

NEXT STEP and NEXT STEP SYMES

– Ultra Low Build Height Symes – 1112 / 1117 / 1122

Symes with Ultra Low Build Height

- Keel only = 1112
- Titanium Pyramid + 1112 keel = 1117
- 36mm threaded adapter + 1112 keel = 1122

PDAC Approved L5972

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)

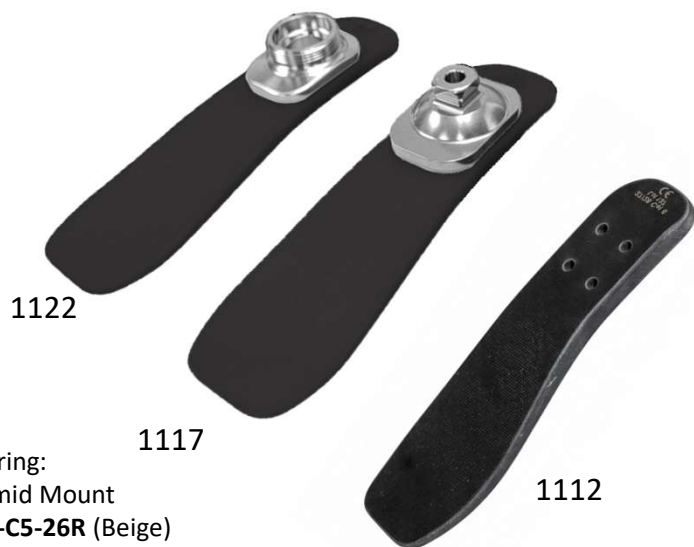
NEXT STEP Keel Only

1112-C5-26R (Beige)

1112-B-C5-26R (Brown)

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

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



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.

After dynamic alignment, torque pyramid adjustment screws to 15Nm with thread locker (i.e., Loctite 242).

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 due to the stress.

Bench Alignment NEXT STEP or NEXT STEP SYMES (Fig. 1-next page)

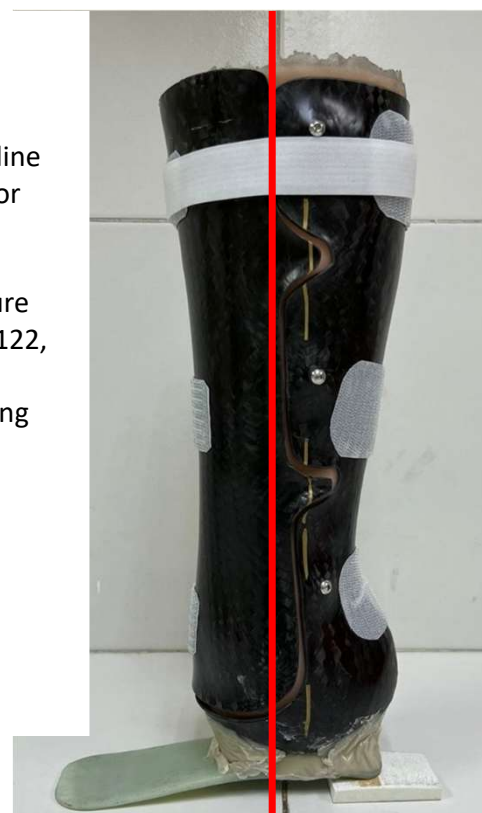
Bench align with a 3/8" (10mm) lift under the heel, or the foot placed in the desired shoe, use a plumb bob or vertical laser line to confirm that the weight line falls at approximately 1/4 of the keel (photo to the right), or 1/3 of the posterior aspect of the assembled foot for optimum response, but placement also will depend on walking characteristics, and possibly, cosmesis of the socket to foot shell. For 1117 pyramid, utilize a 1253 3-prong with receiver adapter for a secure mounting to the socket due to the high dynamic forces generated, or for the 1122, a 1221S 3 prong female threaded adapter.

Note: The 1112 was aligned and bonded directly to the socket, photo right, using 60 second urethane adhesive, then a final lamination was done after verifying dynamic alignment.

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

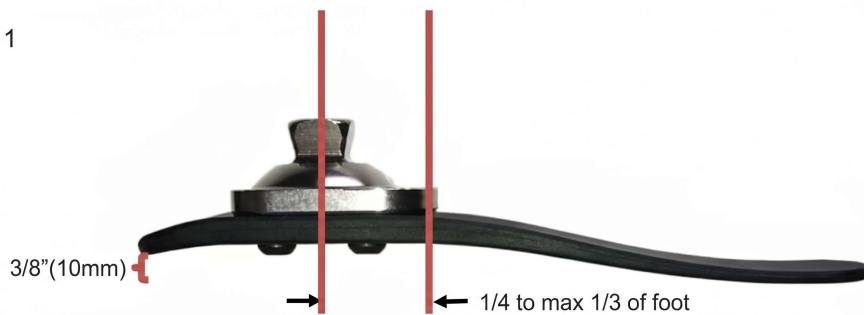
Reinforce lamination accordingly to ensure that the 1112 will not delaminate from the socket.

NOTE: Foot Shell will have to be cut and sanded to fit. Abrupt heel contact will be prominent due to lack of clearance for any heel motion keel design.



Alignment

Fig. 1



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.

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 (During Dynamic Alignment process prior to finish lamination)

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
In certain cases, a foam heel wedge could also be implemented to change foot alignment.

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
In certain cases, a foam heel wedge could also be implemented to change foot alignment.

OPTIONAL: There is filler foam provided that can be used on the dorsum of the toe section to provide adequate filler should the need arise. Replace the foam as necessary. See Photo.

Dorsum of Toe - 6mm thickness:



Symes Specifications

Part Number	Build Height	Heel Height	Weight Complete	Weight Limit
1117 (pyramid)	27mm / 1.06in	10mm / 3/8in	255g	125kg/275lbs
1122 (threaded)	27mm / 1.06in	10mm / 3/8in	538g	136kg/300lbs
1112 (keel only)	17mm / 0.67in	10mm / 3/8in	538g	136kg/300lbs

1122 Threaded version build height is measured at the fully inserted adapter height. Full height of 1122 would be **35.4mm** to top of the 36mm threaded section.

Keel only measurement is with the highest Category, so lower Category will be slightly less.

Measurements include Spectra Sock, foot shell, and respective foot keel in Category 6 for size 26cm.

1117 Pyramid version would have total build height of **41mm** to the top of a **1216T** Rotating Receiver.

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 2017/745 (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.

Useful Life

Service life of the product is covered by the 24-month 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.