Sierra® Instructions for Use

Product Number: FS1

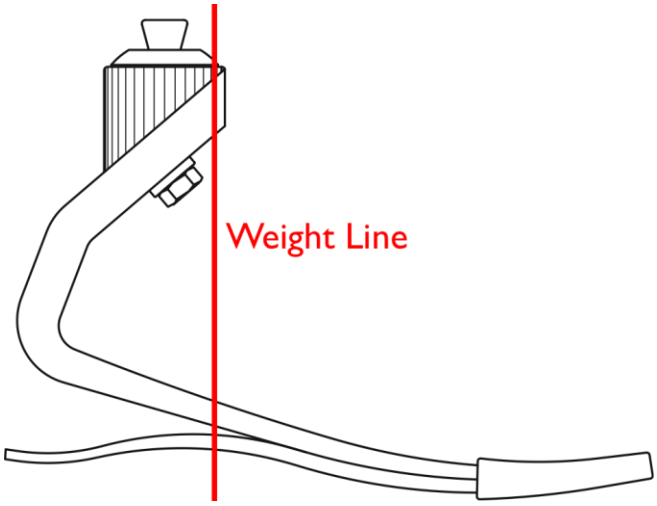
Assembly

The Sierra® foot module is pre-assembled consisting of a graphite component (keel), Spectra™ sock, and foot shell. Rubber *stiffening bumpers* for increasing heel stiffness are provided. After dynamic alignment, torque pyramid adjustment screws to the manufacturer's specifications. Secure pyramid adjustment screws with a thread locking adhesive (i.e., Loctite 242).

Bench Alignment

Prior to donning the prosthesis:

- Plantarflex/Dorsiflexion foot to match the shoe heel height.
- Adduct/Abduct socket to provide appropriate frontal plane angle.
- Flex/Extend socket to provide appropriate sagittal plane angle.
- Move the socket linearly to ensure the weight line falls along the anterior edge of the pylon (see illustration).



Dynamic Alignment

During *loading response*, the heel lever stores energy and releases it during *midstance*. This action provides momentum for the keel to store energy and release it during *terminal stance*. To optimize the heel to toe rollover motion, adjust the following variables:

- Anterior/posterior foot placement
- Dorsiflexion/plantarflexion
- Heel stiffness

Troubleshooting

Heel too soft

Symptoms
- Foot flat occurs too rapidly
- Toe feels excessively stiff
- Knee hyperextension

Solutions
- Shift socket anteriorly in relation to the foot
- Attach rubber *stiffening bumpers*

Heel too hard

Symptoms
- Rapid knee flexion, instability
- Heel to toe progression to rapid
- Lack of energy return sensation

Solutions
- Shift socket posteriorly in relation to the foot
- Verify appropriate foot module category

Foot module too stiff

Symptoms
- Flat spot in rollover motion at slow cadences

Solutions
- Consider a lower category foot module

	Foot module too soft	*Symptoms* • Clicking noise at *initial contact* • Excessive toe deflection with high impact activity *Solutions* • Consider a higher category foot module

Stiffening Bumpers

Rubber *stiffening bumpers* are included to adjust the heel stiffness during *loading response*. The bumpers may be temporarily attached between the heel lever and the keel using the pre-applied adhesive in the location indicated on the bumper package to increase heel stiffness one category. If the heel stiffness is too stiff, move the bumper posteriorly; still too soft, move it anteriorly. For permanent placement, clean off the pre-applied adhesive with Acetone, and adhere bumpers using Super Glue (cyanoacrylate).

Spectra™ Sock

A Spectra™ sock is provided to protect the foot shell and minimize noise. Spectra™ socks must be replaced at intervals appropriate to the user's activity level. Failure to inspect and replace the Spectra™ socks may prematurely wear the foot module, and will void the warranty.

Foot Shell

When removing or installing the foot shell, use the Foot Shell Removal Tool (ACC-00-10200-00) to prevent damage to the foot module.

Sierra® System

Minimum clearance: 146mm-187mm
Maximum user weight: 166 kg (365 lbs)
Available sizes: 22cm-31cm
Heel height: 3/8"
Warranty: Graphite components/pyramid connector (36 months)
Foot shell (6 months)

Maintenance

The foot module requires periodic maintenance.

- Inspect the foot module every six months. If the user is more active, more frequent inspection may necessary. Service as necessary. Replace Spectra™ sock and/or foot shell if worn to prevent damage to the graphite components.
- The foot module may be cleaned and/or disinfected with soap and warm water. If the foot is exposed to water, remove the foot shell to clean and disinfect its interior.

Warnings

Failure to adhere to the guidelines of the *Instructions for Use* will void the warranty.

- Never use the foot module without a foot shell. Failure to comply may cause premature wear, loss of function, and/or product failure.
- Always use the foot module with a sock and shoe. Failure to comply may cause premature wear, loss of function, and/or product failure.
- Never allow aggregates such as sand to remain in the foot shell. Upon exposure to aggregates, immediately disassemble foot module and rinse with water. The abrasive properties of aggregates will quickly wear the graphite components of the foot module.
- Freedom Innovations foot modules are manufactured to fit industry standard pyramids and receivers. It is the prosthetist's responsibility to select and/or fabricate properly fitting attachment components.
- Never attempt to loosen the bolt affixing the pyramid connector.
- Discontinue use and consult your prosthetist if any part of the prosthesis starts to make noise.
- Inform your prosthetist if you lose or gain a significant amount of weight.
- Freedom Innovations foot products are manufactured and tested for a particular weight and activity impact level. Use by another user for whom it was not originally manufactured may cause injury and shall void any written or implied warranty.

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