ProStep VS

1130 Instructions for Use

Description

Pro-Step VS foot is designed for use by moderate impact K3 lower limb amputee ambulators with moderate activity level. Pro-Step VS has a weight limit of 275 lbs. (125 kg). with a 12.7mm / 0.5-inch Vertical shock for impact reduction incorporated with a progressive carbon fiber keel structure. The split Carbon keel allows +/- 7 degrees of inversion and eversion movement of the foot. There is an additional carbon plate that progressively compresses during the stance phase which enhances energy return, yet allows for comfort while walking.

Spectra Sock and Foot Shell included

The Weight line should fall along the mid-line of the shock body. There is a 10mm heel height.

P/N	Description
4200	Foot Shell Removal Tool

INFORMATION

- Please read this document thoroughly before using the product.
- Instruct the user on the appropriate and safe use of the product.
- Follow the safety instructions to prevent patient injury and/or damage to the product.
- Please keep this document with the patient chart.

INTENDED USE

The device is intended as a part of a lower limb prosthetic system.

Suitability, fitment, and adjustment of the device for the prosthesis and the patient must be evaluated by a Certified Prosthetist.

Indications For Use and Target Patient Population

• Lower limb loss, amputation, or deficiency

• No known contraindications

The device is for moderate impact use, e.g., walking, daily obstacles, and not for jogging or running.

GENERAL SAFETY INSTRUCTIONS

Warning: Use of a lower limb prosthetic device carries an inherent risk of falling which may lead to injury.

The Certified Prosthetist should inform the patient about everything in this document that is required for safe use of this device.

Warning: If there is a change or loss in device functionality, or if the device shows signs of damage or wear hindering its normal functions, the patient should stop using the device and contact their prosthetist.

The device is for single patient use.

DEVICE SELECTION

Verify that selected variant of the device is suitable for the impact level and weight limit according to the following table.

Warning: Do not exceed weight limit. Risk of device failure.

Incorrect category selection may also result in poor device function.

Size / Cat	1	2	3	4	5
23					
24					
25					
26					
27					
28					

FOOT INFORMATION	
Product #	1130
Categories:	1-5
Sizes:	23-28
Weight (Sz 27)	740g w/ Foot Shell
Build Height (Sz 27)	160mm w/ Foot Shell
Heel Height:	10mm
Max Patient Weight	125kg
Warranty	24 months
Foot Shell	1130-SH-XXL/R Foot Shell size 23-28 L/R

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

1130-C(indicate category #)-size L or R

Example, if ordering a size 25, right foot, category 3, part number would be: 1130-C3-25R

Activity Weight	50-60Kg 110-132lb	60-75 kg 132-165lb	75-90 kg 165-198lb	90-105 kg 198-231lb	105-125 kg 231-275lb
Low	1	1	2	3	
Moderate	1	2	3	4	5
High	2	3	4	5	5

The Pro-Step VS foot consists of a foot module, Spectra sock, and foot shell.
Warning: Do not tamper with foot or shock modules.
Always use the Foot shell removal tool (P/N 4200) to remove or install the foot shell to avoid damaging the Pro-Step VS foot module.
After dynamic alignment, torque and apply thread locker to pyramid adjustment screws to the manufacturer's specifications.

ASSEMBLY INSTRUCTIONS

Spectra Sock and Foot Shell

Caution: To avoid pinching fingers, always use a shoehorn.
1. Put the foot into the Spectra Sock.
2. Insert foot with Spectra sock into foot shell.
3. Using the longer end of a shoehorn, allow the heel of the foot with the Spectra Sock to slide over and into the rear of the foot shell.
4. Angle the shoehorn up straight to fully push the foot heel into the heel cavity of the foot shell.
5. After alignment is complete, fix the Spectra Sock to the prosthesis to seal against dust and dirt.

Note: The Spectra Sock must be pulled up to prevent it from interfering with moving parts of the foot.
If required remove the Foot Shell as follows:
1. Be sure the Spectra Sock is loose around the top.
2. Insert the shorter end of a shoehorn behind the foot down towards the back of the heel.
3. Push the shoehorn down and towards the back of the heel to leverage it under the heel (It is easier when the heel part is suspended while the fore and mid foot is on a flat surface).
4. Leverage the heel out of the Foot Shell.
5. Fully remove the Spectra Sock.

Prosthesis

Assemble prosthesis with applicable devices.
Warning: Risk of structural failure. Components from other manufacturers have not been tested and may cause excessive load on the device.
Warning: Ensure proper attachment by following the applicable device assembly instructions.
Utilize the pyramid protector during initial alignment.
Remove and discard pyramid protector before delivery assembly.

ALIGNMENT INSTRUCTIONS

Bench Alignment

Bench align with a 10mm / 3/8" lift under the heel, or the foot placed in the desired shoe, confirm that the weight line falls through the center of the shock body / center of the pyramid.
Note: Prioritize knee alignment over foot alignment if there is a mismatch.

Alignment Instructions

1. Position the foot so that the alignment reference line passes through your corresponding socket weight line and through the center of the vertical shock of the foot. Consider the external rotation of the foot.
2. Use the applicable adapters to connect either the socket or the knee to the foot and establish the correct knee center height.
3. If using a prosthetic knee: Position knee according to knee alignment instructions
4. Set the correct socket angles for flexion/extension and abduction/adduction.
5. If using a prosthetic knee: Use the applicable adapters to connect the socket to the prosthesis.

Static Alignment

– Make sure the patient stands with equal weight on both legs.
– Check for correct prosthesis length.
– Check internal / external rotation.
– Check for correct load on toe and heel.

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

Dynamic Alignment

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, and the plantar / dorsi flexion of the foot assessed 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 / dorsi flexed bench alignment position.
Also be sure to assess the attitude position of the foot 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.
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.
Ensure the patient is familiar with the functioning of the device.
The heel to toe action can be influenced by:
– Heel Stiffness
– Anterior-Posterior positioning of device
– Dorsi-Plantarflexion
– Shoe Characteristics

Consider the following actions if needed:

Symptoms

– Device comes to flat position too early (patient feels he/she is sinking into a hole)
– Climbing over the toe requires extra energy
– Toe feels too stiff
– Knee hyperextends

Action

– Check and see if a Wedge is needed
– Shift socket anterior (or device posterior)
– Consider dorsiflexion
– Check heel of the shoe and shoe performance

Symptoms

– Rapid heel to toe movement
– Poor control over prosthesis at initial contact
– Minimal energy return feeling
– Too little push off from the toe
– Knee becomes unstable

Action

– Check and see if a Wedge is needed
– Shift socket posterior (or device anterior)
– Consider plantarflexion
– Check heel of the shoe and shoe performance

Heel Wedges

The small, medium and large keel Wedges are used to change heel stiffness.
The Wedges can be trimmed using sharp scissors to customize stiffness.
For temporary Wedge placement, use tape to secure the wedge in position.
For permanent Wedge placement

• Roughen the upper and lower surface of the heel with abrasive paper.
• Apply instant adhesive on the lower side of the Wedge only.
• Locate in the foot/heel junction and position before adhesive sets.

For removal, the adhesive may be softened by soaking in acetone or cyanoacrylate adhesive remover.
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.

Use Foot Shell Removal Tool to remove Foot Shell from Pro-Step VS keel.

P/N	Description
4200	Foot Shell Removal Tool

Foot Shell is considered a consumable component and can be worn out after a period of usage depending on activity of the patient.
Replace the Foot Shell immediately to prevent any damage on the Pro-Step VS Foot.
Foot Shell has a 6-month warranty for manufacturing defects only. Wearing foot without foot shell wear will void warranty.

USAGE

Cleaning and care

Clean with a damp cloth and a mild soap. Dry with a cloth after cleaning.
The Shock Module should NOT be lubricated.

Clicking Noise

If clicking noise occurs:
Check that the adapter screws are torqued and secured with the recommended values and no debris is in the interconnecting zone of the pyramid dome.
Check or remove dust between the heel and the foot blade. Clean and / or replace the Foot Shell as well as the Spectra Sock if needed

Environmental Conditions

The device is Weatherproof. A Weatherproof device can be used in a wet or humid environment and can tolerate being splashed by fresh water (e. g., rain), no submersion is allowed.
No contact with salt water or chlorinated water is allowed.
Dry with a cloth after contact with fresh water or humidity.
Clean with fresh water in case of accidental exposure to other liquids, chemicals, sand, dust, or dirt and dry with a cloth.

MAINTENANCE

The device and the overall prosthesis should be examined annually or biannually.
Interval should be determined based on patient activity and body weight. If the user is more active, more frequent inspection may be necessary (especially in a dusty, sandy environment).
The shock is not serviceable, do not attempt to disassemble the shock. Do not apply any lubrication! This will attract dirt particles that could cause damage which would void the warranty.
Do not apply baby powder.
Be sure foot shell and Spectra sock are clean and no debris is within the sock or foot shell.
Replace sock if wear is apparent to help protect the keel from premature wear!

Noise from Foot

Noise may occur if sand or debris is present in device. In that case the foot should be inspected by your Prosthetist, and it can be cleaned with the help of compressed air and may need to replace the Spectra sock if it is damaged.

REPORT OF SERIOUS INCIDENT

Any serious incident in relation to the device must be reported to your prosthetist and the manufacturer.

The foot module, and Spectra sock may be cleaned and/or disinfected with soap and warm water solution.

Avoid harsh chemicals.

Be sure both are dry before reassembly.

Warnings

Note: It is the responsibility of the Prosthetist to inform the patient of the information relevant for usage and safety.

Clinician / Practitioner is responsible for assessing that patient is appropriate for this device.

Failure to adhere to the guidelines of the Instructions for Use will void the warranty.

• Never use the foot module without a Spectra Sock or foot shell. Failure to comply may cause premature wear, loss of function, and/or product failure.

• Never expose or submerge the Pro-Step VS foot to salt water, chlorinated water or water in general. Failure to comply may cause premature wear, loss of function, and/or product failure. If such splash exposure should occur, the foot shell, Spectra sock and foot module should be cleaned and dried and reassembled.

• Always use the foot module with a Spectra sock in foot shell, and sock on the foot shell, and 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 composite components of the foot module, and will void the warranty.

• ST&G foot modules are manufactured to fit industry standard pyramids and receivers. It is the prosthetist's responsibility to select and/or fabricate a properly fitting socket, with optimal alignment.

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.

The device must be maintained according to the instructions for use.

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, or it cancels warranty and Liability of the manufacturer, and becomes the liability of the person who resales the device.

LIABILITY

ST&G USA Corporation prosthetic devices are designed and verified to be safe and compatible in combination with each other and custom-made prosthetic sockets with ST&G USA Corporation adapters, and when used in accordance with their intended use.

ST&G USA Corporation does not assume liability for the following:

- Device not maintained as instructed by the instructions for use.
- Device assembled with components from other manufacturers.
- Device used outside of recommended use condition, application, or environment.
- Device used outside of recommended K level.

Disposal

The device and its packaging must be disposed of in accordance with respective national/local environmental regulations.

Specifications subject to change

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