Orthopedic Pin Kit

Range of Implants
- Diameters: 1.5mm and 2.0mm
- Length: 40mm

Easy-to-Use Instruments
- Adjustable inserters
- Disposable instrument set
  - Pin pusher, pin sleeve, pin K-wire/depth-stop
- Simple to use

Indications
- Correction of hallux valgus
- Repair of metacarpal and phalangeal fusion and fractures
General Guidelines for Pre-Measured Implant Insertion

**Create Bone Hole**
A bone clamp or secondary K-wire (packaged separately) can be used to further stabilize the bone segments (Figure 1).

Drill with the provided K-wire/depth-stop assembly through the bone fragment and into the underlying bone (Figure 2). Intraoperative radiographic visualization can be used to guide K-wire placement.

**Measure Hole for ReUnite® Pin**
With K-wire still in bone, slide depth-stop snug to bone (Figure 3).

Remove K-wire from bone and drill, being careful to not move the depth-stop. Read bone hole measurement from the proximal side of the depth-stop (Figure 4).

**Trim ReUnite® Pin to Measured Tunnel Length**
Trim pin to measured length by inserting the pusher into the ReUnite® Pin sleeve pushing the pin out of one end (Figure 5).

Stop inserting the pusher at pre-measured depth via markings on pusher (Figure 6). Trim off exposed pin using heat loop (Figure 7).

The remaining pin in sleeve corresponds to the bone hole depth.

**Insert Pin Into Hole**
Irrigate the bone hole with sterile saline. Position the uncut end of the pin sleeve in line with the drilled bone hole. Introduce the non-cut end of the pin into the bone hole with the pin pusher by pushing or gently tapping the proximal knob of the pusher with a mallet to advance the pin into the bone hole (Figure 8).
General Guidelines for Non-Measured Implant Insertion

Create Bone Hole
A bone clamp or secondary K-wire (packaged separately) can be used to further stabilize the bone segments (Figure 1).

Insert Pin into Hole
Irrigate the bone hole with sterile saline. Position the pin sleeve in line with the drilled bone hole. Introduce the pin into the bone hole with the pin pusher by pushing or gently tapping the proximal knob of the pusher with a mallet to advance the pin into the bone hole (Figure 3).

Stop advancing pin when pin bottoms out in drilled tunnel. Trim exposed pin flush with bone (Figure 4).

Completed Repair for Both Pre-Measured and Non-Measured Implant Insertion

Ordering Information

<table>
<thead>
<tr>
<th>Resorbable Orthopedic Pin Kits</th>
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<tbody>
<tr>
<td>Part No.</td>
<td>Size</td>
<td>Size</td>
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<tr>
<td>948230</td>
<td>1.5 x 40mm</td>
<td>2.0 x 40mm</td>
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Heat Loop
905414

K-wire (optional)
950092 0.62" (1.5mm) Sterile
950093 5/64" (2.0mm) Sterile

Steinmann Pin (optional)
950092 0.62" (1.5mm) Sterile
950093 5/64" (2.0mm) Sterile

Refer to package insert for precautions, indications and warnings.
This brochure is presented to demonstrate the surgical technique utilized by Ron C. Clark, M.D., Valparaiso, Indiana. Arthrotek, as the manufacturer of this device, does not practice medicine and does not recommend this or any other system 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 use on a specific patient. Arthrotek is not responsible for selection of the appropriate product or surgical technique to be utilized for an individual patient.
PROPELLER HEAD

Panel System

Orthopedic Pins

™

Small

Form No. Y-BMT-924/063005/K

web site: www.arthrotek.com • eMail: arthrotek@arthrotek.com

Arthrotek at the contact information provided herein.

4. The plates can be heated and shaped as desired up to and including
3. These devices are resorbable and do not provide permanent
2. The LactoSorb® 5.0 mm Washer is used in conjunction with the Biomet 5.0 mm Bone Screw for ankle fractures, metatarsal fusion, and metatarsal osteotomies (Hallux Valgus) in the presence of appropriate protection or immobilization (e.g. casting, bracing, external fixator).
1. The LactoSorb® Hand System is indicated for surgical fixation of

INDICATIONS

1. Correct selection of the implant is extremely important. The potential
2. Patients with mental or neurologic conditions who are unmindful or incapable of following postoperative care instructions.
3. Patient conditions including blood supply limitations, obesity, insufficient quantity or quality of bone stock or latent infection.
4. Do not use in load bearing procedures (excluding 3.0 screws and Hammer Toe Pins, see above indications).

WARNINGS

1. Correct selection of the implant is extremely important. The potential
2. Improper selection, placement, position, and fixation of the device can lead to failure of the device or the procedure. The surgeon must be familiar with the devices, the method of application, and the surgical procedure prior to performing surgery. The surgeon must select a type or types of internal fixation devices appropriate for treatment.
3. These devices are resorbable and do not provide permanent fixation. Do not use in procedures where a permanent implant is needed.
4. The plates can be heated and shaped as desired up to and including three times using the LactoSorb® Heat Pack or a hot sterile saline/ water bath. LactoSorb® exposure to the bath should be a maximum of 15 seconds per bath with the temperature not exceeding 80°C.
5. Do not heat LactoSorb® Resorbable Bone Screws by any means prior to implantation.
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 fractures of devices can occur if excessive force (torque) is applied while seating.
7. The devices can break or be damaged due to excessive activity or trauma. This could lead to failure requiring additional surgery and device removal.
8. Discard and do not use previously opened or damaged devices.
9. Do not use if there is loosening of the device.
10. When resorbable fixation devices are used to aid in the alignment and stabilization of bones in the hand, appropriate immobilization and rehabilitation is necessary for the desired outcome.
11. These resorbable devices provide temporary fixation and are not intended to replace normal healthy bone or withstand stress of load bearing.
12. Patients that engage in stressful physical activities are to be warned that injury at or near the implant site can lead to failure of the device and/or the treatment.
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 fracture management. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure. Patients may ignore instructions and activity restrictions. The patient is to be instructed in the use of external supports, walking aids, and braces that were intended to immobilize the fracture 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.
14. 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.
15. Cutting of Screws: The screw can be cut with an oscillating or reciprocating saw. No other cutting method may be used. After implantation, screws should only be cut at the distal protrusion.
16. These devices should not be used for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

PRECAUTIONS

1. Do not use Biomet Resorbable implants with resorbable implants made by other manufacturers due to the probability of incompatible fits, size and rate of resorption.
2. Instruments are available to aid in the accurate implantation of Biomet Resorbable Fixations Devices. Intraoperative fracture 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 are only to be used for their intended purpose. All instruments are to be regularly inspected for wear and disfigurement.
3. The patient is to be made aware of the surgical risks and possible adverse effects prior to surgery, and warned that failure to follow postoperative care instructions can cause failure of the implant and the treatment.

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 devices can 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. Nonunion is one of the most important aspects of successful fracture management. Patients with senility, mental illness, alcoholism, or drug abuse may be at higher risk of device failure. Patients may ignore instructions and activity restrictions. 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.

STERILITY

Resorbable implants are sterilized by exposure to Ethylene Oxide (ETO) Gas. Do not resterilize. Do not use past expiration date.

STORE AT 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 by or on the order of a physician.

Comments regarding this device can be directed to: Arthrotek, Regulatory Dept., Biomet Inc., P.O. Box 587, Warsaw, IN 46580 USA, Fax: 574-372-1683.

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 Arthrotek at the contact information provided herein.