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 orstripping
- 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

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 occurring in 9 – 15 months.1-3
Full Threaded Gentle Threads™ Interference Screws

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Round Head Gentle Threads™ Interference Screws

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Gentle Threads™ Revision Screws

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Gentle Threads™ Interference Screw Driver

- 905650
- 905651
- 905659
- 905652
- 905048 6mm
- 905049 7mm
- 905050 8mm
- 905051 9mm
- 905052 10mm

Modular Screwdriver

- 909826

1.5mm Nitinol Guide Wire

- 909826

Gentle Threads™ Disposable Kit

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


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Gentle Threads™ is a trademark of Biomet Sports Medicine, Inc. LactoSorb® is a trademark of Biomet Manufacturing Corp.
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).

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.
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).

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.
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.

The Biomet Sports Medicine® Resorbable Interference Screw is an interference fixation screw used 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. Poly(lactic acid) polyglycolic acid copolymer degrades and resorbs in vivo by hydrolysis to lactic and glycolic acids that are then metabolized by the body.

ATTENTION OPERATING SURGEON

DESCRIPTION

The Biomet Sports Medicine® Resorbable Interference Screw is an interference fixation screw used 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. Poly(lactic acid) polyglycolic acid copolymer degrades and resorbs in vivo by hydrolysis to lactic and glycolic acids that are then metabolized by the body.

CONTRAINDICATIONS

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

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 instruments are subject to wear with normal usage. Instruments, which have experienced extensive use or excessive force, are susceptible to fracture. Intraoperative fracture or breaking of instruments has been reported. 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.

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.

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.

LactoSorb is a registered trademark in the United States.

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CF31 3XA, UK.

CE 0086