

BioPro Accu-Cut® Instructions for Use

For the most current instructions for use and symbol glossary visit www.bioproimplants.com/ifu. Instructions for Use should always be reviewed before using or implanting a device. To receive a printed IFU within 5 business days, please contact orders@bioproimplants.com

Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.

Description

The Accu-Cut Osteotomy Guide System is a disposable, sterile packaged system that includes a guide(s), two universal saw blades, and two double trocar K-wires. Guides are available for the most popular distal metatarsal osteotomies to address mild to moderate hallux valgus deformity.

Materials

The Accu-Cut Guides are manufactured from polyaryletherketone (PAEK) while sawblades and k-wires are manufactured from stainless steel.

Indications for use:

1. For correction of bunion deformity requiring either varus or valgus correction
2. For correction of bunion deformity requiring joint decompression

Contra-indications:

1. A general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. An active infection or a previous infection of the lower extremity that has not been quiescent for at least six months.
3. A local or systemic infection.
4. Significant deficiency in the vascular supply to the extremity.

Precautions and Handling

- Saw blades and k-wires are only for use with surgical power instruments designed for small bone surgery
- Only use the provided saw blades and k-wires within the sterile package
- Inspect the sterile blisters prior to use. Sterilization cannot be assured, and devices should not be used if blister or seal is damaged.
- Devices are single use only
- Do not autoclave devices

Potential Complications and Adverse Effects

- Delayed or non-union of bone
- Delayed healing
- Guides may be cut or broken
- K-wires may bend or break

Sterile:



Sterilized with ethylene oxide gas. Caution: For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device has not been validated.

Instructions for use:

Standard Procedure:

1. Resect a small wafer of medial eminence from the metatarsal head creating a flat medial surface.
2. Affix the device on the metatarsal head at the desired location using a 0.045 k-wire.
3. Use a small hemostat over the posterior k-wire to stabilize the guide against the bone surface.
4. Cut the k-wire flush to the guide and the hemostat.
5. Use a sagittal saw to make through cuts until the capital fragment is free.
6. Remove the hemostat and k-wires.
7. Fixate the osteotomy with the surgeon's desired technique and remove medial eminence created by lateral transportation with sagittal saw.

Precautions:

- When using the DMAA Guide, use only the left and right guides for the appropriate foot (do not use left guide on right foot or right guide on left foot). The post on the DMAA Guide should point away from the toe. Placing the post against the toe will result in an improper cut and a failed procedure.

Two Stage Guide:

1. Resect medial eminence of the first metatarsal in desired fashion.
2. Place 0.045 k-wire into metatarsal head at desired apex point of intended osteotomy.
3. Slide the stage one guide onto wire at apex hole. Cut wire flush over guide.
4. Orient stage one guide in position of intended osteotomy and place 0.045 k-wire into bone through the 2-proximal guide holes.
5. Place a hemostat over proximal most k-wire against guide to prevent migration during cutting.
6. Cut proximal k-wire flush over guide and hemostat.
7. Use slots and saw blade provided to perform through and through osteotomy.
8. Remove guide.
9. Apply desired 5°, 10° or 15° Accu-cut guide onto proximal k-wires and re-apply hemostat.
10. Re-insert saw and perform through and through osteotomy cuts.
11. Remove guide and k-wires.
12. Remove medial based wedge of bone from osteotomy site.
13. Transpose and impact capital fragment at desired position and perform fixation with preferred method.



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