

NEXTSTEP

with GLIDE ANKLE

1113 IFU

Introduction

The NextStep is a proven glass fiber keel offering dynamic response capable of accommodating cambered and uneven surfaces. The 4-Bar Glide Ankle design provides 15° Plantar-Flexion including 2° Dorsi-Flexion during swing phase, providing K2, or K3, wearers exceptionally more balance and comfort while walking. The benefits of the Glide Ankle are reduction of heel contact torque resulting in increased stability and confidence for amputees.



NEXTSTEP (1112) with Glide Ankle (1512A) pictured

The NextStep with Glide Ankle is intended for use by moderate to high K2 and up to moderate K3 level ambulators. Caution should be used when fitting bilateral patients to assess their ability to adapt to the movement of the ankle. Be mindful of the 275lb/125kg weight limit taking into account activities and object carrying does not spike beyond that limit.

Assembly

The NextStep with Glide Ankle comes assembled consisting of a foot and ankle module, Spectra sock and foot shell. After dynamic alignment, torque pyramid adjustment screws to the manufacturer's specifications. Secure pyramid adjustment screws with a thread locking adhesive (i.e., Loctite 242).

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 least 1/2in / 12mm anterior of ankle pivot bolt. Range should be a minimum of 1/2in / 12mm up to a maximum of 1in / 25.4mm.

Prior to donning the prosthesis:

- Plantar-flex/Dorsi-flex foot to match the shoe heel height, but accommodate 2° of Dorsiflexion
- Move the socket linearly so weight line falls 1/2in / 12mm up to 1in / 25.4mm anterior to anterior pivot

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.

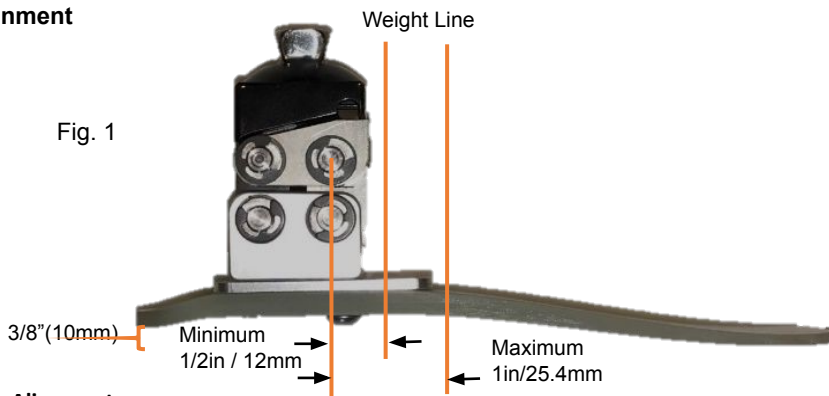
If there is a knee flexing sensation, plantarflex the ankle/foot slightly or shift foot anteriorly.

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

Be sure to have adequate foot placement versus weightbearing line anterior of the anterior ankle pivot.

Foot position will vary from TF to TT applications, and patient preference.

Alignment



Dynamic Alignment

Tip! Angular adjustment of the pyramid will impact the range of movement. Plantarflexion adjustment at the pyramid will decrease the dorsiflexion range of motion, while Dorsiflexion adjustment at the pyramid will decrease the plantarflexion range of motion.

The Glide Ankle will allow up to 15 degrees of Plantar-Flexion at initial contact.

If the motion is too stable making it difficult to progress to mid-stance, the socket and knee will need to be fine tuned with an anterior shift till it is a smoother transition. It maybe necessary to also combine the shift in position with fine tuning the position of the foot in a plantar flexed or dorsi flexed bench alignment position. Also be sure to assess the attitude position of the foot/ankle in the shoe. If there is an excessive amount of heel height, the foot will need to be aligned accordingly to the heel height in order to function properly. Educate your patient on proper footwear selection and being consistent with shoe selection.

The Glide Ankle will allow up to 2 degrees of Dorsi-Flexion during swing, so the patient may notice slight motion while standing to compensate balancing, which will be normal.

What is important, is to have balanced weight transfer through the foot to the toes and the heel during relaxed standing to achieve proper standing alignment with the 2 degrees of Dorsi-Flexion still present for swing.

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)
- Heel stiffness (slight compression is optimal, too stiff not optimal)

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/knee anteriorly in relation to current position

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/knee posteriorly in relation to current position

▲ 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: →



NextStep with Glide Ankle Assembly Ordering Info Part Number 1113
26cm complete foot with ankle, foot shell, keel, and spectra sock is 816.5g

Ordering part number example:

1113-B-C4-25L is for 25cm Category #4 Left Brown Foot shell.

1113-C5-27R is for 27cm Category #5 Right Beige Foot Shell

Size / Category	4 (80kg/176lb)	5 (100kg/220lb)	6 (125kg/275lb)
23			
24			
25			
26			
27			
28			

Glide Ankle Specifications

Foot module will vary depending on foot ordered

Build Height: 65mm / 2.69 in (Glide Ankle) 16mm / 0.63 in (NextStep Foot)

Product Weight: 816.5g (26cm Foot shell, Next Step Keel, Glide Ankle Assembly, Spectra Sock)

User Weight Rating: 125 kg (275 lbs)

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

Connector: Male pyramid proximal, proprietary 4-hole mount distally

Warranty: 2 years

Maintenance

- Inspect the device every six months. If the user is more active, more frequent inspection may be necessary. Service as necessary.
- If lubrication is necessary, apply a dry lube so as not to attract particles that could cause damage which would void the warranty. Do not apply WD-40, as it will remove any factory applied lubricant.
- The foot module may be cleaned and/or disinfected with soap and warm water solution. Avoid harsh chemicals.

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 Toe Flex foot to salt water, chlorinated water or water in general. Failure to comply may cause premature wear, loss of function, and/or product failure. In the event of splash or exposure, the Toe Flex has to be serviced by the fitting clinician to be sure all mechanical aspects are not compromised by corrosion.
- 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 lose 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.

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.

Environment:

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

Storage Temperature Range: between temperatures of -10°C to 50°C [14°F and 122°F]

Do not store in wet or very hot environment.

Allowable environmental conditions

Use – relative humidity: 0 % to 90 %, non-condensing

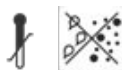
Storage/transportation – relative humidity: 20 % to 90 %, non-condensing

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



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 a 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.

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



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