

BioPro Effi+Pro® 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 Effi+Pro Single-Use Compression/Distractor kit is used for orthopedic compression and distraction. The Effi+Pro is a manually powered single use device used to perform distraction and compression with incremental turns to ensure proper position.

Materials

Stainless Steel and GV-5H

Indications for use:

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

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 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

- Inspect the sterile pouches prior to use. Sterilization cannot be assured, and devices should not be used if the pouch or seal is damaged.
- Device is single use only
- Do not autoclave device
- Every surgeon should verify the acceptable distraction distance
- Every surgeon should consider the acceptable compressive force prior to advancing the instruments
- The kit and its components are not for use outside of surgery
- Effi+Pro components must NOT be implanted
- Positioning pins may NOT be implanted

Potential Complications and Adverse Effects

- Excessive compression and distraction can be harmful and should be avoided
- Damage to soft tissue or bone caused by improper surgical technique
- Delayed healing
- Device 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:

1. Verify placement
2. 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 bicortical 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. Turn the tab handle to compress and distract. Avoid excessive distraction; use incremental turns.
4. Using a pin driver, remove the Effi+Pro® positioning pins and the Effi+Pro Compression/Distractor unit and dispose of all kit components.