

Elite Blade low profile

EBLP24L1-EBLP30R9 EBLP24L1D-EBLP30R9D







endolite

available with separately supplied alignment devices



Instructions for Use

1 Description and Purpose

Application:

These instructions are for use by the Practitioner.

The Elite Blade 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 spring provides 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.



Appropriate footwear must be worn to avoid the risk of slipping in wet environments

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 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
Low	3	1	1	2	3	4	5	6	7	8	9	spring
Mod	4	1	2	3	4	5	6	7	8	9		ot spi
High	4	2	3	4	5	6	7	8	9			Foot

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 transtibial users.

For transfemoral users we suggest selecting a foot spring set one category lower.

lbs)

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Order Example:

EBLP 25L 5 e.g. EBLP25L5

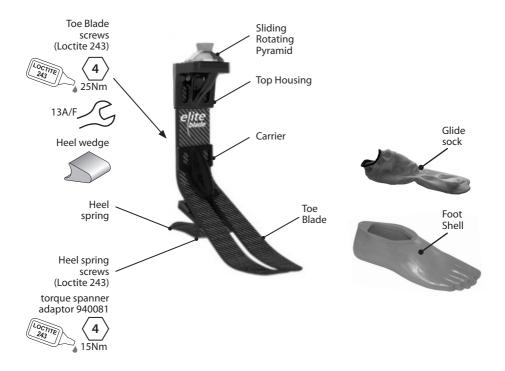
Size Spring Set Side Category Available from size 24 to size 30: EBLP24L1 to EBLP30R9 EBLP24L1D to EBLP30R9D

(add 'D' for a dark tone foot shell)

2 Construction

Principal parts:

- · Carrier Assembly (Aluminium/St. Stl.)
- Heel & Toe Springs (e-Carbon)
- Spring attachment screws (Titanium)
- Glide Sock (UHM PE)
- · Foot shell (PU)



3 Function

The Elite Blade comprises an e-carbon toe spring pylon and independent heel spring. The pylon can be cut to length to suit individual users.

Heel and toe springs are attached to the carrier assy 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 wearer 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 product 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.

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:

The product is water proof to a maximum depth of 1 metre.

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

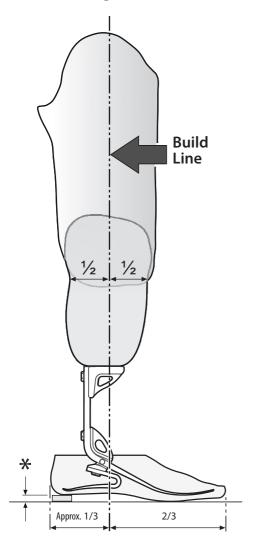
Thoroughly rinse with fresh water after use in salt or chlorinated water.

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.

It is recommended that only Endolite products be used in conjunction with the Elite Blade.

6 Bench alignment



Static alignment

Set Up Length

Note: Shin blade should be vertical when used with a 10mm heel height shoe.

Lower heel height shoes may require the use of a packing piece below the heel.

Typically include 5mm 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

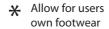
Ensure that M-L thrust is minimal by adjusting relative positions of socket and foot.

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.

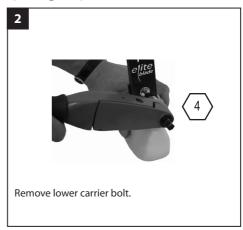
Trans-femoral Alignment

Align trans-femoral devices according to fitting instructions supplied with the knee, keeping the build line relative to the Elite Blade as shown.



7 Foot shell removal & blade/spring replacement











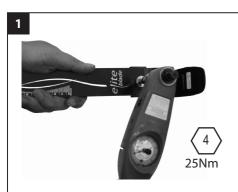
Rotate heel/carrier assy from footshell/glidesock.





(15Nm). Use torque spanner attachment 940081)

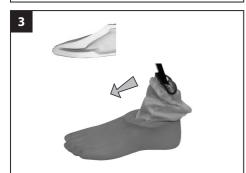
8 Foot shell removal & blade/spring replacement (cont.)



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



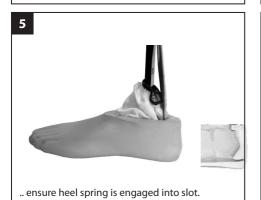
Fit glide sock and lubricate footshell with 928017.



Fit assembly into footshell, engage toe of blade into footshell.



Using a lever, ease assembly into shell....





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

9 Fitting Recommendations

The Elite Blade springs are supplied as matched sets i.e. the shin/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.

Condition	Symptoms	Remedy		
Heel too soft	 Sinking at heel strike Difficulty climbing over the toe, (toe feels too hard) 	Move socket anteriorly in relation to the foot (excess movement may result in drop off) Add heel wedge		
Heel too hard	 Rapid transition from heel strike through stance phase Difficulty in controlling heel action, foot jars into mid- stance Foot feels too rigid 	Remove heel wedge (if fitted) Nove socket posteriorly in relation to foot		
Toe/ Blade too soft	 Rapid progression through mid-stance 'Drop off' at higher activity levels 	1. Move socket posteriorly in relation to foot 2. 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 recommendations above.

10 Technical Data

Operating and -15°C to 50°C Storage Temperature Range: $(5^{\circ}\text{F to }122^{\circ}\text{F})$

Component Weight [size 26]: 587g (1lb 7ozs)

Recommended Activity Level: 3-4

Maximum User Weight: 166kg (365lb)

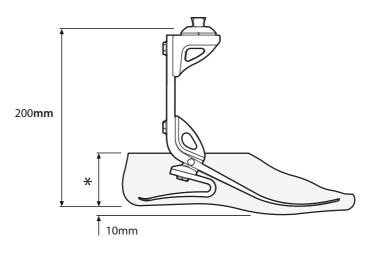
Proximal Alignment attachment: Male Pyramid (Endolite) +/-7°

Build Height: 200mm

[See diagram below]

Heel Height 10mm

Fitting Length



* sizes

24 - 28 = 70mm

29 - 30 = 80mm

11 Ordering Information

Footshell

For dark tone add suffix 'D'.

Left				
24L	539005			
25L	539007			
26L	539009			
27L	539011			
28L	539013			
29L	539015			
30L	539017			

Right				
24R	539006			
25R	539008			
26R	539010			
27R	539012			
28R	539014			
29R	539016			
30R	539018			

Glide Sock

532811 one size fits all

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.

Warrantv

The elite blade is warranted for 36months - foot shell 12 months - glide sock 3 months. See endolite website for the current full warranty statement.

Distributor/Distributeur/Händler/Distributore/Distribuidor

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