

1114-SH (Toe Flex), 1114-SH-B (Toe Flex), 1115-SH(Endurance)

Foot Shell Instructions



Note: When placing an order, please use the below formula.

1114-size L or R Example, 1114-SH-25R

Product #	Fits:
1115-SH (beige)	1115 Endurance
1115-SH (beige)	1116 Endurance LP
1115-SH (beige)	1123 Endurance Contour
1114-SH-B (Brown)	1114 Toe Flex
1114-SH (Beige)	1114 Toe Flex
1114-SH-B (Brown)	1113 Next Step
1114-SH (Beige)	1113 Next Step
Build Height	7.8mm / 0.31in



P/N	Description
1FJ-20	Spectra Sock (Color may vary)



P/N	Description
4200	Foot Shell Removal Tool

- Please read this document carefully before using the product and observe the safety notices.
- Instruct the user in the safe use of the product.
- Please contact the manufacturer if you have questions about the product or in case of problems.
- Please keep this document for your records.

Construction and Function

Foot shells are pulled over compatible prosthetic feet. They are required in order to use the prosthetic feet and give them their natural exterior shape. They are removable and to be used with a Spectra sock. The toenails are not paintable.

Please correspond the foot shell part number is to be used with the corresponding foot part number.

1114-SH or **1114-SH-B** foot shells are to be used with only the **1114** Toe Flex and **1113** Next Step.

1115-SH foot shells are to be used with only the **1115** Endurance, **1116** Endurance LP, **1123** Endurance Contour.

Indications for use

The product is intended exclusively for lower limb exoprosthetic fittings.

Environmental conditions

Observe the prosthetic foot's environmental conditions.

Other environmental conditions	
Hydrolysis	Not resistant
UV light	Not resistant

Lifetime

The product is a wear part, which means it is subject to normal wear and tear.

Foot Shells have a 6 month warranty, does not cover wear and tear or abusive use (i.e. extreme usage, exposure to sand elements, salt water, harsh chemicals). Should be inspected bi-annually, and cleaned inside and out.

WARNING

- ▶ Do not expose this product to pH extremes or corrosive materials (water, salt water or other liquids)
- ▶ Failure to follow these technical instructions or use of this product outside the scope of the Warranty may result in injury to the patient or damage to the product, and will void the warranty
- ▶ Any modification of components will void the warranty.

Safety

Explanation of warning symbols

- ▶ CAUTION Warning regarding possible risks of accident or injury.

NOTICE Warning regarding possible technical damage.

General safety instructions

- ▶ CAUTION!

Risk of injury and risk of product damage

- ▶ Note the combination possibilities/combination exclusions in the instructions for use of the products.
- ▶ Inspect the product regularly for wear and tear. Do not continue using a worn product.
- ▶ The product may only be used by one person; reuse on another person is prohibited.
- ▶ Keep the product away from open flames, embers and other sources of heat.

NOTICE! Risk of product damage and limited functionality

- ▶ Do not expose the product to prohibited environmental conditions.
- ▶ Check the product for damage if it has been exposed to prohibited environmental conditions.
- ▶ Do not use the product if it is damaged or in a questionable condition. Take suitable measures (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop).
- ▶ Clean the product promptly each time after it comes into contact with salt water, chlorinated water or abrasive media (such as sand).
- ▶ To prevent mechanical damage, use caution when working with the product.
- ▶ If you suspect the product is damaged, check it for proper function and readiness for use.
- ▶ Do not use the product if its functionality is restricted. Take suitable measures (e.g. cleaning, repair, replacement, inspection by the manufacturer or a specialist workshop).

Signs of changes in or loss of functionality during use

Among other factors, changes in functionality can be indicated by an altered gait pattern and by the development of noises. If noise should occur, the relevant components must be inspected for integrity. It may be necessary to replace the Spectra sock or foot shell, and in some cases, the foot.

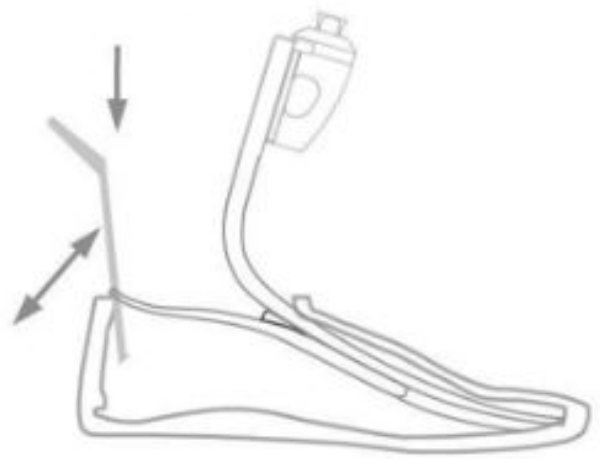
Preparing the product for use

- ▶ CAUTION

Incorrect alignment or assembly

Risk of injury due to damaged prosthetic components

- ▶ Observe the alignment and assembly instructions.



NOTICE

Grinding the foot shell Premature wear resulting from damage to the foot shell

- ▶ Do not grind the foot shell.
- ▶ Do not modify the foot shell
- ▶ Inform the patient to always wear socks and footwear

Applying/removing the foot shell (see figure above)

Applying the foot shell

- Recommended tools: 4200 foot shell tool
 - Pull a protective sock over the prosthetic foot inner keel.
1. Slide the prosthetic foot as deeply into the foot shell as able to.
 2. Insert the long segment of the 4200 foot shell tool under the heel of the keel and into the heel portion of the foot shell providing a ramp so the keel can slide into the designated locking cavity.
 3. Push the foot simultaneously down and into the foot shell until the heel engages cleanly into the heel cavity.

Removing the foot shell

- Recommended tools: 4200 foot shell tool
1. Insert the short side of the 4200 foot shell tool simultaneously into the heel cavity of the foot shell and to the rear being sure to be evenly to the rear of the prosthetic foot, and leverage up the heel of the prosthetic foot. In certain instances, it may be easier to suspend the heel portion off a work surface so that the foot shell tool can freely protrude underneath the prosthetic foot heel portion and then work the foot shell off the foot. The Toe Flex may require more effort to work the foot shell off due to the ankle feature size and foot shell opening. Avoid forcing the 4200 foot shell tool over the heel of the foot to avoid damaging the foot/heel.
 2. Remove the prosthetic foot from the foot shell.

Use

▶ CAUTION

Never wear the foot shell without socks or shoes, as lack of shoes will reduce control.

Risk of injury due to slipping on various surfaces

- ▶ Do not use the product on slippery surfaces
- ▶ Do not use without a shoe

Cleaning

▶ CAUTION

Use of unsuitable cleaning agents or disinfectants

Impairment of functionality and damage due to incorrect cleaning agents or disinfectants

- ▶ Only clean the product with the approved cleaning agents.
- ▶ Only disinfect the product with the approved disinfectants.
- ▶ Observe the instructions for cleaning and care.
- ▶ Clean the foot shell as described in the prosthetic foot instructions for use.
- 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.
- Discontinue use and consult your prosthetist if any part of the prosthesis starts to make noise, or has 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.

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 / ENVIRONMENT

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

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

Do not submerge in water

Store away from UV exposure



LIABILITY

The manufacturer will only assume liability if the product is used in accordance with the descriptions and instructions provided in this document. The manufacturer will not assume liability for damage caused by disregarding the information in this document, particularly due to improper use or unauthorized modification of the product.

Always apply Blue Loctite 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.



Legal information

All legal conditions are subject to the respective national laws of the country of use and may vary accordingly **CE Conformity**

This product meets the requirements Council EU 2017/745 (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. Utilize the pyramid protector during initial alignment! In some cases, galling may negate any credit and the device would be returned to the customer.

• **Never use Red Loctite, ONLY Blue Loctite on any prosthetic adjustment screws or fasteners!**

Inspection / Maintenance Information

It is recommended that you schedule your patients for check-ups according to the Warranty Inspection schedule below.

High patient weight and/or impact level may require more frequent inspections. We recommend you visually inspect the following applicable parts for excessive wear and fatigue Bi-Annually.

- Composite keel and Adapter
- Foot Shell
- Spectra Sock

1114 / 1115 FOOT SHELL IFU REV. C (06-03-26)