



endolite



Instructions for Use
ENS500

1 Description and purpose

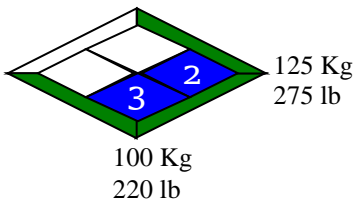
These instructions are for use by the practitioner.

- The ENS500 knee is to be used exclusively as part of a lower limb prosthesis. Intended User:
- Recommended for amputees with Mobility Grades 2 and 3.
- Weight limit for a user is up to 125 kg/275 lbs

Contra-indications

- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance.
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities

Ensure that the user has understood any Instructions for use, drawing particular attention to the safety information.



Product Code

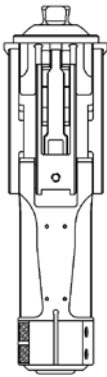
- ENS500

Polycentric pneumatic knee unit (Aluminium)

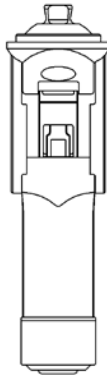
2 Construction

Principal Parts:

- Frame Aluminium Alloy, Brass, Stainless Steel, Steel
- Knee head Aluminium Alloy, Stainless Steel
- Knee control Various materials principally Aluminium Alloy
Stainless Steel, Poly Urethane, Pneumatic Cylinder



(a)



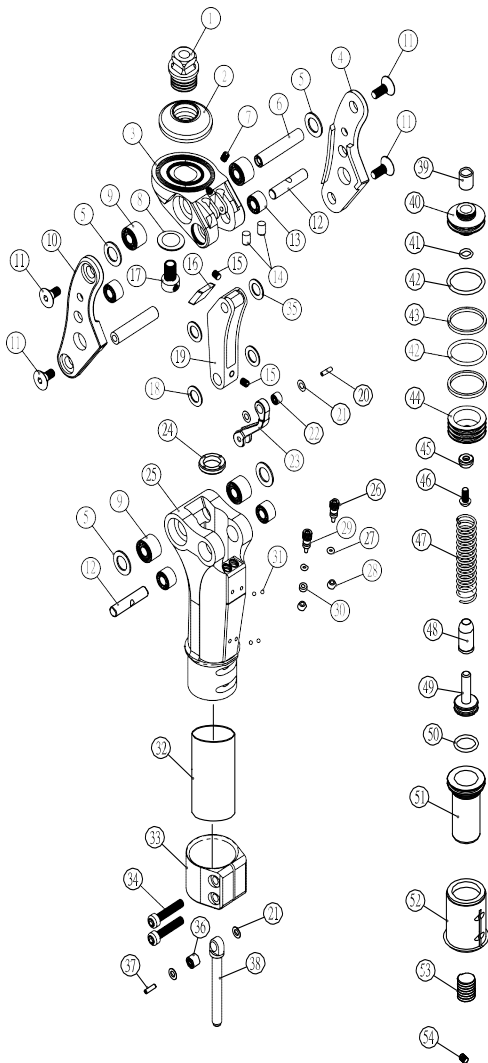
(b)



(c)

Fig. 1 (a) Posterior View, (b) Anterior View, (c) Lateral View of Knee Unit

Spare parts of ENS500 (spare parts available with the spare parts number shown)



Item no	Parts no.	Parts name	Qty/set
1		Head Pyramid	
2		Head Pyramid Base	
3		Knee Head Unit	
4		Right Side	
5	2-01-S500-SPN001	Teflon Washer	4
6		Frontal Head Axis	
7		Linkage Base Fix Screw	
8	2-01-S500-SPN002	Bolt Washer	1
9		Axial bearing	
10		Left Side	
11		Axial Screws	
12		Knee Linkage Latch	
13		Knee Linkage bearing	
14	2-01-S500-SPN003	Flexion Stop Bumper	2
15		Axial Set Screw	
16	2-01-S500-SPN004	Extension Stop Bumper	1
17		Head Pyramid Bolt	
18	2-01-S500-SPN005	Teflon Washer	2
19		Knee Linkage Unit	
20		Cylinder Linkage Latch	
21	2-01-S500-SPN006	Teflon Washer	4
22		Needle bearing	
23		Cylinder Linkage	
24		Cylinder Cap Screw	
25		Knee Body Unit	
26		Flex Resist Adj. Screw Pin	
27	2-01-S500-SPN007	Adj. Screw O Ring	2
28	2-01-S500-SPN008	Flex/Ext. Adj. Valve	2
29		Ext. Resist Adj. Screw Pin	
30		Ext. Valve Reinforcement	
31		Steel Ball Plug	
32		Copper Cylinder Liner	
33		Tube Clamp	
34		Tube Clamp Bolt	
35	2-01-S500-SPN009	Teflon Washer	2
36		Piston Rod Bearing	
37		Piston Rod Latch	
38		Piston Rod	
39		Cylinder Oil Bearing	
40		Cylinder Cap	
41	2-01-S500-SPN010	Small Cylinder O Ring	1
42	2-01-S500-SPN011	Large Cylinder O Ring	2
43	2-01-S500-SPN012	Piston Teflon Ring	2
44		Piston unit	
45	2-01-S500-SPN013	Piston Al Spacer	1
46		Halfround Head Screw	
47	2-01-S500-SPN014	Cylinder Spring	1
48	2-01-S500-SPN015	Spring Cone Spacer	1
49		Spring Base	
50	2-01-S500-SPN016	Spring Base O Ring	1
51		Spring Base Housing	
52		Tube Clamp Inner Tube	
53		Ext. Assist. Adj. Screw	
54		Set Screw	

3 Function

- Adjustable extension assist spring
- Range of Proximal adapters available to facilitate
- Independently adjustable pneumatic flexion and extension resistances.
- Adjustable flexion and extension resistances feature for various users
- The most light weight in the present market

4 Safety Information



The caution symbol highlights safety information which must be followed carefully



Be aware of finger trap hazard at all times



Any changes in performance of the knee e.g. instability or double action in the knee, should be immediately reported to the Clinician/Practitioner.



Any excessive changes in heel height may adversely affect the stability of the knee.



The user should be advised to contact their Clinician/Practitioner if their condition changes

5 Maintenance

Maintenance must be carried out by qualified personnel.

A visual inspection annually is recommended.

Check for visual defects that may affect proper function.

A loaner system is available should servicing be required.

The wearer should be advised:

Any changes in performance of this device must be reported to the Clinician/Practitioner.

Changes in performance may include:

- Increase in knee stiffness
- Knee instability
- Any unusual noises

Cleaning:

Use a damp cloth and mild soap to clean the outside surfaces. DO NOT use aggressive cleaning agents.

If the limb comes into contact with salt or chlorinated water, it should be rinsed with fresh water and dried.

6 Limitations on use

Intended Life:

- Service life of the product is covered by the warranty period.
- This product is recommended for use with other Endolite Products.
- A local risk assessment should be carried out based upon activity and usage when using as part of a hybrid limb build with other manufacturers components.

Lifting Loads:

Amputee weight and activity is governed by the stated limits.

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

Environment:

Avoid abrasive environments such as those containing sand for example as these may promote premature wear.

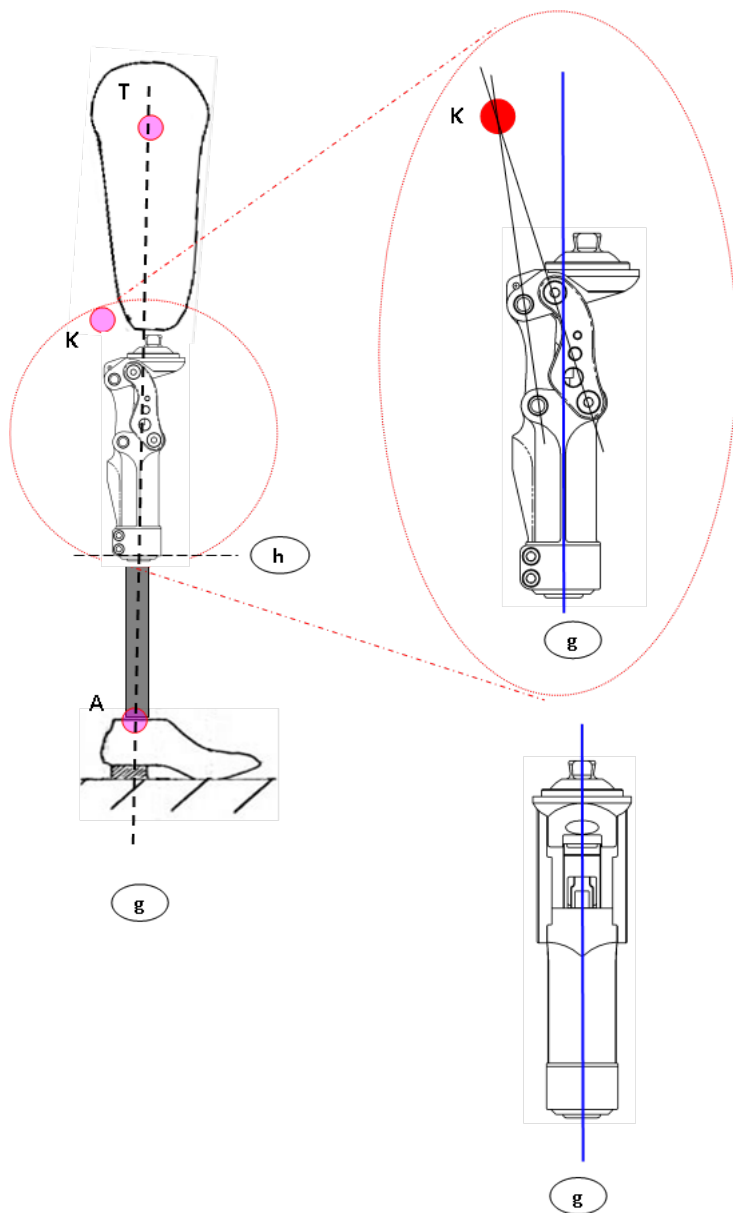
Operating and Storage Temperature Range:

Exclusively for use between temperatures of -10°C and 50°C [14°F and 122°F]

7 Alignment and Set-Up



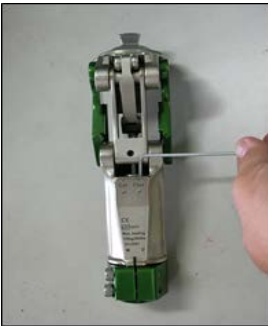
Users be aware of potential finger trap hazard



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- 7.1 Assemble the prosthesis.
 - 7.2 Recommended static/bench alignment is with the foot externally rotated 5 degrees, the socket flexed 5 degrees and abducted 5 degrees. However this will solely be dependent upon the alignment of the residuum.
 - 7.3 Align Socket in appropriate Flexion/Adduction for the patient
 - 7.4 Make sure that foot is perpendicular to the pylon on the ground level.
 - 7.5 Make sure that knee unit is also perpendicular to the ground.
(**h** line is parallel with ground)
 - 7.6 Make sure the gravity line **g** pass through the center of knee bottom.
 - 7.7 Set the static alignment taking into account the heel height of the footwear.

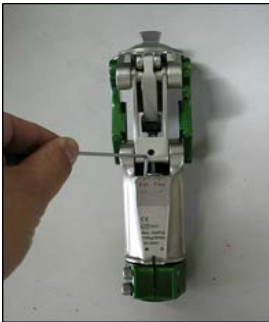
8 Knee Adjustment:

8.1 Extension/Flexion resistance adjustment:



Extension resistance adjustment

Turn the “Extension” screw clockwise with a 2.5 mm wrench driver to narrow the air-flow gap so that it increases the resistance while knee flexes, and vice versa.



Flexion resistance adjustment:

Turn the “Flexion” screw clockwise with a 2.5 mm wrench driver to narrow the air-flow gap so that it increases the resistance while knee flexes, and vice versa.

8.2 Adjusting the extension assist spring:

Use 10mm wrench driver and turn the screw of extension assist spring clockwise to compress the inner spring to increase extension assistance. Turn the screw anti clockwise to decrease the extension assistance.



8.3 Upper male pyramid adaptor adjustment :

Loosen the bolt head of the male pyramid using an 8mm wrench. Adjust the position of male pyramid according to the alignment of prosthesis. When all adjustments are done tighten the 8mm bolt with 30Nm torque setting. Use Loctite 242 to glue the bolt.



8.4 Lamination instructions for Lotus adapter (for use with existing socket)

- 1) Attach lotus plate to socket. Use alignment fixture for pre-aligned position. Center hole must be protected. Only a small amount of epoxy glue is necessary. Do not get wire cage in glue. When epoxy is dried and alignment is secured move the socket to the laminating fixture.
- 2) Apply one layer of a composite material (NSP, Fiberglass or Carbon) under the cage on a well sanded socket.
- 3) Apply a layer of nylon over the cage and ring. Tie a strong fiber around the nylon just below the ring. Do not invert back over.
- 4) Apply a second layer of composite over the Nylon. Tie a strong fiber around the ring groove. Invert the composite then the nylon over.
- 5) Fill distal hole with clay or silicone putty. Lubricate the distal plate with a light coat of petroleum jelly.
- 6) Finish with a PVA bag and lamination

9 Maintenance of Knee Unit

9.1 Change the inner spring of pneumatic unit:



Loosen the bottom clamp, its axial screws, and whole base including an inner spring with a 5mm hexagon wrench.

Replace the old spring with a new one and put the whole bottom section of the knee back by following reversed steps above.



9.2 Change the O-ring of a piston set:

Repeat the steps of 9.1 “Change the inner spring of pneumatic unit“, to take off the whole Extension assist unit to reveal the inner piston.



Loosen the screw of a piston unit with a 3 mm hexagon wrench.

Take off the piston set by using a hook tool





Take off the “O” ring and Teflon rings with a small flared tip screwdriver.

Put cleaned Teflon rings and the replacement of “O” ring back onto the piston.



Clean the inner copper of knee body with Isopropyl alcohol and smear with a thin layer of lubricant.

Reverse all steps above for re-assembling piston and extension assist spring sets back to knee unit.

9.3 Changing the Rubber bumper:



Use a small flared tip screwdriver to take out the old bumper and replace it with a new one.

10 Technical Specification

Operating and Storage Temperature Range:	-10°C to 50°C 14°F to 122°F
Weight:	882g
Recommended Activity:	K2/K3
Maximum User Weight:	K2: 125kg (275lb) K3: 100kg (220lb)
Maximum flexion angle:	145 degrees
Proximal Alignment attachment:	Rotatable socket Attachment plate Rotatable lotus adaptor
Distal Alignment attachment:	Tube Clamp
Tube clamp torque setting:	12Nm
Build Height: Knee to Distal end	220(+20)mm

Materials: Aluminium Alloy, Stainless Steel, Steel, Rubber

Key Dimensions:

Max. 145



11 Warranty

Warranted for 2 years from the date of invoice by Blatchford Products Ltd.

The user should be aware that changes or modifications not expressly approved will void the warranty.

12 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 the 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 I product according to the classification criteria outlined in appendix IX of the guidelines. Please keep this manual in safe place for future use.



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