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.

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).
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 medially 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.

Package Insert

Arthrotek, Inc.
A Philip Henry Subsidiary of howmedica, Inc.
6325 E. Burt Blvd.
Warsaw, Indiana 46581 USA

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

DESCRIPTION

Arthrotek manufactures a variety of internal fixation devices intended to aid in orthopedic, and soft tissue fixation. These devices are used primarily in the treatment of orthopedic, and soft tissue diseases. Implanted devices used for this application include: screws, washers, anchors, pins, and sutures typically available for specialized treatments.

Materials

- Titanium alloy
- Polyetheretherketone (PEEK)
- Polypropylene
- Polyethylene

INSTRUCTIONS

1. The Metal Screw Anchor and Allofit™ PEEK Suture Anchor are indicated for use in soft tissue augmentation procedures in the shoulder, wrist, ankle, and foot in the repair of tendons, ligaments, and muscles.

2. Anchor insertion – Place the anchor into the bone. Mark the appropriate location using a high-speed burr and make a drill hole of the appropriate size. Insert the 3.0mm Ti-Screw Suture Anchor through the drill hole manually until the anchor is fully seated. Insert the 3.0mm Ti-Screw Suture Anchor through the drill hole manually until the anchor is fully seated. Insert the 3.0mm Ti-Screw Suture Anchor through the drill hole manually until the anchor is fully seated. Insert the 3.0mm Ti-Screw Suture Anchor through the drill hole manually until the anchor is fully seated.

3. Suture Passer is used for passing the sutures lateral to medially through the superior labrum (Figure 10). The SLAP tear is now complete utilizing the 3.0mm Ti-Screw Suture Anchors.

4. Laser etched lines are in line with the suture anchor eyelets to assist with anchor orientation for knot tying.

5. Insert the 3.0mm Ti-Screw Suture Anchor through the drill hole manually until the anchor is fully seated. Insert the 3.0mm Ti-Screw Suture Anchor through the drill hole manually until the anchor is fully seated. Insert the 3.0mm Ti-Screw Suture Anchor through the drill hole manually until the anchor is fully seated. Insert the 3.0mm Ti-Screw Suture Anchor through the drill hole manually until the anchor is fully seated.

WARNINGS

1. Infection.

2. The implants can loosen or be damaged and the graft may fail if the device is improperly aligned or the implant is improperly placed. Failure to follow device-specific instructions may result in extrusion or migration of the device or tissue supported by the device.

3. Correct orientation of the implant is extremely important. The potential success of soft tissue fixation is increased by the selection of the proper type of implant. While proper use can result in fixation, improper use can result in failure. The technical aspects of implant placement are detailed in the package insert. This device should not be used in the treatment of any condition or disease that may not be treated by the device.

4. Normal or delayed union, nonunion, or incomplete healing. Therefore, it is important that the patient is immobilized and that the graft is allowed to heal properly before any physical activity. Failure to follow device-specific instructions may result in extrusion or migration of the device or tissue supported by the device.

5. Soft tissue augmentation procedures are used primarily in the treatment of orthopedic, and soft tissue diseases. Implanted devices used for this application include: screws, washers, anchors, pins, and sutures typically available for specialized treatments.

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10. Normal or delayed union, nonunion, or incomplete healing. Failure to follow device-specific instructions may result in extrusion or migration of the device or tissue supported by the device.

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12. Normal or delayed union, nonunion, or incomplete healing. Failure to follow device-specific instructions may result in extrusion or migration of the device or tissue supported by the device.

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14. Neoplasia or delayed union, nonunion, or incomplete healing. Failure to follow device-specific instructions may result in extrusion or migration of the device or tissue supported by the device.

15. Correct orientation of the implant is extremely important. The potential success of soft tissue fixation is increased by the selection of the proper type of implant. While proper use can result in fixation, improper use can result in failure. The technical aspects of implant placement are detailed in the package insert. This device should not be used in the treatment of any condition or disease that may not be treated by the device.

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### Polyethylene Suture

**MaxBraid**

**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:

<table>
<thead>
<tr>
<th>Size Suture</th>
<th>USP Ave. Diameter Specification (mm) &lt;81&gt;</th>
<th>Maximum Oversize Average Diameter (mm)</th>
<th>Maximum Oversize Average Diameter from USP (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-0</td>
<td>0.300 - 0.399</td>
<td>0.363</td>
<td>0.024</td>
</tr>
<tr>
<td>0</td>
<td>0.350 - 0.399</td>
<td>0.459</td>
<td>0.060</td>
</tr>
<tr>
<td>1</td>
<td>0.400 - 0.499</td>
<td>0.574</td>
<td>0.075</td>
</tr>
<tr>
<td>2</td>
<td>0.500 - 0.599</td>
<td>0.617</td>
<td>0.018</td>
</tr>
</tbody>
</table>

#### 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.

#### 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.

#### 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.

#### STERILITY

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

#### 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.

**Stereility**

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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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.

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.

This material is intended for the Arthrotek Sales Force and surgeons only. It is not intended to be redistributed without the express written consent of Arthrotek.

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