



Precautionary Statement (01-50-1059)

Biomet Sports Medicine, Inc.

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01-50-1059

Date: 05/07

Resorbable Meniscal Repair Devices

ATTENTION OPERATING SURGEON

DESCRIPTION:

The Biomet Sports Medicine™ Resorbable Meniscal Repair Devices include a staple and a screw. The staple consists of two rigid barbed legs connected by a bridge, and a headless screw which is fully cannulated. These devices are used in the approximation of tissue, specifically the meniscus.

The Resorbable Meniscal Repair Devices are made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Poly-L-lactic/ polyglycolic acid copolymer degrades and resorbs in vivo by hydrolysis into L-lactic and glycolic acids, which are then metabolized by the body.

MATERIALS

Poly-L-Lactic Acid/Polyglycolic Acid

INDICATIONS:

The Resorbable Meniscal Repair Devices are indicated for the repair of vertical longitudinal full thickness tears (i.e. 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 in the avascular zone of the meniscus.
4. 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 effect 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, neither the device nor grafts, when used are designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. Improper selection, placement, positioning, and fixation of the device can lead to failure of the device or the procedure. The surgeon is to be familiar with the devices, the method of application and the surgical procedure prior to performing surgery. The surgeon must select a type or types of internal fixation devices appropriate for treatment.
3. 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.
4. These devices are resorbable and do not provide permanent fixation. Do not use in procedures where a permanent implant is needed.
5. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device.
6. 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.
7. The use of appropriate immobilization and postoperative management is indicated as part of treatment until healing has occurred.
8. Correct handling of implants is extremely important. Do not modify implants. Do not notch or bend implants. Notches or scratches put in the implant during the course of surgery may contribute to breakage. Intraoperative fracture of devices can occur if excessive force is applied while seating.
9. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure requiring additional surgery and device removal
10. DO NOT USE if there is loss of sterility of the device.
11. Discard and DO NOT USE opened or damaged devices. Use only devices that are packaged in unopened and undamaged containers.
12. Do not use Biomet Sports Medicine™ resorbable implants with resorbable implants made by other manufacturers due to the probability of incompatible fits, size and rate of resorption.
13. 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.
 - o 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.
 - o 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.
 - o The patient is to be made fully aware and warned that the device does not replace normal healthy bone and tissue, and that the device can break, bend or be damaged as a result of stress, activity, load bearing, or weight bearing.
 - o 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 warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.
 - The patient is to be advised of the need for regular postoperative follow-up examination as long as the device remains implanted.
 - Patients that engage in stressful physical activities are to be warned that injury at or near the implant site can lead to failure of the device and/or the treatment.
14. Noncompliance with postoperative instructions could lead to failure of the device, which could require additional surgery and device removal.

PRECAUTIONS:

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 that have experienced extensive use or excessive force are susceptible to fracture. Surgical instruments are only to be used for their intended purpose. Biomet Sports Medicine recommends that all instruments be regularly inspected for wear and disfigurement.

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:

The Resorbable Meniscal Repair Devices are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

STORE AT OR BELOW ROOM TEMPERATURE. DO NOT EXPOSE PRODUCT TO TEMPERATURES GREATER THAN 120 °F (49 °C).

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 Attn: Regulatory Dept, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-1683

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