

PRIME 1119

The PRIME Foot provides K2 users a cost-effective, yet highly functional foot with a variety of features utilizing a high-tech composite construction and integrated foot shell. The foot is designed with a walking friendly design that enhances heel compression for increased foot flat at loading response to mid-stance for ensured ease of single limb support, walking stability, and extremely smooth roll over into swing due to the curved dynamic keel.



1119

(shown without Spectra Sock for illustration)

PDAC Approved: L5972

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

1119-size L or R Example, 1119-25R

Product #	1119
Sizes:	23-28
Weight of Foot Size 26	620g Complete foot
Build Height of Foot Size 26	73 mm Complete foot
Heel Height:	10mm
Maximum Patient Weight	125kg / 275lb
Warranty	2 year

Features and Benefits

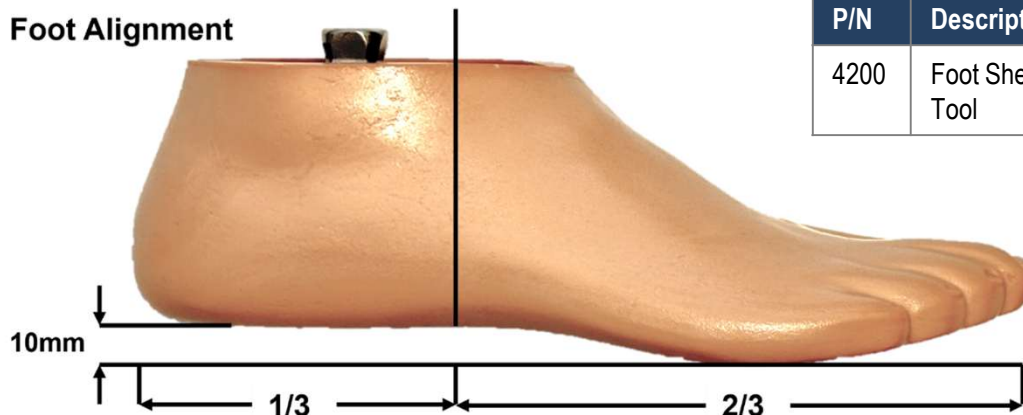
- Low profile
- High Tech composite for optimized movement
- Compliant heel helps with increased walking stability
- Split Toe Design
- Foot shell and spectra sock included
- Integrated pyramid



- Foot shell comes in beige
- Replacement available

P/N	Description
1119-SH-XXL/R	Foot Shell size 23-28 L/R

Foot Alignment



P/N	Description
4200	Foot Shell Removal Tool

PRODUCT DESCRIPTION

This prosthetic foot device is constructed with an integrated pyramid, and composite toe spring. The foot shell fits over the removable foot shell with a Spectra sock.

INTENDED USE

The Prime is a prosthetic foot designed to replace one or more functions of the biologic human foot. It is recommended to use ST&G components with the Prime foot

INDICATIONS:

- K2 amputees with a lower limb amputations

CONTRAINDICATIONS:

- K3 amputees

PROTECTIVE COVER ON PYRAMID DOME:

Remove the protective cover on the pyramid dome after alignment is completed and before patient leaves clinic. This protective cover is to eliminate pyramid gouging in case foot needs to be returned for any reason prior to delivery of the prosthesis. Otherwise, a returned foot with damage will incur a fee.

TECHNICAL SPECIFICATIONS

FOOT SIZE	WEIGHT LIMIT	BUILD HEIGHT	FOOT WEIGHT*
23-24 cm	275 lbs / 125 kg	2.76in / 70mm	
25-26 cm	275 lbs / 125 kg	2.87in / 73mm	620 g
27-28 cm	275 lbs / 125 kg	2.99in / 76mm	

*26cm Complete foot with foot shell and sock

MOUNTING

Use only high quality proximal endoskeletal components. The service-free Prime foot comes assembled in a foot shell within a Spectra Sock.

STATIC ALIGNMENT

For optimal function, balance the patient's weight evenly between the heel and toe.

- The Prime was designed with a 3/8" (10 mm) heel rise.
- The load line divides the foot at the rear 1/3 of the foot

DYNAMIC ALIGNMENT

For a firmer toe response, plantarflex the foot, or move load line posterior

For a softer toe response, dorsiflex the foot, or move load line anterior

For a firmer heel response, dorsiflex the foot, or move load line anterior

For a softer heel response, plantarflex the foot, or move load line posterior

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.

WARRANTY 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

- 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 connector.
- 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

Don not submerge in water

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 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.

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).

Warranty Period is 3 years for the Keel and 6 months for the foot shell.

* Alignment screw galling will incur charges if trying to return foot. Utilize the pyramid protector during initial alignment!

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