INDICATIONS

The JuggerKnot Soft Anchors are intended to be used for soft tissue to bone fixation for the following indications:

**Shoulder**
- Bankart lesion repair
- SLAP lesion repair
- Acroromic-clavicular repair
- Capsular shift / capsulolabral reconstruction
- Deltoid repair
- Rotator cuff tear repair
- Biceps tenodesis
- Pectoralis major repair

**Foot and Ankle**
- Medial / lateral repair and reconstruction
- Mid- and forefoot repair
- Hallux valgus reconstruction
- Metatarsal ligament/tendon repair or reconstruction
- Achilles Tendon Repair

**Elbow**
- Ulnar or radial collateral ligament reconstruction
- Lateral epicondylitis repair
- Biceps tendon reattachment

**Knee**
- Extra-capsular repair: MCL, LCL, and posterior oblique ligament
- Iliotibial band tenodesis
- Patellar tendon repair
- VMO advancement
- Joint capsule closure
- MPFL repair or reconstruction
- Quadriceps tendon repair

**Hand and Wrist**
- Collateral ligament repair
- Scapholunate ligament reconstruction
- Tendon transfers in phalanx
- Volar plate reconstruction

**Hip**
- Acetabular labral repair
- Proximal hamstring repair

CONTRAINDICATIONS

1. Infection.
2. Patient conditions including blood supply limitations and insufficient quantity or quality of bone or soft tissue.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions or patients who are otherwise unwilling or incapable of doing so.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

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 bone or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of nonunion, delayed union, or 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 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 material aspects of the surgical implants.

Patient selection factors to be considered include: 1) need for soft tissue to bone fixation, 2) ability and willingness of the patient to follow postoperative care instructions until healing is complete, and 3) a good nutritional state of the patient.

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, 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 device, 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 and the graft can fail when subjected to increased loading associated with nonunion or delayed union. 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. 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 ensure 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. Do not modify implants.
8. Correct handling of the device is extremely important. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders.
9. Do not use excessive force when inserting the device. Excessive force may cause damage to the device and/or adversely affect its performance.
10. The device can break or be damaged due to excessive activity or trauma. This could lead to failure requiring additional surgery and device removal.
11. DO NOT USE if there is a loss of sterility of the device.
12. DO NOT USE opened or damaged devices. Use only devices that are packaged in unopened or undamaged containers.
13. Ensure contact of tissue to bone when implanting.
14. 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 fracture management.
   - Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure. These patients may ignore instructions and activity restrictions.
• The patient is to be instructed in the use of external supports (walking aids, slings, braces, etc.) that are intended to immobilize the treatment 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 bone, 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 of the surgical risks and possible adverse effects prior to surgery, and 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.

15. Noncompliance with postoperative instructions could lead to failure of the device, which could require additional surgery and device removal.
16. Do not reuse implants. While an implant may appear undamaged, previous stress may have created imperfections that would reduce the service life of the implant. Do not treat with implants that have been, even momentarily, placed in a different patient.
17. Device is single use only. After use, the device may be a potential biohazard. Reuse of devices labeled for single-use may result in product contamination, patient infection and/or failure of the device to perform as intended.
18. Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.

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.

All trial, packaging, and instrument components must be removed prior to closing the surgical site. Do not implant.

POSSIBLE ADVERSE EFFECTS
1. Nonunion or delayed union, which may lead to breakage of the implant.
2. Bending or fracture of the implant.
3. Loosening or migration of the implant.
4. Allergic reaction to a foreign body.
5. Pain, discomfort, or abnormal sensation due to the presence of the device.
6. Nerve damage due to surgical trauma.
7. Necrosis of bone or tissue.
8. Inadequate healing.
9. Intraoperative or postoperative bone fracture and/or postoperative pain.

MR
IMPLANTS – MRI INFORMATION
The specific components of the JuggerKnot Soft Anchors are made from ultra-high molecular weight polyethylene (UHMWPE), polypropylene, nylon, and polyester. These materials are nonconducting and nonmagnetic. Therefore, in accordance with the definition stated in ASTM F-2503-08, Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment, the devices are determined to be “MR Safe – an item that poses no known hazards in all MR environments.”

STERILITY
Biomet Sports Medicine internal fixation implants are supplied sterile by Ethylene Oxide Gas (ETO). Single Use Only. Do Not Reuse. Do not resterilize. Do not use past expiration date. Do not use any component from an opened or damaged package.

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

Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw IN 46581 USA, Fax: 574-372-3968.

All trademarks herein are the property of Biomet, Inc. or its subsidiaries unless otherwise indicated.

CE Mark on the package insert (IFU) is not valid unless there is a CE Mark on the product (description) label.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend
CF31 3XA UK

Sterilized using Ethylene Oxide
Sterilized using Irradiation
Sterile
Sterilized using Aseptic Processing Techniques
Sterilized using Steam or Dry Heat

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Do not use if package is damaged (Pack Damage)
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