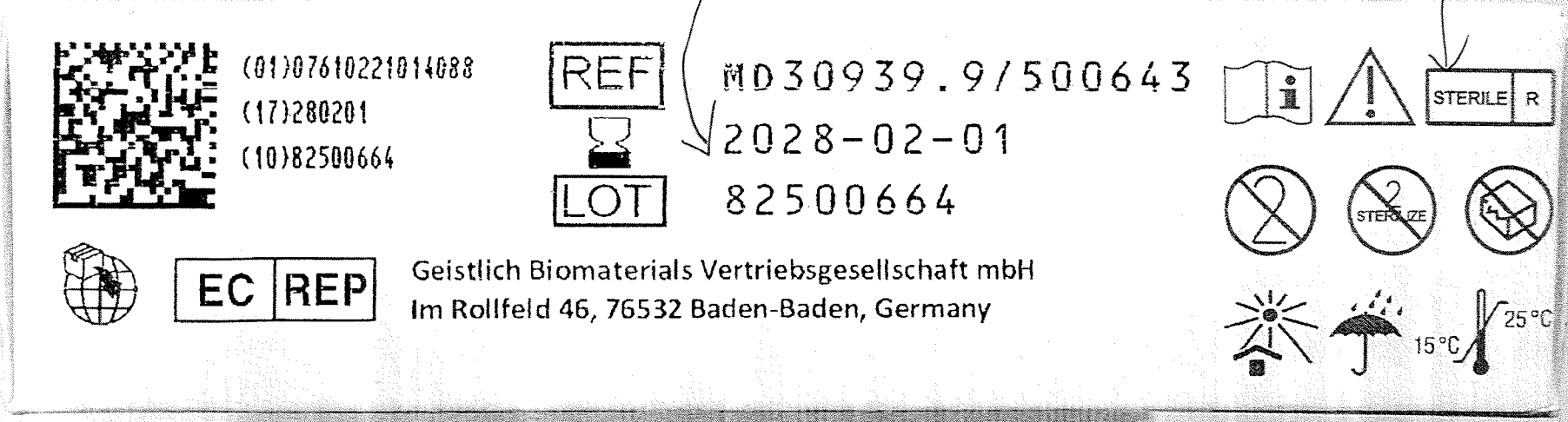
40 × 50 mm

swiss made

8.4. Pakuotė sterili, supakuota po 1 vnt.

8.1. Galiojimas ne maziau kaip du metai

8.4. Pakuotė sterili



eistlich
Surgery
Geistlich Pharma AG
Bahnhofstrasse 40
6110 Wolhusen
Switzerland
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Made in
Switzerland
0123
ifu.geistlich-pharma.com

4

## Bioengineered to Leverage the Body's Own Healing Potential

Chondro-Gide® is a porcine bilayer Collagen I/III membrane. It has a unique structure, being compact and smooth on one side and rough and porous on the other. This provides a protective environment for the stabilization of tissue repair.[14,16]

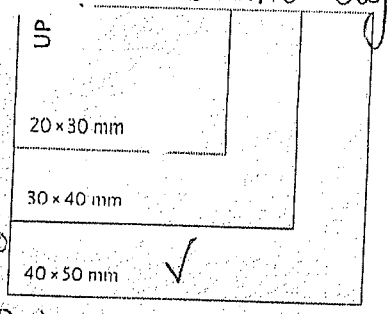
8.1. Chondro-Gide yra dvisluoksnė I/III tipo kolagenu membrana, kuri yra lygi ir stipri, iš vienos pusės išsiskiria, atskyta iš kitos. Tai suteikia apsauginę aplinką audinių atstatymo stabilizavimui.

Trys dydžiai

### CHONDRO-GIDE IS AVAILABLE IN THREE SIZES

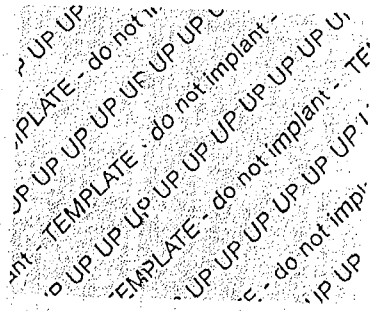
The top layer of the membrane is marked with the word "UP" in one corner.

Membranos dydis




### A STERILE ALUMINUM TEMPLATE IS INCLUDED

The size and shape of the membrane patch can be determined with the sterile aluminum template.




8.4. Specialus aliuminio šablonas membranos pritaikymui pagal defekto dydį.

8.2 Barjeras, saugantis ląstelių difuziją. Lygus stiprus viršutinis sluoksnis, pakankamai tvirtas, apsaugantis ląsteles ir naujai besiformuojantį kremzlę nuo trinties streso sąnaryje.

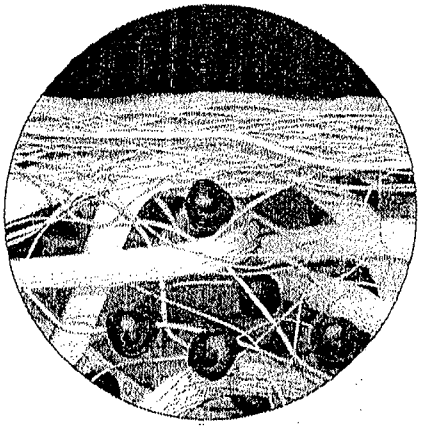
### A Barrier to Prevent Cell Diffusion[14,17]

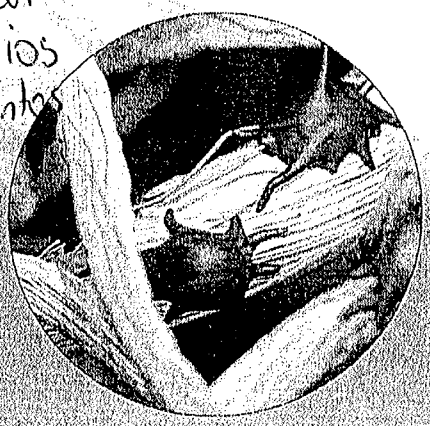
The smooth, compact top layer is also sturdy enough to protect the cells and newly forming cartilage from shear stress in the joint, while the cartilage regenerates and patients undergo rehabilitation.

8.2. Šiurkštus, akytas apatinis sluoksnis prilimpa prie defekto, užkloja membraną viršuje. Ląstelės, kurios mikrofraktūros pagalba yra išlaisvintos arba, kitos, čiulpus stimuliuojančios technikos pagalba išlaisvintos ląstelės, prilimpa prie šio sluoksnio, kur jos auginasi.

### A Rough, Porous Bottom Layer

This layer adheres to the defect, keeping the membrane in place. Cells that are released through MFx or other marrow stimulation techniques attach themselves to this layer, where they proliferate and produce new tissue.[15,16]





Chondro Gide - Dvisluoksnė kolageno membrana

# Chondro-Gide® – Bilayer Collagen Matrix

8.1.

## 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.

8.1. 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.

8.3. biologiškai suderinama su žmogaus audiniais, natūraliai rezorbuojasi

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.

## Safety and Quality

vienos kuokšnin nupjaukite dvi kolagenos juostas ir padėkite ant mezenchiminių kamieninių ląstelių įterpimo.

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®).

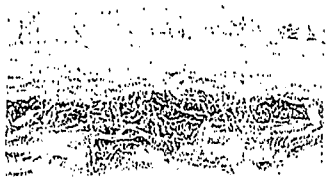


Image 1. Unique bilayer structure of Chondro-Gide® (100x)

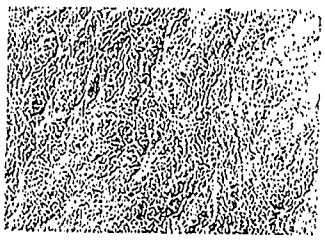


Image 2. Compact, cell occlusive surface (SEM 1500x)

Image 3. Porous, cell adhesive surface (SEM 1500x)

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.

8.1.

Gydymo technikai ortopedijoje

(Naudojama klubo, kelio, čiurnos sąnarinės kremzlės defektų pažeidimui, artroskopinės operacijos metu.

### 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 EMS 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

Chondro-Gide® is a bilayer collagen membrane developed specifically for cartilage regeneration. Made from highly refined porcine collagen, it is produced in Switzerland following a rigorous quality assurance system to ensure its safety and quality.

The illustration shows how Chondro-Gide® works to leverage the body's own healing potential to regenerate human cartilage.

To learn more about Chondro-Gide® and cartilage regeneration, visit www.geistlich-surgery.com.

Schematic illustration of Chondro-Gide® (CH-TOC)


1. [illegible]
2. [illegible]
3. [illegible]
4. [illegible]
5. [illegible]
6. [illegible]
7. [illegible]
8. [illegible]


8.2.

## A Smooth, Compact Top Layer

lyguos, stiprus virsutinis sluoksnis

## A Barrier to Prevent Cell Diffusion

The top layer of the Chondro-Gide® faces the joint cavity. It is made up of collagen fibers in a compact arrangement. Strong and cell-occlusive, this layer provides a protective barrier that prevents premature progression cells from diffusing into the joint cavity and getting lost in the regeneration process.[1]

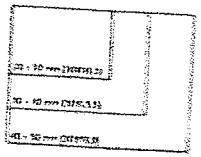
## Flexible and Strong, to Protect New Cartilage

The Chondro-Gide® acts as the roof of a biological chamber that forms around the defect and is filled with cells and blood. The chamber protects the cells and newly forming cartilage from shear forces while the cartilage regenerates and matures undergo remodeling. Safe, supple and soft when wet, the Chondro-Gide® can be trimmed and shaped to conform to defects of [illegible]

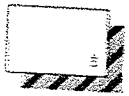
## Safety and Quality

Chondro-Gide® is a CE-certified product that is manufactured according to a proprietary process in Switzerland and marketed by Geistlich Pharma AG. It is available in [illegible] sizes, and each one of the manufacturing process, a specialized production environment, rigorous inspections and final control ensure our ability to provide surgeons with a consistently high quality product they can rely on.

Chondro-Gide® is available in three sizes:




A sterile aluminium template is included.



8.2.

[illegible], Porous Bottom Layer

šviesus, akytas apatinis sluoksnis

## A Bio-Derived Collagen Membrane

This layer faces the defect. Rough and porous on [illegible], it is made up of a dense network of collagen fibers, which [illegible] a flexible but compact matrix. The rough side of the Chondro-Gide® adheres to the defect, allowing the [illegible]

## Ideal Conditions for Cell Attachment and Growth

The porous and rough bottom layer of the Chondro-Gide® provides an ideal environment for cell attachment and growth. Cells from the [illegible] migrate into the matrix of the membrane and [illegible] are embedded through [illegible] Chondrocyte proliferation (cell growth) [illegible] the layer, where they [illegible] and produce new tissue.

## A Stable Environment for Regeneration

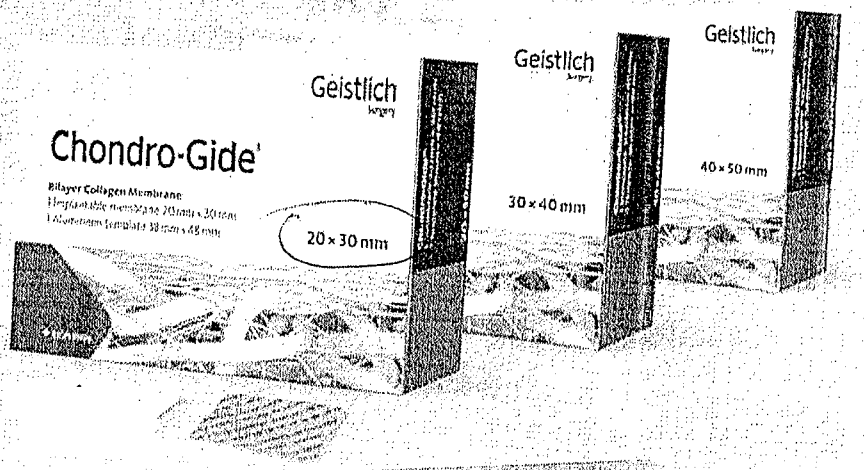
The chondrocytes continue to grow and produce [illegible] the Chondro-Gide® membrane. Over time, the Chondro-Gide® is [illegible]

∞

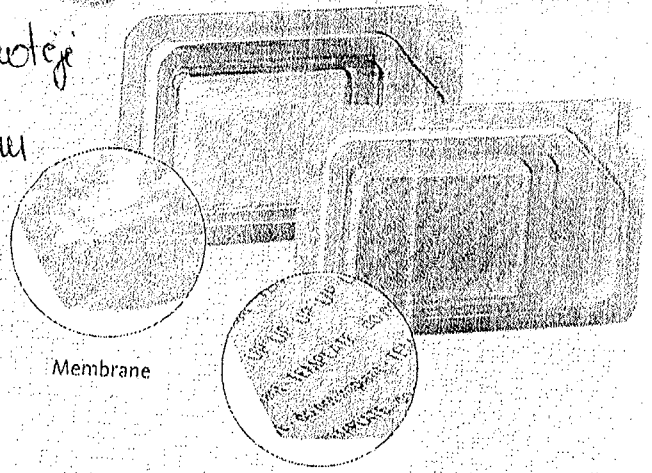
# Geistlich Chondro-Gide®

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 paketėje po 1 vnt. su specialiu šablonu membranos pritaikymui.




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)

2 SCHIAVONE PANNI, A., et al. Good clinical results with autologous matrix-induced chondrogenesis (Amic) technique in large knee chondral defects. Knee Surg Sports Traumatol Arthrosc, 2018 Apr 26(4):1130-36 (Clinical study)

3 WALTHER, M., et al. Scaffold based reconstruction of focal full thickness talar cartilage defects. Clinical Research on Foot & Ankle, 2013, 1-5. (Clinical study)

4 MITHOEFER, K., et al. The microfracture technique for the treatment of articular cartilage lesions in the knee. A prospective cohort study. J Bone Joint Surg Am. Sep 2005, 87(9), 1911-1920. (Clinical study)

5 GOYAL, D., et al. Evidence-based status of microfracture technique: a systematic review of level I and II studies. Arthroscopy. Sep 2013, 29(9), 1579-1588. (Review of clinical studies)

6 FONTANA, A., et al. Sustained five-year benefit of autologous matrix-induced chondrogenesis for femoral acetabular impingement-induced chondral lesions compared with microfracture treatment. Bone Joint J. May 2015, 97-B(5), 628-635. (Clinical study)

7 GAO, L., et al. Early loss of subchondral bone following microfracture is counteracted by bone marrow aspirate in a translational model of osteochondral repair. Nature Scientific Reports, 2017, 7:45189. (Pre-clinical study)

8 FRANK, R.M., et al., Failure of Bone Marrow Stimulation Techniques, Sports Med Arthrosc Rev. 2017, 25 (1) (Review of clinical studies)

9 KAISER, N., et al. Clinical results 10 years after AMIC in the knee. Swiss Med Wkly. 2015. 145 (Suppl 210), 43S. (Clinical study)

10 MITHOEFER, K., et al. Clinical Efficacy of the Microfracture Technique for Articular Cartilage Repair in the Knee: An Evidence-Based Systematic Analysis. AJSM, 2009. (Review of clinical studies)

11 VOLZ, M., et al. A randomized controlled trial demonstrating sustained benefit of Autologous Matrix-Induced Chondrogenesis over microfracture at five years. Int Orthop, Apr 2017, 41(4), 797-804. (Clinical study)

12 JANNELLI, E , et al. Arthroscopic treatment of chondral defects in the hip: AMIC®, MACI, microfragmented adipose tissue transplantation (MATT) and other options. SICOT J. 2017,3(43). (Clinical study)

13 STEINWACHS, M.R.,et al. Systematic Review and Meta-Analysis of the Clinical Evidence on the Use of Autologous Matrix-Induced Chondrogenesis in the Knee. Cartilage. 2019:1947603519870846. https://www.ncbi.nlm.nih.gov/pubmed/31508990 (Review of clinical studies)

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)

16 GILLE, J., et al. Cell-Laden and Cell-Free Matrix-Induced-Chondrogenesis versus Microfracture for the Treatment of Articular Cartilage Defects: A Histological and Biomechanical Study in Sheep. Cartilage OnlineFirst, January 7, 2010, doi:10.1177/1947603509358721 (Pre-clinical study)

17 MUMME, M., Nasal chondrocyte-based engineered autologous cartilage tissue for repair of articular cartilage defects: an observational first-in-human trial. Lancet, 2016, 388 (10055) 1985-1994. (Clinical study)

18 FULCO, I., et al. Engineered autologous cartilage tissue for nasal reconstruction after tumour resection: an observational first-in-human trial. Lancet, Jul 26 2014, 384(9940), 337-346. (Clinical study)

19 Niemeyer, P., et al., Significance of Matrix-augmented Bone Marrow Stimulation for Treatment of Cartilage Defects of the Knee: A Consensus Statement of the DGOU Working Group on Tissue Regeneration. Z Orthop Unfall. 2018 DOI: https://doi.org/10.1055/a-0591-6457

20 Chondro-Gide® IFU 2019, Geistlich Pharma AG(Review of clinical studies)

21 STEADMAN, J.R.,Microfracture Technique for Full-Thickness Chondral Defects: Technique and Clinical Results. Operative Techniques in Orthopaedics. 1992. 7(4), 300-304. (Clinical study)

22 SCHAGEMANN, J., et al. Mid-term outcome of arthroscopic AMIC for the treatment of articular cartilage defects in the knee joint is equivalent to mini-open procedures. Arch Orthop Trauma Surg, Jan 22 2018. (Clinical study)

23 PIONTEK, T., et al. All-arthroscopic AMIC® procedure for repair of cartilage defects of the knee. Knee Surg Sports Traumatol Arthrosc, May 2012, 20(5), 922-925. (Clinical study)

24 SADLIK, B., et al. Biological reconstruction of large osteochondral lesions of the talar dome with a modified "sandwich" technique-Midterm results. Foot Ankle Surg. Dec 2017, 23(4), 290-295. (Clinical study)

25 KNUTSEN, G., et al. A Randomized Multicenter Trial Comparing Autologous Chondrocyte Implantation with Microfracture: Long-Term Follow-up at 14 to 15 Years. J Bone Joint Surg Am, Aug 17 2016, 98(16), 1332-1339. (Clinical study)

26 KREUZ, P. C., et al. Results after microfracture of full-thickness chondral defects in different compartments in the knee. Osteoarthritis Cartilage, Nov 2006, 14(11), 1119-1125. (Clinical study)

27 FOSSUM, V., et al. Collagen-Covered Autologous Chondrocyte Implantation Versus Autologous Matrix-Induced Chondrogenesis: A Randomized Trial Comparing 2 Methods for Repair of Cartilage Defects of the Knee. Orthopaedic Journal of Sports Medicine. 2019;7(9) (Clinical study)

28 VOLPI, P., et al. Treatment of chondral defects with AMIC technique (Autologous Matrix Induced Chondrogenesis) compared to AMIC enhanced by concentrated bone marrow. ICRS Meeting 2009 (Clinical study)

29 STEINWACHS, M.R., et al. Matrix-associated chondroplasty: a novel platelet-rich plasma and concentrated nucleated bone marrow cell-enhanced cartilage restoration technique. Arthroscopy Techniques, 2014, (3) 4, pp e279-e282 (Clinical study)

30 LEE, Y. H., et al. Autologous Matrix- induced Chondrogenesis in the Knee: A Review. Cartilage, Jul 2014, 5(3), 145-153. (Review of clinical studies)

31 GOBBI, A., et al. One-step surgery with multipotent stem cells for the treatment of large full-thickness chondral defects of the knee. Am J Sports Med, Mar 2014, 42(3), 648-657. (Clinical study)

32 PRUSINSKA, A., et al. A summary of the process of rehabilitation of patients after knee full arthroscopic amic(autologous matrix-induced chondrogenesis) based on biomechanical evaluation results in the respective steps: 6, 12 and 24 months after surgery. Knee Surgery, Sports Traumatology, Arthroscopy. May 01 2016. 24(Supplement 1), 4-114. (Clinical study)

33 STEINWACHS, M., et al., Scientific Evidence Base for Cartilage Injury and Repair in the Athlete, Cartilage, 2012, 3(Suppl. 1) 115-175, DOI: 10.1177/1947603511418411 (Review of clinical studies)

34 STEINWACHS, M., et al., Regenerative Knorpeltherapie, Orthopädie und Unfallchirurgie, 2014, OE279-301 OEDOI: http://dx.doi.org/10.1055/s-0035-1557981 (Review of clinical studies)


9

8.5.

Komplekte su fibrinuiais

Elpsais

Baxter United States

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

For Topical Use Only

SKU: 1504514 Sistema suvienai klijuoti

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 |

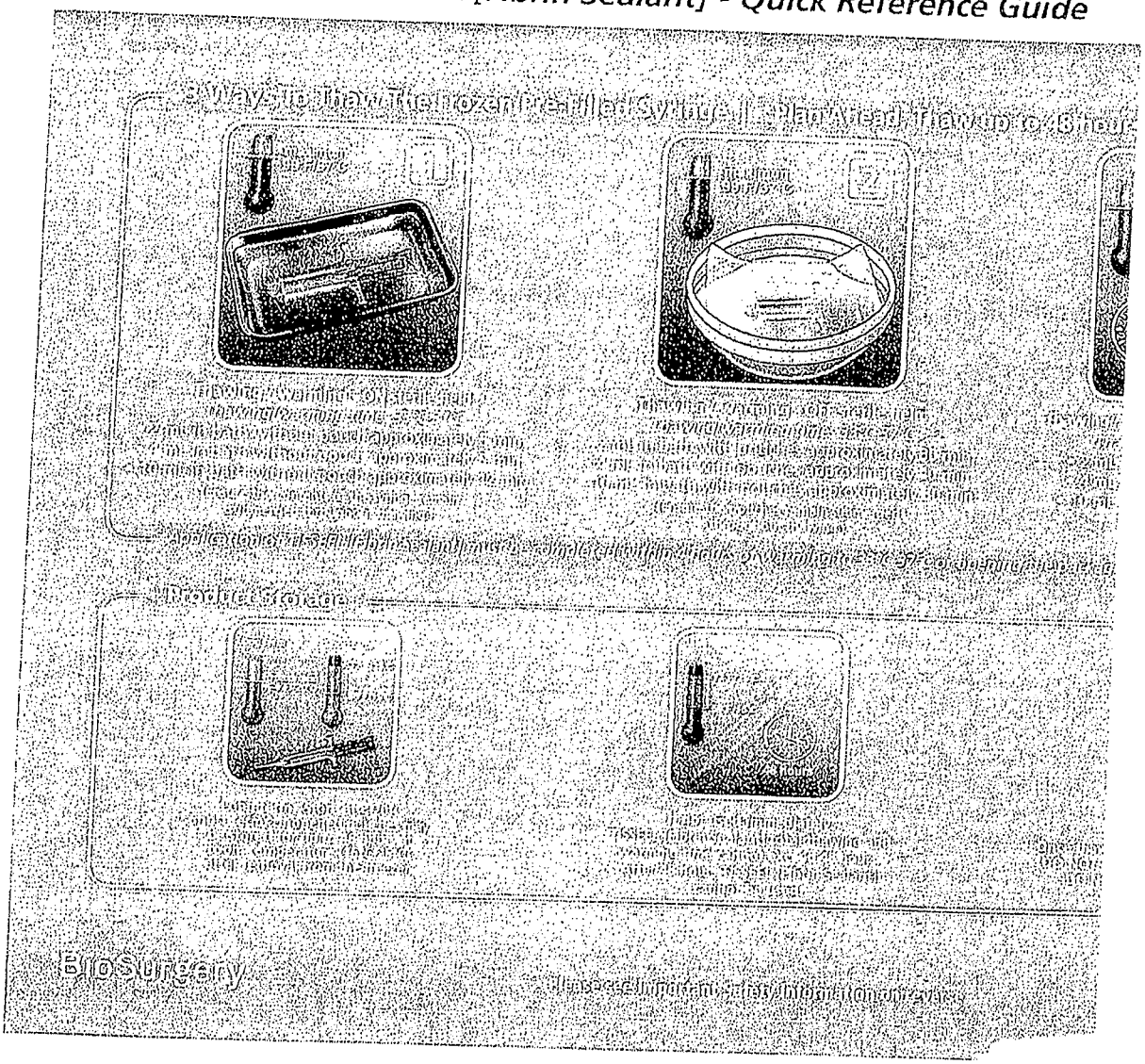


10

8.5. Komplett yra tarki su fibrininiais klijais

TISSEEL
[Fibrin Sealant]

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




11

**CHONDRO-GIDE®**
**LITERATURE HIGHLIGHT**

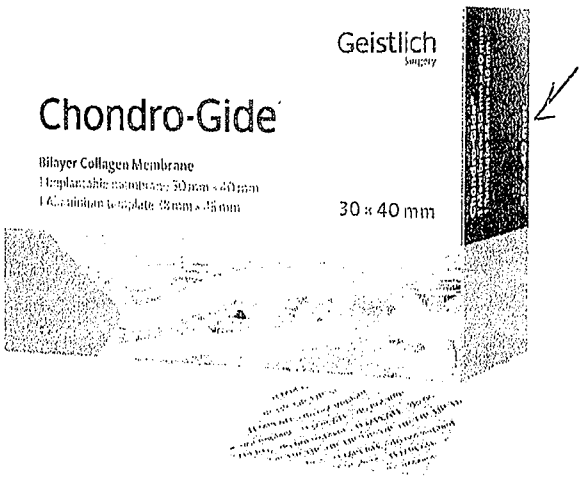
This literature highlight addresses important aspects of the evidence for the use of Chondro-Gide®.

# XPERIENCE THE EVIDENCE

## 100+ peer-reviewed publications

AMIC® Chondro-Gide®

- Combines bone marrow stimulating techniques with the collagen membrane[1]
- Compatible with a range of cost-efficient, one-step cartilage regeneration techniques[2]
- Stable results over 10+ years[3]
- More than 15 years of clinical success
- Biocompatible and naturally resorbed[1]




pebrotejo superficiale po 1 ut. su specialin šablonu


1 Geistlich Pharma AG, data on file (bench tests and pre-clinical studies)
2 Kramer J, et al., *Cell Mol Life Sci.* [illegible] (Clinical study)
3 Walther M, et al., *Oper Orthop Traumatol.* [illegible] (Clinical study)
4 Fossum V, et al., *Orthop J Sports Med.* [illegible] (Clinical study)
5 Kaiser N, et al., *Arch Orthop Trauma Surg.* [illegible] (Clinical study)



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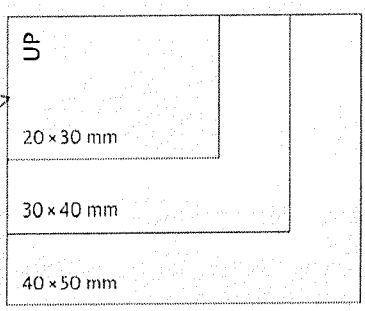
www.geistlich-surgery.com

## Bioengineered to Leverage the Body's Own Healing Potential

Chondro-Gide® is a porcine bilayer Collagen I/III membrane. It has a unique structure, being compact and smooth on one side and rough and porous on the other. This provides a protective environment for the stabilization of tissue repair.[14,16]

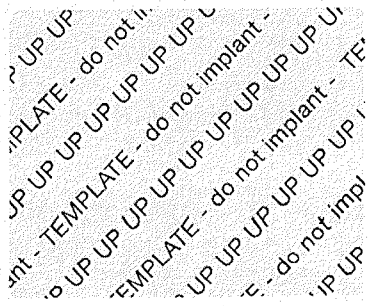
### CHONDRO-GIDE IS AVAILABLE IN THREE SIZES

The top layer of the membrane is marked with the word "UP" in one corner.




### A STERILE ALUMINUM TEMPLATE IS INCLUDED

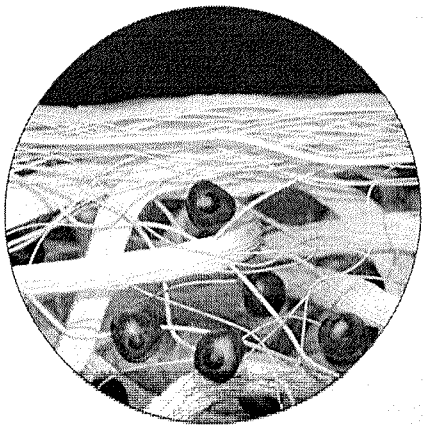
The size and shape of the membrane patch can be determined with the sterile aluminum template.




38 × 48 mm

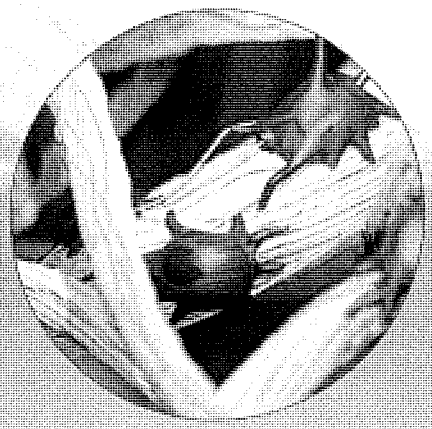
### A Barrier to Prevent Cell Diffusion[14,17]

The smooth, compact top layer is also sturdy enough to protect the cells and newly forming cartilage from shear stress in the joint, while the cartilage regenerates and patients undergo rehabilitation.



### A Rough, Porous Bottom Layer

This layer adheres to the defect, keeping the membrane in place. Cells that are released through MFx or other marrow stimulation techniques attach themselves to this layer, where they proliferate and produce new tissue.[15,18]



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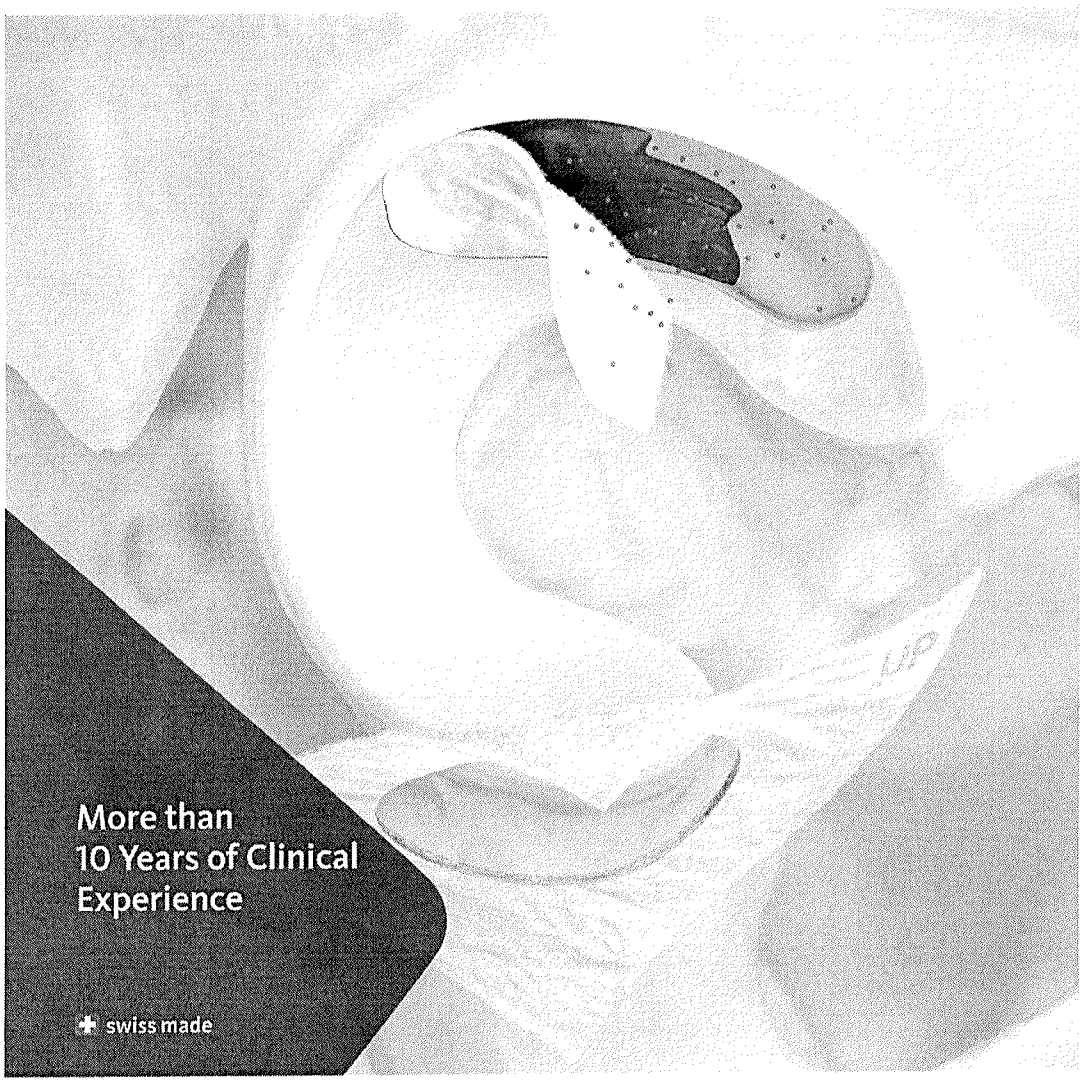
# AMIC® Chondro-Gide® in the Hip (Klubui)



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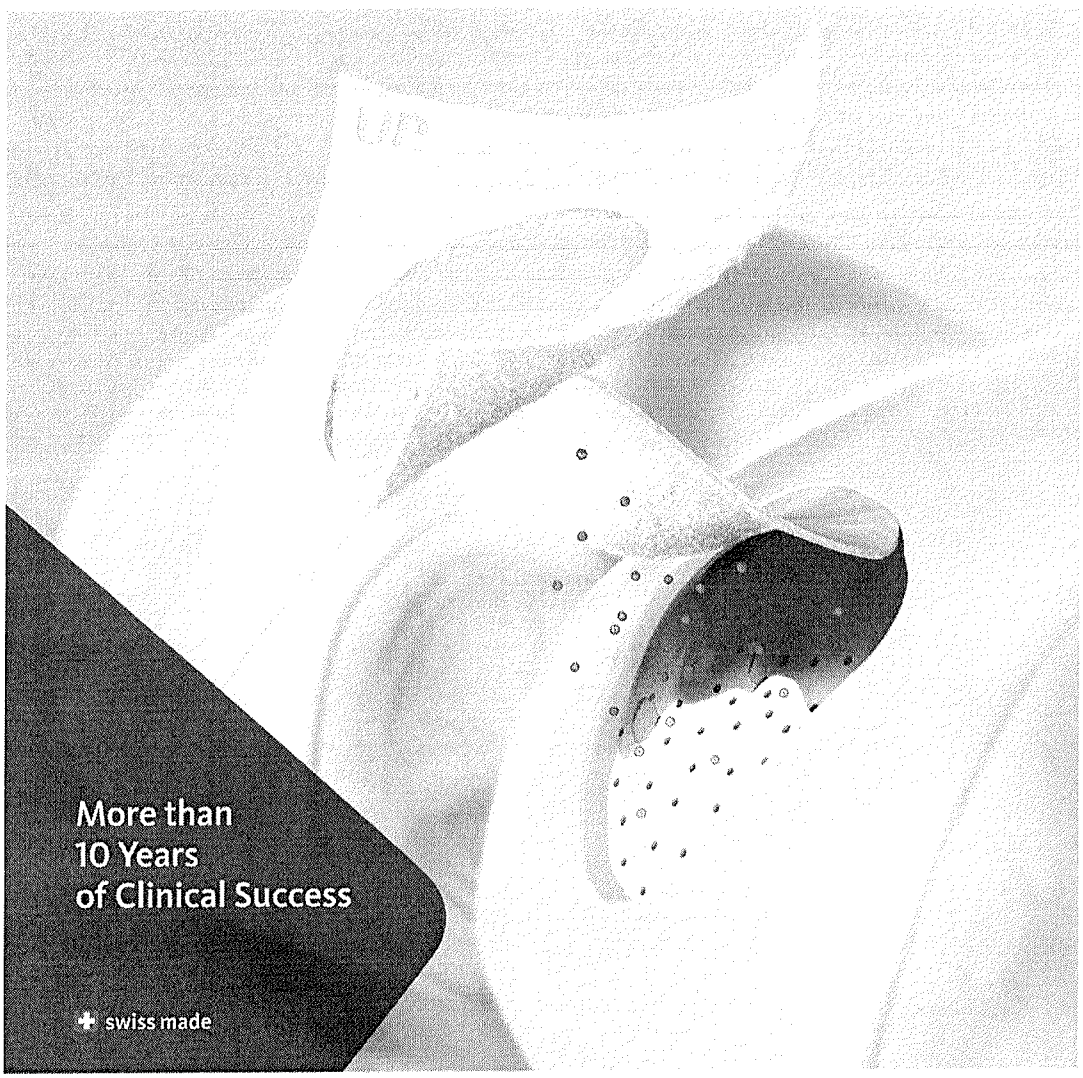
# AMIC® Chondro-Gide® in the Knee (Kelvin)



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# AMIC® Chondro-Gide®
# in the Ankle Joint (Ξωπνος σεμινάριο)