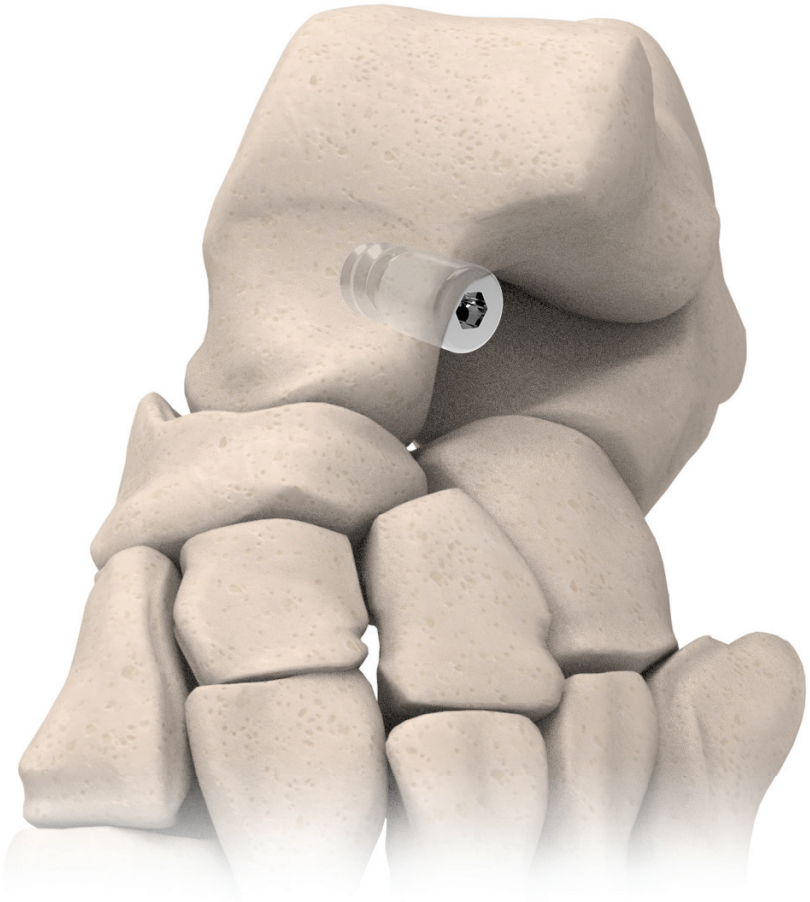
Biologically Oriented Prostheses

BIOPRO

Horizon® Subtalar

Surgical Technique



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Indications & Contraindications

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.

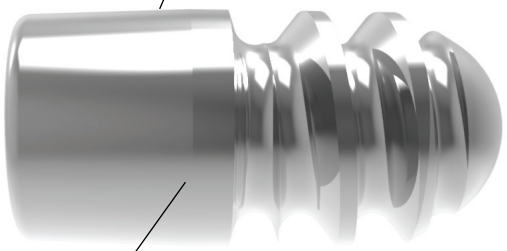
MR Safety Information
The Standard Horizon Subtalar has been evaluated for safety and compatibility in the MR environment and are MR conditional. Contact BioPro for MR parameters. Contact surgeon if a change in performance or pain level is noticed. Warning: The Hybrid Subtalar has not been evaluated 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.

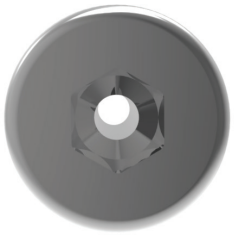
Implant Specifications

The BioPro Horizon Subtalar Implant is used for the treatment of flatfoot and posterior tibial tendon dysfunction.

The implant incorporates several key features that reduce postoperative sinus tarsitis and allow normal subtalar joint motion.

A smooth lateral surface ensures the talus and calcaneus interface with a smooth, broad surface during the dynamic phase of gait, opposed to sharp threads.





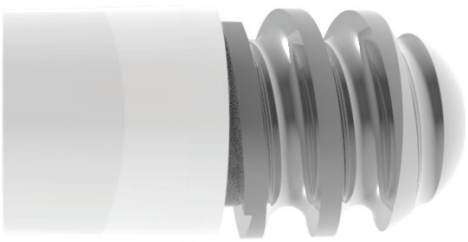
Cannulation allows the implant to be inserted over a guide wire.

The slight taper on the smooth lateral surface ensures the implant cannot migrate laterally during the dynamic phase of gait.

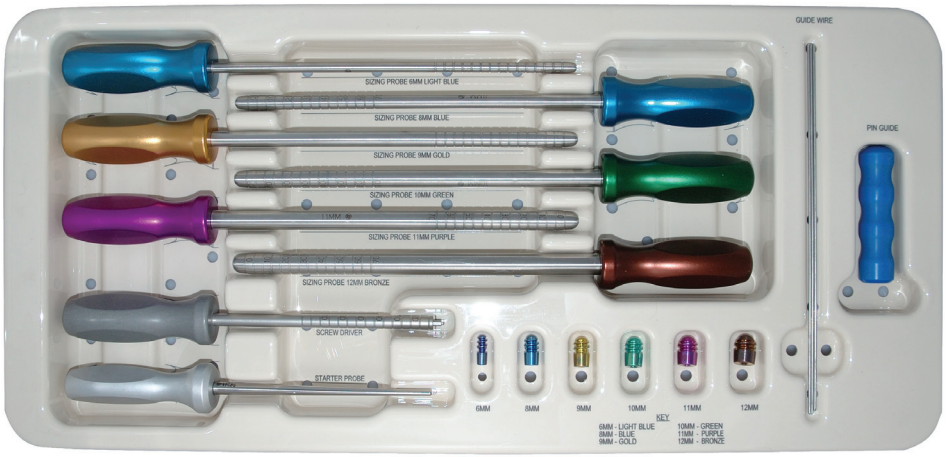
	Specifications
Material	Titanium
Length (mm)	16.4
Outer Diameter (mm)	6, 8, 9, 10, 11, 12

A hybrid design incorporates a polyethylene sleeve over the lateral portion of the implant, offering a softer, more forgiving surface to interface the talus and calcaneus with.

Important Note
The hybrid design is not available in 6mm diameter.



Instrument Specifications



Instrument kit

The instrument kit (ref 17307) provides the surgeon with all the instrumentation for a simple surgical procedure.

Sizing probes

Six color coded cannulated sizing probes with depth markers (ref 17481/ 17185/ 17186/ 17187/ 17188/ 17189) allow for correct implant sizing.

Hex drivers

A cannulated hex screw driver with depth markers (ref 17228) allows for insertion of the final implant.

Starter probe

A cannulated starter probe (ref 17455) is provided to enlarge the sinus and establish the subtalar joint axis.

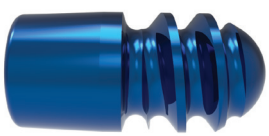
Guide wires

Guide wires are provided with the instrument kit.

Optional instruments

Six color coded trial implants are included for optional implant sizing.

A pin guide for guide wire placement.



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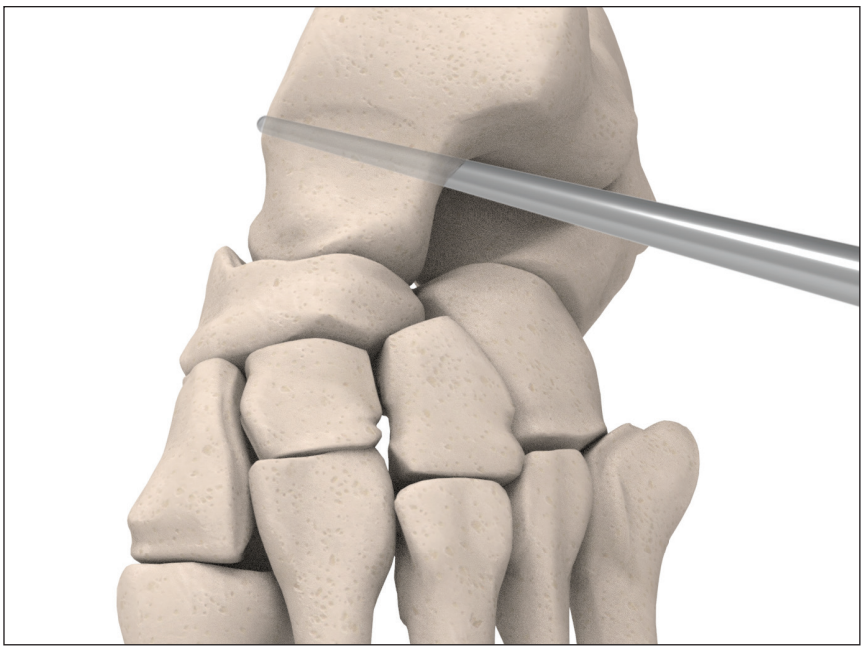

Fig 1

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. Next, a linear incision is made into the retinaculum to expose the sinus tarsi.

Step Two:
The starter probe (ref 17455) is used to slightly enlarge the sinus as well as the canalis tarsi and also to establish the subtalar joint axis. (Fig 1) 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.

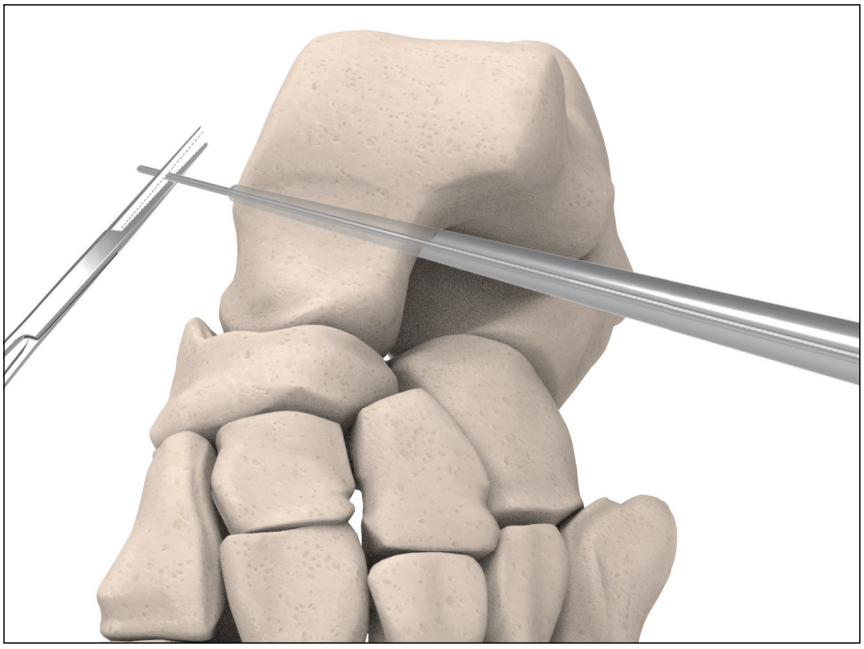

Fig 2

Step Three:
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. (Fig 2) The starter probe can now be removed laterally.

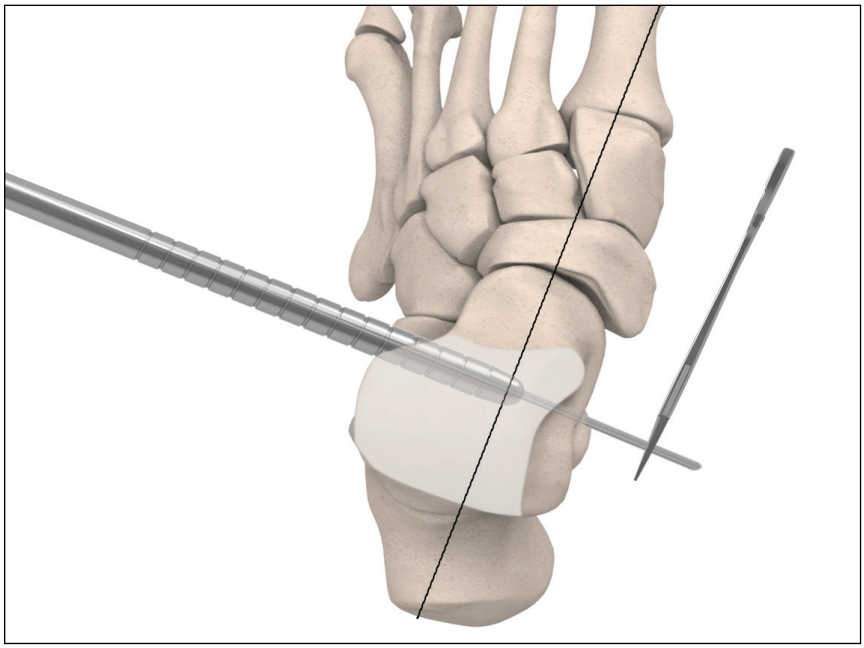

Fig 3

Step Four:
Place the sizer probes (ref 17481/ 17185/ 17186/ 17187/ 17188/ 17189) 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. (Fig 3) Continue inserting the sequentially sized 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.

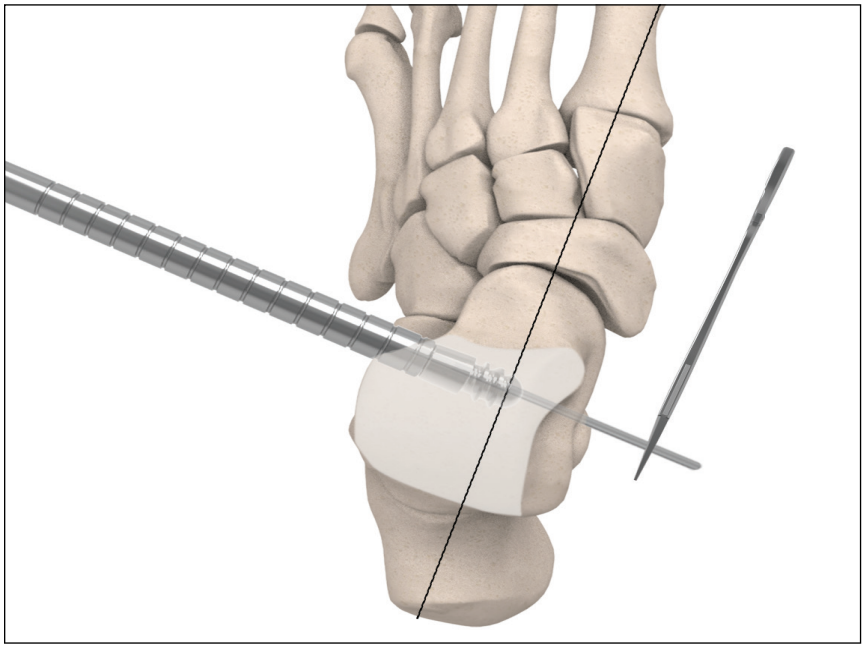

Fig 4

Step Five:
The appropriately sized final implant is chosen, inserted over the guide wire, and threaded into place with the cannulated screwdriver (ref 17228). (Fig 4) At this time the graduated markings of the screwdriver should match and correlate to the sizer probe placement markings.

Important Note
Color-coded trial implants are available in the instrument kit, but it is recommended to progress directly to the final implant once proper correction is achieved with the sizer probes.

Important Note
The sizer markings should not supersede the interoperative subtalar joint motion evaluation of the surgeon.

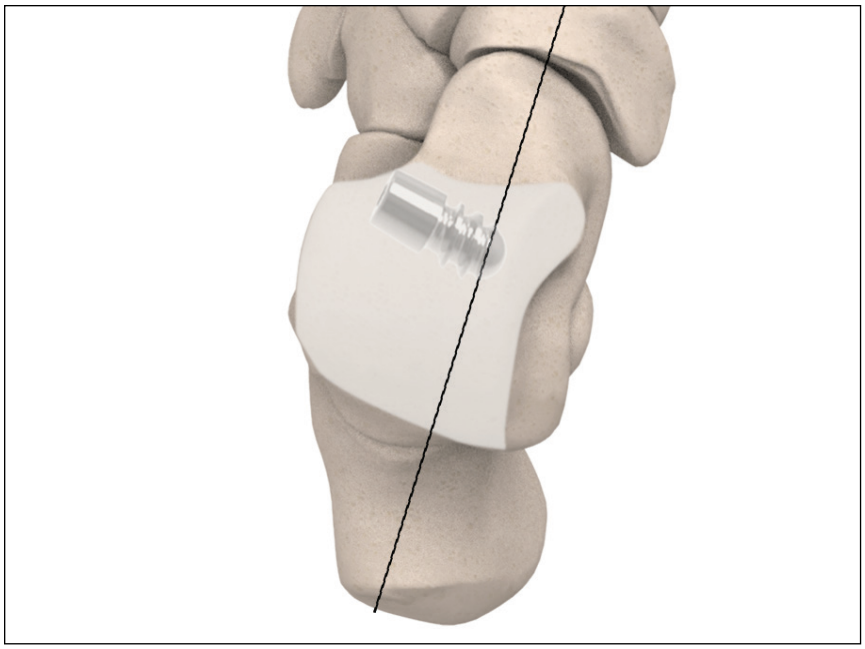

Fig 5

Step Six:

Again, subtalar joint motion is evaluated and clinical correction is appreciated. At this time the placement of the implant can be viewed (surgeon's discretion) with the C-arm on anterior to posterior ankle view.

Important Note
The positioning should be noted where the medial or leading edge of the implant should go slightly past the longitudinal bisection of the talus (1-2mm). (Fig. 5)

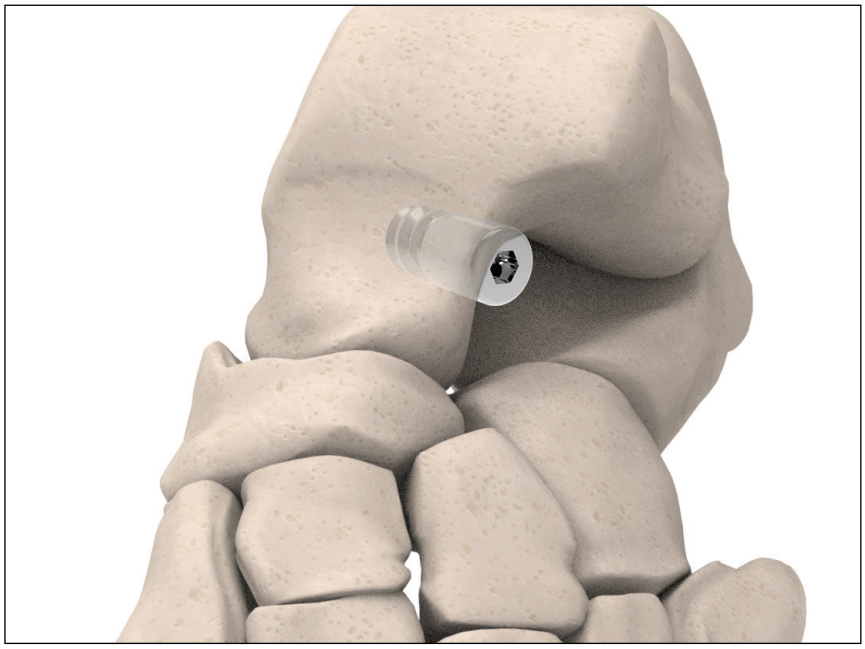

Fig 6

Step Seven:

The guide wire is removed laterally and closure is achieved per surgeon's preference (Fig 6).

Postoperative Suggestions

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.

By design the implant should reduce the incidence of sinus tarsitis, however, all patients should be advised of intermittent sinus tarsitis for approximately two to three months. A short acting corticosteroid injection may be indicated with persistent sinus tarsitis. Also, patients should be educated on custom molded orthotics as an integral postoperative protocol.

If other adjunctive procedures are performed then the postoperative protocol is tailored to those procedures and combined with the above mentioned protocol. If an Achilles Tendon lengthening is performed in conjunction with the subtalar implant, the patient is placed in a below the knee, non-weightbearing fiberglass cast for four weeks. The patient is then gradually advanced into a walking cast or a removable AFO for approximately two weeks. At this time physical therapy is advised consisting of muscle strengthening, stretching, and range of motion exercises. If medial column arthrodesis is performed in conjunction, the usual and customary postoperative period is required for bony consolidation in a non-weightbearing, below the knee cast. Rehabilitation and physical therapy are advised at this time.

Caution should be taken if a calcaneal navicular coalition resection is performed in conjunction with the implant. This can lead to the implant dislodging. It is suggested that these procedures not be performed concurrently.

Implant Ordering

ITEM #	DESCRIPTION	SIZE
17478	HORIZON SUBTALAR	6MM
17221	HORIZON SUBTALAR	8MM
17222	HORIZON SUBTALAR	9MM
17223	HORIZON SUBTALAR	10MM
17224	HORIZON SUBTALAR	11MM
17225	HORIZON SUBTALAR	12MM
17085	HORIZON HYBRID SUBTALAR	8MM
17086	HORIZON HYBRID SUBTALAR	9MM
17087	HORIZON HYBRID SUBTALAR	10MM
17088	HORIZON HYBRID SUBTALAR	11MM
17089	HORIZON HYBRID SUBTALAR	12MM

Replacement Instrument Ordering

ITEM #	DESCRIPTION
17307	HORIZON SUBTALAR COMPLETE KIT
17228	DRIVER
17455	STARTER PROBE
17481	SIZER 6MM
17185	SIZER 8MM
17186	SIZER 9MM
17187	SIZER 10MM
17188	SIZER 11MM
17189	SIZER 12MM
17479	TRIAL 6MM
17190	TRIAL 8MM
17191	TRIAL 9MM
17192	TRIAL 10MM
17193	TRIAL 11MM
17194	TRIAL 12MM
17523	PIN GUIDE
17230	GUIDE WIRE 8MM
17606	GUIDE WIRE 12MM
17280	SUBTALAR INSTRUMENT TRAY

BIOLOGICALLY ORIENTED PROSTHESES

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