

Elite Blade

Low Profile

Instructions for Use

EBLP22L1S-EBLP30R9S
EBLP22L1SD-EBLP30R9SD

Blatchford:

1 Description and Purpose

Application

These instructions are for the practitioner.

The term *device* is used throughout these instructions for use to refer to Elite Blade Low Profile.

This device is to be used exclusively as part of a lower limb prosthesis.

A lightweight, high-energy-return foot, ideal for high impact use from the casual jogger to the serious runner. The flexible extended pylon reduces shock load transmission making it suitable for work, leisure and sports activities. Independent heel and toe springs provide axial deflection. The split toe provides good ground compliance.

This device is recommended for users that have the potential to achieve Activity Level 3 or 4. Of course there are exceptions and in our recommendation we want to allow for unique, individual circumstances and any such decision should be made with sound and thorough justification.



To minimise the risk of slipping and tripping, appropriate footwear that fits securely onto the footshell must be used at all times.

Contra-indications

This device may not be suitable for Activity Level 1 individuals or for competitive sports events, as these types of users will be better served by a specially designed prosthesis optimized for their needs.

Intended for a single user.

Ensure that the user has understood all instructions for use, drawing particular attention to the section regarding maintenance.

Spring Set Selection

| | | User Weight | | | | | | | | | | |
|--------|----------|--------------------|--------------------|--------------------|--------------------|--------------------|---------------------|----------------------|----------------------|----------------------|----------------------|-----------------|
| Impact | Activity | 44-52 (100-115) | 53-59 (116-130) | 60-68 (131-150) | 69-77 (151-170) | 78-88 (171-195) | 89-100 (196-220) | 101-116 (221-255) | 117-130 (256-285) | 131-147 (286-325) | 148-166 (326-365) | kg (lb) |
| Low | 3 | 1 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | Foot Spring Set |
| Mod | 4 | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | | |
| High | 4 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | | | |

Low Daily walking and occasional sports such as golf and hiking

Moderate Aggressive walking, frequent or daily sports such as jogging

High Daily activities such as distance running, climbing, lifting and carrying heavy objects for vocational purposes

Important: For higher impact users, do not exceed the weight limit for individual springs.

Note:

If in doubt choosing between two categories, choose the higher rate spring set.

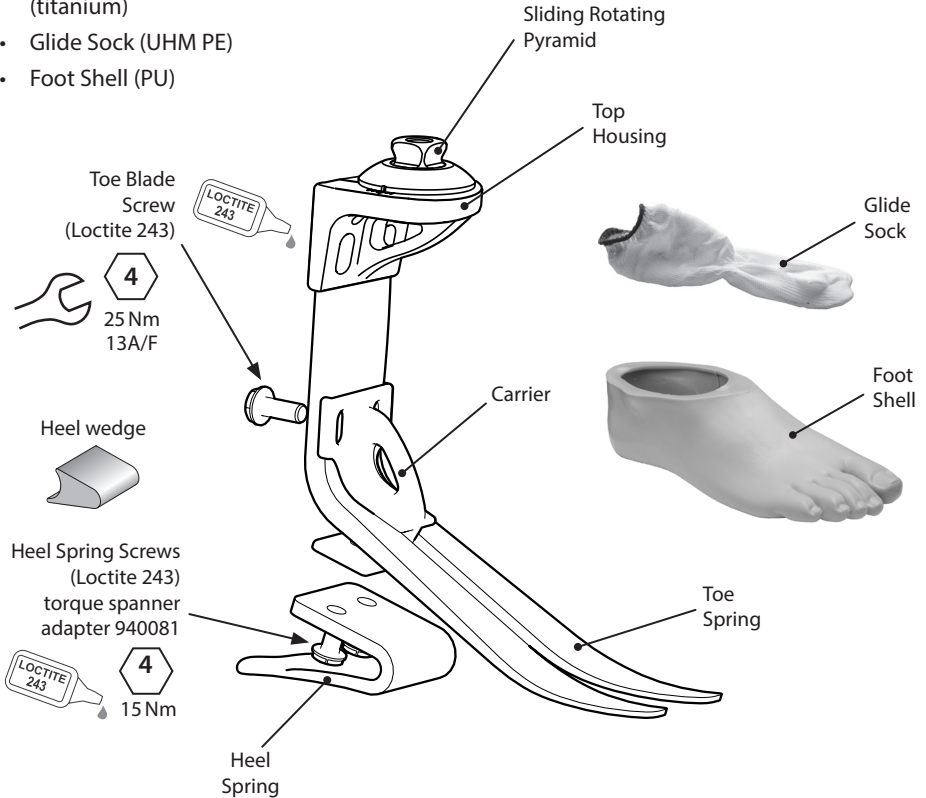
Foot spring set recommendations shown are for trans-tibial users.

For transfemoral users we suggest selecting a spring set one category lower, refer to fitting advice Section 8 to ensure satisfactory function and range of movement.

2 Construction

Principal Parts:

- Carrier, Pyramid Dome (aluminum)
- Heel & Toe Springs (e-carbon)
- Spring Attachment Screws, Pyramid (titanium)
- Glide Sock (UHM PE)
- Foot Shell (PU)



3 Function

This device comprises an e-carbon toe spring pylon and independent heel spring. Heel and toe springs are attached to the carrier assembly using titanium screws. The foot is wrapped in a UHM PE sock which is in turn surrounded by a PU foot shell.

4 Maintenance

Maintenance must be carried out by competent personnel.

It is recommended that the following maintenance is carried out annually:

- Remove the foot shell and glide sock, check for damage or wear and replace if necessary.
- Check all screws for tightness, clean and reassemble as necessary.
- Visually check heel spring and toe blade for signs of delamination or wear and replace if necessary. Some minor surface damage may occur after a period of use, this does not affect the function or strength of the foot.

The user must be handed the user information card supplied, and be advised of the following:

- Any changes in performance of this device must be reported to the practitioner e.g. reduced energy return or unusual noises.
- The practitioner must also be informed of any changes in body weight and/or activity level.

If this device is used for extreme activity, the maintenance level and interval should be reviewed and if required advice and technical support sought to plan a new maintenance schedule dependent upon the frequency and nature of the activity. This should be determined by a local risk assessment carried out by a suitably qualified individual.

The user should be advised that a regular visual check of the foot is recommended, signs of wear that may affect function should be reported to their service provider (e.g. significant wear or excessive discoloration from long term exposure to UV).

Cleaning

Use a damp cloth and mild soap to clean outside surfaces, do not use aggressive cleansers.

5 Limitations on use:

Intended Life

A local risk assessment should be carried out based upon activity and usage.

Lifting Loads

User weight and activity is governed by the stated limits.

Load carrying by the user should be based on a local risk assessment.

Environment

This device is waterproof to a maximum depth of 1 meter.

Thoroughly rinse this device with fresh water after use in abrasive environments, such as those that may contain sand or grit, to prevent wear or damage to moving parts.

Thoroughly rinse with fresh water after use in salt or chlorinated water.

Foot products must be adequately finished to prevent

water ingress into the foot shell where possible. If water enters the foot shell, the limb should be inverted and dried before further use.

Exclusively for use between -15 °C and 50 °C (5 °F to 122 °F).

We recommend using only Blatchford products with this device.



Suitable for submersion

6 Bench Alignment

Static Alignment

Setup length

Note... Shin blade should be vertical when used with a 10 mm heel height shoe. Lower heel height shoes may require the use of a packing piece below the heel.

Typically include 5 mm to allow for axial compression of heel and toe.

Build line

This should fall 1/3 of the foot length from the heel.

Dynamic Alignment

Coronal plane

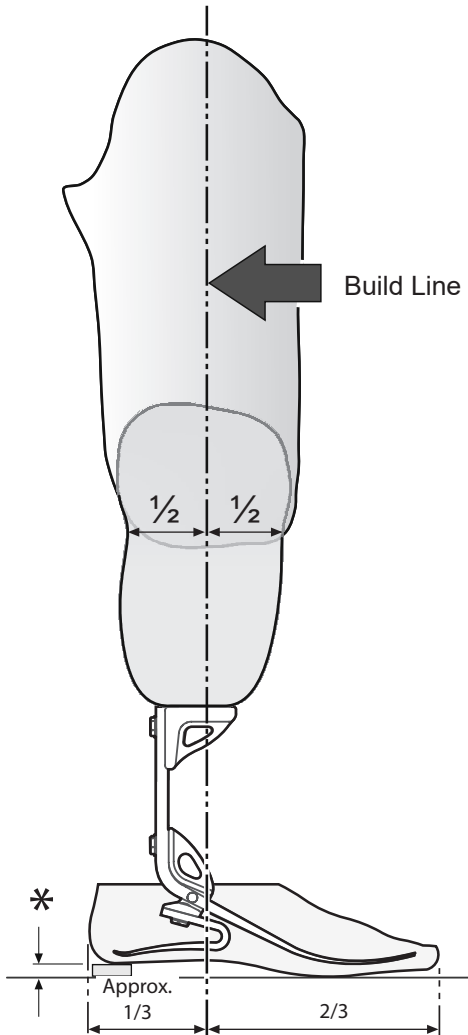
Ensure that M-L thrust is minimal by adjusting relative positions of socket and foot.

Sagittal plane

Check for smooth transition from heel strike to toe-off. Ensure also that when standing the heel and toe are evenly loaded and that both are touching the floor.

Transfemoral alignment

Align transfemoral components according to fitting instructions supplied with the knee, keeping the build line relative to this device as shown.



* Allow for users own footwear

7 Foot Shell Removal & Blade/Spring Replacement



Use appropriate health and safety equipment at all times including extraction facilities.



Be aware of finger trap hazard at all times.

1



Remove top housing from blade.

2



Remove lower carrier bolt.

3



Remove blade from carrier/foot shell.

4



Rotate heel/carrier assembly from foot shell/
glide sock.

5



13 mm

Remove heel spring from carrier.
(13 mm spanner 940273)

6




15Nm
940081

Fit new heel spring, Loctite (243) & tighten
bolts (15 Nm). Use torque spanner attachment
940081)

7 Foot Shell Removal & Blade/Spring Replacement (cont.)

7



Attach blade to heel carrier. Loctite (243) & tighten bolt (25 Nm).

4
25 Nm

LOCTITE 243

elite blade

Detailed description: A hand is shown using a torque wrench to tighten a bolt on the heel carrier of an 'elite blade'. A small bottle of Loctite 243 is shown next to a hexagonal icon containing the number 4 and the text '25 Nm'.

8



Fit glide sock and lubricate foot shell with 928017.

928017

elite blade

Detailed description: A hand is shown fitting a white glide sock onto the foot shell. A small bottle of lubricant labeled '928017' is shown in the top right corner. The 'elite blade' is visible inside the sock.

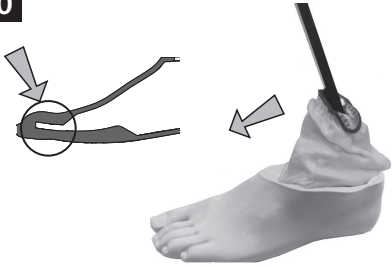
9

If a foam cosmesis is to be fitted, roughen top surface of foot shell to provide ideal bonding surface.



Detailed description: A diagram shows a foot shell with a circular area on the top surface being roughened. An arrow points to this area.

10



Fit assembly into foot shell, engage toe of blade into foot shell.

Detailed description: A diagram shows the assembly being inserted into the foot shell. An arrow points to the toe of the blade engaging with the shell.

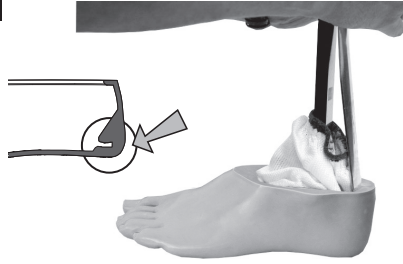
11



Using a lever, ease assembly into shell.

Detailed description: A diagram shows a hand using a lever to push the assembly into the foot shell. An arrow points to the lever.

12




Ensure heel spring is engaged into slot.

Detailed description: A diagram shows a hand ensuring the heel spring is engaged into the slot of the foot shell. An arrow points to the heel spring.

13

Attaching top housing. Loctite (243) & tighten bolts (25 Nm). Re-apply cosmesis if applicable.



4
25 Nm

LOCTITE 243

Detailed description: A hand is shown using a torque wrench to tighten bolts on the top housing. A small bottle of Loctite 243 is shown next to a hexagonal icon containing the number 4 and the text '25 Nm'.

8 Fitting Advice

Springs are supplied as matched sets i.e. the blade/toe and heel springs are designed to work together to give smooth progression for most users.

Heel Wedge

A heel wedge is supplied with the foot. Fitting the wedge will have the effect of stiffening the heel spring. These can be taped in place for trial. For permanent fitting, wedges should be adhered in place by application of Loctite 424 (926104) between the lower contacting surface of the heel and the wedge.

Heel Stiffness

Progression throughout the stance phase should be smooth; heel function is key to this process:

- Too soft a heel or load line excessively posterior will result in sinking at heel strike and difficulty in getting over the toe.
- Too hard a heel or load line excessively anterior will result in a rapid progression through mid-stance or jarring at heel strike.

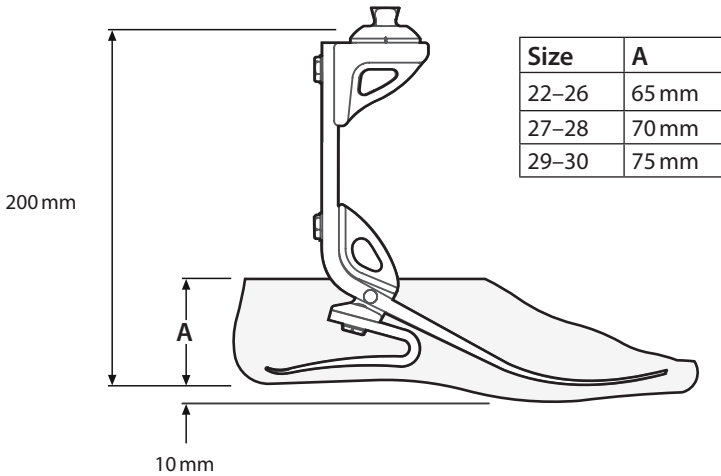
| | Symptoms | Remedy |
|----------------------------|--|---|
| Heel too soft | <ul style="list-style-type: none">• Sinking at heel strike• Difficulty climbing over the toe (toe feels too hard) | <ol style="list-style-type: none">1. Move socket anteriorly in relation to the foot (excess movement may result in drop off)2. Add heel wedge |
| Heel too hard | <ul style="list-style-type: none">• Rapid transition from heel strike through stance phase• Difficulty in controlling heel action, foot jars into mid-stance• Foot feels too rigid | <ol style="list-style-type: none">1. Remove heel wedge (if fitted)2. Move socket posteriorly in relation to foot |
| Toe/ Blade too soft | <ul style="list-style-type: none">• Rapid progression through mid-stance.• 'Drop off' at higher Activity Levels | <ol style="list-style-type: none">1. Move socket posteriorly in relation to foot2. Plantarflex foot slightly - note: some re-alignment may be required |

Please contact your supplier if it is not possible to achieve a smooth gait after following the advice above.

9 Technical Data

| | |
|--|-------------------------------------|
| Operating and Storage Temperature Range: | -15 °C to 50 °C (5 °F to 122 °F) |
| Component Weight (size 26): | 740 g (1 lb 10 oz) |
| Activity Level: | 3–4 |
| Maximum User Weight: | 166 kg (365 lb) |
| Proximal Alignment Attachment: | Male Pyramid (Blatchford) +/- 7° |
| Build Height: | 200 mm |
| Heel Height | 10 mm |

Fitting length



10 Ordering Information

Order example

| | | | | | |
|-------------|-----------|-----------------|------------|------------|----------|
| EBLP | 25 | L | N | 5 | S |
| Size | Side | Width* (N/W) | Spring Set | Sandal Toe | |

e.g. EBLP25L5S

Available from size 22 to size 30:

EBLP22L1S to EBLP30R9S
EBLP22L1SD to EBLP30R9SD
(Add 'D' for a dark tone foot shell)

*Sizes 25-27 only. For all other sizes, omit the Width field.

Foot Shell

For dark add suffix D

| Size/Side | Narrow | Wide |
|-----------|----------|----------|
| 22L | 539038S | - |
| 22R | 539039S | - |
| 23L | 539040S | - |
| 23R | 539041S | - |
| 24L | 539042S | - |
| 24R | 539043S | - |
| 25L | 539044SN | 539044SW |
| 25R | 539045SN | 539045SW |
| 26L | 539046SN | 539046SW |
| 26R | 539047SN | 539047SW |
| 27L | 539048SN | 539048SW |
| 27R | 539049SN | 539049SW |
| 28L | - | 539050S |
| 28R | - | 539051S |
| 29L | - | 539052S |
| 29R | - | 539053S |
| 30L | - | 539054S |
| 30R | - | 539055S |

Glide Sock

| Size | Part No. |
|-------|----------|
| 22-24 | 531011 |
| 25-30 | 532811 |

Liability

The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use supplied with the device. The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer.

CE Conformity

This product meets the requirements of 93/42/EEC guidelines for medical products. This product has been classified as a Class 1 Product according to the classification criteria outlined in Appendix IX of the guidelines. The Declaration of Conformity was therefore created by Blatchford Products Limited with sole responsibility according to Appendix VII of the guidelines.

Warranty

This device is warranted for 36 months - foot shell 12 months - glide sock 3 months. The user should be aware that changes or modifications not expressly approved could void the warranty, operating licenses and exemptions. See Blatchford website for the current full warranty statement.

Environmental Aspects

Where possible the components should be recycled in accordance with local waste handling regulations.

Trademark Acknowledgements

Elite Foot and Blatchford are registered trademarks of Blatchford Products Limited.

blatchford.co.uk/distributors

UK

Blatchford Products Ltd.
Unit D Antura
Kingsland Business Park
Basingstoke
RG24 8PZ
UNITED KINGDOM
Tel: +44 (0) 1256 316600
Fax: +44 (0) 1256 316710
Email: customer.service@blatchford.co.uk
www.blatchford.co.uk

US & Canada

Blatchford Inc.
1031 Byers Road
Miamisburg
Ohio 45342
USA
Tel: +1 (0) 800 548 3534
Fax: +1 (0) 800 929 3636
Email: info@blatchfordus.com
www.blatchfordus.com

Manufacturer's Registered Address

Blatchford Products Limited, Lister Road, Basingstoke RG22 4AH, United Kingdom

© Blatchford Products Limited 2020. All rights reserved.



9383005/2-0120