Rotator Cuff Repair Utilizing the Ti-Screw Suture Anchor

Portal Placement
A standard posterior portal is utilized along with a traditional anterior portal for instrument passage for diagnostic arthroscopy. The arthroscope is placed in the subacromial space through the posterior portal to visually assess pathology (Figure 1).

A tissue grasper is passed through a standard lateral portal into the subacromial space to reduce the cuff to the lateral aspect of the tuberosity to determine the medial-to-lateral mobility of the defect (Figure 2).

Complete Preparation of Tuberosity
The Ti-Screw 2.5mm step-drill (902567) and/or the 5.0mm Ti-Screw tap (902565) is utilized prior to inserting the 5.0 mm Ti-Screw Suture Anchor. The drill and/or tap is to be positioned at a 45° “Deadman’s” angle to increase the resistance of suture anchor pull-out (Figure 3). The holes are placed approximately 4 – 5mm off the articular margin. Advance the drill and/or tap until the horizontal laser etch line is flush with the proximal aspect of the cortical bone.

Place the 5.0mm Ti-Screw Suture Anchor in the pre-made holes at the existing 45° angle (Deadman’s Angle) (Figure 4). Screw in the anchor manually until the horizontal laser etch line is flush with the proximal aspect of the cortical bone (Figure 5). The vertical laser etched lines are in line with the suture anchor eyelets to assist with anchor orientation for knot tying.
Surgical Technique

The BiPass™ Suture Passer is used for passing the sutures through the torn rotator cuff. The MaxBraid™ Suture is loaded approximately 3 cm from the end of the suture to maximize ease of passing. The Arthrotek® 7mm cannula is to be used with the BiPass™ Suture Passer. (Figure 6)

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. The rotator cuff tear is now complete utilizing the 5.0mm Ti-Screw Suture Anchors (Figure 7).

Figure 6

Figure 7

Package Insert

Artrovitec, Inc.
1505 W. Chairman Avenue
Szilvásy, Texas 78162 USA

Artrovitec® - Non-Evolvable, Soft Tissue Anchoring Devices
ATTENTION OPERATING SURGEON

DESCRIPTION
Artrovitec manufactures a variety of internal fixation devices intended to assist orthopaedic and trauma surgeons in the repair of bone and soft tissue injuries. Internal fixation devices are used to repair many bone and soft tissue injuries, and in many cases may help to prevent complications such as nonunion, delayed union, or incomplete healing. Therefore, the use of internal fixation devices may help to achieve the goal of early motion and functional recovery.

INDICATIONS
Artrovitec devices are indicated for repair of bone and soft tissue injuries in the following locations:

- Elbow and distal radius fractures
- Shoulder (glenohumeral, acromioclavicular, and acromioplasty)
- Wrist (capitate, lunate, hamate, triquetrum, and other carpal bones)
- Metacarpal and proximal phalangeal fractures
- Forearm shaft fractures
- Ankle (tibia, fibula, talus, and calcaneus)

CONTRAINdications
3. Patients with mental or neurologic conditions who are unwilling or incapable of following instructions until healing is complete. A total hip replacement patient is one of the most important aspects of successful fracture management. Patients with mental or neurologic conditions may be at a higher risk of device failure. These patients may require instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and other devices that may be necessary to minimize the risk of fracture and subsequent failure. Patients who are unable to follow instructions and activity restrictions are contraindicated.

STABILITY
Artrovitec internal fixation implants are supplied sterile, and are sterilized by exposure to a minimum of 25kGy of gamma radiation or by Ethylene Oxide Gas (ETO) if device contains biocompatible titanium metals. The MaxBraid suture is intended to be used in conjunction with the Suture Passer. (Figure 6)

Figure 7

The information contained in these package insert is 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 Artrovitec at the contact information provided herein.
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 bired 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.

<table>
<thead>
<tr>
<th>Size Suture</th>
<th>USP Ave. Diameter Specification (mm) &lt;861&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>0.048</td>
</tr>
<tr>
<td>0</td>
<td>0.350 – 0.399</td>
<td>0.409</td>
<td>0.080</td>
</tr>
<tr>
<td>1</td>
<td>0.400 – 0.499</td>
<td>0.497</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>

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 Suture for wound closure, as the risk of wound dehiscence may vary with the site of application and the suture material used.

ADVERSE REACTIONS
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.

STABILITY
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.

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
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Telephone 800-367-7874 (USA only)
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Suture CE marked by Teleflex

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