

BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

Value Analysis Resource Guide
Accu-Cut™ Osteotomy Guide System



Contents

Company Information

Founded in 1987, BioPro Inc. is an independently owned medical device manufacturer focused on creating solutions that improve patient's lives.

As an FDA registered and ISO certified manufacturer, BioPro designs, develops, manufactures, and distributes products for companies across the globe.

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Product Overview

Description

The BioPro Accu-Cut Osteotomy Guide System is a sterile packaged system that includes cutting guide(s), two k-wires and two universal saw blades. The Accu-Cut Osteotomy Guide System allows surgeons to make precise metatarsal cuts for bunion correction.

Benefits

- Results in more precise osteotomy for all experience levels¹
- Sterile packaged system reduces OR setup time and eliminates instrument cleanup²
- Simple technique allows performance of complex osteotomies quickly and efficiently
- Provides the surgeon with everything needed to perform the desired osteotomy



Indications for use:

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

Contraindications:

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

Competition

The Accu-Cut Osteotomy Guide System is a one-of-kind system that allows for precise osteotomy cuts every time. The single-use sterile packaged system includes everything a surgeon needs to perform the desired osteotomy for bunion correction. The osteotomy can be paired with a BioPro Go-EZ Cannulated Screw or HBS Cannulated Screw for fast and secure fixation.

Label and Packaging

Sterilized with ethylene oxide gas.

Caution

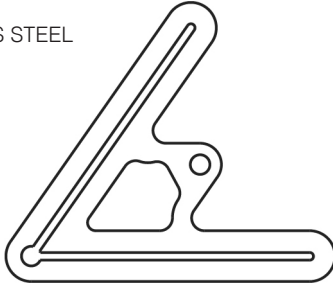
For one procedure only. Do not re-sterilize. Do not use if package is open or damaged. This is a single use device. Re-use of this device can result in the transfer of materials not limited to bone, tissue, blood, or infectious disease. The device is provided sterile and re-sterilization of the device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



ACCU-CUT™

ACCU-CUT™ OSTEOTOMY GUIDE SYSTEM
 (GUIDE NAME)
 MATERIAL: PAEK AND STAINLESS STEEL


QTY


1



REF XXXXX	LOT XXXXXX
 MFG Date YEAR-MM-DD	 Expiration Date YEAR-MM-DD

 Consult IFU

 Single Use

 Do not use if package is damaged

 Caution

 Manufactured by

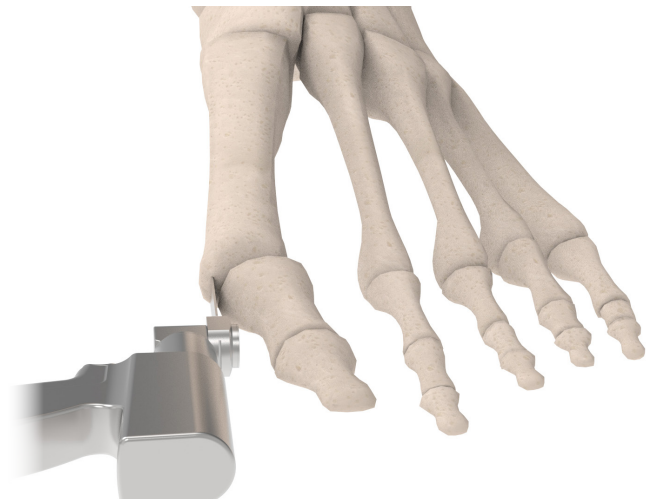
STERILE **EO** Sterilized using ethylene oxide

 Prescription Use Only

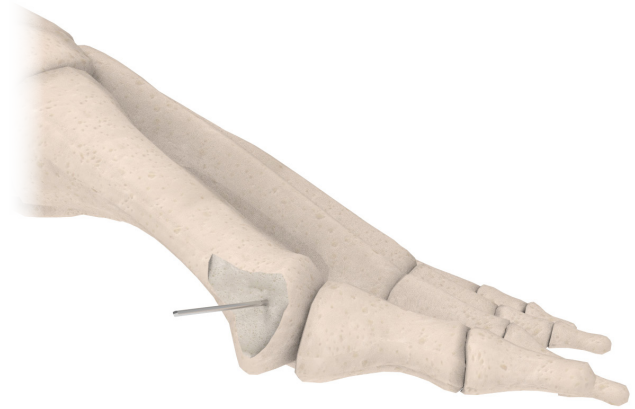
Instructions for Use

Precautions

- a) 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).
- b) 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.



1. Resect a small wafer of medial eminence from the metatarsal head creating a flat medial surface.



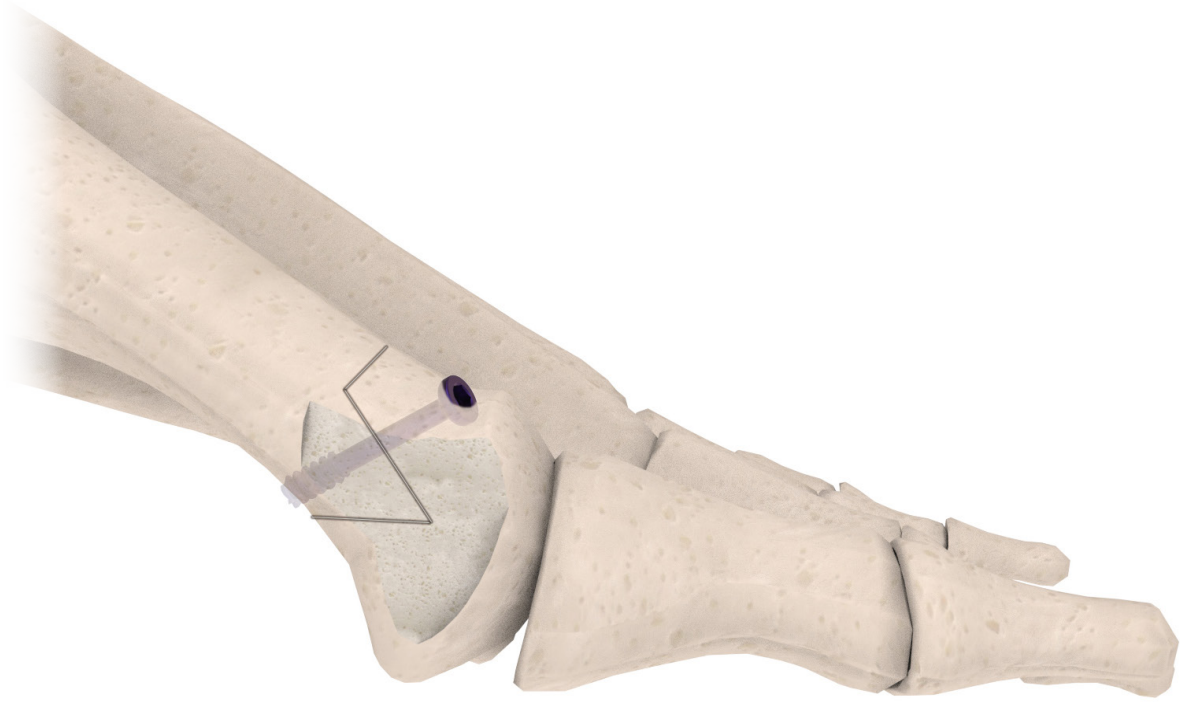
2. Affix the device on the metatarsal head at the desired location using the provided 0.045" k-wires.



3. Place a small hemostat over the posterior k-wire to stabilize the guide against the bone surface.



4. Use one of the provided saw blades in a sagittal saw to make through cuts until the capital fragment is free.



5. Remove the hemostat and k-wires. Fixate the osteotomy with the surgeon's desired technique and remove medial eminence created by lateral transportation with sagittal saw.

Ordering

ITEM #	DESCRIPTION
19505	AUSTIN/CHEVRON GUIDE
19506	YOUNGSWICK 1MM GUIDE
19507	YOUNGSWICK 2MM GUIDE
19508	YOUNGSWICK 3MM GUIDE
19509	2-STAGE PASA/DMAA GUIDE
19510	LONG ARM CHEVRON GUIDE
19511	Z (SCARF) GUIDE
19720	DMAA GUIDE

Reimbursement

Outpatient Reimbursement

CPT Code	Description	National Medicare Average [†]	
		Hospital Outpatient	Ambulatory Surgical Center
28296	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method	\$3,084	\$1,518
28306*	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal	\$6,816	\$3,392

Physician Reimbursement

CPT Code	Description	National Medicare Average [†]
		Facility
28296	Correction, hallux valgus (bunionectomy), with sesamoidectomy, when performed; with distal metatarsal osteotomy, any method	\$508
28306*	Osteotomy, with or without lengthening, shortening or angular correction, metatarsal; first metatarsal	\$404

* Only applies to Z (Scarf) Guide system

[†]Payment may vary by location. Prices shown are national averages, based on Medicare's 2024 payments and copayments. Treatments may include one or more procedures.

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FDA Information

Propriety Name: ACCU-CUT

Classification Name: GUIDE, SURGICAL, INSTRUMENT

Product Code: FZX

Device Class: 1

Registration Number: 878.4800

Registered Establishment Name: BIOPRO, INC.

Registered Establishment Number: 1833506

Owner/Operator Number: 9001497

Establishment Operations: Manufacturer

*Note the Accu-Cut Osteotomy Guide System is

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References

1. Evaluation of surgical experience and the use of an osteotomy guide on the apical angle of an Austin osteotomy The Foot, Volume 18, Issue 3, Pages 159-164 V.J. Hetherington, J.S. Kawalec-Carroll, J. Melillo-Kroleski, T. Jones, M. Melillo, N. McFarland, M. Blazer, J.A. Favazzo
2. Siegel, Geoffrey, MD, et. al. Cost analysis and surgical site infection rates in total knee arthroplasty comparing traditional vs. single-use instrumentation. The Journal of Arthroplasty 30 (2015) 2271-2274

This content is provided as an educational tool only and is not meant as medical advice in the usage of specific BioPro products. A healthcare professional must use their professional judgment in making any final determinations in product usage and technique. The product's Instructions for Use, should always be reviewed prior to surgery. Postoperative management is patient-specific and dependent on the treating professional's assessment. Individual results will vary and not all patients will experience the same postoperative activity level or outcomes. This information does not constitute medical, legal, or any other type of professional advice and should not be relied upon as such. It is not to be redistributed, duplicated, or disclosed without the express written consent of BioPro, Inc.



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