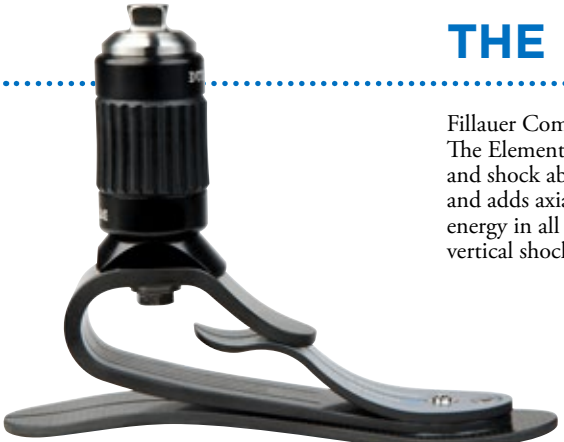
element DS
FOOT SYSTEM™

PRODUCT MANUAL

eMOTIS

patent pending



THE ELEMENT^{DS} FOOT SYSTEM

Fillauer Companies proudly introduces the latest addition to a line of innovative foot systems, Element^{DS}. The Element^{DS} combines the 3rd Element technology from the Element Foot System with the axial rotation and shock absorption of the DuraShock. Adding the DuraShock increases the vertical shock absorption and adds axial rotation. The elastomers and carbon components work in unison to absorb, store and return energy in all three planes. The result is the smoothest rollover from heel to toe and the added benefits of vertical shock absorption and axial rotation with a build height of 6.5”.

FEATURES AND BENEFITS

- Smooth rollover and superior stability
- Vertical shock and 60° of axial rotation
- Innovative Micro-Slice technology for multi-axial performance
- Adjustable heel wedge for fine tuning heel stiffness
- Maintenance free design
- Low profile design—6.5 in. build height
- Rated for patients up to 275 lbs (125 kg)
- Durable; meets the ISO-22675 test standard

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

- Weight Rating: 275 lbs (125 kg)
- Foot Sizes: 22-30 cm
- Heel Height: 3/8 in. (10 mm)
- Foot Height (in shell to base of pyramid): 6.5 in. (16.5 cm)
- Foot Weight (27cm): 22.3 oz (632 g)
- Attachment: Modular Pyramid

L-CODES

- L-5984 - All endoskeletal lower extremity prosthesis, axial rotation unit.
- L-5987 - All lower extremity prosthesis, shank foot system with vertical loading pylon.

Suggested L-Codes are provided as a reference only. It is the responsibility of the practitioner to confirm this information.

ELEMENT^{DS} FOOT SYSTEM - PART NO. 105-10-XX-XXXX

Kit includes: Element foot with Durashock unit attached, spectra sock, heel band, heel wedge and instructions. Foot selection is determined by foot size and patient weight. The foot model recommendations on the selection chart are based on average patients, engaged in normal activities. If your patient is much more active than average or is lifting heavy loads as part of their daily routine, then going up one weight category is advised.*

		22 cm	23 cm	24 cm	25 cm	26 cm	27 cm	28 cm	29 cm	30 cm
100-119 lbs	45-54 kg	22-A11R	23-A11R	24-A11R	25-A32R	26-A32R	NR	NR	NR	NR
120-139 lbs	54-63 kg	22-A11R	23-A11R	24-A11R	25-A32R	26-A32B	27-A43B	28-A43B	NR	NR
140-159 lbs	64-72 kg	22-A11R	23-A11R	24-A11R	25-A32B	26-A32B	27-A43B	28-A43K	29-C64K	30-C64K
160-179 lbs	73-81 kg	22-A22R	23-A22B	24-A22B	25-A43B	26-A43B	27-A43K	28-A43K	29-C64K	30-C64K
180-199 lbs	82-90 kg	22-A22B	23-A22B	24-A22B	25-B43B	26-B43K	27-B54K	28-B54K	29-C64K	30-C64K
200-224 lbs	91-102 kg	22-A32B	23-A32K	24-A32K	25-B53K	26-B53K	27-B54K	28-B54K	29-D75K	30-D75K
225-249 lbs	102-113 kg	NR	NR	NR	25-C54K	26-C54K	27-C65K	28-C65K	29-D75K	30-D75K
250-275 lbs	113-125 kg	NR	NR	NR	25-C64K	26-C64K	27-C65K	28-C65K	29-D75K	30-D75K

** If you are not sure which foot to select, please consult with one of our technical service representatives.*

MCV FOOT SHELL

XX XX 13 CC 3 Micro Coated Vinyl Foot Shell

Example: 45 24 13 13 3 = Left, Size 24, Color 13

To order, select the side (left or right) and foot length (24–30 cm) from the chart below. Then, choose the color (CC 03, 09, or 13).

	22 cm	23 cm	24 cm	25 cm	26 cm	27 cm	28 cm	29 cm	30 cm
Left	45 22	45 23	45 24	45 25	45 26	45 27	45 28	45 29	45 30
Right	46 22	46 23	46 24	46 25	46 26	46 27	46 28	46 29	46 30

Custom colors are available as a special order with three weeks lead time. Please contact Fillauer Customer Service for more details.

DAILY CARE AND MAINTENANCE

INSTRUCTIONS TO THE PRACTITIONER

- Please review the indications, contraindications and F.A.Q. sections of the manual before use of the foot. These instructions for use should be read and followed to ensure the proper integration of the Element^{DS} foot into the patient's prosthetic system.
- The foot model recommendations on the selection chart are based on average patients, engaged in normal activities. If your patient is much more active than average or is lifting heavy loads as part of their daily routine; going up one weight category is advised. If you are not sure which foot to select, please consult with one of our technical service representatives.

INSTRUCTIONS TO THE PATIENTS

- Patients should clean the prosthetic foot shell with a soft cloth and a soap and water solution weekly. The patient should also inspect the shell for the presence of sand or other debris weekly if the leg is not covered. The foot shell may also be cleaned with rubbing alcohol (70%). The foot shell should not be cleaned with acetone as this will damage the coating on the shell.
- If the foot performance changes or if it begins to make noise, the patient should contact his or her practitioner immediately to have the foot inspected.
- As with all prosthetic devices, the foot should be inspected every six months by a certified practitioner.

INSTALLATION

Deviating from the installation instructions or modifying the foot in any way will void any product warranty and could lead to product failure and injury to the patient.

1.0 - 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.

1.1 - Heel Wedge Installation

The heel stiffness and heel deflection of the Element^{DS} foot are affected by alignment and the position of the heel wedge. To install it in the initial position, slide the wedge into the split in the lower foot plate so that the small side is under the heel and the larger plastic side is on top of the lower foot plate. Some rubbing alcohol or talc will help the wedge slide

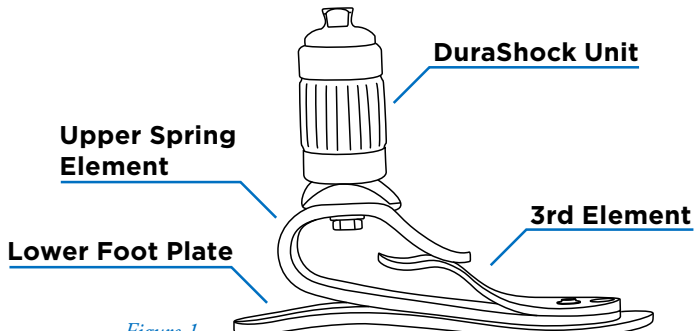
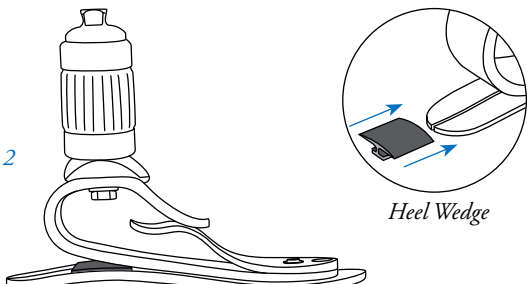


Figure 1

into position. Slide it forward so the front edge of the wedge is in contact with the upper spring element and lower foot plate creating a bumper between the two. This is the initial position for the wedge during set up and alignment as shown in Figure 2. Secure the wedge temporarily by securing the black band around the heel just behind the wedge.

Figure 2



2.0 - 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 3/8" 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.

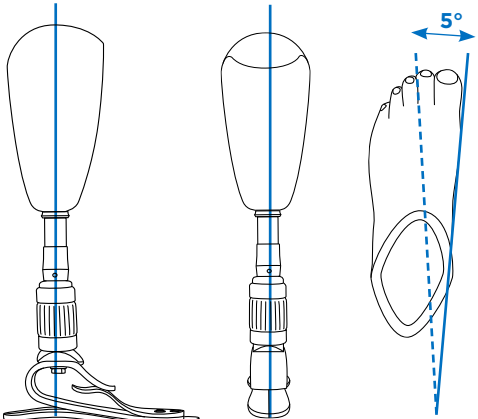


Figure 3

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 3).

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 3).

2.1 - 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 this does not, see Section 2.2 on changing the heel stiffness.
- 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 not, see Section 2.2 on changing the heel stiffness.
- 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.

Maintenance

The Element^{DS} is designed to be maintenance free. The DuraShock unit is sealed and does not require lubrication. The Element^{DS} foot is water resistant. However, if the foot and Durashock are exposed to saltwater it is recommend that the foot, foot shell and DuraShock unit be rinsed with fresh water and dried soon after getting out of the water. The Element^{DS} should be inspected every 6 months to ensure no damage has occurred and that the attachment/alignment screws are secure.

2.2 - Changing the Heel Stiffness

If the heel is too soft or the foot is slow to transition to midstance, moving the heel wedge (See Figure 2) forward may increase the heel firmness and smooth the transition from heel to midstance. This will speed up transition from heel to midstance. If the patient transitions too rapidly from midstance to forefoot, move the wedge posterior or plantar-flex the foot. If the heel is still too soft, then check the pylon angle and A/P position of the socket to ensure alignment has been established as described in section 2.0 above and correct if indicated. Generally, moving the socket more anterior will cause the heel to feel firmer and the toe to be softer.

2.3 - Securing the Heel Wedge

Before the patient leaves the office, the heel wedge should be glued into place. To do so, clean the wedge and heel plate with 70% isopropyl alcohol and place two drops of Superglue® on the bottom surface of the heel wedge and reinstall in the position determined as optimal in section 2.2.

2.4 - Changing the Toe Stiffness

The stiffness of the foot is driven by the combination of components used as well as the angle at which they are loaded. The heel stiffness and flexion angle will have an effect on the loading of the 3rd element and toe of the Element^{DS} foot. Increasing the heel stiffness with the heel wedge supplied will allow the foot to be dorsiflexed. This will increase the angle of loading and firmness in the forefoot while maintaining appropriate firmness in the heel.

2.5 - 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.

3.0 - 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.

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 4).

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.

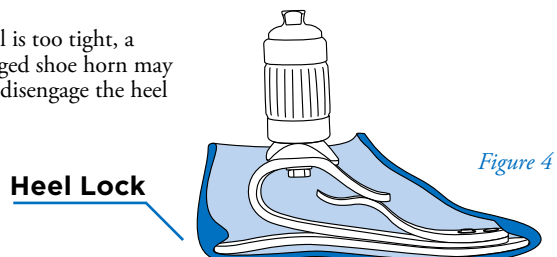


Figure 4

FREQUENTLY ASKED QUESTIONS

What can the practitioner do if the heel or toe is too soft or too firm?
The deflection load and rollover of the heel can be increased or decreased by changing the position of the heel wedge. In addition, the practitioner may choose to plantar or dorsiflex the forefoot to fine tune the heel and toe stiffness.

Should the practitioner "go up one category" to accommodate more active patients or heavy lifting load?
The Element^{DS} foot is designed for average patients that would be engaged in average activities. Higher activity levels and moderately high loads are accommodated within the foot design. However, if your patient is much more active than average or is lifting heavy loads as part of their daily routine; going up one category is advised.

How long should the foot shell last?
The foot shell is designed to provide realistic appearance and maximum performance of the Element^{DS} foot. While the warranty of the foot shell is six months, the life of the shell will depend on the actual level of activity and degree to which it is protected from wear and damage with socks and shoes.

Can the DuraShock unit be removed and pyramid attached?
No, the DuraShock should not be removed or altered in any way. Removing the DuraShock will void the warranty and could put the patient at risk of injury. Any repairs or modifications, if warranted, should be made by Fillauer LLC.

What is the material on top and bottom of the 3rd Element?
The 3rd Element is laminated with a special formulation of Polyethylene (PE) that is very durable and extremely wear resistant on the upper and lower surfaces.

What is the weight rating of the Element^{DS} Foot?
The Element^{DS} foot is rated for patients weighing up to 275lbs (125kg) using the new ISO-22675 standard. Element^{DS} feet are selected for a specific patient weight range. It is important to use the properly rated foot in order to ensure safety, durability and maximum performance. The individual components of the Element^{DS} foot: Upper Spring Element, Lower Foot Plate, 3rd Element spring and DuraShock unit are combined based on a patient's weight and their foot size.

What is the ISO-22675 Standard?
The ISO-22675:2006 Test Standard is the newest and most comprehensive standard for testing feet and ankle-feet devices. This standard simulates the dynamic loading conditions of stance phase of walking from heel strike to toe-off during two million (2,000,000) cycles. The standard also requires the foot to pass a static ultimate strength test in which the heel and forefoot are loaded to 1200 lbs (544kg). As required, these tests were performed on two different Element^{DS} feet. In passing this high standard, the Element^{DS} has established its strength and durability, ensuring outstanding performance and a long service life.

The DuraShock has a lot of rotation. Will the patient adapt to this function?
Yes, in most cases. Although, rotation in the lower extremity is natural, it is not a component of many prosthetic designs. The control of this range of motion may require a few days to master. After a week or so, most patients like it so much they find it hard to return to a limb without axial rotation.

Can the rotation and shock function be adjusted or fine tuned?
Yes, using the dampening ring you can fine-tune the performance of the device. See instructions under “Dampening Ring” in this manual.

Can Talc or baby powder be used to reduce noises in the foot and foot shell?
Never pour talc or baby powder directly into the foot shell or spectra sock to stop noises in the foot. It may contaminate the wear surface of the 3rd Element and cause it to squeak.

The foot is making noise. How can this be corrected?
The most often reported noise is snapping or popping as the foot rolls to midstance. This is may be caused by the heel wedge sticking and releasing from the spring elements. To correct the issue, remove the wedge and coat it with a small amount of talc. The wedge should then be secured in position with super glue as instructed in section 2.3. The foot should be cleaned with compressed air or a soft cloth and inspected for visible damage to the foot or debris in the foot shell. Also, insure that the spectra sock is free of holes, then reinstall in foot shell per instructions in section 3.0.

WARRANTY

- 36 Months from the date of shipment to the practitioner

  The Element[DS] Foot System 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.

- Foot Shell - 6 months from date of shipment to the practitioner

SATISFACTION GUARANTEE

- 30 days from the date of shipment to the practitioner

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