

A white line drawing of a motion foot assembly is positioned on the left side of the cover. It features a cylindrical top section with a flange, a central vertical shaft, and a rectangular plate below it. The plate is mounted on a curved base with two circular components. The drawing is rendered in a clean, technical style.

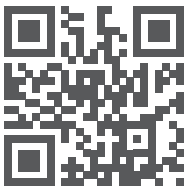
Motion Foot SLX

Product Manual

Fillauer[®]

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Intended Use

The Motion Foot® SLX hydraulic prosthetic foot is intended for use in lower extremity prostheses. The Motion Foot SLX sets itself apart by combining a two-spring prosthetic foot design with a hydraulic mechanism that allows for plantar and dorsiflexion range of motion. Fillauer has designed the Motion Foot SLX to support each phase of foot function in the gait cycle—from heel strike, to mid-stance, to toe off. The result is a foot that adapts well to sloped conditions, creating early stance phase stability with solid energy return. This provides unsurpassed smoothness, stability, and performance from initial contact, to mid-stance, to terminal stance.

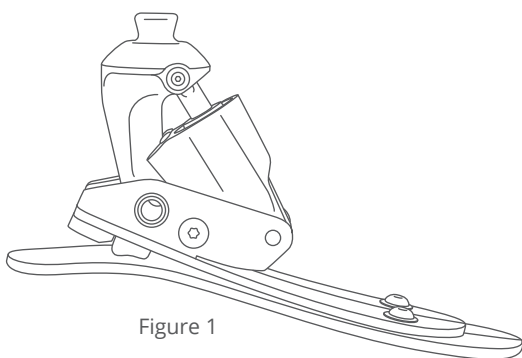


Figure 1

Indications

- Moderate to active transtibial or transfemoral amputees as defined by functional K3 activity levels
- Unilateral or bilateral patients
- Patients that would benefit from increased flexibility and smooth rollover
- Patients weighing up to 275 lbs. (125 kg)

Contraindications

- Clearance below 4.08 in. (10.36 cm)
- Patients weighing over 275 lbs. (125 kg)
- Patients wanting to run or jog regularly on the device

The device is intended for single patient use only.

Performance Characteristics

- Patient weight: Up to 275 lbs. (125 kg)
- Foot weight: 22.7 oz. (645 g)
- Build height: 4.08 in. (10.36 cm)

- Range of motion: 17 degrees total, 14 degrees plantarflexion and 3 degrees dorsiflexion (hydraulic unit alone)
- Functional level: K3
- Durable; meets ISO-10328 standard
- Primary Materials: Carbon composite, stainless steel, titanium, and aluminum
- Waterproof: The foot unit is waterproof to 1 meter. See additional information below.

Storage and Handling

It is recommended that prosthetic feet are stored between -5 – 50 °C in a clean, dry environment away from harsh chemicals (chlorine, acids, acetone, etc.).

Warnings and Precautions



CAUTION: Do not exceed the specified weight limit



CAUTION: All fasteners must have thread locker applied and must be torqued according to the manufacturer's instructions prior to final delivery.



CAUTION: The Motion Foot SLX is designed to be maintenance free and should not be disassembled. The hydraulic unit on the foot is permanently attached to the main and top spring and should not be removed.



CAUTION: For patient safety and device compatibility, only Fillauer or equal, ISO 10328 compliant, pyramid receivers should be used with this foot.



CAUTION: Abnormal or improper environmental conditions will lead to malfunctioning and damage of the prosthesis and is not covered under the warranty of the device. This prosthetic/orthotic component must not be subjected to dust/debris, liquids other than fresh water, abrasives, vibration, activities which would damage the biological limb, or extreme temperatures (< -5 °C or > 50 °C). Do not allow debris or liquids to remain in the prosthesis and its components during use. Rinse the foot with fresh water and dry immediately after exposure.



CAUTION: The foot unit is waterproof to 1 meter; however, if the foot is submerged, the foot and foot shell should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris. The foot shell and sock will experience significant deterioration if not allowed to fully dry before return to normal use and are not covered under warranty for this failure.



NOTICE: Fillauer has tested (ISO 10328) and recommends the use of standard adult endoskeletal components from Fillauer together. Components from other manufacturers may or may not be compatible. Failure due to use of other manufacturers' products is not covered under warranty.



NOTICE: The foot should be inspected by the clinician every 6 months for signs of abnormal wear and to assure that the attachment/alignment screws are secure.



NOTICE: The foot stiffness is based on weight and activity level. Please provide accurate patient information so that the appropriate foot may be selected.



NOTICE: Attachment, alignment, and delivery of the foot must be performed by or under the direct supervision of a qualified prosthetist. Any adjustment or modifications should be done by the clinician and not by the user.



NOTICE: If any serious incidents occur in relation to the usage of the device, contact your Fillauer Representative and the competent authority in your country.



NOTICE: Avoid carrying loads over 50 lbs. (22.6 kg). Lifting heavy objects could put the wearer above the limits of the carbon spring elements causing failure.



NOTICE: The patient's weight should be regularly monitored. Extra weight could exceed the weight/activity category and a new configuration would be necessary. Contact Fillauer with concerns.

Alignment (Specifications & Preparations Before Use)

Proximal Attachment

Attachment of the foot may be achieved via the proximal pyramid to any ISO 10328 compliant, Fillauer or equal, standard adult pyramid receiver. Torque all set screws to the setting specified by the manufacturer of the pyramid receiver. For Fillauer components, this is 15 N·m. Proper thread locker must be used for final delivery per the component manufacturer's specifications.

Static and Bench Alignment

Standard bench alignment techniques may be used for the Motion Foot SLX foot (Figure 2). Before aligning, the initial heel height should be established. The Motion Foot SLX 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.

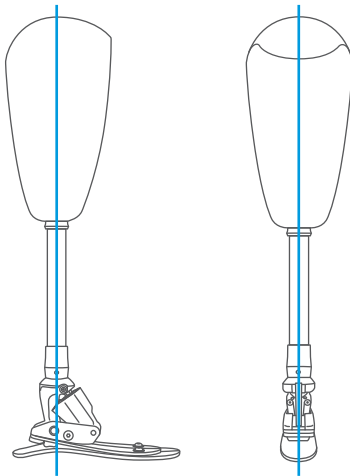


Figure 2

Transtibial Bench Alignment

The foot should be set in the proper amount of inset found in the evaluation. 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 externally rotated approximately 5° by aligning the medial border of the foot with the line of progression.

Transtibial	Transfemoral
Bisect the socket in the sagittal plane	Follow knee manufacturer's guidelines for bench alignment
5° of socket flexion, plus any flexion contracture	
A plum-bob or laser line should bisect the socket and fall through the junction of the posterior and middle thirds of the foot.	
5° of toe out	
Use the heel height of the patient's shoe or an equivalent heel wedge.	

Transtibial Static Alignment

Static alignment should always be done inside the parallel bars. They will sense hydraulic movement of the ankle, but should not feel like they are falling forward or backward. Use alignment to position the foot where they feel most balanced.

Symptom	Alignment Change
Falling backward	Shift the foot posterior relative to the socket
Falling forward	Shift the foot anterior relative to the socket

Transfemoral Bench Alignment

Alignment at the transfemoral level should be consistent with the instructions provided by the manufacturer of the prosthetic knee in use.

Dynamic Alignment

The Motion Foot SLX hydraulic Range of motion allows it to conform well to the ground. This characteristic may make the foot appear to be properly aligned after the static alignment. Small adjustments in the alignment however will smooth the transition from heel to toe, optimize gait and efficiency. Patient feedback during this process is essential. In the dynamic alignment of the foot, the socket flexion angle and heel stiffness are altered to achieve optimal alignment and patient gait.

Desired Result	Valve Adjustment
Firmer Plantarflexion	Turn the left valve clockwise (more resistance)
Softer Plantarflexion	Turn the left valve counterclockwise (less resistance)
Firmer Dorsiflexion	Turn the right valve clockwise (more resistance)
Softer Dorsiflexion	Turn the right valve counterclockwise (less resistance)

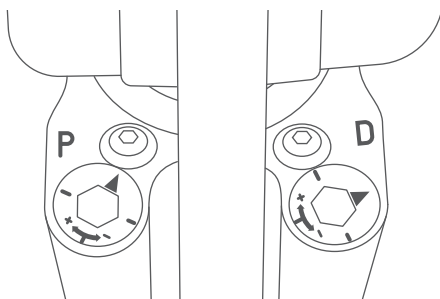
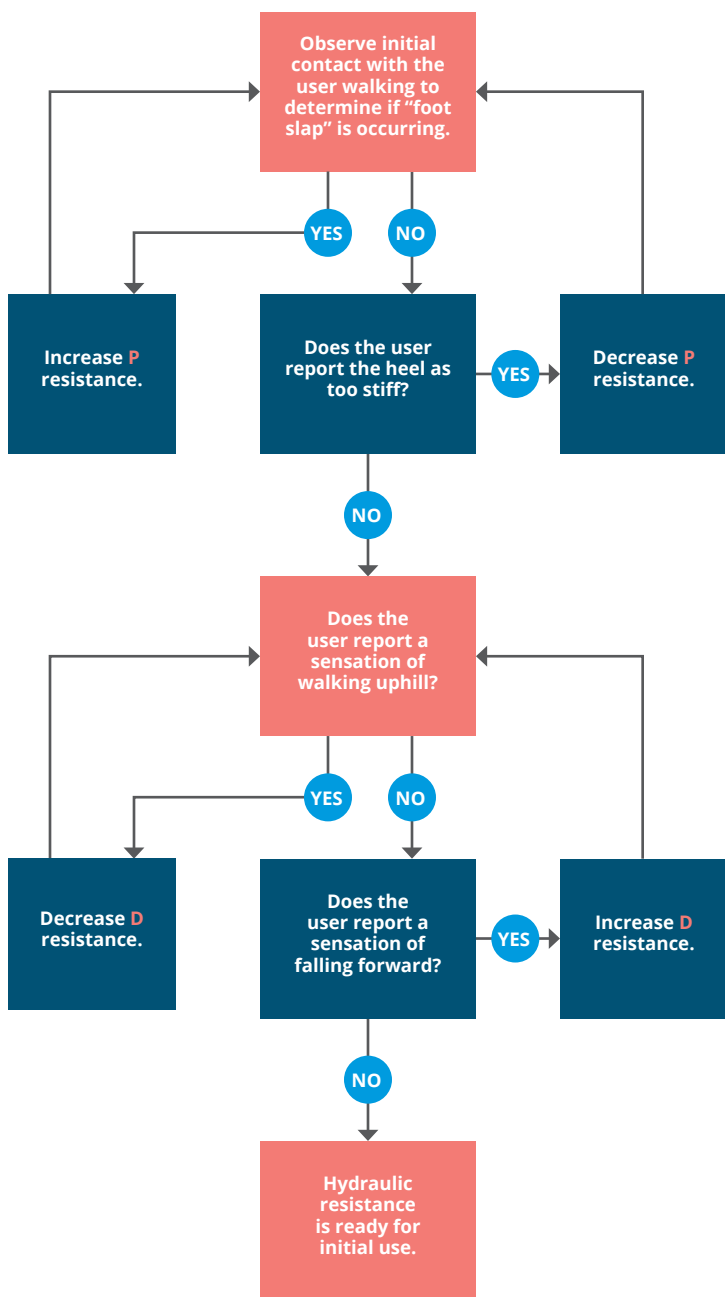


Figure 3

- The valve to adjust plantarflexion will always be on your left and the valve to adjust dorsiflexion will be on your right regardless of side of amputation.
- Out of the box, the valve for each is completely open.
- Plantarflexion resistance affects the user's gait from initial contact to loading response.
- Dorsiflexion resistance affects the user's gait through midstance as the body travels over the foot.

Motion Foot SLX Dynamic Alignment Procedure



Please walk the tester at least 100 meters before finalizing the hydraulic resistance settings to stabilize the hydraulic fluid viscosity.

- Check for smoothness of gait and ground contact during stance phase.
- If the heel is too soft, there may be delayed heel rollover from heel strike to midstance. Dorsiflexing the foot or increasing plantarflexion resistance may solve this issue.
- If the heel is too firm, heel rollover may be too rapid from heel strike to mid stance. Also, patient may complain of anterior distal pressure. Plantarflexing the foot or decreasing plantarflexion resistance may solve this issue.
- If the anterior keel rollover progresses too quickly from midstance to toe loading, the patient may say that they are “walking down a hill.” Plantarflex the foot to or increase dorsiflexion resistance provide more anterior support.
- If the anterior keel rollover hesitates from midstance to toe loading, the patient may say that they are “walking up a hill.” Dorsiflex the foot or decrease dorsiflexion resistance to increase the rate of rollover.

If a smooth stance phase of gait cannot be achieved, contact Fillauer for additional assistance.

Foot Shell and Prosthetic Sock (Consumable Components)

The Motion Foot SLX uses a unique cosmetic foot shell that is flexible and durable (sold separately). Use care in the installation and removal of the foot shell to maintain its appearance and durability. Always use the shell with an internal prosthetic sock. Never use a sharp-edged tool such as a screwdriver to install or remove the foot shell.

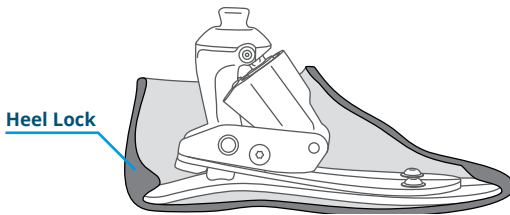


Figure 4

Installation

- Pull the prosthetic sock 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. The heel must lock (Figure 4) in place for proper function and safety.
- The prosthetic sock should be inspected and replaced if needed every 3-6 months by the prosthetist. The plantar surface of the foot should be inspected at this time and if there is excessive wear of the protective soling, it should be replaced.
- The foot shell should be inspected daily by the user and replaced by the clinician when tears or breaks are evident in the surface of the shell.

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 shoehorn may be used to disengage the heel lock.

Compatibility

Fillauer feet are appropriate for use with Fillauer or equal, ISO 10328 compliant, Endoskeletal components. A Fillauer prosthetic sock and foot shell should be used with this device, the fit of other manufacturers shells cannot be guaranteed.

Disposal / Waste Handling

The product must be disposed of in accordance with applicable local laws and regulations. If the product has been exposed to bacteria or other infectious agents, it must be disposed of in accordance with applicable laws and regulations for the handling of contaminated material.

All metal components may be removed and recycled at the appropriate recycling facility.

Warranty

- 36 months from date of patient fitting against manufacturer defects.
- Foot Shell (sold separately) — 6 months from date of patient fitting.

User Instructions

The providing health care professional must review the following information directly with the user.

Care and Maintenance



WARNING: If the foot performance changes or it begins to make noise, the patient should immediately contact his or her practitioner. **This may be as sign of a failure of the foot or other part of the prosthesis that could result in a fall or other serious injury.**



CAUTION: The foot should be inspected by the clinician every 6 months for signs of abnormal wear and to assure that the attachment/alignment screws are secure.



CAUTION: Attachment, alignment, and delivery of the foot must be performed by or under the direct supervision of a qualified prosthetist. Any adjustment or modifications should be done by the clinician and not by the user.



CAUTION: The foot is waterproof to 1 meter; however, if the foot is submerged, the foot and foot shell should be rinsed with fresh water and dried immediately to remove salt, chlorine, or debris.



CAUTION: The foot shell is designed to provide realistic appearance and maximum performance of the Motion Foot SLX. 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. Socks and shoes should be worn at all times and should be allowed to dry fully after exposure to water to prevent damage to the shell.



CAUTION: Patients should inspect the shell daily for signs of cracks or holes and for the presence of sand or other debris. If the foot shell shows signs of failure, it should be replaced as soon as possible to prevent damage to the carbon fiber and soling materials. If debris is present, the foot and shell should be rinsed and allowed to fully dry.



CAUTION: The foot shell may also be cleaned soft cloth and a soap and water solution or with rubbing alcohol (70%). Do not use acetone. It will damage the foot shell.

Serious Incidents

In the unlikely event a serious incident occurs in relation to the use of the device, users should seek immediate medical help and contact their prosthetist, local competent authority and Fillauer at the earliest possible convenience. Clinicians should at any time contact their local Fillauer representative and local competent authority immediately in the event of any device failure.

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