

A white line drawing of a Traverse AV machine, showing its top and side profile. It has a cylindrical tank at the back, a sloped body with various ports and a handle, and a long, flat base with several circular features. The drawing is set against a dark blue background.

Traverse AV

Product Manual

Fillauer®

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Performance Characteristics

- Patient weight: Up to 276 lbs. (125 kg)
- Foot weight: 28.5 oz. (809 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). Note that this depends on how the foot is aligned.
- Functional level: K3
- Durable; meets ISO-10328 standard
- IP67 rated dust and water resistance
- Primary Materials: Carbon composite, stainless steel, titanium, and aluminum

Intended Use

The Traverse AV hydraulic prosthetic foot sets itself apart by combining a two-spring plate design with a novel hydraulic mechanism that locks the foot at foot flat. The locking feature allows for automatic slope adaptation and provides greater energy storage and return than standard hydraulic prosthetic feet. It is designed to support each phase of foot function in the gait cycle—from heel strike, to mid-stance, to toe off. It actively toe-lifts during the swing phase which gives the user additional ground clearance to reduce trips and falls. The result is a foot that adapts well to sloped conditions, creating early stance phase stability with high energy return. This provides unsurpassed smoothness, stability, and performance from initial contact, to mid-stance, to terminal stance.

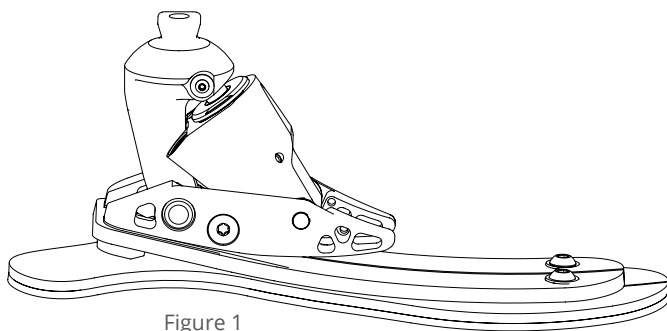


Figure 1

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 stability, high energy return, and smooth rollover
- Patients weighing up to 276 lbs. (125 kg)

Contraindications

- Clearance below 4.08 in. (10.36 cm)
- Patients weighing over 276 lbs. (125 kg)
- Patients wanting to run or jog regularly on the device
- Not indicated for patients with Ottobock Genium knees

The device is intended for single patient use only.

Storage and Handling

It is recommended that prosthetic feet are stored between -5 to 40 °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 Traverse AV is designed to be maintenance free and should not be disassembled. The hydraulic unit on the foot is permanently attached to the main body of the device 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 should not be subjected to chemicals, abrasives, vibration, activities which would damage the biological limb, excessively dirty environments, or extreme temperatures (< -5 °C or > 40 °C). Do not allow debris or liquids to remain on the prosthesis and its components for long periods of time. Rinse the foot with fresh water and dry immediately after exposure.



CAUTION: The foot unit is waterproof to 1 meter. If the foot is submerged, the foot and foot shell should be rinsed with fresh water and dried immediately. 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.



NOTICE: Fillauer has tested (ISO 10328) and recommends the use of standard adult prosthetic components from Fillauer with this product. 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: Foot stiffness is determined by the patient's weight, activity level, and foot size. Please provide accurate patient information to ensure the correct foot is selected.



NOTICE: Attachment, alignment, and user 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, seek medical help and contact your prosthetist and local competent authority at the earliest possible convenience.



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 Traverse AV foot (Figure 2). Before aligning, the initial heel height should be established. The Traverse AV 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.

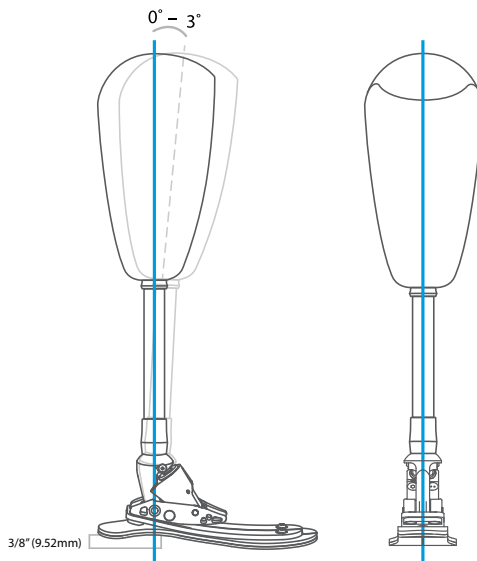


Figure 2

Transtibial Bench Alignment

The foot should be set in the proper amount of inset found in the evaluation. 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
Use the heel height of the patient's shoe or an equivalent heel wedge.	
Bisect the socket at the posterior trimline. It should fall through the lower ankle axis as seen in figure 2.	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 at the posterior trimline and fall through the junction of the posterior and middle thirds of the foot.	
5° of toe out	

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 Traverse AV 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 to 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)

- The valve has a total of 270 degrees of adjustment.. It may be wise to fully close the valve and incrementally open it for setup.

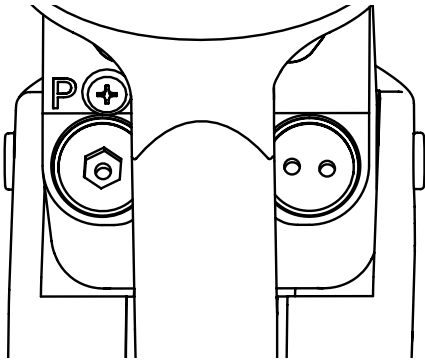
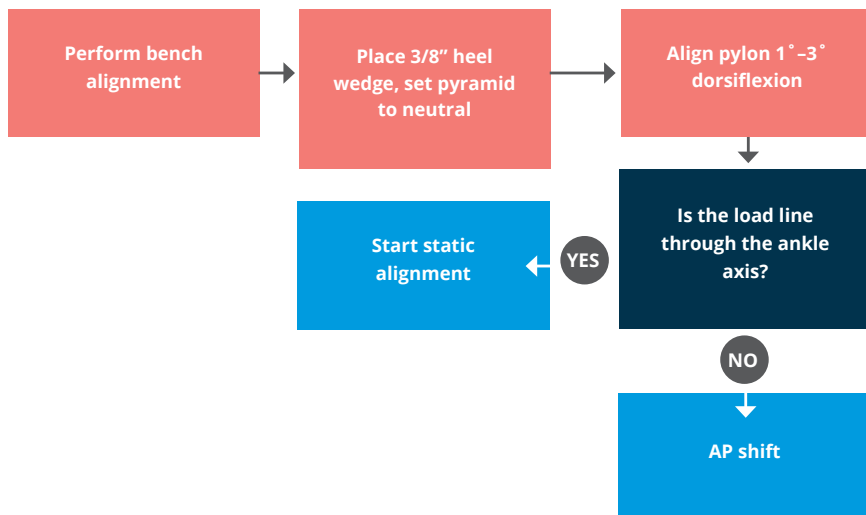


Figure 3

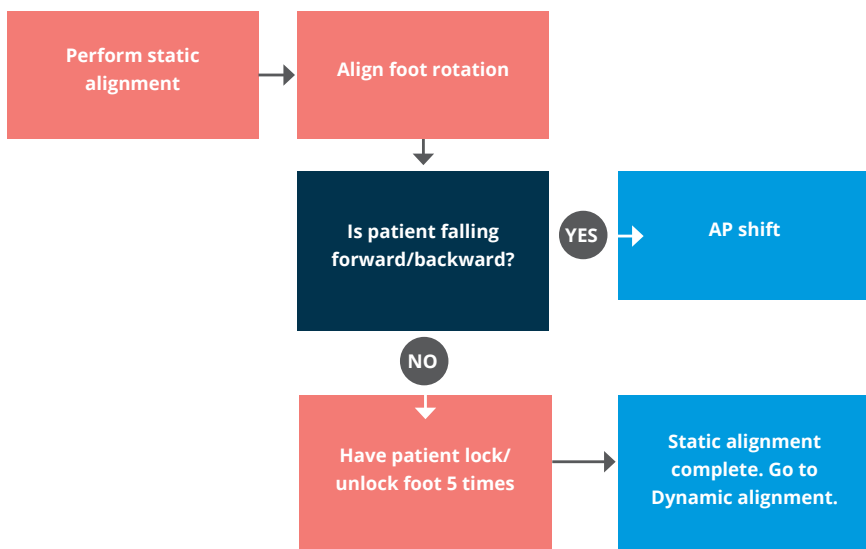
- The valve to adjust plantarflexion will always be on your left regardless of side of amputation. Out of the box, the valve is completely open.
- **Do not** make any adjustments to the right side valve as this will cause the the locking mechanism to fail.
- Plantarflexion resistance affects the user's gait from initial contact to loading response.

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

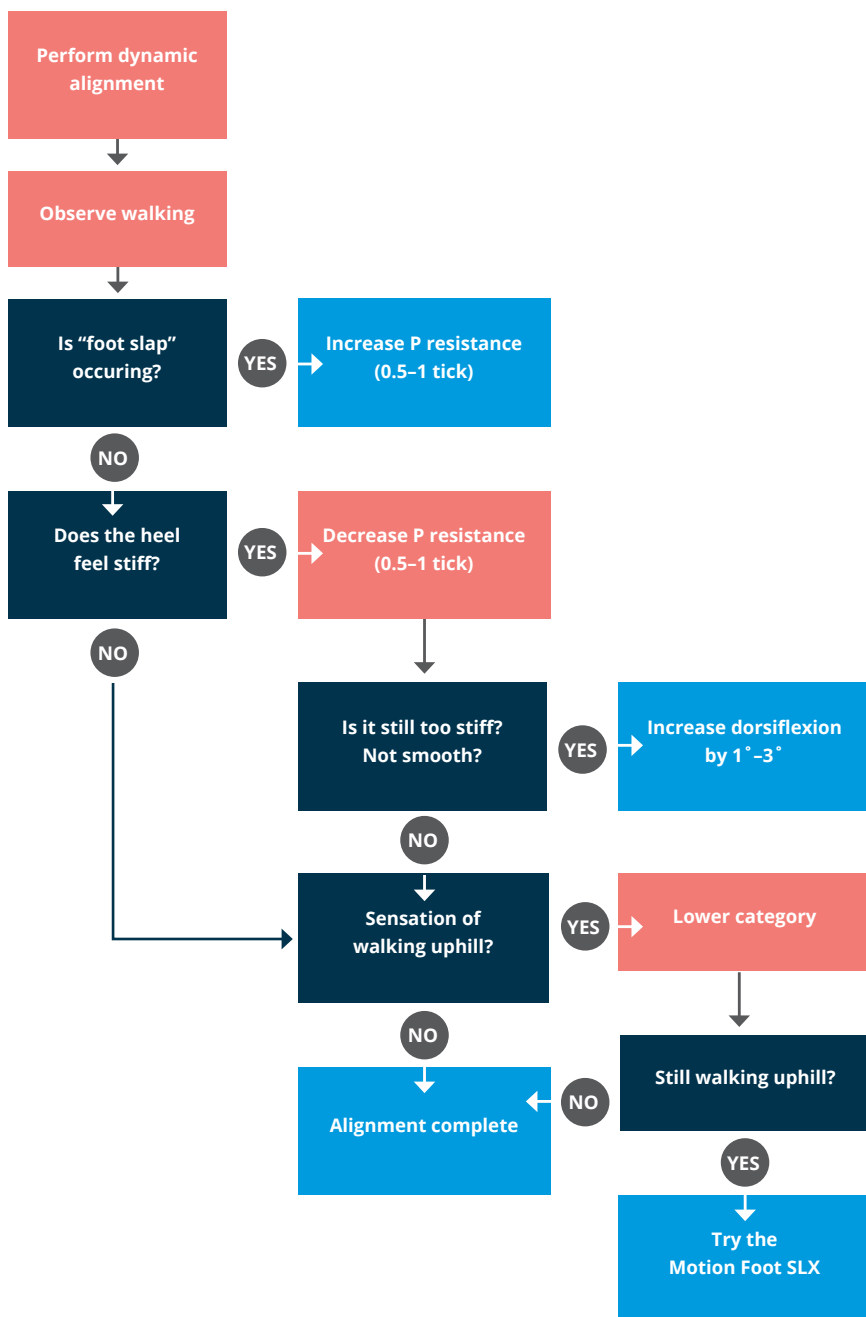
Motion Foot SAF Bench Alignment Procedure



Motion Foot SAF Static Alignment Procedure



Motion Foot SAF Dynamic Alignment Procedure



- 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. Aligning the foot more dorsiflexed 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, a patient may complain of anterior distal pressure. 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.” Try shifting the foot anteriorly or increase a category..
- If the anterior keel rollover hesitates from midstance to toe loading, the patient may say that they are “walking up a hill.” Try shifting the foot posteriorly or decrease a category if appropriate for activity level. If a smooth stance phase of gait cannot be achieved, contact Fillauer for additional assistance.

Setting and Testing Alignment

Patients have a better experience when they practice with the Traverse AV locking mechanism after alignment and plantarflexion resistance are established. Patients then learn to predict and utilize the locking feature. Some patients feel the foot behaves unpredictably without this step. The exploration can look something like this:

- Ask the patient to dramatically plantarflex the foot and tell them they’ve engaged the lock. Ask them to shift their weight toward the toe and to notice that there is a spring-like resistance. Ask them to shift their weight off the toe briefly and then slowly shift it forward again. The patient will notice that resistance is not there this time; the foot is toe-lifting. Repeat until the patient feels they can predict the foot’s logic. Ask the patient to take some steps with the new understanding.
- Ask the patient to stand in a neutral stance. Keeping the locking mechanism in mind, ask them to shift their weight from side-to-side and take small steps in various directions. Ask the patient to pay attention to how the foot is behaving and ask them to play with locking and unlocking the foot during this exercise to better understand it.

Foot Shell and Prosthetic Sock (Consumable Components)

The Traverse AV uses the Low Profile Foot Shell from Fillauer. See the Low Profile Foot Shell manual for installation, care, and maintenance



Compatibility

Fillauer feet are appropriate for use with Fillauer or equal, ISO 10328 compliant, prosthetic 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. Warranty is for repair only.
- Foot Shell (sold separately) — 6 months from date of patient fitting.
- Device service life: 5-years.

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 Traverse AV. 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 using a soft cloth and a soap and water solution, or with rubbing alcohol (70%). Do not use acetone or other solvents, 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 and local competent authority. Clinicians should make sure that medical help is received and contact their local Fillauer representative at the earliest possible convenience.

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