BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Go-EZ® Screw 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 BioPro Go-EZ Screw System is a headed cannulated bone screw manufactured from titanium available in multiple diameters and lengths.

Material
6-4 Eli Titanium (ASTM F136)

Indications for use:
Bone fractures, Osteotomies, Arthrodesis, Osteochondritis, and tendon re-attachment. It is intended for but not limited to hand surgery, plastic surgery, and podiatric surgery, but is not intended for use in the spine.

Contra-indications:
1. A debilitating general health problem that might pose a significant threat to the life of the patient if subjected to a major surgical procedure.
2. Comminuted bone surface that would mitigate against screw placement.
3. Pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the screw.
4. Foreign body sensitivity to metals specifically titanium. Where material sensitivity is suspected, appropriate tests should be made prior to implantation.

Precautions and Handling:
- Inspect the sterile blisters used for the implants prior to use. Sterilization cannot be assured, and screws should not be used if blister or seal is damaged.
- The screws are a single use device
- Do not autoclave screws

Potential Complications and Adverse Effects:
- Allergic reactions to metal
- Delayed or Non-union of bone
- Delayed Healing
- Screws may bend or break
- Screws may extrude or back out of the surgical site

Contact surgeon if a change in performance or pain level is noticed.

MR Safety Information
The Go-EZ Screw has been evaluated for safety and compatibility in the MR environment and is MR conditional. Contact BioPro for MR parameters.

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:
Please note that the screw packaging features a color-coding system that coordinates screw diameter with drill diameter. Always ensure the drill diameter chosen matches the color code on the screws packaging.

1. Tightly oppose bone segments and drive the appropriately sized guide wire to the far cortex.
2. Countersink and measure in one step with the included appropriately sized depth gauge.
3. If necessary, over drill the proximal aspect of the surgical site with included, appropriately sized, drill bit.
4. Assemble the appropriate hex driver into the ratchet handle. Slide the screw over the wire and drive to depth. Ensure that the screw head seats flush into the countersunk hole created in step two, using care to not overtighten and strip the screw.

Sterilization Guidelines for Instrument Trays

These guidelines are intended to provide a better understanding of the care and handling of BioPro surgical instruments. These guidelines are not intended for use with electrical, pneumatic, or other powered surgical instruments. All instruments are shipped in a NON-STERILE condition and must be cleaned and sterilized prior to use.

General Care and Handling
Use instruments only for their intended purpose, such as cutting, holding, retracting, torquing, etc. Avoid undue stress or strain when handling or cleaning. Always transport contaminated or soiled items in or on a cart. Tap water can contain many minerals that may discolor and stain surgical instruments; therefore, it is recommended that deionized water be used for the final rinsing to prevent spotting. For instruments contaminated with protein material, prevention of drying prior to cleaning will facilitate cleaning. Placing instruments in water until cleaning can prevent drying.

NOTE: Ensure that any instrument inserted into the handle is disassembled prior to cleaning.

Cleaning: Follow these steps to thoroughly clean all instruments

1. Submerge instruments in an enzymatic detergent. Prepare detergent according to the manufacturer's recommendations. Soak the instruments for ten (10) minutes in the protein solubilizing detergent.
2. Scrub the submerged instruments with a soft sponge and agitate.
3. Use a pipe cleaner or brush in any lumens and crevices.
4. Rinse in warm (38-49 degree C) tap water for one (1) minute.
5. Thoroughly flush all lumens and other difficult to reach areas.
6. Ultrasonically clean the instruments for ten (10) minutes in a neutral pH detergent (Neutrad or acceptable alternative). Prepare the detergent according to the manufacturer's recommendations.
7. Rinse the instruments with clean tap water for at least one (1) minute, repeat twice.
8. Dry the instruments thoroughly with a clean, lint free cloth.
9. Visually Inspect instruments for any damage or remaining contaminates instruments should be visually clean.
10. Repeat cleaning procedure if necessary if contamination remains. The instrument must be thoroughly clean.
11. Contact BioPro if any instruments are damaged.

Sterilization
Following the cleaning process, place a sterilization indicator in each instrument tray along with the instruments. Instrument tray is to be wrapped in a double layer of CSR wrap. Steam sterilization is required with the following parameters:

For pre-vacuum cycle:
Wrapped items: 4 minutes exposure at a minimum temperature of 132° C (270° F), maximum temperature of 143° C (290°F), 4 pulses, 30 minutes dry time

Examination Prior to Use
All instruments should be carefully examined for wear or damage by surgeons and staff in operating centers prior to surgery. The examination shall include a visual and functional inspection. It should also include verifying the cleanliness of the device, as well as the absence of any cracks, distortion, wear, corrosion, or other change.
Like any precision surgical device, all instruments should undergo regular checks by knowledgeable personnel to ensure that they remain in good condition and continue to act as intended. Do not use any instrument or device that is damaged, incomplete, showing signs of excessive wear and tear, or that has been repaired outside the control of the manufacturer.

Warnings and Precautions

- Devices must only be used by surgeons who have been trained in the surgical technique and are familiar with the instruments provided.
- Use care in handling and storage. Some instruments are sharp and incorrect use or handling may result in puncture wounds.
- Improper use may result in breakage of the instrumentation during operation.
- Remove all broken instrument fragments. As a result of mechanical features required, the device is made of medical grade but not implant grade materials. Failure to remove broken instruments from the patient could result in patient complications and further intervention.
- Incorrect maintenance, cleaning or handling may render the instrument unsuitable for its intended use, cause corrosion, dismantling, distortion and/or instrument breakage or injury to the patient or operating staff. Potential complications include device breakage, leaching of debris, lack of component engagement, infection, and damage to tissue.

Unique Device Identification (UDI)
All BioPro components can be identified by M209XXXXX, where "XXXXX= Item #". For a complete listing of BioPro item numbers visit www.bioproimplants.com/udi

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