INSTRUCTION FOR USE

EN

BioStep™

BSEVO
BioStep EVO

BSPRO
BioStep PRO

BSCL
BioStep Classic

BSXT
BioStep EVO

BSLP
BioStep PRO

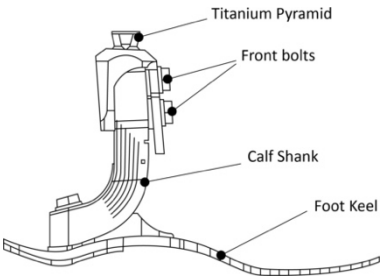
This manual is intended for use by a certified professional

1 - DESCRIPTION

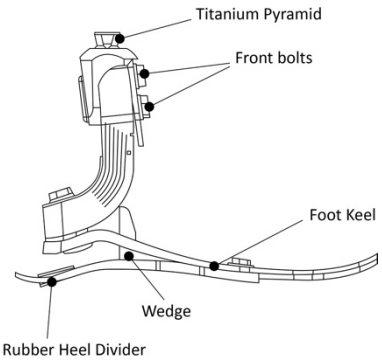
The device is a prosthetic foot with integrated male pyramid. It is composed of a carbon fiber keel connected to a calf shank.

The structural elements are protected by a spectra sock and covered by a cosmetic foot shell.

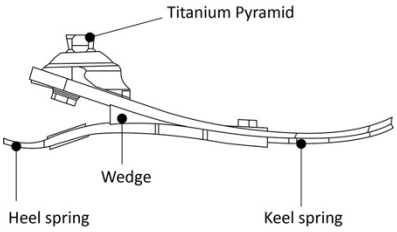
Biostep CL, Biostep PRO, Biostep XT - Part list



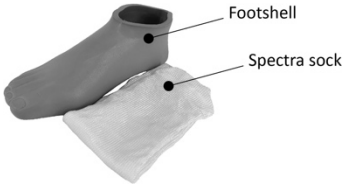
Biostep EVO Part list



Biostep LP - Part list



Spectra sock and cosmetic foot shell



Intended use

The device is intended to be used as a part of a lower limb prosthetic leg. The device replaces the foot and ankle function of the missing lower limb for patients with below or above knee amputation.

The device must be fitted and adjusted by a certified professional.

2- PATIENT POPULATION, ACTIVITY LEVEL, WEIGHT LIMITATIONS

Target patient population

Lower limb amputees, both transfemoral and transtibial.

The device is for single patient use.

The device is indicated for medium to high activity level (K3 and K4 activity levels; can be beneficial also for high K2).

- Activity Level K2: single speed cadence, with the ability to traverse low level environmental barriers. Typical of the limited community ambulator.
- Activity Level K3: variable cadence, with the ability to traverse most environmental barriers. May have vocational, therapeutic, or exercise activity that demands prosthetic utilization beyond simple locomotion.
- Activity Level K4: variable cadence, with the ability for prosthetic ambulation that exceeds basic ambulation skills, exhibiting high impact, stress, or energy levels.

Maximum patient weight

Do not exceed the weight limit indicated in the chart below. Risk of device failure.

Lifting and carrying loads. Verify that the accumulated weight (patient + loads) does not exceed the weight limit indicated in the chart below.

	SIZE (cm)	Activity K2 Low	Activity K3 Medium	Activity K4 High
BioStep CL BioStep PRO	22-24	113 kg / 250 lbs	101 kg / 224 lbs	101 kg / 225 lbs
	25-30	183 kg / 405 lbs	183 kg / 405 lbs	147 kg / 325 lbs
BioStep XT	22-30	152 kg / 335 lbs	140 kg /310 lbs	120 kg / 265 lbs
BioStep EVO	22	113 kg / 250 lbs	102 kg / 224 lbs	90 kg / 200 lbs
	23-24	125 kg / 275 lbs	113 kg / 250 lbs	102 kg / 224 lbs
	25-30	158 kg / 350 lbs	147 kg / 325 lbs	125 kg / 275 lbs
BioStep LP	22-24	100 kg/221 lbs	88 kg/194 lbs	77 kg /177 lbs
	25-30	165 kg/365 lbs	147 kg/324 lbs	130 kg/287 lbs

3 – LIMITATIONS AND CONTRAINDICATIONS

Weight limit, activity level, carrying loads

Do not exceed the weight limits reported in the above chart. Risk of device failure.

Intended Life

This device has been tested according to ISO 10328 standard to two million load cycles. Depending on the amputee's activity this corresponds to two to three years of use.
For an extended use beyond this time frame, periodic safety checks are recommended, taking into consideration the level and the type of activities performed with the prosthetic leg, the user weight, the effective operating time of the product. Inspect the device and discontinue the use in case of signs of wear or deterioration.

Environment

The device can be used in temperatures between -23° C (–10° F) and 93°C (200° F).
The device is weather proof: it is not intended for patient activities that will routinely and repeatedly cause the foot to be submerged in salt or chlorinated water or to be exposed to corrosive environments (such as sand, mud or salt water).
If occasional submersion/contact occurs, the following protocol must be followed by a certified professional:

- Remove foot shell and spectra sock
- Rinse the foot shell, spectra sock, and the foot with tap water
- Thoroughly dry the foot shell, spectra sock, ankle shank, foot keel, and proximal pyramid components with a clean towel
- A household hair dryer on a low to medium heat setting can be utilized to facilitate the drying process

4 - SAFETY INFORMATION AND WARNINGS

The certified professional must inform the patient about everything in this document that is required for safe use of this device.

Warnings for the professional user ⚠

- **Accessories.** The device must be used with a foot cover (foot shell) and spectra sock, supplied with the product.
- **Product selection**. Carbon fiber elements (calf/shank and keel) come in different grades of stiffness, based on the activity level and weight of the patient. An incorrect selection may result in poor device function or increased risk of product failure. For appropriate selection, we recommend using our online product code selector or contacting our customer service.
- **Maximum patient weight.** Do not exceed the weight limit. **Risk of device failure**.
- **Lifting and carrying loads.** The accumulated weight (patient + loads) must not exceed the maximum weight limit. **Risk of device failure.**
- **Installation and maintenance of the device.** Installation and maintenance must be carried out only by a certified professional. These activities include: removing and donning the foot shell, inspecting and replacing the spectra sock, installation of the heel wedge, connecting the device to the prosthetic leg, aligning the prosthetic leg.
- **Visual check.** Visually check for product integrity before installation.
- **Connection with the prosthetic leg.** Before delivering the prosthetic leg to the patient, make sure Loctite has been applied to the screws of the connecting adaptors and that the appropriate torque has been applied, as per the manufacturer's indications.
- **Installation of the wedge**. BioStep EVO and BioStep LP are supplied with a wedge to adjust the heel stiffness. Once the appropriate heel wedge has been determined, secure the heel wedge with Loctite 495 Instant Adhesive (or equivalent). Do not force the wedge forward towards the bolts or unnecessary stress will cause bolts to fail prematurely. Please check fitting and alignment instruction section.
- **Device failure.** Failure of the device may lead the patient to fall and could lead to broken bones or other injuries requiring medical treatment.

- **No modification of the device.** The device should not be modified by cutting or grinding the calf shank or foot keel; fasteners, set to the proper tension and sealed with Loctite, should not be loosened. Any structural alterations or adjustments made by the certified professional or by the patient may create liability and will void the product warranty.

<u>Warnings for the patient</u>

Please explain this section to the patient before delivering the device.

- **Change in performance, weight, activity**
  - Patient must immediately contact a certified professional and discontinue the use of the device until an accurate inspection is performed by the certified professional in the following cases:
  - there is a change or loss in device performance or functionality
  - unusual noise
  - the device shows signs of damage or wear
  - the patient has increased levels of physical activity with his prosthetic leg
  - If the patient experiences a weight gain equal to or greater than 20 lbs (9.1 kg)

- **Correct use and maintenance of the device**
  The patient should be further informed that:
  - wearing a shoe with an extreme heel height or walking barefoot may result in a misalignment of the prosthetic leg and increase the risk of falls
  - a regular visual check of the foot is recommended. Signs of wear that may affect function should be reported to a certified professional
  - dry with a cloth after any contact with water or humidity
  - the device is not intended for patient activities that will routinely and repeatedly cause the foot to be submerged in salt or chlorinated water or to be exposed to corrosive environments (such as sand, mud or salt water). If occasional submersion/contact occurs, a certified professional should be contacted immediately

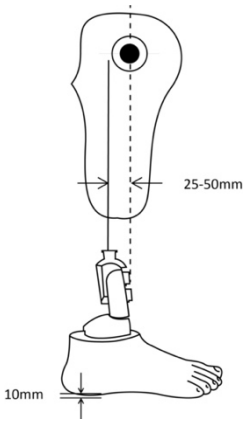
5- FITTING AND ALIGNMENT INSTRUCTIONS

FITTING HEIGHT

Foot Model	Fitting height (cm)	Fitting Height (inches)
BioStep CL	15 cm	5-7/8"
BioStep PRO	15 cm	5-7/8"
BioStep XT	18,5 cm	7-5/16"
BioStep EVO	17 cm	6-11/16"
BioStep LP	6,8 cm	2-11/16"

BIOSTEP CL, BIOSTEP PRO, BIOSTEP XT: fitting and alignment instructions

Static alignment



Divide the socket in half.

The midline of the socket should run 25-50 mm anterior to the midline of the male pyramid with top of pyramid parallel to the ground with a 10 mm heel rise.

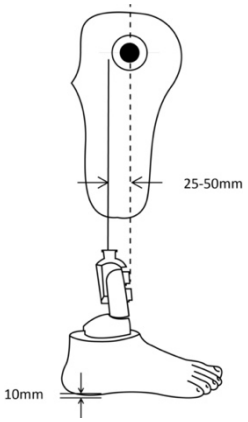
For the initial bench alignment run the midline of the socket through the front of the top pyramid bolt as shown.

Dynamic alignment

Adapt the prosthetic alignment adjustments and/or sliding adjustments in order to ensure correct heel contact, easy roll-over, and optimal shifting of weight onto the contralateral side. For transtibial amputees please ensure there is physiological knee flexion during stance phase.

BIOSTEP EVO: fitting and alignment instructions

Static alignment



Divide the socket in half.

The midline of the socket should run 25-50 mm anterior to the midline of the male pyramid with top of pyramid parallel to the ground with a 10 mm heel rise.

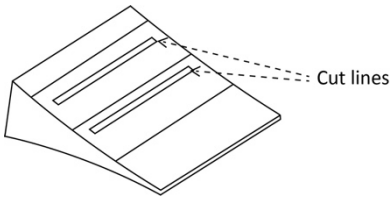
For the initial bench alignment run the midline of the socket through the front of the top pyramid bolt as shown.

Dynamic alignment

Adapt the prosthetic alignment adjustments and/or sliding adjustments in order to ensure correct heel contact, easy roll-over, and optimal shifting of weight onto the contralateral side. For transtibial amputees please ensure there is physiological knee flexion during stance phase.

Adjusting the heel resistance

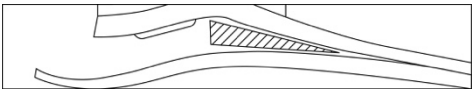
The foot is supplied with a heel wedge to increase the heel stiffness. To soften the heel, shorten the wedge by cutting along the cut lines. For temporary installation, secure with double sided tape. For permanent installation, secure the heel wedge with Loctite 495 Instant Adhesive (or equivalent).



Green Wedge is provided with 22-27 BioStep EVO

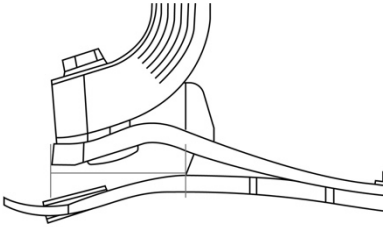
Purple Wedge is provided with 28-30 BioStep EVO

Attention!
Do not force the wedge forward towards the bolts or unnecessary stress will cause bolts to fail prematurely.



BIOSTEP LP: fitting and alignment instructions

Static alignment

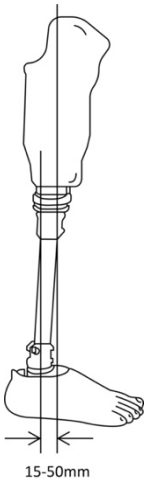


Measurements from back of keel to back of heel wedge (mm)

Keel size (length)	Measurement (mm)
22 - 24	40
25 - 27	43
28 - 30	48

BIOSTEP LP: fitting and alignment instructions

Static alignment



Divide the socket in half.

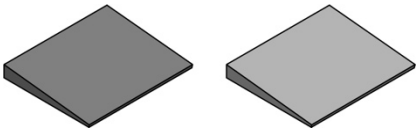
The midline of the socket should run 15-50 mm anterior to the midline of the male pyramid with top of pyramid parallel to the ground with a 10 mm heel rise; the midline of the socket will roughly divide the foot in 1/3 – 2/3.

Dynamic alignment

Adapt the prosthetic alignment adjustments and/or sliding adjustments in order to ensure correct heel contact, easy roll-over, and optimal shifting of weight onto the contralateral side. For transtibial amputees please ensure there is physiological knee flexion during stance phase.

Adjusting the heel resistance

The foot is supplied with a heel wedge to increase the heel stiffness. For temporary installation, secure with double sided tape. For permanent installation, secure the heel wedge with Loctite 495 Instant Adhesive (or equivalent).

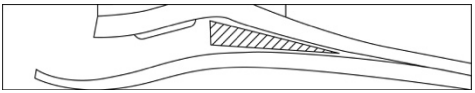


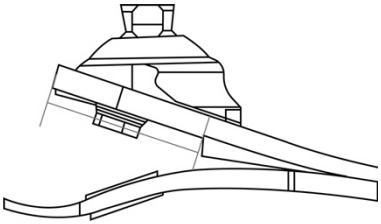
Red Wedge (Medium)

Blue Wedge (Firm)

Note: Only install one wedge at a time per patient

Attention!
Do not force the wedge forward towards the bolts or unnecessary stress will cause bolts to fail prematurely.





Measurements from back of keel to back of heel wedge (mm)

Keel size (length)	Measurement (mm)
22 - 24	26
25 - 27	43
28 - 30	48

6- ASSEMBLY/DISASSEMBLY

Caution: To avoid pinching fingers, always use a metal shoehorn.

Doffing (removing) the foot shell

- slide the end of the shoehorn behind the foot
- push the shoehorn down and pull the foot out of the footshell
- fully remove the spectra sock
- replace the spectra sock if worn out

Donning (install) the foot shell

- put the spectra sock on the foot
- use the end of the shoehorn to position the foot with the spectra sock into the foot shell
- move the shoehorn up to fully push the foot into the foot shell
- verify that the foot's carbon structure is firmly seated into the foot shell and does not move up/down
- the spectra sock must be pulled up to prevent it from interfering with moving parts of the foot

7- USAGE

Cleaning and Care

Clean with a damp cloth and a mild soap. Dry with a cloth after cleaning

8 - MAINTENANCE

The device and the overall prosthesis must be examined by a certified professional. Interval should be determined based on patient activity and usage of the device. We recommend carrying out regular safety checks every 12 months or less.

Maintenance includes, but it is not limited to, the following activities:

- Remove the foot shell and glide sock, check for damage or wear and replace if necessary
- Clean and check moving parts for signs of damage due to ingress of debris
- Check all screws for tightness
- Visually check the heel and toe springs for signs of delamination or wear. Some surface damage may occur after a period of use, this does not affect the function or strength of the foot

9 – WARRANTY AND LIABILITY

Warranty terms

ALPS BioStep feet are covered by the following warranty terms against manufacturing defects:

3 years warranty on the structural/metal elements (carbon fiber elements, bolts and titanium elements)

6 months warranty on foot shell.

1 month warranty on the spectra sock.

Specific exclusions from this warranty are: devices used beyond the recommended use conditions, in adverse environmental conditions or without respecting weight bearing limits; devices not fitted appropriately according to the instructions for use; devices not maintained as directed. The user should be aware that any changes or modifications carried out on the device which have not been expressly approved will void the warranty.

Return authorization

To obtain an ALPS Return Authorization Number (RA#) for a warranty call ALPS Customer Service and provide an ALPS representative with the following information:

Customer ID # – Invoice # – Date of Invoice – Nature of Return

The RA# must be displayed on the exterior of the returned item box or it will be refused at the dock

30 days free return period

ALPS BioStep feet benefit of a 30 days unrestricted return policy for risk-free comparison and evaluation.

Important notice: Products not returned within 30 days are considered sold, with full payment due. Return will be accepted only if the pyramid cover protector has been used during the installation of the prosthetic leg

Symbol Legend		
Manufacturer	Medical device	Single patient multiple use
		

Disposal

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

The device is a composite of different materials (metal, carbon fiber, epoxy resin, sealant) and should be treated as mixed and undifferentiated materials. Please verify your local and national environmental regulation and dispose in accordingly.

CE Conformity

This product meets the requirements of the European Regulation EU2017/745 for medical devices.

This product has been classified as a class I device accordingly to the classification rules outlined in Annex VIII of the regulation.

Reporting of serious incidents

In the unlikely event of a serious incident occurring in relation to this device, it should be reported to the manufacturer and your national competent authority.

ALPS South LLC
2895 42nd Ave. N
St. Petersburg, FL 33714, USA
Tel 1-727-528-8566
Fax 1-727-528-5426
info@easyliner.com
www.easyliner.com

EC AUTHORIZED REPRESENTATIVE
CEpartner4U
Esdoornlaan 13
3951DB Maarn
The Netherlands
www.cepartner4u.com

UK RESPONSIBLE PERSON
UKCApartner4U
7 Campion Way, Bingham,
Nottingham, NG13 8TR
United Kingdom
www.ukcapartner4u.com

EC IMPORTER
ALPS CZECH ENGINEERING s.r.o
Božkovské náměstí 17/21
32600 Plzeň – Czech Republic
Tel: +420 377 223 127
Fax: +420 377 223 010
info@easyliner.eu
www.easyliner.eu