BIOLOGICALLY ORIENTED PROSTHESES
BIOPRO

BioPro Horizon® Subtalar 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 Horizon Subtalar is threaded conical implant with a smooth lateral surface that is implanted within the sinus tarsi.

Material
Standard: 6-4 Eli Titanium (ASTM F136)
Hybrid: 6-4 Eli Titanium (ASTM F136) and UHMW Polyethylene (ASTM 648)

Indications for use:
The BioPro Horizon Subtalar Implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block forward, downward, and medial displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and the resulting sequela.

Conditions include:

- Flat foot treatment in children and adolescents
- Congenital flat foot
- Unsuccessful long term orthopedic treatment (orthotics)
- Tarsal coalitions
- Painfully flat foot
- Supple deformity in posterior tibial tendon dysfunction
- Paralytic flat foot
- Subtalar instability

Contra-indications:
The age of the patient must be balanced against the severity of the disability and the need for surgery.

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. A previously infected joint that has not been quiescent for at least six months
3. A local or systemic infection (i.e., osteomyelitis)
4. Insufficient bone stock to support the prosthesis
5. Foreign body sensitivity to metals including titanium or polyethylene. 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 devices should not be used if blister or seal is damaged.
- Implants are single use devices
- Do not autoclave devices

Potential Complications and Adverse Effects

- Allergic reactions to metal
- Delayed Healing
- Loosening or migration of the implant
- Subluxation or dislocation of implant resulting in return of pronation
- Bone fracture by trauma or improper surgical technique
- Pain due to bone remodeling or reaction to implant components

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

MR Safety Information
The Standard Horizon Subtalar has been evaluated for safety and compatibility in the MR environment and are MR conditional. Contact BioPro for MR parameters. Contact surgeon if a change in performance or pain level is noticed. **Warning**: The Hybrid Subtalar has not been evaluated for safety and compatibility in the MR environment. The Hybrid Subtalar has not been tested for heating or migration in the MR environment. The safety of the device in the MR environment is unknown. Scanning patients who have these devices may result in patient injury.

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 implant packaging features a color-coding system that coordinates implant diameter.

1. Attention is directed to the sinus tarsi. A linear incision centering over the sinus tarsi is made into Relaxed Skin Tension Line (RSTL), approximately 2cm in length. The intermediate dorsal cutaneous nerve is identified, carefully retracted, and preserved. Next, a linear incision is made into the retinaculum to expose the sinus tarsi.
2. A probe is used to slightly enlarge the sinus as well as the canalis tarsi and also to establish subtalar joint axis. The leading edge of the probe should be palpated at the medial aspect of the subtalar joint with slight tenting of the skin. This should be appreciated just inferior to the posterior tibial tendon and slightly inferior and anterior to the medial malleolus. Care is taken to preserve the interosseous talocalcaneal ligament.
3. Pass one of the provided guide wires through the cannulation on the Starter Probe until palpable under the skin on the medial aspect of the foot. Create a small incision over the point of the guide wire and pass through approximately 5mm of guide wire. Clamp a hemostat over the exposed guide wire to stabilize the wire. The Starter Probe can now be removed laterally.
4. Place the Sizer probes over the guide wire and insert into the Subtalar joint until the end of the probe is just past the longitudinal bisection of the talus, continue inserting the sequentially sized Sizer Probes until the desired restricted Subtalar joint motion and clinical correction is achieved. This can be assessed intraoperatively by everting and inverting the calcaneus and at the same time loading the lateral column. Approximately 4° to 6° of eversion of the

calcaneus should be noted. Note the position of the skin line along the graduated markings on the sizing probe. Now, the Sizer Probe is removed, and the guide wire is maintained. Note: color-coded trial implants are available in the instrument kit, but it is recommended to progress direction into the final implant once proper correction is achieved with the Sizer Probes.

5. The appropriately sized final implant is chosen, inserted over the guide wire, and then threaded into place with the cannulated screwdriver. At this time the graduated markings of the screwdriver should match and correlate to the Sizer Probe placement markings. Important: the sizer markings should not supersede the interoperative Subtalar joint motion evaluation of the surgeon.
6. Subtalar joint motion is evaluated, and clinical correction is appreciated. At this time the placement of the implant can be appreciated (surgeon's discretion) with the C-arm on anterior to posterior ankle review. Important: the positioning should be noted where the medial or leading edge of the implant should be slightly past the longitudinal bisection of the talus (1-2mm).

Postoperative management
When only an isolated arthroereisis procedure or combination arthroeresis and gastrocnemius recession has been performed, the postoperative care consists of a mildly compressive dressing with a removable AFO for three to four weeks. Gradually the patient is placed into a good walking or athletic type of shoe. Physical therapy may be necessary. Contact surgeon if a change in performance or pain level is noticed.

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.

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