The CMI is a biocompatible scaffold comprised of resorbable Type I collagen that can be used to reinforce and repair a meniscus defect following partial meniscectomy or symptomatic loss of meniscus tissue requiring surgery.

In repairing meniscus defects, the patient must have an intact meniscus rim with both posterior and anterior horn attachments. The meniscal defect must extend at least into the red/white zone of the meniscus to provide sufficient vascularization. The CMI is sized and trimmed to fit the defect at the time of surgery.

Based on histological data, the CMI provides a scaffold for cellular ingrowth. After implantation, the patient's own cells fill the interstices of the CMI. As the CMI is resorbed and tissue remodeling takes place, the patient is left with new meniscal-like fibrochondrocytic tissue.

**U.S. CLINICAL TRIAL RESULTS OF CHRONIC PATIENTS**

- CMI patients regained significantly more lost activity than controls.
- Average meniscal surface area increased by 97% at 1 year postop.
- CMI patients had 2.7x fewer reoperations than the control group during 5-year follow-up.

**U.S. CLINICAL TRIAL RESULTS OF ACUTE PATIENTS**

Acute meniscus tear patients that received the CMI showed a significant increase in tissue filling the meniscus defect compared to pre-op. While there were statistically significant improvements in Pain, Lysholm Scores and Self-assessment from pre-op to 5 year follow-up, these were not significantly different from the control group. Investigators conclude that the onset of joint changes in acute patients with partial meniscectomy takes longer than the 5-year study period, and that this group of patients likely needed to be followed for a longer period of time to demonstrate a benefit.

**Arthroscopic Surgical Procedure Overview**

**FIG A.** Standard arthroscopic portals are used.

**FIG B.** The meniscus is prepared to receive the CMI. Standard shaver blades and biters are used.

**FIG C.** The prepared defect is measured with the CMI Measuring Device.

**FIG D.** The CMI is trimmed to fit the meniscus defect.

**FIG E.** The CMI is inserted with the Delivery Clamp.

**FIG F.** The CMI is sutured to the meniscal rim with meniscal repair suturing devices.

**Overview of Implants & Instruments**

- **CMI Medial 7.5mm**
  - Part No. 4600

- **CMI Medial 9.0mm**
  - Part No. 4601

- **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
    - 2-0 UHMWPE | Part No. HS4704

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Q Who would be a good candidate for the CMI?
A Those patients who have had a previous partial meniscectomy and continue to experience knee pain or patients with a new meniscal tear requiring greater than 25% loss of meniscus tissue. Both anterior and posterior horns of the meniscus must be intact, and the knee joint must not show signs of malalignment.

Q What type of tissue fills the defect once the CMI is resorbed?
A On the basis of the histological evaluations from biopsies taken at one year in the U.S. Multicenter Study, the CMI appears to provide a scaffold for the formation of meniscus-like fibrochondrocytic matrix by the host. When an interface between the CMI and the host meniscus rim could be identified, incorporation of the new tissue generated by the implant into the host tissue was consistently present and characterized by an angiogenic track connecting the implant matrix into the host tissue. Visual estimates indicated that about 10% to 25% of the Collagen Meniscus Implant remained at one year. Additional patient biopsies, at longer time periods, from other studies show that this tissue continues to mature over time and that the remaining CMI matrix continues to be resorbed until no remnants remain.

Q What is the recommended post-operative rehabilitation program?
A The knee is braced and the patient uses crutches for the first eight weeks with a gradual increase in weight-bearing and range of motion. By week nine, the patient should have unrestricted full range of motion and weight-bearing and still be able to enjoy normal daily activities. However, the patient will still be participating in a focused exercise program through month six to ensure optimal healing and benefit from the CMI surgery and return to vigorous activities and sports.

Q How is the CMI reimbursed?
A Ivy Sports Medicine is working toward full universal coverage for the CMI, and has a staff to answer questions and assist in attaining coverage on a patient-by-patient basis.

Q How do you handle surgeon training?
A Participation in a CMI training session is required to perform a CMI implantation. Multiple sessions are planned each year and led by experienced CMI surgeons.