fillauer Element Instruction Manual

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Intended Use

The Aeris Activity 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. The first high-energy-return, multiaxial foot for amputees with Syme or Boyd amputations, the Aeris Activity accommodates the minimum clearance required for long transtibial amputations without compromising the function.

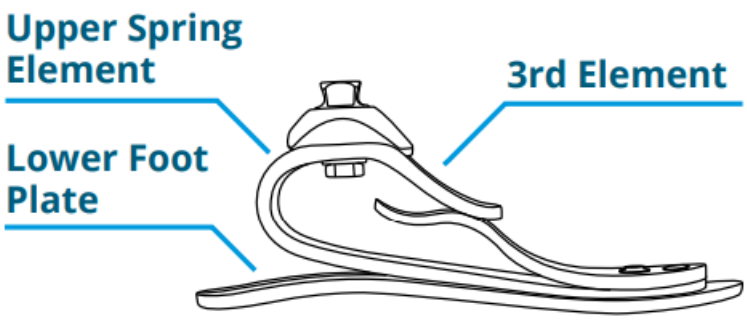

Figure 1

Indications

- Moderate to high activity transtibial 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 275 lbs. (125 kg)

Contraindications

- Clearance below: Build height for sizes 22 – 24: 1.5 in. (3.8 cm), Build height for sizes 25–30: 1.75 in. (4.4 cm)
- Patients weighing over 275 lbs. (125 kg)
- Transfemoral amputees The device is intended for single patient use only.

Performance Characteristics

- **Patient weight:** Up to 275 lbs. (125 kg)
- **Foot weight:** 17.6 oz. (500 g)
- **Build height for sizes 22 – 24:** 1.5 in. (3.8 cm)
- **Build height for sizes 25 – 30:** 1.75 in. (4.4 cm)
- **Functional level:** K3-K4
- **Durable;** meets ISO-22675 standard
- **Primary Materials:** Carbon composite and stainless steel
- **Waterproof:** The foot unit is waterproof to 1 meter. See additional information below

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

Warnings and Precautions

WARNING: The distal end of the socket must be NO MORE THAN ⅜ in. (9 mm) from the upper carbon plate. The socket may be built up (through lamination or addition of firm crepe) to achieve this distance, but failure to do so will result in a fracture of the prosthetic foot. The distal end of the socket must also be built sufficiently strong to resist impact of the foot (through the Poron® pad) on the distal end. Failure to failure to follow these instructions will cause the foot to fail and lead to falls or other patient injuries.
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 is 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 six 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 appropriate authority in your country.

Alignment (Specifications & Preparations Before Use)

Proximal attachment
The Posterior Mounting Bracket (PN 180-10-2000), 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 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 Aeris Activity employs a 0° posterior lean (Figure 1) with a ⅜ inch (10 mm) heel block to preload the anterior keel. When the patient isweight bearing, the socket bisection should settle to a vertical to slightly flexed position. This will require some extension to be built into the socket in bench alignment or through the addition of wedges as described in the Posterior Mounting Bracket Manual. It Is recommended that the included Posterior Mounting Bracket is used to establish height and rotation of the foot prior to final lamination, this can be done in either the test socket phase and/or 10 mm before the final lamination. For final attachment, use of the Posterior Mounting Bracket is recommended (see Posterior Mounting Bracket instruction manual) for adjustability; however, the foot can be mounted directly to the posterior socket wall.

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.

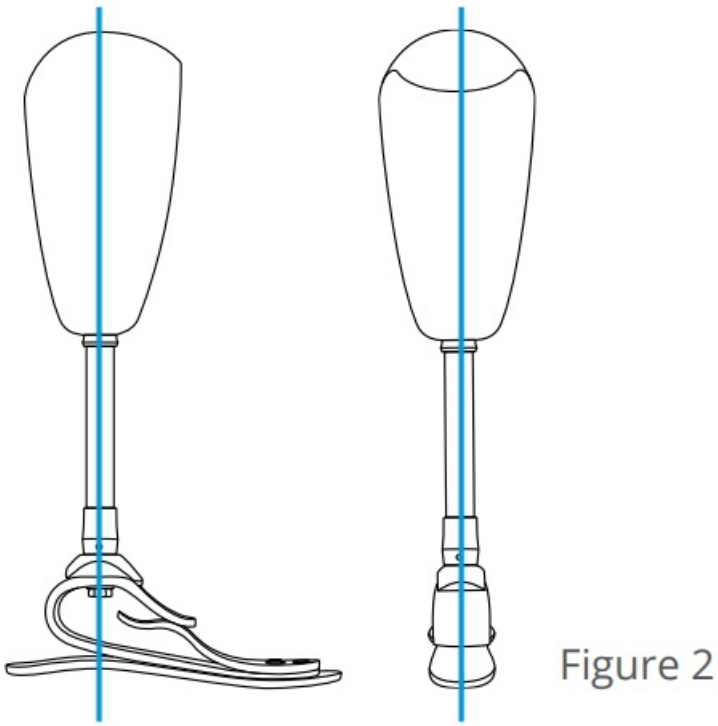

Figure 2

Transverse Plane Alignment
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.

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. Patient feedback during this process is essential. The included, adhesive backed Poron® pad may be used to affect dorsiflexion range and moment by allowing the socket to resist dorsiflexion. The pad may be used during the test fitting without adhering to determine the optimal location. A more proximal/posterior pad location will minimally affect dorsiflexion while a more distal/anterior location will resist dorsiflexion range and increase resistance. If using the Posterior Mounting Bracket, 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, 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, plantarflexion of the foot or distal/anterior movement of the Poron® pad may solve this problem.
4. If the rollover is too rapid from midstance to toe loading, plantarflexion of the foot or distal/anterior movement of the Poron® pad may solve this problem.
5. If the rollover from midstance to toe loading is delayed, dorsiflexion of the foot or proximal/posterior movement of the Poron® pad may solve 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.

Installation of the Foot
The Aeris Activity can be directly mounted to the socket or attached using the Posterior Mounting Bracket, PN 180-10-2000. If using the Posterior Mounting Bracket, follow the instructions included with it.

To mount the foot directly to the socket:

1. Determine the approximate location of the foot on the socket.
2. The distal end of the socket should be no greater than ⅜ inch (10 mm) from the dorsal surface of the upper carbon plate or attached foam bumper (Figure 3). This allows proper function of the toe. A piece of ¼ inch (6 mm) Poron with adhesive backing is supplied, but crepe applied to the distal end of the socket can also be used to tighten the gap and to fine tune the dorsiflexion characteristics of the foot.
3. If lower build height is needed, the foot may be placed in contact with the socket, but a piece of PTFE film tape, such as Shearban® must be used in the interface and will need more frequent replacement. The patient may also note an audible contact between the foot and socket when thinner materials are used in the interface. It should also be noted that the foam interface should extend from the anterior contact point of the socket back to a point on the pylon that prevents direct contact with the socket (see Poron location in Figure 3).
4. With 80 grit sand paper, sand the area of the socket where the foot will be bonded ~ 3 × 3 inch (7.6 × 7.6 cm).
5. Sand the foot in the same area to prep for bonding.
6. Clean both surfaces thoroughly with rubbing alcohol.
7. Bond the foot to the socket with +PLUSeries® Composite 1 Minute Adhesive or equivalent.
8. Wrap with fiberglass casting tape to test alignment.
9. Remove foot to change alignment and retape.

10. When proper alignment is obtained, laminate the foot to the socket using sufficient carbon to prevent the foot from tearing out.

Consumable Components: Foot Shell and Spectra® Sock

The Aeris Activity uses a unique cosmetic foot shell that is flexible and durable (sold separately). Use care in the installation and removal of the foot shell to maintain its appearance and durability. Always use the shell with an internal Spectra sock (included). Never use a sharp-edged tool such as a screwdriver to install or remove the foot shell.

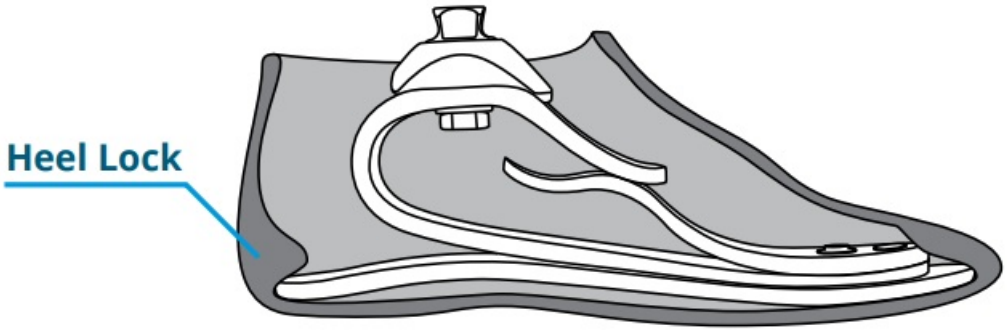

Figure 3

Installation

- Slide the provided Spectra sock onto the foot from toe to heel, pulling excess material to the ankle so that it does not bunch under the heel or toe of the foot.
- Insert the forefoot into the foot shell as far as possible. Set the heel on a supportive surface with the toe up and push the shell onto the foot until the toe is in position.
- Rotate the foot side to side to allow the foot shell to slide onto the heel.
- Push the foot shell up onto the heel or, if necessary, insert a shoehorn into the foot shell and allow the heel to slide down a shoehorn into the heel lock. The heel must lock (Figure 4) in place for proper function and safety.
- The foot shell should be inspected daily by the user and replaced by the clinician when tears or breaks are evident in the surface of the shell.
- The Spectra sock should be inspected and replaced if needed every 3–6 months by the prosthetist. The plantar surface of the foot should be inspected at this time and if there is excessive wear of the protective soling, it should be replaced.

Removal

- Place the foot on the bench so that the heel is hanging over the edge of the bench.
- Apply downward force to the top portion of the foot shell at the heel. The heel plate should pop out of the heel lock, allowing removal of the foot shell by hand.
- If the foot shell is too tight, a smooth-edged shoehorn may be used to disengage the heel lock.

Compatibility

Fillauer's adult posterior mounting feet are appropriate for use with the adult sized, Fillauer Posterior Mounting

Bracket. A Fillauer spectra sock and foot shell (not included) should be used with this device, the fit of other manufacturers shells cannot be guaranteed.

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

- 36 months from date of patient fitting
- Foot Shell (sold separately)—6 months from date of patient fitting.

User Instructions

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

Care and Maintenance

- **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:** 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 and foot shell should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.
- **CAUTION:** The foot shell is designed to provide a realistic appearance and maximum performance of the Aeris Activity. The life of the foot shell will depend on level of activity and degree to which it is protected from wear and damage with socks and shoes. Socks and shoes should be worn at all times and should be allowed to dry fully after **exposure** to water to prevent damage to the shell.
- **CAUTION:** Patients should inspect the shell daily for signs of cracks or holes and for the presence of sand or other debris. If the foot shell shows signs of failure, it should be replaced as soon as possible to prevent damage to the carbon fiber and soling materials. If debris is present, the foot and shell should be rinsed and allowed to fully dry.
- **CAUTION:** The foot shell may also be cleaned with a soft cloth and a soap and water solution or with rubbing alcohol (70%). Do not use acetone. It will damage the foot shell.

Serious Incidents

In the unlikely event of a failure resulting in a fall and/or injury, seek immediate medical help and contact your prosthetist at the earliest possible convenience.

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- www.fillauer.com

Documents / Resources

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References

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