

CMI™

a new technique for the treatment of meniscus injuries



The CMI™ collagen meniscus implant has been renamed Menaflex™. All CMI references throughout this brochure can be replaced with Menaflex.



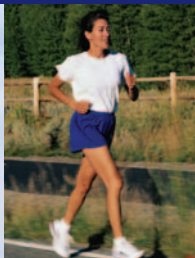
What is the CMI?

Why use the CMI?

Is the CMI procedure arthroscopic?

What are the rehabilitation and recovery times?

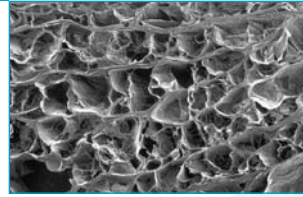
What is the clinical benefit to the patient?



REGENERATING TISSUE | RESTORING MOBILITY | REJUVENATING LIFESTYLES

A Proven SAFE and EFFECTIVE NEW TREATMENT for MENISCUS Injuries

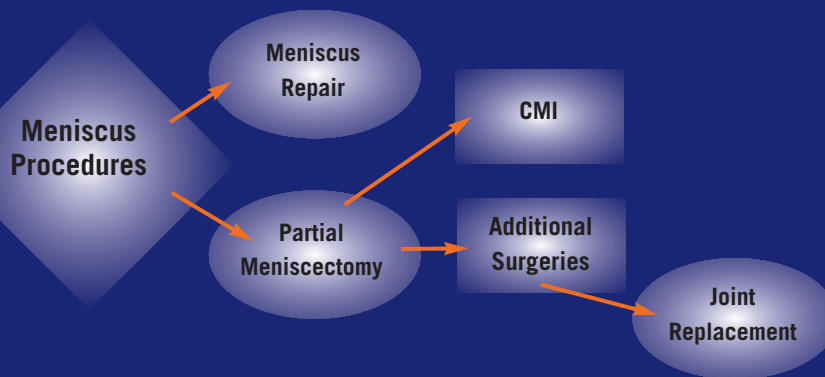
The ReGen® CMI™ is a Type I collagen device designed to guide new tissue growth using the body's own healing process in patients with an irreparable meniscus tear or loss of meniscus tissue.



The CMI provides a resorbable Type I collagen scaffold for the growth of new tissue in the meniscus.

A Proven New Technique

Approximately 85% of all meniscus procedures involve a partial meniscectomy. The CMI can be inserted during this surgery to provide a matrix for the growth of new tissue. Use of the CMI produces positive patient results and can reduce the need for additional surgeries or replacement procedures.



Why Use the CMI

The CMI assists patients in returning to a more active lifestyle. The new technique helps generate new tissue and the additional tissue may delay or prevent development of degenerative joint disease. Partial meniscectomy is the most commonly performed arthroscopic procedure. The CMI provides the surgeon with an additional surgical option for patients who undergo a partial meniscectomy and lose their beneficial meniscus tissue. The CMI:

- Supports growth of new tissue;
- Increases patient activity level;
- Decreases pain per unit of activity;
- May delay/prevent development of degenerative joint disease by introducing new tissue.

When to Use the CMI

Indications:

- Irreparable injury or previous loss of meniscus tissue which extends to at least the red-white zone
- Intact meniscus rim
- Intact chondral surfaces

Contraindications:

- Total meniscus loss
- Advanced arthritis with full thickness articular cartilage loss
- Axial malalignment of the involved knee
- Repairable meniscus tear

"The unique feature of the CMI is the fact that it gives the possibility to the patient to regrow his own meniscus-like tissue. After reviewing the clinical, radiological and anatomical results, I am convinced that the implant is a big step forward in reconstructive knee surgery."

*—Dr. Koen Lagae,
Antwerp, Belgium*

Arthroscopic Surgical Procedure

Complexity Similar to Meniscus Repair or ACL Reconstruction

The primary surgical steps include:

1. Routine Diagnostic Arthroscopy –
Confirm the extent of injury and appropriateness of CMI procedure.



2. Meniscus Preparation –
Remove only the damaged tissue.



3. Measuring the Defect and CMI Preparation – Measure the defect length; trim the CMI to the correct length using standard surgical scissors.



4. CMI Placement in the Joint –
Correctly place the CMI in position.



5. Suturing the CMI – Preferably use inside-out technique with ReGen's SharpShooter® system.



Standard Recovery Time:

- Similar to recovery time for a complex meniscus repair or for an ACL reconstruction.
 - Protected weight bearing, limited motion, and gradual increase in activity.
- Structured rehabilitation program followed for six months, and then unrestricted activity.

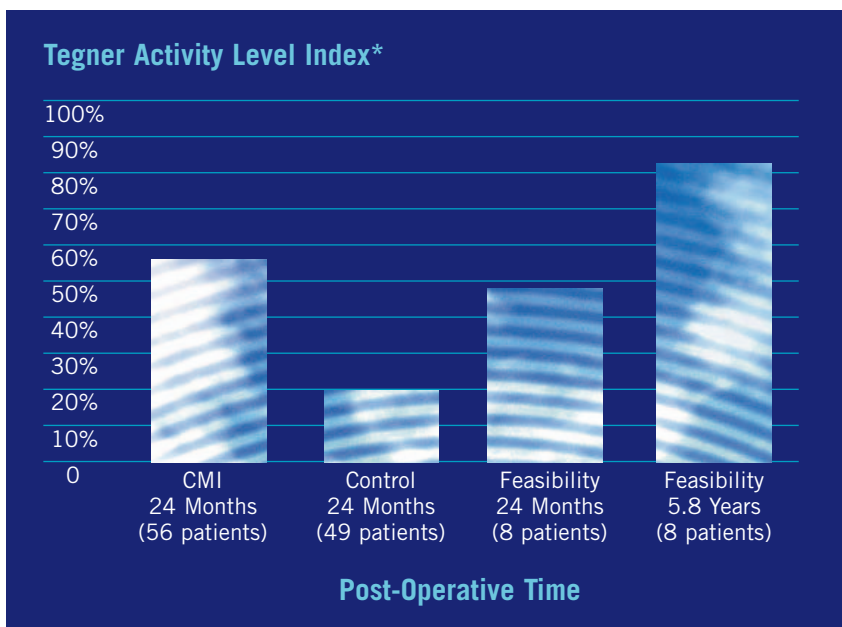
Clinical Studies Support the Use of the CMI

The CMI has been the subject of international and U.S. clinical studies to investigate its safety and effectiveness.

The results show that the CMI supports growth of new tissue and CMI patients* regain a higher level of activity than control patients.

CMI Patients Have More Tissue

Results show that using the CMI after a partial meniscectomy, patients* double the amount of meniscus tissue.



CMI Patients Are More Active

At 24 months, CMI patients* regained significantly more lost activity than the control patients. In the Feasibility Study, the patients regained 50% of lost pre-injury activity levels two years post-surgery and 80% at five years post-surgery.

CMI Patients Are More Satisfied

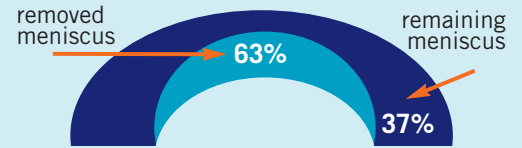
CMI patients* reported higher levels of satisfaction compared to control patients. After two years, 70% (n=70) of CMI patients were satisfied or very satisfied compared to 50% (n=63) for the control group.

CMI Is Safe

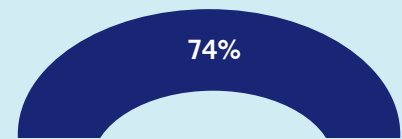
As with any surgery, there are risks associated with the CMI procedure. However, based on extensive controlled studies in the U.S. and Europe, the safety of the CMI was established by the lack of clinically significant complications. There have been no documented incidents of immune or allergic reactions to the CMI.

Patients have double the tissue volume with the CMI*

U.S. Clinical Trial: Post Partial Meniscectomy (n=75)



Post CMI (one year re-look arthroscopy)



74% of meniscus volume regained with the CMI by 1 year

Clinical Outcomes

European Study (93 patients)

- Surgeons and patients positive about CMI outcomes.
- One year: CMI patients showed a significant improvement in average values for pain and function.
- CE mark issued.

U.S. Feasibility Study (8 patients)

- One year: double the tissue as measured by the re-look arthroscopy.
- Two years: CMI patients return to 50% pre-injury activity levels (published).
- Five years: CMI patients return to 80% of pre-injury activity levels, and the amount of meniscus tissue remained largely unchanged as measured by an additional re-look arthroscopy (published).

U.S. Multicenter Clinical Trial (300+ patients)¹

- Included 162 patients (1:1 control) who had undergone from one to three prior partial meniscectomy surgeries.
- One year: double the tissue as measured by the re-look arthroscopy.
- Two years: CMI patients return to almost 60% pre-injury activity levels, three times the level of control patients, and CMI patients are more satisfied than control patients.

* CMI patients who had undergone one to three prior partial meniscectomy surgeries.
The clinical studies support the usage of the CMI.

References

Clinical Benefits of the CMI

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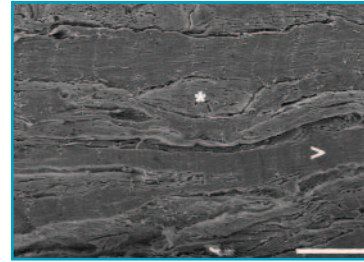
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Scanning electron microscopy of a CMI biopsy 7 months after implantation.

The multilamellar structure of the implant scaffold (▶) has been invaded by newly synthesised connective tissue (*) (Bar = 50 µm).

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Basic Science and Background Information of the CMI

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¹ The information contained in this brochure regarding the U.S. Multicenter Trial is part of an ongoing clinical trial that is not yet complete. The data was current on the date the brochure was printed. However, additional analyses may have been conducted after that date. To obtain the most current information on clinical outcomes, please visit www.regenbio.com or contact ReGen Biologics.