Rotator Cuff Repair Utilizing the ALLthread™ Suture Anchor

by Scott Kuiper, M.D.
**Biomet Sports Medicine recognizes the benefit of material options.** Many times surgeons require different materials for different applications. These requirements may be dependent upon anatomic location, bone quality, or patient acceptance. Biomet Sports Medicine is proud to offer a wide range of ALLthread™ Suture Anchors manufactured with innovative materials to meet your needs. The ALLthread™ Suture Anchors are fully-threaded to achieve fixation in cortical bone to maximize resistance to pullout and displacement. Dual eyelet configurations ensure suture sliding during the knot tying process. Knot strength of 39.45 lbs. is achieved with the addition of MaxBraid™ PE Suture.

**The Material Difference**

<table>
<thead>
<tr>
<th>Material</th>
<th>Features</th>
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</thead>
<tbody>
<tr>
<td>PEEK-Optima® Polymer</td>
<td>- Fully-threaded to achieve cortical fixation</td>
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<tr>
<td>LactoSorb® L15 Resorbable Copolymer</td>
<td>- Dual and triple eyelet configurations to ensure suture sliding while knot tying</td>
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<tr>
<td>Titanium Dual Eyelet</td>
<td>- Loaded with MaxBraid™ PE Suture</td>
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<tr>
<td>Titanium Triple Eyelet</td>
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Biomet Sports Medicine is proud to be one of the first to provide implants manufactured with PEEK-Optima Polymer. This significant polymer advancement has provided benefits from both metal and resorbable technologies. PEEK-Optima Polymer exhibits an optimal combination of strength, stiffness and toughness, while being radiolucent and revisable, making it ideally suited for suture anchors. PEEK-Optima polymer provides physiological load sharing between the implants and the surrounding tissues.

LactoSorb L15 Resorbable Copolymer

LactoSorb L15 Copolymer is comprised of 85% L-lactic acid and 15% glycolic acid. This formulation provides a balance of properties, i.e., strength retention/loss timed to complement healing, complete mass loss and enhanced biocompatibility during degradation principally due to the lack of crystallinity. The elimination of future implant removal surgery, clearer radiographs and more physiological load sharing between the implants and the surrounding tissues are a few of the benefits of LactoSorb Technology.

Titanium

This traditional material is clinically proven for biocompatibility and strength. Titanium allows for fast and easy insertion techniques making it one of the easiest materials to use on the market. The high strength of titanium allows for design variations such as the ALLthread™ Ti III Suture Anchor—a triple eyelet suture anchor loaded with three sutures to provide additional fixation when necessary.

MaxBraid PE Suture

Suture plays a significant role in repairs made with suture anchors. Biomet Sports Medicine’s incredible strength MaxBraid Suture is comprised of polyethylene, to help eliminate suture fray and prevent breakage. MaxBraid Suture has high tensile strength, but also possesses great knot tying characteristics. The unique braid cinches on itself, providing confidence when tying knots.
Options

Rotator Cuff Repair. Repairing a torn rotator cuff can present a multitude of challenges. Biomet Sports Medicine offers the ALLthread™ Suture Anchor in multiple sizes, suture configurations and options with needles to allow the surgeon to select fixation methods based on the needs of the patient. Biomet Sports Medicine also offers the SportMesh™ Soft Tissue Reinforcement to augment the repair.

<table>
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<tr>
<th>Part No.</th>
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SportMesh™ Soft Tissue Reinforcement

- Soft tissue reinforcement scaffold
- Facilitates anatomical footprint restoration
- Long-term biocompatible augmentation
- Helps to restore of joint mechanics
- Assisting to make the first repair the best repair possible
Portal Placement
Beach chair or lateral decubitus position is utilized per surgeon preference. A standard posterior portal is utilized along with a traditional anterior portal for instrument passage for diagnostic arthroscopy. Intra-articular pathology is addressed including, evaluation of the undersurface of the rotator cuff. The arthroscope is passed into the subacromial space via the posterior portal (Figure 1).

Visualization of the Subacromial Space
Bursectomy is performed using a combination of shavers and electrocautery to visualize the subacromial space, rotator cuff, acromion and coracoacromial ligament. Debridement is carried out with motorized instruments to remove any loose and devascularized flaps of rotator cuff. (Figure 2)

An acromioplasty is performed with a high-speed burr until smooth and flat. The coracoacromial ligament is released and AC joint pathology is addressed.

The rotator cuff tear is visualized from the posterior and lateral portals to determine tear type, configuration, and size, as well as amount of retraction.
**Mobilization of the Rotator Cuff**

The rotator cuff, if retracted, is mobilized by freeing the rotator cuff both superiorly and inferiorly in the planes medial to the glenoid. Anterior and posterior slide procedures can be performed if the rotator cuff is severely retracted and scarred.

Margin-convergence techniques are then utilized to repair splits in the tendon anteriorly and posteriorly. Margin-convergence repair is performed by using the appropriate 45° left or right Speed Pass™ device passing MaxBraid™ Suture across the tear (Figure 3). When anterior and/or posterior splits in the tendon have been repaired, the remaining defect is evaluated for repair to the greater tuberosity.

A tissue grasper is utilized to make sure the tendon can be reduced to bone without any undue tension (Figure 4). Viewing posteriorly and working through a lateral portal, the greater tuberosity is lightly decorticated with a high-speed shaver.
Position the ALLthread™ Tap

The ALLthread™ tap is used to create threaded holes for the ALLthread™ Suture Anchors. To afford the proper angle for insertion, an accessory portal may be made slightly anterior or posterior to the traditional lateral portal. The tap is positioned at a 45° “dead man’s” angle to increase the resistance of suture anchor pull-out (Figure 4). The tap is started with hand pressure, approximately 4 – 5 mm off the articular margin.

Insert the ALLthread™ Tap

The ALLthread™ Suture Anchors are inserted in an anterior to posterior direction at the same angle of the threaded holes created by the tap. The anchor is advanced into the hole such that the proximal threads of the anchor are seated just below the cortical surface. The vertical laser-etched lines are in line with the suture anchor eyelets to assist with anchor orientation for knot tying.

*Note: ALLthread™ Titanium Suture Anchors

The ALLthread™ Titanium Suture Anchors requires pre-drilling prior to insertion.
Pass the Suture Through the Rotator Cuff

Individual sutures from the anchor are passed out the lateral portal and the BiPass™ Suture Passer is then used for passing suture through the rotator cuff tendon (Figure 7). The MaxBraid™ Suture is loaded approximately 2 cm from the end of the suture, passed through the tendon, and then brought back out the lateral portal with the BiPass™ Suture Punch. This suture is then passed back out either the accessory portal or anterior portal for suture management. This procedure is repeated until one limb of each suture has been through the tendon edge for simple suture repair of the rotator cuff to bone.

Repair the Tendon

After all sutures have been passed, repair of the tendon progresses from posterior to anterior. A secure sliding knot with multiple half-hitches using alternating posts secure the tendon to the tuberosity. A probe is used to check fixation. The rotator cuff repair is now complete utilizing the ALLthread™ Suture Anchors (Figure 8).

If a double row repair is to be utilized, an anchor is placed along the articular cartilage margin and sutures are brought through the tendon 1 cm medial to the lateral edge of the tendon using a horizontal mattress configuration prior to traditional anchor placement.
ATTENTION OPERATING SURGEON

DESCRIPTION

Biomet Sports Medicine 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 are as follows:

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

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

Elbow Indications – Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forearm reconstruction.

Ankle/Foot Indications – Ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.

Elbow Indications (ALLthread™ PEEK Suture Anchor Only) – Lateral epicondyritis repair.

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

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

Shoulder: (Harp® and Mini-Harp® Suture Anchors; Hitch™ PEEK Suture Anchors – Bankart repair; SLAP lesion repair; acromio-clavicular separation, rotator cuff repair; capsule repair or capsulolabral reconstruction, biceps tendon repair.

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

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

Knee Indications (Harp® and Mini-Harp® 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 medialis 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

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 metallurgical aspects of the surgical implant.

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. Implanted metals and alloys subject them to constant changing environments of salts, acids, and alkalies 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 matching 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 hand hammer blow) may cause fracture or bending of the device. Prior to insertion of the implant, preload, 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 over tightened.

12. Adequately inform 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, postoperative 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. Biomet Sports Medicine 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

Biomet Sports Medicine™ 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.
Warton Industrial Estates,
Bridgend, South Wales
CF31 3XA, U.K.
ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet Sports Medicine® Soft Tissue Anchoring Devices are resorbable repair devices used to attach soft tissue to bone. The devices are available with or without a suture. The devices are implanted into a predrilled bone hole and are made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Polylactide/polyglycolic acid copolymer degrades and resorbs in vivo by hydrolysis to lactic and glycolic acids, which are then metabolized by the body.

MATERIALS

Poly-L-Lactic Acid/Polyglycolic Acid
Ultra-High Molecular Weight Polyethylene (UHMWPE)
Polyester
Polypropylene

INDICATIONS

LactoSorb® L-15 Screw and Washer and MicroMax™ Suture Anchor are preloaded with suture for attachment of soft tissue to bone. The devices are available with or without a suture. The devices are implanted into a predrilled bone hole and are made of a resorbable copolymer, a polyester derivative of lactic acid and glycolic acid. Polylactide/polyglycolic acid copolymer degrades and resorbs in vivo by hydrolysis to lactic and glycolic acids, which are then metabolized by the body.

CONTRAINDICATIONS

LactoSorb® L-15 Screw Anchor (85% PLLA/15% PGA) and the ALLthread™ LactoSorb® Suture Anchor:

1. Active infection.
2. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
3. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
4. Pathologic soft tissue conditions, which would prevent secure fixation.

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 soft tissue, or withstand the stress placed upon the device by full or partial weight bearing or load bearing, particularly in the presence of incomplete healing. Therefore, it is important that immobilization (use of external support, sling, 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 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 polymeric aspects of the surgical implants.

1. 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 risk, the device is not designed to withstand the unsupported stress of full weight bearing, load bearing or excessive activity.
2. The implants can loosen or be damaged when subjected to increased loading associated with weight bearing. 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. Appropriate 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 for 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. 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.
5. The use of appropriate immobilization and postoperative management is indicated as part of the treatment until healing has occurred.
6. 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 devices can occur if excessive force (torque) is applied while seating.
7. 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.
8. Do NOT USE if there is loss of sterility of the device.
9. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened or undamaged containers.
10. Ensure contact of tissue to bone when implanting. DO NOT OVERTIGHTEN the screw.
11. 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 soft tissue management. Patients affected 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 that are intended to immobilize the repair 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 tissue, and 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 examination as long as the device remains implanted.

12. MicroMax™ Suture Anchor – Loss of bone fixation may occur if flanged wings are not properly deployed.

PRECAUTIONS

Instruments are available to aid in the accurate implantation of internal fixation devices. Internal fracture or breaking of instruments has been reported. Surgical instruments are subject to wear with normal usage. Instruments that have experienced excessive 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.

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

POSSIBLE ADVERSE EFFECTS

1. Infection can lead to failure of the procedure.
2. Neurovascular injuries can occur due to surgical trauma.
3. Bending, fracture, loosening, rubbing, and migration of the implant may occur as a result of excessive activity, trauma, or load bearing.
4. Implantation of foreign materials can result in an inflammatory response or allergic reaction.
5. Inadequate healing.
6. Pain, discomfort, or abnormal sensation due to the presence of the device.
7. Necrosis of the bone or tissue.

STERILITY

Biomet Sports Medicine® resorbable implants are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

STORE AT OR BELOW ROOM TEMPERATURE. DO NOT EXPOSE PRODUCT TO TEMPERATURES GREATER THAN 120°F OR 49°C.

Caution: Federal Law (USA) restricts this device to sale, distribution, or use 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.
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CF31 3XA U.K.

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 Biomet Sports Medicine 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 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.

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 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™ Sutures are 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.

ADVERSE REACTIONS
Adverse effects associated with the use of this device include: wound dehiscence, calculus 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™ Sutures are 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 Biomet Sports Medicine, 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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References
1. Data on file at Biomet Sports Medicine, Inc. Bench test results are not necessarily indicative of clinical results.

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