CHARLOTTE™
SHOULDER SYSTEM

ARTHROSCOPIC BANKART LESION REPAIR

Using the 3.5mm LactoScrew® Suture Anchor

Surgical Technique

Diagnostic Arthroscopy

- Standard posterior portal (Figure 1)
- Anterior/superior rotator interval portal placed just off anterior edge of acromion (more superior than usual)
- Assess for …
  - ***Bankart lesion***
  - ***Integrity of anterior / inferior ligaments (MGHL, IGHL, inferior pouch)***
    - *May be seen best with scope in anterior/superior portal*
    - *Intrasubstance tearing*
    - *HAGL*
  - ***Hill-Sachs lesion or other articular injury***
  - ***SLAP lesion***
  - ***Biceps tendon integrity / stability***
  - ***Articular surface rotator cuff tear***

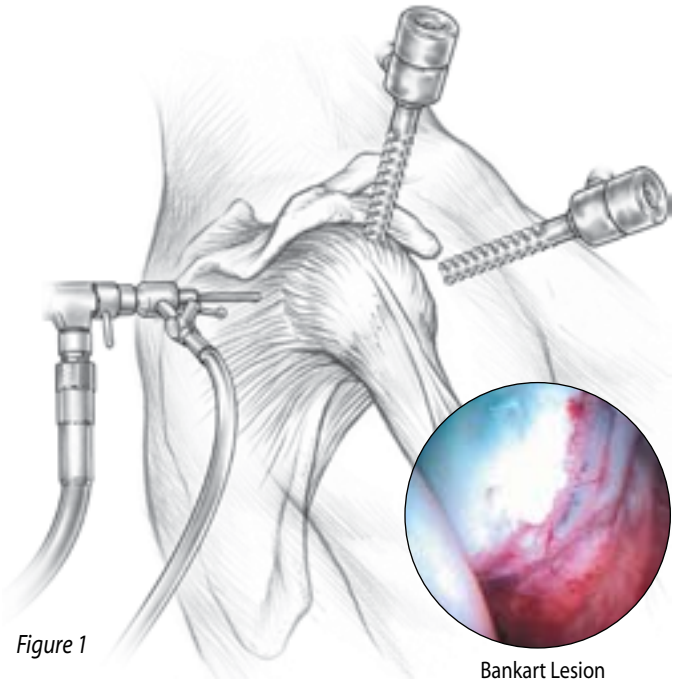


Figure 1

Bankart Lesion
View from Anterior Cannula

Establish Anterior Trans-Subscapularis Portal

- Be aware of axillary nerve position at medial / inferior border of subscapularis (Figure 2)
- 2mm guide pin through muscular portion of subscapularis (below superior subscapularis tendon, mid-substance)
- 7mm cannulated obturator +7mm cannula placed over guide pin

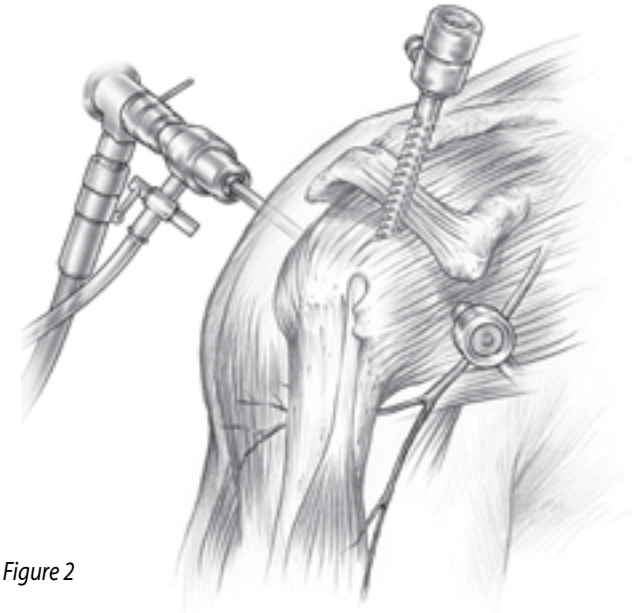


Figure 2

ARTHROTEK®
A Biomet Company

Surgical Technique

Anterior/Inferior Labral Debridement/ Bony Preparation (Figure 3)

- Place 30° scope in anterior/superior portal or 70° scope in posterior portal to maximize visualization
- Contour edges of torn labrum (conservative debridement)
- Small, curved shaver (3.5mm) to debride anterior/inferior glenoid bone
- Small burr (3.5mm) to decorticate anterior/inferior glenoid bone
  - ***Avoid deep trough***
  - ***Avoid glenoid articular cartilage injury***

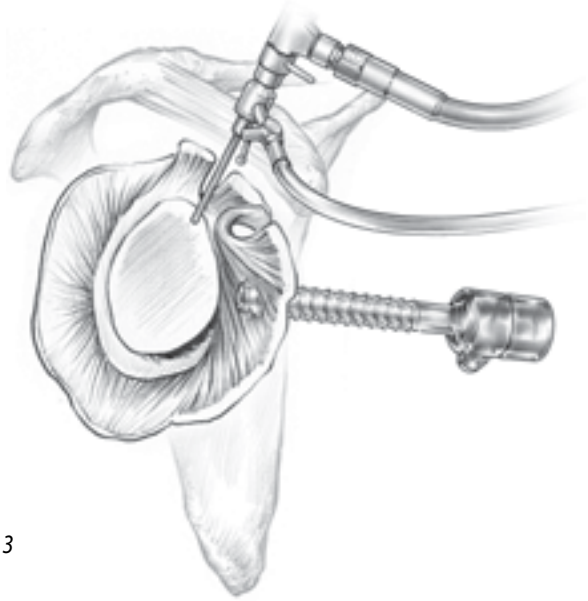


Figure 3

Placement of Suture Anchors

- If utilizing 30° scope, place in anterior/superior portal to enable placement of suture anchor(s) under direct visualization
- If utilizing 70° scope in posterior portal, probe may be placed in anterior/superior portal deviating labrum medially, exposing prepared anterior/inferior glenoid bone
- Suture anchor(s) placed through anterior transsubscapularis portal
- Place suture anchors right on articular margin (Figure 4)
- Drill/tap to laser mark depth
- LactoScrew® Suture Anchor placed to laser mark depth
- Assess stability of anchor under direct visualization
- Pull superior suture limbs through anterior/ superior cannula

Figure 4

Placement of Suture Throught Labrum

- Mini suture punch through anterior/superior portal, piercing labrum (Figure 5)
- Retrieve suture limbs from anterior/superior cannula through anterior portal
- Avoid suture crossing/tangling
- Prepare for knot tying if single anchor is utilized

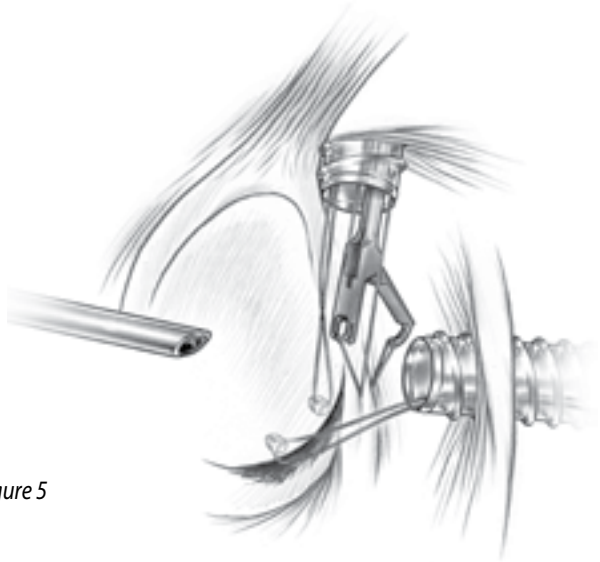


Figure 5

If Second Suture is Desired

- Retrieve previously placed anchor sutures from anterior portal through anterior/superior portal
- Remove and replace anterior/superior cannula with sutures left **outside** this cannula (avoids entanglement of sutures)
- Repeat steps of suture anchor placement and placement of suture through labrum (above)

Knot Tying[1]

- Tie sutures from inferior anchor first, utilizing anterior transcapularis portal after retrieving from anterior/superior portal (Figure 6)
- **First two throws:** should utilize suture through labrum as post
- **Second throw:** two half-hitches, same direction, around desired post utilizing Nordt™ Knot Tightner
- **Third throw:** half-hitch, opposite direction, alternate post (locking the knot)
- **Fourth throw:** half-hitch, opposite direction, alternate post
- **Fifth throw:** half-hitch, opposite direction, alternate post
- Cut suture ends 1– 2mm above knot
- Pull second suture ends from outside anterior/superior cannula through anterior portal
- Repeat knot tying of superior anchor sutures (Figure 7)
- Assess stability of repair

Address Ligamentous Plastic Deformation if Present by…

- Electrothermal capsulorrhaphy
- Arthroscopic suture capsulorrhaphy

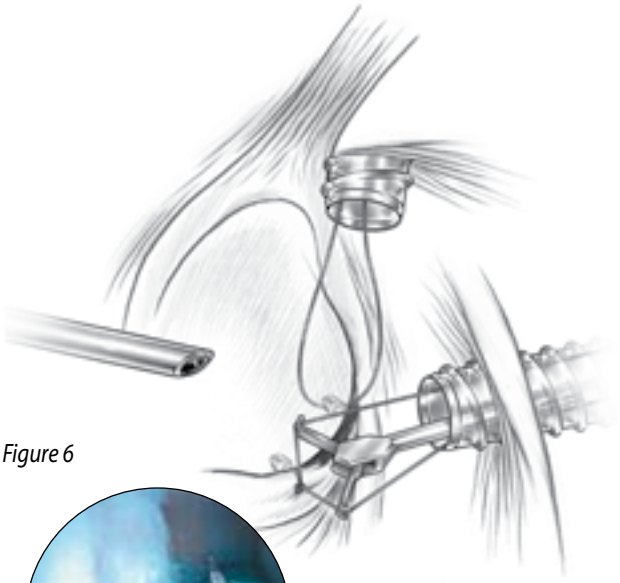


Figure 6

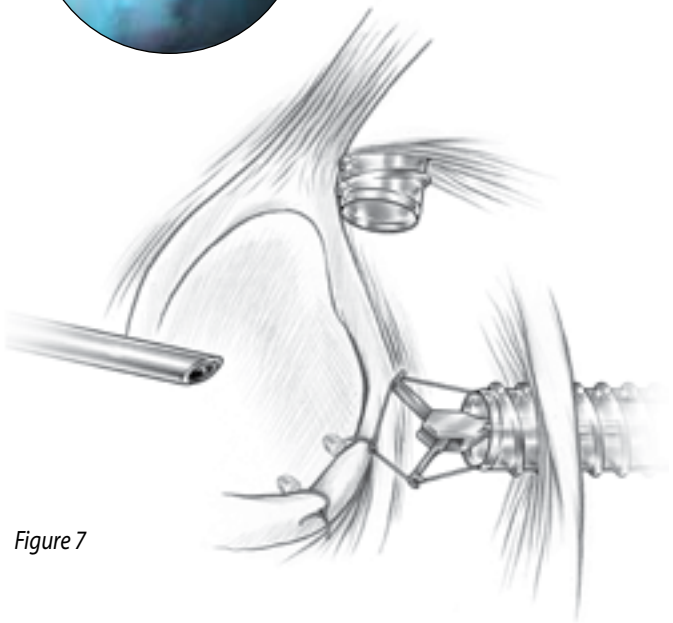
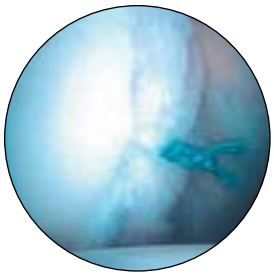
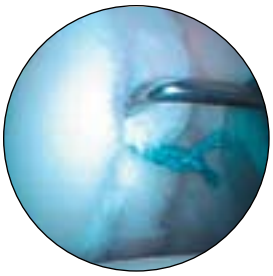


Figure 7



Complete



Assess for Stability

1. Connor PM, Milia M. Arthroscopic knot tying techniques: a critical assessment. *J Arthroscopy*, Submitted for publication, 2000.

Developed in conjunction with Patrick M. Connor, M.D. and Donald F. D'Alessandro, M.D., Charlotte, North Carolina.

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01-50-1072
Date: 02/05

ARTHROTEK® SOFT TISSUE ANCHORING DEVICES
ATTENTION OPERATING SURGEON

DESCRIPTION

The Arthrotek® Soft Tissue Anchoring Devices are resorbable repair devices used to attach soft tissue to bone. LactoSorb® Soft Tissue Screw and Washer and MicroMax™ Suture Anchor are used with or without a suture. LactoSorb® L-15 Screw Anchors consist of a screw and head design and are used with 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. Polylactic/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

1. LactoScrew® L-15 Screw Anchor (85% PLLA/15% PGA):
   Shoulder
   Bankart repair
   SLAP lesion repair
   Acromio-clavicular separation
   Rotator cuff repair
   Capsule repair or capsulolabral reconstruction
   Biceps tenodesis
   Deltoid repair
   Wrist/Hand
   Scapholunate ligament reconstruction
   Ulnar/radial collateral ligament reconstruction
   Ankle/Foot
   Lateral stabilization
   Medial stabilization
   Achilles tendon repair/reconstruction
   Hallux valgus reconstruction
   Mid- and forefoot reconstruction
   Elbow
   Tennis elbow repair
   Ulnar or radial collateral ligament reconstruction
   Biceps tendon reconstruction
   Knee
   Medial collateral ligament repair
   Lateral collateral ligament repair
   Posterior oblique repair
   Joint capsule closure
   Iiotibial band tenodesis
   Patellar ligament/tendon repair
2. LactoSorb® L-15 Screw and Washer (85% PLLA/15% PGA) and MicroMax™ Suture Anchor:
   Shoulder Indications
   Bankart Repair
   SLAP Lesion Repair
   Acromio-clavicalur Separation Repair
   Rotator Cuff Repair
   Capsule Repair and Capsulolabral Reconstruction
   Biceps Tenodesis
   Deltoid Repair
   Wrist Indications
   Scapholunate ligament reconstruction
   Elbow Indications
   Tennis Elbow Repair
   Biceps Tendon Reattachment
   Medial and Lateral Repairs
   Ulnar or Radial Collateral Ligament Reconstruction
   Knee Indications
   Extra-Capsular Repair
   Medial Collateral Ligament Repair
   Lateral Collateral Ligament Repair
   Posterior Oblique Ligament Repair
   Joint Capsule Closure
   Iliotibial Band Tenodesis Reconstruction
   Patellar Ligament/Tendon Repair
   Vastus Medialis Obliquus (VMO) Muscle Advancement

LactoSorb® L-15 Screw and Washer and MicroMax™ Suture Anchor are preloaded with suture for use at the discretion of the physician.

CONTRAINDICATIONS

1. Active infection.
2. Patients with mental or neurologic conditions who are unwilling or incapable of following postoperative care instructions.
3. Patient conditions including: blood supply limitations, insufficient quantity or quality of bone, or latent infections.
4. Pathologic soft tissue conditions, which would prevent secure fixation.

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 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 affect 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. 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, 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 inadequate healing. 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 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 if there is loss of sterility of the device.
8. Discard and DO NOT USE opened or damaged devices, and use only devices that are packaged in unopened or undamaged containers.
9. 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.
10. 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 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 examination as long as the device remains implanted.
11. 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. 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. 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

Arthrotek® 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.

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