

## BioPro Break-Out™ Instructions for Use

For the most current instructions for use and symbol glossary visit [www.bioproimplants.com/ifu](http://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](mailto:orders@bioproimplants.com)

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

### Description

The BioPro Break-Out screw remover is a small stainless steel instrument with reverse operating edges. When inserted into a broken cannulated screw and rotated counterclockwise, the device will engage the walls of the interior portion of the broken screw. The interference allows for the screw to spin and be removed.

### Materials

Stainless Steel

### Indications for use:

1. For the removal of broken cannulated bone screws.

### 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

### Potential Complications and Adverse Effects

- 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. Expose the site of the hardware to be removed via preferred surgical method.
2. Using the appropriate driver, remove the proximal fragment, if able. If proximal screw head is stripped, insert Break-Out extractor into cannula until firmly seated against screw walls and remove in a counterclockwise fashion.
3. Once the proximal segment is removed, insert a fresh Break-Out extractor into the bony canal until firmly seated in the cannula of the distal fragment. C-arm fluoroscopy may facilitate this process. Using manual extraction, remove the distal fragment by rotating the AO quick connect driver counterclockwise. The bony canal is the same size as the screw that was removed. A new, same size screw may be utilized or a slightly larger screw, based on the surgeon's preference and the findings at the time of the procedure.