Element DS

Product Manual

Fillauer®

Instructions

The Element DS 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 DS should be inspected every 6 months for signs of abnormal wear and that the attachment/alignment screws are secure.

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 DS 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 275 lbs. (125 kg)

Contraindications

- Build height below 6.5 in. (16.5 cm)
- Patients weighing over 275 lbs. (125 kg)

Product Specifications

- Patient weight: Up to 275 lbs. (125 kg)
- Foot weight: 6.5 in. 22.3 oz (632 g)
- Build height: 6.5 in. (16.5 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 DS 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 DS foot uses three carbon composite elements that comply, resist and store energy during gait. The Element DS foot's integrated DuraShock is designed to be used with any pyramid receiver device (Figure 1). The DuraShock unit is permanently attached to the composite spring and should not be removed.

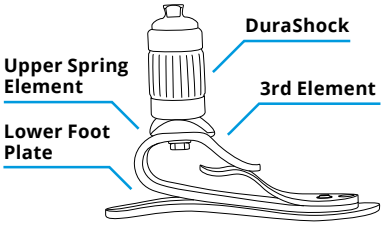

Figure 1

Static (Bench) Alignment

Standard bench alignment techniques can be used for the Element DS foot. Before aligning, the initial heel height should be established. The Element DS is designed for a ⅜ 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. 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).

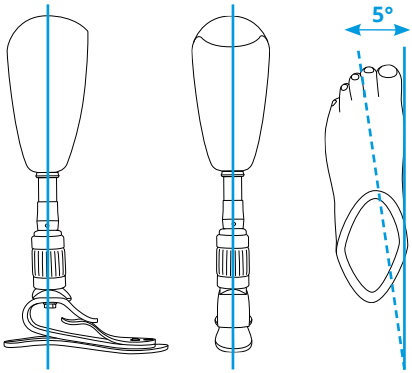

Figure 2

Transfemoral Bench Alignment

Standard TKA alignment can be utilized with the trochanter line bisecting the distal ankle. The knee is set 3 – 6 mm 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 DS 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

Special considerations for the DuraShock component of the Element DS

Due to the torsion in the DuraShock component of the Element DS, it is very important to establish the proper external rotation of the foot in relationship to the socket. If the foot rotates too far internally or externally it may feel unstable. Making an external rotation adjustment may enhance the stability of the forefoot and improve the rollover characteristics of the foot.

DuraShock Adjustment

A black “dampening ring” (clamp) is provided with the Element DS and is used to “fine tune” the performance of the unit. Tightening the dampening ring decreases the vertical shock and rotation by limiting the movement of the elastomer. The ring is placed around the elastomer section and tightened down by hand or with wide-jaw pliers such as channel locks. The more the dampening ring is tightened, the less rotation and vertical travel the unit will have. Placing the ring more proximal or distal will limit the shock absorption. Placing it in the center will limit both the shock and rotation. Ensure that the ring always has some tension on it to keep it from sliding off the shock. The dampening ring is released by sliding two grooved sections apart by pushing one side toward the foot and the other toward the socket.

Securing the Foot After Alignment

The alignment of the Element DS 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 DS 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 DS shell is designed to provide realistic appearance and maximum performance of the Element DS. 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.

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.

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