BIOLOGICALLY ORIENTED PROSTHESES

BIOPRO

BioPro Hybrid Subtalar Implant

Indications for use:
The BioPro Hybrid 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:
1. Flat foot treatment in children and adolescents
2. Congenital flat foot
3. Unsuccessful long term orthopedic treatment (orthotics)
4. Tarsal coalitions
5. Painfully flat foot
6. Supple deformity in posterior tibial tendon dysfunction
7. Paralytic flat foot
8. Subtalar instability

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. A previously infected joint that has not been quiescent for at least six months
3. A local or systemic infection (i.e. osteomylitis)
4. Insufficient bone stock to support the prosthesis

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

Sterile: STERILE EO

℞ Only

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. Do not use in patients who exhibit a sensitivity to titanium. 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. Contact surgeon if a change in performance or pain level is noticed.

Instructions for use:
Step One:
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. A linear incision is made into the retinaculum to expose the sinus tarsi.

Step Two:
A probe is used to slightly enlarge the sinus as well as the canalis tarsi and to establish the 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. The probe is removed.

Step Three:
Utilizing the K-wire holder, a guide wire is placed into the sinus and canalis tarsi repeating the same direction and technique as mentioned above. Appropriately and sequentially sized dilators are placed over the guide wire until 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. The dilator is removed and the guide wire is maintained. At this time the graduated markings on the sizer should be noted.

Step Four:
The appropriate implant is chosen according to the sized dilators and is placed over the guide wire and screwed into position. Again, 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 view. The graduated markings on the driver can be used to approximate the position of the implant. Important: the sizer markings should not supersede the interoperative subtalar joint motion evaluation of the surgeon. The area should be irrigated copiously with normal sterile saline. Assess range of motion. Closure is then achieved using the surgeon's preference.

Optional Step Between Three and Four
The appropriately sized trial implant can be used according to the sized dilator. The graduated markings on the driver can be used to approximate the position of the trial implant. At this time the placement of the trial implant can be appreciated (surgeon's discretion) with the C-arm on anterior to posterior ankle view. Once the appropriate sized trial has been identified it is removed and replaced with the appropriate sized implant as noted in step four.
Important: The medial or leading edge of the implant should be 1-2mm past the longitudinal bisection of the talus.

For a complete glossary of symbols, please visit www.bioproimplants.com/IFU. To receive a printed version within 5 business days, please contact orders@bioproimplants.com

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Optional Step Between Three and Four
The appropriately sized trial implant can be used according to the sized dilator. The graduated markings on the driver can be used to approximate the position of the trial implant. At this time the placement of the trial implant can be appreciated (surgeon's discretion) with the C-arm on anterior to posterior ankle view. Once the appropriate sized trial has been identified it is removed and replaced with the appropriate sized implant as noted in step four.
Important: The medial or leading edge of the implant should be 1-2mm past the longitudinal bisection of the talus.

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