

NEXT STEP SYMES

– Ultra Low Build Height Symes – 1117 / 1122

Symes with Ultra Low Build Height

- Integrated Titanium Pyramid - 1117 or Male 36mm threaded adapter - 1122
- Composite keel conforms with forefoot inversion / eversion
- Low Build Height of 45mm (pyramid) with foot shell
- Comes with foot shell and spectra sock
- Rated up to 125kg / 275lb
- Sizes 23 - 28cm
- 10mm heel height

Size / Category	4 (80kg/175lb)	5 (100kg/220lb)	6 (125kg/275lb)
23			
24			
25			
26			
27			
28			



Ordering:

Pyramid Mount

1117-C5-26R (Beige)

1117-B-C6-26L (Brown)

36mm Threaded Mount

1122-C5-26R (Beige)

1122-B-C5-26L (Brown)

Replacement Foot Shell (1114-SH-size/side)

- 1114-SH-XXL/R (Beige)
- 1114-B-SH-XXL/R (Brown)

The 1117 Symes is a low profile dynamic foot for K2-K3 Symes amputees. The Symes foot is intended for lower extremity prosthetic use only. In cases with a very low clearance requirement, the foot can accommodate a 45mm Build Height. The Symes is available in sizes 23cm–27cm, and includes the Spectra Sock, and foot shell. After dynamic alignment, torque pyramid adjustment screws to the manufacturer's specifications with a thread locking adhesive (i.e., Loctite 242). Foot shells are available in 2 colors – beige and brown.

Note: The ankle moments of the Symes could cause heavy strain on the adjacent prosthetic components including the socket adapter and therefore, it is necessary to use adapters rated up to 125 kg / 275 lbs. No aluminum adapters are permitted with this foot.

Bench Alignment (Fig. 1)

Bench align 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 at approximately 1/4 to 1/3 of the posterior aspect of the keel (photo to the right) for optimum response, but placement also will depend on walking characteristics and cosmesis with the socket to foot shell. It is recommended to utilize a 1253 3-prong adapter with the Symes foot for a secure mounting to the socket due to the high dynamic forces generated, or a 1221S 3 prong female threaded adapter for the 36mm male threaded foot adapter.

Note: In the case to the right, 60 second urethane adhesive was used, then a final lamination was done after verifying alignment.

- Match the keel heel height of 10mm / 3/8" with appropriate shoe
- Move the socket linearly for optimum cosmetic and foot response



Static Alignment

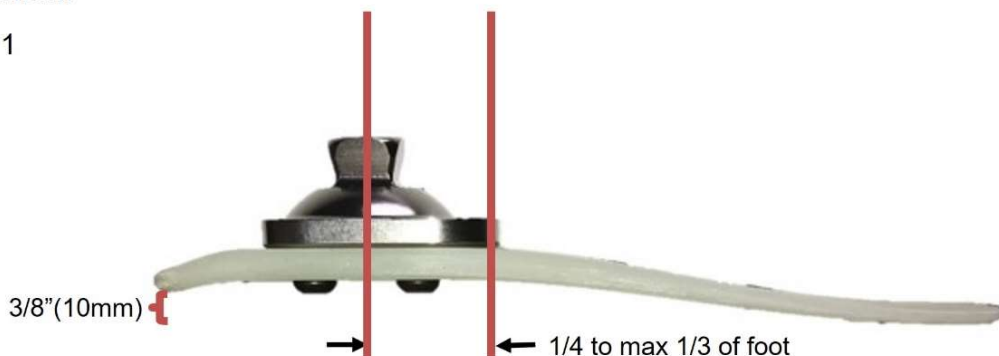
To complete the static alignment, stand the patient in a set of parallel bars. The patient should be able to stand comfortably with even weight distribution on both feet.

If there is a knee flexing sensation, plantarflex the ankle/foot slightly or shift foot anteriorly.

If there is a knee hyperextension sensation, dorsiflex the ankle/foot slightly or shift foot posteriorly.

Alignment

Fig. 1



Dynamic Alignment

To optimize the heel to toe rollover motion, fine tune the following variables:

- Anterior/posterior foot placement (should visually be close to anatomical)
- Dorsiflexion/plantarflexion (there may tend to be more heel pressure bias while standing)

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

Troubleshooting

Long Duration Plantar Flexion/Knee Hyperextension :

Symptoms

- Foot flat occurs too rapidly and long duration
- Patient feels unstable with tendency to lean posteriorly
- Difficult to roll over foot
- Knee hyperextension

Solutions

Shift socket anteriorly in relation to current position, or reduce plantar flexion of foot

Abrupt Plantar Flexion:

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 current position, or reduce dorsi flexion of foot

⚠ IMPORTANT: Be sure that there is filler foam attached at the dorsum of the toe section to provide adequate filler so that the foot shell does not move. Should the foot shell begin to move on the keel, inspect that the foam is not degraded. In such case, replace the foam so that there is 6mm/0.25 in total thickness of keel and foam. See Photo.

Toe of foot should reflect 6mm thickness here:



Symes Specifications

Foot module will vary depending on foot ordered

Build Height: 45mm / 1.77 in (pyramid mount with foot shell – threaded will be lower)

Product Weight: 255.8g (26cm Foot shell, Next Step Symes, Spectra Sock)

User Weight Rating: 125 kg (275 lbs)

Typical Heel Height (Foot dependent): 10 mm / 3/8 in

Connector: Male pyramid or Male 36mm threaded, proprietary 4-hole mount distally

Warranty: 24 months

Maintenance

- Inspect the device every six months. If the user is more active, more frequent inspection may be necessary.
 - Do not use baby powder or any lubricant.
 - The foot module may be cleaned and/or disinfected with soap and warm water solution. Avoid harsh chemicals.
- ▲ IMPORTANT:** Be sure that there is filler foam attached at the dorsum of the toe section to provide adequate filler so that the foot shell does not move. Should the foot shell begin to move on the keel, inspect that the foam is not degraded. In such case, replace the foam so that there is 6mm/0.25 in total thickness of keel and foam.

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.
- Never expose or submerge the Next Step Symes to salt water, chlorinated water or water in general. Failure to comply may cause premature wear, loss of function, and/or product failure.
- 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.

ADVISE YOUR PATIENT:

- Discontinue use and consult their prosthetist if any part of the prosthesis starts to make noise.
- Inform their prosthetist if there is a loss or gain in 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 voids 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

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

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



Device 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.

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.

Useful Life

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

Single use only, not to be used for any patient than initially delivered to. Cancels Warranty and Liability of the manufacturer which will fall upon the party reusing device.



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 / instructions subject to change. Refer to website for most up to date information.

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