BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

Effi+Pro®

Effi+Pro® Single-Use Compression/Distraction Kit

Description: The Effi+Pro® Single-Use Compression/Distraction kit is used for orthopedic compression and distraction. The Effi+Pro® is a manually powered single use device. The Effi+Pro® positioning pins are single use. Prior to use, every surgeon should review the instructions. The kit is sold sterile. The Effi+Pro® is a Single-Use device used to perform distraction and compression with incremental turns to ensure proper position. The Effi+Pro® Single-Use Compression/Distraction kit components must NOT be implanted, and are, thus, contraindicated for implantation.

Regulatory Classification: Part 888- Orthopedic Devices Subpart E- Surgical Devices Sec. 888.4540 Orthopedic manual surgical instrument. (a) Identification. An orthopedic manual surgical instrument is a non powered hand-held device intended for medical purposes to manipulate tissue,, or for use with other devices in orthopedic surgery. This generic type of device includes the cerclage applier, awl, bender, drill brace, broach, burr, corkscrew, countersink, pin crimper, wire cutter, prosthesis driver, extractor, file, fork, needle holder, impactor, bending or contouring instrument, compression instrument, passer, socket positioner, probe, femoral neck punch, socket pusher, reamer, rongeur, scissors, screwdriver, bone skids staple driver, bone screw starter, surgical stripper, tamp, bone tap, trephine, wire twister, and wrench. (b) Classification. Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in 888.9 [52 FR 33702, Sept. 4, 1987, as amended at 59 FR 63014, Dec. 7, 1994; 66FR 38815, July 25, 2001].

Instructions for Use

Surgical procedures and techniques are the responsibility of the medical professional. The guidelines are for information purposes only. Every surgeon must determine proper technique according to his or her medical training and experience. Prior to use, every surgeon should consider warnings, precautions, indications, contraindications, and adverse effects.

Webiste: www.bioproimplants.com

Rx ONLY

Manufactured by:
BioPro, Inc.
2929 Lapeer Road
Port Huron, MI 48060
P 810.982.7777
F 810.982.7794

Indications for Use

The device is intended for bone distraction and compression during orthopedic procedures.

Contraindications

The kit and its components are not for use outside of surgery. The Effi+Pro® components must NOT be implanted. Positioning pins may NOT be implanted.

Warnings/Precautions

Every surgeon should take precautions during distraction and compression. Incremental adjustments are highly recommended. Care should be taken to verify acceptable distraction distance as well as compressive force prior to advancing the instruments.

Adverse Effects

Excessive compression and distraction can be harmful and should be avoided.

How Supplied

The Effi+Pro® Single-Use Compression/ Distraction Kit is sold sterile. (via ETO)

*Do not use open or damaged packages

Disposal

The device should be disposed of by user according to normal biohazard material disposal procedures

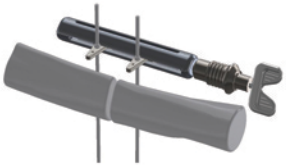
STERILE EO

1. Placement of the Effi+Pro®

Verify placement.

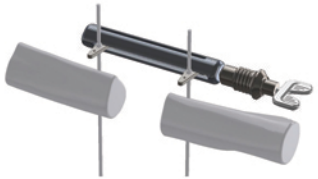
2. Setting the Effi+Pro®

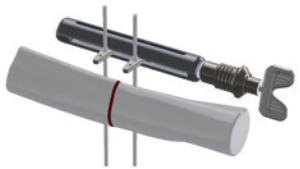
Select the positioning pins that will be appropriate for use in the procedure. Using a pin driver, drive the selected pin into the bone near the procedure site. Drive a second pin, parallel to the first pin, on the opposite side of the procedure site. Consider whether a bi-cortical placement is appropriate. Advance the positioning pins with micro-adjustments. With both pins in place, adjust the Effi+Pro® so that the ends of the pins will pass through the holes of the tip attachments. Slide the Effi+Pro® unit over the pins. Position the device as close as possible to the surgical site to avoid bending the positioning pins.



3. Distract (Open the Device); Compress (Close the Device)

Turn the tab handle to compress and distract.
Avoid excessive distraction; use incremental turns.



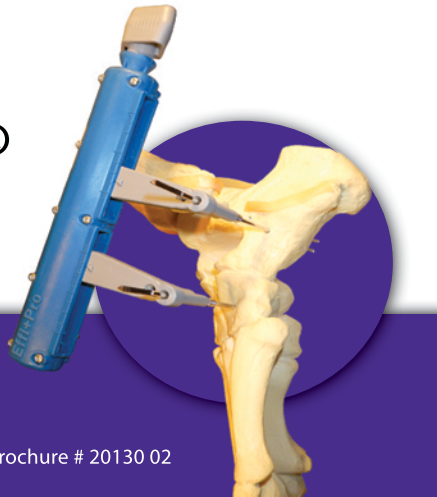


4. Removing the Effi+Pro®

Using a pin driver, remove the Effi+Pro® positioning pins and the Effi+Pro® Compression/Distraction unit and dispose of all kit components.

Effi+Pro®

Patent # 8,491,582



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800.252.7707 www.bioproimplants.com
2929 Lapeer Road, Port Huron, MI 48060

Brochure # 20130 02