

Element

Product Manual

Fillauer®

Instructions

The Element is designed to be maintenance free. The foot is water resistant; however, if the foot is submerged in water, the foot and foot shell should be rinsed with fresh water and dried immediately. The Element should be inspected every 6 months for signs of abnormal wear and that the attachment/alignment screws are secure.

US Patent 9,011,554

Instructions to the Practitioner

- Please review the indications, contraindications, and FAQ sections of the manual before use of the foot. These instructions should be read prior to fitting and followed to ensure the proper integration of the Element into the patient's prosthetic system.
- The foot stiffness is based on weight and activity level. Please provide accurate patient information so that the appropriate foot may be selected.

Product Specifications

Indications

- Moderate to Active BK or AK Amputees as defined by Functional K3 and K4 Levels
- Unilateral or Bilateral Patients
- Patients that would benefit from increased flexibility and smooth rollover
- Patients weighing up to 300 lbs. (136 kg)

Contraindications

- Build height below 3.75 in. (9.5 cm)
- Patients weighing over 300 lbs. (136 kg)

Product Specifications

- 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 – K4
- Durable; meets ISO-22675 standard

Warranty

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

The Element 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.

Satisfaction Guarantee

- 60 days from date of patient fitting

Installation

Product Description

The Element foot uses three carbon composite elements that comply, resist and store energy during gait. The Element foot's integrated pyramid is designed to be used with any pyramid receiver device (Figure 1). The pyramid is permanently attached to the composite spring and should not be removed.

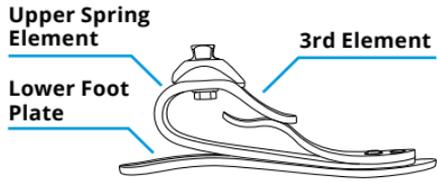


Figure 1

Static (Bench) Alignment

Standard bench alignment techniques can be used for the Element foot. Before aligning, the initial heel height should be established. The Element is designed for a 3/8 in. 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 in the proper amount of inset found in the evaluation. When using an integrated shuttle lock/distal attachment component, the plum line from the bisection of the socket at the proximal brim in the frontal and sagittal plane should bisect the ankle pyramid.

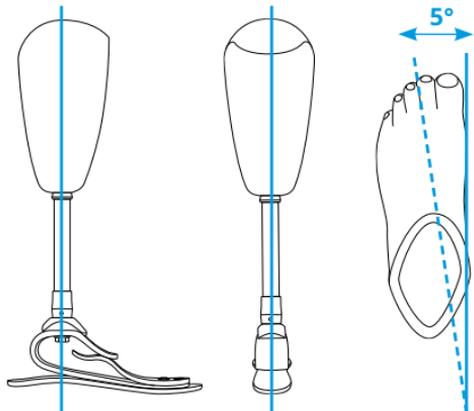


Figure 2

When using separate suspension and attachment components, 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 at 10 – 12 mm. The longitudinal axis of the foot will be outset approximately 5° by aligning the medial border of the foot with the line of progression (refer to Figure 2).

Transfemoral Bench Alignment

Standard TKA alignment can be utilized with the trochanter line bisecting the distal ankle. The knee is set 3-6mm posterior to the TKA line. A plum line may also be used from the proximal sagittal socket bisection, falling 10 mm anterior to the knee axis (or through the knee axis for an SNS unit) and the 10 – 15 mm posterior to the midfoot. The knee and foot should both be aligned with 5° of toe out and external rotation respectively. The socket should also be set in the proper adduction angle of 7 – 12° and the flexion angle should be 5° more than the hip flexion contracture if present (refer to Figure 2).

Dynamic Alignment

The Element foot is flexible and conforms well to the ground. This characteristic may mask forefoot loading anomalies during static alignment that may then become more noticeable during dynamic alignment. Small alignment changes will smooth the transition from heel to toe, and optimize gait. Patient feedback during this process is essential. Adjustments of the plantar and dorsi flexion angles will help the patient achieve a smooth transition from heel to toe. The pylon should remain vertical in the frontal plane throughout gait.

- Check for smoothness of gait and ground contact throughout the stance phase of gait.
- If the tibial progression is slowed from heel strike to midstance, or the heel compression is too great, dorsiflexion of foot may correct this problem.
- If the socket progresses rapidly forward from heel strike to midstance or the heel seems too hard, plantarflexion of the foot may solve this problem.
- If the foot progresses too quickly from midstance to toe loading, increased plantarflexion may solve this issue.

- If the foot hesitates from midstance to toe loading, dorsiflexion may be indicated.
- Check to make sure pylon is vertical throughout gait. If there is a medial lean, tighten proximal medial screw; if there is a lateral lean tighten proximal lateral screw

Maintenance

The Element is designed to be maintenance free. The Element foot is water resistant. However, if the foot is exposed to saltwater it is recommended that the foot and foot shell be rinsed with fresh water and dried soon after getting out of the water. The Element should be inspected every 6 months to ensure no damage has occurred and that the attachment/alignment screws are secure.

Securing the Foot After Alignment

The alignment of the Element foot is achieved by adjusting the 4 set screws in the pyramid receiver. After proper alignment is achieved and the patient is ready to leave the prosthetist's office, all set screws should be properly secured with Loctite® threadlocker and be tightened to the manufacturer's recommended torque specification. The alignment/attachment screws should be inspected every twelve months for signs of fatigue or corrosion and should also be re-tightened to the manufacturer's recommended torque specification at that time.

Foot Shell Installation and Removal

The Element foot features a unique foot shell that is flexible, durable and cosmetically

appealing. Using care in the installation and removal of the foot shell will allow it to maintain its appearance and durability.

NOTE: Never use a sharp edged tool such as a screwdriver to install or remove the foot shell.

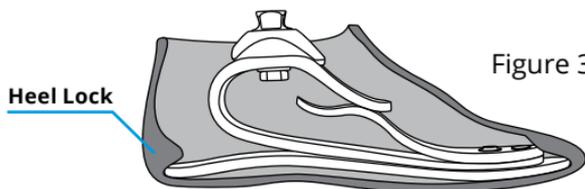


Figure 3

Installation

- Pull the Spectra sock provided onto the foot from toe to heel, pulling excess material to the ankle so that it does not bunch under the foot or get trapped between moving parts 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 foot shell up onto heel or if necessary insert shoehorn into foot shell and allow heel to slide down shoehorn into the heel lock.

IMPORTANT: The heel of the Lower Foot Plate must slide into the heel lock in the foot shell for proper alignment and to secure the foot in the foot shell (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 of foot shell at the heel and the heel plate should pop out of the lock allowing removal of the foot shell by hand.
- If foot shell is too tight, a smooth edged shoe horn may be used to disengage the heel lock.

Frequently Asked Questions

How long should the foot shell last?

The Element 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.

Can the pyramid be removed so that the foot can be bolted directly to the socket or other attachment?

No, the pyramid attachment should not be removed or altered in any way. Doing so will void the warranty and could put the patient at risk of injury.

Daily Care for the Patient

- Patients should clean the prosthetic foot shell with a soft cloth and a soap and water solution and should inspect the shell for the presence of sand or other debris weekly. The foot shell may also be cleaned with rubbing alcohol (70%). **Do not use acetone. It will damage the foot shell.**
- If the foot performance changes or if it makes noise, the patient should immediately contact his or her practitioner.

The logo for Fillauer, featuring the brand name in a blue, cursive script font with a registered trademark symbol.

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