



Element

Product Manual

Fillauer[®]

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Intended Use

The Element prosthetic foot is intended for use in lower extremity prostheses. The Element sets itself apart from other low-profile, two-spring prosthetic foot designs by adding an innovative 3rd Element. Fillauer has designed the Element to support each phase of foot function in the gait cycle—from heel strike to midstance and midstance to toe off. The result is a foot with unsurpassed smoothness, stability and performance throughout the gait cycle.

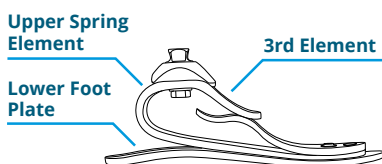


Figure 1

Indications

- Moderate to active transtibial or transfemoral amputees as defined by functional K3 activity levels
- Unilateral or bilateral patients
- Patients that would benefit from increased flexibility and smooth rollover
- Patients weighing up to 300 lbs. (136 kg)

Contraindications

- Clearance below 3.75 in. (9.5 cm)
- Patients weighing over 300 lbs. (136 kg)
- Patients wanting to run or jog regularly on the device

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

Performance Characteristics

- Patient weight: Up to 300 lbs. (136 kg)
- Foot weight: 12 oz. (340 g)
- Build height: 3.75 in. (9.5 cm)
- Functional level: K3
- Durable; meets ISO-22675 standard
- Primary Materials: Carbon composite, stainless steel, titanium, and aluminum
- 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



CAUTION: The Element is designed to be maintenance free and should not be disassembled. The pyramid dome on the foot is permanently attached to the pylon (main and top) spring and should not be removed.



CAUTION: Fillauer has tested (ISO 10328) and recommends the use of standard, adult, endoskeletal components from Fillauer with all Fillauer feet. Components from other manufacturers may or may not be compatible. Failure due to use of other manufacturers' products is not covered under warranty.



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 done by the clinician and not by the user.

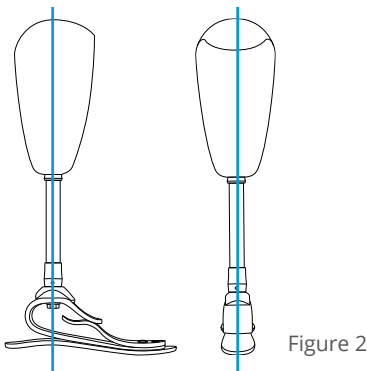


NOTICE: If any serious incidents occur in relation to the usage of the device, contact your Fillauer Representative and the appropriate authority in your country.

Alignment (Specifications & Preparations Before Use)

Proximal attachment

Attachment of the foot may be achieved via the proximal pyramid to any ISO 10328 compliant, Fillauer or equal, standard adult pyramid receiver. Torque all set screws to the setting specified by the manufacturer of the pyramid receiver. For Fillauer components, this is 15 N·m. Proper threadlocker must be used for final delivery per the component manufacturer's specifications.



Static and Bench Alignment

Standard bench alignment techniques may be used for the Element (Figure 2). Before aligning, the initial heel height should be established. The Element is designed for a $\frac{3}{8}$ inch or 1 cm heel height. The initial heel height can be established with a simple spacer under the heel. The top of the pyramid should be parallel with the work surface before proceeding with alignment. A backward leaning pylon indicates that the heel height is too low and will make late-stance rollover difficult.

Transtibial Bench Alignment

The socket should be set with the proper amount of inset found in the evaluation. The plum line from the bisection of the socket at the proximal brim in the frontal and sagittal plane should bisect the ankle pyramid. The foot may be slightly inset, 1–12 mm, depending on the limb length. Short limb lengths are set with very little inset of 2–3 mm and longer limb lengths may tolerate a greater varus thrust of 10–12 mm. The longitudinal axis of the foot will be externally rotated approximately 5° by aligning the medial border of the foot with the line of progression.

Transfemoral Bench Alignment

Alignment at the transfemoral level should be consistent with the instructions provided by the manufacturer of the prosthetic knee in use.

Dynamic Alignment

The Element is flexible and conforms well to the ground. This characteristic may make the foot appear to be properly aligned after the static alignment. However, small adjustments in the alignment however will smooth the transition from heel to toe and optimize gait and efficiency. Patient feedback during this process is essential. In the dynamic alignment of the foot, the socket flexion angle, and heel stiffness are altered to achieve optimal alignment and patient gait.

- Check for smoothness of gait and ground contact during stance phase.
- If the heel is too soft, there may be delayed heel rollover from heel strike to midstance. Dorsiflexing the foot or moving the heel bumper anteriorly may resolve this issue.
- If the heel is too firm, heel rollover may be too rapid from heel strike to mid stance. Also, patient may complain of anterior distal pressure. Plantarflexing the foot or moving the heel bumper posteriorly may resolve this issue.

- If the anterior keel rollover progresses too quickly from midstance to toe loading, the patient may say that they are “walking up a hill.” Plantarflex the foot to provide more anterior support.
- If the anterior keel rollover hesitates from midstance to toe loading, the patient may say that they are “walking down a hill.” Dorsiflex the foot to increase the rate of rollover.

Bumper Replacement

If the heel bumper needs to be moved or replaced, it can be removed by application of heat and solvent **being sure not to allow any solvent to contact the Poron® pad that is between the pylon and foot plate**. The pylon should then be lightly sanded with 120 grit sandpaper to provide a good bonding surface. The bumper is then adhered to the carbon using cyanoacrylate instant adhesive (commonly referred to as “super glue”). The bumper **MUST NOT** be placed more anteriorly than the main foot bolt connecting the DuraShock unit. Contact Fillauer for the proper bumper for the foot size.

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

Consumable Components: Foot Shell and Spectra® Sock

The Element 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.

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 3) 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.

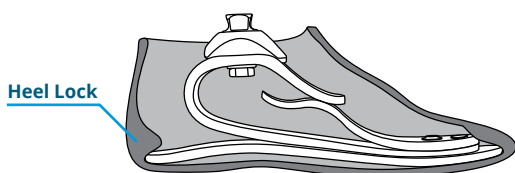


Figure 3

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 feet are appropriate for use with Fillauer or equal, ISO 10328 compliant, endoskeletal components. A Fillauer Spectra sock and foot shell 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 done 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 realistic appearance and maximum performance of the Element. 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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