

CMITM

Meniscus Implant

**Replacing
Lost
Meniscus Tissue**



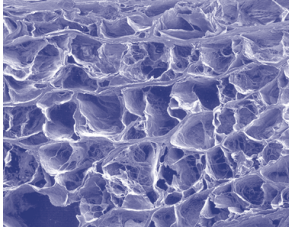
Patient Information



REGEN
Biologics

Contents:

The Knee Joint	3
What is the Function of the Meniscus?	4
Meniscal Injury and Treatment	5
How does the CMI work?	7
Clinical Experience with CMI	8
Chances of Success and Follow-Up Treatment	9
Who should receive CMI-Therapy?	10



Porous Structure of the CMI
(Microscopy of Cross-Section)



The Knee Joint



The knee joint is the largest and most heavily loaded joint in the body. It connects the upper leg with the lower leg and transfers the entire weight of the body to the lower leg.

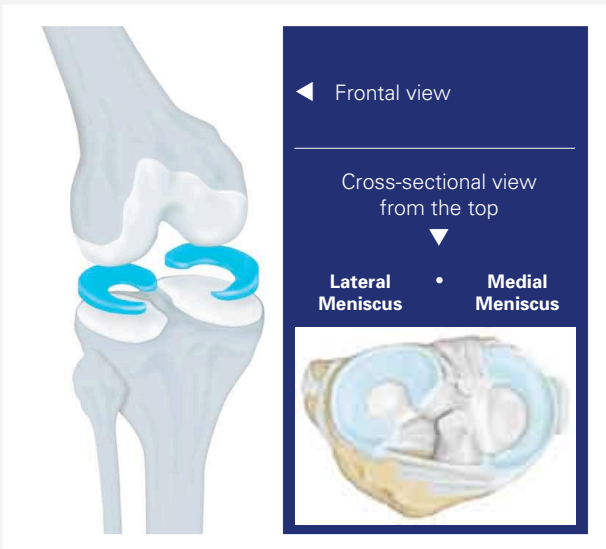
Especially during sports activities involving rotational and transverse movements, strong forces act on the knee joint. This often leads to excessive strain and painful injury to the knee structures, in particular the cruciate ligaments, cartilage surfaces, and menisci. Very often there is combined ligament and meniscus damage. Given that this type of injury leads to an unstable knee and excessive wear and tear of the joint, earliest possible surgical stabilization is essential.

What is the Function of the Meniscus?

The menisci are two crescent-shaped disks consisting of fibrous cartilage located in the knee joint between the femur and the tibia. There is a medial and a lateral meniscus.

The menisci play an important role in knee function. In particular, they transfer the load from the upper to the lower leg and stabilize the knee during bending, stretching and torsional movements. In addition, the menisci distribute the load on the articular surfaces, act as shock absorbers, and help lubricate and nourish the knee joint.

In view of these important functions it makes good sense to keep the menisci intact for as long as possible.



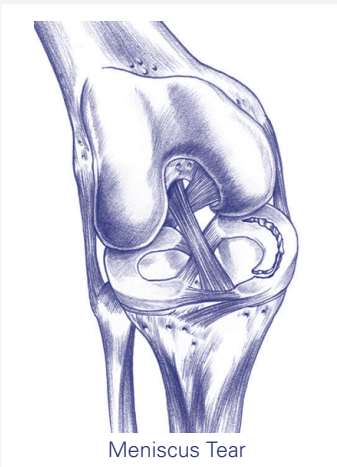
Meniscal Injury and its Treatment

Along with ligament and cartilage damage, meniscal injuries often result from sports accidents, causing pain in the knee joint.

Today, nearly all knee injuries can be treated by a minimally invasive approach. For such arthroscopic surgery, a miniature camera is introduced in the knee joint through a small skin incision, permitting examination of the affected knee. The surgery itself is then performed through 1–2 additional small access openings allowing insertion of surgical instruments and, if necessary, implants for repairing the injured structures. These surgical procedures are generally very well tolerated by the patient. Arthroscopic treatment of meniscal damage is an established surgical procedure performed in many orthopaedic clinics and surgical centres.

Often meniscus tears located in the periphery of the meniscus can be repaired using arthroscopic suture systems. The repaired area heals and an intact meniscus is formed typically consisting of fibrous cartilage tissue. However, frequently the injuries are such that suturing the tears is not possible because they are

located in the non-vascularised part of the meniscus or the tissue is destroyed beyond repair. In this case, partial removal of the tissue is unavoidable.

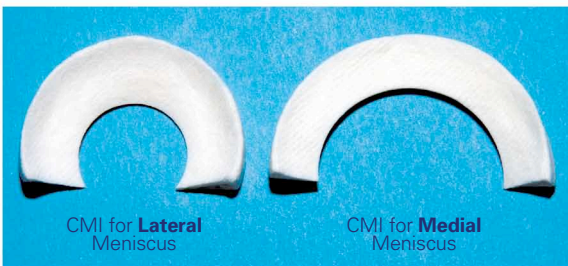


Meniscus Tear

Studies have revealed that even partial removal of the meniscal tissue can increase cartilage stresses and lead to degenerative changes of the articular surfaces. These likely result in osteoarthritis of the knee associated with considerable pain and loss of motion. Due to the irreparable nature of osteoarthritis, many patients whose meniscus was removed may eventually need an artificial knee joint.

To delay or prevent the later consequences of partial meniscectomy, an international team including the well-known American sports physician Dr. Richard Steadman has developed a biological implant that supports growth of new meniscus-like tissue filling the defect.

Dr. J. Richard Steadman
(Vail/Colorado)



The Meniscus Implant – how does it work?

The CMI is a biological, resorbable implant with a spongy texture consisting of a highly purified collagen. Its shape adapts to the human medial and lateral meniscus. The implant is arthroscopically sutured into the defect to replace the lost or removed meniscus tissue. It then uses the body's own healing capacity to regenerate tissue. The porous structure of the implant serves as a guide for the ingrowth of new tissue.

The body's own cells progressively migrate into the implant and build up meniscus-like tissue. After about one year the CMI is largely resorbed and has been replaced by new native tissue.



(Arthroscopic images)

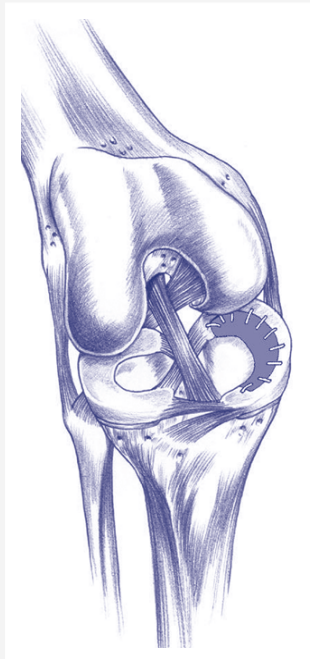
Courtesy of Dirk Holsten, MD (Koblenz)

Clinical Experience with CMI

The results of clinical studies conducted in the U.S. and Europe prove that CMI supports the growth of new tissue. Patients have reduced pain significantly and regain an activity level comparable to that before the injury.

The first CMI procedures were performed in US patients in 1993 as part of a feasibility study. The good results led to multicenter studies started in 1997 in the U.S. and Europe. In the year 2000, the positive results in Europe resulted in the CE certification for the medial implant. Subsequently, the CMI has also been approved in Europe for the lateral meniscus and is now in clinical use.

The American multicenter study with more than 300 patients demonstrated the benefits of CMI treatment in terms of tissue regeneration and improved attainment of pre-injury activity levels. Patients with chronic meniscus injuries experienced an improvement in activity levels over the partial meniscectomy control patients while experiencing an equivalent level of pain. While not statistically significant, these same patients had a higher level of satisfaction over the partial meniscectomy patients. The average time required for a CMI implantation procedure compares to that for conventional meniscus repair.



Medial CMI Sutured in Place

Treatment Success and Follow-Up

To date, more than 1,700 patients worldwide have successfully undergone the CMI procedure. These were primarily people to whom regaining their sports activity was of great importance. In about 90 % of the CMI patients, the desired treatment success has manifested itself by new tissue growth within the meniscal defect. After the CMI procedure, these patients have on average regained over 70 % of their original meniscus tissue volume.*

The CMI is a temporary biological implant consisting of a soft collagen structure which becomes stronger as the body's own cells grow into it. To maximize the success of this regenerative method it is extremely important that patients understand and follow the recommended rehabilitation program especially during the first months after CMI implantation.

The rehabilitation program extends over a total of 6 months. Initially, weight-bearing and range of motion must be increased gradually. Typically, after two months full weight-bearing and full range of motion of the affected knee is possible and the patient can start with specific training to return to usual sports activities. However, a sedentary activity – such as office work – can be resumed as early as the first few weeks after the operation if approved by the treating surgeon. It is important to remember that the newly regenerated tissue is undergoing a maturation process, so that even without pain, the tissue is still weak and should not be exposed to excessive stresses.

Strict adherence to the recommended rehabilitation program is of utmost importance for a successful treatment, ultimately manifested by the formation of the body's own, stable, meniscus-like tissue. Return to previously performed sports activities will be possible after about 6 months.

* Result of the randomized US multicenter trial involving more than 300 patients.

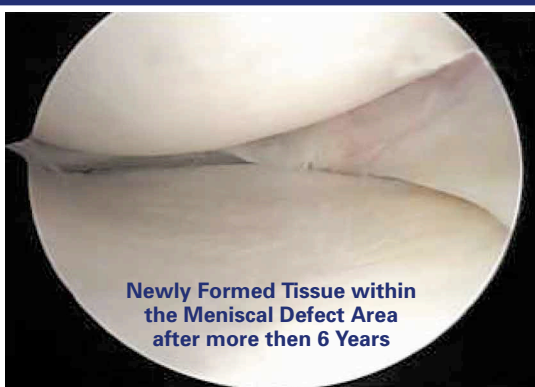
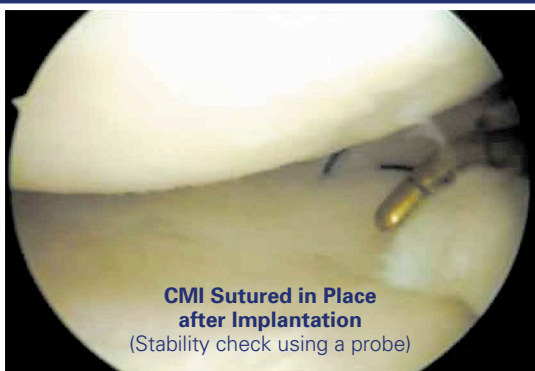
Who should receive CMI Therapy?

Today, a CMI implant is the only biological method to replace lost or damaged meniscal tissue and to restore, where possible, the normal function of the meniscus.

For the success of the treatment it is critically important for the patient to follow the specific rehabilitation program. Additional medical requirements include the following:

- The meniscus injury involved cannot be treated by any other method.
- Implant suturing requires an intact meniscus rim and stable meniscus ends.
- The amount of damaged tissue must be greater than 25% of the total meniscus tissue and extend at least into the red-white zone.
- No advanced degeneration of the articular surfaces should be present
- Axial malalignment of the involved knee must be corrected prior to the CMI implantation.
- No ligamentous instability.
- The patient is motivated and will follow the recommended rehabilitation program.

Arthroscopic Images of a CMI Patient:



Courtesy of Richard Steadman, MD (Vail, Colorado)

Additional information and an overview
of scientific literature can be found at

www.regenbio.com

Distributed by:

ReGen Biologics AG

Intl. Marketing & Sales Office

Zugerstrasse 72

CH-6340 Baar

Switzerland

Manufactured by:

ReGen Biologics, Inc.

545 Penobscot Drive

Redwood City, CA 94063

USA

Presented to you by your Medical Specialist:

