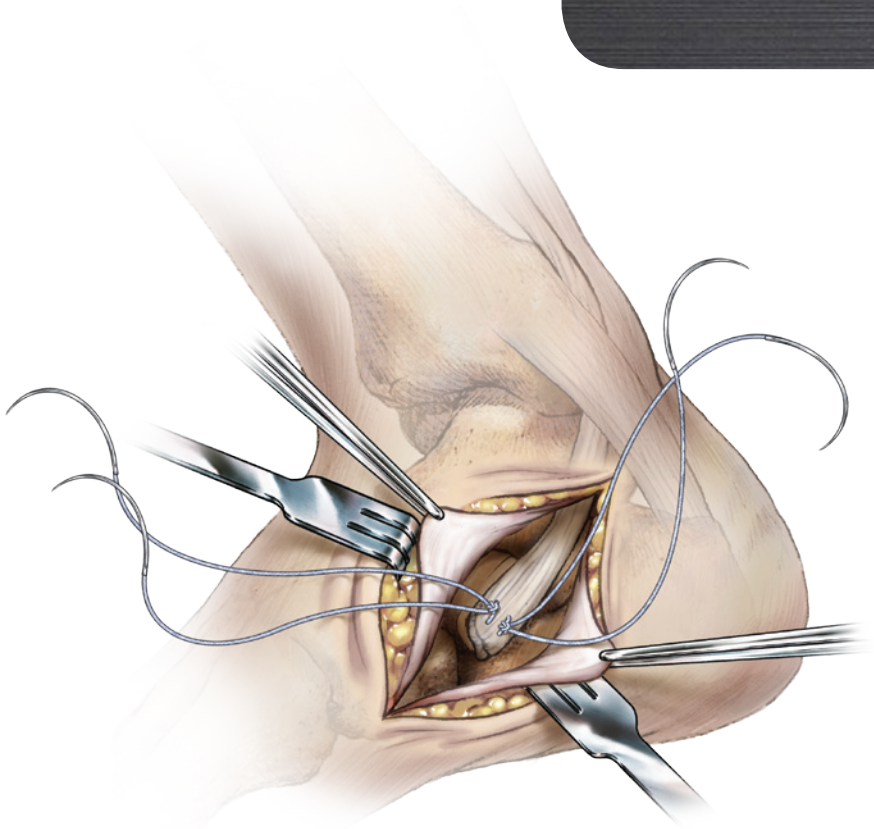
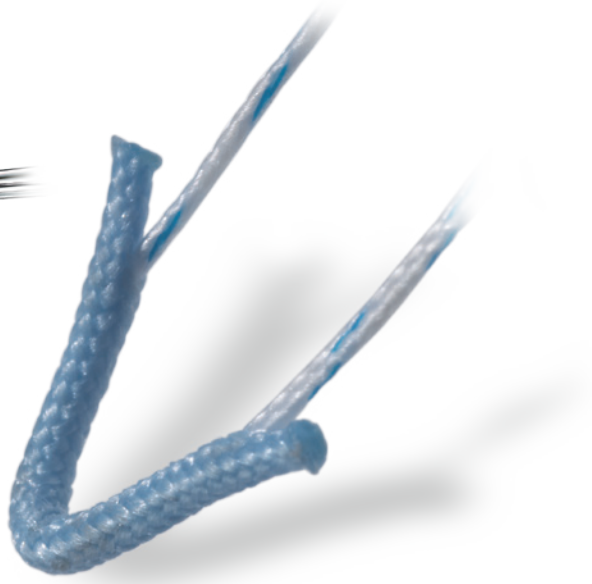
JuggerKnot™ SOFT ANCHOR





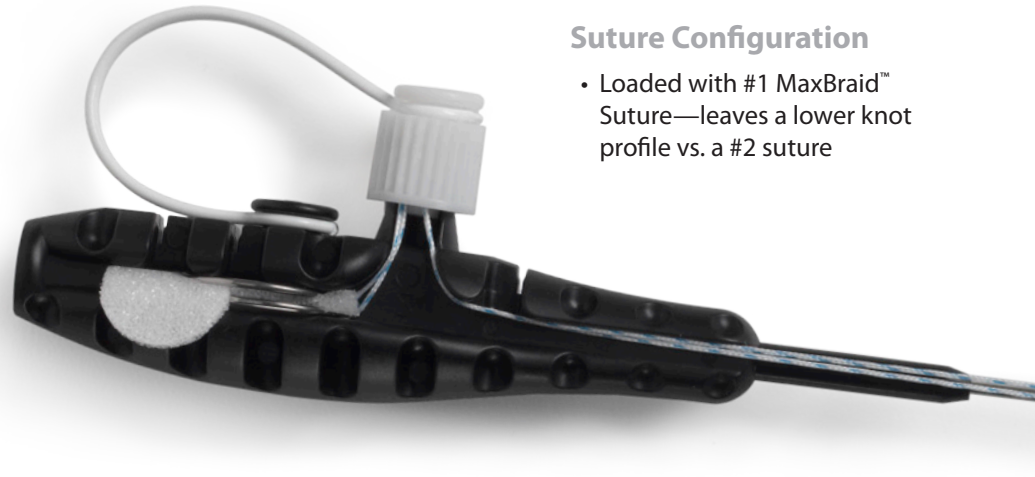
Midfoot Repair

Surgical Protocol by
Stuart Miller, M.D.

BIOMET® SPORTS MEDICINE

It’s small. It’s strong. And it's all suture.

The **JuggerKnot™ Soft Anchor** represents the next generation of suture anchor technology. The 1.4mm deployable anchor design is a completely **suture-based** system, and is the **first of its kind**.

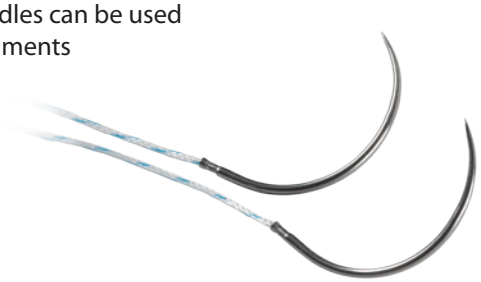


Suture Configuration

- Loaded with #1 MaxBraid™ Suture—leaves a lower knot profile vs. a #2 suture

Needles

- Tapered #5 needles can be used to tie down ligaments



This brochure is presented to demonstrate the surgical technique and postoperative protocol utilized by Stuart Miller, 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.

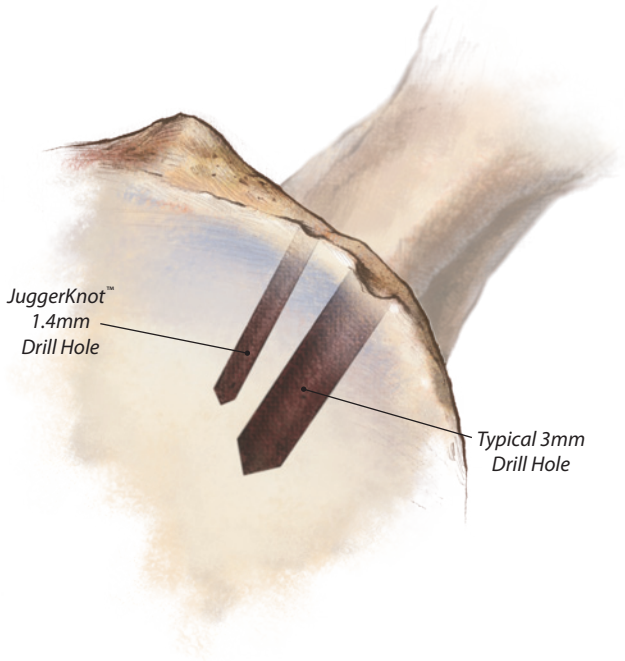
JuggerKnot™ SOFT ANCHOR

Minimal Size

- Smaller drill guide is less invasive to surrounding tissue
- Smaller anchor diameter allows multiple anchors to be placed
- Reduces likelihood of intersecting anchors when placing multiple anchors

Soft Material

- Soft anchor deployment system—completely suture based implant
- Implant made from #5 polyester suture
- Eliminates the possibility of rigid material loose bodies in the joint



Reduced Bone Removal

- The volume of bone that is removed with a 3.0mm drill is equivalent to four JuggerKnot™ device drill holes

Surgical Technique

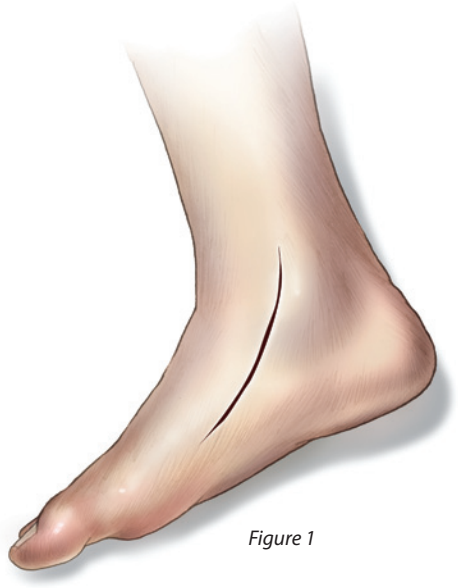


Figure 1

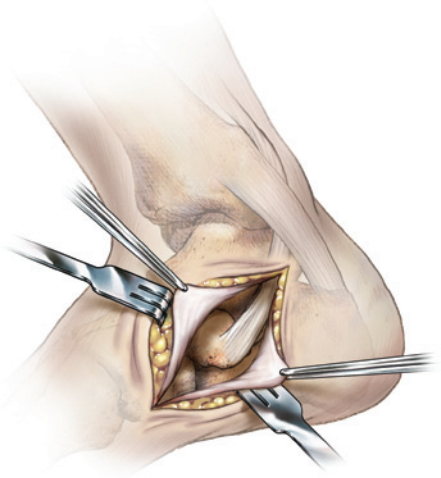


Figure 2

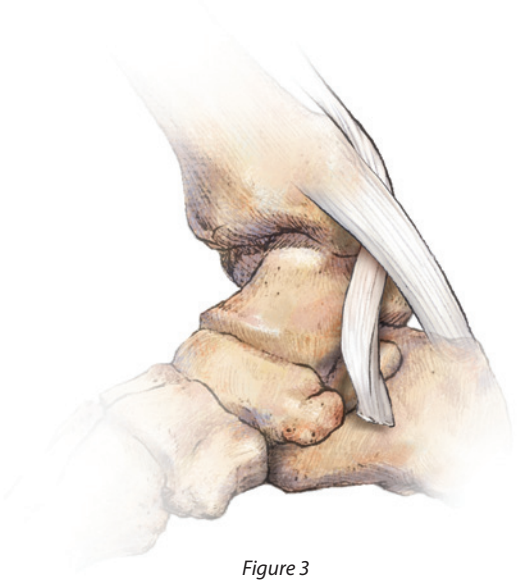


Figure 3

Positioning and Preparation

The patient is placed in a supine position with a small bump under the contralateral hip or on a beanbag. The ankle can be blocked with local anesthetic to minimize anesthetic needs and ease post-operative pain. A thigh-tourniquet can be placed or a distal Esmarch compression wrap may be chosen. The leg is prepped to just below the knee.

Incision

The pole of the navicular is the most easily noted landmark. An incision is brought from the tip of the medial malleolus to just plantar to the pole along the line of the posterior tibial tendon (Figure 1). Small vessels can be cauterized as encountered and the sheath of the posterior tibial tendon will be easily seen. This sheath is incised and the posterior tibial tendon visualized (Figure 2). The tendon can be carefully peeled from its attachment to the pole of the navicular (or the os trigonum) on the dorsum; often the surgeon will trim the lateral extensions to narrow the tendon to uniform width. The tendon will now be completely released from its distal insertion (Figure 3).

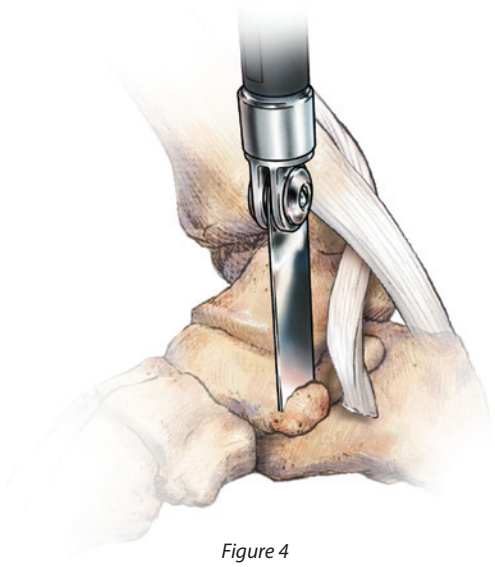


Figure 4

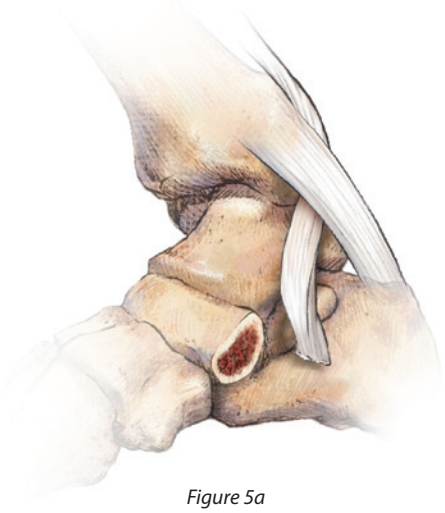


Figure 5a

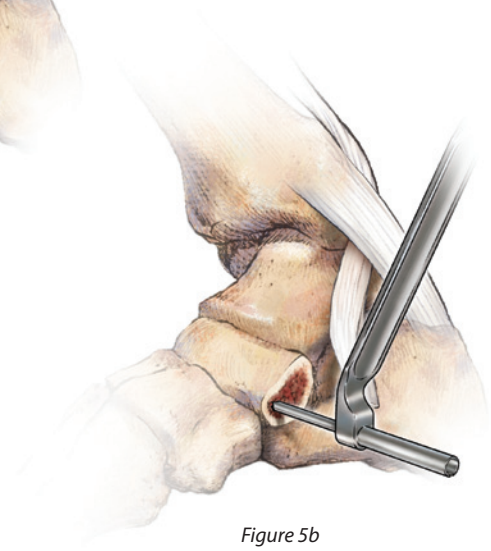


Figure 5b

If an os navicular bone is suspected, the plane of the fibrous connection can be discerned and opened with a Freer elevator. This often vertical line can be more easily seen with slight resection of the dorsal bone using a small chisel, osteotome, or microsagital saw. The accessory bone removed, the surgeon can then smooth the medial contours of the remaining navicular bone. A prominent pole can be resected generously and the "landing zone" for the reattachment of the posterior tibial tendon should be smooth bleeding bone (Figure 4). The tendon should be inspected for any damage, which is fortunately rare in most patients.

Note: The classic midfoot procedure advances the posterior tibial tendon to the cuneiform rather than the described and now more common reattachment to the navicular bone. Should the surgeon prefer such a measure, the incision is extended distally to the cuneiform and that bone prepared similarly.

Placement of the JuggerKnot™ Guide

Two JuggerKnot™ suture anchors can be utilized to secure the posterior tibial tendon to the navicular. They will be on the more plantar aspect of the prepared bone, usually one above the other. The anatomy of the talo-navicular joint MUST be respected; some surgeons fail to appreciate the substantial curvature and may erroneously enter the joint. Place the JuggerKnot™ Guide on the more plantar aspect of the resected accessory navicular where the posterior tibial tendon will be reattached (Figures 5a & 5b). When in doubt, a small C-arm fluroscan can help visualize the drill bit location prior to anchor placement.

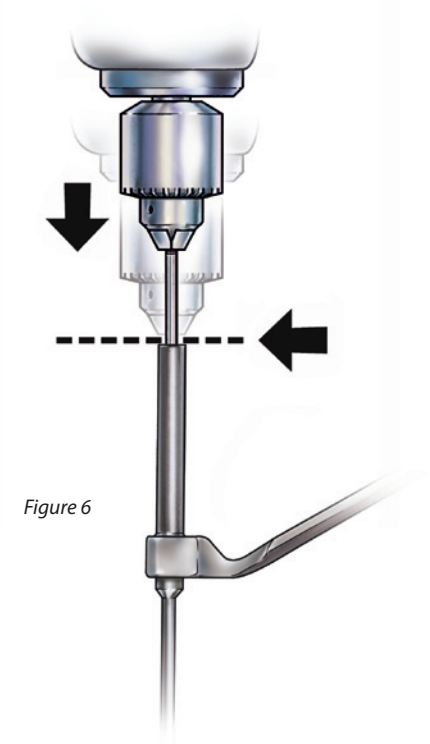


Figure 6

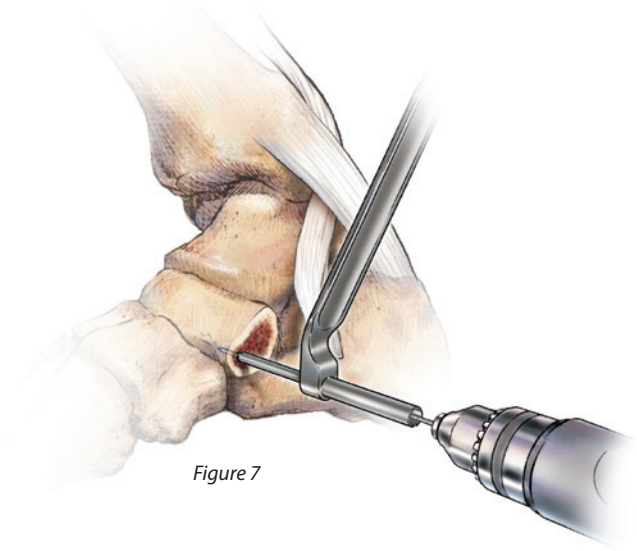


Figure 7

Drill the Pilot Hole

Insert the JuggerKnot™ drill bit into a power drill to the proximal laser-etch line to ensure appropriate depth as the collar of the drill contacts the back of the guide (Figure 6). Insert the JuggerKnot™ drill into the drill guide. Advance the drill until contact is made with the guide (Figure 7).

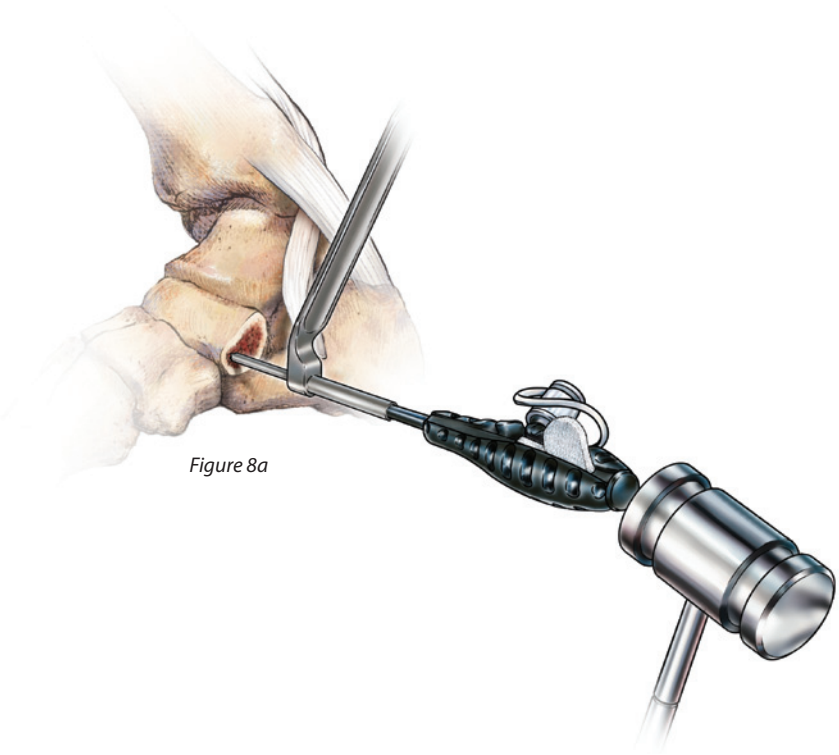


Figure 8a

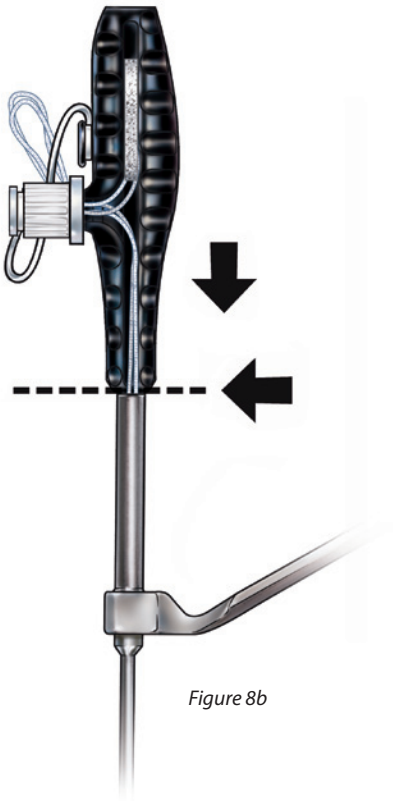


Figure 8b

Insert the Anchor

Remove the drill. **Note: Caution must be taken to maintain precise guide position over the pilot hole during removal.** While maintaining the guide position firmly against the bone, insert the JuggerKnot™ Soft Anchor through the guide and into the pilot hole. Lightly mallet until the handle bottoms out on the guide to fully seat the anchor into the bone (Figures 8a & 8b).

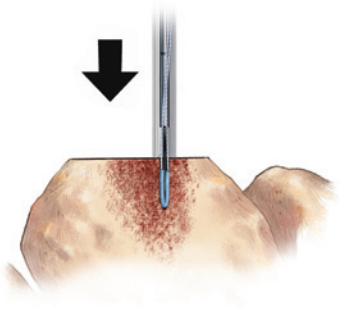


Figure 9a

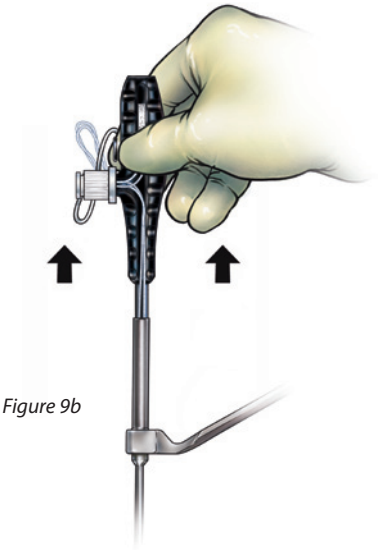


Figure 9b

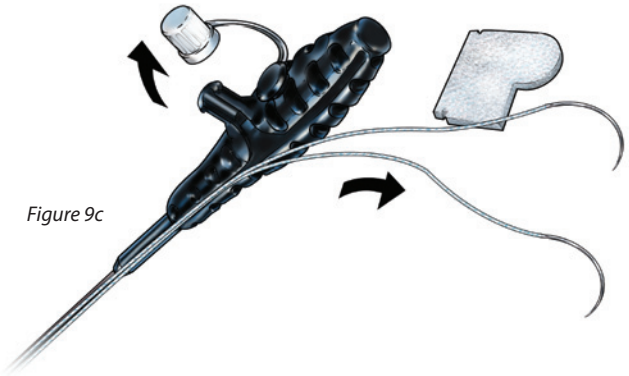


Figure 9c

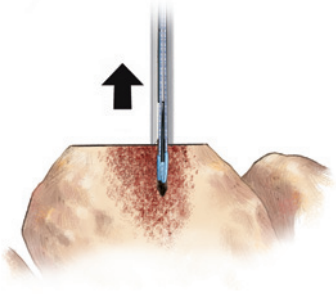


Figure 9d

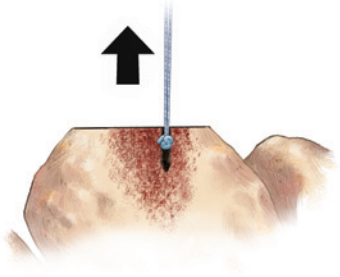


Figure 9e

Deploy the Anchor

Once the anchor has been fully seated into the navicular bone (Figure 9a) lightly pull back on the anchor inserter handle to set the anchor (Figure 9b). Release the suture from the handle by unscrewing the luer lock. Remove the needles by pulling on the foam tab exiting the implant handle (Figure 9c). Pull the anchor inserter handle directly back from the guide. Lightly pull on both sutures to set the anchor (Figures 9d & 9e).

Follow the same steps to place the second JuggerKnot™ Soft Anchor (Figure 10).

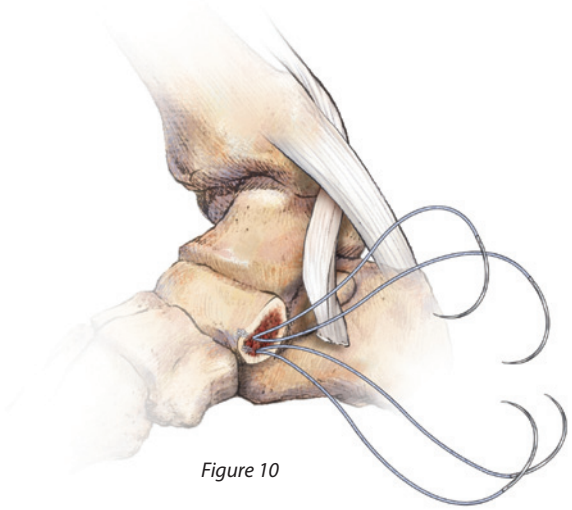


Figure 10

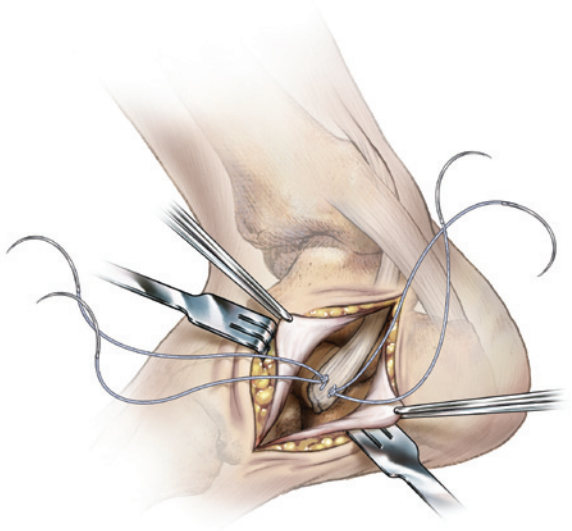


Figure 11

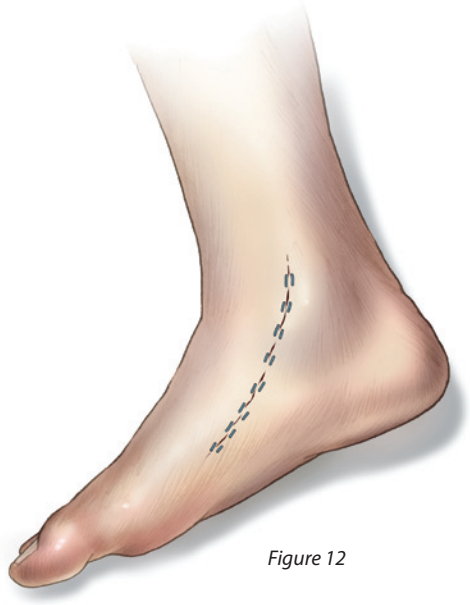


Figure 12

Attachment of the Posterior Tibial Tendon

The tendon can then be tensioned and an appropriate position of the anchoring sutures into the tendon determined. This step poses some subjectivity, as the tendon should attach to the bone with tension. The foot can be slightly inverted to help discern proper length. Once decided, the needles attached to the MaxBraid™ Suture coming from the JuggerKnot™ Soft Anchor can be brought from lateral to medial on the tendon. The second anchor's suture should then be brought through the tendon. The sutures are then tied over the tendon, drawing it to the navicular bone. The sutures can then be brought through the posterior tibial tendon in several "tendon grabbing" passes to better secure the tendon to the bone and minimize knot prominence (Figure 11). The foot should be able to evert to a neutral position.

Closure

The posterior tibial tendon sheath can often be reapproximated with 2-0 Vicryl and the subcutaneous tissues repaired with 4-0 Vicryl. Skin closure is per surgeon's choice, Monocryl has worked well (Figure 12).

Post-Op Protocol/Management

The patient is splinted in a bulky dressing with plaster medial to lateral U and a posterior L to hold the limb. This splint is removed in 8–10 days and the patient is placed in a range of motion walker boot. They may come out of the boot for motion exercises. Non-weight bearing should be maintained for six weeks to allow tendon healing to bone.

Package Insert

Biomet Sports Medicine
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581 USA

01-50-1218
Date: 2011-03

JuggerKnot™ Soft Anchors

ATTENTION OPERATING SURGEON

DESCRIPTION

The JuggerKnot™ Soft Anchors consist of a coreless sleeve structure and suture. The anchors are intended for use in soft tissue fixation by bunching against bone when deployed.

MATERIALS

Suture	Ultra-High Molecular Weight Polyethylene (UHMWPE)/Polypropylene UHMWPE/Polyester, UHMWPE/Nylon or Polyester
Sleeve	UHMWPE/Polypropylene or Polyester

INDICATIONS

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

Shoulder
Bankart lesion repair
SLAP lesion repair
Acromio-clavicular repair
Capsular shift / capsulolabral reconstruction
Deltoid repair
Rotator cuff tear repair
Biceps tenodesis

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

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

Hip
Acetabular labral 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 package 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.

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 trials, 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.

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 resterilize. Do not use past expiration date.

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.

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, South Wales
CF31 3XA UK

CE 0086

Symbol Legend

- Manufacturer
- Date of Manufacture
- Do Not Reuse
- Caution
- STERILE EO — Sterilized using Ethylene Oxide
- STERILE R — Sterilized using Irradiation
- STERILE — Sterile
- STERILE A — Sterilized using Aseptic Processing Techniques
- STERILE — Sterilized using Steam or Dry Heat
- MR — MR Safe
- Use By
- WEEE Device
- REF — Catalogue Number
- LOT — Batch Code
- Flammable
- EC REP — Authorized Representative in the European Community

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet Sports Medicine at the contact information provided herein.

Ordering Information

JuggerKnot™ Soft Anchor Short w/Needles	
912068	1.4mm Single Loaded
912069	1.4mm (Package of 10)

JuggerKnot™ Soft Anchor Short 1.4mm Drill Bit (Disposable)

912071 Sterile

JuggerKnot™ Soft Anchor Short 1.4mm Guide (Reusable)

912072 Non-Sterile

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert and Biomet's website.

BIOMET®
SPORTS MEDICINE
One Surgeon. One Patient.℠

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