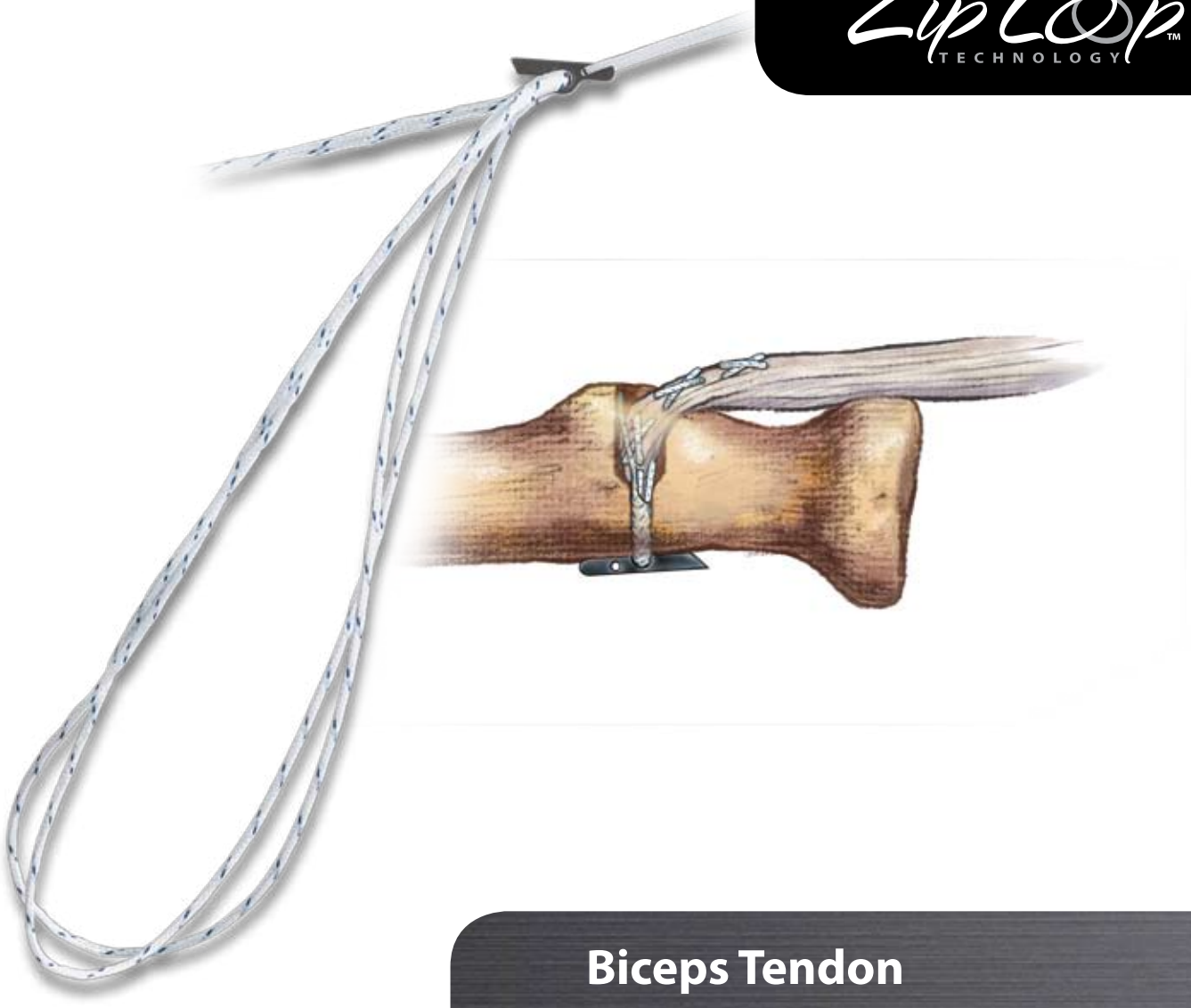
ToggleLoc™
FIXATION DEVICE

with ZipLoop™ TECHNOLOGY



Biceps Tendon Reattachment

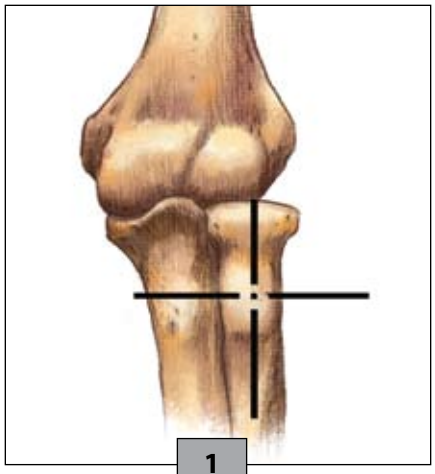
Surgical Protocol by
Mark J. Albritton, M.D.

BIOMET®
SPORTS MEDICINE

Distal Biceps Reattachment with the ToggleLoc™ Fixation Device with ZipLoop™ Technology

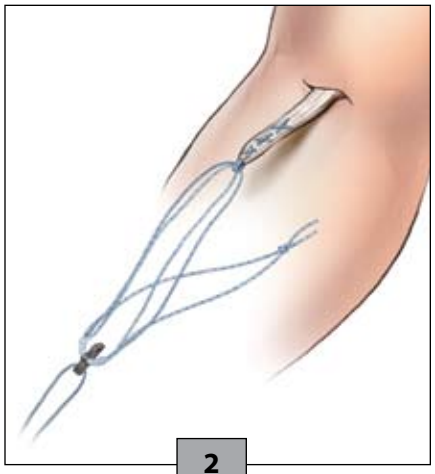
This brochure is presented to demonstrate the surgical technique utilized by Mark J. Albritton, M.D. Biomet Sports Medcine, as the manufacturer of this device, does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and utilizing the appropriate techniques for such procedure for each individual patient. Biomet Sports Medicine is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient.

Surgical Overview



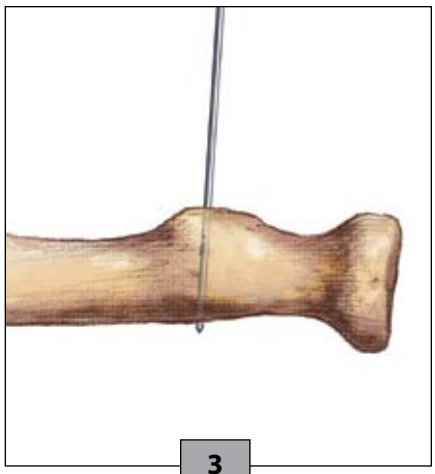
1

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.



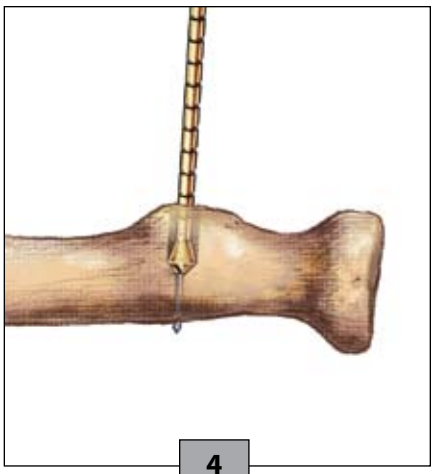
2

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.



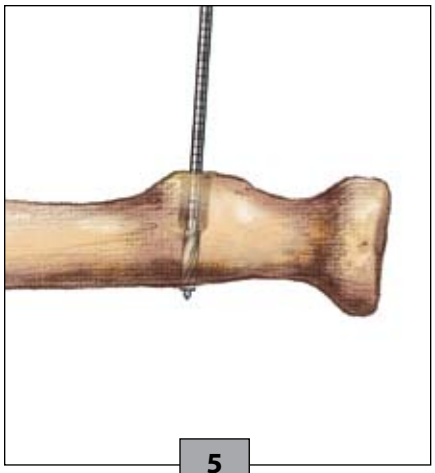
3

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.



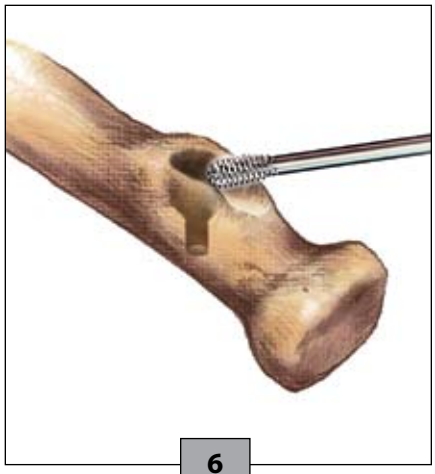
4

Advance a 6mm acorn reamer over the guide pin and through the near cortex; do not breach the posterior cortex.



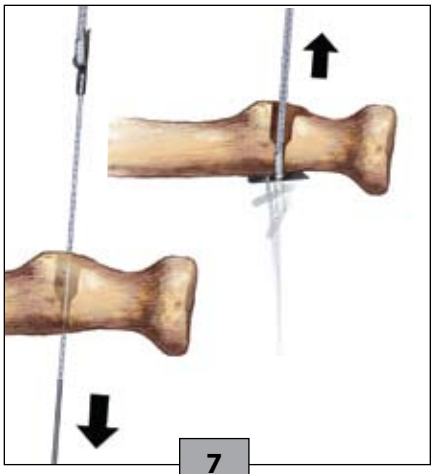
5

Carefully drill through the posterior cortex over the guide pin with the ToggleLoc™ cannulated 4.5mm drill.



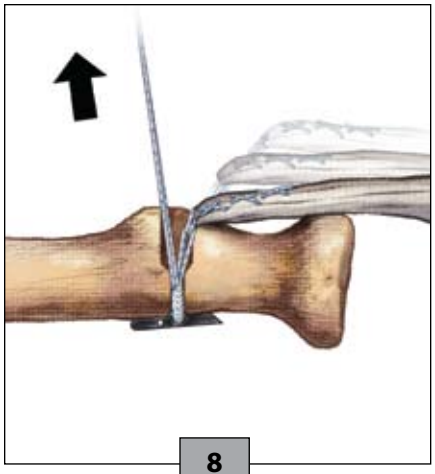
6

Use a burr or ronguer to create a longitudinal trough large enough to accept the biceps tendon into the bone tunnel.



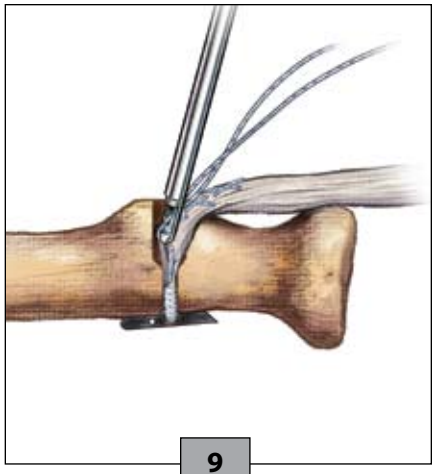
7

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.



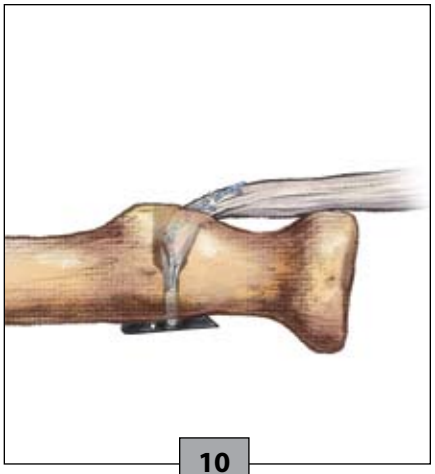
8

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.



9

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



10

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

Biomet Sports Medicine
4861 E. Airport Dr.
Ontario, CA 91761, USA

21282015
Rev. A
Date: 01/09

Biomet Sports Medicine™ Toggleloc™ Systems

ATTENTION OPERATING SURGEON

DESCRIPTION
The Toggleloc™ system is a non-resorbable system intended to aid in arthroscopic and orthopedic reconstructive procedures requiring soft tissue fixation, due to injury or degenerative disease.

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:

Shoulder
Bankart lesion repair
SLAP lesion repairs
Acromio-clavicular repair
Capsular shift/capsulolabral reconstruction
Deltoid repair
Rotator cuff tear repair
Biceps Tenodesis

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 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)

Elbow
Ulnar or radial collateral ligament reconstruction
Lateral epicondylitis repair
Biceps tendon reattachment

Knee
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
Collateral ligament repair
Scapholunate ligament reconstruction
Tendon transfers in phalanx
Volar plate reconstruction

Hip
Acetabular labral repair

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
The Toggleloc™ system of 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 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

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. Implanting metals and alloys subjects them to constant changing environments of salts, acids, and alkalis 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 marrying them to a common goal, i.e., screws and plates.
5. Care is to be taken to insure 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.
8. DO NOT USE if there is a loss of sterility of the device.
9. Discard and DO NOT USE opened or damaged devices, and use only devices that are package in unopened or undamaged containers.
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 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, 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 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
The Toggleloc™ system of implants are supplied sterile and are sterilized by exposure to Ethylene Oxide Gas (ETO) if device contains MaxBraid™ PE suture. Do not resterilize. Do not use any component from an opened or damaged package. Do not use past expiration date.

Caution: Federal law (USA) restricts this device to sale, distribution, or use by or on the order of a physician.

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: 574-372-3968.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estate
Bridgend, South Wales
CF31 3XA, U. K.

CE 0086

The information contained in this package insert was current on the date this brochure was printed. However, the package insert may have been revised after that date. To obtain a current package insert, please contact Biomet Sports Medicine at the contact information provided herein.

For product information, including indications, contraindications, warnings, precautions and potential adverse effects, see the package insert and Biomet's website.

BIOMET®
SPORTS MEDICINE

One Surgeon. One Patient.

P.O. Box 587, Warsaw, IN 46581-0587 • 800.348.9500 ext. 1501

Form No. BSM0191.0 • REV022809

www.biometsportsmedicine.com