MaxFire™ Meniscal Repair System

Surgical Technique

Overview

The MaxFire™ Meniscal Repair System is an all-inside, all-suture anchor meniscal repair system. The technique uses a cannula system to safely and precisely control the placement of meniscal sutures. Cannulas are available in straight, side-to-side curved and upward-curved designs. Interchangeable, color-coded barrels attach to the various cannula designs to safely control needle depth and suture anchor penetration into the meniscus and capsule.

The MaxFire™ meniscal inserter comes preloaded with two needle inserters, each with a suture anchor connected to one another and a single, pre-tied sliding locking knot. The MaxFire™ meniscal inserter locks into the desired cannula allowing the surgeon to maneuver the inserter/cannula assembly as a single unit. Suture anchors may then be positioned in either a horizontal and/or vertical mattress configuration. The pre-tied sliding locking knot advances to secure the fixation by simply pulling the post strand of suture exiting the knee. The MaxCutter™ knot pusher/cutter is used to complete the fixation.

Diagnostic Arthroscopy

Assess the location of the meniscal tear and determine the reparability of the lesion. Using a meniscal depth gauge, measure the thickness of the meniscus at the repair site. (Figure 1). Using this measurement, attach the coressponding color-coded handle to the preferred cannula (Figure 2).

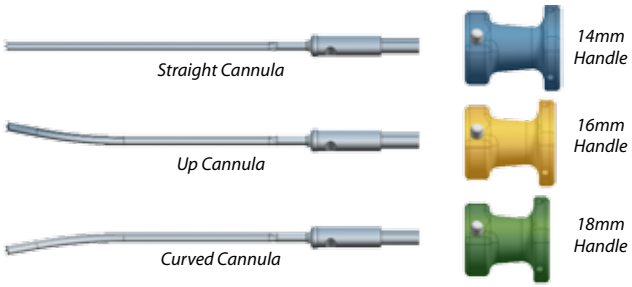

Figure 2

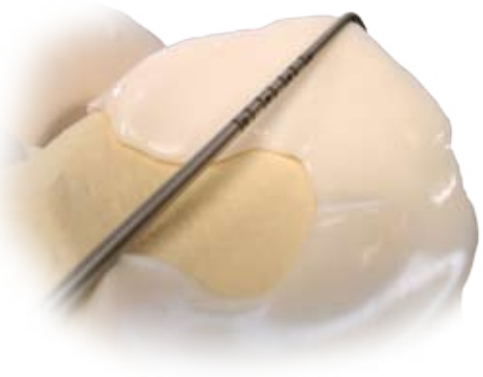

Figure 1

Positioning the Cannula and Loading the MaxFire™ Meniscal Repair Device

Once the appropriate cannula and barrel have been assembled, load the obturator and insert the cannula/barrel/obturator assembly into the desired compartment of the knee joint (Figure 3). Under direct arthroscopic visualization, maneuver the cannula tip against, or adjacent to, the desired portion of the meniscus (Figure 4). Remove the obturator.

Figure 3

Figure 4

Surgical Technique

Insert the MaxFire™ Meniscal Repair device into the cannula/barrel assembly by aligning the flat on the tip of the barrel with either flat on the tip of the MaxFire™ inserter handle (Figure 5). Advance the inserter handle until the device seats completely inside the cannula. When seated properly, the inserter handle will click into place, flush against the flat on the barrel. **Note: Do not pull back on the MaxFire™ inserter handle at any time once the MaxFire™ needles are engaged inside the cannula.**

Figure 5

Using the MaxFire™ inserter handle, apply gentle but firm pressure against the meniscus (Figure 6).

Figure 6

Deploying the MaxFire™ All-Suture Anchors

While maintaining gentle but firm pressure on the meniscus, pass the first all-suture anchor by advancing the green lever to its forward mechanical stop (Figure 7).

Once the green lever has reached its forward mechanical stop, pull the green lever back to its original position. **Note: The red lever cannot be advanced until the green lever has been completely advanced and then pulled back to its original position.**

Reposition the cannula to the desired location on the meniscus in preparation for passing the second all-suture anchor. **Note: Always move the cannula in a direction away from the first anchor (green lever). For example, when performing a horizontal mattress stitch, move the cannula tip toward the red lever**.

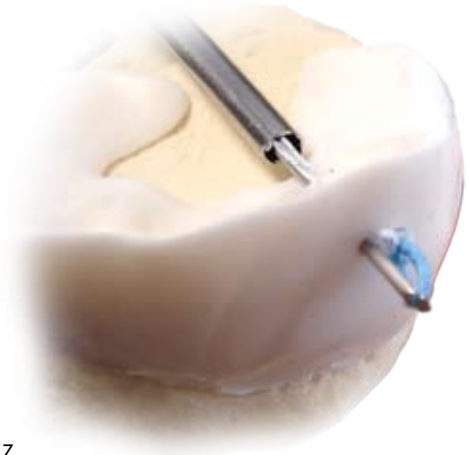

Figure 7

To pass the second suture anchor, completely advance the red lever while maintaining gentle but firm pressure on the meniscus (Figure 8). Next, pull the red lever back to its original position. This ensures that the suture is not crossed and that the distance between the anchors is determined precisely by the positioning of the cannula tip on the meniscus, particularly when using a curved cannula.

When performing a vertical mattress stitch, insert the first anchor (green lever) into the superior aspect of the meniscus and the second anchor (red lever) into the inferior aspect of the meniscus. This will position the knot on the inferior aspect of the meniscus making it easier to visualize the knot, apply tension and cut the suture.

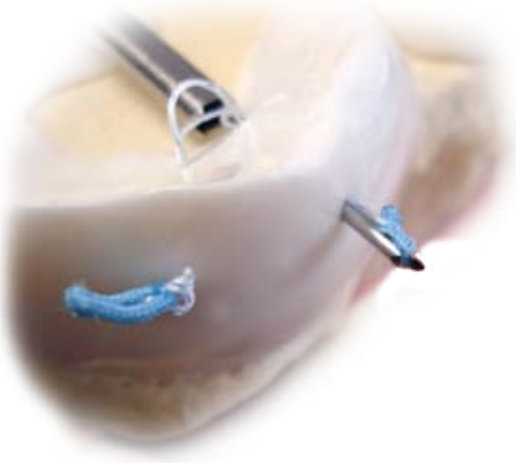

Figure 8

Tensioning and Cutting the Suture

Once both suture anchors have been deployed across the tear, simultaneously remove the MaxFire™ inserter/cannula/barrel assembly from the joint. A single strand of suture should still remain outside the portal site. (Figure 10). Tension the knot by pulling the suture, and secure the repair as desired.

Next, using a MaxCutter™ device (Figure 9), pass the suture through the bottom side (concave side) of the instrument. Insert the MaxCutter™ device into the portal and push the knot to achieve the appropriate tension (Figure 10). Advance the cutter lever to cut the suture. Assess fixation. Repeat as needed to complete the repair. **Note: It is recommended that suture anchors be placed 5mm apart when repairing meniscal tears.**

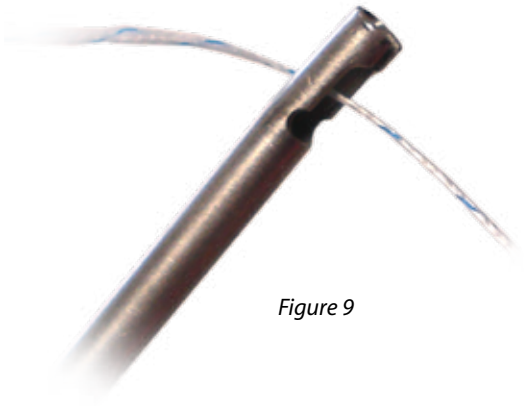

Figure 9

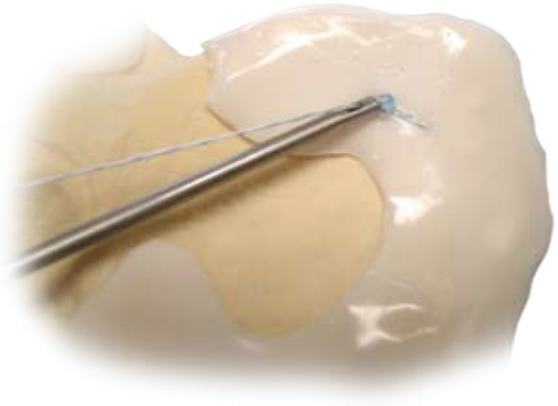

Figure 10

This brochure is presented to demonstrate the surgical technique utilized by Keith W. 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.

Rehabilitation activities vary depending on the individual patient and physician's recommendations.

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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

Suture	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 cannot 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. Discard 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.

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