



endolite



Instructions for Use
ENS200

1 Description and purpose

These instructions are for use by the practitioner.

- The ENS200 single axis knee with manual lock and rotating pyramid is designed for lower extremities.
- Recommended for amputees with Mobility Grade K1-K2
- Weight limit for a user is up to 100 kg/220 lbs

Contra-indications

- Residual muscular weakness, contractures or proprioceptive dysfunction including poor balance.
- Contra lateral joint instabilities or pathology
- Complicated conditions involving multiple disabilities
- Activity Level K3-K4 users

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

Product Code

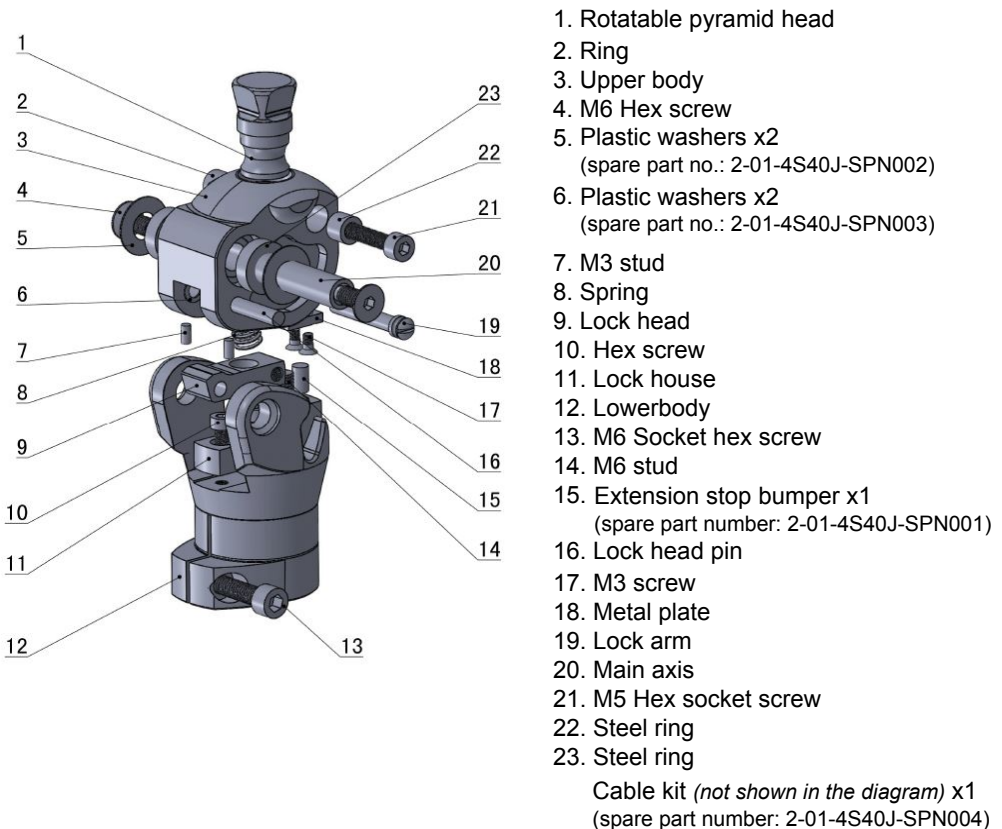
ENS200: Single axis knee unit with manual lock and rotating pyramid (Aluminium)

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: Posterior view and spare parts of ENS200 (*spare parts available with the spare parts number shown*)



3 Function

This knee has a standard 30mm diameter hole at the lower joint part in order to be assembled with 30mm diameter tubes. There is a rotating pyramid on the top of the knee which is modular for the receptacles with a spherical segment (standard). The locking mechanism is controlled by a lanyard. The amputee remotely unlock the knee by pulling the lanyard. The knee is made of high-strength aluminium alloy.

4 Safety Information

- 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

- 7.1 Assemble all necessary components into prosthesis
- 7.2 Put the prosthesis on the laser guided alignment machine and set the toe-out degree at 5°, socket abduction and flexion at 5° respectively
- 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 (line is parallel with ground)
- 7.5 Make sure the gravity line pass through the knee bottom
- 7.6 Do the bench alignment with a shoe on is recommended

8 Knee Adjustment

Rotation of pyramid

Use 5mm wrench driver and turn the pyramid set screw (part 21 Fig.1.) counterclockwise. Rotate the pyramid (part 1 Fig.1.) to desired location. Apply thread locker Loctite 242 to the pyramid set screw and turn clockwise to 10Nm torque.

Unlock the knee

The knee is unlocked by pulling the cable and is locked by forcing the knee in extension

Switching the lock arm (part 19 Fig. 1)

The lock arm can be switched left or right by loosening the screw (part 19 Fig. 1)

9 Technical Specification

Operating and Storage Temperature Range:	-10°C to 50°C 14°F to 122°F
Weight:	358g
Recommended Activity:	K1-K2
Maximum User Weight:	100kg (220lb)
Maximum flexion angle:	180 degrees
Proximal Alignment attachment:	Pyramid adaptor
Distal Alignment attachment:	Tube clamp
Tube clamp torque setting:	12Nm
Build Height: Knee to Distal end	85(+11) mm

Materials: Aluminium Alloy, Stainless Steel, Steel, Poly Urethene Bumper

10 Technical Specification

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.

11 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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