BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Non-Sterile HBS® 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 HBS Screw System is a headless cannulated bone screw manufactured from titanium available in multiple diameters and lengths.

Material
6-4 Eli Titanium (ASTM F136)

Indications for Use:

HBS-Mini (2.5mm)
- Scaphoid fractures
- Lunate fractures
- Capitate fractures
- Trapezial fractures
- Metacarpal and metatarsal fractures
- Phalangeal fractures
- Radial head fractures
- Ulnar styloid fractures
- Osteochondral fractures
- Small joint fusions

HBS Standard (3.0mm)
- Scaphoid fractures
- Carpal fractures and non-unions
- Capitellum fractures
- Metacarpal fractures
- Phalangeal fractures
- Distal radial fractures
- Radial head fractures
- Ulnar styloid fractures
- Small joint fusions
- Humeral head fractures
- Glenoid fractures
- Intercarpal fusions
- Interphalangeal fractures
- Metatarsal osteotomies
- Tarsal fusions
- Malleolar fractures
- Patellar fractures
- Osteochondral fractures

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:
- The screws are a single use device
- Ensure tray is cleaned and sterilized prior to use

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 HBS Screw has been evaluated for safety and compatibility in the MR environment and is MR conditional. Contact BioPro for MR parameters.

℞ Only

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 non-sterile and sterilization of the device is required prior to use.

Instructions for Use:
Please note that the screw packaging features a color-coding system that coordinates screw diameter.

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 star 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 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 de-ionized 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.

Cleaning: Follow these steps to thoroughly clean all instrument's

1. Use a neutral pH enzyme soaking solution that has been prepared per the manufacturers recommendations
2. Completely submerge the instrument in enzyme solution and allow it to soak for 20 minutes. (Use a soft-bristled brush to gently clean the device paying particular attention to crevices, lumens, mated surfaces and other hard-to-clean areas until all visible soil has been removed. Lumens should be cleaned with a long, narrow, soft bristled brush (i.e. pipe cleaner brush).
   Note: The enzyme solution should be changed when it becomes grossly contaminated (bloody and/or turbid).
3. Remove the device from the enzyme solution and rinse in purified water (from one or any combination of the following process: ultra-filter, RO, DI and/or distilled) for a minimum of 3 minutes. Thoroughly flush lumens, holes and other difficult to reach areas.
4. Prepare the pH cleaning (detergent) solution and place in a sonication unit.
5. Completely submerge device in cleaning solution and sonicate for 10 minutes, preferably at 45-50 kHz
6. Rinse instrument in purified water (from on or any combination of the following processes: ultra-filter, RO, DI and/or distilled) thoroughly for at least 3 minutes or until there is no sign of blood or soil in the rinse stream
7. Visually inspect instruments for any damage or remaining contaminants. Instruments should be visibly clean.
8. Repeat step 5 with freshly prepared cleaning solution as needed.
9. Repeat step 6 for thorough rinsing to remove any cleaning solution residues.
10. Dry the instrument with a clean, disposable, absorbent, non-shedding wipe.
11. Contact BioPro if 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:

Either validated method

Gravity cycle for 30 minutes at a minimum temperature of 132° C (270° F), maximum temperature of 143° C (290° F)

Pre-vacuum cycle for 10 minutes exposure at minimum 132° C (270° F), maximum 143° C (290° F)
Dry times will vary according to load size and should be increased for larger loads.

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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