

1114 Toe Flex

Instructions for Use

Introduction

The Toe Flex foot/ankle system combines a unique combination of articulating ankle and toe segments with a carbon fiber heel, to provide low to moderate impact K2/K3 ambulators an exceptionally normal walking gait. The result is good stability and confidence for trans tibial, trans femoral, and bilateral trans tibial amputees.

- Articulated ankle movement provides Dorsi and Plantar flexion motion, with slight adaption to slopes for enhanced stability and overall comfort.
- An innovative flexible toe break and spring mechanism enhances smooth roll over
- Heel stiffness can be fine tuned with included heel wedge bumpers
- The unique Toe Flex design delivers articulation on slight grades, stairs, and level ground for stability.

The Toe Flex is intended for use with lower limb prosthetic fittings only. Caution should be used when fitting bilateral patients to assess their ability to adapt to the movement of the ankle. Toe Flex has a weight limit of 275 lbs. (125 kg).

Assembly

Be sure the pyramid protector is on the Toe Flex foot/ankle system. The Toe Flex consists of a foot/ankle module, Spectra sock and foot shell. After dynamic alignment, torque pyramid adjustment screws to the manufacturer's specifications. Secure pyramid adjustment screws with Loctite 242.

Bench Alignment

Bench alignment with a 3/8" (10mm) lift under the heel or the foot placed in the desired shoe, use a plumb bob or vertical laser line to confirm that the weight line falls through the middle of the anterior bumper (1/2" or 12mm anterior to center of ankle pivot bolt).

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).

Static Alignment

To complete the static alignment, stand the patient in a set of parallel bars. The patient should be able to stand comfortably without feeling as if the knee is flexing or hyperextending. If the knee is flexing, shift the foot anteriorly. If the knee is hyperextending, shift the foot posteriorly.

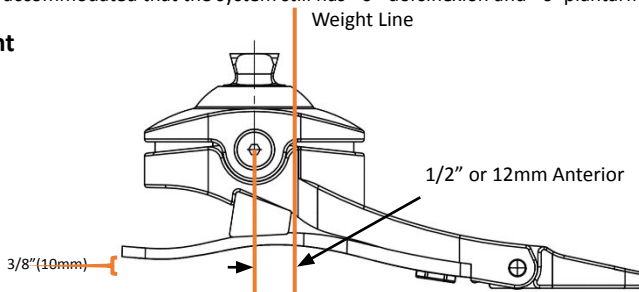
Tip! Angular adjustment of the pyramid will impact the ratio of the 12 degrees of combined movement.

Plantarflexion adjustment at the pyramid will decrease the dorsiflexion range of motion provided by the ankle.

Dorsiflexion adjustment at the pyramid will decrease the plantarflexion range of motion.

Ensure that the range of dorsiflexion and plantarflexion motion is maintained during static alignment. Check when flexion is properly accommodated that the system still has <6° dorsiflexion and >6° plantarflexion.

Alignment



Toe Flex System

Sizes:	23-28cm
Average Build Height per size:	65.5mm / 2.58" (23/24) / 68mm / 2.65" (25/26) / 70.3mm / 2.77" (27/28)
Product Weight:	757.7g (23/24) / 816.4g (25/26) / 884.5g (27/28)
User Weight Rating:	125 kg (275 lbs)
Heel Height:	10 mm (3/8 in)
Connector:	Male pyramid
Warranty:	24 months (shell 6 months)

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Dynamic Alignment

During loading response, the heel lever stores energy and releases it during midstance. This action provides momentum for ankle motion from plantarflexion towards dorsiflexion and to toe rollover. To optimize the heel to toe rollover motion, adjust the following variables:

- Anterior/posterior foot placement (should visually be close to anatomical)
- Dorsiflexion/plantarflexion (should be even toe/heel pressure standing)
- Heel stiffness (slight compression is optimal, too stiff not optimal)

Once a stable static alignment is achieved, begin walking the patient in the parallel bars to optimize alignment and function on level ground.

Stiffening Bumpers

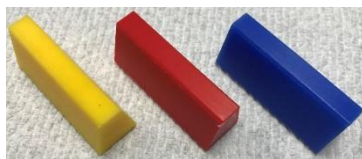
Using your patient's feedback, change from the yellow, out of the box, heel bumper (if needed) to promote smooth symmetrical walking transition. Visible heel compression is optimum, but excessive and lingering heel compression is not recommended.

To change the bumper, remove foot shell and spectra sock with the foot shell removal tool. The bumper can be pulled out while the heel is pulled into a slight extension motion away from the keel. Insertion is the opposite of removal.

NOTE: If you patient is more active, switching to the next stiffer RED bumper may actually enhance the smoothness of the heel to toe transition during walking.

Dynamic Alignment

Rubber stiffening bumpers are included to adjust the heel stiffness during loading response. The bumpers may be swapped out by carefully removing inserted bumper, and reinserting bumper of choice. If the heel stiffness is too stiff, go to the next softer bumper. If softest bumper is inserted and is still too soft, check foot A/P alignment.



Troubleshooting

Heel too soft:

	Soft	→	Firm
Symptoms	• Foot flat occurs too rapidly and long duration • Difficult to roll over foot • Knee hyperextension		
Solutions	• Shift socket anteriorly in relation to the foot • Switch to stiffer rubber bumper		

Heel too stiff:

Symptoms	• Rapid knee flexion, very short duration on heel • Heel to toe progression too rapid • Lack of energy return sensation
Solutions	• Shift socket posteriorly in relation to the foot • Verify appropriate heel bumper stiffness

Operating & Storage Temperature Range: -10°C to 50°C (14°F to 122°F)

Allowable relative humidity 0 % to 90 %, non-condensing

Foot shell and Spectra sock should not be exposed to extreme/continuous UV exposure. 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.



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, or foot shell, and may void the warranty.

Foot Shell

When removing or installing the foot shell, use the Foot Shell Removal Tool (ST&G Foot shell Removal Tool) to prevent damage to the foot module.

Maintenance

- Inspect the foot module every six months. If the user is more active, more frequent inspection may be necessary. Service as necessary. Replace Spectra sock and/or foot shell if worn to prevent damage to the Toe Flex components.
- Toe springs should be inspected at least every 4 months. If necessary, springs can be serviced and installed in your office with the dowel guide tool and available replacement joint pin, springs. These are available for purchase, and the installation process is relatively simple.
- If lubrication is necessary, apply a dry lube so as not to attract particles that could cause damage which would void the warranty. Do not apply WD-40, as it will remove any factory applied lubricant.
- The foot module may be cleaned and/or disinfected with soap and warm water solution. Avoid harsh chemicals.



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.
- Clinician / Practitioner is responsible for instructing patient of relevant content related to operation and safety of this device
- It is the responsibility of the Prosthetist to determine that the patient is appropriate for this device.
- Never expose or submerge the Toe Flex foot to salt water, chlorinated water or water in general. Failure to comply may cause premature wear, loss of function, and/or product failure. In the event of splash or exposure, the Toe Flex has to be serviced by the fitting clinician to be sure all mechanical aspects are not compromised by corrosion.
- Always use the foot module with a Spectra sock in foot shell, and sock on the outside with a 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 Toe Flex composite components of the foot module.
- ST&G 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 any bolts affixing the Toe Flex Foot system connectors or heel modules.
- 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.
- 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.

Environment:

Store at room temperature, and avoid extremely hot, cold, or moist storage environments Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F]

Do not store in wet or very hot environment.

Allowable environmental conditions

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

Storage/transportation – relative humidity: 20 % to 90 %, non-condensing

Splash - Fresh water, rain, salt water, urine, dust, sand, particles of foam cosmetics

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

Unallowable environmental conditions

Storage/transportation: high vibrations, impacts

Cleaning agents containing solvents



Environment

Operating and Storage Temperature Range: between temperatures of -10 °C to 50 °C [14 °F and 122 °F]

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.



Disposal

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

Disclaimer: Actual production version may vary from pre-production photo representation on IFU. Specifications subject to change

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