



WAVE SPORT

from Fillauer LLC

**PRODUCT
MANUAL**

Fillauer
COMPANIES

THE WAVE SPORT FOOT SYSTEM

From extreme sports to light jogging, the Wave Sport has the performance active amputees desire. The Wave foot design uses an innovative wave spring between the pylon and heel plate to provide shock absorption and stability. The full heel plate allows it to be used in a foot shell and worn with standard athletic shoes. This makes the Wave Sport a more versatile, high performance alternative to single bladed running feet.

FEATURES AND BENEFITS

- Unique Wave-Spring heel technology
- Designed for foot shell and most athletic shoes
- Excellent shock absorption
- Full length heel for greater stability and dynamics
- “C-shaped” composite pylon for maximum energy return
- Custom built for each patient
- Choice of adapters for optimum alignment: 36 mm threaded adapter, dual 4-hole plate, posterior, or pyramid adapter
- Modular adapters for easy alignment
- Light weight carbon composite construction
- Accommodates a wide range of activity levels
- Durable; meets the ISO-22675 test standard

INDICATIONS

- Moderate to very high activity BK or AK amputees as defined by functional K3–K4 levels
- Unilateral or bilateral patients
- Patients that would benefit from greater energy return and faster cadence speeds
- Patients weighing up to 275 lbs. (125 kg)

CONTRAINDICATIONS

- Build height below 4.0 in. (10 cm)
- Patients weighing over 275 lbs. (125 kg)

PRODUCT SPECIFICATIONS

- Standard build height: 9.5 in. (24 cm)
- Low profile build height: 4.0 in. (10 cm)
- Rated for patients up to 275 lbs.
- Weight: 1.2 lbs. (550 g) for size 27 cm
- Moderate to very high activity levels

L-CODES

L5987* 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 and/or patient care facility submitting this claim to determine and submit the correct coding within all established rules and guidelines.**

WARRANTY

- 24 months from date of patient fitting





The Wave Sport 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 (sold separately) - 6 months from date of patient fitting

SATISFACTION GUARANTEE





- 30 days from date of patient fitting

ORDERING INFORMATION

Pylon Adapter	Product Number	Pylon Height*	Size Range	Build Height
 <p>4-Hole Plate</p>	127-10-XX-XXXL	Low Profile	25–30 cm	8.5 in. (22 cm)
	127-10-XX-XXXS	Standard Height	22–24 cm	9 in. (23 cm)
	127-10-XX-XXXS	Standard Height	25–30 cm	10 in. (25 cm)
 <p>36 mm Threaded</p>	129-10-XX-XXXL	Low Profile	25–30 cm	8.5 in. (22 cm)
	129-10-XX-XXXS	Standard Height	22–24 cm	9 in. (23 cm)
	129-10-XX-XXXS	Standard Height	25–30 cm	10 in. (25 cm)
 <p>Direct Mount Pyramid</p>	129-12-XX-XXXL	Low Profile	25–30 cm	7.75 in. (20 cm)
	129-12-XX-XXXS	Standard Height	22–24 cm	8.25 in. (21 cm)
	129-12-XX-XXXS	Standard Height	25–30 cm	9.25 in. (23 cm)
 <p>Wave Sport V3**</p>	128-10-XX-XXXS	Standard Height	25–30 cm	4 in. (10 cm)

* Contact your distributor for recommendations.

** Socket and socket mount not included

4-Hole Adapters (sold separately)		36 mm Threaded Adapters (sold separately)	
 <p>60254 Hosmer Ti Pyramid</p>	 <p>60293 Pyramid Receiver</p>	 <p>129-40-4000 Ti Pyramid with 36 mm Thread</p>	 <p>12-40-4010 Ti Receiver with 36 mm Thread</p>

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).

	24 cm	25 cm	26 cm	27 cm	28 cm	29 cm	30 cm
Left	45 24	45 25	45 26	45 27	45 28	45 29	45 30
Right	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 Wave Sport 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 Wave Sport is a high performance foot and should be inspected every 3–4 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 Wave Sport foot 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.

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. The foot shell may also be cleaned with rubbing alcohol (70%). Acetone will damage the coating on the shell.
- If the foot performance changes or if it makes noise, the patient should immediately contact his or her 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 Wave Sport foot uses deflection from three carbon springs to give excellent energy return and shock absorption throughout the gait cycle. The large C-spring provides the energy return expected from a running foot while the wave spring and foot plate give excellent shock absorption at heel strike and energy return at mid-stance. The design of the Wave Sport foot allows the user to wear a standard foot shell which can in turn be used with activity appropriate footwear. The foot comes with several proximal designs and adapters for easy attachment to any socket shape and length.

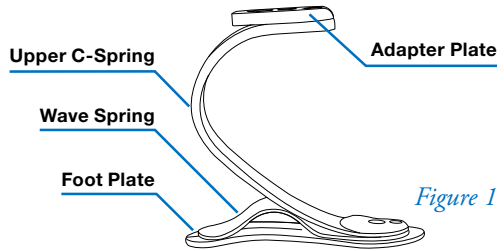


Figure 1

2.0 - STATIC ALIGNMENT - SAGITTAL PLANE

Before aligning, the initial heel height should be established. The Wave Sport employs a unique alignment with the interface at neutral and a 1 cm (3/8 in.) spacer under the forefoot to preload the anterior keel.

2.1 - TRANSTIBIAL FRONTAL PLANE ALIGNMENT

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 2). Most runners prefer a wider base of support with the foot slightly lateral to the distal bisection 7–13 mm. The longitudinal axis of the foot will be externally rotated approximately 5–8° by aligning the medial border of the foot with the line of progression (Figure 3).

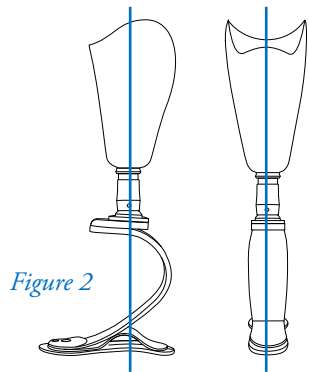
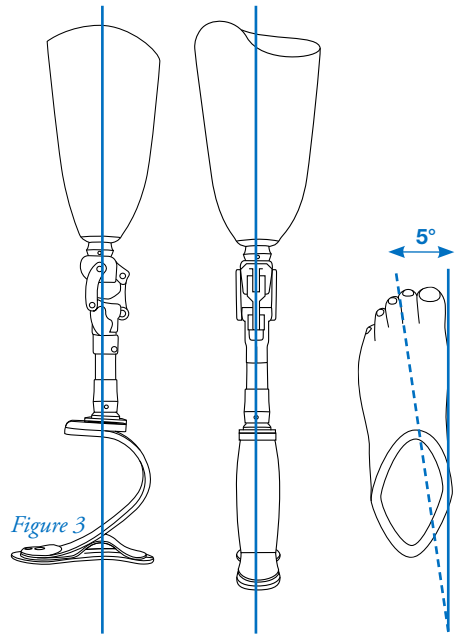


Figure 2

2.2 - TRANSFEMORAL STATIC BENCH ALIGNMENT

Standard TKA alignment can be utilized with the trochanter line bisecting the distal ankle. The knee center is set 3–6 mm posterior to the TKA line. Another alignment option is use a 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 (Figure 3). The knee and foot should both be aligned with 5° of toe out and external rotation respectively (Figure 3). The socket should also be set in the proper adduction angle and the flexion angle should be 5° more than the hip flexion contracture if present.



2.3 - DYNAMIC ALIGNMENT

The Wave Sport foot is a high performance foot intended for higher cadence speeds from slow jogging to running. As a result, it is important to align the prosthesis so that the anterior keel is loaded sufficiently to provide dynamic response late in stance. Some compression of the C-spring is desirable for optimal performance and foot deflection may be more noticeable during dynamic alignment. For a dedicated running or sport leg, ½ in. (12 mm) additional height accommodates for spring deflection during high activity. 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/dorsiflexion angles will help the patient achieve a smooth transition from heel to toe.

- Check for smoothness of gait and ground contact throughout the stance phase of gait.
- If the heel rollover is delayed 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 heel rollover is too rapid from heel strike to midstance, or the heel is too hard, plantarflexion of the foot may solve this problem. If not, see Section 2.2 on use of the heel stiffness.

- If the heel rollover is too rapid from heel strike to midstance to toe loading, increased plantarflexion may be required.
- If the heel rollover from midstance to toe loading is delayed, dorsiflexion may be indicated.
- Check to make sure pylon is vertical in the frontal plane throughout gait. If there is a medial lean, tighten proximal medial screw; if there is a lateral lean tighten proximal lateral screw.

SPECIAL CONSIDERATIONS

If there is a lack of anterior support during high activity, then drop-off may occur. This is potentially dangerous especially for transfemoral patients. Often a stiffer keel is indicated.

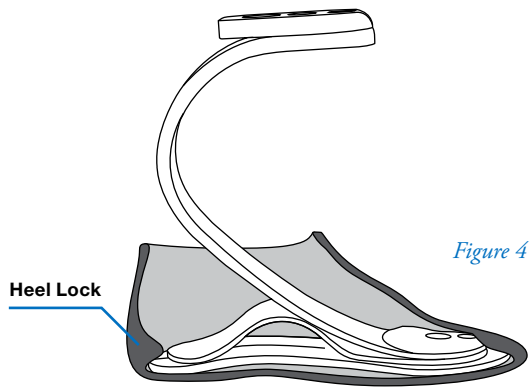
3.0 - FOOT SHELL INSTALLATION AND REMOVAL

The Wave Sport 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 tightly onto the foot, pulling excess material proximally to the ankle to eliminate wrinkling.
- 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 over the 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 a flat surface so that the heel is hanging over the edge.
- 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 foot shell is too tight, a smooth edged shoehorn may be used to disengage the heel lock.

3.1 - USE WITHOUT A FOOT SHELL

The foot may be used without a foot shell; however some type of protective covering must be used to protect the composite blades from abrasion and high impact. A durable sole material must be permanently bonded, using Master® or similar contact cement, to the plantar surface of the foot to provide the necessary traction and protection. Any foreign materials or grit must be routinely cleaned away to prevent excessive wear.

FREQUENTLY ASKED QUESTIONS

WHAT IS THE WEIGHT RATING OF THE WAVE SPORT FOOT?

The Wave Sport foot is rated for patients weighing up to 275 lbs. (125kg) The products were tested in accordance with the ISO-22675 standard. Wave Sport 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 Wave Sport foot: Upper “C” Spring, Wave spring, and Foot Plate are combined based on a patient’s weight and their foot size.

WHAT CAN THE PRACTITIONER DO IF THE HEEL OR TOE IS TOO SOFT OR TOO FIRM?

The heel and toe rollover resistance may also be fine-tuned during the dynamic alignment (section 2.3) by plantarflexing or dorsiflexing the forefoot.

CAN THE PROXIMAL ADAPTER PLATE BE REMOVED OR ALTERED?

No, the adapter plate 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 Wave Sport 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 FOOT BE WORN WITHOUT A FOOT SHELL?

Yes, but the plantar surface of the foot must be permanently covered with a protective sole material as discussed in section 3.1.

WHAT IS CONSIDERED NORMAL WEAR?

As the foot is used, some wear may be observed between the sliding composite springs. This may be especially noticeable where the wave spring contacts the foot plate. Special polymer coatings are used on the external wear surfaces to prevent excessive wear and prevent noise from occurring.

THE FOOT IS MAKING NOISE. HOW CAN THIS BE CORRECTED?

Noise can emanate from the wave spring contacting the upper c-spring as the foot rolls to midstance. This may be corrected by adding a leather pad to the contact area.

The causes of other noises should be investigated by removing the foot from the foot shell. If necessary, the foot should be cleaned with compressed air or a soft cloth. The foot shell should also be inspected for visible damage or debris periodically. Also, insure that the spectra sock is free of holes, then reinstall in foot shell per instructions in section 3.0.



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