Geistlich Surgery

# AMIC® Chondro-Gide® U.S. PIVOTAL STUDY

## CALL FOR STUDY SITES

# SECURE

A ProSpective, MulticEnter, Concurrently Controlled Clinical Study of Chondro-Gide ArticUlar Cartilage CoveR for the Treatment of Large Chondral Lesions in the KnEe

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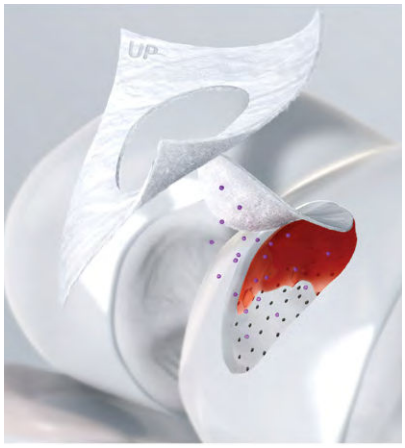
With more than 80 peer reviewed publications, the Geistlich AMIC® Chondro-Gide® for the knee is the most widely published product in its category. AMIC®, or Autologous Matrix-Induced Chondrogenesis, performed in conjunction with Chondro-Gide®, a bioderived collagen membrane, is a 1-step treatment for repairing cartilage lesions.

Geistlich Surgery is now pleased to announce the SECURE study, a pivotal trial that will be conducted to secure regulatory clearance/approval in the United States. Geistlich Surgery is actively recruiting qualified clinical study sites to participate in this ground breaking initiative!

Read on to learn more.




## What is the SECURE Study?

**A ProSpective, MulticEnter, Concurrently Controlled Clinical Study of Chondro-Gide® ArticUlar Cartilage CoveR for the Treatment of Large Chondral Lesions in the KnEe (SECURE)**

| | |
|---|---|
| **Study Design Objective** | Multi-center, prospective, concurrently controlled, non-randomized, double-blind (patient and assessor) Assess the benefit / risk profile of the Chondro-Gide® Articular Cartilage Cover for treating large ($\geq$ 3 cm$^2$ and $<$ 8 cm$^2$) chondral lesions of the knee in comparison to the benefit / risk profile of microfracture alone for treating small ($<$ 3 cm$^2$) chondral lesions |
| **Study Duration** | Up to 36 months of recruitment, plus an additional 24 months of follow-up for a total of up to 60 months |
| **Primary Endpoint** | The primary endpoint will be the proportion of patients achieving composite clinical success (CCS) at 24 months follow-up, with CCS defined as a patient meeting all of the three following criteria:<br>1. Improvement in the Pain sub-scale of the Knee Injury and Osteoarthritis Outcomes Score (KOOS) of at least 11.1 points from baseline to 24 months follow-up<br>2. Improvement in function, defined as an improvement in the International Knee Documentation Committee (IKDC) score of at least 12.6 points, from baseline to 24 months follow-up<br>3. Freedom from device- or procedure-related serious adverse events (SAEs) |
| **Technique** | Arthroscopic or mini-open techniques allowed |

## What Does the Evidence Say?

| Publication Title | Authors | Journal | Conclusions |
|---|---|---|---|
| Systematic Review and Meta-Analysis of the Clinical Evidence on the Use of Autologous Matrix-Induced Chondrogenesis in the Knee | Matthias R. Steinwachs, Justus Gille, Martin Volz, Sven Anders, Roland Jakob, Laura De Giromlamo, Piero Volpi, Alfredo Schieavone-Panni, Sven Scheffler, Eric Reiss, Udo Wittmann | Cartilage 2019 | "According to this review, Chondro-Gide® is by far the most used membrane for enhanced MFx procedures having also the longest and most documented safe and efficient evidence concerning the clinical follow-up". |
| Collagen-Covered Autologous Chondrocyte Implantation Versus Autologous Matrix-Induced Chondrogenesis: A Randomized Trial Comparing 2 Methods for Repair of Cartilage Defects of the Knee | Vegard Fossum MD, Ann Kristin Hansen, MD, PhD, Tom Wilsgaard, Prof. Gunnar Knutsen, MD, PhD | Orthopaedic Journal of Sports Medicine, Volume 7, Issue 9, 17 September 2019 | "This RCT comparing ACI-C and AMIC® as a treatment for cartilage defects of the knee indicated that the 2 treatments result in similar clinical outcomes at 2-year follow-up. If the conclusion of the present study stands and is confirmed by further clinical trials, AMIC® could be considered an equal alternative to techniques based on chondrocyte transplantation for treatment of cartilage defects of the knee. If considering the AMIC® is a less expensive 1-step procedure, one could even argue that AMIC® should be preferred." |
| A randomized controlled trial demonstrating sustained benefit of Autologous Matrix-Induced Chondrogenesis over microfracture at five years | Martin Volz, Jens Schaumburger, Hubert Frick, Joachim Grifka, Sven Anders | International Orthopaedics, 2017 41:797-804 | At five years significant higher improvement and stable results over time in the AMIC® group. Decline of improvement seen in the MFx group after two years. |
| A Randomized, Controlled Trial Comparing Autologous Matrix-Induced Chondrogenesis (AMIC) to Microfracture: Analysis of 1- and 2-Year Follow-Up Data of 2 Centers | Sven Anders, Martin Volz, J. Gellissen | Open Orthop J, 2013, 7: p. 133-43 | This interim analysis confirms the mid-term results for AMIC® reported in literature. It demonstrates clearly that clinical outcomes at 1-year post-operation are maintained at 2-years. Therefore we consider enhancing MFx with Chondro-Gide® is a valid and safe cartilage repair option for small- to medium-sized cartilage defects of the knee. |
| Mid-term results of Autologous Matrix-Induced Chondrogenesis for treatment of focal cartilage defects in the knee. | Gille J, Schuseil E, Wimmer J, Gellissen J, Schulz AP, Behrens P | Knee Surgery Sports Traumatology Arthroscopy, 010 Nov;18(11):1456-64. doi: 10.1007/ S00167-010-1042-3. Epub 2010 Feb 2 | Significant improvement ($P < 0.05$) of all scores was observed as early as 12 months after AMIC®, and further increased values were notable up to 24 months postoperatively. MRI analysis showed moderate to complete filling with a normal to incidentally hyperintense signal in most cases. |

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## What is required of a clinical study site?

- Investigator must be willing to perform microfracture (or microfracture plus Chondro-Gide® Articular Cartilage Cover) on subjects with post-debridement chondral lesions with defect sizes <3 $cm^2$ (and ≥3 $cm^2$ - <8 $cm^2$).
- Investigator must have an adequate patient population in order to meet enrollment goals for the study.
- Investigator must have appropriately trained site personnel to support the conduct of a FDA-regulated study.

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**Interested in Learning More?**
**Please email us at:**

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