

CMI™

SURGICAL TECHNIQUE - LATERAL



 **Menaflex™**
COLLAGEN MENISCUS IMPLANT

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



REGENERATING TISSUE | RESTORING MOBILITY | REJUVENATING LIFESTYLES

INTRODUCTION

As for any operative procedure, implantation of the ReGen® CMI™ implant functions best if the surgical procedure is done carefully and correctly. The recommended surgical procedure for the CMI requires that the surgeon be proficient with meniscus suturing techniques. ReGen *Biologics* attaches great importance to providing thorough training for every surgeon on both the handling and the implantation of the CMI.

Indications and Contraindications, Warnings and Precautions

Indications:

- Prior loss of lateral meniscus tissue.
- Irreparable lateral meniscus tears requiring partial meniscectomy.
- Either traumatic or chronic posttraumatic lateral meniscus tear.
- Lateral meniscus damage requiring greater than 25% removal.
- Intact anterior and posterior attachments of the lateral meniscus.
- Intact rim over the entire circumference (except for the area of popliteal hiatus) of the involved lateral meniscus.
- ACL deficiencies corrected within 12 weeks of CMI surgery.
- Patients willing to follow post-operative rehabilitation program.
- Patients should be capable of understanding and following the doctor's instructions.

Contraindications:

- Concomitant PCL insufficiency of the involved knee.
- Diagnosis of untreatable grade IV degenerative cartilage disease in the affected joint.
- Uncorrected malformations, axial malalignment of the involved knee.
- Documented allergy to collagen of animal origin.
- Documented allergy to chondroitin sulfate of animal origin.
- Systemic or local infection.
- History of anaphylactoid reaction.
- Systemic administration of any type of corticosteroid, antineoplastics, immunostimulating or immunosuppressive agents within 30 days of surgery.
- Evidence of osteonecrosis in the involved knee.
- Medical history that is positive for, but not restricted to, the following diseases:
 - Rheumatoid arthritis.
 - Relapsing polychondritis.
 - Severe degenerative osteoarthritis.
 - Inflammatory arthritis.
- General neurological abnormalities or neurological conditions that tend to pre-empt the patient's mental ability or willingness to fulfill the requirements of the rehabilitation program.

For precautions and warnings refer to the package insert.

Overview of Implant and Instruments Required for the Lateral CMI Procedure:

Lateral CMI



Measuring Rod



Measuring Cannula



Delivery Clamp



Meniscus Suturing System



e.g. SharpShooter® Tissue Repair System consisting of handle, zone-specific cannula set, and non-resorbable 2-0 polyester suture for inside-out suturing, or else use an outside-in or all-inside suture system.

In addition, general surgical instruments for arthroscopic meniscus surgery including a microfracturing awl for soft tissue manipulation are needed.

Surgical Technique - Lateral

1. Patient Position

The patient is positioned supine. The affected leg is positioned with the knee flexed to 90° to allow easier access during the implant fixation procedure.

2. Surgical Exposure

Routine anteromedial and anterolateral portals are made. The following landmarks are used to identify the correct position of the arthroscopic portals: the anterolateral portal is placed distal to the pole of the patella at the soft spot, approximately 1-2 cm lateral to the patellar tendon; the anteromedial portal is placed at the same level, approximately 1-2 cm medial to the patellar tendon.



Figure 1: Anteromedial and anterolateral portals.

During the surgical procedure accessory portals may be required for better view or access.

3. Arthroscopic Inspection of the Affected Knee

A thorough arthroscopic inspection of the entire knee joint should be conducted. The damaged lateral meniscus is then evaluated to determine the applicability

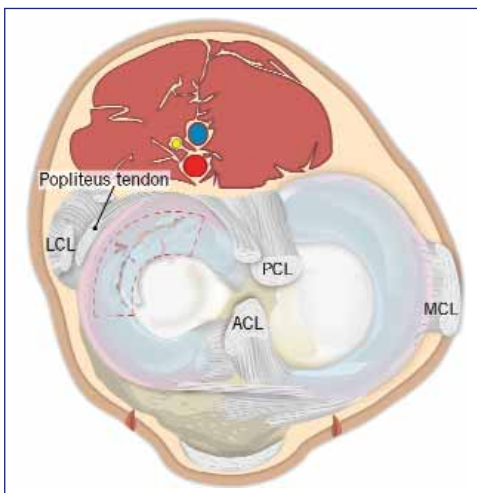


Figure 2: Knee with irreparable, lateral meniscus defect, and intact anterior as well as posterior attachment points. Note the proximity of the neurovascular structures to the posterior aspect of the lateral meniscus. ACL, PCL = anterior and posterior cruciate ligament, MCL, LCL = medial and lateral collateral ligament.

of the lateral CMI. The surgeon should determine if the torn meniscus meets all of the appropriate indications.

4. Preparation of Implant Bed

Preparation of the implant site will result in a full thickness meniscus defect (i.e., no flaps, loose or degenerative tissue remains). The remaining meniscus rim should be kept intact over the entire length if at all possible. Further consideration may be necessary if there is complete disruption of the rim at the popliteal hiatus. The prepared defect site should maintain a uniform width of the meniscus rim and extend into either the red/white or red/red zone of the meniscus. In all cases where the rim extends only to the red/white zone, it is advised to access the blood supply by making puncture holes in the rim with a soft tissue microfracture awl or a similar instrument. Additionally, the synovium should be roughened as well by using the awl or a rasping instrument. The anterior and posterior attachment points should be trimmed square (radially) if possible to accept the CMI (Fig. 3).

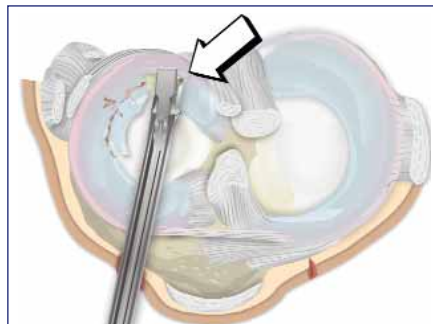


Figure 3: Preparing the defect ends: the posterior end is best prepared using a straight overbiter punch while for preparation of the anterior end an angled duckbill basket punch is very useful (arrows pointing to squared-off ends).

5. Measurement of Defect Size

Once the implant site is prepared, the meniscus defect is measured using the measuring device through the ipsilateral portal. Since the CMI is designed with fixed widths and curvatures, the arc length of the defect site is needed to properly size the implant.

Measurements are taken by using the measuring rod. Twist the rod several times around your index finger with the measurement scale towards the finger.



Figure 4: Measurement of defect length using the specific measuring device.

This will result in a strong curvature in the measurement rod, since the memory in the material will maintain the curvature and help facilitate a proper measurement of the defect length. Load the Teflon measuring rod into the stainless steel measuring cannula and begin measuring from the posterior aspect of the lesion. Follow the circumference of the defect in the meniscus and note the correct arc length (Fig. 4).

6. Sizing of CMI Implant

Remove the CMI from the sterile packaging. The length of the CMI should be measured along the outer rim. The required implant length is 10-15% longer than the measured defect length. The additional length is required to compensate for any measurement error as well as to create a press fit sizing of the implant within the defect site such that the CMI stays in place. Any excess implant material can be removed during final placement of the CMI. In case of disruption or absence of meniscus tissue at the popliteal hiatus, it is essential to add 15-20% to the measured defect length since the CMI may recess into the hiatus during fixation. After the final implant length is determined, the dry CMI is trimmed using a fresh scalpel (Fig. 5).



Figure 5: Cutting the dry implant to the required length.

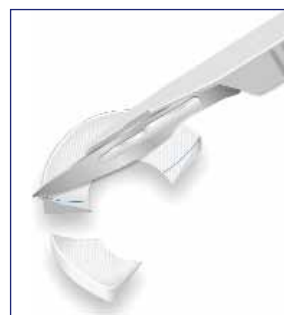


Figure 6: Shape of implant tailored to defect.

Care should be taken to tailor the anatomical shape of the CMI such that the implant matches the shape and especially the angles of the ends of the meniscus defect since the radial aspect of the lesion cannot always be trimmed to be exactly at a right angle (Fig. 6). The final measurement should then be reconfirmed.

7. Loading the CMI into the Delivery Clamp

The dry CMI is inserted into the joint space using the delivery clamp. The CMI should be placed directly into the delivery clamp and the instrument jaws gently closed. If possible, place the CMI fully within the clamp to protect it while it is being inserted into the joint (Fig. 7).



Figure 7: CMI fully inserted into clamp.

8. Setting the Loop Suture (Optional)

It may be useful to use a loop stay suture to help stabilize the CMI in the correct location for later suturing. The loop suture is placed around the meniscus rim at the mid portion of the defect and will temporarily hold the CMI in place. Monofilament sutures (size 2-0 or larger) and a meniscus repair zone specific cannula may be used. Care should be taken to assure that the suture needles exit at anatomically safe locations when placing the loop suture.

9. Delivery of CMI into the Prepared Implant Bed

Before insertion of the implant the lateral portal should be enlarged so that it is large enough to accommodate the tip of the fifth finger (Fig. 8).



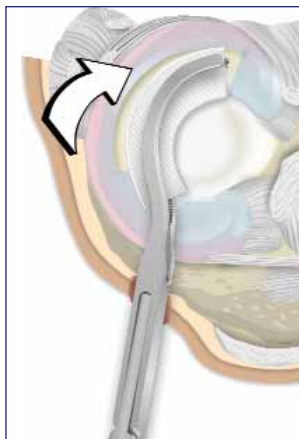
Figure 8:
Enlarged lateral portal.

Insert the clamp holding the lateral CMI into the knee joint through the ipsilateral portal under direct arthroscopic visualization and through the optional loop suture if it was previously placed. Begin delivering

the CMI in the posterior aspect of the lesion by advancing the instrument to the desired position. Care should be taken not to damage the articular cartilage with the distal end of the clamp. Open the instrument jaws to release the implant and withdraw the instrument. As the implant is exposed, the optional loop suture is tightened just enough to hold the CMI in place.

Excess pressure should not be placed on the loop because this suture can cut or otherwise damage the CMI. Continue to withdraw the clamp until the implant is free from the delivery device. A probe or small grasper can be used to manipulate the implant into the correct position. To prevent any damage to the implant, care must be taken to use only blunt instruments when positioning the CMI.

Figure 9:
CMI being delivered into lateral meniscus defect.



Precaution: In a tight lateral compartment extreme care must be exercised to avoid damage to the chondral surfaces as well as to the CMI. ReGen does not recommend release of the lateral collateral ligament (as might be done for the medial collateral ligament) because of limited clinical experience and the possibility of secondary complications including but not limited to poor healing and lateral laxity.

If the lateral compartment is too tight, it may not be possible to place the CMI into the defect making a CMI implantation impossible in this patient.

10. Suturing the Implant to the Remaining Meniscus

Fixation of the CMI to the remaining meniscus rim may be done using an inside-out suturing technique. If inside-out suturing is difficult to perform due to the anatomic location of the meniscus lesion, ReGen recommends the use of the all-inside FasT-Fix™ suture system by Smith & Nephew.

Very often a hybrid suturing technique is used with all-inside sutures in the posterior and middle aspect and inside-out or outside-in sutures in the anterior aspect of the meniscus (Fig. 12).

Precaution: Care should be taken while suturing in the area of the popliteal hiatus to avoid, if possible, placing nonabsorbable sutures directly through the popliteal tendon.

The inside-out and all-inside suturing technique are described in detail below.

A) Using an Inside-Out Suturing Technique

If inside-out suturing is performed to fix the implant to the meniscus rim a posterolateral skin incision may be needed to assist identification and capture of the needles during the suturing procedure and to ensure the proper identification and protection of neurovascular structures. The incision should be approximately 3–5 cm in length, 1/3 above and 2/3 below the lateral joint line, and in the interval between the posterior edge of the iliotibial band and the anterior edge of the biceps femoris tendon. The incision is deepened with blunt dissection by developing an interval between the deep portion of the gastrocnemius muscle and the posterolateral capsule until the capsule is reached. A tissue protection spoon retractor is placed in the incision as deeply as possible. This instrument will help protect the neurovascular structures while the suture needles are passed from the inside of the joint to the lateral outer aspects of the knee.

Once the CMI is positioned properly in the meniscus defect, the CMI is fixed to the host meniscus rim. By using the SharpShooter® Tissue Repair System, or conventional inside-out suturing cannulae, the CMI is sutured to the remaining meniscus with size 2-0 braided polyester. The anterior and posterior aspects of the implant are secured with horizontal sutures while vertical mattress sutures are used throughout the entire length of the implant. The suturing can be done either from the posterior to the anterior end of the implant or vice versa. A change of suturing direction during the suturing procedure is not recommended.

The first horizontal suture is typically placed in the posterior aspect of the meniscus defect. Using a double-armed suture, the first arm is typically placed into the native meniscus remnant and the second arm into the CMI. The sutures should be placed midway between the inner and outer margins of the CMI. This technique provides the greatest resistance to the sutures cutting through the implant. Sutures should be placed approximately every 5 mm. The final horizontal suture is placed in the anterior junction of the CMI and the defect.

When using the SharpShooter® Tissue Repair System, it is helpful to advance the needle of the second arm about 2 mm out of the cannula before placing the stitch.

With the advanced needle, the CMI can be picked up mid-width and proper positioning of the implant can be assured before advancing the needle. Care must be taken to ensure that the two arms of the sutures are pulled together at the same time to avoid any sawing action of the suture on the CMI which could damage the implant. If the suture arms are uneven and need to be balanced, a probe can be held under the suture during the evening process to protect the CMI.

If the CMI becomes displaced during positioning, a probe should be gently used to reposition the implant into the correct location.

If a suture is improperly placed, it should be removed and reinserted. A tissue protection spoon retractor should be used in the posterolateral incision to facilitate identification and capture of the needles. Care should be taken to avoid damage to the surrounding neurovascular structures. After placement of all sutures, they should be tied over the capsule through the posterolateral skin incision while the CMI remains under visual control of the arthroscope. When tying the sutures, the tension should just allow apposition of the CMI to the meniscus rim, but the sutures should not be tied tightly like a meniscus repair suture. Tying the sutures too tightly can damage the CMI. The direct visualization will help to assure that the sutures are tied with the correct tension.

B) Using an All-Inside Fixation Technique

If inside-out suturing is difficult to perform, the CMI can be fixed to the prepared meniscus rim using the all-inside Fast-Fix™ suture system by Smith & Nephew. The Fast-Fix system is available in three configurations: with a straight, an inside curved, and a reverse (outside) curved needle delivery system. Laboratory and clinical experience indicate that the curved Fast-Fix system is the most appropriate one for fixation of the CMI.

The Fast-Fix system should always be used in accordance with the user instructions provided by Smith & Nephew.

It is preferable to use the white depth penetration limiter instead of the split cannula. The depth penetration limiter is cut depending on the preferred insertion site, but at a maximum length of 18 mm before insertion into the joint. That length should be adequate to allow the needle tip of the Fast-Fix system to penetrate the CMI and the meniscus rim while preventing the tip from jeopardizing the neurovascular structures, especially in the posterior aspect of the knee.

The anterior and posterior ends of the implant are fixed using horizontal sutures. Throughout the length of the CMI, however,

vertical mattress sutures are placed. Typically, suturing should start with the most posterior horizontal suture (Fig. 10).

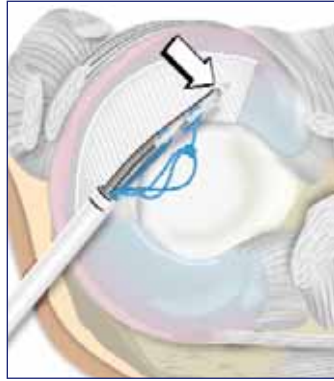


Figure 10: *Placing the posterior horizontal suture.*

In order not to damage the posterior neurovascular structures, the following procedure is recommended: The Fast-Fix delivery needle initially penetrates the CMI approximately mid width with the curve pointed posterior. With the tip of the delivery needle already inside the CMI the implant is then positioned snugly into the squared off portion of the defect in the posterior horn. The delivery needle is then rotated so that its curve points towards the squared off corner of the posterior horn, thus pointing away from the neurovascular structures. The needle is then advanced and penetrates the full thickness of the CMI and the meniscus rim. With this slightly oblique suture the CMI is pulled snugly into the prepared corner of the posterior horn.

When the needle tip can be felt to penetrate the meniscus rim, or when the depth penetration limiter prevents further penetration, the Fast-Fix delivery needle is pulled out of the tissue with a careful, oscillating movement.

By this movement, the first suture bar will be released behind the native meniscus rim. With the tip of the Fast-Fix visualized, the gold trigger is slid forward to advance the second suture bar into the “ready” position. Ensure that the trigger is fully advanced (with an audible click) and the implant is fully seated at the end of the delivery needle. The delivery needle is then inserted again into the meniscus tissue for the second stitch to complete either a vertical or horizontal suture as noted above.

The delivery needle is then completely removed from the joint with care to assure that the free suture end also is exteriorized. Under direct arthroscopic visualization, the suture construct is tightened by advancing the sliding knot either with the assistance of a knot pusher or by hand. Care should be taken not to over tighten the suture construct otherwise the CMI may be damaged. Using a suture cutter or arthroscopic scissors, the suture is cut 2-3 mm behind the knot.

This procedure is repeated to place as many suture constructs as necessary to obtain a complete and secure fixation of the implant. The distance between individual suture constructs is approximately 1 cm. Thus, for an average implant size of about 3-5.5 cm, 3-5 Fast-Fix suture constructs are typically used (Fig. 12).

It is recommended to first place the posterior suture construct. The second suture construct is typically a vertical suture, and then the remaining vertical sutures will be placed from posterior to anterior (Fig. 11). Finally, the anterior horizontal suture is placed.

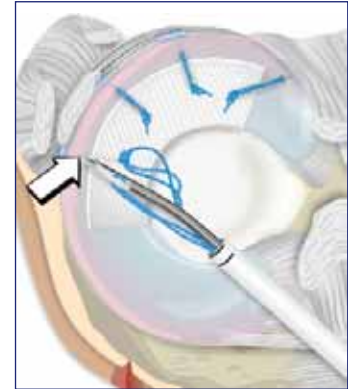


Figure 11: *Placing a vertical suture using an all-inside technique.*

11. Probing

Once the CMI is sutured or otherwise fixed in place, use a probe to check the stability of the meniscus implant construct. The optional loop suture, if placed, can be removed and a final check on the implant should be performed. To remove the loop suture, cut it intraarticularly so that it does not damage the CMI as it is removed.

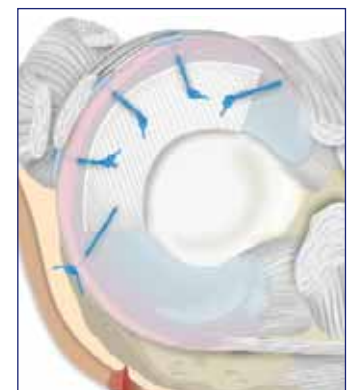


Figure 12: *Lateral CMI sutured in place using a hybrid technique: the most anterior suture is an inside-out suture since the all-inside technique is difficult to use in this area of the meniscus.*

After insertion and fixation of the implant, 3 to 4 microfracture holes should be made in the intercondylar notch (away from the articular cartilage and other structures) to encourage marrow bleeding. This step is not necessary if a concurrent ACL reconstruction with bone tunnels has been performed.

Surgical Tips and Frequently Asked Questions

1. Fixation of the Implant to the Native Meniscus Rim – Fixation Material:

ReGen *Biologics* has an extensive and controlled clinical experience with the inside-out suture technique to fix the CMI implant to the native meniscus rim with use of the SharpShooter® or hand-held zone specific cannulae. The use of non-absorbable suture material is recommended for inside-out suturing.

The safety and effectiveness using all-inside meniscus repair devices to fix the CMI to the native meniscus rim have not been established in controlled studies.

2. Posterior or Anterior Gap:

In case a 1–2 mm posterior or anterior gap has developed between the posterior or anterior horns of the meniscus and the implanted and sutured CMI, a microfracture awl may be used to scarify the synovium to stimulate a proliferative response at the gap interface. If the gap is more than 2 mm, the implant should be replaced.

3. Combination of CMI with Other Surgical Procedures:

ACL Reconstruction:

ACL reconstruction can be performed concurrently with the lateral CMI implantation. Typically, after the meniscus defect site has been prepared, the graft for ACL replacement is harvested. While the graft is being prepared, the tibial and femoral tunnels are made. The graft is fixed proximally, the CMI is then inserted and sutured to the meniscus rim, and finally the ACL graft is fixed at the distal site. If the procedures are to be staged, the CMI implantation typically should be performed first. The ACL reconstruction should be completed within 12 weeks after CMI implantation since knee instability is detrimental to the implant.

Leg Alignment Correction:

If there is any angular deformity of the involved knee, it should be corrected before or at least concurrently with the implantation of the CMI. If doing the procedures concurrently, the type of osteotomy might influence the order in which the combined procedures are performed. Typically, in case of an opening-wedge HTO, the CMI is implanted after the HTO. In case of a closing-wedge HTO, the CMI is usually implanted first and then the HTO is performed. Consideration must be given to the CMI-specific rehabilitation program.

Chondral Resurfacing:

For the combination of chondral resurfacing procedures (such as microfracture, osteochondral transplantation or autologous chondrocyte implantation), few documented clinical data are currently available. It is therefore the surgeon's choice to perform a chondral resurfacing procedure concomitantly with CMI implantation. Limited clinical experience suggests that staging the two procedures by doing the chondral resurfacing first and the CMI later may help preserve the CMI.

Postoperative Protocol

It is essential for the patient to follow the outlined postoperative rehabilitation program. While the rehabilitation protocol is more rigorous than needed for partial meniscectomy, it is similar to the rehabilitation protocols used after a meniscus repair procedure. The rehabilitation program outlined for patients receiving the CMI is designed specifically to maximize the potential for tissue regrowth and long-term success.

Please refer to the appropriate materials, outlining the recommended rehabilitation protocol.

The surgical procedure for the Lateral CMI was developed in collaboration with a group of experienced European CMI surgeons including (in alphabetical order):

- Dr. P. Bulgheroni (Varese, IT)
- Dr. R. Crespo (Alcazar, ES)
- Dr. D. Holsten (Koblenz, DE)
- Dr. K. Lagae (Antwerp, BE)
- Prof. M. Marcacci (Bologna, IT)
- Dr. J.C. Monllau (Barcelona, ES)
- Dr. S. Zaffagnini (Bologna, IT)

Distributed by
ReGen *Biologics* AG
Feldstrasse 11
CH-9050 Appenzell
Switzerland
Tel +41 (0) 79 820 6242
Fax +41 (0) 860 79 820 6242



www.regenbio.com

ReGen *Biologics*, Inc.

509 Commerce Street, East Wing · Franklin Lakes, NJ 07417 USA · 201.651.3516

© Regen® and SharpShooter® are registered trademarks of ReGen *Biologics*, Inc. The CMI has received a CE Mark and is cleared for sale in the EU and certain other countries. CAUTION: In the U.S., the CMI is an investigational device limited by United States law to investigational use only. This brochure is not intended for distribution in the U.S.

FasT-Fix™ is a trademark of Smith & Nephew, Inc.