Meniscal Repair
Surgical Protocol by Keith Lawhorn, M.D.
The next generation of all-inside, all-suture meniscal repair

This brochure is presented to demonstrate the surgical technique utilized by Keith Lawhorn, M.D. Biomet Sports Medicine, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. Biomet Sports Medicine is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.
Building upon the **proven strength**\(^1\) of the MaxFire™ Device, the MaxFire™ MarXmen™ Meniscal Repair Device now incorporates a new **easy-to-use**\(^2\) one-handed trigger delivery system.

The MaxFire™ MarXmen™ trigger delivery system requires the least amount of insertion force when compared to other all-inside meniscal repair devices.\(^2\)

The MaxFire™ Meniscal Repair Device was shown to be stronger in load-to-failure pullout testing in porcine meniscus.\(^1\)

The MaxFire™ Meniscal Repair Device was shown to be stronger in cyclic loading testing in porcine meniscus.\(^1\)

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Rigid Tube Cannula
• Helps protect the surrounding structures in the joint
• Houses the needle sled when the device is inserted into the joint space
• Available in curved and straight geometries

Needle Sled
• Guides deployment path of MaxFire™ Device
• Depth markings in 2mm increments to control depth of penetration through the meniscus
• Blunk pusher wire deploys implant to the back side of the meniscus

MaxFire™ Device
• All-suture implant
• Incorporates ZipLoop™ Technology—eliminating pre-tied knots near the articular surface of the knee
• Proven strength of original implant

ZipLoop™ Technology is a unique weave in which a single strand of braided polyethylene is woven through itself twice in opposite directions. This construct allows Biomet Sports Medicine to produce innovative products that can vary in length and compression/tension addressing the individual needs of each patient. Products utilizing ZipLoop™ Technology are resistant to slippage without tying knots. Procedure-specific animations, surgical protocols and surgery videos are available at www.ziploop.net.
Depth Indicator
- Provides a visual indication of the depth of needle sled penetration into the meniscus

Trigger
- Allows one-handed deployment of the MaxFire™ device

Thumb Wheel
- Retracts cannula
- Controls the depth penetration of the needle sled
Diagnostic Arthroscopy
Assess the location of the meniscal tear and determine the repairability of the lesion. Determine optimum medial portal placement using an 18-gauge spinal needle and direct arthroscopic visualization to create medial working portal. Optimum position is achieved when the needle enters just above the anterior medial meniscus parallel to the tibial joint surface (Figure 1).

Avoid placing the portal too superior. Ensure the medial portal is large enough to readily pass the inserter and suture cutter. Measure the distance from the back side of the meniscus to the desired needle penetration point at the repair site using a meniscal depth gauge (Figure 2).
Position the MaxFire™ MarXmen™ Inserter

Insert the disposable MaxFire™ MarXmen™ inserter into the joint. Both straight and curved-up cannulas are available to optimize implant positioning for repair. Use of a probe through the medial portal can help determine whether a straight or curved cannula would be optimal. To maximize safety, all posterior horn tears whether medial or lateral, should be approached from the medial portal.

Mid-body tears can be approached from the contralateral portal. Anterior horn tears can be approached from the ipsilateral portal (Figure 3). Under direct arthroscopic visualization, maneuver the cannula tip against, or adjacent to, the desired portion of the meniscus (Figure 4).

Note: Avoid excessive torque of the cannula upon insertion into the joint.
Inserting Needle Sled

Place the long finger in the space between the trigger and the body of the inserter (Figure 5). Retract the cannula and expose the needle sled by pushing the thumb wheel and rolling it upwards (Figure 6). This will set the initial deployment length setting. **Note: Do not squeeze the trigger until the needle sled is in position to deploy the first anchor.** The needle deployment length is adjusted by rolling the thumb wheel.

Laser markings on the needle sled and a dial on the body of the inserter can be used to verify deployment depth. Each laser marking on the needle sled represents a 2mm increment. **Insert the needle sled into the desired location in the meniscus with the depth indicator set at 10mm** (Figure 7). Once the sled has been inserted into the meniscus, set the depth to the pre-determined setting (Figure 8) and advance the cannula until it is flush with the meniscus (Figure 9).
Deploy the First Anchor

Once the needle sled is advanced completely into the meniscus at the desired length, hold gentle but firm pressure against the meniscus. Position the middle finger over the outside of the trigger. Squeeze the trigger and maintain pressure to deploy the implant (Figures 10 A, B & C). A gentle click will be felt once the implant has been completely advanced to the desired length. Release the trigger and pull the needle sled gently from the meniscus (Figures 11A & B).

Note: Squeeze the trigger completely once for each anchor. Multiple trigger pulls (particularly with the insertion of the first anchor) will deploy both anchors at the same location.
Set depth to desired setting and advance needle sled into meniscus. Once the needle sled is advanced completely into the meniscus at the desired length, hold gentle but firm pressure against the meniscus. Squeeze the trigger and maintain pressure to deploy the implant (Figure 13). A gentle click will be felt once the implant has been completely advanced to the desired length.

Deploy the Second Anchor
Re-position the needle sled to a new desired location on the meniscus 5 – 10mm from the first anchor (Figure 12). Note: the needle sled may be retracted into cannula while moving to new position if desired to prevent inadvertent chondral injury. Adjust depth of needle penetration to 10mm. Advance the needle sled into the meniscus in the desired location taking care not to impale the suture or damage the articular cartilage. This is particularly important when creating a vertical mattress stitches.
Vertical Mattress Technique: Insert the first anchor on the superior meniscal rim or surface. Implants in this superior meniscal location will require shorter distances of deployment since the depth of meniscus will be less compared to the inferior meniscus. Insert the second anchor in the inferior meniscus. Needle depth penetration will need to be increased to ensure deployment of the anchor through the meniscus and capsule. (Figure 15).

Release the trigger and pull the needle sled gently from the meniscus. Remove the MaxFire™ MarXmen™ inserter from joint (Figure 14).
Surgical Technique

Tension the Suture
A large loop and a free strand of suture will remain outside the portal site (Figure 16). Grab each of the loop strands leaving the single strand free. Pull on the strands to determine which strand tightens the inner short loop at the meniscus. Note: Pulling the appropriate strand should NOT result in shortening of the single strand outside of the joint. With the appropriate loop strand identified, alternately pull the appropriate loop strand and the single strand (Figure 17). Visualize tightening the suture at the meniscal repair site. Once a small loop remains outside of the joint, simply pull the single strand until the second large loop is seated against the meniscal tissue (Figure 18).
Cut the Suture
Slide the suture into the opening of the disposable MaxCutter™ Suture Cutter. Insert the cutter through the portal and to the level of the meniscus. Advance the cutter lever to sever the suture (Figure 19). Assess fixation with a probe. Fixation is now complete (Figure 20).

Note: It is recommended that suture anchors from a given pair (single MaxFire™ construct) be spaced 5 – 10mm apart. Each MaxFire™ anchor construct should also be spaced 5 – 10mm apart to ensure subsequent anchors are not inserted into, or too close, to previously placed anchors.
## Ordering Information

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<th>MaxFire™ MarXmen™ Meniscal Repair Device with ZipLoop™ Technology</th>
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- **Disposable Cutter**
  - 905732
- **Calibrated Probe**
  - 905727
- **Rasp**
  - 901011
Biomet Sports Medicine MaxFire™ Meniscal Repair Device

ATTENTION OPERATING SURGEON

DESCRIPTION
Biomet Sports Medicine MaxFire™ Meniscal Repair Device incorporates two loops and a sliding knot. The loops are inserted on either side of a meniscal tear and tightened to form anchors on the backside of the meniscus. By tensioning the suture, the sliding knot allows the anchors to be drawn closer to one another and the meniscal tear is compressed.

MATERIALS
Sutures Polyethylene/Polypropylene
Sleeve Polyester or Polyethylene
Inserter ABS, Nitinol, Stainless Steel and Polyethylene, or PTFE (polytetrafluoroethylene)

ACTIONS
The polyethylene suture elicits a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue.

INDICATIONS
Biomet Sports Medicine MaxFire™ Meniscal Repair Device is indicated for the repair of vertical longitudinal full thickness tears (e.g. bucket-handle) in the red-red and red-white zones. These devices are not to be used for meniscal tears in the avascular zone of the meniscus.

CONTRAINDICATIONS
1. Active infection.
2. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
3. Meniscal tears not suitable for repair because of the degree of damage (marked irregularity and complex tearing) to the meniscus body including degenerative, radial, horizontal cleavage and flap tears.

WARNINGS
Biomet Sports Medicine internal fixation devices provide the surgeon with a means to aid in the management of meniscal tears. While these devices are generally successful in attaining these goals, they are not to be expected to replace normal healthy soft tissue or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of incomplete healing. Therefore, it is important that immobilization (use of external support, walking aids, braces, etc.) of the treatment site be maintained until healing has occurred. Surgical implants are subject to repeated stresses in use, which can result in fracture or damage to the implant. Factors such as the patient's weight, activity level, and adherence to weight bearing or load bearing instructions have an affect on the implant. The surgeon must be thoroughly knowledgeable not only in the medical and surgical aspects of the implant, but also must be aware of the mechanical and polymeric aspects of the surgical implants.

1. Correct selection of the implant is extremely important. The potential for success in soft tissue fixation is increased by the selection of the proper type of implant. While proper selection can help minimize risks, the device is not designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. The implants can loosen or be damaged when subjected to increased loading associated with inadequate healing. If healing is delayed, or does not occur, the implant or the procedure may fail. Loads produced by weight bearing and activity levels may dictate the longevity of the implant.
3. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device.
4. Care is to be taken to assure adequate fixation of the meniscal tissue at the time of surgery. Failure to achieve adequate fixation through improper positioning or placement of the device can contribute to a subsequent undesirable result.
5. The use of appropriate immobilization and postoperative management is indicated as part of treatment until healing has occurred.
6. Correct handling of suture is extremely important. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
7. DO NOT USE if there is loss of sterility of the device.
8. DEXTRAN and DO NOT USE opened or damaged devices. Use only devices that are packaged in unopened and undamaged containers.
9. Adequately instruct the patient. Postoperative care is important. The patient's ability and willingness to follow instructions is one of the most important aspects of successful soft tissue management. Patients affected with senility, mental illness, alcoholism, and drug abuse may be at a higher risk of device or procedure failure. These patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that are intended to immobilize the repair site and limit weight bearing or load bearing. The patient is to be made fully aware and warned that the device does not replace normal healthy tissue, and that the device can break, or be damaged as a result of stress, activity, load bearing, or weight bearing. The patient is to be made aware and warned of general surgical risks, possible adverse effects, and to follow the instructions of the treating physician. The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.

PRECAUTIONS
1. Material sensitivity reactions. Introduction of foreign material in tissues can result in histological reactions involving various sizes of macrophages and fibroblasts. The clinical significance of this effect is uncertain, as similar changes may occur as a precursor to or during the healing process.
2. Instruments are available to aid in the accurate implantation of Biomet Sports Medicine implants. Intraoperative fracture of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Surgical instruments are only to be used for their intended purpose. All instruments are to be regularly inspected for wear and disfigurement.

If device contains MaxBraid™ suture, refer to manufacturer package insert for further information.

POSSIBLE ADVERSE EFFECTS
1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.
3. Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
4. Implantation of foreign materials can result in an inflammatory response or allergic reaction.
5. Inadequate healing, which may lead to breakage of the implant or failure of the graft material.
6. Pain, discomfort, or abnormal sensation due to the presence of the device.
7. Necrosis of bone or tissue.

STERILITY
Biomet Sports Medicine MaxFire™ Meniscal Repair Device is sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

Caution: Federal Law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

Comments regarding this device can be directed to:
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