



Ivy Sports Medicine

Life is Movement



COLLAGEN MENISCUS IMPLANT

Surgical Technique Medial and Lateral



The CMI® implant is a type I collagen-based meniscus implant designed to facilitate growth of new tissue to replace removed or missing meniscus tissue in the human knee.



Collagen Meniscus Implant (CMI®) For Regeneration of Body's own Tissue



For warnings and precautions refer to the CMI® package insert.

As for any operative procedure, the implantation of the Ivy Sports Medicine's Collagen Meniscus Implant (CMI®) functions best if the surgical procedure is done carefully and correctly. The recommended surgical procedure for the CMI implant requires that the surgeon is proficient with meniscus suturing techniques. Ivy Sports Medicine attaches great importance to providing thorough training for every surgeon on both the handling and the implantation of the CMI device.

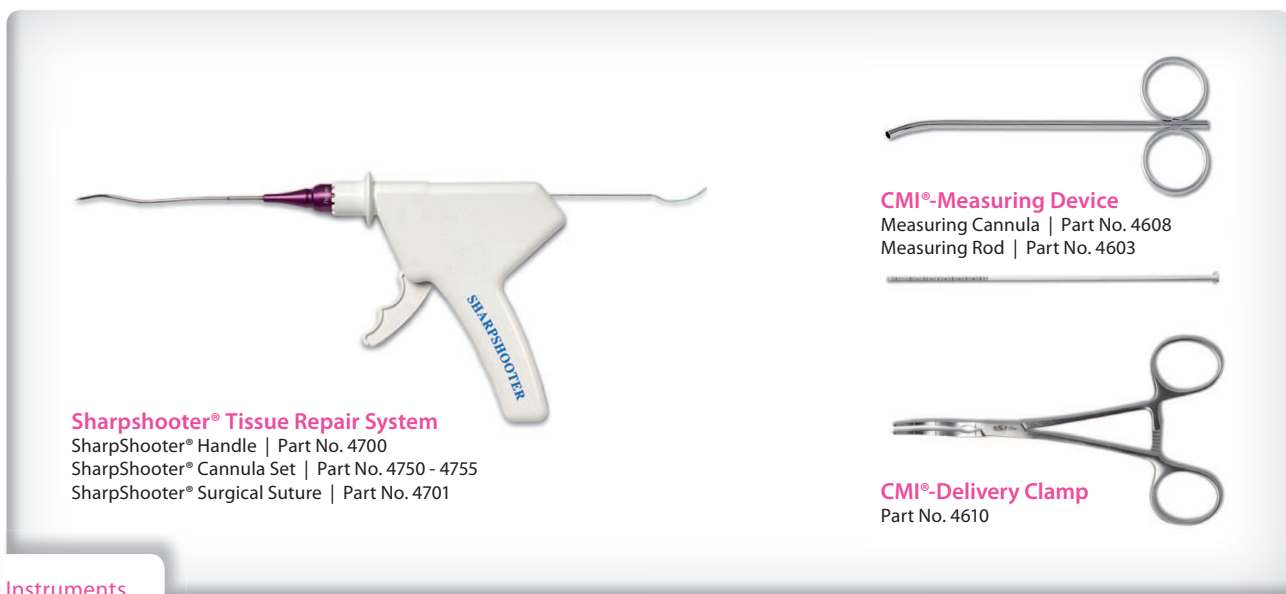
Indications

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

Contraindications

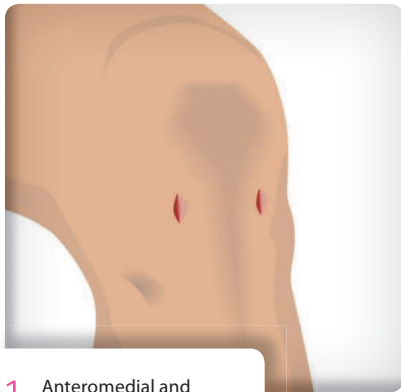
- Concomitant PCL insufficiency of the involved knee
- Diagnosis of uncorrected grade IV degenerative cartilage disease in the affected joint
- Uncorrected malformations or axial malalignment in the involved knee
- Documented allergy to collagen of animal origin
- Documented allergy to chondroitin sulfate 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
- General neurological abnormalities or neurological conditions that tend to preempt the patient's mental ability or willingness to fulfill the requirements of the rehabilitation program
- Medical history that is positive for, but not restricted to, the following diseases: rheumatoid arthritis, relapsing polychondritis, severe degenerative osteoarthritis, inflammatory arthritis

Overview of Implants and Required Instruments

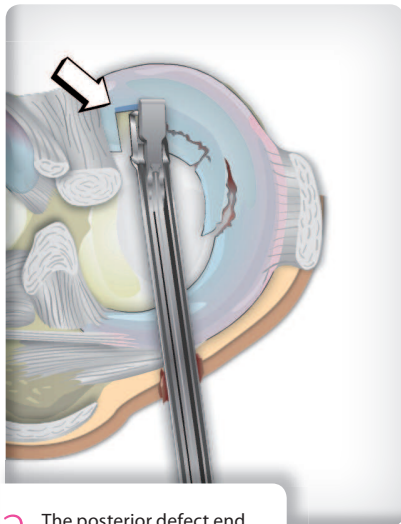


The following additional instruments generally used for arthroscopic meniscus repair are recommended for the CMI procedure:

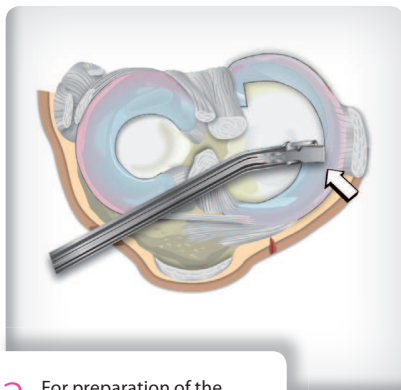
- Straight overbiter punch and angled punches for preparation of the implant bed
- Microfracturing awl for perforation of the meniscal rim
- Meniscus rasp for roughening of the meniscus rim and synovium
- Blunt probe (e.g. trocar or obturator) for positioning of the implant within the defect
- All-inside meniscus suturing system with non-resorbable sutures for fixation of the implant
The ULTRA FAST-FIX™ All-Inside Suture System by Smith & Nephew is the only all-inside meniscus suturing system appropriate for use with the CMI implant
- Inside-out (e.g. Ivy Sport Medicine's SharpShooter® Tissue Repair System) suturing system with non-resorbable sutures for fixation of the implant (e.g. 2-0 U.S.P braided polyester)



1 Anteromedial and anterolateral portals



2 The posterior defect end



3 For preparation of the anterior end

1. Patient Position

Position the patient supine. Position the affected leg with the knee flexed to 90° to allow easier access during the fixation procedure of the CMI implant.

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 (**Fig. 1**).

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 meniscus is then evaluated to determine the applicability of the CMI implant. The surgeon should determine if the torn meniscus meets all of the appropriate indications.

4. Preparation of the Implant Bed

Preparation of the implant site with appropriate punches will result in a full thickness meniscus defect with all flaps, loose or degenerative tissue removed (**Figs. 2 and 3**). The posterior defect end is best prepared using a straight overbiter punch. For preparation of the anterior end an angled duckbill punch is very useful.

The remaining meniscus rim should be kept intact over the entire length if at all possible (except for the area of the popliteal hiatus in the lateral meniscus). The anterior and posterior attachment points should be trimmed square (radially) if possible to accept the CMI implant (**Fig. 3**).

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 rather than to the red/red zone, it is advised to access the blood supply by making puncture holes in the rim with a soft tissue microfracture awl or similar instrument (**Fig. 4**).

Additionally, the synovium should be roughened as well by using the awl or a rasping instrument.

5. Measurement of Defect Size

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

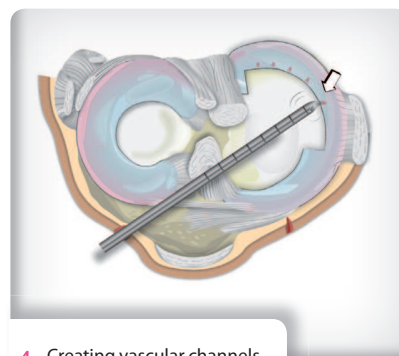
Take measurements using the measuring rod. If required, twist the rod around your index finger with the measurement scale towards the finger. This will result in a stronger curvature in the measurement rod, and may facilitate a proper measurement of the defect length. Load the measuring rod into the 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. 5**).

6. Sizing the CMI Implant

Remove the device from the sterile packaging. The length of the CMI implant should be measured along the outer rim. For the medial implant, the required length is 5-10% longer than the measured defect length, whereas for the lateral implant the required length should be oversized by 10-15%.

The additional length is required to compensate for any measurement error as well as to create a press fit sizing of the device within the defect site such that the CMI implant stays in place. 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 implant may recess into the hiatus during fixation. After the final length is determined, trim the dry CMI implant using a fresh scalpel (**Fig. 6**).

Care should be taken to tailor the anatomic shape of the device such that it matches the shape of the defect. This is especially important if the anterior corner of the native meniscus cannot be trimmed at a right angle but has a shallow ($>90^\circ$) angle (**Fig. 6**). The final length of the device should then be reconfirmed.



4 Creating vascular channels in the native meniscus rim using a microfracturing awl



5 Measurement of defect length using the specific measuring device



6 Cutting the dry CMI implant to the required length

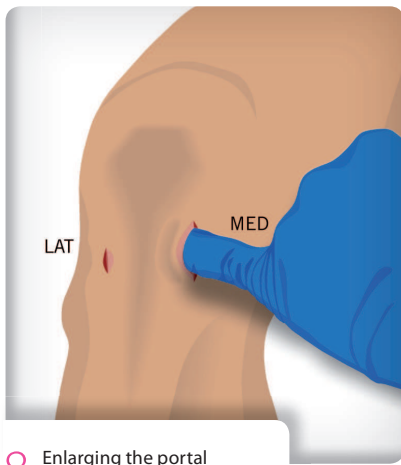
7. Loading the CMI Implant into the Delivery Clamp and Preparation of the Portal



7 CMI implant fully inserted into delivery clamp

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

Before insertion of the device, enlarge the portal (ipsilateral portal in the case of a lateral CMI implantation or the medial portal in case of a medial CMI implantation) with a vertical cut to approximately 3 cm so that it is large enough to easily accommodate the tip of the fifth finger (**Fig. 8**).

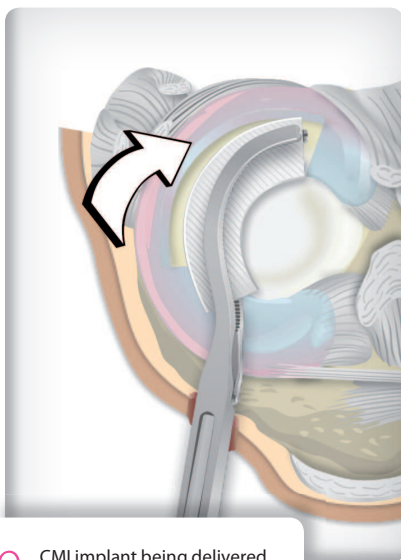


8 Enlarging the portal (the medial portal is shown)

8. Delivery of CMI Implant into the Prepared Implant Bed

Insert the clamp holding the CMI implant into the knee joint with a screwing motion through the corresponding ipsilateral portal under direct arthroscopic visualization. Begin delivering the implant in the posterior aspect of the lesion by advancing the delivery clamp to the desired position (**Fig. 9**). Care should be taken not to damage the articular cartilage with the distal end of the clamp. Open the clamp jaws to release the CMI implant and withdraw the instrument. It may be necessary to re-grip the CMI implant and advance the delivery clamp posteriorly several times during this insertion procedure in order not to pull the implant out of the joint while withdrawing the clamp. Continue to withdraw the clamp until the implant is free from the delivery clamp. A blunt probe (e.g. trocar or obturator) can be used to carefully manipulate the implant into the correct position.

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9 CMI implant being delivered into the lateral meniscus defect

In case of a very tight medial compartment, it might be helpful to open up the joint space by performing a partial release of the deep fibers of the medial collateral ligament.

PRECAUTION!

In a tight lateral compartment, extreme care must be exercised to avoid damage to the chondral surfaces as well as to the implant. Ivy Sports Medicine does not recommend release of the lateral collateral ligament because of the possibility of secondary complications including, but not limited to, poor healing and lateral laxity. If the lateral compartment is too tight, the CMI implant cannot be placed into the defect making a CMI implantation impossible in this patient.

9. Suturing the CMI Implant to the Remaining Meniscus

Fixation of the CMI implant to the remaining meniscus rim may be done using different meniscus suturing techniques such as all-inside, inside-out, or outside-in sutures.

Most often, a hybrid 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.

If the operating surgeon wishes to use all-inside suturing, Ivy Sports Medicine recommends the use of the ULTRA FAST-FIX™ All-Inside Suture System by Smith & Nephew. The ULTRA FAST-FIX™ Suture System is available in three configurations: with a straight, an inside curved, and a reverse (outside) curved needle delivery system. Clinical experience indicates that the curved needle systems are the most appropriate ones for fixation of the CMI implant. These systems 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 system to penetrate the CMI implant 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 device are fixed using horizontal sutures, while throughout the remaining length of the CMI implant, vertical mattress sutures are placed. Typically, suturing starts with the most posterior horizontal suture (**Fig. 10**).

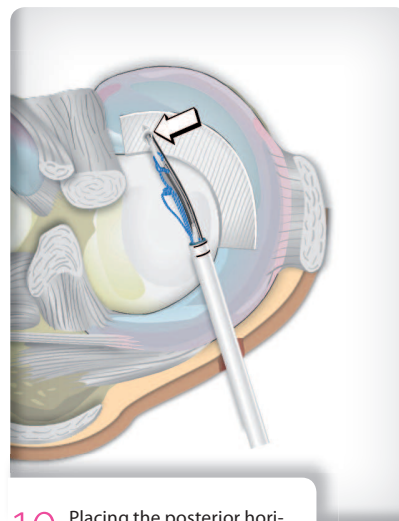
In order not to damage the posterior neurovascular structures, the following procedure is recommended: The ULTRA FAST-FIX™ delivery needle initially penetrates the CMI implant approximately mid-width with the curve pointed posterior. With the tip of the delivery needle already inside the CMI implant, the device 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 implant and the meniscus rim. This slightly oblique suture pulls the CMI implant 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 first anchor is deployed behind the native meniscus rim. Once deployed, the suture system is withdrawn from the meniscus until the tip of the ULTRA FAST-FIX™ is visible. The needle is positioned to deploy the second anchor. The delivery needle is then inserted again into the meniscus tissue and the anchor deployed behind the native meniscus rim to complete the stitch. The delivery needle is then completely removed from the joint with care to assure that the free suture end also is exteriorized.

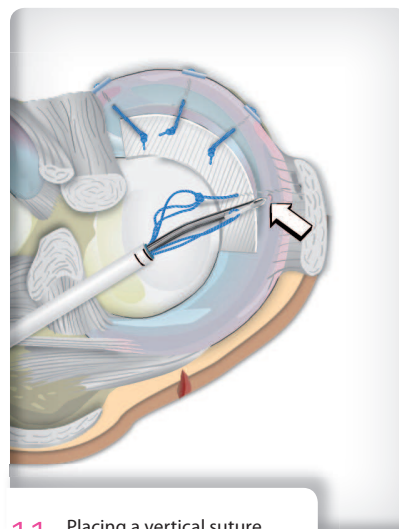
Under direct arthroscopic visualization, the suture construct is tightened by advancing the sliding knot either with the assistance of a knot pusher or by hand. Care should be taken not to overtighten the suture construct otherwise the CMI implant may be damaged. Using a suture cutter or arthroscopic scissors, the suture is cut 2-3 mm behind the knot.

It may be helpful to slide the tip of a probe behind the sliding knot and use it as a pulley when tightening the knot. The probe provides resistance against the suture tension and thus prevents the suture from cutting through the CMI implant while tightening the knot.

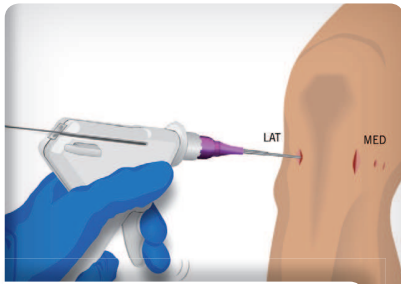
The second suture construct is typically a vertical suture and is placed as described above. Along the remaining length of the CMI implant, vertical sutures are then placed from posterior to anterior (**Fig. 11**).



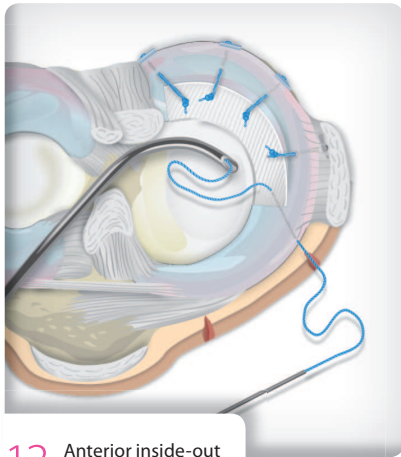
10 Placing the posterior horizontal suture on a medial CMI implant



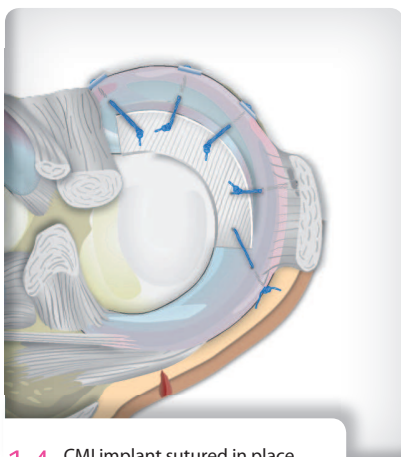
11 Placing a vertical suture using an all-inside technique



12 Anterior inside-out suture using Ivy Sports Medicine's SharpShooter® Tissue Repair System



13 Anterior inside-out suture (inside view)



14 CMI implant sutured in place using a hybrid suturing technique

Finally, the anterior horizontal suture is placed. This slightly oblique suture pulls the CMI implant snugly into the prepared corner of the posterior horn. Since the all-inside suture system is difficult to use in the very anterior area of the meniscus, often an inside-out suture is placed with the knot tightened over the capsule through a small skin incision (**Fig. 12 and Fig. 13**).

The distance between all-inside suture constructs is 10-15 mm. Thus, for an average CMI implant size of about 4 to 5 cm, 4 to 5 suture constructs (e.g. 4 ULTRA FAST-FIX™ sutures and 1 inside-out suture) are typically used (**Fig. 14**). If only inside-out sutures are used, the distance between sutures is approximately 5 mm.

PRECAUTION!

With the lateral meniscus, 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.

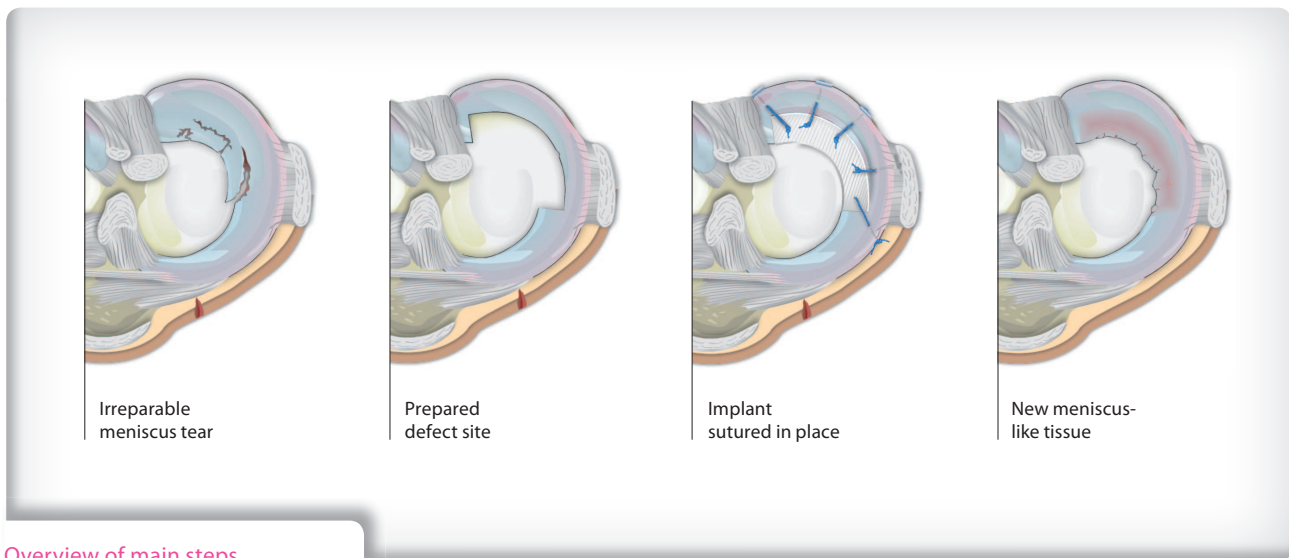
10. Probing

Once the CMI implant is sutured in place, use a probe to perform a final check on the stability of the meniscus-implant construct.

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.

11. After Surgery

Placement of a drain after surgery depends on whether an isolated or a combined meniscus procedure was performed (e.g. with concurrent ACL reconstruction). If a drain is placed, it should not be put on suction.



Overview of main steps

Main Steps

1. Placement of anteromedial and anterolateral portals
2. Preparation of implant bed
3. Measurements of defect size
4. Sizing of CMI implant
5. Loading the CMI implant into the delivery clamp and preparation of the portal
6. Delivery of CMI implant into the prepared implant bed
7. Suturing the CMI implant to the remaining meniscus
8. Final check of meniscus-implant construct

a) 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 CMI device, 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 CMI implant should be replaced.

b) Amount of Tissue Required for Fixation:

The amount of tissue required at the posterior horn attachment and along the remaining rim should be such that stable stitches can be placed. Insufficient fixation at the posterior attachment and along the rim may lead to implant instability and hamper regeneration.

c) What if Implant sticks too far into the Joint:

If truly excessive, the inner (thin) edge of the implant may be trimmed intra-operatively using a basket punch. However, since the soft matrix will conform to the shape of the condyles, this is not necessary. In fact, such trimming could damage the implant if not done with extreme care.

d) Combination of CMI Implant with Other Surgical Procedures:

ACL Reconstruction

ACL reconstruction can be performed concurrently with a 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 implant 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 CMI 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 CMI implantation. 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 device is implanted after the HTO. In case of a closing-wedge HTO, the CMI device is usually implanted first and then the HTO is performed. Consideration must be given to the CMI-specific rehabilitation protocol.

Chondral Resurfacing

For the combination of chondral resurfacing procedures (such as microfracture, osteochondral transplantation or autologous chondrocyte implantation), little documented clinical data are currently available. However, the limited clinical experience that is available suggests that staging the two procedures by doing the chondral resurfacing first and implanting the CMI device later may help preserve the CMI implant.

e) Postoperative Protocol:

It is essential for the patient to follow the specific postoperative rehabilitation protocol after a CMI surgery. While the rehabilitation protocol is more rigorous than the one following partial meniscectomy, it is similar to the rehabilitation protocols used after a meniscus repair procedure.

A short overview of the rehabilitation protocol is included in this document; however, the full rehabilitation protocol is included in the CMI Rehabilitation Protocol Brochure. Please refer to the rehabilitation brochure for the complete CMI rehabilitation protocol which is designed specifically to maximize the potential for tissue regrowth and long-term success.

Short Overview* Rehabilitation after CMI® Implantation

WEEK 1–4

MOTION: Only passive motion exercises on CPM machine or motion exercises using the well leg to support the operated leg.

Range of motion: 0 to 60 degrees (setting CPM machine: 0-0-60 degrees).

WEIGHT-BEARING:

Week One: No weight should be placed on the affected leg when ambulating with crutches.

Week Two: Partial weight bearing of up to 30% of body weight may be placed on the affected leg when ambulating with crutches.

Week Three through Four: Gradual increase of partial weight bearing from 30 to 50% of body weight on affected leg when ambulating with crutches.

STRENGTHENING: Exercises in horizontal position.



Week 1–4 and Week 5–6

WEEK 5–6

MOTION: Passive motion exercises on CPM machine or motion exercises using the well leg to support the operated leg.

Range of motion: 0 to 90 degrees (setting of CPM machine: 0-0-90 degrees)

WEIGHT-BEARING: Gradual increase of partial weight bearing from 50 to 90% of body weight on affected leg when ambulating with crutches.

STRENGTHENING: Exercises in horizontal position.



Week 7–8

WEEK 7–8

MOTION: Begin active motion exercises and gradually increase to full range of motion as tolerated.

WEIGHT-BEARING: Increase to full weight bearing on the affected leg while ambulating with crutches. As soon as patient is able to walk without a limp, the crutches can be discarded.

STRENGTHENING: Exercises in horizontal position, short arc quadriceps extension exercise, cycling (home trainer) without resistance.



Week 9–End of Month 4

WEEK 9–MONTH 4

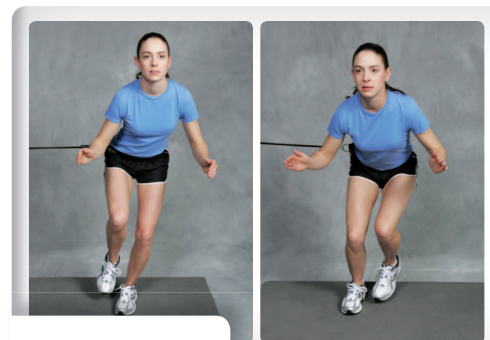
MOTION: Unrestricted full range of motion.

WEIGHT-BEARING: Full unrestricted weight-bearing.

STRENGTHENING: Cycling (home trainer) with increased resistance, Shallow knee bends, Water exercise (optional).

MONTH 5–MONTH 6

STRENGTHENING: Exercises with elastic resistance cord.



Month 5 – Month 6

* The complete rehabilitation protocol is available in the CMI Rehabilitation Protocol Brochure.



Ivy Sports Medicine

Life is Movement

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