

THE COLLAGEN MENISCUS IMPLANT



The CMI[®] implant is a resorbable collagen scaffold designed to reinforce and repair a defect in the medial meniscus.

SURGICAL TECHNIQUE

COLLAGEN MENISCUS IMPLANT (CMI®) FOR REPAIR OF THE MEDIAL MENISCUS

FOR WARNINGS AND PRECAUTIONS REFER TO THE CMI® PACKAGE INSERT.



Indications

- Prior loss of meniscus tissue
- Irreparable meniscus tears requiring partial meniscectomy
- Either traumatic or chronic posttraumatic meniscus tear
- Meniscus damage requiring greater than 20% removal
- Intact anterior and posterior horn attachments of the involved meniscus
- Intact rim over the entire circumference of the involved meniscus
- ACL deficiencies corrected simultaneously or within 12 weeks of CMI implantation
- Patients willing to follow post-operative rehabilitation program
- The use of the CMI in patients with acute injuries should be considered with caution
- Acute patients should be limited to those necessitating the surgical removal of at least 40% of the posterior half of the meniscus

Contraindications

- Concomitant PCL insufficiency of the involved knee
- Diagnosis of uncorrected grade IV degenerative cartilage disease in the affected joint
- Uncorrected axial malalignment in the involved knee
- Documented allergy to animal-derived products or chondroitin sulfate.
- 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
- Patients unable or unwilling to follow the rehabilitation program.

OVERVIEW OF IMPLANTS & INSTRUMENTS

COLLAGEN MENISCUS IMPLANT



CMI Medial 7.5mm
Part No. 4300



CMI Medial 9.0mm
Part No. 4301

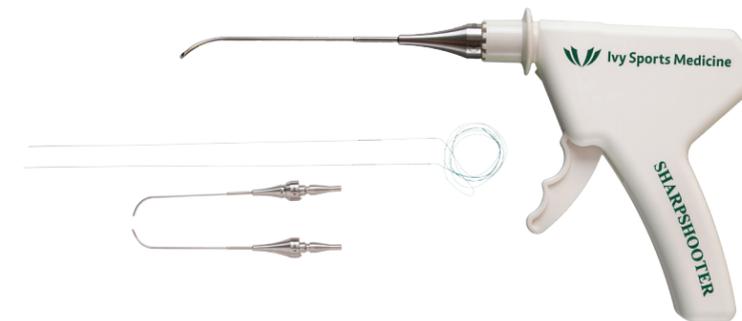
INSTRUMENTS



CMI®-Measuring Device
Measuring Cannula | Part No. 4608
Measuring Rod | Part No. 4603



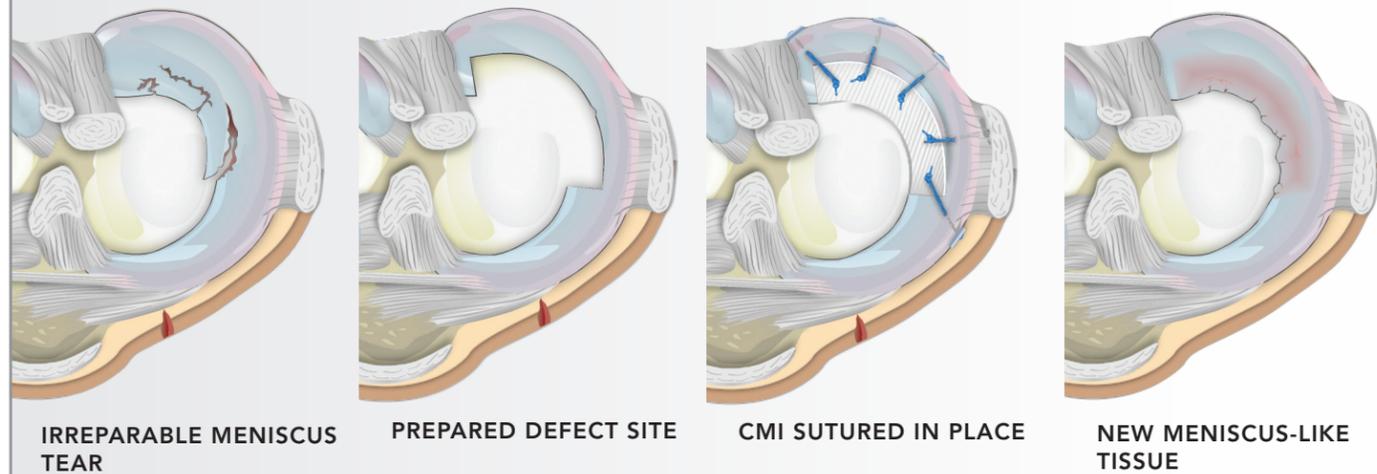
CMI®-Delivery Clamp
Part No. 4610



Sharpshooter Tissue Repair System
SharpShooter® Handle | Part No. 4700
SharpShooter® Cannula Set | Part No. 4750 - 4755
SharpShooter® Surgical Suture
2-0 braided polyester | Part No. 4701
SharpShooter® Surgical Suture
2-0 UHMWPE | Part No. 4754

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

- Straight duckbill and angled punches for preparation of the implant bed
- Microfracturing awls 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
- 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 or 2-0 High Strength UHMWPE Sutures)



COMBINATION OF CMI IMPLANT WITH OTHER SURGICAL PROCEDURES:

ACL Reconstruction

ACL reconstruction can be performed concurrently with a CMI implantation. Typically, the native ACL remnants are debrided and the tibial and femoral tunnels are drilled. After preparing the joint to receive the ACL graft, the meniscus is prepared for CMI implantation. The CMI implant is inserted and sutured to the meniscal rim. Once the CMI is implanted and secured, insertion of the ACL graft and completion of the ACL reconstruction can be accomplished.

Knee Realignment

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.

1. Patient Positioning & Surgical Exposure

- Position the patient supine
- Flex the knee to 90°. FIG 1
- Both portals are placed distal to the pole of the patella at the soft spot
 - Anterolateral portal placed 1-2 cm lateral to the patella tendon
 - Anteromedial portal placed 1-2 cm medial to the patella tendon
- During the procedure, accessory portals may be needed for better arthroscopic visualization or joint access.

2. Preparation of The Meniscus

- Use of appropriate arthroscopic handheld baskets and punches will result in a full thickness meniscus defect with all flaps, loose or degenerative tissue removed. FIG 2A
- The meniscus rim should be kept intact over the entire length of the meniscus.
- The anterior and posterior edges of the defect should be trimmed square (radially). FIG 2B
- The prepared defect site should maintain a uniform width of the meniscus rim and extend into the red/white or red/red zone.

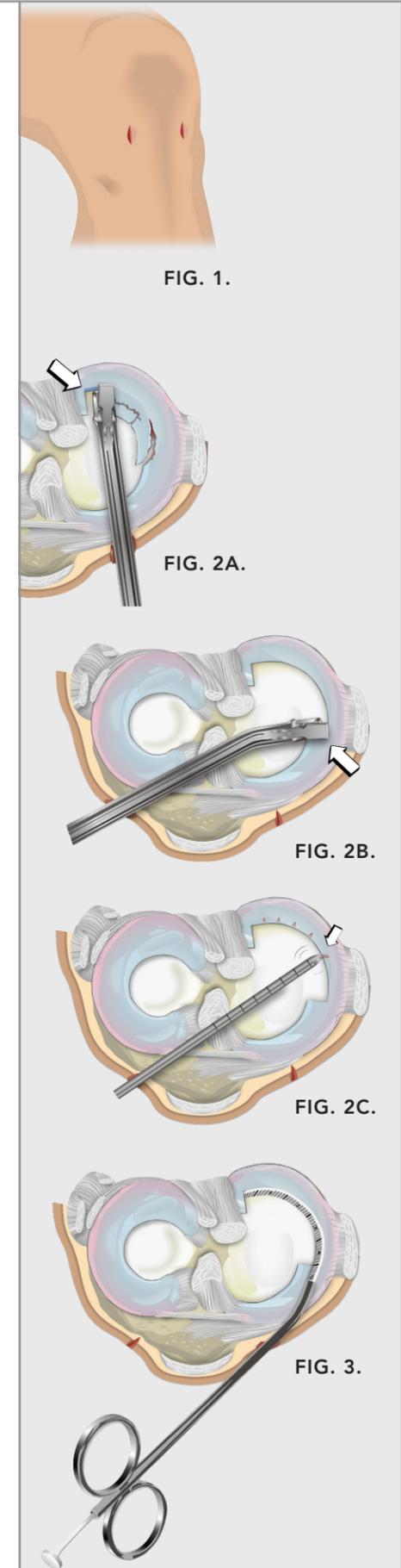
CAUTION:

- Insufficient fixation strength at the posterior horn attachment and along the meniscal rim may lead to CMI instability and hamper meniscal repair.
- Important that the remaining meniscal tissue at the posterior horn attachment and along the meniscal rim be able to accept and support stable suture fixation.
- In cases where the meniscal rim extends only to the red/white zone, create puncture holes, with a microfracture awl or similar instrument through the rim and into the red/red zone. FIG 2C

3. Sizing The Defect

After the defect is trimmed and prepared, measure the total length of the defect by using the Measuring Cannula and Measuring Rod.

- Insert the Measuring Rod into the Measuring Device cannula
- Insert the Measuring Device assembly into the knee joint through the ipsilateral portal
- Begin measuring from the posterior aspect of the meniscal defect and then following the defect circumference. Note the arc length. FIG 3



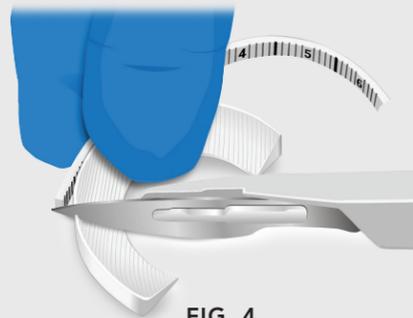


FIG. 4.

4. Sizing The CMI Implant

CAUTION: The CMI Implant should be kept dry while trimming to correct size.

- Remove the CMI from its sterile package
- Measure along the outer rim of the CMI Implant. **FIG 4**
- The required CMI length is 10% longer than the measured defect length
- Cut the dry CMI to the measured length with a No. 10 blade.

5. Preparing to Deliver The CMI into The Knee

- Enlarge the medial portal with a vertical cut to approximately 3cm (enough to accommodate a fingertip). Enlarging the portal with the fifth finger helps to create an open path so that the CMI is less likely to get caught on tissue during insertion into the capsule and potentially damage the implant. **FIG 5A**
- Place the dry and trimmed CMI implant into the Delivery Clamp and gently close the instrument jaws. **FIG. 5B**

CAUTION:

- It is important to place as much of the CMI within the clamp as possible to prevent implant damage during insertion.
- If significant resistance is met when inserting through the portal, remove the Delivery Clamp and implant. Enlarge and clear the path into the knee joint and reinsert the CMI as described above.

FIG. 5A.

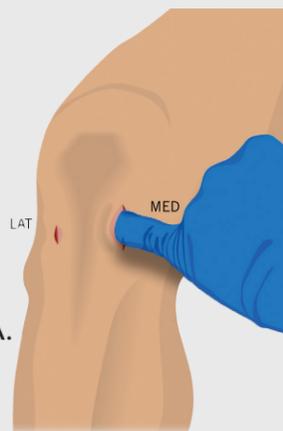


FIG. 5B.



6. Placing The CMI into The Defect

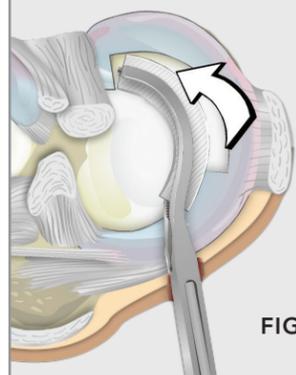
Under direct arthroscopic visualization:

- While using a threading motion, insert the Delivery Clamp with the CMI through the enlarged medial portal.
- Advance the Delivery Clamp aiming the CMI into the posterior aspect of the defect. **FIG 6.**
- Open the jaws of the Delivery Clamp to release the CMI implant.
- Remove the Delivery Clamp from the knee.

CAUTION:

- It may be necessary to re-grip, reposition and release the CMI several times to properly place the CMI into the defect.
- A blunt probe may be advantageous in carefully manipulating the CMI into position.
- In the case of a very tight medial compartment, it may be helpful to perform a partial release of the deep fibers of the medial collateral ligament.

FIG. 6.



7. Suturing the CMI Implant to the Meniscal Rim

Fixation of the CMI implant to the rim is accomplished by utilizing meniscal repair suturing methods.

8. Meniscus Suturing Tips

CAUTION: It is important not to over tighten sutures as it may cause damage to the CMI implant.

- The anterior and posterior ends of the CMI are fixed using horizontal sutures.
- Vertical mattress sutures are used throughout the remainder of the CMI implant.
- Suturing begins at the posterior aspect.

All-Inside Technique

- Clinical experience has demonstrated that curved needle systems are the most appropriate for fixation of the CMI.

All-Inside Suturing:

- The curved delivery needle is aimed to enter mid-width of the CMI implant with the inner curve of the needle pointed towards the posterior horn. **FIG 8A**
- The needle tip is then advanced and penetrates the full thickness of the CMI implant and the meniscus rim.
- When the needle tip penetrates the meniscus rim, the first anchoring device is deployed.
- Once deployed, the needle is withdrawn and the second anchoring device is deployed about 10mm from the first in the same fashion.

CAUTION: The distance between all-inside stitches should 10-15mm. Therefore, for a CMI implant size of 4-5cm, 4-5 complete stitches are required.

- Once both anchors are deployed, the suture stitch is tightened via its sliding knot.
- The oblique angle of the curved needle will allow the suture anchoring system to pull the CMI snugly into the prepared corner of the posterior horn.
- A knot pusher or probe tip should be used when advancing the knot and cinching it down as it acts as a pulley, thereby relieving tension force across the CMI implant.
- Once the stitch is knotted, the suture is cut leaving a 2-3mm suture tail.
- The second stitch, and those after, are vertical suture stitches and placed from posterior to anterior. **FIG 8B**

CAUTION: Anterior Horn Fixation

The all-inside technique may be difficult to use in the very anterior of the meniscus, therefore an inside-out stitch is placed with the knot tied over the knee capsule through a small skin incision. **FIG 8C**

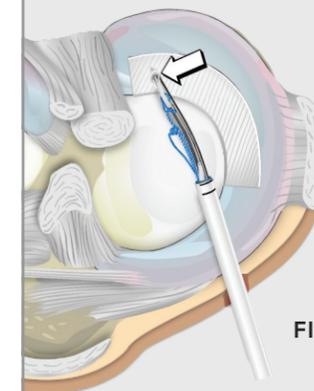


FIG. 8A.

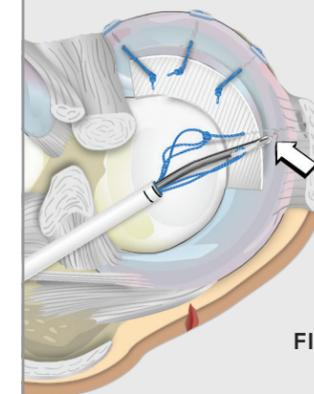


FIG. 8B.

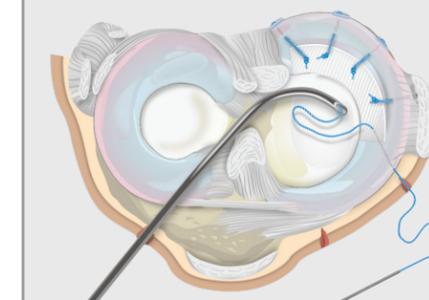


FIG. 8C.

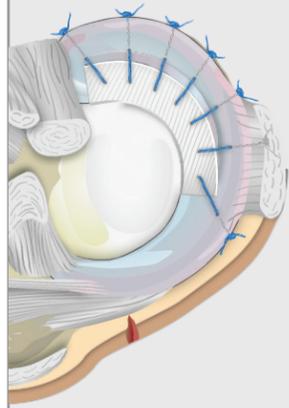


FIG. 8D.

Inside-Out Technique

- Clinical experience has demonstrated the following differences with the all-inside technique:
 - A greater number of sutures can be used in suturing the CMI implant to the meniscal rim due to the smaller diameter of meniscus repair needles and correspondingly smaller puncture holes through the CMI implant (versus the all-inside delivery needles). **FIG. 8D**

NOTE: The distance between inside-out placed stitches can be 5mm (versus 10-15mm with all-inside). Therefore, 8-10 stitches can be placed in a CMI implant size of 4-5cm.

- The overall cost of an inside-out suturing procedure is much less than the all-inside systems.
- Please refer to Ivy Sports Medicine's SharpShooter® Technique Guide for inside-out technique instructions. **FIG 8E**

Hybrid Technique

- A growing cost efficient suturing technique is the hybrid technique. Typically, the hybrid method would employ an all-inside device for use in the posterior aspect of the meniscus followed by inside-out suturing through the remaining length of the CMI implant (ending at the anterior aspect).

9. Inspecting the Sutured CMI

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

NOTE: Intracondylar Notch Microfracture

Following adequate inspection of the implanted CMI, 3 to 4 microfracture holes can be made into the intercondylar notch (away from articular cartilage) to encourage marrow bleeding. (If a concomitant ACL reconstruction is performed, this step is not necessary).

10. After Surgery

- If a drain is used, it should not be placed on suction
- It is essential for the CMI patient to follow the specific postoperative rehabilitation protocol. While the rehabilitation protocol is more rigorous than the one following partial meniscectomy, it is similar to the protocols used after a meniscus repair procedure.

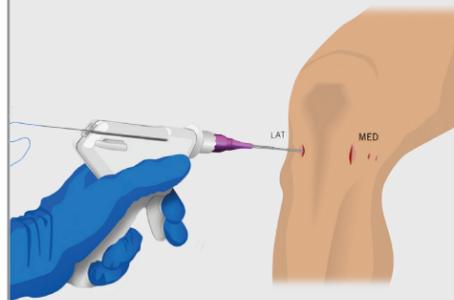


FIG. 8E.

THE CMI POSTOPERATIVE REHABILITATION PROTOCOL



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°.

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 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°.

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.



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