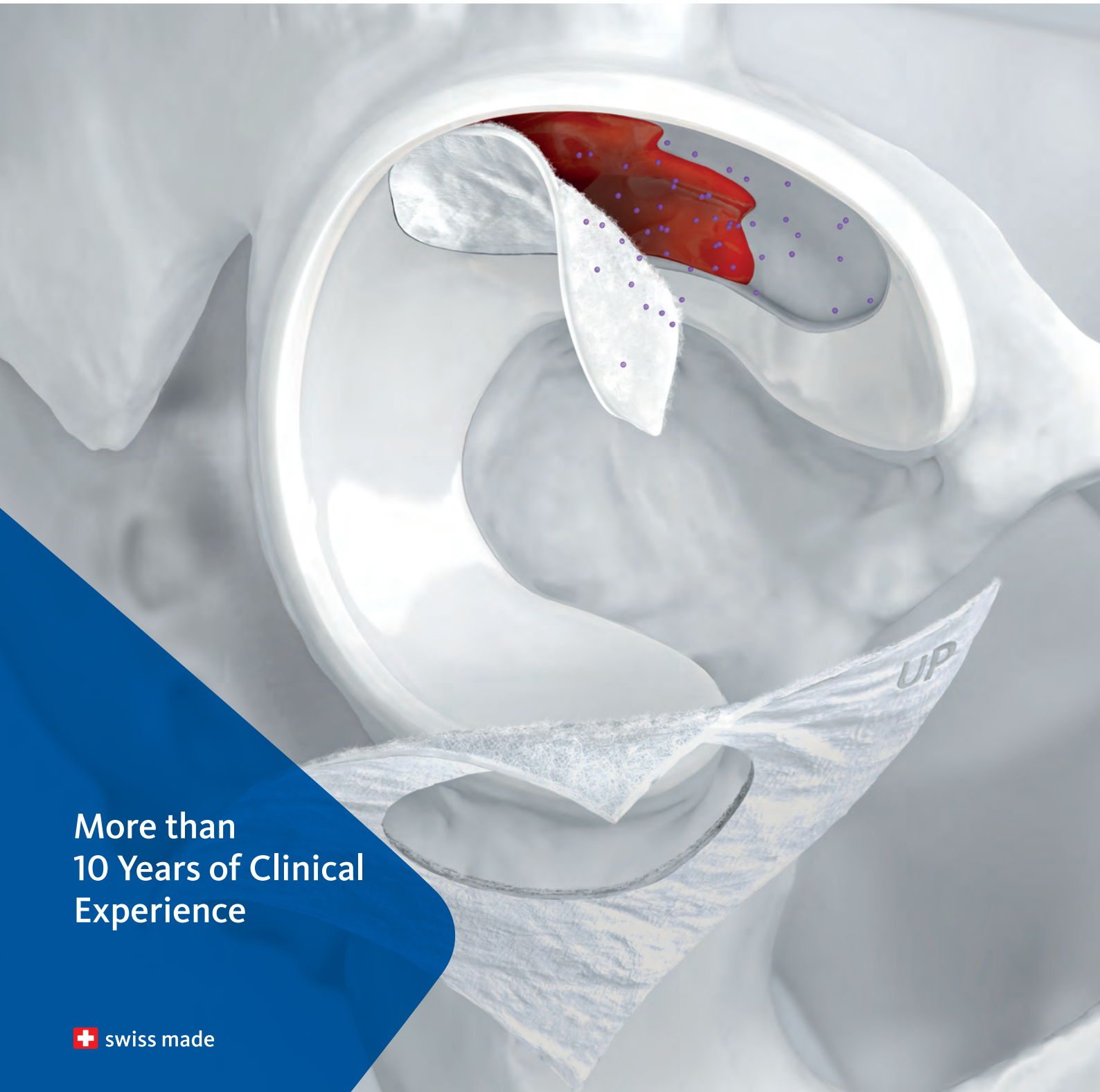
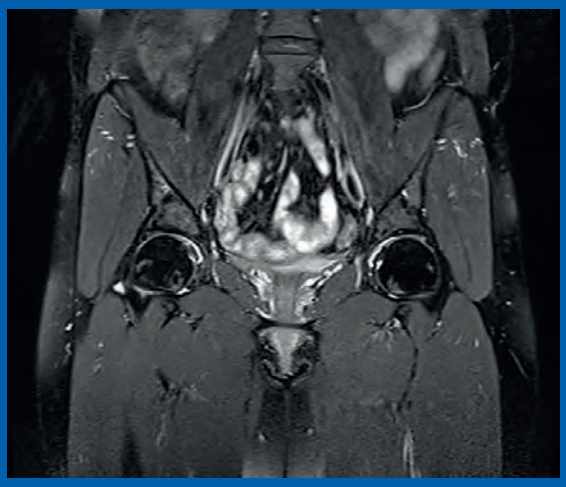
Geistlich
Surgery

AMIC® Chondro-Gide® in the Hip



More than
10 Years of Clinical
Experience

swiss made



Preoperative MRI of the right hip with evidence of a chondrolabral separation and adjacent cartilage damage to the acetabulum. Image courtesy of Dr. Wolfram Steens

Chondral defects in the hip, whether acute or chronic, can cause severe dysfunction and joint pain. Trauma, osteonecrosis, labral tears, and loose bodies are among the many possible causes. In addition, femoralacetabular impingement (FAI) is one of the most common causes of localized cartilage defects and damage requiring hip arthroscopy.[1]

Damaged cartilage has limited capacity to heal itself. If left untreated, the damage can worsen over time. With minimally-invasive arthroscopic treatment approaches for chondral defects in the hip, it is now possible to preserve the hip-joint cartilage and delay or possibly even avoid total hip replacement surgeries[1]. One such treatment approach is AMIC® Chondro-Gide® in the hip.

Correct diagnosis of cartilage defects in the hip is challenging. A patient's medical history can provide pointers to a cartilage defect, if symptoms have persisted for a long time. However, they tend to be heterogeneous in early phases.[2]

The differential diagnosis of cartilage defects in the hip is based on physical examination, followed by radiography and magnetic resonance imaging (MRI). It can be extended to include computed tomography (CT) scans and ultrasonography[1,3]. Arthroscopy is the gold standard when determining the location, size, and depth of the defect and also the surrounding bone and soft tissue, particularly the labrum.

Different classification systems are used to describe the location and grade of the lesion. Haddad combines the anatomical location with the morphological grading of the lesion. The modified classification by Griffin provides a more precise definition of its location.

Debridement and microfracture (MFx) are widely accepted treatments for chondral defects in the hip. Janelli et al. describe debridement as the preferred method for patients with a grade one or two chondral defect. MFx is indicated for focal and contained lesions, typically less than 2 cm^2 in size.[3] AMIC Chondro-Gide is indicated for full-thickness symptomatic grade three or four chondral defects larger than 2 cm^2.[4]

AMIC® for Cartilage Regeneration

Your Challenge

As an orthopedic surgeon today, you face a growing number of treatment challenges. Your patients are living longer, more active lives than previous generations. At the same time, obesity rates are rising. Active patients with cartilage damage expect a quick return to sports. Baby boomers want to stay active as long as possible, and avoid invasive surgical treatments.

With these changes in demographics, mindsets, and lifestyles, finding more regenerative treatment approaches for your patients will be critical in the coming years.

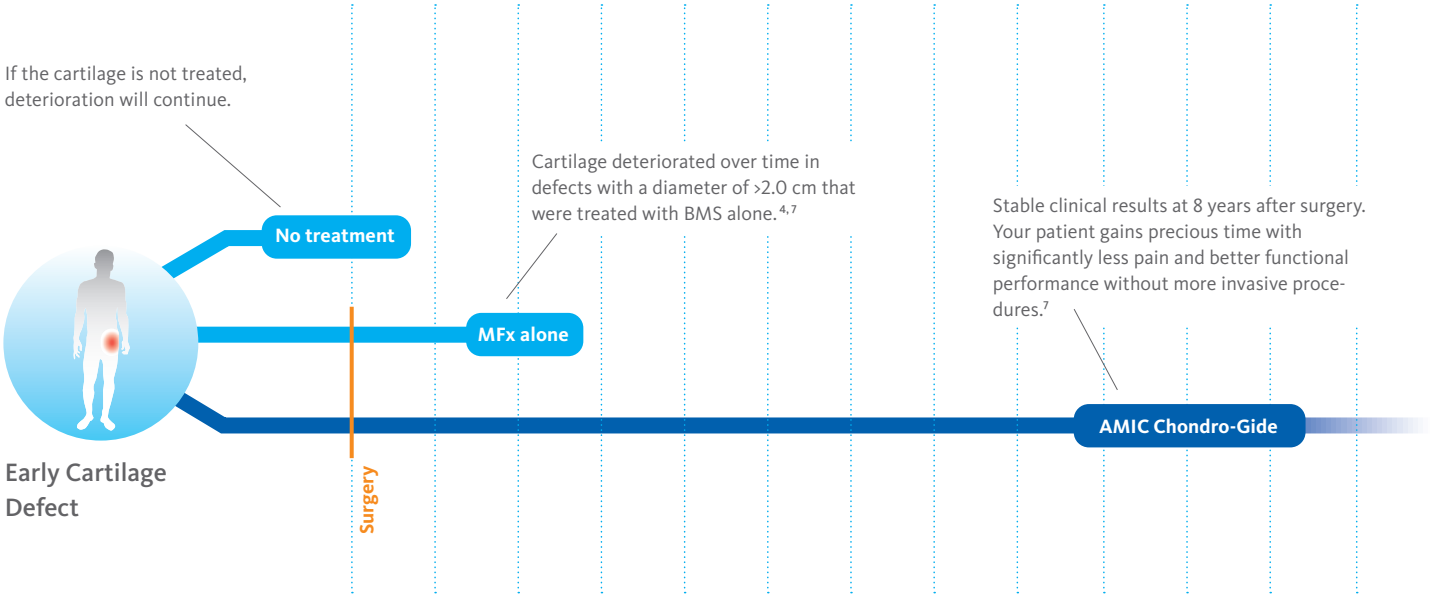
The Solution

Chondro-Gide®, a bio-derived collagen membrane, combined with Autologous Matrix-Induced Chondrogenesis (AMIC®) is a 1-step treatment for repairing cartilage lesions. Developed by Geistlich Surgery in collaboration with leading surgeons, AMIC uses bone marrow stimulation (BMS) in combination with Chondro-Gide to support the body's own healing potential.

Why Chondro-Gide

Backed by more than 10 years of clinical experience[5], AMIC Chondro-Gide is an effective and cost-effective technique[6] for repairing cartilage lesions, alleviating or preventing pain, and slowing the progression of damage.

FIGURE 1: REGENERATION OF CARTILAGE BUYS PRECIOUS TIME



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]

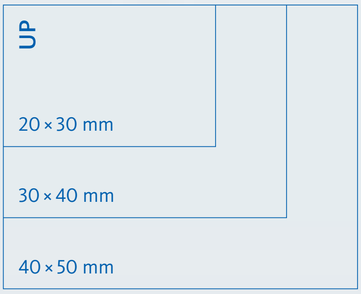
- Bio-derived, bilayer Collagen I/III membrane[10]
- Biocompatible and naturally resorbed[10]
- Easy to handle: supple and tear-resistant[10]
- Can be glued[10]
- Compatible with a range of tissue regeneration techniques[11]
- 1-step procedure[10]

Bioengineered to Leverage the Body's Own Healing Potential

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.[10, 12]

CHONDRO-GIDE IS AVAILABLE IN THREE SIZES

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



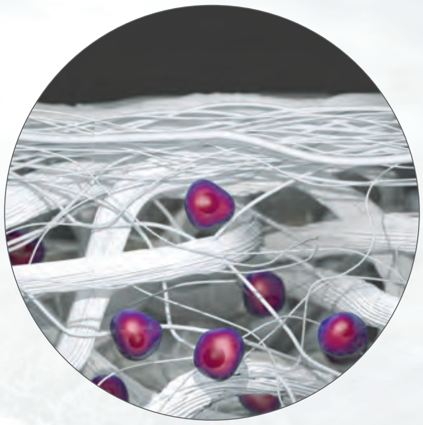
A STERILE ALUMINUM TEMPLATE IS INCLUDED

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

38 × 48 mm

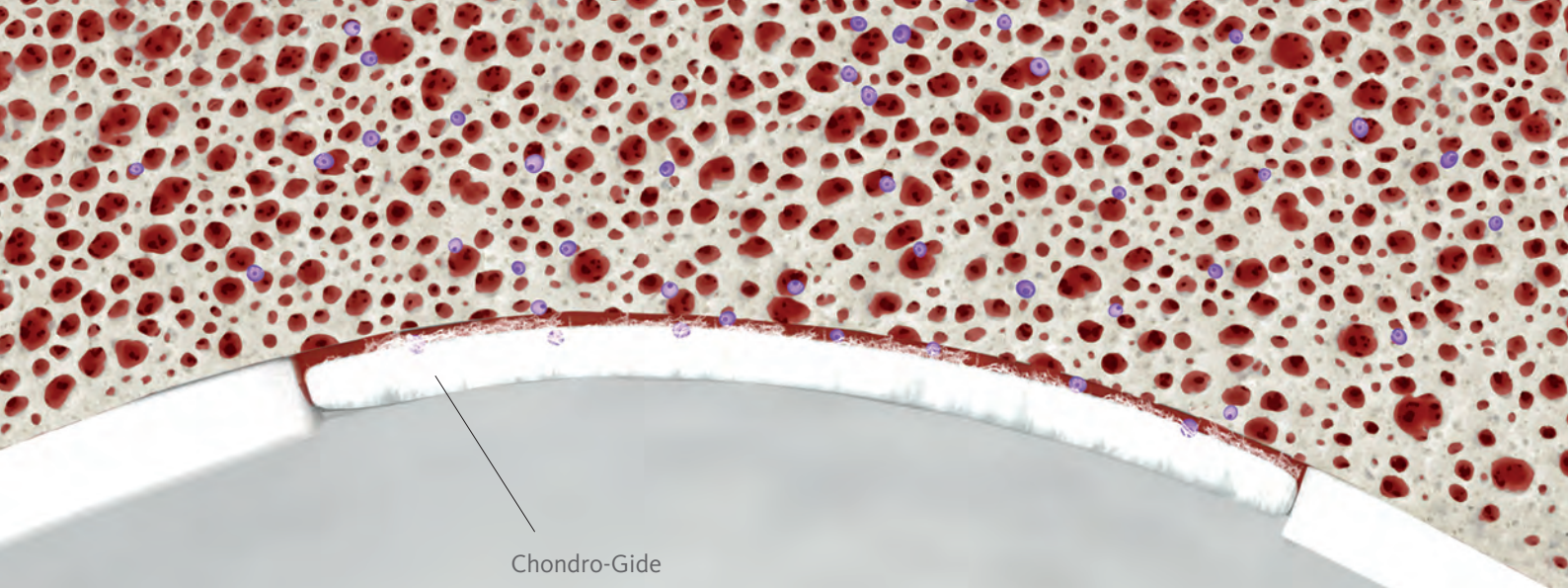
A Barrier to Prevent Cell Diffusion[10, 14]

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[11, 13]



AMIC® Chondro-Gide®

The Benefits of Using AMIC Chondro-Gide

AMIC Chondro-Gide supports the body's own potential to heal itself. Damaged cartilage is removed, and BMS is used to bring regeneration-supporting cells into the defect.

The Chondro-Gide covers the defect and serves as a protective shield that contains the cells and minimizes the impact of shear forces on the delicate superclot. At the same time, it functions as the roof of a biological chamber that forms over the defect. The biocompatible collagen material provides an environment for cell growth[10] and is replaced by native tissue over time.

After MFx alone, fibrous tissue is frequently formed. However, some evidence in the literature shows that after AMIC Chondro-Gide, hyaline-like tissue is formed. Studies show that the reparative fibrous tissue that forms after MFx alone is mechanically inferior to hyaline cartilage and will deteriorate over time.[12]

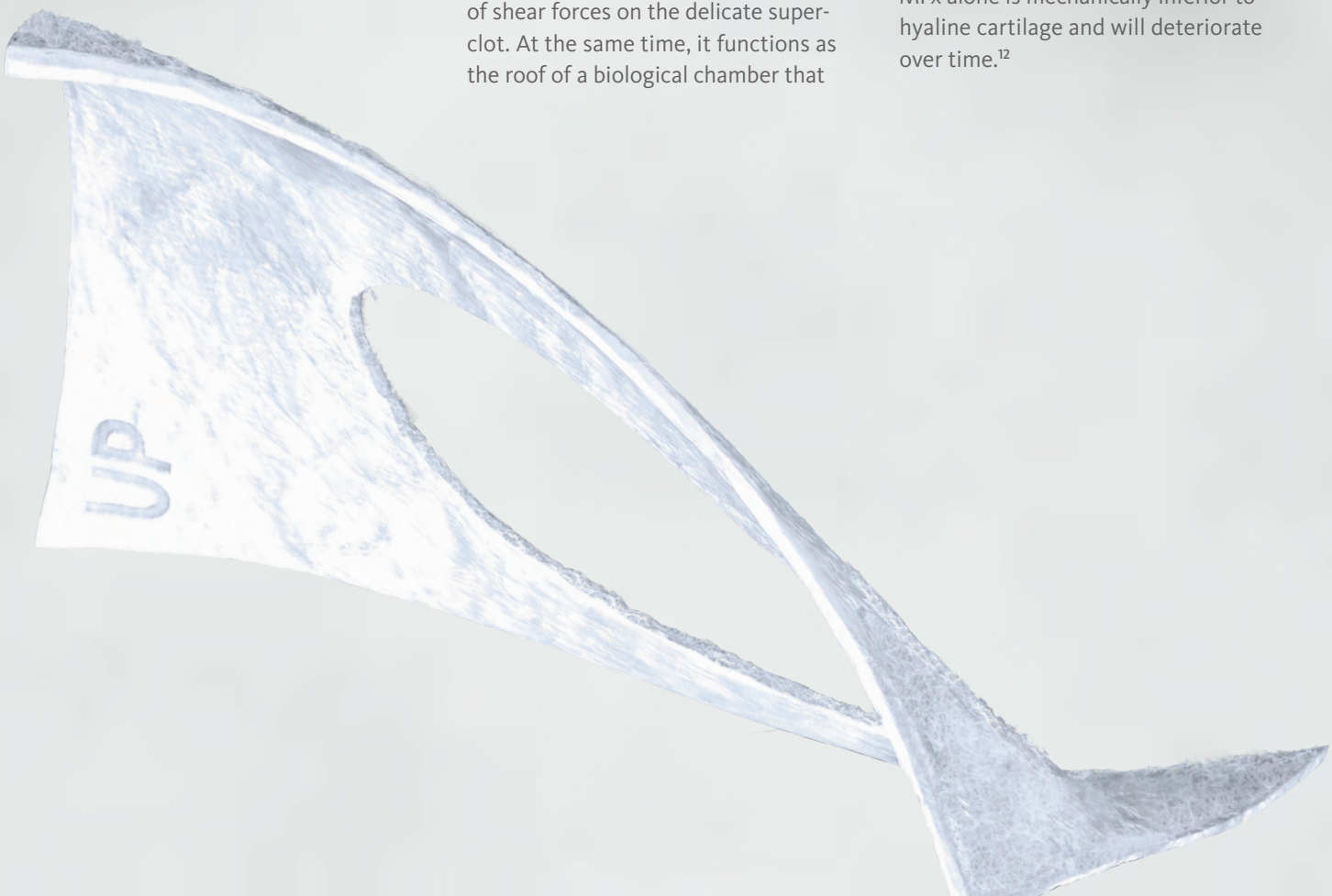
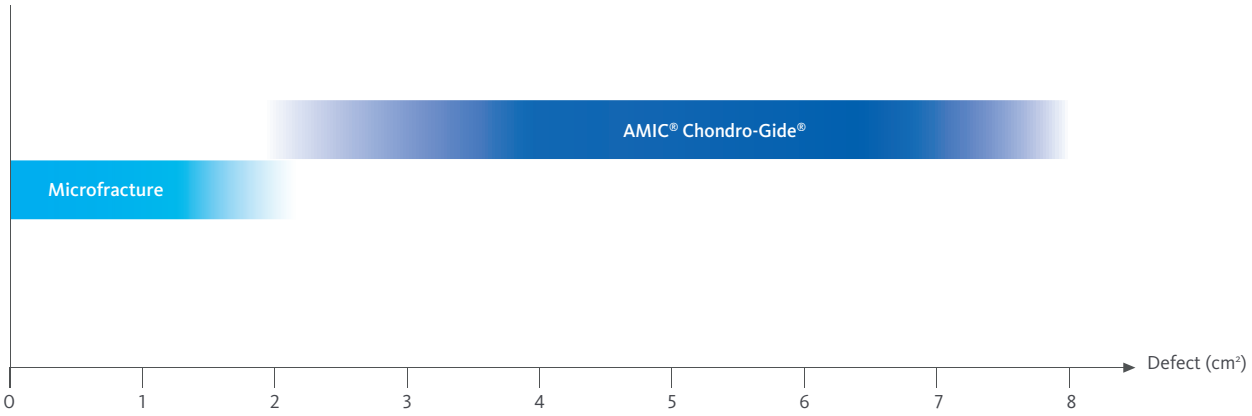


FIGURE 2: INDICATION FOR AMIC CHONDRO-GIDE IN OUTERBRIDGE/ICRS GRADE III/IV DEFECTS



INTENDED USE[15]

Chondro-Gide is used to cover cartilage defects treated with autologous chondrocyte implantation (ACI) or bone marrow stimulation techniques (e.g., AMIC – Autologous Matrix Induced Chondrogenesis) and to cover meniscal or osteochondral defects. Surgical approaches include arthrotomy or arthroscopy. The defects can be acute or chronic and be caused by a fall, accident, or other traumatic events. Defects are located at articular cartilage surfaces including hyaline cartilage in the knee, hip, ankle foot, wrist, elbow, and shoulder; and fibrous cartilage including meniscus.

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LIMITATIONS ON USE / PRECAUTIONS

Contraindications

Chondro-Gide should not be used in patients with:

- a known allergy to porcine collagen
- acute or chronic infection at surgical site
- acute or chronic inflammatory joint disease.

Precautions

- Chondro-Gide should only be used by surgeons, familiar with cartilage and meniscal repair techniques.
- Chondro-Gide should be used with special caution in patients who take medications or have diseases impairing tissue regeneration.
- Chondro-Gide should be used only under standard sterile surgical conditions.
- Use of non-powdered gloves should be considered when preparing and handling Chondro-Gide to prevent transfer of particulate to the surgical site.
- Insufficient fixation of the membrane can lead to its displacement.
- Consistent with clinical practice of cartilage repair, any axial limb malalignment, joint instability or meniscal pathologies should be treated in parallel or prior to the cartilage repair procedure.
- Abstinence from smoking during or after treatment is advised.
- Direct mixing of Chondro-Gide with medicinal products, alcohol, disinfectants or antibiotics is not advisable and has not been studied.
- Intraoperatively, if there is need to remove the product, complete removal can be achieved. In the postoperative phase, complete removal may not be possible since the product is intended to resorb over time
- There is no data available on the use of Chondro-Gide during pregnancy or lactation. For safety reasons, pregnant women and breastfeeding mothers should therefore not be treated with Chondro-Gide.
- The safety and efficacy of Chondro-Gide have not been studied in children.
- The template must not be implanted.
- The product is intended for single patient, single surgery use, the product must not be re-sterilized. Any unused material should be discarded.

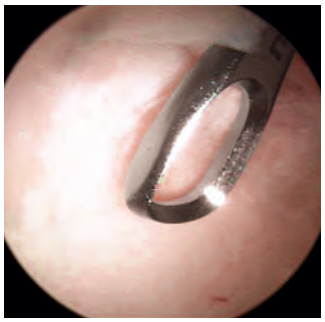
Side Effects

As Chondro-Gide is a collagen product, allergic reactions to collagen may not be totally excluded.

Surgical Technique described by Fontana

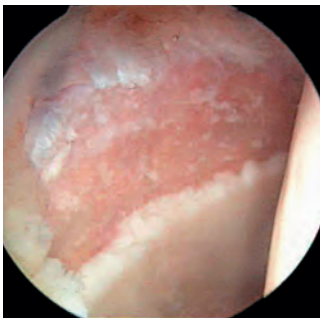
Prior to surgery, during diagnostic arthroscopy, carefully assess the size and classification of the defect. If necessary, carry out concomitant interventions, e.g., treat labral tears, FAIs, cam and pincer impingement or synovial lesions.

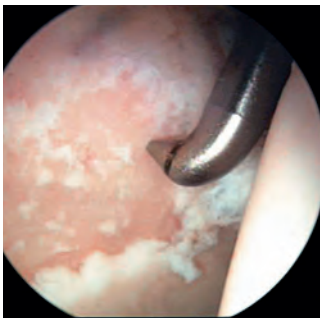
Images courtesy of
Dr. A. Fontana



Prepare the Surgical Site

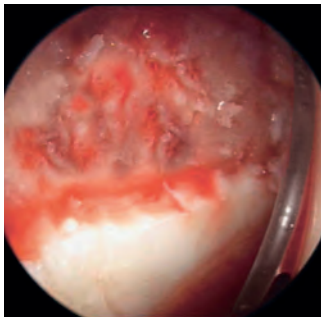
Remove damaged and unstable cartilage using angled curettes or motorized shavers for a well-contained defect.





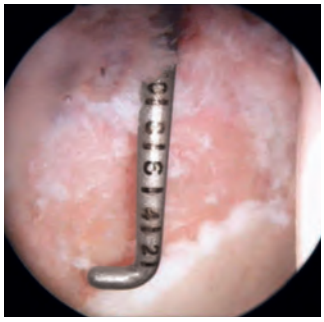
Bone Marrow Stimulation

Use a sharp angled awl to perforate the subchondral bone at the base of the lesion. Start at the periphery of the lesion and then move toward the center at intervals of 4–5 mm. Make sure to penetrate the subchondral bone at a right angle. As an alternative, microabrasion can be performed.



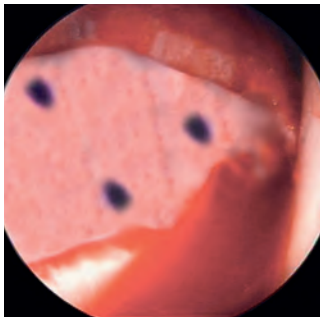
Remove Residual Tissue

Carefully remove residual tissue and check for adequate subchondral bleeding.



Prepare the Chondro-Gide®

Use an arthroscopic probe to measure the defect. When trimming the Chondro-Gide, remember to cut it 10–15% smaller, as the area of the membrane will expand once moistened. If needed, use a sterile pen to lightly mark the smooth (top) layer that will face the joint cavity.



Position the Chondro-Gide

Remove residual fluid from the joint space. Use a grasper and an arthroscopic cannula to place the Chondro-Gide into the defect with the rough (bottom) layer facing the bone surface.

Examine the Repair

Release traction and perform 4–6 extension and rotation movements. Then reapply traction and verify the position of the Chondro-Gide arthroscopically. Use fibrin glue to enhance stability of the membrane

Clinical Summaries

The use of Chondro-Gide® in the hip is well established. Data up to 8 years post-op clearly demonstrates the long-term advantages of AMIC® Chondro-Gide compared to MFx alone in acetabular defects with a size of 2–8 cm².[4,7]

In a study comparing arthroscopic MFx alone with AMIC Chondro-Gide, Fontana et al. investigated 109 patients. Patients with chondral defects in the hip that were associated with FAIs, were treated with AMIC Chondro-Gide or MFx. There was no significant difference in age or the average defect size between the two patient groups.

At baseline

Chondral defects in the hip associated with FAIs, treated with AMIC Chondro-Gide or MFx.
No significant difference in age or the average defect size between the two patient groups

Follow-up after 2 years

All patients showed a significant improvement. After 2 years, the clinical results with AMIC were already better than the results with MFx.

Follow-up after 8 years[7]

Based on Modified Harris Hip Scores (MHHS), AMIC results remained stable and were independent of lesion size. However, the results of the MFx group deteriorated significantly from 2–8 years, showing an increase in hip dysfunction.

No patients in the AMIC group were required to undergo total hip arthroplasty (THA)

11 Patients in the MFx group were required to undergo THA.

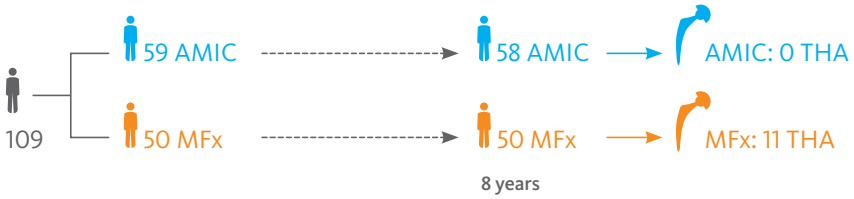
Graph showing mean (95% confidence interval) of the differences in the post- versus pre-operative MHHS for both groups. AMIC patients show significantly better results at 2 years and later ($P < .005$). (AMIC; MHHS.)

A subgroup analysis by lesion size shows significantly better outcomes in the AMIC group for patients with lesions ≥ 4 cm².[7]

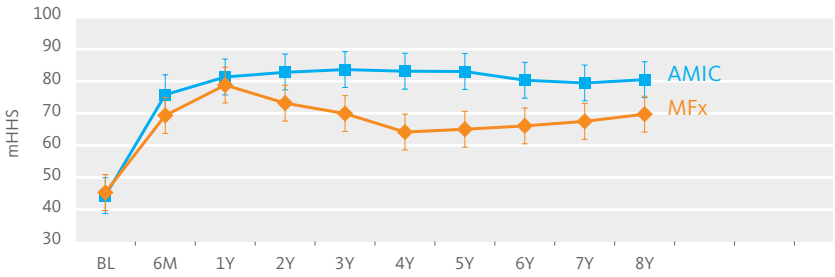
AMIC results remain stable up to 8 years, while MFx results worsen after 2 years Over 8 years, no AMIC patients required further hip procedures. However, 22% of MFx patients needed hip replacement surgeries.

An analysis of the data performed by de Girolamo et al. after 8 years supports the stability of AMIC Chondro-Gide results. The Kaplan Meyer graphs developed by de Girolamo et al., with the endpoint THA for AMIC and MFx show that the value for AMIC remains stable at 100%. However, the survival rate for MFx declines continuously after the first year and reaches 78% after 8 years.[7]

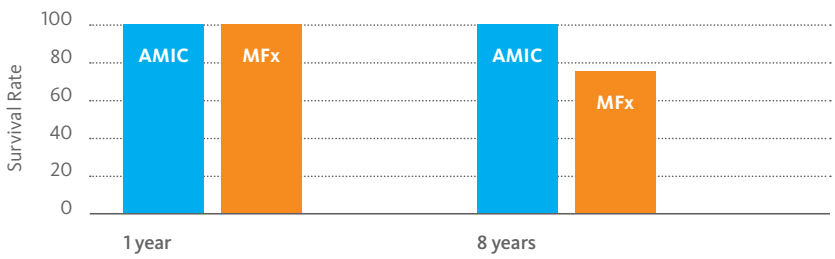
OVER 8 YEARS, NO AMIC PATIENTS REQUIRED FURTHER HIP PROCEDURES. HOWEVER, 22% OF MFX PATIENTS NEEDED HIP REPLACEMENT SURGERIES.



AMIC RESULTS REMAIN STABLE UP TO 8 YEARS, WHILE MFX RESULTS WORSEN AFTER 2 YEARS



SURIVIVAL RATE WITH AMIC REMAINS STABLE AFTER 1 YEAR, WHILE RATE WITH MFX ALONE DECLINES CONTINUOUSLY



A study by Mancini and Fontana compared the outcome of AMIC Chondro-Gide and matrix-induced autologous chondrocyte implantation (MACI) techniques for the treatment of ace-tabular chondral defects between 2 and 4 cm^2 caused by FAI. Patients were monitored up to 5 years post-op. Both groups demonstrated significant hip score improvements 6 months post-op.[16]

The MHHS continued to improve up to 3 years post-op and remained stable until the final follow-up at 5 years post-op. There were no significant differences between the groups. Both AMIC and MACI were evaluated as valid procedures for the repair of medium-sized chondral defects. AMIC offers additional benefits as a 1-step, minimally-invasive procedure that can reduce total treatment time and minimize morbidity. AMIC and MACI shown to be equally successful for treatment of medium-sized defects.

Follow-up Treatment

Thrombosis prophylaxis with low molecular weight heparin is recommended until full weight-bearing is achieved.

Non-steroidal anti-inflammatory drugs can be administered as analgesics.

	1 D	2 D to < 4 W	4 W to 6 M	6 M to < 1 Y	1 Y
Weight-bearing	› None	› None	› Partial load bearing up to 7 weeks; afterwards, full	› Full	› Full
Mobilization	› Continuous passive motion at 60° of hip flexion	› Regain step-wise full range of motion	› No restriction	› No restriction	› No restriction
Physiotherapy and Sports	› No sporting activities › Isotonic and isometric quadriceps exercises	› No sporting activities › Active and passive physiotherapy	› Light sporting activities (e. g. swimming and cycling)	› Jogging	› Full

D=Day, W=week, M=month
Source: Dr. A. Fontana, Como, Italy

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.

1 MARQUEZ-LARA, A. et al., 2016, Arthroscopic Management of Hip Chondral Defects: A Systematic Review of the Literature. Arthroscopy: The Journal of Arthroscopic & Related Surgery. 2016. Vol. 32, no. 7, p. 1435-1443. DOI 10.1016/j.arthro.2016.01.058. Elsevier BV (Review).

2 FICKERT, S. et al., 2017, Biologic Reconstruction of Full Sized Cartilage Defects of the Hip: A Guideline from the DGOU Group "Clinical Tissue Regeneration" and the Hip Committee of the AGA. Zeitschrift für Orthopädie und Unfallchirurgie. 2017. Vol. 155, no. 06, p. 670-682. DOI 10.1055/s-0043-116218. Georg Thieme Verlag KG (Guideline).

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4 FONTANA, A. and DE GIROLAMO, L., 2015, Sustained 5-year benefit of autologous matrix-induced chondrogenesis for femoral acetabular impingement-induced chondral lesions compared with microfracture treatment. The Bone & Joint Journal. 2015. Vol. 97-B, no. 5, p. 628-635. DOI 10.1302/0301-620x.97b5.35076. British Editorial Society of Bone & Joint Surgery (Clinical study).

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9 GOTTSCHALK, O., et al., 2017, Functional Medium-Term Results After Autologous Matrix-Induced Chondrogenesis for Osteochondral Lesions of the Talus: A 5-Year Prospective Cohort Study. The Journal of Foot and Ankle Surgery. 2017. Vol. 56, no. 5, p. 930-936. DOI 10.1053/j.jfas.2017.05.002. Elsevier BV (Clinical study).

10 Data on file at Geistlich Pharma AG (Pre-clinical study), Wolhusen, Switzerland.

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

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

14 MUMME, M., 2016, 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).

15 Chondro-Gide® IFU 2019, Geistlich Pharma AG.

16 MANCINI, D., and FONTANA, A., 2014, Five-year results of arthroscopic techniques for the treatment of acetabular chondral lesions in femoroacetabular impingement. International Orthopaedics. 2014. Vol. 38, no. 10, p. 2057-2064. DOI 10.1007/s00264-014-2403-1. Springer Science and Business Media LLC (Clinical study).

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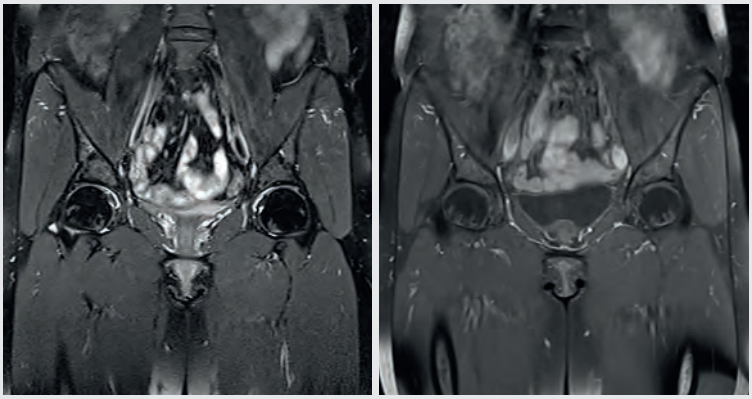
swiss made

More than 10 Years Clinical Experience in the Hip



Follow-up 31 months postoperatively shows acetabular healing of the cartilage damage treated with labral fixation and AMIC Chondro-Gide. Images courtesy of Dr. Wolfram Steens

To start using AMIC® Chondro-Gide® to alleviate or prevent patient pain and slow the progression of cartilage damage, contact your local Geistlich representative.