

1114 Toe Flex

Instructions for Use



Intended Use

The 1114 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.

Assembly

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.

Torque pyramid adjustment screws with Loctite 242 to manufacturers specifications.

Be sure the pyramid protector is on the Toe Flex foot/ankle system.

Bench Alignment

Setup: Use a 10mm heel lift or shoe. Ensure the weight line falls 12mm anterior to the ankle pivot bolt and along the pylon's anterior edge.

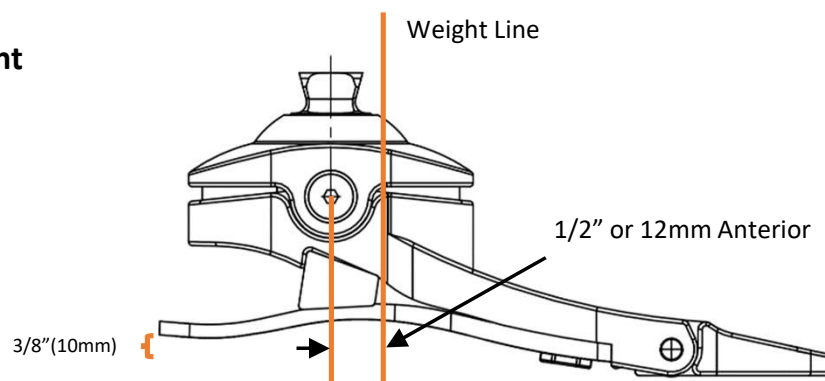
Adjustments: Align the socket angles (frontal/sagittal) and match the foot flexion to the shoe heel height.

Static Alignment

Stability: In parallel bars, adjust for knee stability: shift the foot anteriorly if the knee flexes or posteriorly if it hyperextends.

Range of Motion (ROM): Pyramid adjustments shift the 12° total motion ratio. Ensure you maintain at least 6° of both plantarflexion and dorsiflexion.

Alignment



Sizes	Build Height	Weight	Heel Height	Weight Limit
23-24	65.5mm / 2.58"	757.7g	10mm	125kg/275lbs
25-26	68mm / 2.65"	816.4g	10mm	125kg/275lbs
27-28	70.3mm / 2.77"	8845g	10mm	125kg/275lbs

Ordering: Example- 1114-B-26R (26 Right Brown Toe Flex)

P/N	Description
1114-SZ(L/R)	Toe Flex Beige Foot Shell, 23-28 cm L/R
1114-B-SZ(L/R)	Toe Flex Brown Foot Shell, 23-28 cm L/R

Dynamic Alignment & Bumper Guide

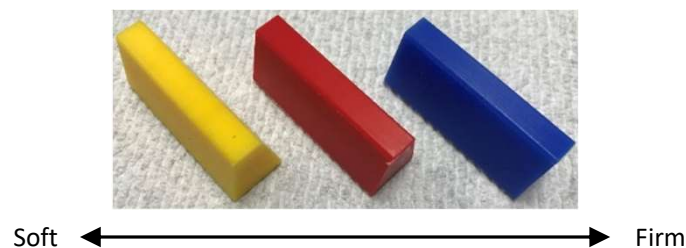
Static Alignment: Adjust A/P placement, flexion (ensure even pressure), and heel stiffness (target slight compression) before walking.

Dynamic Trial: Begin walking in parallel bars to optimize level-ground function.

Bumper Selection: Use the **Yellow** (standard) bumper initially. Switch to **Red** for active users to smooth transitions, or **Blue** for higher body weights.

Adjustment: To swap, remove the foot shell/sock. Pull the heel into extension to replace the bumper. If it's too stiff, use a softer bumper; if still too soft, re-check A/P alignment.

1114Y / 1114R / 1114B Bumper Kit



The 1114Y/R/B bumper kit is included with the Toe Flex foot with the Yellow bumper installed. Should the need arise, the bumpers are swappable by extending the heel, and pulling the bumper out. The new bumper can be slid into place. Do not lubricate the bumper for installation.

Troubleshooting

Heel too soft:

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

Allowable Operating & Storage environmental conditions

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.

Store at room temperature, and avoid extremely hot, cold, or moist storage environments

Do not store in wet or very hot environment.

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

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 and Cleaning

Inspections: Check the foot module every 6 months (more often for active users) and toe springs every 4 months. Replace worn socks or shells to protect internal components.

In-Office Service: Toe springs are easily serviced using a dowel guide tool and replacement pins/springs.

Lubrication: Use **dry lube** only. Avoid WD-40, as it removes factory lubricant and voids the warranty.

Cleaning: Use warm, soapy water; avoid harsh chemicals.

Warnings

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

- **Usage:** Always use the foot module with a foot shell, Spectra sock, and shoe. Never loosen system bolts.
- **Clinical Oversight:** The prosthetist must ensure patient appropriateness and provide safety training. Contact them immediately if the device makes noise or if your weight changes significantly.
- **Environment:** Avoid all water (salt, chlorine, or fresh) and sand. If exposed, rinse and have a clinician service the device immediately to prevent corrosion or wear.
- 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.
- 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.

Warranty: Guidelines must be followed to maintain the warranty. The device is for single patient use only, resale or transfer voids all liability.



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