INDICATIONS

The RapidLoc™ system is intended for use in the arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle lesions) located in the vascularized area of the meniscus (red-red and red-white areas).

CONTRAINDICATIONS

1. Surgical procedures other than those listed in the INDICATIONS section.
2. Pathological conditions in the tissue that would impair secure fixation by suture.
3. Physical conditions that would eliminate, or tend to eliminate, adequate tissue strength, or retard tissue healing, i.e. blood supply limitation, infection, etc.
4. Conditions that tend to preempt patient’s ability to heal or the healing period, such as senility, mental illness or alcoholism are contraindicated.

PRECAUTIONS

1. A surgeon should not begin clinical use of the RapidLoc fixation system without reviewing the instructions for use and practicing the procedure in a skills laboratory.
2. Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks.
3. Discard used needles in sharps containers.

WARNINGS

Users should be familiar with the arthroscopic surgical procedures and techniques for repair of meniscal tissue before using the RapidLoc fixation system for meniscal tissue repair. The RapidLoc fixation system and delivery needle must never be reused. Do not resterilize. Discard opened and unused implants.

CAUTION:

Federal Law (USA) restricts this device to sale by or on the order of a physician.

For more information, call your Mitek representative at 1-800-382-4682 or visit us at www.mitek.com. Mitek Products, Division of ETHICON, Inc., 60 Glacier Drive, Westwood, Massachusetts 02090.
**RapidLoc™ Meniscal Repair System**

The RapidLoc™ Meniscal Repair System is a second-generation “all-inside” system that offers several advantages over current systems, including “inside-out” repair techniques and current “all-inside” rigid implants. This system is quick, simple, reproducible, reliable, and flexible in many ways, all while decreasing iatrogenic morbidity.

The implant consists of three components: 1) a soft tissue anchor called a “Backstop”; 2) a connecting suture; and, 3) a “TopHat” which compresses the meniscus tear against the Backstop.

The soft tissue anchor called a Backstop is easily deployed without the need for measuring. The Backstop is connected to an implant that resembles the shape of a “TopHat” via a suture. The TopHat is simply slid down the suture. The technique consists of mainly three steps. A good technique for evaluation and preparation is critical and can be further tightened or tensioned as needed without loosening. The suture provides several advantages. Most importantly, it allows flexibility within the system, which equates to reliability and ease of use. There is no fixed length of the implant. The location of the tear does not dictate the size of the implant. Depressible compression will be obtained between the Backstop and the TopHat as the suture is simply slid down the suture to the desired length. It is not a rigid device and, therefore, minimizes fatigue more noticeable with rigid devices. Polyethylene fibers allow the TopHat to pivot and lie flush against the articular surface of the meniscus while allowing increased surface area for fixation of the meniscus. A strong fixation system has a minimal chance of loosening in the rare event of arthroscopic stress. It is a dependable fixation allowing any system currently on the market. The technique consists of mainly three steps which will be discussed in detail:

1. **Deploy the Backstop:**
   - Insert the applier through a standard medial or lateral portal. The applier may be inserted through a cannula, or with the aid of a minimally invasive tool. This applier is connected to an implant that resembles the shape of a “TopHat”.
   - Anchor the implant in the popliteal fossa avoiding any neurovascular injury as the tubing. Take care to aim the needle away from the popliteal fossa avoiding any nervous injury as the tubing. Take care to aim the needle away from the popliteal fossa avoiding any nervous injury as.
   - Pass the needle through the meniscal substance and into the pericapsular tissue posteriorly. While not necessary, the silicone tubing may hold the meniscus for deployment of the Backstop and TopHat. Note if the tissue has not been penetrated sufficiently, the needle may be further advanced. The silicone tubing will collapse to allow for further advancement of the needle. There is approximately 12mm of needle length beyond the tubing. Take care to aim the needle away from the popliteal fossa avoiding any nervous injury as one would with any inside-out repair.
   - Pull on the limb of the suture to assure capture and fixation of the Backstop (FIG. 7).
   - Gently slide the pusher down the length of the suture through the tip of the arthroscopic pusher. (FIG. 8). Note: If the tissue has not been penetrated sufficiently, the needle may be further advanced. The silicone tubing will collapse to allow for further advancement of the needle. There is approximately 12mm of needle length beyond the tubing. Take care to aim the needle away from the popliteal fossa avoiding any nervous injury as one would with any inside-out repair.
   - Cut the suture (FIG. 9).

2. **Seat the TopHat:***
   - Using the arthroscopic pusher when the tip contacts the knot, initiate a pushing/pulling action. (FIG. 10) Pull on the suture with slightly more pressure than applied to the pusher. This will prevent the accumulation of slack in the suture, allowing the TopHat and knot to slide smoothly. Continue to pull on the limb of the suture to advance the knot and TopHat down to the surface of the meniscus.
   - Seat the TopHat snugly into the meniscal tear. Continue to pull on the position until the knot is seated and the meniscus is “dimpled” as the suture is tensioned. This will prevent the accumulation of slack in the suture.
   - Cut the suture (FIG. 10).

3. **Secure the meniscal tear:***
   - Use the needle and silicone tubing, reduce the meniscal tear (FIG. 11).

**Surgical Technique**

The RapidLoc Meniscal Repair System is indicated for standard repairable meniscus tears. The meniscus tear is evaluated and prepared in the usual manner. A good technique for evaluation and preparation is critical as with any meniscal repair (FIG. 1).

The implant is preloaded onto a needle. There are three different needles – Straight, 12˚ Curved and 27˚ Curved. Choose the appropriate needle and load it into the applier. Insert the applier through a standard medial or lateral portal. The applier may be inserted through the portal alone, through a cannula, or with the aid of a minimally invasive tool (FIG. 2). The graft retractor allows easy insertion of the sharp needle and avoids “hang-up” on the fat pad. The graft retractor can quickly be removed, negating any restrictions imposed by the cannula.

**Post Operative**

Postoperative treatment is important. A recommendation is to place the patient in a hinged brace with motion from 0-30˚ for the first two weeks and gradually increase motion over the first six weeks (0-60˚ for two weeks, 0-90˚ for the next two weeks, 0-90˚ for the following two weeks, then discontinue the brace). Also keep the patient at light/medium weight bearing for the first month, then partial weight bearing for the following two weeks. Allow the patient full weight bearing when the brace is discontinued after six weeks postoperatively. The patient should start working with a physical therapist immediately postoperatively for quadriceps strengthening, mobilization and range of motion within the limits of the brace. Deep squats and full contact sport activity are discouraged for the first 4 to 5 months postoperatively.

Postoperatively, swelling and bruising are to be expected. Some patients develop symptoms of pain and fullness with activity that may respond to antiinflammatory medication for a period of 6 weeks postoperatively. If symptoms persist beyond this period, please consult with your physician.

**NOTE:** To use the RapidLoc implant, an arthroscopic pusher (22MM) is required.