SLAP Repair Utilizing the Ti-Screw Suture Anchor

With the scope in the glenohumeral joint, visually assess the SLAP tear through a standard posterior portal (Figure 1). A probe is passed through a standard anterior rotator interval portal into the glenohumeral joint space to assess the superior labrum (Figure 2).

The glenohumeral ligaments may be scarred down to the scapular neck. Utilize the curved rasp with elevator to free the labrum from the scapular neck to gain lateral mobility (Figure 3). Prepare the superior glenoid bone by abrading with a small burr to a bleeding surface. This will assist with fibroblastic healing.

Establish a mid-lateral portal superiorly (Figure 4). Position a spinal needle transversely through the myotendonous junction of the supraspinatus to establish portal placement. The spinal needle is removed and replaced with an Arthrotek® 7mm cannula. This size is recommended for suture passing instruments.

Figure 4

Figure 5

Place the offset fish mouth guide through the mid-lateral portal on to the glenoid rim superiorly (Figure 5). The Ti-Screw 1.5mm step-drill (902562) and/or the 3.0mm Ti-Screw tap (902566) is utilized to create a pre-made bone hole prior to inserting the 3.0mm Ti-Screw Suture Anchor (Figure 6). Proceed to drill and/or tap until the horizontal laser etch line is flush with the proximal aspect of the cortical bone (Figure 7).

ARTHROTEK®
A Biomet Company

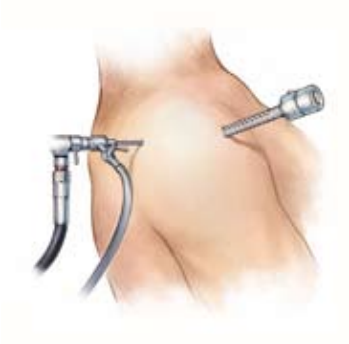

Figure 1

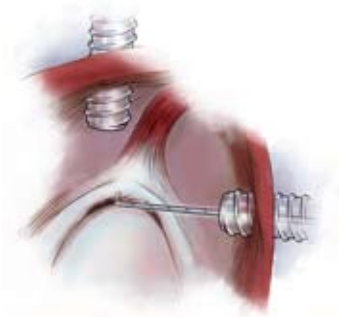

Figure 2

Figure 3

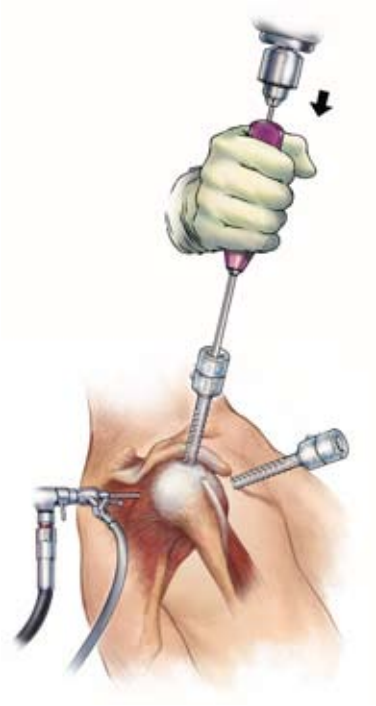

Figure 6

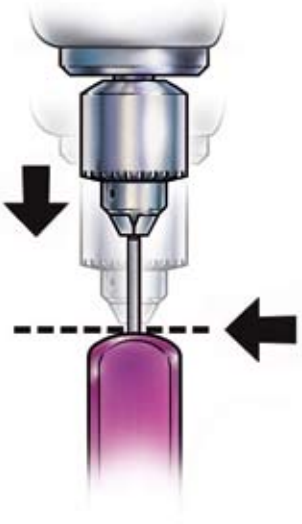

Figure 7

Surgical Technique

Insert the 3.0mm Ti-Screw Suture Anchor through the offset guide until the anchor meets bone (Figure 8). Screw in the anchor manually until the horizontal laser etched line is flush with the proximal aspect of the cortical bone. The vertical laser etched lines are in line with the suture anchor eyelets to assist with anchor orientation for knot tying.

The SpeedPass™ Suture Passer is used for passing the sutures lateral to medial through the superior labrum (Figure 9). After passing the MaxBraid™ Suture through the rotator cuff, knots are to be tied in order from posterior to anterior. Use a probe to check fixation (Figure 10). The SLAP tear is now complete utilizing the 3.0mm Ti-Screw Suture Anchors.

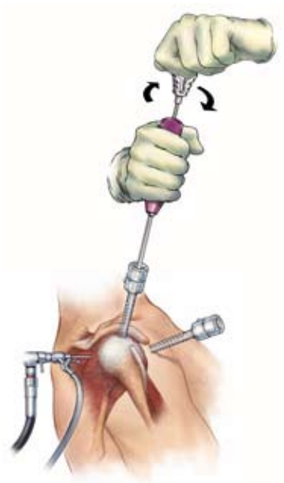

Figure 8

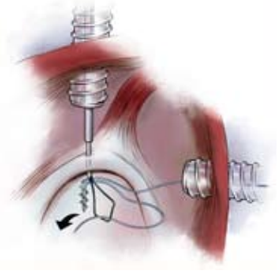

Figure 9

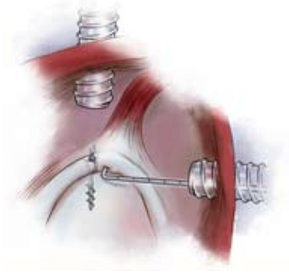

Figure 10

Package Insert

Arthrotek, Inc.
A Wholly Owned Subsidiary of Biomet, Inc.
P.O. Box 587
56 East Bell Drive
Warsaw, Indiana 46581 USA

01-50-1078
Date: 11/06

Arthrotek® Non-Resorbable, Soft Tissue Anchoring Devices
ATTENTION OPERATING SURGEON

DESCRIPTION
Arthrotek manufactures a variety of internal fixation devices intended to aid in arthroscopic and orthopedic reconstructive procedures requiring soft tissue fixation, due to injury or degenerative disease. Implants used for this application include: screws, washers, anchors, pins, and suture. Specialty implants are available for specialized treatments.

Materials
316 LVM Stainless Steel
Titanium Alloy
Ultra-High Molecular Weight Polyethylene (UHMWPE)
Polyester
Polyetheretherketone (PEEK)
Polypropylene

INDICATIONS
The Metal Screw Anchor and ALLthread™ PEEK Suture Anchor are indicated for use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications as follows:

Shoulder Indications – Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.

Wrist/Hand Indications – Scapholunate ligament reconstruction **(not including ALLthread™ Ti Suture Anchors)**, ulnar/radial collateral ligament reconstruction.

Ankle/Foot Indications – Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.

Elbow Indications – Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction

Elbow Indications **(ALLthread™ PEEK Suture Anchor Only)** – Lateral epicondylitis repair

Knee Indications – Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis, and patellar ligament/tendon repair.

Harpoon® (and Mini-Harpoon®) Suture Anchors and the Hitch™ PEEK Suture Anchors include use in soft tissue reattachment procedures. Specific Indications are:

Shoulder Indications **(Harpoon® and Mini-Harpoon® Suture Anchors; and Hitch™ PEEK Suture Anchors)** – Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, deltoid repair.

Wrist **(Mini-Harpoon® Suture Anchor only and Hitch™ PEEK Suture Anchors)** – Scapholunate ligament reconstruction

Elbow **(Harpoon® and Mini-Harpoon® Suture Anchors; Hitch™ PEEK Suture Anchors)** – Biceps tendon reattachment, Ulnar or radial collateral ligament reconstruction,.

Knee Indications **(Harpoon® and Mini-Harpoon® Suture Anchors; Hitch™ PEEK Suture Anchors)** – Extracapsular Repair: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis reconstruction, and patellar ligament and tendon repair, vastus medalis obliquus (VMO) muscle advancement.

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.

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.
4. Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to implantation of the device.

WARNINGS
Arthrotek® 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 metallurgical 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, neither the device nor grafts, when used, are designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. 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.
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. 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.
4. Implant materials are subject to corrosion. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis that can cause corrosion. Putting dissimilar metals and alloys in contact with each other can accelerate the corrosion process that may enhance fracture of implants. Every effort should be made to use compatible metals and alloys when marrying them to a common goal, i.e. screws and plates.
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 screws can occur if excessive force (torque) is applied while seating bone screws.
8. Do not use excessive force when inserting suture anchors. Excessive force (e.g. long hard hammer blows) may cause fracture or bending of the device. Prior to insertion of the implant, predrill, awl, or tap.
9. DO NOT USE if there is a 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. Ensure contact of tissue to bone when implanting. DO NOT OVERTIGHTEN the screw. Structural damage to the tissue and implant may occur if the screw is overtightened.
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 fracture management. Patients effected 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 fracture 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, 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 advised of the need for regular postoperative follow-up examinations as long as the device remains implanted.

PRECAUTIONS
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.

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

If device contains MaxBraid™ suture, refer to manufacturer package insert for further information.

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. Metal sensitivity or 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.

STERILITY
Arthrotek internal fixation implants are supplied sterile, and are sterilized by exposure to a minimum dose of 25kGy of gamma radiation or by Ethylene Oxide Gas (ETO) if device contains MaxBraid™ PE suture. Do not resterilize.

Caution: Federal law (USA) restricts this device to sale 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.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estates,
Bridgend, South Wales
CF31 3XA, U. K.

CE 0086

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

Package Insert

Distributed by:
Arthrotek, Inc.
A Wholly Owned Subsidiary of Biomet, Inc.
56 East Bell Drive
Warsaw, Indiana 46582 USA

01-50-1134
Date: 08/05

MaxBraid
POLYETHYLENE SUTURE
Non-absorbable Surgical Suture
U.S.P. except for oversized diameter.

Sterile: Contents sterile unless package has been opened or damaged. Single Use Only, Do Not Resterilize.

DESCRIPTION
MaxBraid™ Polyethylene Surgical Suture is a nonabsorbable, sterile surgical suture composed of ultra high molecular weight polyethylene. MaxBraid™ Polyethylene Suture is provided braided as a co-braid of undyed polyethylene and blue monofilament polypropylene or undyed (white). MaxBraid™ sutures are U.S.P. except for diameter in the following sizes:

MaxBraid™ sutures exceed USP specifications for diameter.

Size Suture	USP Ave. Diameter Specification (mm) <861>	Maximum Oversize Average Diameter (mm)	Maximum Oversize Average Diameter from USP (mm)
2-0	0.300 – 0.399	0.363	0.024
0	0.350 – 0.399	0.459	0.060
1	0.400 – 0.499	0.574	0.075
2	0.500 – 0.599	0.617	0.018

INDICATIONS
MaxBraid™ Polyethylene Nonabsorbable Surgical Sutures are indicated for use in approximation and/or ligation of soft tissues, including use of allograft tissue for orthopedic surgeries.

ACTIONS
MaxBraid™ Polyethylene Surgical Suture elicits a minimal acute inflammatory reaction in tissues, which is followed by gradual encapsulation of the suture by fibrous connective tissue.

WARNINGS
Do not resterilize. Do not use if package is opened or damaged. Discard open, unused sutures.

Users should be familiar with surgical procedures and techniques involving nonabsorbable sutures before employing Polyethylene Surgical Suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

As with any foreign body, prolonged contact of this or any other suture with salt solutions, such as those found in urinary or biliary tracts, may result in calculus formation. Acceptable surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds.

PRECAUTIONS
In handling this or any other suture material, care should be taken to avoid damage from handling. Avoid crushing or crimping damage due to application of surgical instruments such as forceps or needle holders. Adequate knot security requires the accepted surgical technique of flat, square ties, with additional throws as warranted by surgical circumstance and the experience of the surgeon.

Users should exercise caution when handling surgical needles to avoid inadvertent needle sticks. Discard used needles in "sharps" containers.

This device should be handled and disposed of in accordance with all applicable regulations including, without limitation, those pertaining to human health and safety and the environment.

ADVERSE REACTIONS
Adverse effects associated with the use of this device include: wound dehiscence, calculi formation in urinary and biliary tracts when prolonged contact with salt solutions such as urine and bile occurs, infected wounds, minimal acute inflammatory tissue reaction, and transitory local irritation.

HOW SUPPLIED
MaxBraid™ Polyethylene Surgical Suture is available in USP sizes 2-0 through 2 (metric sizes 3 through 5). MaxBraid™ Surgical Suture is provided sterile as a co-braid of undyed polyethylene and blue monofilament polypropylene or undyed (white).

The suture is provided in a variety of lengths, with and without needles, with or without pledgets, and may be supplied in a variety of cut lengths or on ligating reels. Finished suture may be packaged in cartons as single packs, multipacks, or procedure packs.

STERILITY
MaxBraid™ Polyethylene Nonabsorbable Surgical Sutures are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

MaxBraid™ is a trademark of Arthrotek, Inc.

Caution: Federal law (USA) limits this device to sale 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.

Manufacturer: Teleflex Medical
600 Airport Road
Fall River, MA 02720 USA
508-677-6600

Telephone 800-367-7874 (USA only)
+1-508-677-6600

Suture CE marked by Teleflex

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This brochure is presented to demonstrate the surgical technique utilized by Patrick M. Connor, M.D., Charlotte, North Carolina. Arthrotek, 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. Arthrotek is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

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web site: www.arthrotek.com
Form No. Y-BIV-023/113006

INVENTING THE FUTURE OF ARTHROSCOPY