



Precautionary Statement (01-50-1062)

Biomet Sports Medicine, Inc. 01-50-1062

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WARNINGS AND PRECAUTIONS FOR USE OF THE ArthroRivet™ Tack

ATTENTION OPERATING SURGEON

DESCRIPTION:

The ArthroRivet™ Tack is a resorbable repair device used to attach soft tissue to bone. The resorbable device is implanted into a prepared hole in the bone and is used to reattach damaged soft tissue. The device is made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Polylactic/Polyglycolic acid copolymer degrades and resorbs in vivo by hydrolysis to lactic and glycolic acids, which are then metabolized by the body.

MATERIALS:

Poly-L-Lactic Acid/Polyglycolic Acid

INDICATIONS:

The ArthroRivet™ Tack is indicated for use in soft tissue reattachment in the following shoulder procedures:

1. Instability repairs in the shoulder (Bankart Procedures)
2. SLAP lesion repair
3. Acromio-clavical separation repairs
4. Rotator cuff tear repairs
5. Capsular shift or capsulolabral reconstructions
6. Biceps tenodesis
7. Deltoid repairs

CONTRAINDICATIONS:

1. Active infection
2. Patients with mental or neurological conditions who are unwilling or incapable of following postoperative care instructions.
3. Patient conditions including blood supply limitations, insufficient quantity or quality of bone, or latent infections.
4. Pathologic soft tissue conditions, which would prevent secure fixation.

WARNINGS:

Biomet Sports Medicine™ internal fixation devices provide the surgeon with a means to aid in the management of soft tissue to bone reattachment procedures. 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, sling, 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 activity level and adherence to weight bearing or load bearing instructions have an effect on the service life of 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 to bone 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. These devices are resorbable and do not provide permanent fixation. Do not use in procedures where a permanent implant is needed.
4. Inadequate fixation at the time of surgery can increase the risk of loosening and migration of the device or tissue supported by the device. Sufficient bone quantity and quality are important to adequate fixation and success of the procedure. Bone quality must be assessed at the time of surgery. Adequate fixation in diseased bone may be more difficult. Patients with poor quality bone, such as osteoporotic bone, are at greater risk of device loosening and procedure failure.
5. Care is to be taken to assure adequate soft tissue fixation at the time of surgery. Failure to achieve adequate fixation or improper positioning or placement of the device can contribute to a subsequent undesirable result.
6. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
7. 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 (torque) is applied while seating.
8. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure requiring additional surgery and device removal.
9. DO NOT USE if there is loss of sterility of the device.
10. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened or undamaged containers.
11. 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.
12. 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 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, bend 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 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.
13. 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 internal fixation devices. Intraoperative fracture or breaking 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 should only 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.
6. Pain, discomfort, or abnormal sensation due to the presence of the device.
7. Necrosis of the bone or tissue.

STERILITY:

ArthroRivet™ is 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 OR 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, P.O. Box 587, Warsaw, IN 46581 USA, FAX: 574-372-1683

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