

1109 - Motion Step

Foot Instructions for Use



Intended use:

This device is exclusively for lower extremity prosthetic fittings.

The 1109 Motion Step foot/ankle system combines a multiaxial ankle with a split toe, flexible keel foot, to provide low to moderate impact K2/K3 ambulators a smooth walking gait. The result is good stability and environmental compliance for trans tibial or trans femoral amputees

- Multiaxial ankle movement provides Dorsi and Plantar flexion motion, with good adaption to off camber surfaces for enhanced stability and overall comfort
- A flexible keel foot enhances smooth roll over
- Heel height can be adjusted through positioning the mounting surface of the foot and ankle

Patient Selection:

The Motion Step is intended for use by low to moderate impact transtibial and transfemoral K2/K3 level ambulators.

Motion step foot has a weight limit of **K1-K2 275 lbs. (125 kg), K3 220lbs. (100kg)** with Blue Rubber Donut installed.

It is the responsibility of the Prosthetist to determine that the patient is appropriate for this device.

It is the responsibility of the Prosthetist to inform the patient of the information relevant to usage and safety.

This device is intended for lower extremity prosthetic use only.

Assembly:

The Motion Step foot/ankle system requires assembly of the foot to the **1109** ankle module. Care should be taken to: Align the washer so that the conical face is towards the plantar foot bolt mounting area (fig. a), and the flat face is against the bolt head (fig. b).

Ankle fairing extends down towards the front and is open in the back (fig. c).

The mounting serrations (fig. d) so that they are engaged. Be sure to apply the thread locker and torque the 8mm hex head foot bolt to **30 Nm** and pyramid adjustment screws to the manufacturer's specifications.



Fig. a

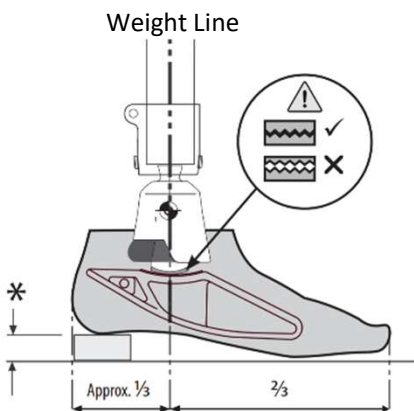


Fig. b



Fig. c

Alignment

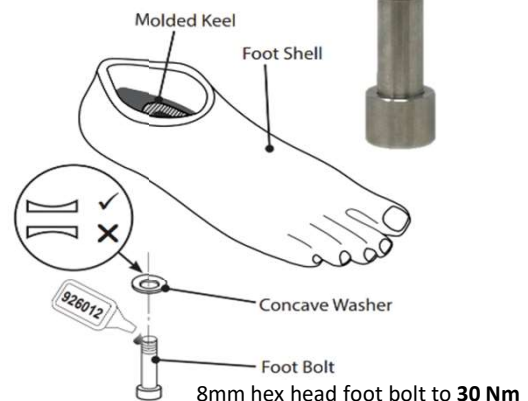


Socket Weight Line should end up centered as pictured.

Fig. d

⚠ Check that the serrations are engaged before tightening the foot bolt.

Set to desired heel height by engaging serration and tightening ankle bolt at desired position.



It is recommended to use a new foot bolt when replacing the foot.



IMPORTANT: Be sure that the mounting serrations are engaged when tightening the foot bolt!
Misalignment can result in fall risk, and damage to the foot and ankle mating surface which will void warranty!

Intended Life

User weight and activity is governed by the stated limits.
Load carrying by the user should be based on a local risk assessment.
For Single User only, do not reuse on another prosthesis!



Bench Alignment

Bench align in desired shoe, use a plumb bob or vertical laser line to confirm that the weight line falls through the middle of the ankle unit. (pictured in alignment section)

Static Alignment

To complete the static alignment, stand the patient in a set of parallel bars. The patient should be able to normally stand balanced, comfortably, and stable.

Dynamic Alignment

Ensure that during static standing, the heel and ball of foot are evenly loaded. Basic gait cycle should be observed, and the ankle motion should be smooth during walking.

Ankle motion

Replacement Snubber PN: **1109 SNB-B** – K2 Range up to 125kg (275 lbs) – (Blue)

Motion Step Foot

Sizes: 22-27cm

Average Build Height: 60 mm / 2.36 in (26 cm)

K2 User Weight Rating: Up to 125 kg / 275 lbs - (Blue)

K3 User Weight Rating: Up to 100 kg / 220 lbs – (Blue)

Heel Height: Tool adjustable with mounting serration engagement range

Connector: Male pyramid

Warranty: Foot / Multiaxial ankle 1 year

Maintenance:

- Inspect the foot module every six months. If more active, more frequent inspection is needed. Service as necessary. Replace ankle donut should signs of wear be present.
- The foot module may be cleaned and/or disinfected by wiping with soap and warm water solution. Avoid harsh chemicals.
- Never allow the foot and ankle to be exposed to aggregates such as sand. Upon exposure to aggregates, immediately clean off the surface as best as possible so the rubber donut does not accumulate the aggregate and initiate deterioration of the surface. The abrasive properties of aggregates will quickly wear the high load donut or foot surface.
- Foot and ankle should not be submerged in any water.

Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing

Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F]
relative humidity: 20 % to 90 %, non-condensing

Do not store in wet or very hot environment, or with UV exposure



Unallowable environmental conditions

Storage/transportation: high vibrations or impacts

Cleaning agents containing solvents

Avoid extreme/continuous UV exposure, as this will prematurely affect the Foot shell and Spectra sock

Always use a covering such as a clean sock and shoes and be sure to routinely change the sock to keep the enclosed environment clean and debris free.

Splash okay for fresh water or rain, but not salt water, urine, chlorinated water, dust, sand, or particles of foam cosmetics

Cleaning required after contact with salt-laden air, salt water, chlorinated water, urine, and sand.



⚠ Warnings:

- ST&G foot modules are manufactured to fit industry standard pyramid receivers. It is the prosthetists' responsibility to select and/or fabricate properly fitting attachment components.
- Discontinue use and consult your prosthetist if any part of the prosthesis starts to make noise.
- Failure to adhere to the guidelines of the Instructions for Use will void the warranty!
- 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 or liability. The liability shall fall upon those that resale/provide the product to anyone other than the original user the foot was delivered to. Not to be resold by private party.

CE Conformity

This product meets the requirements Council EU 2017/745 (EU) 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.



Useful Life

Service life of the product is covered by the warranty period of 1 year.

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

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Specifications subject to change