



PRODUCT MANUAL

eMOTIS



patent
pending



THE AERIS PERFORMANCE FOOT

The foundation of the Aeris Performance foot system is our successful Ibex foot. The Aeris Performance adds Compliant Composite Technology (CCT) that is derived by using multiple springs to increase the range of flexibility. The result is a unique Advanced Energy Release (AER) pylon design composed of nested parallel springs that enable the foot to react in a compliant manner at heel strike and then work together to create a dynamic transition from push-off to toe release. The AER pylon takes advantage of independent spring action to provide smooth, stable progression while increasing the axial rotation which minimizes the forces transmitted to the residual limb.

FEATURES AND BENEFITS

- Innovative Micro-Slice pylon for multi-axial function
- Compliant Composite Technology (CCT)
- Advanced Energy Release (AER) pylon
- Enhanced plantarflexion for stability at heel strike
- Improved axial rotation
- Designed for patients up to 275 lbs. (125 kg)
- Weight 520 grams
- Build height 6.75 in. (17 cm)
- Durable; meets ISO-22675 standard
- 3 year warranty/30 day patient trial
- 6 month foot shell warranty

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 greater energy return and multi-axial function
- Patients weighing up to 275 lbs. (125 kg)

CONTRAINDICATIONS

- Build height below 6.75 in. (17 cm)
- Patients weighing over 275 lbs. (125 kg)

PRODUCT SPECIFICATIONS

- Patient weight: 275 lbs. (125 kg)
- Foot sizes: 22-30 cm
- Heel height: 3/8 in. (10 mm)
- Foot height (in shell to base of pyramid): 6.75 in. (17.15 cm)
- Foot weight (27 cm): 18.35 oz. (520 g)
- Attachment: modular pyramid

L-CODES

- L5980* – All Lower Extremity Protheses, Flex Foot System
- L5986* – All Lower Extremity Protheses, Multi-Axial Rotation Unit (“MCP” or Equal)

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

AERIS PERFORMANCE - PART NO. 121-10-XX-XX

Kit includes: Foot, elastomer heel wedge, heel band, Spectra Sock, and instruction manual. Foot selection is determined by foot size and patient weight.

		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-A2	23-A2	24-A2	25-B4	26-B4	*	*	*	*
120-139 lbs	54-63 kg	22-A2	23-A2	24-A2	25-B4	26-B4	27-C5	28-C5	*	*
140-159 lbs	64-72 kg	22-B3	23-B3	24-B3	25-B5	26-B5	27-C5	28-C5	29-D6	30-D6
160-179 lbs	73-81 kg	22-B3	23-B3	24-B3	25-B5	26-B5	27-C6	28-C6	29-D6	30-D6
180-199 lbs	82-90 kg	22-B4	23-B4	24-B4	25-C6	26-C6	27-C6	28-C6	29-D7	30-D7
200-224 lbs	91-102 kg	22-B4	23-B4	24-B4	25-C6	26-C6	27-D7	28-D7	29-D7	30-D7
225-249 lbs	102-113 kg	NA	NA	NA	25-D7	26-D7	27-D7	28-D7	29-E8	30-E8
250-275 lbs	113-125 kg	NA	NA	NA	25-D7	26-D7	27-E8	28-E8	29-E8	30-E8

** Contact your distributor for recommendations.*

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

The Aeris Performance is designed to be maintenance free and comes with a Lycra sleeve around the mid-foot to prevent dirt and debris from lodging between the pylon springs. The sleeve should be replaced if it becomes worn. 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 soon after getting out of the water. The Aeris Performance should be inspected every 6 months to ensure no damage has occurred and that the attachment/alignment screws are secure.

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 Aeris Performance 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 PATIENT

- 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 and, if any problem, corrected.
- As with all prosthetic devices, the foot should be inspected every six months by a certified practitioner.

INSTALLATION

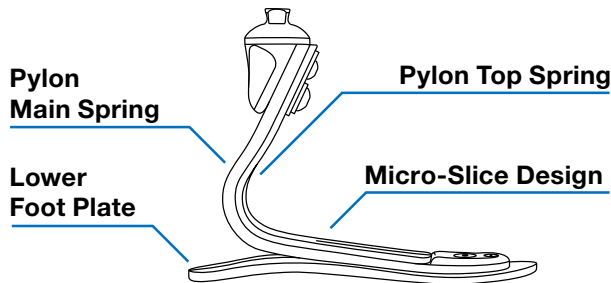
Deviating from the installation instructions or modifying the foot in any way will void any product warranty and could lead to product failure and injury to the patient.

1.0 - Product Description

The Aeris Performance foot uses two carbon composite elements that conform to terrain while storing and releasing energy during gait. The Aeris Performance foot is designed to be used with most pyramid receiver devices (Figure 1). The pyramid dome for the Aeris Performance foot is permanently attached to the pylon (main and top) spring and should not be removed.

1.1 - Heel Wedge Installation

The heel stiffness and heel deflection of the Aeris Performance 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



into position. Slide it forward so the front edge of the wedge is in contact with the pylon 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.

2.0 Static (Bench) Alignment

Standard bench alignment techniques may be used for the Aeris Performance foot. Before aligning, the initial heel height should be established. The Aeris Performance is designed for a $\frac{3}{8}$ 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.

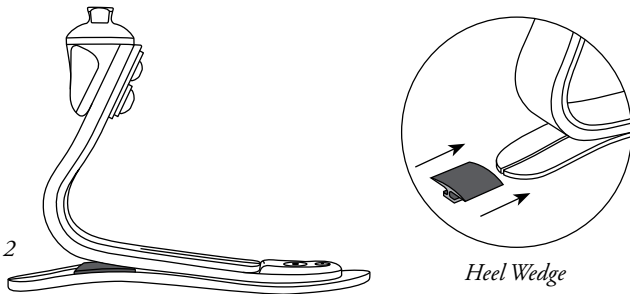


Figure 2

Heel Wedge

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.

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)

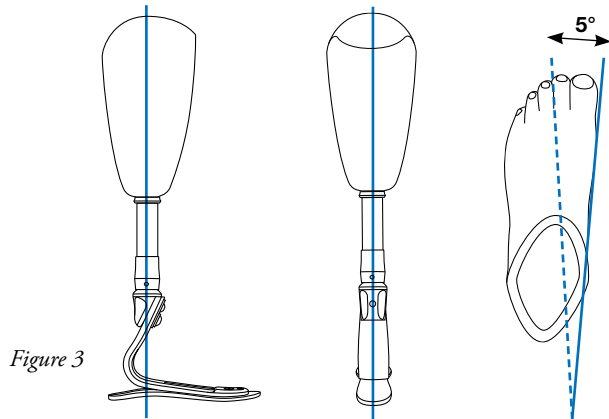


Figure 3

and the 10-15 mm posterior to the mid-foot. 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.

2.1 - Dynamic Alignment

The Aeris Performance foot is flexible and conforms to uneven terrain. 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 dorsiflexion 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 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 use of 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 the pylon is vertical throughout gait. If there is a medial lean, tighten the proximal medial screw; if there is a lateral lean, tighten the proximal lateral screw.

Special Considerations

Due to the torsion compliance of the Aeris Performance, 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 less stable to the patient. Making an external rotation adjustment during the dynamic alignment should fine-tune the stability of the forefoot and improve the rollover characteristics of the foot.

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 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 Wedge After Alignment

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

3.0 - Foot Shell Installation and Removal

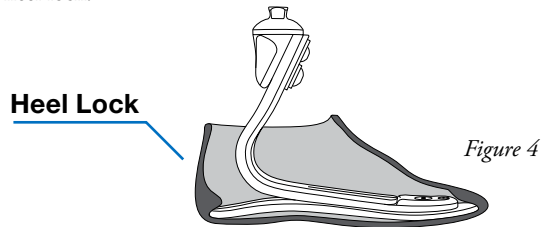
The Aeris Performance foot features a unique cosmetic foot shell that is flexible and durable. Use care in the installation and removal of the foot shell to maintain its appearance and durability. NOTE: Never use a sharp edged tool such as a screwdriver to install or remove the foot shell.

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 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.
- **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 portion of the foot shell at the heel and 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 shoe horn may be used to disengage the heel lock.



FREQUENTLY ASKED QUESTIONS

What is the weight rating of the Aeris Performance Foot?

The Aeris Performance foot is rated for patients weighing up to 275 lbs. (125 kg). The product was tested in accordance with the new ISO-22675 standard. Aeris Performance 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 Aeris Performance foot: pyramid, upper spring element, and lower foot plate are combined based on a patient's weight and their foot size.

Should the practitioner “go up one category” to accommodate more active patients or heavy lifting load?

The Aeris Performance foot is designed for an average patient 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.

What can the practitioner do if the heel or toe is too soft or too firm?

The deflection load and rollover of the heel may be increased or decreased by sliding the heel wedge anterior or posterior as discussed in section 2.2. In addition, the heel and toe rollover resistance may also be fine tuned during the dynamic alignment (section 2.1) by plantarflexing or dorsiflexing the forefoot.

What is the ISO-22675 Standard?

The ISO-22675:2006 Test Standard is the most comprehensive standard for testing feet and ankle-foot 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 1,200 lbs. (544 kg). As required, these tests were performed on two different Aeris Performance feet. In passing this high standard, the Aeris Performance has established its strength and durability, ensuring outstanding performance and a long service life.

Can the pyramid assembly be removed or altered?

No, the pyramid assembly should not be removed or altered in any way. Removing or altering the pyramid assembly will void the warranty and could put the patient at risk of injury. Any repairs or modifications, if required, should be made by Fillauer, LLC.

How long should the foot shell last?

The foot shell is designed to provide realistic appearance and maximum performance of the Aeris Performance 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.

The foot is making noise. How can this be corrected?

The most commonly reported noise is snapping or popping as the foot rolls to midstance. This may be corrected by removing the foot from the shell and adjusting the position of the heel wedge then reattaching it 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, ensure that the spectra sock is free of holes, then reinstall in foot shell per instructions in section 2.2.

Why is a Lycra sleeve used over the midfoot?

A Lycra sleeve is used to protect the foot. It prevents dirt and debris from lodging between the pylon springs. The sleeve should be replaced if it becomes worn or torn.

WARRANTY

- 36 months from the date of shipment to the practitioner

The Aeris Performance 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



Fillauer LLC

Worldwide distributor
2710 Amnicola Hwy.
Chattanooga, TN 37406
800.251.6398
423.624.0946
Fax 423.629.7936
www.fillauer.com

Centri®

Kung Hans Väg 2
192 68 Sollentuna, Sweden
+46 8 505 332 00
Fax +46 8 505 332 05
www.centri.se