Formula Ultra

Product Manual

Fillauer®

Contents

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Intended Use

The Formula Ultra posterior-mounted, prosthetic foot is intended for use in lower extremity prostheses. The foot uses a long carbon pylon to maximize energy storage and release during gait, similar to a “running blade”. It is also an exceptional walking foot for strong users and especially those with longer residual limbs and the height requirements that come with those limbs. The Formula Ultra is the ideal balance of flexibility and power, creating a dynamic foot design intended for highly active users/patients. The long, lightweight carbon pylon provides critical energy return to the user through the posterior attachment while the compact shape of the ankle allows for better cosmetic finishing without hindering foot performance when worn with a shoe. Everyday users to elite athletes will admire the active feel of the Formula Ultra, and practitioners will appreciate the diverse range of fitting options for their patients. The Formula Ultra bridges the gap between everyday foot and sport specific prosthesis in a single device.

Indications

- High to very high activity transtibial or transfemoral amputees as defined by functional K3 and K4 activity levels.
- Unilateral or bilateral patients
- Patients that would benefit from high energy return.
- Patients that would benefit from low build height.
- Patients weighing up to 330 lbs. (150 kg)

Contraindications

- Clearance below 3 in. (7.6 cm)
- Patients weighing over 330 lbs. (150 kg)

Performance Characteristics	
Patient weight	Up to 330 lbs. (150 kg)
Foot weight	24 oz. (675 g)
Build height	3 in. (7.6 cm)
Pylon height	12 – 20 in. (30 – 21 cm)
Functional level	K3 – K4
Durable; meets ISO-22675 standard	
Primary materials	Carbon composite and stainless steel
Waterproof	Carbon composite and stainless steel

The device is intended for single user/patient use only.

Storage and Handling

It is recommended that prosthetic feet are stored in a cool clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

Warnings and Precautions

CAUTION: Soling material must be installed on the plantar surface and sides of the heel set and distal pylon where normally covered by a shoe to protect the carbon from impact and abrasion that could cause delamination.

CAUTION: For patient safety and device compatibility, only the appropriate Fillauer Posterior Mounting Bracket should be used with any Fillauer Posterior Mounted Foot.

CAUTION: Abnormal or improper environmental conditions will lead to malfunctioning and damage of the prosthesis and are not covered under the warranty of the device. This prosthetic/orthotic component must not be subjected to dust/debris, liquids other than fresh water, abrasives, vibration, activities which would damage the biological limb, or prolonged, extreme temperatures (< -5 °C or > 50 °C). Do not allow debris or liquids to remain in the prosthesis and its components during use. Rinse the foot with fresh water and dry immediately after exposure.

CAUTION: The foot unit is waterproof to 1 meter; however, if the foot is submerged, the foot and foot shell should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris. The foot shell and sock will experience significant deterioration if not allowed to fully dry before return to normal use and are not covered under warranty for this failure.

NOTICE: The foot should be inspected by the clinician every 6 months for signs of abnormal wear and to assure that the attachment/alignment screws are secure.

NOTICE: The foot stiffness is based on weight and activity level. Please provide accurate patient information so that the appropriate foot may be selected.

NOTICE: Attachment, alignment, and delivery of the foot must be performed by or under the direct supervision of a qualified prosthetist.

Any adjustment or modifications should be made by the clinician and not by the user.

NOTICE: If any serious incidents occur in relation to the usage of the device, contact your Fillauer Representative and the competent authority in your country.

Qualified Provider

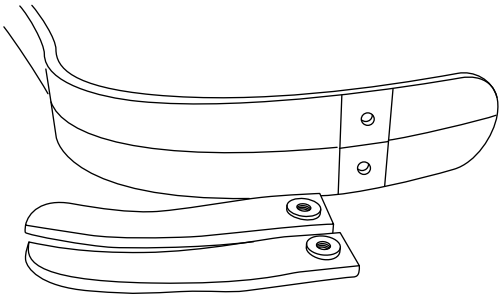
Attachment, adjustment, alignment, and delivery of this device must be performed by or under the direct supervision of a qualified prosthetist. Unless stated in this manual, any such activities should not be attempted by the user and will potentially void the device warranty.

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

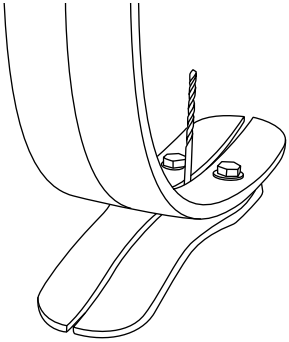
Pylon & Foot Plate Setup

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.

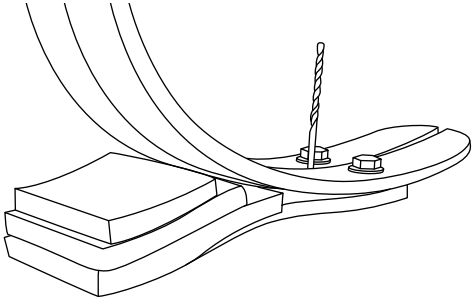


2. Attach the heels with a minimum gap of ⅛ in., and separate toe springs with a ⅛ in. spacer, such as a drill bit, to hold them apart temporarily. If two sets of

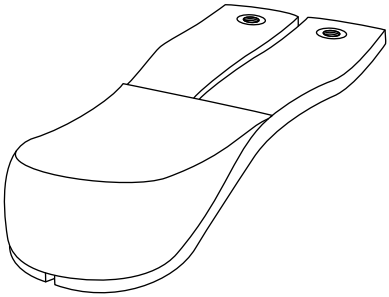
bolts are included, be sure to choose the bolt set that does not extend through the T-nuts.



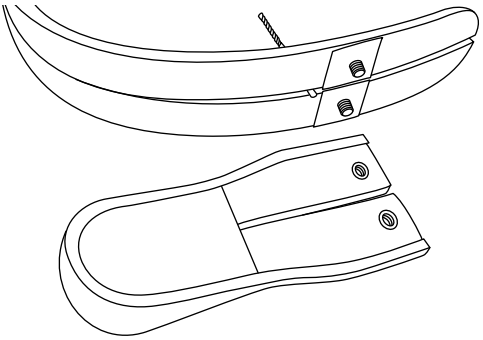
3. With the ⅛ in. spacer in place, glue 3 pieces of ⅜ in. cloud crepe to the topside of heels. All crepe gluing in this process must be done with heated material so it molds properly.



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 ¼ in. of additional crepe to outside in step 5.

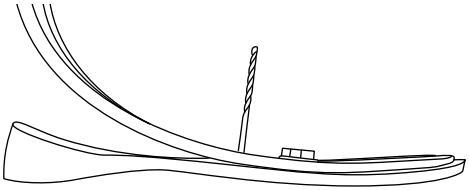


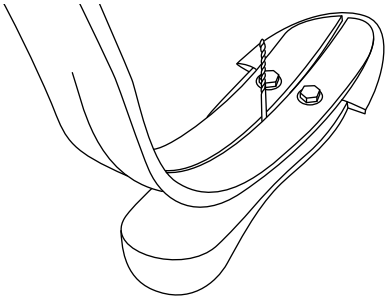
5. Glue Soleflex (moderately dense) crepe around the outside of the heel plate and sand the top and bottom to match the contour of heel plate and the wedge created in step 4.



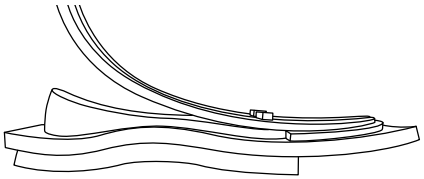
6. Reattach the heel section to the pylon using the bolts and epoxy provided. Be sure to spread the epoxy on T-nuts where they contact the heels, on the bonding area between the heels and the pylon, and on the threads of the bolts. Then torque to 18 – 20 N·m.

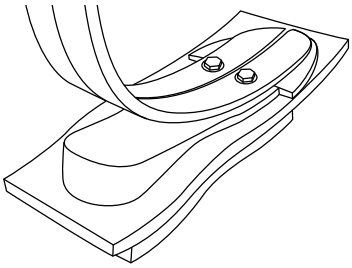
7. Measure the desired length of the foot. Always cut back the length from the toe, never from the heel. Cut and sand the asymmetric shape of the toe of the foot (right or left). With the drill bit still holding the toe apart, glue ¼ in. Soleflex crepe to plantar surface of toe only



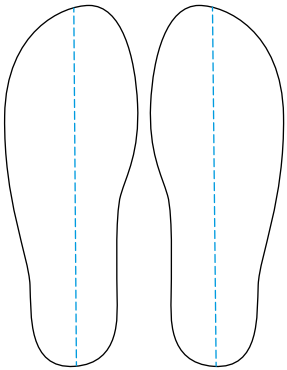


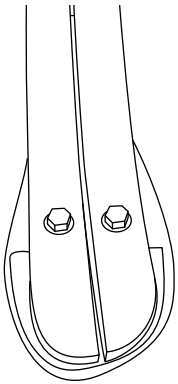
8. Glue ½ inch Soleflex on the full length of foot, and another ½ inch on posterior two thirds. Remove the drill bit.



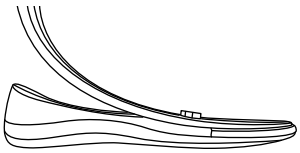


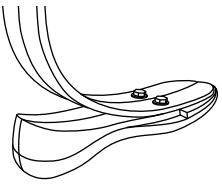
9. Sand the shape of the foot so it fits in the desired shoe. The shape must have a medial arch carved to match the last of the shoe. It is important that the lateral edge matches the shape of the shoe so the foot does not shift or cause damage to the shoe over time. Use a band saw to split the sole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

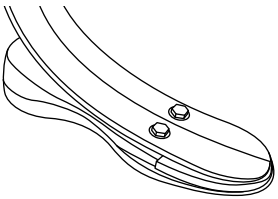




10. The foot should have a slight arch from the heel to the metatarsal heads, and then rocker slightly from metatarsal heads to the toe. Flatter shoes will require less arch; dress shoes, boots, and shoes with higher heel angles will require more arch. Plantar/dorsiflexion of the foot is done by sanding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

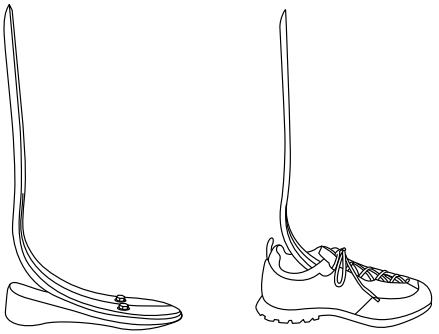






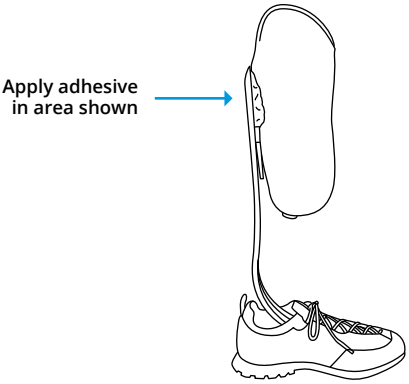
Proximal Attachment

1. The Adjustable Alignment Bracket (**PN 180-10-4000**) may be used for temporary, adjustable attachment during alignment. The Posterior Mounting Bracket (**PN 180-10-2010**), typically used for permanent attachment, may also be used in a temporary setting but only allows angular adjustments. Permanent attachment of the foot may be achieved via direct lamination or use of the Posterior Mounting Bracket. See Posterior Mounting Bracket or Adjustable Alignment Bracket instructions for more information or request assistance from Fillauer for further instruction in this process. Alignment can also be achieved without an alignment bracket using steps 4 – 7 below. This method may be difficult for first time users.
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.

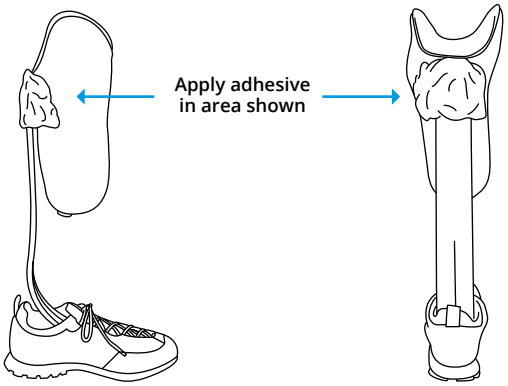


3. Alignment of the foot can be done by following a tracing of the patient's current prosthesis or a dynamically aligned test socket. The socket should be attached with an additional 3 – 5° of posterior lean to accommodate compression of the longer foot (this will be a starting point but will vary due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

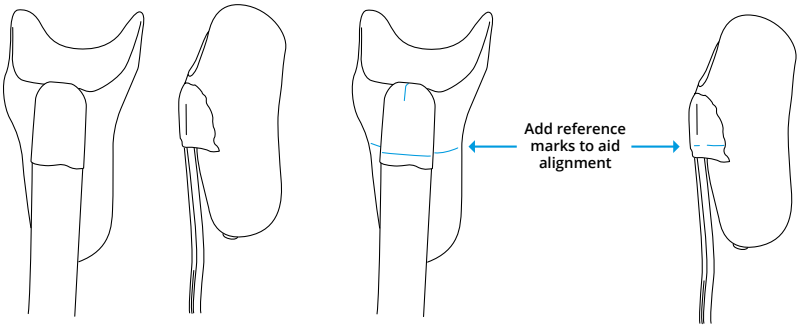
4. Bond the socket to the pylon using Fabtech PLUSeries® Composite Adhesive as shown. Check the alignment and correct by rebonding the setup before proceeding to the next step.



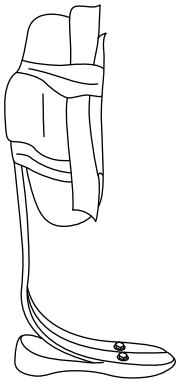
5. Once the static alignment is complete, apply an outer layer of adhesive to hold the foot in place for dynamic alignment (for larger patients, fiberglass cast tape may be necessary for safety).



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 the socket position while the foot is reattached.

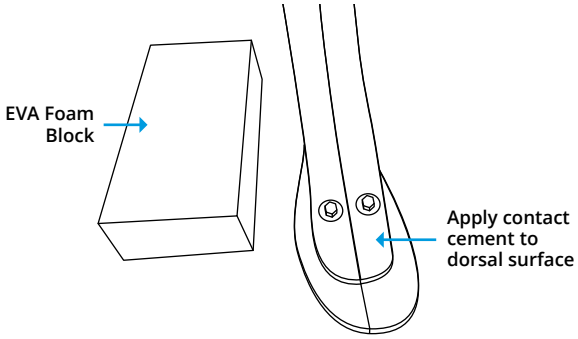


7. Repeat steps 4 – 6 until optimal alignment is achieved.
8. As an alternative to the direct lamination attachment, the Fillauer alignment plate may be used to attach the foot but an additional ⅜ in. posterior offset is required.
9. Sand the exterior of the adhesive and the socket to just past the midline 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.

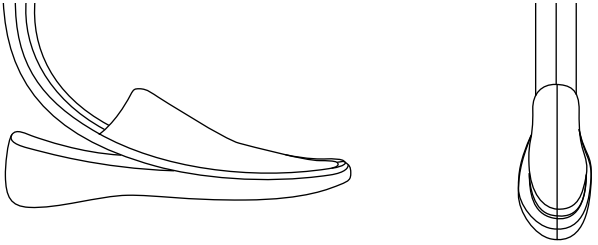


Top Cover Fabrication

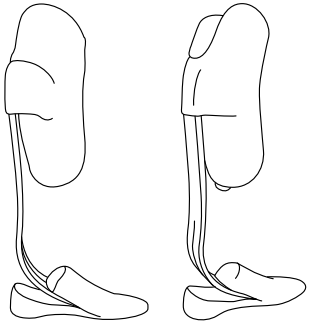
1. Use EVA foam to create the dorsal section of the foot cover



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.

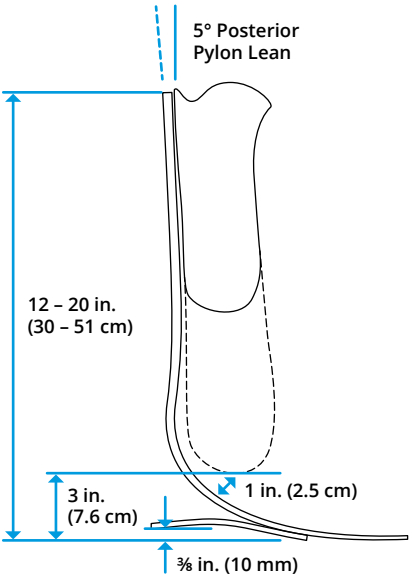
Specifications and Preparations Before Use (Risk Management for Installation and Calibration)

Proximal attachment

The Adjustable Alignment Bracket (PN 180-10-4000) may be used for temporary, adjustable attachment during alignment. The Posterior Mounting Bracket (PN 180-10-2010), typically used for permanent attachment, may also be used in a temporary setting but only allows angular adjustments. Permanent attachment of the foot may be achieved via direct lamination or use of the Posterior Mounting Bracket. See Posterior Mounting Bracket or Adjustable Alignment Bracket instructions for more information or request assistance from Fillauer for further instruction in this process.

Static Alignment—Sagittal Plane

Before aligning, the initial heel height should be established. The Formula Ultra employs a 5° posterior lean (Figure 1) with a 10 mm (⅜ in.) heel block to preload the anterior keel. When the patient is weight bearing, the socket bisection should settle to a vertical to slightly flexed position.



Transtibial Frontal Plane Alignment

A plum line from the bisection of the socket at the proximal brim in the frontal and sagittal plane should bisect the keel of the foot (Figure 2). The foot may be slightly inset 1 – 12 mm depending on the limb length. Most runners prefer a wider base of support with the foot slightly lateral to the distal bisection, 7 – 13 mm. 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.

Transfemoral Static Bench Alignment

Alignment at the transfemoral level should be consistent with the instructions provided by the manufacturer of the prosthetic knee in use. Attachment to the prosthesis will be challenging with transfemoral amputees and the method of doing so is at the discretion of the treating clinician.

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. Up to ½ in. (12 mm) additional height may be needed to accommodate for spring deflection. Patient feedback during this process is essential. Use the Adjustable Alignment Bracket Kit for easier alignment of any Fillauer posterior mounted foot. If using the Posterior Mounting Bracket alone, adjustment of plantar/dorsiflexion angles using the and alignment wedges will help achieve a smooth transition from heel to toe and provide adjustment of transverse plane foot rotation.

1. Check for smoothness of gait and ground contact throughout the stance phase of gait.
2. If the heel rollover is delayed from heel strike to midstance, or the heel compression is too great, removal and/or reshaping of material from 30% of foot length forward to the toe, addition of material from the heel to 30% of foot length, or dorsiflexion of foot may correct this problem.
3. If the heel rollover is too rapid from heel strike to midstance, or the heel is too hard, removal and/or reshaping of material from the heel to 30% of foot length, addition of material from 30% of foot length forward to the toe, or plantarflexion of the foot may solve this problem.
4. If the rollover is too rapid from midstance to toe loading, removal and/or reshaping of material from the heel to 30% of foot length, addition of material from 30% of foot length forward to the toe, or plantarflexion of the foot may solve this problem.
5. If the rollover from midstance to toe loading is delayed, removal and/or reshaping of material from 30% of foot length forward to the toe, addition of material from the heel to 30% of foot length, or dorsiflexion of foot may correct this problem.
6. Check to make sure pylon is vertical in the frontal plane at midstance. This angulation will be done by moving the bracket, so extra time spent in bench alignment to properly match the patient's current angulation is advised

If a smooth stance phase of gait cannot be achieved, contact Fillauer for additional assistance.

Compatibility

Fillauer's adult posterior mounting feet are appropriate for use with the adult sized, Fillauer **Posterior Mounting Bracket** and **Adjustable Alignment Bracket**. Soling material must be installed on the plantar surface and sides of the heel set and distal pylon where normally covered by a shoe to protect the carbon from impact and abrasion that could cause delamination.

Disposal / Waste Handling

The product must be disposed of in accordance with applicable local laws and regulations. If the product has been exposed to bacteria or other infectious agents, it must be disposed of in accordance with applicable laws and regulations for the handling of contaminated material.

All metal components may be removed and recycled at the appropriate recycling facility.

Warranty

24 months from date of patient fitting.

User Instructions

The providing health care professional must review the following information directly with the user.

Warnings and Precautions for the User

WARNING: If the foot performance changes or it begins to make noise, the patient should immediately contact his or her practitioner. **These things may be as sign of a failure of the foot or other part of the prosthesis that could result in a fall or other serious injury.**

CAUTION: Attachment, alignment, and delivery of the foot must be performed by or under the direct supervision of a qualified prosthetist.

Any adjustment or modifications should be made by the clinician and not by the user.

CAUTION: Patients should inspect the foot cover daily for signs of cracks, tears, or holes and for the presence of sand or other debris. If the foot cover shows signs of failure, it should be replaced as soon as possible to prevent damage to the carbon fiber. If debris is present, the foot and cover should be rinsed and allowed too fully dry.

CAUTION: The foot cover may also be cleaned with a soft cloth and a soap and water solution. Do not use acetone or other solvents. It may damage the foot cover.

CAUTION: The foot should be inspected by the clinician every six months for signs of abnormal wear and to assure that the attachment/alignment screws are secure.

CAUTION: The foot is waterproof to 1 meter. However, if the foot is submerged, the foot should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.

Serious Incidents

In the unlikely event a serious incident occurs in relation to the use of the device, users should seek immediate medical help and contact their prosthetist, local competent authority, and Fillauer at the earliest possible convenience. Clinicians should at any time contact their local Fillauer representative and local competent authority immediately in the event of any device failure.

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