

Integra®

Subtalar MBA® and bioBLOCK® Implant

SURGICAL TECHNIQUE



INTEGRA®
LIMIT UNCERTAINTY



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Subtalar MBA® Implant Description

The Subtalar MBA® titanium implant is the original, time-tested metallic arthroereisis implant for the correction of hyperpronated foot.

Indications

The Subtalar MBA® Implant is indicated for use in the treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the anterior and inferior displacement of the talus, thus allowing normal subtalar joint motion but blocking excessive pronation and resulting sequela.

- Severly pronated foot
- Walking intemperance
- Calcaneal stance position greater than 5°
- Manually correctable deformity
- Mid-tarsal breach (arch pain)
- Forefoot varus greater than 10°

Contraindications

- Vertical calcaneus
- Rigid flatfoot (unreducible)
- Rearfoot varus
- Peroneal spasm
- Ankle joint valgus
- Excessive ligament laxity
- Degenerative joint disease of the subtalar joint
- Severe obesity
- Asymptomatic flatfoot condition
- Patients less than 3 years of age

bioBLOCK® Implant Description

The bioBLOCK® Implant is a resorbable arthroereisis device constructed of poly-L-lactic acid (PLLA). It is designed to provide support and hold the foot in alignment while adjunctive procedures heal.

Indications

The bioBLOCK® Implant is indicated for internal support to primary surgical interventions in the treatment of flatfoot.

Contraindications

- Vertical calcaneus
- Rigid flatfoot (unreducible)
- Rearfoot varus
- Peroneal spasm
- Ankle joint valgus
- Excessive ligamentous laxity
- Degenerative joint disease of the subtalar joint
- Severe obesity
- Asymptomatic flatfoot condition
- Patients less than 3 years of age

Pre-Operative Considerations

In order to ensure the bioBLOCK® Implant provides adequate support and correction, Integra LifeSciences Corporation recommends that the bioBLOCK® Implant not be used in patients weighing more than 250 pounds. Exceeding this weight may cause the shape of the implant to change, resulting in deformation of the implant shape. The implant may still provide support and correction in this altered state, however it is not recommended.

Surgical Technique



As the manufacturer of this device, Integra LifeSciences Corporation does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

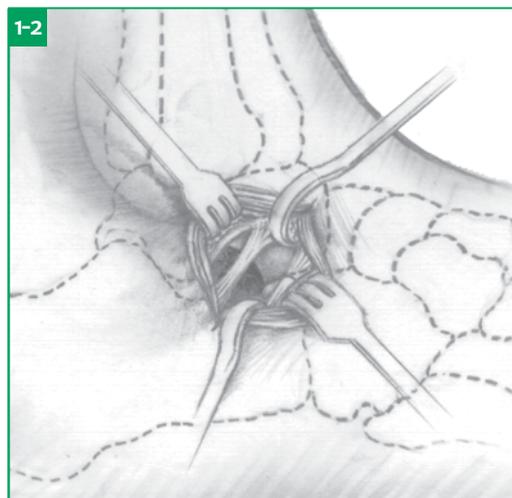
Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner.

Step 1 • Incision and Dissection

1-1 The surgical technique is performed through a 2-4cm skin incision over the sinus tarsi along the relaxed skin tension lines (Figure 1-1).

Care should be taken to avoid the intermediate dorsal cutaneous nerves superior to the incision as well as the sural nerve which should course inferior to the incision.

The deep fascia is identified and bluntly dissected allowing entrance into the sinus tarsi canal. It is important that minimal blunt dissection only be performed in the sinus tarsi. A (sinus tarsi) exposure or sectioning of the talo-calcaneal ligament structures is not performed (Figure 1-2).



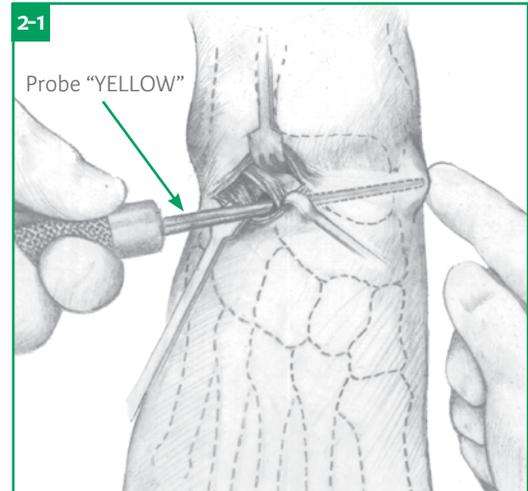
Step 2 • Probe Insertion

- 2-1** Insert the yellow probe instrument through the sinus tarsi into the sinus canalis from lateral to medial until tenting is noted on the medial aspect of the foot (Figure 2-1).

The probe should be positioned perpendicular to the lateral wall of the calcaneus, angled slightly posterior and superior.

Move the probe in a clockwise and counter clockwise direction to slightly dilate the tarsal canal.

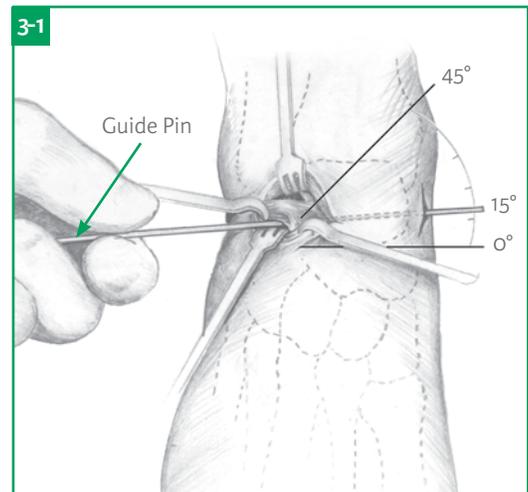
Remove probe.



Step 3 • Guide Pin Insertion

- 3-1** The guide pin is then inserted into the sinus tarsi from lateral to medial until tenting is noted on the medial aspect of the foot (Figure 3-1). The guide pin should be positioned on the floor of the calcaneus and against the lateral process of the talus as the pin is inserted from lateral to medial and slightly posterior. It is suggested that a small incision be made minimally to allow passage of the guide pin through the medial aspect of the foot, just inferior to the tibialis posterior tendon and anterior and slightly inferior to the medial malleolus.

Note: Tenting is optional.



Step 4 • Sizer Insertion

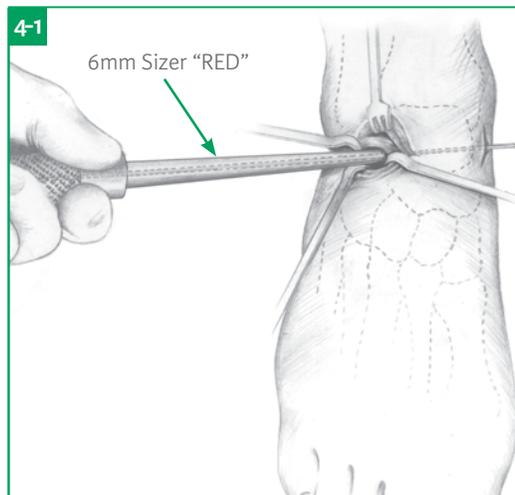
4-1 Subtalar MBA® Implant Sizer Insertion

Place the cannulated 6mm sizer over the guide pin and insert it through the sinus tarsi into the sinus canalis from lateral to medial (Figure 4-1).

Continue to insert the remaining sizers (8, 9, 10, 12mm) through the sinus tarsi lateral to medial until proper correction is achieved.

Assess the range of motion of the subtalar joint.

The appropriate sizer should limit “abnormal” joint eversion. The appropriate size will allow the calcaneal subtalar joint complex to evert to approximately 2–4 degrees. However, a rectus calcaneal position is acceptable, and usually preferred.



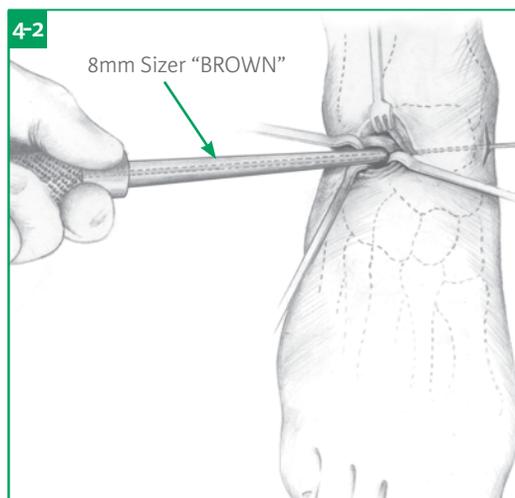
bioBLOCK® Implant Sizer Insertion

Place the cannulated 8mm sizer over the guide pin and insert it through the sinus tarsi into the sinus canalis from lateral to medial (Figure 4-2).

Continue to insert the remaining sizers (9, 10, 11, 12mm) through the sinus tarsi lateral to medial until proper correction is achieved.

Assess the range of motion of the subtalar joint.

The appropriate sizer should limit “abnormal” joint eversion. The appropriate size will allow the calcaneal subtalar joint complex to evert to approximately 2–4 degrees. However, a rectus calcaneal position is acceptable, and usually preferred.



Note: An 11mm bioBLOCK® Implant is available; however, there is not a corresponding 11mm Sizer. If the 12mm over-corrects the deformity, and the 10mm Sizer provides too little correction, the 11mm implant is recommended.

Step 5 • Trial Implant Insertion

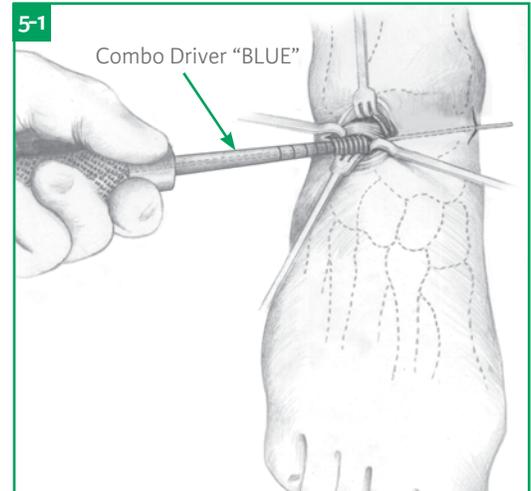
- 5-1** After the appropriate size implant is determined, the sizer is removed and a “sized” trial implant is placed in the sinus tarsi, utilizing the inserting device and guide pin.

Insert the corresponding trial implant using the cannulated 3.5mm Hex combo driver (Figure 5-1).

bioBLOCK® Implant Combo Driver

- The insertion tool used to place the implant is double-sided, with a 3.5mm hex on one end of the driver and a torx on the opposite end of the driver.
- The metal portion of the driver may be removed from the blue handle to switch between the two different interfaces.
- To switch from the hex to the torx interface, pull the metal portion away from the blue handle. To expose the torx interface, flip the metal portion over, and insert the 3.5mm hex interface into the blue handle. Range of motion of the subtalar joint and clinical correction is assessed and determined.

Use Intra-operative imaging to evaluate the degree of correction and placement of the Trial implant.

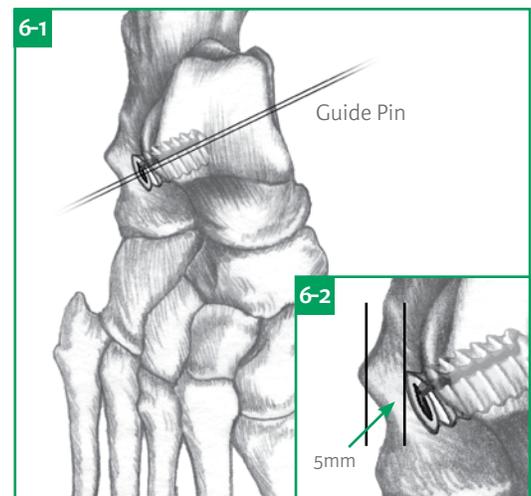


Step 6 • Intra-Operative Radiographs

- 6-1** To determine the correct position on the AP view, the leading edge of the trial implant should approach, but not cross the longitudinal dissection of the talus (Figure 6-1).

The trailing edge of the implant should be at least 5mm medial to the lateral wall of the calcaneus (Figure 6-2).

Examining the lateral view, the trial implant should be angled posterior and the implant should not be sitting on the floor of the calcaneus.



Step 7 • Implantation

7-1 Once the appropriate sized trial implant is determined, remove the trial implant.

The equivalent size sterile implant is placed onto the insertion tool (bioBLOCK® Implant is placed into the torx side of the combo driver) over the guide pin and threaded in a clockwise direction until clinical correction is noted.

Intra-operative imaging is essential to verify proper positioning of the implant.

Subtalar MBA® Implant refer to Step 6.

bioBLOCK® Implant refer to Step 8.

Once the implant has been properly positioned, assess the range of motion of the subtalar joint.

The appropriate size will allow 2-4 degrees of subtalar joint eversion.

Step 8 • bioBLOCK® Implant Intra-Operative Imaging

8-1 The bioBLOCK® Implant is not visible under fluoroscopy, but the leading and trailing edges of the implant may be viewed using the combo driver (Figure 8-1).

The combo driver is left in place during imaging. The leading edge of the tool indicates the leading edge of the Implant.

It is recommended that the guide wire be retracted laterally into the placement driver, so that only the tip of the driver is visible under the fluoroscopy.

The trailing edge of the driver's torx feature indicates the trailing edge of the implant.



Step 9 • Guide Pin Removal and Closure

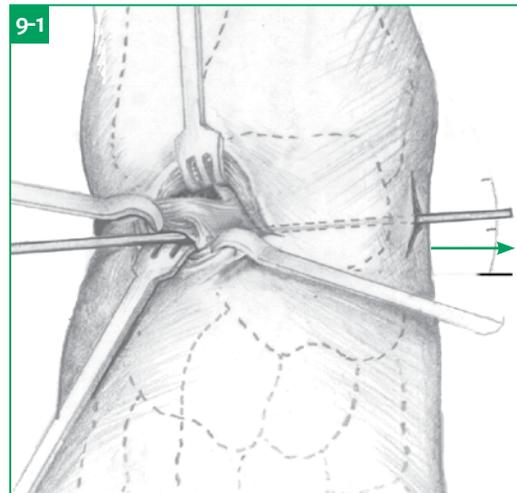
9-1 Remove the guide pin medially if the small incision was made during Step 3 of the procedure (Figure 9-1).

Note: If tenting was performed, the guide pin will be removed laterally.

Copiously irrigate the area with saline and reevaluate subtalar joint motion.

Close the deep tissue fascia, subcutaneous and skin layers.

Place the foot in a mildly compressive dressing.



Step 10 • Post-Op / Follow-Up

10-1 Restrict ambulation for the first 48 hour, followed by protective weight-bearing in a removable, below-the-knee walking cast for two weeks.

Allow a gradual return to activity over the course of the next month.

Note: Typically, adjunctive procedures are performed, so the appropriate post-operative care should be followed for these procedures.



Subtalar MBA® Implant Features

- The Subtalar MBA® Implant system has the longest history of successful clinical outcomes.*
- Barrel-shaped implant provides optimal medial support.
- Uniform implant diameter minimizes lateral discomfort.
- Patented slotted design helps prevent extrusion.
- Simple, minimally-invasive surgical procedure.

*Data available upon request.

Component Materials

- Subtalar Implant: Titanium Alloy

Reference	Description	Size
05-0106	Subtalar Implant	6mm
05-0108	Subtalar Implant	8mm
05-0109	Subtalar Implant	9mm
05-0110	Subtalar Implant	10mm
05-0112	Subtalar Implant	12mm
05-0017	Guide Pin	2mm (.078 in.)
04-1040	Combo Driver	
05-5000	Instrument Set	

bioBLOCK® Implant Combo Driver

- The insertion tool used to place the implant is double-sided, with a 3.5mm hex on one end of the driver and a torx on the opposite end of the driver.
- The metal portion of the driver may be removed from the blue handle to switch between the two different interfaces.
- To switch from the hex to the torx interface, pull the metal portion away from the blue handle. To expose the torx interface, flip the metal portion over, and insert the 3.5mm hex interface into the blue handle. Range of motion of the subtalar joint and clinical correction is assessed and determined.

bioBLOCK® Implant Features

- Constructed of poly-L lactic acid (PLLA).
- Provides temporary support while adjunctive procedures heal.
- Ideal for patients with metal sensitivity.
- Provides an alternative treatment option to a metallic device.
- Simple, minimally-invasive surgical procedure.
- Driver allows viewing under fluoroscopy.

Component Materials

- Subtalar Implant: poly-L lactic acid (PLLA)

Reference	Description	Size
04-0008	Subtalar Implant	8mm
04-0009	Subtalar Implant	9mm
04-0010	Subtalar Implant	10mm
04-0011	Subtalar Implant	11mm
04-0012	Subtalar Implant	12mm
05-0017	Guide Pin	2mm (.078 in.)
04-1040	Combo Driver	
05-5000	Instrument Set	



Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Always refer to the appropriate instructions for use for complete clinical instructions.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

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