

# Formula<sup>TM</sup>

Product Manual

*Fillauer*<sup>®</sup>

# Instructions

The Fillauer 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 11 before use of the foot. These instructions should be read prior to fitting and followed to ensure the proper integration of the Formula foot into the patient's prosthetic system.
- The foot selection is primarily based on the patient's weight and foot size. The patient's height should be considered as well as the height of attachment. A Fillauer Product specialist can help determine the appropriate category for your patient. Contact Customer Service at 1-800-251-6398.

## Product Specifications

Weight rating: 330 lbs. (150 kg)

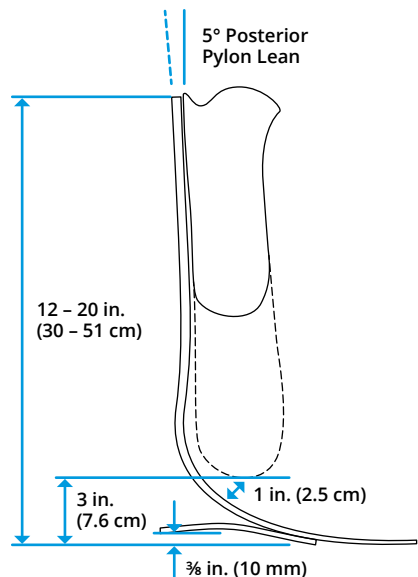
Foot size: 22 – 31 cm

Functional levels: K3 – K4

Weight (27 cm foot): 24 oz. (675 g)

Pylon height: 12 – 20 in. (30 – 51 cm)

Build height: 3 in. (7.6 cm)

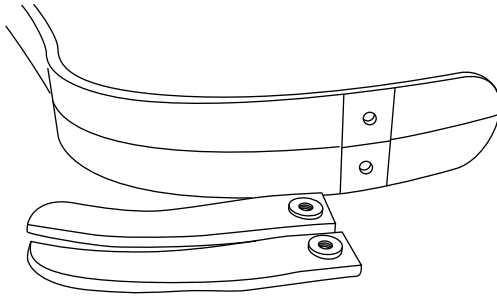


# Installation

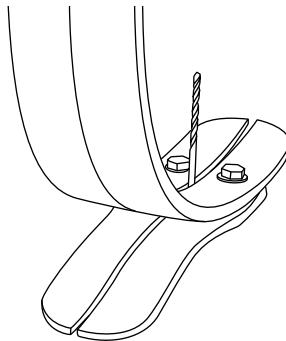
**Attention:** Deviating from the installation instructions or modifying the foot in any way other than as recommended in this manual will void any product warranty and could lead to product failure and injury to the patient.

## Pylon & Foot Plate Setup

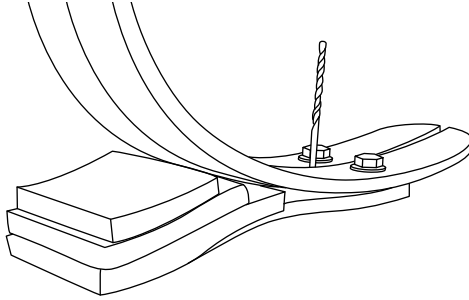
1. Clean the plantar surface of both the heels and the plantar surface of the pylon from the point of the heel attachment holes to the toe to ensure a proper bond of the sole.



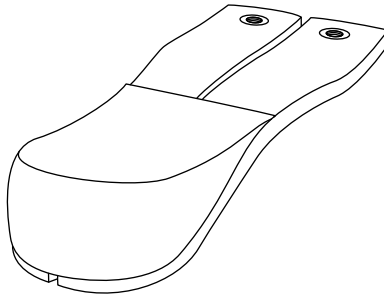
2. Attach the heels with a minimum gap of  $\frac{1}{8}$  in., and separate toe springs with a  $\frac{1}{8}$  in. spacer, such as a drill bit, to hold them apart temporarily. If two sets of bolts are included, be sure to choose the bolt set that does not extend through the T-nuts.



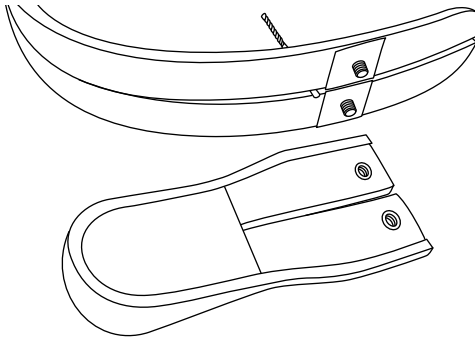
3. With the  $\frac{1}{8}$  in. spacer in place, glue 3 pieces of  $\frac{3}{8}$  in. cloud crepe to the topside of heels. All crepe gluing in this process must be done with heated material so it molds properly.



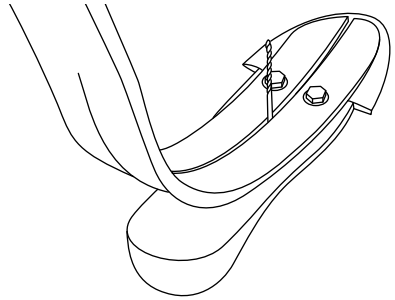
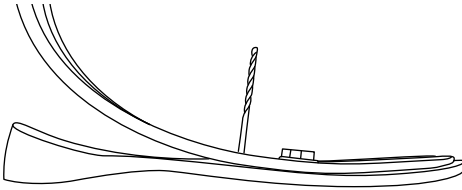
4. Remove the heel and sand to the shape of the outer edge of the heel plates. Keep in mind that we will be adding  $\frac{1}{4}$  in. of additional crepe to outside in step 5.



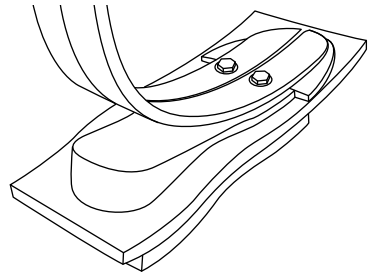
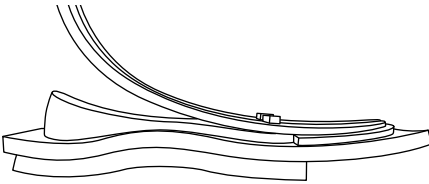
5. Glue Soleflex (moderately dense) crepe around the outside of the heel plate and sand the top and bottom to match the contour of heel plate and the wedge created in step 4.



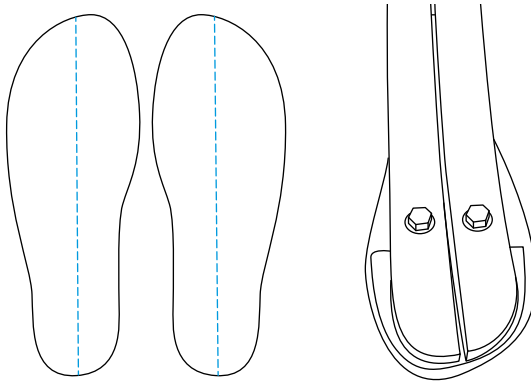
6. Reattach the heel section to the pylon using the bolts and epoxy provided. Be sure to spread the epoxy on T-nuts where they contact the heels, on the bonding area between the heels and the pylon, and on the threads of the bolts. Then torque to 18 – 20 N·m.
7. Measure the desired length of the foot. Always cut back the length from the toe, never from the heel. Cut and sand the asymmetric shape of the toe of the foot (right or left). With the drill bit still holding the toe apart, glue  $\frac{1}{4}$  in. Soleflex crepe to plantar surface of toe only.



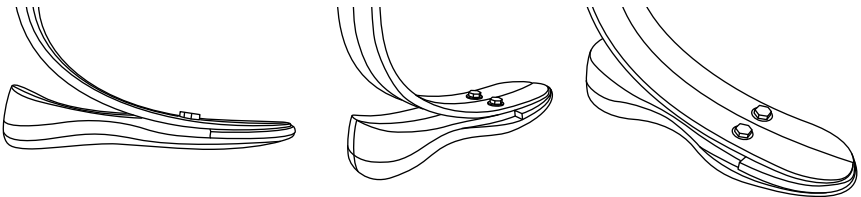
8. Glue  $\frac{1}{2}$  in. inch Soleflex on the full length of foot, and another  $\frac{1}{2}$  in. on posterior two thirds. Remove the drill bit..



9. Sand the shape of the foot so it fits in the desired shoe. The shape must have a medial arch carved to match the last of the shoe. It is important that the lateral edge matches the shape of the shoe so the foot does not shift or cause damage to the shoe over time. Use a band saw to split the sole down the center by following the split in the foot plate. The entire sole needs to be split so the two halves move independently.

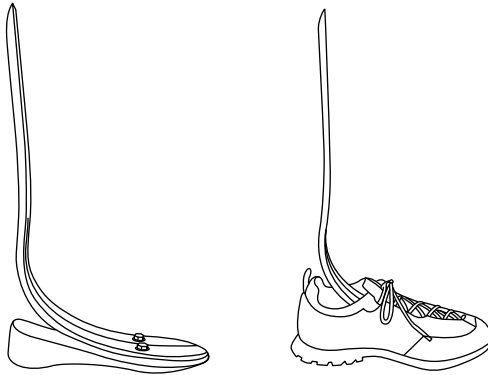


10. The foot should have a slight arch from the heel to the metatarsal heads, and then rocker slightly from metatarsal heads to the toe. Flatter shoes will require less arch; dress shoes, boots, and shoes with higher heel angles will require more arch. Plantar/dorsiflexion of the foot is done by sanding the desired angle to the plantar surface of the crepe material.

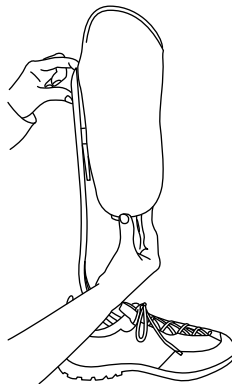


## Installation & Alignment

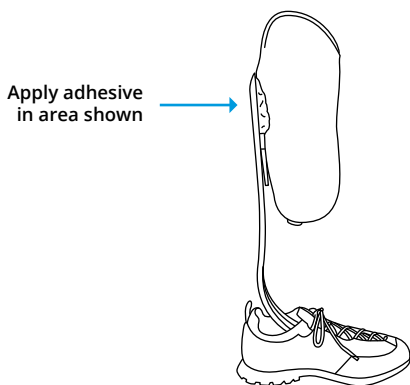
1. An alignment plate and instructions are available from Fillauer (PN 180-10-2010); however, for the best cosmetic finish direct lamination of the foot to the socket can be easily accomplished.
2. The foot should first be cut to length to allow attachment as proximal as can be allowed by the posterior trimline of the socket. The proximal edge should then be beveled to prevent excess bulk or hard edges.



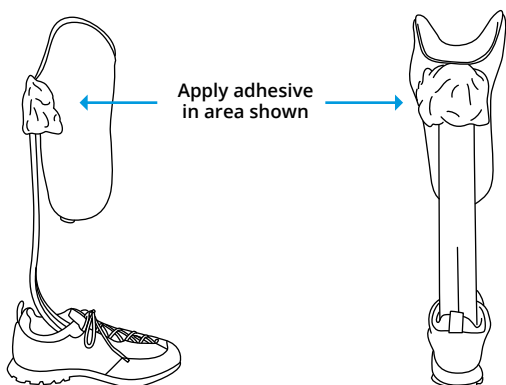
3. Alignment of the foot can be done by following a tracing of the patient's current prosthesis or a dynamically aligned test socket. The socket should be attached with an additional 3 – 5° of posterior lean to accommodate compression of the longer foot (this will be a starting point but will vary due to patient weight, posture, and the length of the proximal pylon).



4. Bond the socket to the pylon using Fabtech PLUSeries® Composite Adhesive as shown. Check the alignment and correct by rebonding the setup before proceeding to the next step.

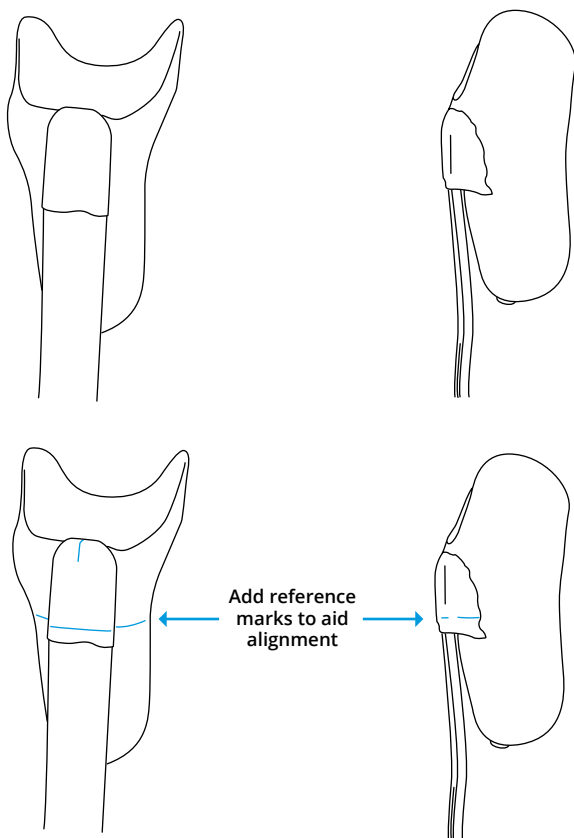


5. Once the static alignment is complete, apply an outer layer of adhesive to hold the foot in place for dynamic alignment (for larger patients, fiberglass cast tape may be necessary for safety).



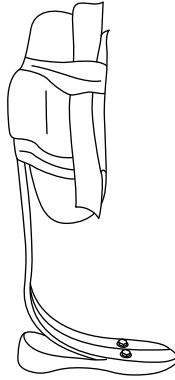


6. To make any changes to alignment during the dynamic alignment stage, grind away the outer layer of adhesive to release the foot and mark the foot as shown above to make changes easy to visualize. Also, a simple wedge can be used to hold alignment changes changes the socket position while the foot is reattached.



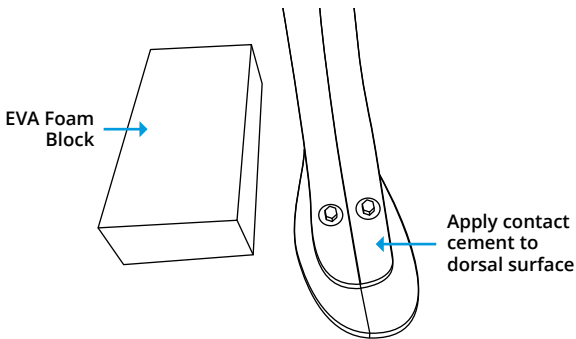
7. Repeat steps 4 – 6 until optimal alignment is achieved.
8. As an alternative to the direct lamination attachment, the Fillauer alignment plate may be used to attach the foot but an additional  $\frac{3}{8}$  in. posterior offset is required.

9. Sand the exterior of the adhesive and the socket to just past the midline to allow for a solid bond of the lamination. Mask the socket anterior to trimline and distal and proximal to the adhesive. Apply carbon fiber braid, fully saturated with resin, to the sanded area and tightly wrap with PVA to seal as the lamination sets.

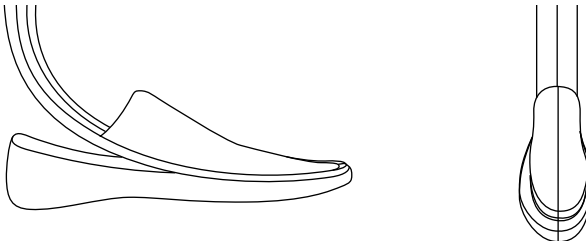


### Top Cover Fabrication

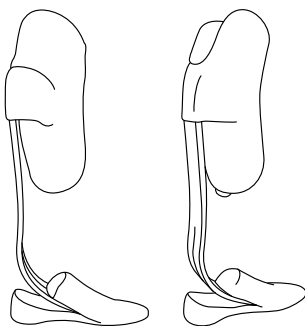
1. Use EVA foam to create the dorsal section of the foot cover



2. Heat the foam until pliable and glue to the upper surface of the pylon. Grind the foam block to shape it to the appropriate size for the foot.



3. Heat ¼ in. thick crepe and glue over the EVA foam to create a durable top cover.



4. The final product may then be sanded and a finish lamination or clear coat of paint may be applied to the socket for a gloss finish.

## Frequently Asked Questions

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### What can the practitioner do if the heel or toe is too soft or too firm?

The heel and toe rollover resistance may also be fine-tuned during the dynamic alignment (page 8) by plantarflexing, dorsiflexing, shifting the foot anterior or posterior, or sanding the desired angle to the plantar surface of the crepe material.

### Can the foot be worn without a shoe?

Yes, the foot may be used without a shoe; however, some type of protective covering must be used on the plantar surface to protect the composite blades from abrasion and high impact. A durable sole material must be permanently bonded using Master® All-Purpose Cement or equivalent adhesive to the plantar surface of the foot assembly to provide the necessary traction and protection.

### Can I get my Formula wet?

The Formula is designed to be maintenance free. The foot is water proof; however, if the foot is submerged in salt water, the proximal foot bolts should be rinsed with fresh water and dried immediately. Also, if the crepe becomes soaked, it should be allowed to dry outside the shoe.

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

The 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. Any foreign materials or grit must be routinely cleaned away to prevent excessive wear.

## 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

The logo for Fillauer, featuring the brand name in a stylized, cursive script font.

[www.fillauer.com](http://www.fillauer.com)

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