Pediatric Formula™

Product Manual

Fillauer®

Instructions

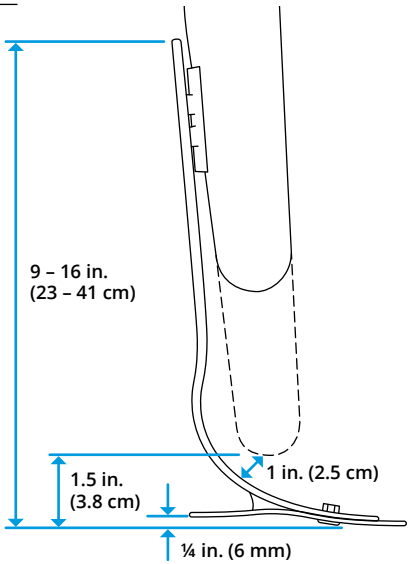
The Pediatric Formula™ foot system has been designed and manufactured for specific patient weights. Failure to follow the weight guidelines and/or overload conditions caused by the patient, such as heavy lifting, high impact sports, or abusive activities that would otherwise damage the natural limb,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

- Please review the FAQ section of the manual on page 6 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: 00 oz. (000 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 Selection

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 both the toe and at the proximal end. The Custom version of the foot arrives pre-trimmed and ready to use with an included Pediatric Posterior Mounting Bracket (180-10-3000). A bracket must be ordered for the Standard version if it is desired. **Please consider patient weight and growth when selecting weight category as the foot comes with a single footplate that may be increased two sizes before a new pylon must be used**.

Pylon Modification (Standard only)

The pylon must be modified when it arrives. The Standard version has a 16 in. (41 cm) pylon that will need to be trimmed to no less than 9 in. (23 cm). Typically, the pylon will trimmed to sit just below the proximal, posterior brim of the socket; however, it should be left at a height that does not cause discomfort during maximal flexion. This pylon can be drilled and used with the Pediatric Posterior Mounting Bracket or laminated directly to the patient's socket (see the adult Formula manual for direct mounting instructions). The pylon may be drilled as specified in the instructions for the bracket. Failure to follow those instructions will void the product warranty and may result in failure of the product and/or injury to the patient.

The distal end of the pylon must also be trimmed, referring to the attached sticker to match the desired footplate length. The foot is best trimmed using a bandsaw or cast saw and then ground to the indicated profile.

Foot Plate Attachment (Standard Formula and replacement foot plates only)

The foot plate arrives unattached; however, the hardware is included and the bolts have thread-locker pre-applied. Once the pylon is trimmed (see above), the foot plate is attached 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 while torquing the bolts to 10 – 12 N·m with a 10 mm socket. The thread-locker used will be removable for exchange of foot plates.

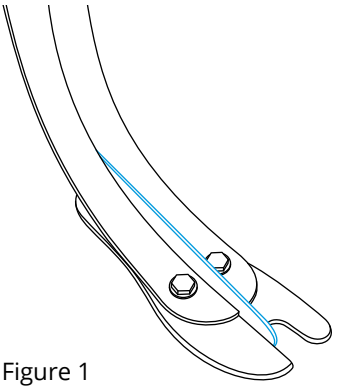


Figure 1

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.

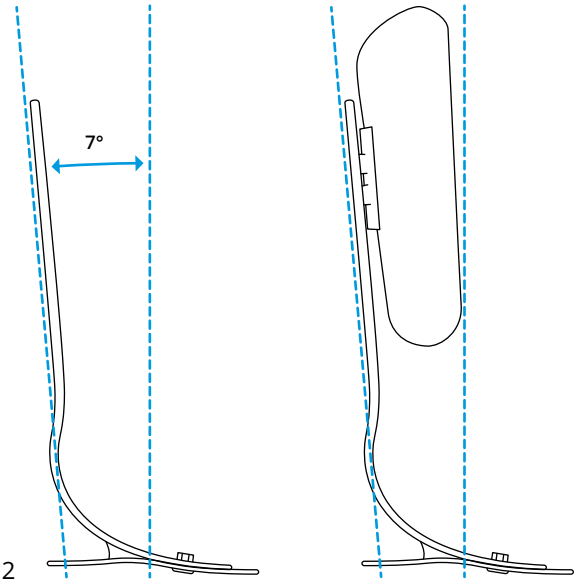


Figure 2

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 accomodate for congenital abrnomalities 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.

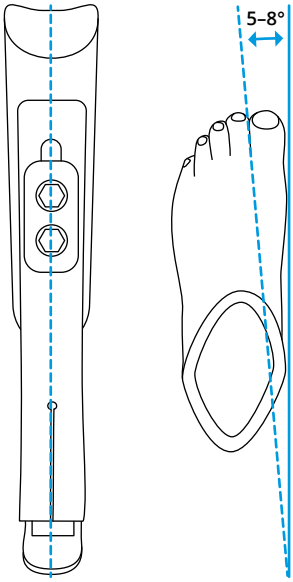


Figure 3

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.

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.

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.

Warranty

- 24 months from date of patient fitting

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Patient Trial

- A patient trial is not available for posterior mounted feet

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