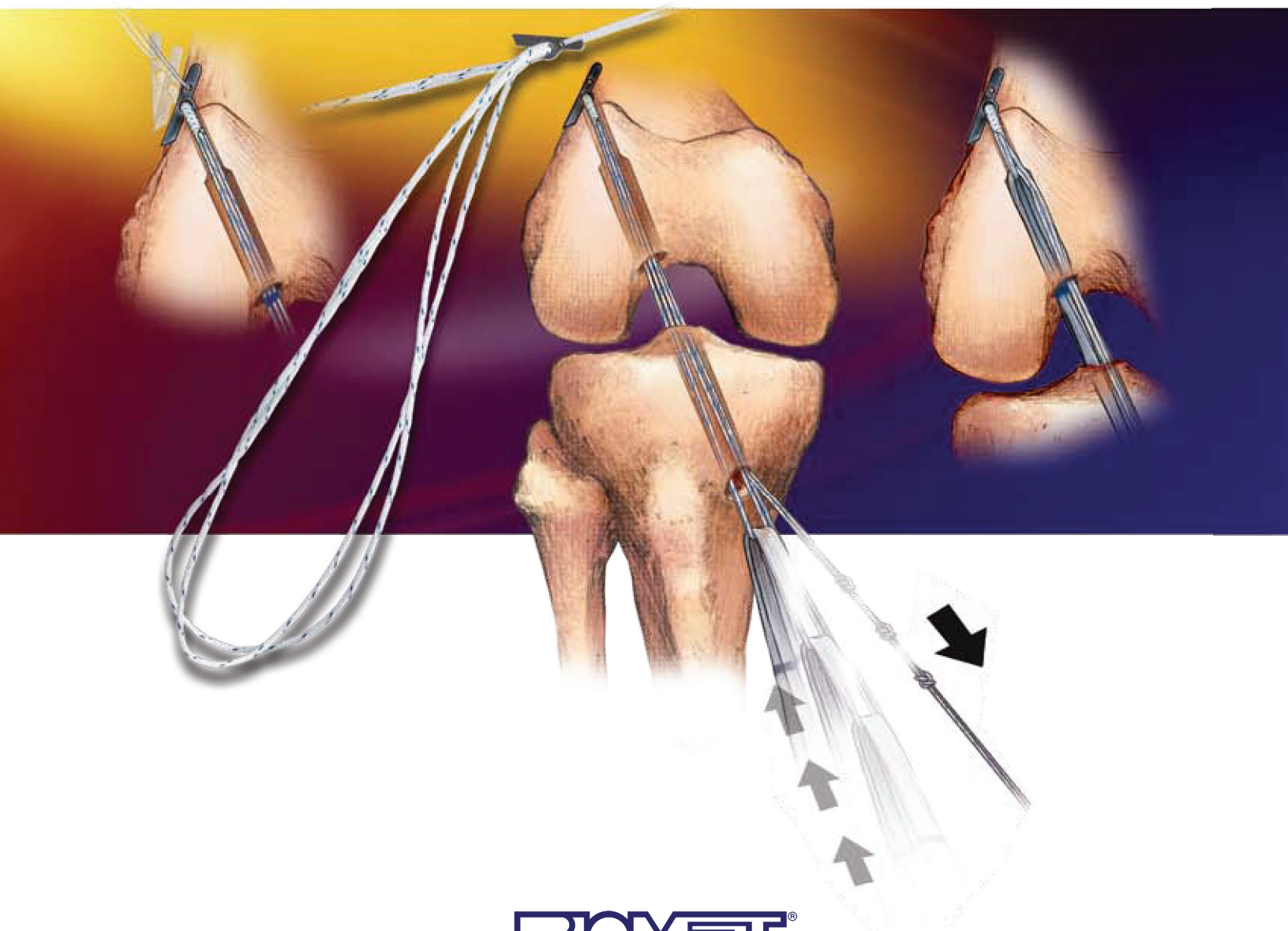


ToggleLoc™

FEMORAL FIXATION DEVICE

with Zip Loop™
TECHNOLOGY

Surgical Protocol written by Mark Gittins, D.O.



BIOMET®
SPORTS MEDICINE



TraumaPro

ToggleLoc™

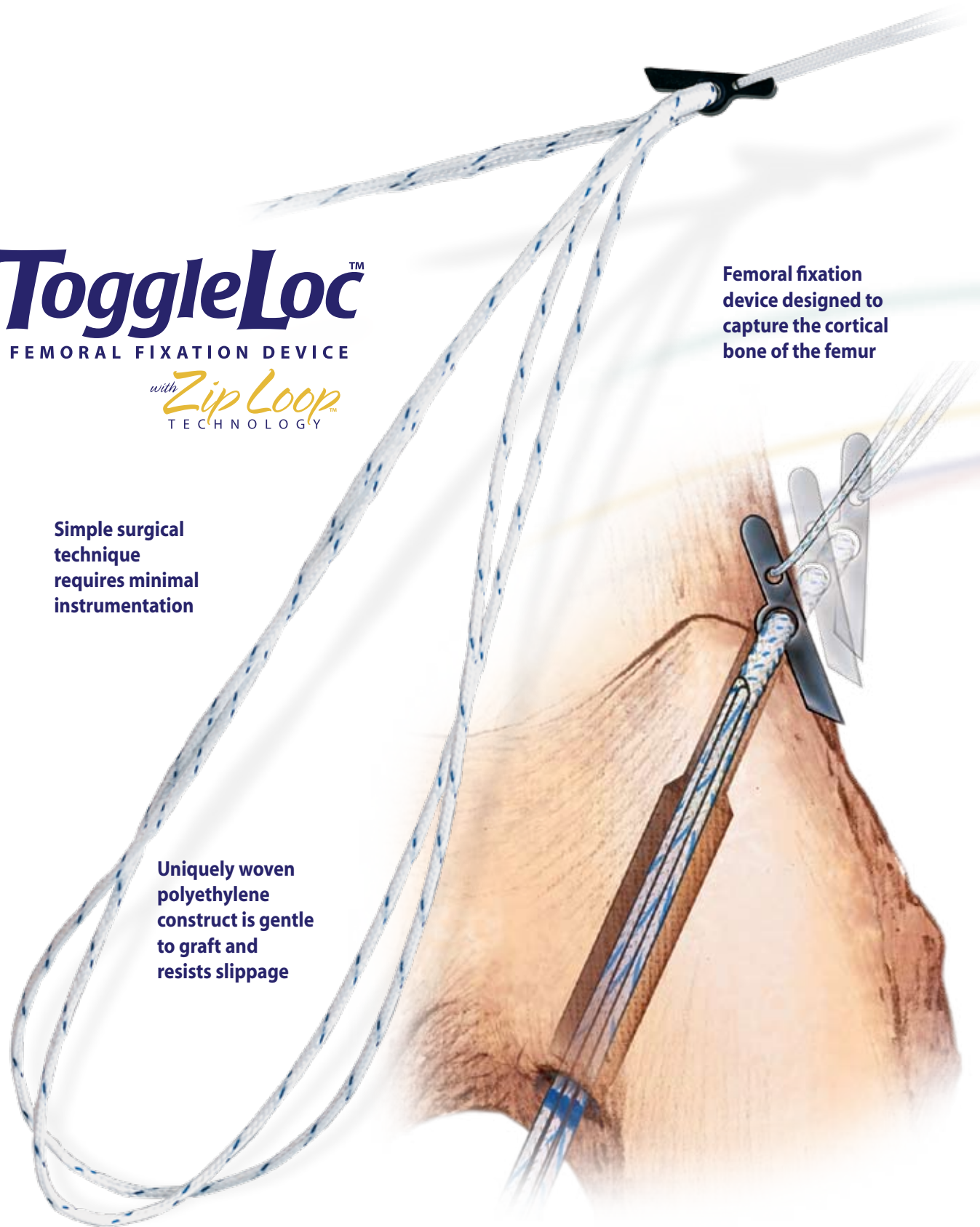
FEMORAL FIXATION DEVICE

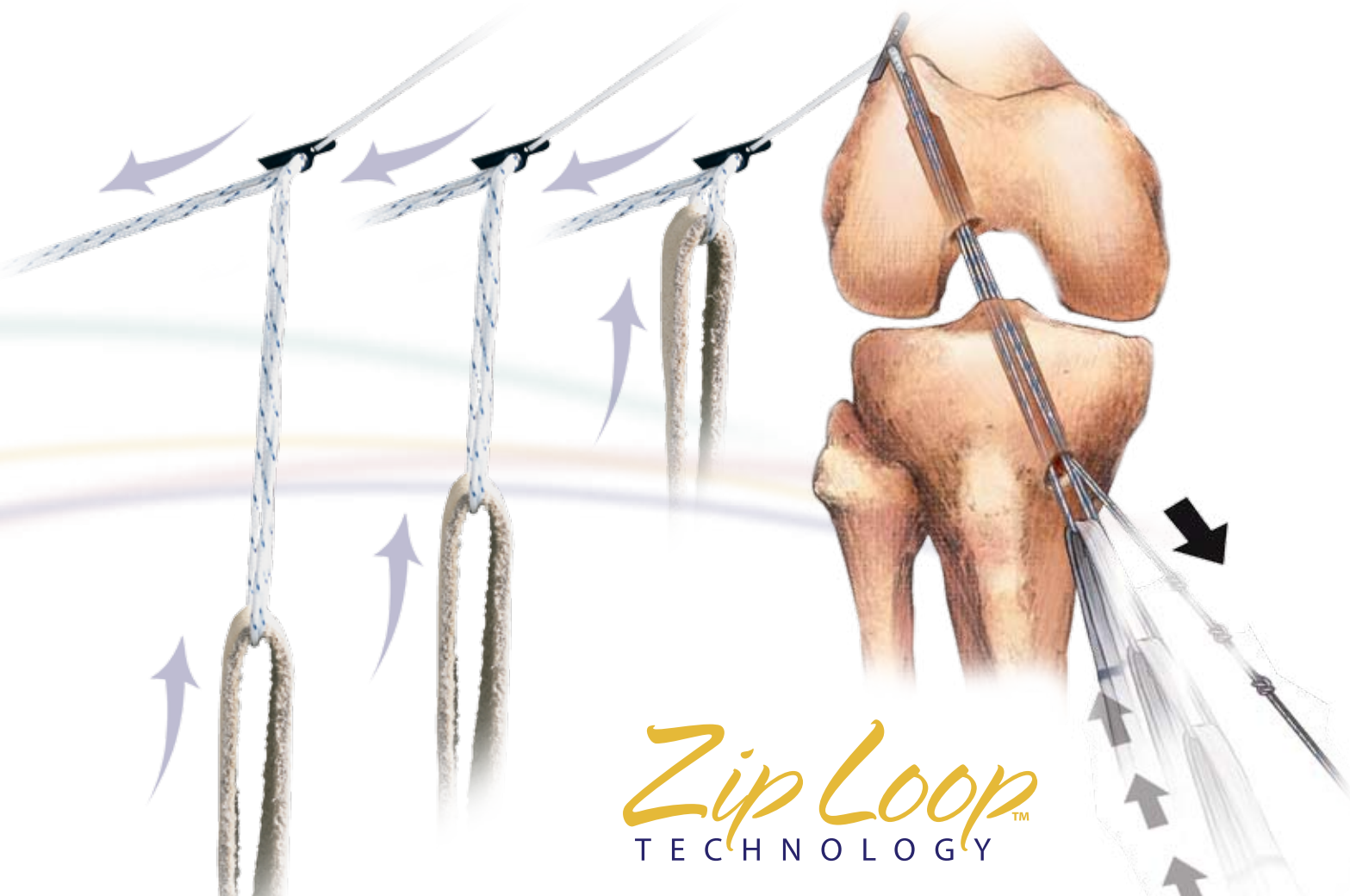
with *Zip Loop™*
TECHNOLOGY

Simple surgical
technique
requires minimal
instrumentation

Uniquely woven
polyethylene
construct is gentle
to graft and
resists slippage

Femoral fixation
device designed to
capture the cortical
bone of the femur





Features

- Maximizes soft tissue graft-to-tunnel interface
- One implant for varying tunnel lengths—eliminates the need for multiple sizes
- For use in both transtibial and anteromedial portal ACL reconstruction
- Tension may be applied from femoral side after tibial fixation has been achieved
- Virtually no slippage after cyclic loading¹

This brochure is presented to demonstrate the surgical technique utilized by Mark Gittins, D.O. Biomet Sports Medicine, 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 and products for each individual patient. Biomet Sports Medicine is not responsible for selection of the appropriate surgical technique to be utilized for an individual patient. Rehabilitation activities vary depending on the individual patient and physician's recommendations.

1. Data on file at Biomet Sports Medicine, Inc. Bench test results are not necessarily indicative of clinical performance.

Surgical Technique

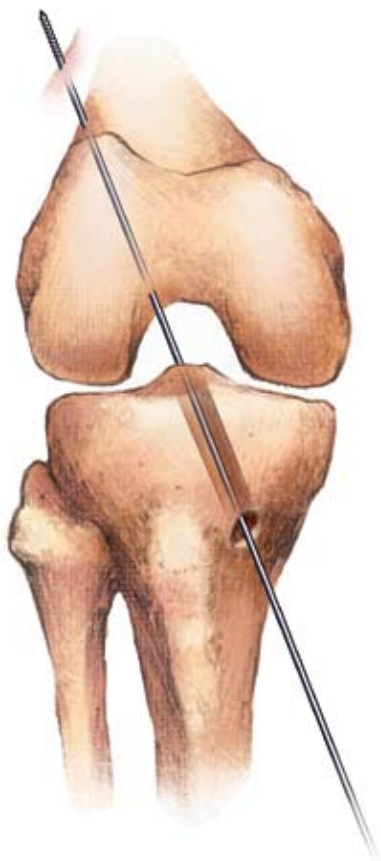


Figure 1

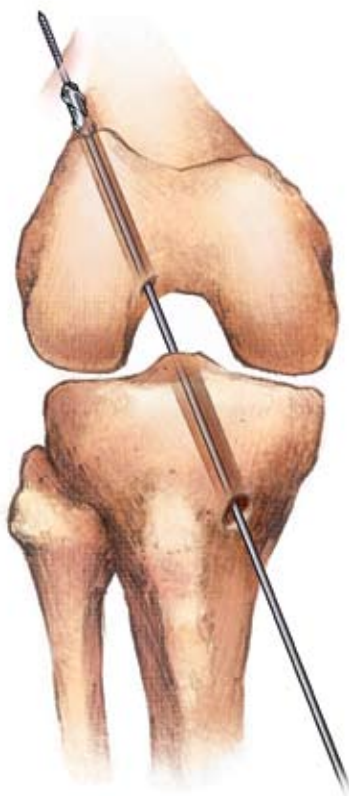


Figure 2

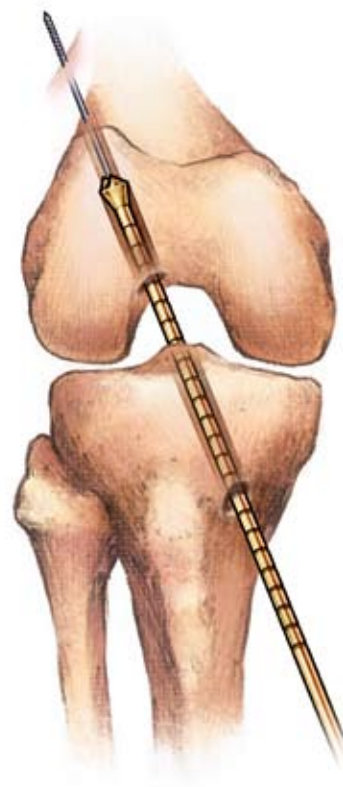


Figure 4

Tunnel Preparation

Utilizing a tibial guide that allows for optimal tunnel placement, position the tibial guide appropriately and drill the guide wire. After the graft size has been determined, ream over the guide wire with the corresponding reamer.

After the tibial tunnel has been completed, position a Femoral Aimer transtibially into the over-the-top position. Drill a calibrated guide wire through the Femoral Aimer and the lateral cortex of the femur (Figure 1). Drill over the previously placed guide wire with the 4.5mm ToggleLoc™ drill bit through the lateral cortex of the femur (Figure 2). After the 4.5mm tunnel is drilled, remove the guide wire.

Assess Room for Femoral Tunnel

Pass the ToggleLoc™ depth gauge transtibially into the 4.5mm femoral tunnel and measure the tunnel length from the lateral cortex of the femur to the tunnel exit point in the joint space to ensure that there is sufficient room to drill an adequate length femoral tunnel (Figure 3).



Figure 3

Drill Full Diameter Femoral Tunnel

Re-insert the guide wire into the femoral tunnel and out the skin of the lateral thigh. Select the endoscopic reamer that corresponds with graft diameter and ream to the depth that will allow the desired soft-tissue graft-to-tunnel interface (typically around 30mm). **The reamer should not exit the femoral cortex (Figure 4).** Clean any debris from the tunnel to ensure smooth graft passage.

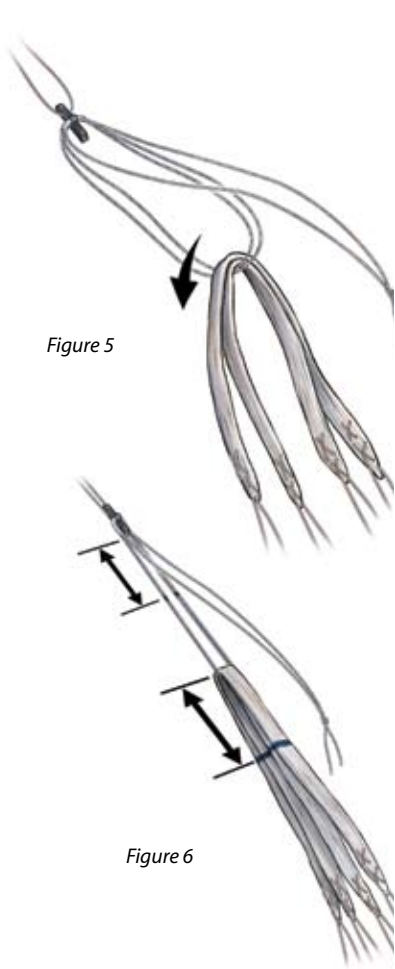


Figure 5

Figure 6

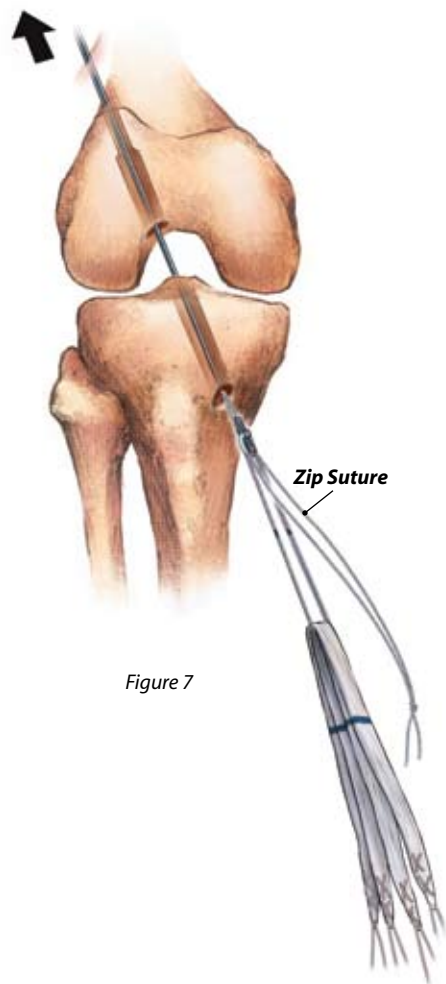


Figure 7

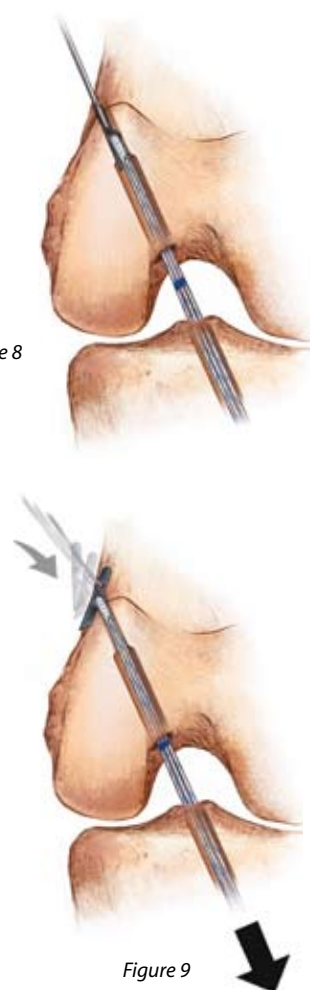


Figure 8

Figure 9

Prepare ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology

Pass the soft tissue grafts through both loops of the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology (Figure 5). Balance the soft tissue grafts in the loops of the implant to allow equal amounts of the soft tissue on either side of the loop. Use the measurement previously obtained with the ToggleLoc™ depth gauge to mark the loops of the implant to ensure deployment on the lateral cortex. Measure from the distal end of the ToggleLoc™ device toward the loops and mark (Figure 6).

Make a second mark on the graft by measuring the depth of the "graft tunnel" (typically 30mm). This mark will aid in optimal graft positioning later in the procedure (Figure 6).

Thread the passing suture of the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology through the eyelet of the guide wire, which should be exiting the tibial tunnel. Pull proximally on the guide wire to pull the passing suture through the tibial tunnel, joint space and femoral tunnel, exiting through the skin.

Insert Implant into Tunnel

Prior to fixation, ensure that the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology is oriented laterally, as it will deploy on the femur's lateral cortex. The "zip suture" should be on the anterior side of the soft-tissue graft prior to graft placement within the femoral tunnel (Figure 7).

Pull the passing suture proximally until the mark on the loops of the ToggleLoc™ device reach the entrance of the femoral tunnel. Position the implant just beyond the lateral cortex of the femur (Figure 8). Pull on the distal end of the soft tissue grafts to feel the implant catch on the lateral femoral cortex, achieving femoral fixation (Figure 9).

Surgical Technique

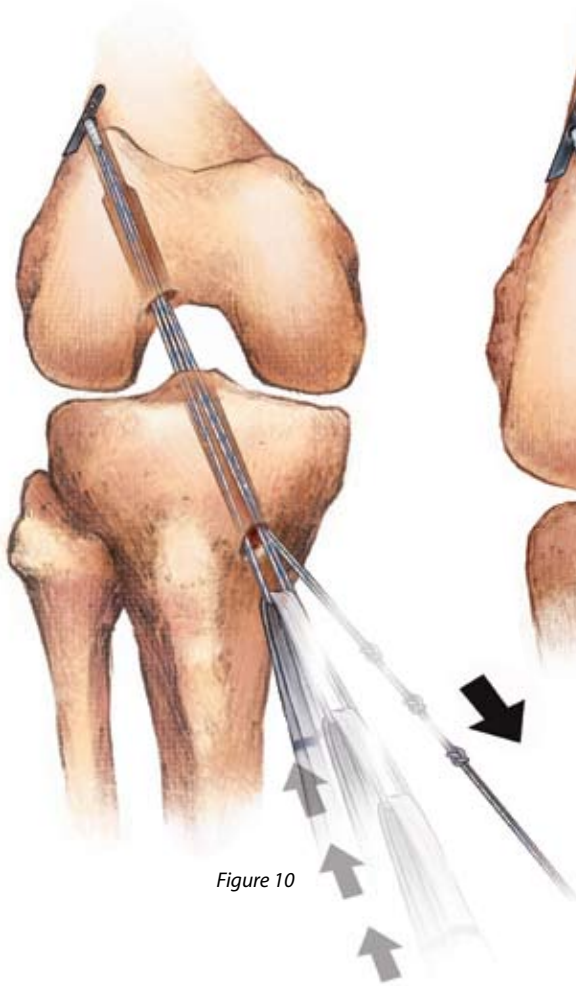


Figure 10

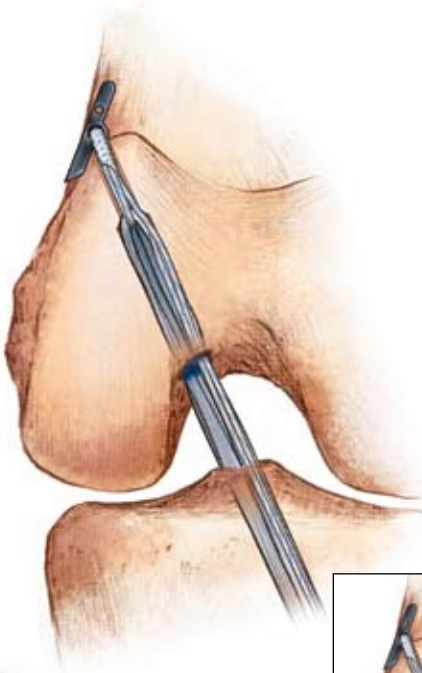


Figure 11

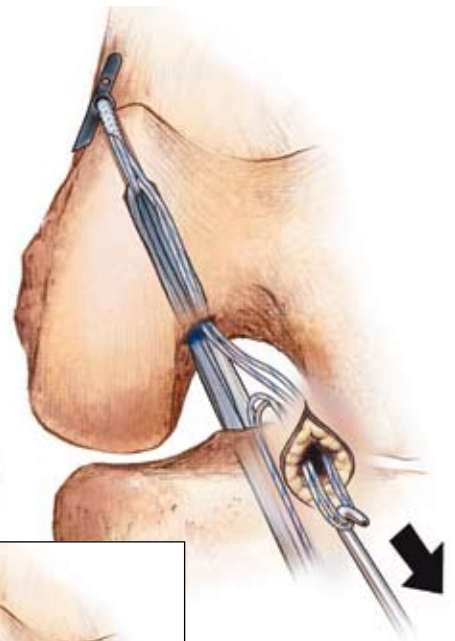


Figure 12

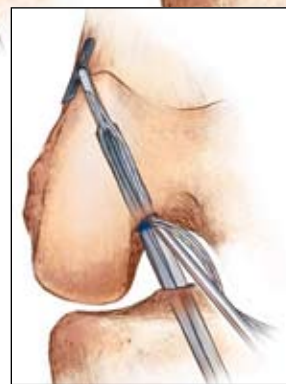


Figure 13

Position Graft in Femoral Tunnel

Ensure the "zip suture" is anterior to the graft and pull distally to draw the graft through the tibial tunnel and into the femoral tunnel. This will shorten the loop of the ToggleLoc™ Femoral Fixation Device with ZipLoop™ Technology and accurately position the soft-tissue graft in the femoral tunnel (Figure 10). Correct placement is indicated when the mark on the graft enters the femoral tunnel (Figure 11).

Complete ACL Graft Fixation

After graft positioning, retrieve the "zip suture" through the medial portal with a crocheting hook or other suture grasping device (Figure 12). Pass the knot of the "zip suture" through the key shaped hole in the Super MaxCutter™ instrument. Advance the Super MaxCutter™ through the medial portal and sever the suture near the entrance of the femoral tunnel in the joint space (Figure 13). Cycle the knee and implant the desired method of tibial fixation (Figure 14).

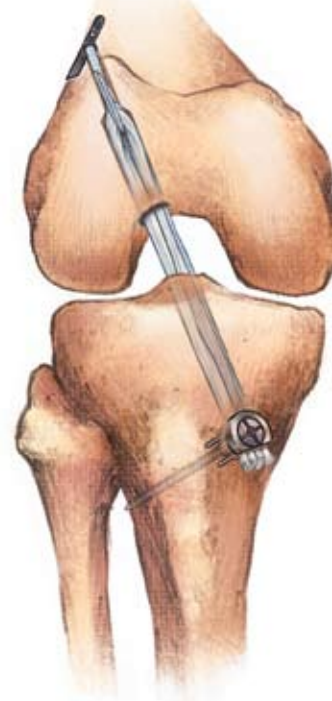


Figure 14

Package Insert

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

21282002
Rev. D
Date: 02/07

Biomet Sports Medicine™ Internal Fixation Devices

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
Polypropylene

INDICATIONS

Bone Mulch™ Screws are intended for use in fixation of semitendinous and/or gracile tendon grafts in ACL reconstruction only.

Interference Screws and Set Screws are intended for use in fixation of patellar bone-tendon-bone grafts in ACL reconstruction.

Screw and Washers are indicated for soft tissue fixation to bone, and bone-to-bone fixation in orthopedic procedures specifically during Ligament reconstruction.

Toggle anchors (i.e., ToggleLoc™, ToggleLoc™ buttons and EZLoc™) are indicated for use for fixation of tendons and ligaments during orthopedic reconstruction procedures such as Anterior Cruciate Ligament (ACL) reconstruction.

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 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, 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. 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, hard hammer blows) may cause fracture or bending of the device. Prior to insertion of the implant, predrill, 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 package 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 overtightened.
12. 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.
13. The ToggleLoc™ Buttons are used with a size #2 polyester suture or one of equivalent or greater strength, unless otherwise indicated.

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.

Authorized Representative: Biomet U.K., Ltd.
Waterton Industrial Estates,
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.

Ordering Information

**ToggleLoc™ Femoral Fixation Device
with ZipLoop™ Technology**

904755

4.5mm Drill Bit

904760 Disposable

904765 Reusable

ToggleLoc™ Depth Gauge

904766

ToggleLoc™ Disposable Kit

909846

Includes:

2.4mm x 13" Drill Point K-Wire

2.4mm x 16" Graft Passing Pin

ToggleLoc™ 4.5mm Drill Bit

2.4mm x 10" Drill Point K-Wire

3.2mm Drill Bit

ACL Bone Plug

Marking Pen

6" Ruler

Super MaxCutter™ Suture Cutter

900342

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