

Pediatric Formula™

Product Manual

Fillauer®

Instructions

The Pediatric Formula™ foot system has been designed and manufactured for specific patient weights. Failure to follow the weight guidelines and/or overload conditions caused by the patient, such as heavy lifting, high impact sports, or abusive activities that would otherwise damage the natural limb, will void the warranty.

- Please review the FAQ section of the manual on page 8 before use of the foot. These instructions should be read prior to fitting and followed to ensure the proper integration of the foot into the patient's prosthetic system.
- The foot stiffness is based on weight. Please provide accurate patient information so that the appropriate foot may be selected.

Product Specifications

Weight rating: 125 lbs. (57 kg)

Foot size: 16 – 24 cm

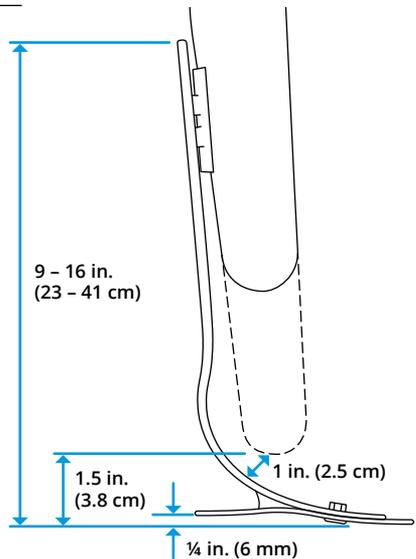
Functional levels: K3 – K4

Product weight (Standard 19 cm):

12 oz. (340 g)

Pylon height: 16 in. (41 cm) — can be cut to 9 in. (23 cm)

Build height: 1.5 in. (3.8 cm)



Installation

Attention: Deviating from the installation or modification instructions will void any product warranty and could lead to product failure and injury to the patient.

Pylon Versions

The Pediatric Formula foot is available in two versions. The Standard version of the foot arrives with a 16 in. (41 cm) pylon that will need to be trimmed to length at the proximal end. The Custom version arrives with a pre-trimmed proximal end and is ready to use with an included Pediatric Posterior Mounting Bracket (180-10-3000).

Pylon Modification — Standard Version

Trim the proximal end of the pylon just below the proximal, posterior brim of the socket; The pylon can be drilled and used with the Pediatric Posterior Mounting (PM) Bracket or laminated directly to the patient's socket (see the Adult Formula Installation manual for direct mounting instructions). The pylon must be drilled as specified in the instructions for the PM bracket.

The distal end of the pylon must also be trimmed if it was purchased as an independent component. Use the guidelines printed on the forefoot to match with the desired foot plate length. Trim the foot using a bandsaw or cast saw and then sanded to the indicated profile.

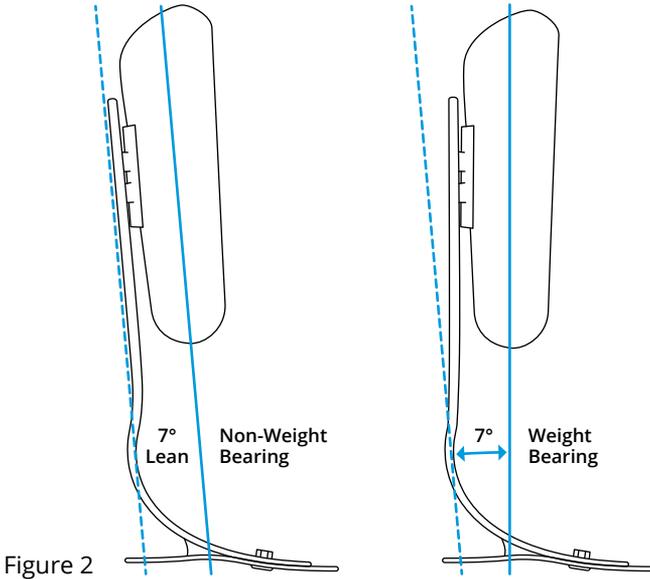
Pylon Modification — Custom Version

If the Custom version was purchased as part of a complete foot assembly, the pylon will be pre-cut. If purchased as a separate component, the forefoot of the pylon must be trimmed to match the desired foot plate length using the guidelines printed on the forefoot. The foot is best trimmed using a bandsaw or cast saw and then sanded to the indicated profile.

Static Alignment—Sagittal Plane

Before aligning, the initial heel height should be established. Using the upper pylon for reference, the Pediatric Formula employs a 7° posterior lean (Figure 2) with a 6 mm (¼ in.) heel block to preload the anterior keel.

When the patient is weight bearing, the patient's weight line should fall between 30 – 35% of the foot length and the socket should achieve a neutral sagittal alignment.



Frontal Plane

A plumb line from the bisection of the socket at the proximal brim in the frontal plane should bisect the keel of the foot (Figure 3). The foot may be slightly inset 1 – 12 mm being sure to accommodate for congenital abnormalities and/or limb length. The longitudinal axis of the foot will be externally rotated approximately 5 – 8° by aligning the medial border of the foot with the line of progression.

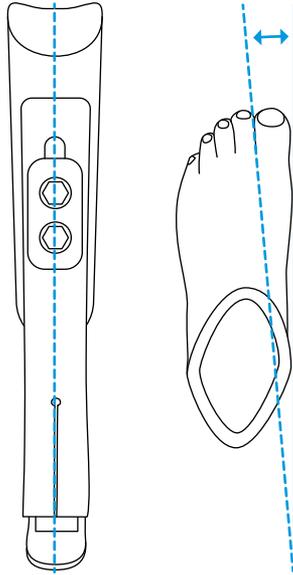


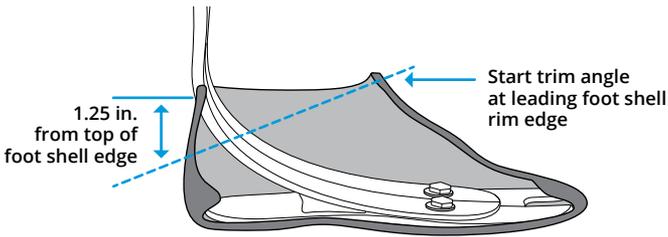
Figure 3

Dynamic Alignment

It is important to align the prosthesis so that the anterior keel is loaded sufficiently to provide dynamic response late in stance. Some bending of the carbon pylon is desirable for optimal performance and foot deflection may be more noticeable during dynamic alignment. Additional height may be used to accommodate for spring deflection during high activity as needed. Patient feedback during this process is essential and slow-motion video (available on most smart phones and tablets) can be very helpful in fine tuning the patient's gait pattern.

Foot Shell Selection

The Pediatric Formula footplate comes trimmed for a sandal toe foot shell.



Trim the posterior brim of the footshell since it will most likely come into contact with the pylon as it exits. This can cause the footshell to unclip from the foot.

Removing the Foot Plate

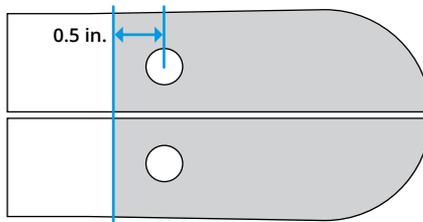
CAUTION: Use a low heat setting to avoid overheating the composite material. Excessive heat may damage the foot. Remove the old foot plate by using a heat gun to soften the epoxy glue which will aid removal of the screws. Apply heat to both proximal/distal surfaces around the screws by continuously moving the heat gun around the area with the hardware for 1 minute. The temperature of composite should not exceed 200 °F (93 °C). **If unsure, it may be useful to periodically measure the temperature of the composite during this process.** Remove the bolts and separate the pylon from the foot plate. If screws are difficult to remove, apply additional heat for another minute. Remove excess adhesive from the pylon with a rotary wire wheel or similar abrasive.

Attaching the Foot Plate

All Pediatric Formula feet must have the foot plate bonded to the pylon.

Once the pylon is trimmed (see above), attach the foot plate so that the split in the pylon matches the split in the footplate. This can be done visually or by placing a tongue depressor or ruler into the splits (Figure 1) to align them. Bond the foot plate using the provided epoxy adhesive or equivalent. Fabtech +PLUSeries adhesive is acceptable. Clean both bond surfaces with rubbing alcohol or acetone and let dry.

Apply adhesive to the underside of the pylon from the distal end to approximately 0.5 in. behind the bolt holes (Figure 2.) Torque the bolts to 10 – 12 N·m with a 10 mm socket. Allow adhesive to fully cure before foot is used.



Frequently Asked Questions

Can the foot be worn without a foot shell?

Yes, the foot may be used without a foot shell; however, some type of protective covering must be used to protect the composite blades from abrasion and high impact. A durable sole material must be permanently bonded, using Master® All-Purpose Cement or similar contact cement, to the plantar surface of the foot to provide the necessary traction and protection. Any foreign materials or grit must be routinely cleaned away to prevent excessive wear. An untrimmed footplate may be ordered to extend the length of the footplate carbon.

Can I get my Formula wet?

The Pediatric Formula is designed to be maintenance free. The foot is water proof; however, if the foot is submerged in water, the foot and foot shell should be rinsed with fresh water and dried immediately to eliminate debris and salt deposits.

Is there regular maintenance on the foot for which I should see my prosthetist?

The Pediatric Formula is a high-performance foot and should be inspected every 6 months for signs of abnormal wear and that the attachment/alignment screws are secure. This also allows the prosthetist to lengthen the pylon to match growth.

What should I do if my foot is no longer performing as well or is making noise when in use?

If the foot performance changes or if it makes noise, the patient should immediately contact his or her practitioner.

How should I clean my foot?

Patients should clean the prosthetic foot with a soft cloth and a soap and water solution. The foot should be inspected for the presence of sand or other debris on a weekly basis. Periodic cleaning is highly recommended to prevent any excessive wear or noise issues.

Warranty

- 24 months from date of patient fitting

The Pediatric Formula foot system has been designed and manufactured for specific patient weights. Failure to follow the weight guidelines and/or overload conditions caused by the patient, such as heavy lifting, high impact sports, or abusive activities that would otherwise damage the natural limb, may void the warranty.

Patient Trial

- A patient trial is not available for posterior mounted feet

Fillauer®

www.fillauer.com

Fillauer LLC

2710 Amnicola Highway
Chattanooga, TN 37406
423.624.0946
Fax 423.629.7936



© 2019 Fillauer LLC
M074/04-10-18/06-19-19