Identify the ruptured biceps tendon and sharply debride the macerated portions of the tendon. Attach the ToggleLoc™ device to the end of the biceps tendon utilizing a locking whipstitch.

With the patient supine and the arm extended on a standard hand table, place the arm in maximum supination to protect the posterior interosseous nerve and expose the radial tuberosity. During exposure, care should be taken to identify and protect the lateral antebrachial cutaneous nerve and not to traumatize the interosseous membrane.

With the arm in full supination, insert the 2.4mm guide pin into the footprint of the biceps tendon on the radial tuberosity. Aim the pin slightly distal and medial to angle away from the posterior interosseous nerve. The pin should be placed bicortically, but care should be taken not to plunge through the posterior cortex.

Advance a 6mm acorn reamer over the guide pin and through the near cortex; do not breach the posterior cortex.
Use a burr or ronguer to create a longitudinal trough large enough to accept the biceps tendon into the bone tunnel.

Carefully pass a Beath pin with the passing sutures from the ToggleLoc™ fixation device with Ziploop™ Technology through the trough and through the 4.5mm hole in the posterior cortex. Pull the device through the posterior cortex and pull back on all of the ZipLoop suture to engage the posterior cortex and lock it into place.

With the elbow in flexion, tension the “zip suture” to pull the tendon securely into the bone tunnel. Test the repair and retention as needed. Remove the passing sutures.

Use the Super MaxCutter™ to cut the “zip suture” at the repair site.

The repair is now complete.

Ordering Information

Distal Biceps Tendon Disposable Kit
909854 Includes: ToggleLoc™ Fixation Device, guide pin, marking pen, surgical ruler, #2 MaxBraid™ Suture with needle and 4.5mm cannulated drill

Super MaxCutter™ Suture Cutter
900342
The ToggleLoc™ System of devices provide the surgeon with a means to aid in the management of soft tissue to bone fixation for the following indications:

- Shoulder
  - Bankart repair
  - SLAP lesion repair
  - Acromioclavicular repair
  - Capsular shift/upsalabral reconstruction
  - Rotator cuff repair
  - Biceps tendonos
- Foot and Ankle
  - Medial/lateral repair and reconstruction
  - Mid- and forefoot repair
  - Hallux valgus reconstruction
  - Metatarsal ligament/tendon repair or reconstruction
  - Achilles tendon repair
  - Ankle Syndromic fixation (Syndromes disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc™ with TopHat)

- Elbow
  - Ulnar or radial collateral ligament reconstruction
  - Lateral epicondylosis repair
  - Biceps tendon reattachment
  - ACL/PCL repair / reconstruction
  - ACL/PCL patellar bone-tendon-bone grafts
  - Double Tunnel ACL reconstruction
  - Extracapsular repair: MCL, LCL, and posterior oblique ligament
  - Illiotibial band tenodesis
  - Patellar tendon repair
  - VMO advancement
  - Joint capsule closure
- Hand and Wrist
  - Carpal ligament repair
  - Scapholunate ligament reconstruction
  - Tendon transfers to phalanges
  - Volar plate reconstruction
- Hip
  - Femoral linear/lateral repair
  - CONTRAINDICATIONS
    - 1. Infections
    - 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 unresponsive to 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
  - The ToggleLoc™ system of devices provide the surgeon with a means to aid in the management of soft tissue to bone fixation 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 numerous, delayed unions, or incomplete healing. Therefore, it is important that immobilization (use of external supports, 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 fatigue 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 implants, but also must be aware of the mechanical and metallurgical aspects of the surgical implants.
  - 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.

- MATERIALS
  - Titanium Alloy
  - Ultra-High Molecular Weight Polyethylene (UHMWPE)
  - Polypropylene
  - Nylon
  - Polyester
  - Stainless Steel

- INDICATIONS FOR USE
  - The ToggleLoc™ System Devices are intended for soft tissue to bone fixation for the following indications:

- Hips
  - Medial/lateral repair and reconstruction
  - Lateral epicondylitis repair
  - Ulnar or radial collateral ligament reconstruction
  - Elbow
  - Weber B and C ankle fractures (only for ToggleLoc™ with TopHat)
  - Ankle Syndesmosis fixation (Syndesmosis disruptions) and as an adjunct in connection with trauma hardware for Weber B and C ankle fractures (only for ToggleLoc™ with TopHat)
  - Acromioclavicular repair
  - SLAP lesion repairs
  - Bankart lesion repair

- Sterility
  - All implants are subjected to a sterilization process to ensure sterility of the device. The process used for sterilization is Ethylene Oxide (ETO). The implants are sterilized in an ETO chamber. The implants are then baked for 16-24 hours at 121°C to inactivate any residual ETO in the device. After baking, the implants are packaged and stored in a dry environment until shipped.

- Comments regarding the use of this device can be directed to Attn: Regulatory Affairs, Biomet, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax 574-372-3998.

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