

AMIC[®] Chondro-Gide[®]
U.S. PIVOTAL STUDY

CALL FOR STUDY SITES

SECURE

A ProSpective, MulticEnter, Concurrently
Controlled Clinical Study of Chondro-Gide
ArticUlar Cartilage CoverR 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 ($\geq 3 \text{ cm}^2$ and $< 8 \text{ cm}^2$) chondral lesions of the knee in comparison to the benefit / risk profile of microfracture alone for treating small ($< 3 \text{ cm}^2$) 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: <ol style="list-style-type: none">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-up2. 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-up3. 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.

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 $<3 \text{ cm}^2$ (and $\geq 3 \text{ cm}^2 - <8 \text{ cm}^2$).
- 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:

SECURE@telospartnersllc.com