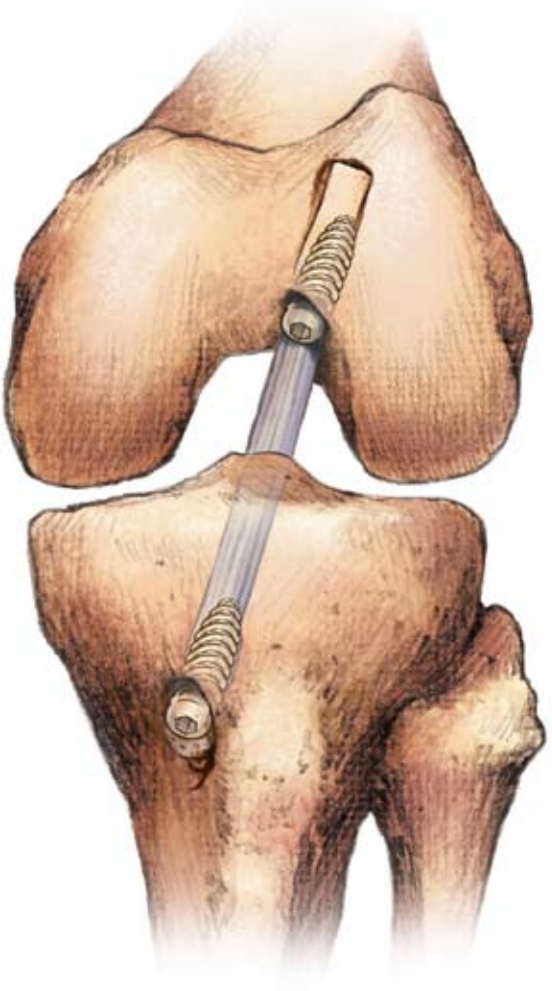
Gentle Threads™
Interference Screws

Advantages

- Blunt thread design assists in protecting the graft
- Driver design distributes torque evenly throughout the entire screw to help prevent the screw from breaking or stripping
- Screws are compatible with 1.5mm Nitinol™ guide wires
- Easy-out screw remover virtually eliminates the fiddle-factor of removing screws
- Available in revision, round head and fully-threaded designs



Round Head *Fully Threaded* *Revision*

LactoSorb® Resorbable Copolymer

LactoSorb® Copolymer is comprised of 82% L-lactic acid (PLLA) and 18% glycolic acid (PGA). This unique formulation incorporates the high strength properties of PGA with the intermediate absorption characteristics of PLLA to form a biocompatible, resorbable copolymer that retains over 80% of its mechanical strength during the first eight weeks of healing with complete mass loss occuring in 9 – 15 months.[1–3]

Ordering Information

Fully Threaded Gentle Threads™ Interference Screws	
905600	7mm x 20mm
905601	7mm x 25mm
905602	7mm x 30mm
905603	8mm x 20mm
905604	8mm x 25mm
905605	8mm x 30mm
905606	9mm x 20mm
905607	9mm x 25mm
905608	9mm x 30mm
905627	9mm x 35mm
905609	10mm x 20mm
905628	10mm x 25mm
905629	10mm x 30mm
905630	10mm x 35mm

Round Head Gentle Threads™ Interference Screws	
905612	7mm x 20mm
905613	7mm x 25mm
905614	8mm x 20mm
905615	8mm x 25mm
905616	9mm x 20mm
905617	9mm x 25mm
905620	10mm x 25mm

Gentle Threads™ Revision Screws	
905623	11mm x 25mm
905626	12mm x 25mm

Gentle Threads™ Interference Screw Driver
905650

Tunnel Dilator
905651

Threaded Dilator
905659

Tunnel Notcher
905652

Modular Taps

905048	6mm
905049	7mm
905050	8mm
905051	9mm
905052	10mm

Modular Screwdriver
905656

Gentle Threads™ Interference Screw Instrument Tray
905653

1.5mm Nitinol™ Guide Wire
906850

Gentle Threads™ Disposable Kit
909826
Includes:

909640	*Graft Passing Pin 2.4mm x 16"*
909894	*Drill Point K-Wire 2.4mm x 13"*
906850	*Nitinol® Guide Wire 1.5mm x 14"*
906853	*Nitinol® Guide Wire 1.1mm x 9"*
909693	*ACL Bone Plug*

Easy-Out Screw Remover
905654

Revision Gentle Threads™ Driver
905657

Revision Gentle Threads™ Dilator
905658

References

1. An YH, *et al.*: Fixation of osteotomies using bioabsorbable screws in the canine femur. *Clinical Orthopedics and Related Research*, 355: 330–311, 1998.
2. Pietrzak WS, *et al.*: Effect of simulated introperative heating and shaping on mechanical properties of a bioabsorbable fracture plate material. *Applied Biomaterials*, 38(1): 17–24; 1997.
3. Rodeo, SA, *et al.*: Tendon-healing in a bone tunnel. A biomechanical and histological study in the dog. *Journal of Bone Surgery*, 75-A(12): 1795–1803; 1993.

BIOMET® SPORTS MEDICINE

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BSM0007.1 REV083107

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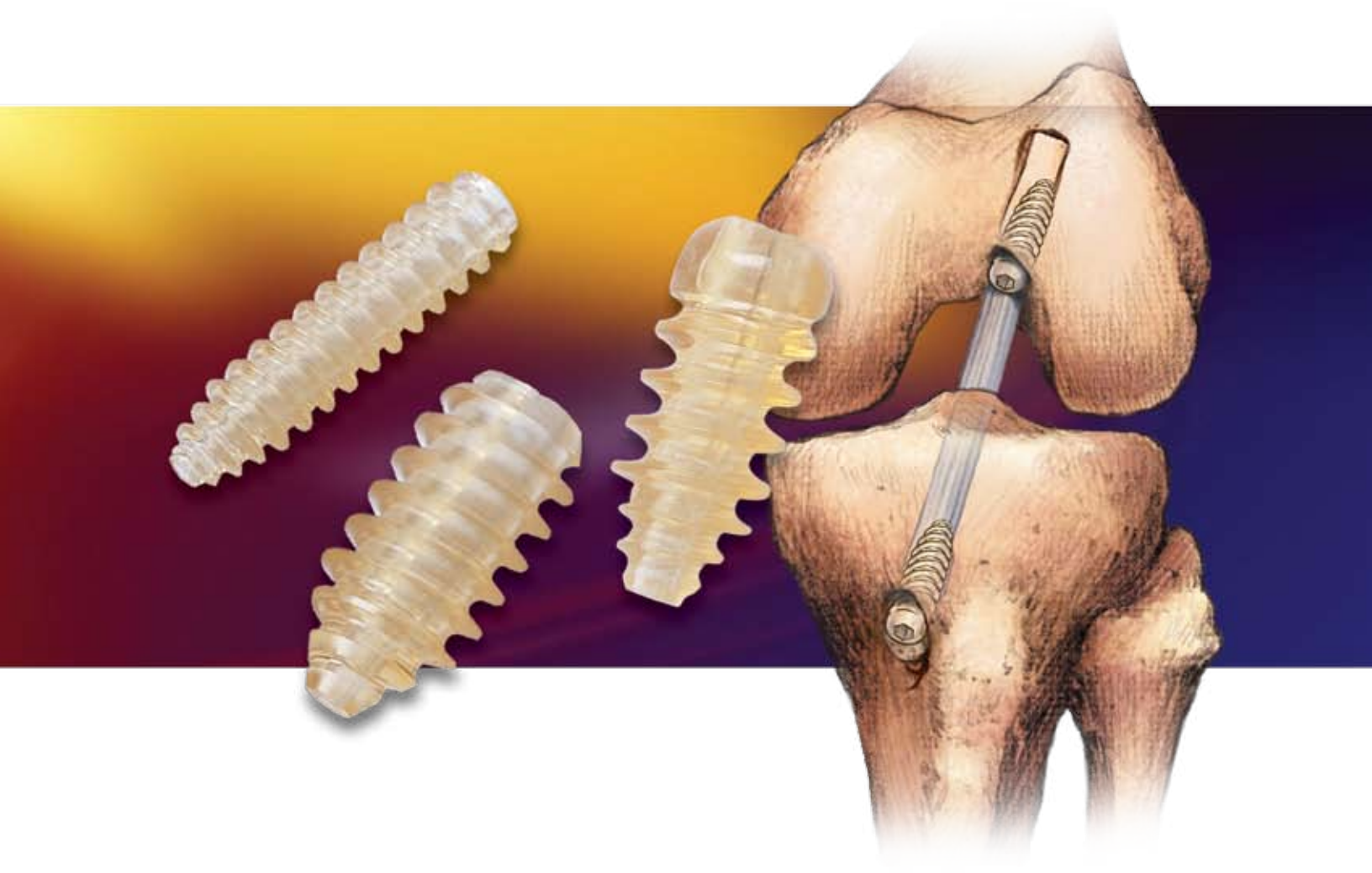
Gentle Threads™
Interference Screws



BIOMET®
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Surgical Technique

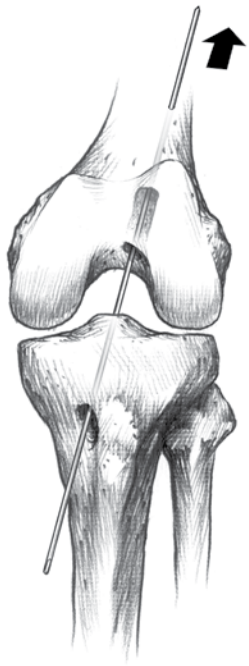

Figure 1

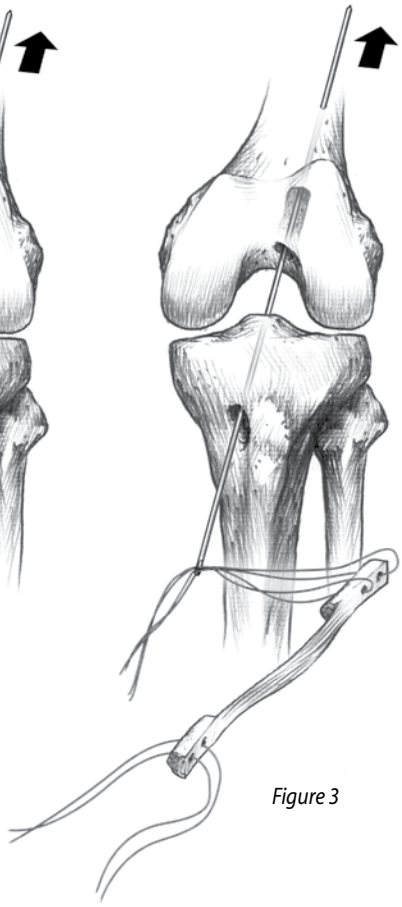

Figure 3

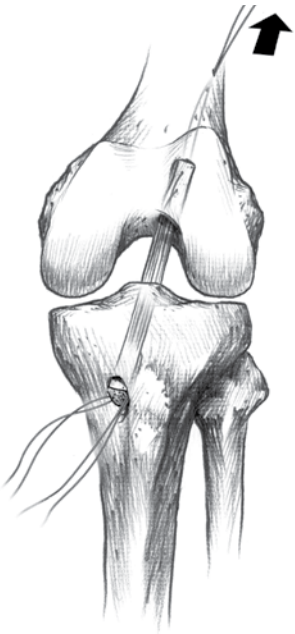

Figure 4

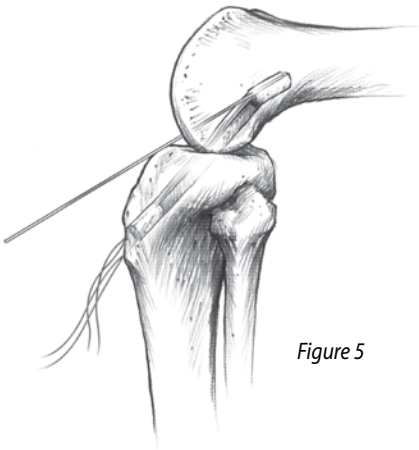

Figure 5

Drill through the femoral aimer with a graft passing pin until the pin penetrates the patient's skin. Using an acorn reamer, ream the desired length of femoral tunnel. Do not remove the graft passing pin (Figure 1).

At this time, use the Gentle Threads™ tunnel notcher to scratch a groove into the femoral tunnel wall. This may enable the surgeon to more easily place the Nitinol™ guide wire. It can also be used after the graft has been passed (Figure 2).

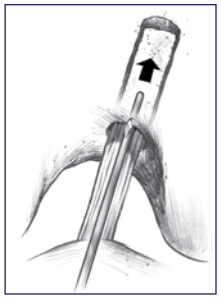

Figure 2

Slide the sutures from the graft through the eyelet of the graft passing pin (Figure 3). Pull the pin through the lateral femoral cortex, and use the sutures to fully seat the graft (Figure 4).

With the knee hyper-flexed, enter the knee through the anterior portal and insert a 1.5mm Nitinol™ guide wire into the femoral tunnel adjacent to the graft at the desired position of the Gentle Threads™ Interference Screw. Tap the wire into the end of the femoral tunnel to stabilize (Figure 5).

Place the Gentle Threads™ dilator over the guide wire and tap into the tunnel approximately the same depth as the length of the screw (Figure 6). In hard bone, tapping may be necessary prior to the insertion of Gentle Threads™ Interference Screws.

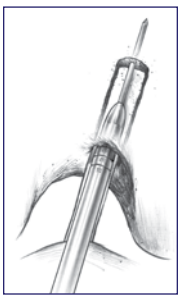

Figure 6

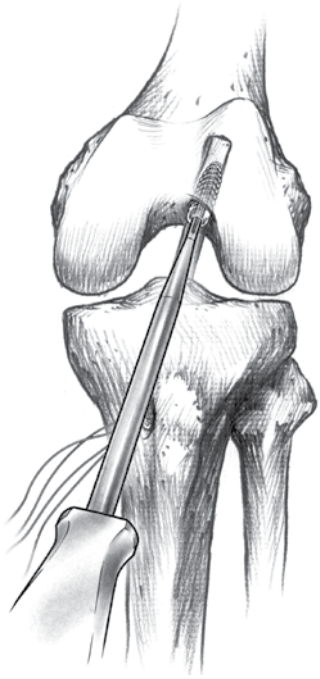

Figure 8

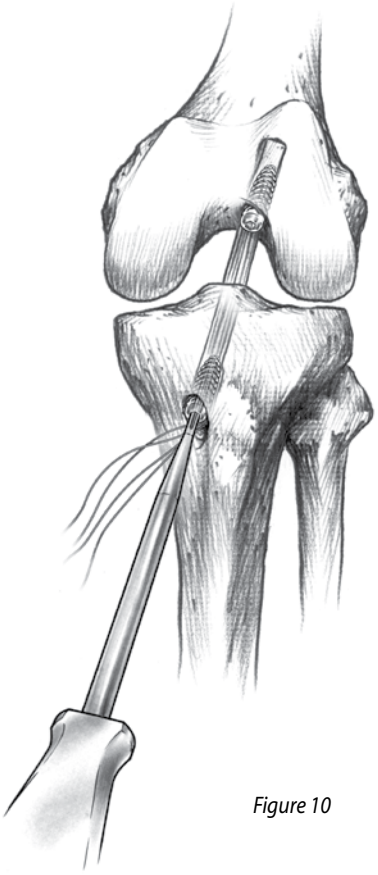

Figure 10

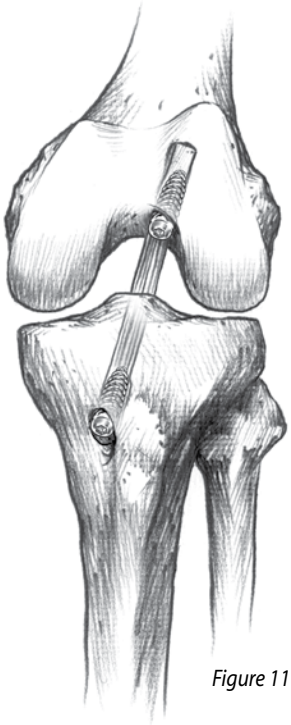

Figure 11

Fully seat a round head Gentle Threads™ Interference Screw on the Gentle Threads™ driver. The driver should slide into the screw until it is two-thirds or three-fourths of the distance to the tip of the screw (Figure 7).

Then, insert the screw into the tunnel (Figure 8). During insertion, the driver must remain fully seated in the screw. Do not allow the driver to partially slide out of the screw (Figure 9).

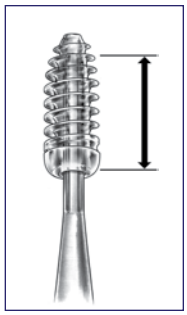

Figure 7

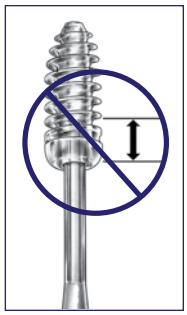

Figure 9

Next, remove the Nitinol™ guide wire. After the femoral screw is inserted, seat the tibial screw on the driver.

Insert the guide wire in the tibia at the desired position of the screw. Introduce the dilator into the tibial tunnel until the desired depth is reached. Then, insert a fully-threaded Gentle Threads™ Interference Screw into the tunnel (Figure 10).

When the screw is fully seated, remove the guide wire and driver (Figure 11). At this time, remove the sutures from the graft.

This surgical technique is presented to demonstrate the surgical technique utilized by James L. Comadoll, M.D., Salisbury, North Carolina. 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 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.

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01-50-1058
Date: 03/07

Resorbable Interference Screw

ATTENTION OPERATING SURGEON

DESCRIPTION
The Biomet Sports Medicine™ Resorbable Interference Screw is an interference fixation screw for use in soft tissue reattachment procedures. The implant is made of LactoSorb®, a resorbable copolymer, which is 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 that are then metabolized by the body.

MATERIALS
Poly-L-Lactic Acid/Polyglycolic Acid

INDICATIONS:
Indications for the Resorbable Interference Screw include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow, and knee. Specific indications include the following:

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tenodesis, and deltoid repair.

Wrist/Hand: Scapholunate ligament reconstruction and ulnar/radial collateral ligament reconstruction.

Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, and mid- and forefoot reconstruction.

Elbow: Tennis elbow repair, ulnar or radial collateral ligament reconstruction, and biceps tendon reconstruction.

Knee: Extra-capsular repair, medial collateral ligament (MCL) repair, lateral collateral ligament (LCL) repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tenodesis reconstruction, patellar ligament/tendon repair, and vastus medialis obliquus (VMO) muscle advancement.

In addition to the above indications, 7.0mm, 8.0mm, 9.0mm, 10.0mm, 11.0mm, and 12.0mm screws are indicated for the following uses:

1. To provide interference fixation of patellar bone-tendon-bone grafts in anterior cruciate ligament (ACL) reconstruction.
2. To provide interference fixation during femoral and/or tibial fixation in anterior cruciate ligament reconstruction using a soft tissue graft (semitendinosus, gracilis).
3. To provide interference fixation during posterior cruciate ligament (PCL) reconstruction.

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 for attachment or latent infections.
4. Pathologic soft tissue conditions, which would prevent secure fixations.

WARNINGS
Biomet Sports Medicine™ internal fixation implants 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 implant 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. 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 implant 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 implant or tissue supported by the implant. 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. Care is to be taken to assure adequate soft tissue fixation at the time of surgery. Failure to achieve adequate fixation through improper positioning or placement of the implant 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 screws can occur if excessive force (torque) is applied while seating bone screws.
7. Do not use excessive force when inserting the Resorbable Interference Screw. Excessive force (i.e., long, hard hammer blows) may cause fracture or bending of the device. Prior to insertion of the implant, dilate or tap in hard bone.
8. Do not overtighten the screw. Structural damage to the tissue and implant may occur if overtightened.
9. Do not heat LactoSorb® Resorbable Interference Screws by any means prior to implantation.
10. DO NOT USE if there is loss of sterility of the implant. Discard and DO NOT USE opened or damaged implants, and use only implants that are packaged in unopened and undamaged containers.
11. DO NOT USE where a permanent implant is indicated.
12. Do not use LactoSorb® implants with resorbable implants made by other manufacturers due to the probability of incompatible fits, size and rate of resorption.
13. 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.

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.

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 which may lead to breakage of the implant or failure of the graft material..
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, Inc., P.O. Box 587, Warsaw, IN 46581 USA, Fax: 574-372-1683.

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