

Endurance – 1116 Instructions for Use

The Endurance is designed for active users that have enough Build Height. This foot is intended for lower extremity and to be single prosthesis use only, not to be reused on another prosthesis.

Assembly

The Endurance foot module is pre-assembled consisting of an inner 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 locker (i.e., Loctite 242).

NOTE:

The Prosthetist is responsible to inform the patient on any relevant information related to use or safety of this device. Patient should be instructed to return to their prosthetist immediately if they notice any unusual noise, motion, or change in performance that may occur from what could be a damaged module.

Warranty can be void due to: Unusual usage or abuse (ex. excessive dusty environmental usage), Tampering with any fasteners, Modification to the module such as sanding or damaging the finish, patient weight too close to weight limit of foot module (we recommend a 20-25 lb. buffer). Warranty Period is 3 years for the Keel and 6 months for the foot shell.

Inspection: Biannual interval of the Endurance is recommended: Check for corrosion, sign of wear, or damage of the bolts, spectra sock, and of the foot module or associated parts.

BENCH ALIGNMENT (Diagram B)

- Fit foot with selected cover.
- Be sure pyramid protector is utilized for pre-delivery visits. *
- Adjust to appropriate heel height (using the shoe).
- Introduce appropriate socket angles flexion/ extension and abduction/adduction.
- Divide the foot cover length into 3 equal portions.
- The load line should fall at the junction of the posterior and the middle third portions as shown in the diagram.

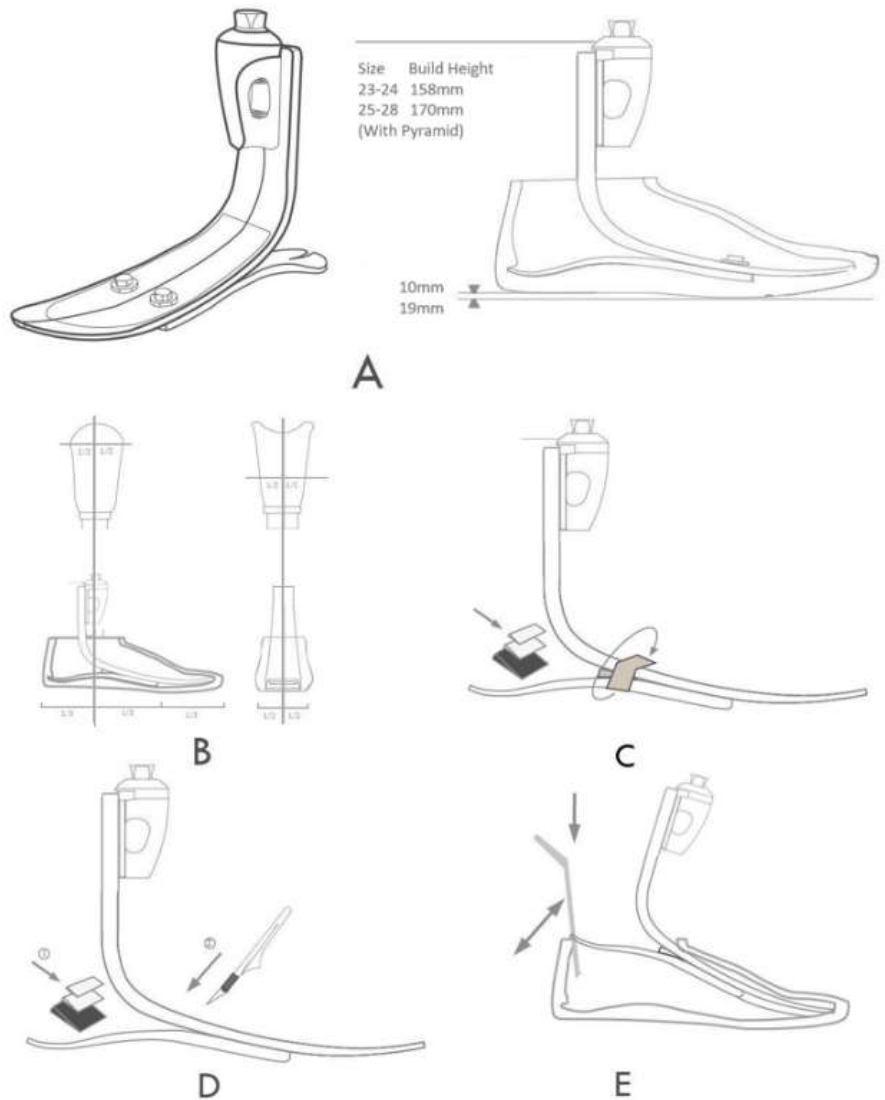
DYNAMIC ALIGNMENT

The heel stores energy after initial contact, slowly releasing it into midstance.

The forward momentum generated by this action results in the toe being loaded for optimum energy release at terminal stance.

The heel to toe action can be influenced by:

- A-P positioning of foot
- Dorsiflexion / Plantarflexion
- Heel Stiffness



TROUBLESHOOTING

Heel too soft

Symptoms: • Rapid Foot flat (amputee feels he/she is sinking into a hole).

- Extra energy is required to climb up over the toe (Toe will feel too stiff).
- Knee may hyperextend.

Solution: • Add polyurethane heel wedge.

- Shift socket anterior (or foot posterior).

Heel too hard

Symptoms: • Rapid heel to toe movement

- Rapid initial contact the amputee has poor control of his prosthesis
- Minimal energy return feeling
- Knee may become unstable

Solution: • Replace heel wedge with a smaller one.

- Shift socket posterior or foot anterior

Foot module too stiff (Reverify foot module selected with appropriate module needed)

Symptoms: • Flat spot in rollover motion at slow cadences

- 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

Heel Wedge

Temporary wedge placement:

Cut the heel wedge to the same width of the carbon foot.

Roughen the upper and lower part of the wedge, then place wedge in the space between forefoot module and heel module.

Use tape to wrap around the foot module to retain the wedge. (Diagram C)

Permanent wedge placement:

Cut the wedge to the same width of the carbon foot.

Place the Wedge between the forefoot module and heel module, and apply glue only to the upper part of the wedge, then insert to apply to the forefoot module.

The wedge will need to be cut in half so that the split toe can move freely. (Dia. D).

Heel Divider:

Place the Heel Divider in the middle of the posterior aspect of the heel module (Dia. A).

Toe Cushion:

Shape the Toe Cushion to match the forefoot module. Glue and apply under the toe section, and split the Toe Cushion to match the forefoot module.

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 Removal Tool (Dia. E):

Use the Foot Shell Removal Tool to install or remove foot shell from the foot module.

The Longer side is for installation, while the shorter side if for removal.

Care should be taken to prevent damaging the carbon heel module.

Note: Tampering with the pyramid attachment bolts will void the warranty of the product

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, including;

- 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 Spectra™ sock and thoroughly rinse out aggregate with water. The abrasive properties of aggregates will quickly wear the graphite components of the foot module.
- Foot modules are manufactured to fit industry standard pyramids and receivers. It is the prosthetist's responsibility to properly select fitting attachment components.
- Never attempt to loosen the bolt affixing the pyramid connectors or module connectors.
- Discontinue use and consult your prosthetist if any part of the prosthesis starts to make Noise, or reduced performance. This may be a sign of abnormal wear, or possible failure.
- Inform your prosthetist if you lose or gain a significant amount of weight.
- ST&G 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.

WEATHERPROOF A weatherproof device allows use in a wet and/or humid environment but does not allow submersion. Fresh water splashing against the enclosure from any direction shall have no harmful effect. Dry thoroughly after contact with fresh water. Fresh water: Includes tap water. Excludes salt and chlorinated water.

Contact with dusty environment should require follow up to ensure that foot shell is clean of debris so as not to prematurely damage the foot module. Signs of abuse or dusty environment will void warranty.

Foot shell and Spectra sock should not be exposed to extreme and continuous UV exposure, as it will prematurely fade and break down the material. Always use a covering such as a clean sock and shoes, and be sure to routinely change the sock so as to keep the enclosed environment clean and debris free.

STORAGE Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)
Allowable relative humidity 0 % to 90 %, non-condensing
Store away from UV exposure



LIABILITY

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use. The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer.

Always apply thread locker to all alignment screws and assembly fasteners with appropriate torque. This is the responsibility of the Certified Prosthetist to ensure device integrity. Do not over torque the alignment screws, as this will damage the foot mounting pyramid faces.

CE Conformity

This product meets the requirements Council EU 2017/1745 (MDR).

for medical products. This product has been classified as a class I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.

Warranty covers defects in workmanship for the given warranty period. Signs of abuse, lack of biannual inspection, improper installation are examples of areas not covered by warranty.

Useful Life

Service life of the product is covered by the warranty period. Not to be used on another wearer other than original intended wearer.

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations. Do not expose Carbon feet to sand, talcum powder, or wet environments

Warranty can be void due to: Unusual usage or abuse (ex. excessive dusty/sand environmental, swimming, overly high impact (jumping), non-typical usage), Tampering with any fasteners, Modification to the module such as sanding or damaging the finish, patient weight too close to weight limit of foot module (we require a 20-25 lb. buffer).



*Alignment screw galling will incur charges if trying to return foot. If unsure, always ask in advance for a Demo Foot. Specifications subject to change
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