



endolite



Instructions for Use **ENS400**

1 Description and purpose

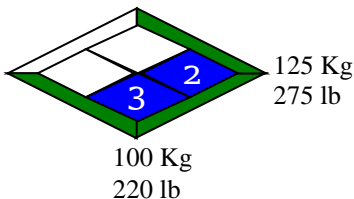
These instructions are for use by the practitioner.

- The ENS400 knee is to be used exclusively as part of a lower limb prosthesis. Intended User:
- Recommended for amputees with Mobility Grades 2/3.
- 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
- Non Level K2/K3 users.

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



Product Code

- ENS400

Polycentric mechanical knee unit with lock (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 Bumper

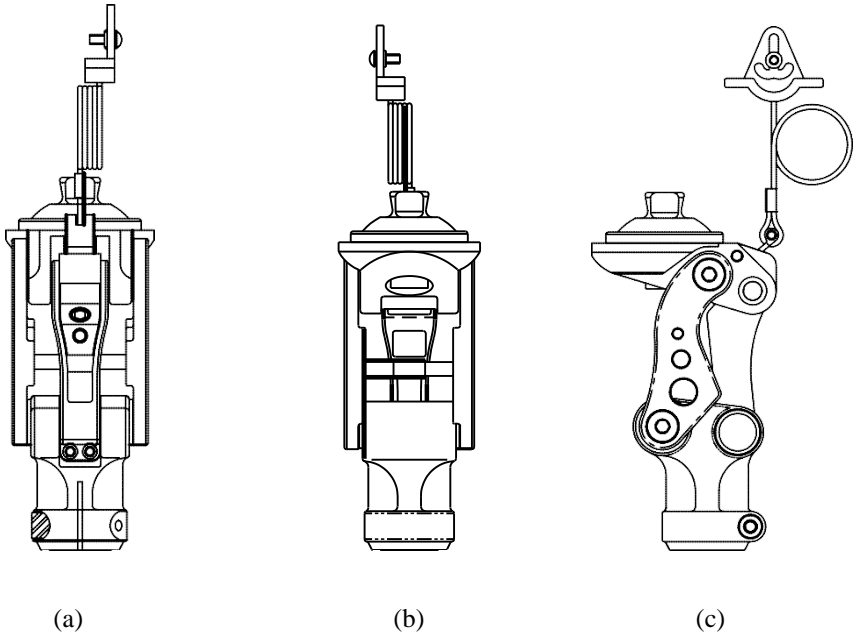
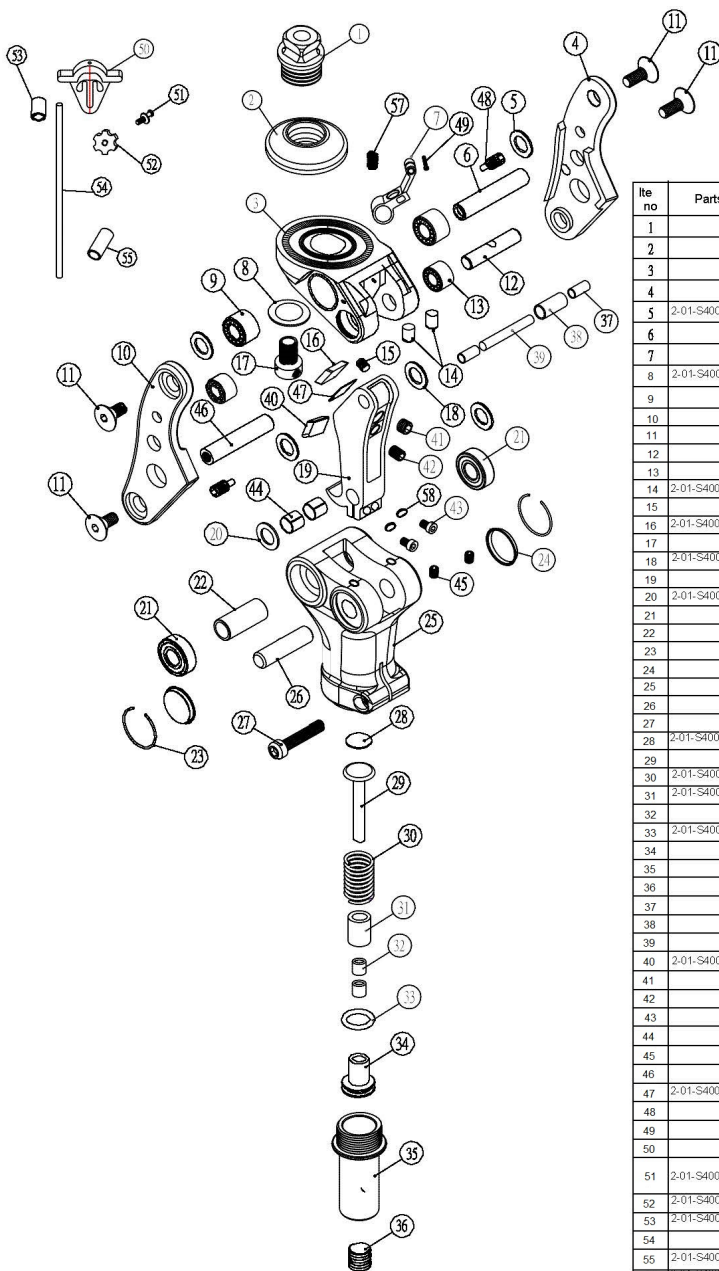


Fig. 1 (a) Posterior View, (b) Anterior View, (c) Lateral View of Knee Unit

Spare parts of ENS400 (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 Bar	
5	2-01-S400L-SPN001	Teflon Washer	2
6		Head Front Axis	
7		Lock Handle	
8	2-01-S400L-SPN002	Bolt Washer	1
9		Head Axial Bearing	
10		Left Side Bar	
11		Axial Screws	
12		Head Rear Axis	
13		Knee Linkage Bearing	
14	2-01-S400L-SPN003	Flexion Stop Bumper	2
15		Axial Set Screw	
16	2-01-S400L-SPN004	Extension Stop Bumper	1
17		Head Pyramid Bolt	
18	2-01-S400L-SPN005	Teflon Washer	2
19		Knee Linkage Unit	
20	2-01-S400L-SPN006	Teflon Washer	2
21		Body Axial Bearing	
22		Body Axial Shell	
23		C Spring	
24		Axial Cap	
25		Knee Body	
26		Body Rear Axis	
27		Tube Clamp Bolt	
28	2-01-S400L-SPN007	Linkage Slip-sheet	1
29		Spring Rod	
30	2-01-S400L-SPN008	Ext. Assist. Spring	1
31	2-01-S400L-SPN009	Rubber Shell	1
32		Oil Bearing	
33	2-01-S400L-SPN010	O Ring	1
34		Ext. Assist. Spring Base	
35		Spring Base Housing	
36		Ext. Assist. Adjust Screw	
37		Flexion I/II Stop Support	
38		Flexion I/II Stop Shell	
39		Flexion I/II Stop Bar	
40	2-01-S400L-SPN011	Flexion I/II Bumper	1
41		Head Level Adj. Screw	
42		Flexion I/II Force Adj. Screw	
43		Flex./Ext. Resist. Adj. Screw	
44		Linkage Oil Bearing	
45		Axial Set Screw	
46		Body Front Axis	
47	2-01-S400L-SPN012	Bumper Backplate	1
48		Set Screw	
49		Cable Latch on Lock Handle	
50		Control Handle	
51	2-01-S400L-SPN013	Attach Screw on Control Handle	1
52	2-01-S400L-SPN014	Attachment Screw Nut	1
53	2-01-S400L-SPN015	Copper Conjunction	1
54		Plastic Cable	
55	2-01-S400L-SPN016	Steel Conjunction	1
57	2-01-S400L-SPN017	Lock Handle Spring	1
58	2-01-S400L-SPN018	Lock Handle Spring Washer	2

3 Function

- Adjustable extension assist spring.
- Upper pyramids facilitating alignment adjustment for all socket designs
- Adjustable the head level of knee
- A low profile carbon body for variety of residual limb lengths
- The Flex/Ext resistance of knee Adjustable

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.



Always use a hand rail when descending stairs and at any other time if available.



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 cleansing 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.

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.

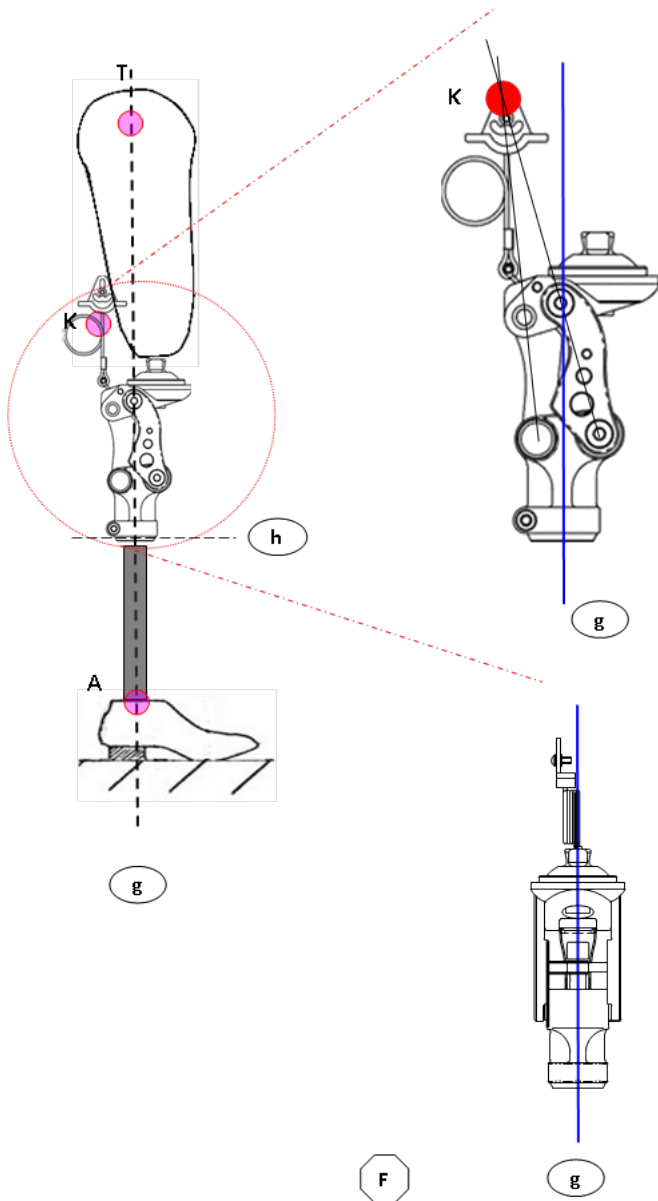
Operating and Storage Temperature Range:

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

7 Alignment and Set-Up



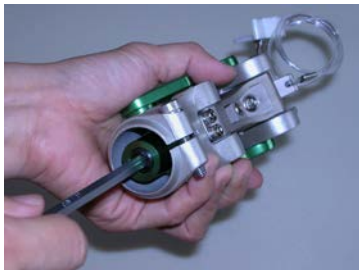
Users be aware of potential finger trap hazard



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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 Make sure that foot is perpendicular to the pylon on the ground level.
 - 7.4 Make sure that knee unit is also perpendicular to the ground.
(**h** line is parallel with ground)
 - 7.5 Make sure the gravity **g** line pass through the center of knee bottom.
 - 7.6 Set the static alignment taking into account the heel height of the footwear..

8 Knee Adjustment:

8.1 Extension assist adjustment of the base spring unit



Use 6mm wrench driver and turn the screw of base spring unit clockwise to compress the inner spring to increase extension assistance. Turn the screw anti-clockwise to decrease the extension assistance.

8.2 Adjusting the Flex/Ext resistance of knee:



Use a 3mm wrench driver and turn both two screws on the back of linkage clockwise to increase resistance of movement. Contrarily, turn both two screws on the back of linkage anti-clockwise to decrease resistance of movement.



Please turn both screws equally so that the force on inner bearer is distributed evenly.

8.3 Adjusting the head level of knee



Use 5 mm wrench driver turn the screw located in linkage clockwise to make knee head tilting back (high front/low rear). Contrarily, turn the screw anti-clockwise to make knee head tilting forward (low front/high rear).



In general, making head tilting backwards is the most common adjustment. On the other hand, too much knee head leaning forward will lower the function of rubber bumper between head and back linkage.

8.4 The upper male adaptor adjustment



Loose the bolt of head male pyramid by a 8mm wrench driver. 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.

8.5 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 Front Head Axial Cover:



Use a small screw driver to pick out the “C” spring so that the front axial cover can be taken off for replacement.

9.2 Change Rubber Bumpers

Use a small screw driver to pick out the rubber bumper of knee level adjusting screw which is located on upper linkage bar and replace it with a new one.



Use a small screw driver to pick out the rubber bumper of two-level adjusting screw which is also located on linkage bar but beneath the rubber bumper of “knee level adjusting screw” and replace it with a new one.

9.3 Disabling Lock Mechanism

Use a 2.5 mm wrench driver and turn the screw as shown in the picture to disable the lock function. Therefore, patient can walk this knee as a normal four bar knee temperately.



9.4 Change the spring of knee base.



Use this special tool to take out whole base set of knee.



Carefully remove the spring from base.



Replace new spring or other components of this base.



Clean all components of base if necessary. Assemble the whole base unit back to knee by following reversed steps.



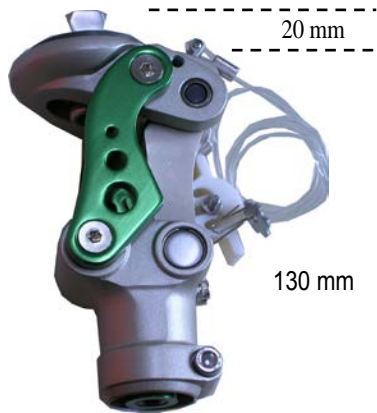
10 Technical Specification

Operating and Storage Temperature Range:	-10°C to 50°C 14°F to 122°F
Weight:	678g
Recommended Activity:	K2/K3
Maximum User Weight:	K2: 125kg (275lb) K3: 100kg (220lb)
Maximum flexion angle:	145 degrees
Proximal Alignment attachment:	Rotatable Socket Attachment PlateRotatable Lotus Adaptor
Distal Alignment attachment:	Tube Clamp
Tube clamp torque setting:	12Nm
Build Height: Knee to Distal end	130(+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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