



SENSOR HYDRAULIC KNEE

2SR500

For patients up to 125kg

Instructions for Use



DESCRIPTION

The Sensor weight-activated hydraulic knee is unique to Ortho Europe and is widely recognized as an ideal choice for moderately to high active amputees. The highly sophisticated hydraulic system allows the amputee to walk naturally with smooth transitions between speeds & smooth movement throughout the gait cycle, with little effort.

APPLICATION

The Sensor Knee has the unique feature of a Manual Lock, a Stance Lock and Stance Yield - all within the same unit. The use of these functions will allow a new amputee to develop from a first time user to one who will demand and receive a high performance.

Proximally the Sensor Knee has an oversized pyramid receiver which will also accept a standard pyramid and comes fitted with a plastic insert for this purpose. For angulation only 'DO NOT' remove the insert.

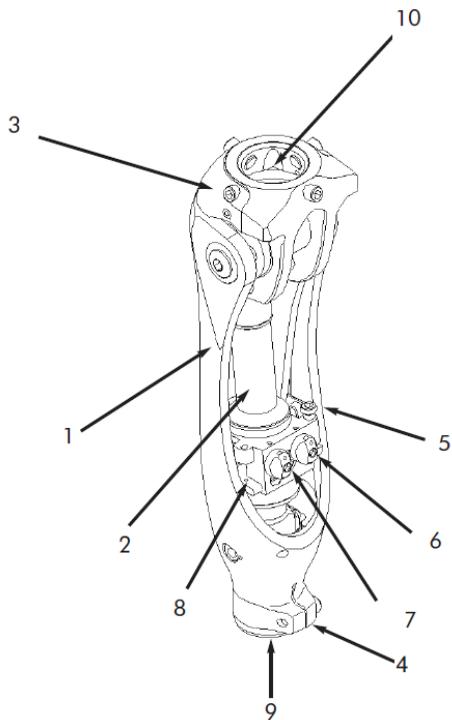
Hydraulic cylinder adjustment provides independent control of Stance Lock or Stance Yield, Knee Sensitivity, Swing Flexion Resistance + Stance Flexion Resistance (or Yield). Additionally there is terminal impact dampening which provides the limb wearer a sense of position of the prosthesis ready for heel strike.

CONSTRUCTION AND ASSEMBLY

- A range of components are available to complement and support the use of the Sensor Knee:
 - Sensor tube clamp
 - ø30mm x 250mm aluminium tube
 - Knee pyramid (Part number - 6PC508)
 - M8 Short screw alternative pack of 10



1. Lightweight frame
2. Hydraulic unit
3. Knee ball with pyramid receiver
4. Distal 30mm tube clamp attachment
5. Silver sensitivity screw
6. Silver flexion screw
7. Black yield screw
8. Yield / Lock Switch
9. Terminal impact dampening screw
10. Plastic insert



TECHNICAL DATA

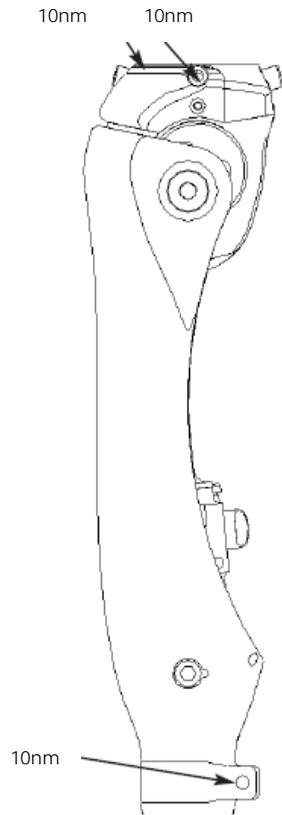
Product Weight	Patient Weight Limit	Max Flexion	Activity Level	Operating Temperature
1141g	125kg	120 degrees	Low to High	-10 TO 50°C

Sensor Alignment

Weight line from Trochanter through midline of socket with appropriate patient flexion

Weight line through center of knee

Weight line at foot following the appropriate point of manufactures recommendations



FEATURES

The Sensor Knee has a hydraulically controlled stance phase, initiated on weight bearing at heel strike and released at toe off. Swing phase aspects of heel rise, swing extension and terminal dampening are controlled and explained in detail later.

INTENDED PURPOSE AND INTERFACING

The Sensor Knee is a hydraulic knee for external prostheses for Trans-femoral (or higher) lower limb amputations. The Sensor Knee has been tested to cover amputees weighing up to 125kg/275lbs. It is preferable to use the Sensor Knee with other Premier or Sensor parts, each of the parts used in the trial or definitive prosthesis must be suitable to the amputee's weight rating. Ortho Europe recommends suitable interfacing in the product catalogue, a table with effective end of stump to Knee Centre can be found on page 1.12.

ROTATION

Depending on the accessory used, a rotation option is possible. With the use of a Shuttle Lock 3LK406 or Clutch Lock 3LK405 with rotational pyramid slackening two grub screws at right angles in the knee ball allows axial rotation above the knee centre. Re-tighten to secure the rotation. When using the Knee Pyramid 6PC508, more screws may need to be undone due to the close fit of the pyramid in the knee ball pyramid receiver.

ANGULATION

WHEN A STANDARD SIZE MALE PYRAMID IS INSERTED INTO THE KNEE BALL, THIS MUST BE CARRIED OUT WITH THE PLASTIC INSERT ITEM 10 IN PLACE.

Tighten all four screws prior to walking trial. To disassemble the pyramid from the receiver, while retaining the previous set alignment, loosen the two most deeply set, adjacent adjustment screws. Secure all screws with Loctite 243. All allen grub screws and pinch bolts must be torqued and loctited before issue to the end user.

STANCE PHASE CONTROL

The Sensor Knee allows the patient 2 different stance modes - Stance Lock and Stance Yield. In Stance Lock mode the knee will be locked by the body weight applied at heel strike, up to approximately 15 - 20 degrees of knee flexion. On release of body weight, the knee will then switch to being in swing phase. We recommend that the amputee starts off in Stance Lock position, before progressing to Stance Yield. The Yield/Lock switch (8) allows switching between Yielding and Locking at heel strike, and the Black Yield screw (7) sets the rate of yield. Yield is possible when the Yield / Lock switch is in the up position. To increase resistance rotate the Black Yield screw clockwise and to decrease resistance rotate anti-clockwise. Note: 'Yield' refers to the controlled knee flexion underweight bearing to aid slope and down stairs walking.



SENSITIVITY

The Sensor Knee is weight activated. The stance phase is engaged during heel strike under load (patient's weight) The Sensitivity Screw (5) should be adjusted to suit the load. There are two factors to consider, the physical size of the amputee and the manner in which the amputee walks. A hesitant gait will need a much more sensitive setting than an aggressive walker. Where a sensitive setting facilitates an easily achieved stance phase (either lock or yield mode), too sensitive a setting in the more active patient may cause some 'sticking' at toe-off. If the screw is set too insensitive, then buckling of the knee could occur at heel strike.

We recommend at initial fitting of the knee, that the amputee does a static heel-strike test (between the parallel bars) to ensure that the sensitivity screw is adequately set. When the sensitivity screw is turned clockwise, the sensitivity is decreased, turning anti-clockwise increases the sensitivity. Changing the sensitivity must be done with due care. Too sensitive a setting may cause difficulty in swing initiation, and too insensitive a setting may result in unsafe heel strike conditions.

THE CLINICIAN MUST ENSURE THAT THE LIMB PERFORMANCE IS CORRECT, AND ADVISE THE AMPUTEE NOT TO ADJUST THE SENSITIVITY SETTING.

SWING PHASE CONTROL

Swing Phase is controlled by the Silver Flexion screw (6) and the terminal impact dampening (9).

FLEXION SCREW

The Flexion screw (6) controls the heel rise and resistance to knee flexion in swing. Clockwise rotation increases the resistance, turning anti-clockwise decreases resistance.



TERMINAL IMPACT DAMPENING

Terminal impact dampening (9) can be adjusted by removing the tube from the tube clamp and turning the adjusting hexagon screw (inside the 30mm tube clamp) clockwise with a 2mm Allen key to increase terminal impact dampening, and anticlockwise to decrease the dampening. Make sure that the knee extends fully in the end of swing. If not, decrease the sensitivity screw a little (1/2 turn) until satisfied. NOTE: Because there is no extension resistance in the Sensor Knee amputees with experience of other knee units will report reduced energy expenditure.

FITTING PROCEDURES

Familiarise your amputee with the knee and its functions with the limb fitted and the amputee standing preferably between parallel bars:

1. Check that, with the Yield/Lock Switch (8) down, the knee locks when weight applied at heel strike; simulate with the heel in front and attempt to bend the knee. With the Switch up confirm an acceptable level of resistance for safe stance stability. Repeat the simulation.
2. Check that in normal standing the amputee feels stable and secure.
3. When taking the first steps confirm that the knee releases readily on toe-off.

NOTE: In the event of the knee sticking at toe-off decrease the sensitivity.

DOWN STAIRS WALKING - STEP OVER STEP

Ensure the Yield / Lock switch is in the 'up' position. The correct technique is for the amputee to place the heel on the stair, load the limb and flex the knee.

Adjust the Black Yield Screw (7) to achieve the correct level of resistance. The patient must place the prosthetic foot so that the edge of the stair is midfoot. If the foot is placed too far back it is difficult to 'break' the knee and if too far forward there is a risk that the heel will slip off the stair. Encourage your amputee to practice correct foot positioning.

DOWN SLOPE WALKING

When the amputee becomes competent at down stairs walking, slope walking may be practiced. For gentle slopes the new amputee will probably compensate for the slope by pushing his stump posteriorly in the socket and endeavour to 'walk over' the prosthetic limb. For slopes greater than 20 degrees the amputee should be encouraged to use the yield function of the Sensor Knee by 'sitting back' in the socket and allowing the knee to flex under the yield resistance. NOTE : Whenever a change is made to the yield valve or sensitivity screw, ALWAYS let the amputee try and confirm the suitability of the new stance setting by placing their heel in front of them and try to break or yield the knee to their satisfaction.



For completion of the alignment, ensure that the grub screws are not screwed into the knee ball more than 1 thread depth, and do not protrude more than three thread turns posteriorly. Enhance with longer or shorter grub screws as desired. Use loctite 243 and torque to 10nm to set the screws in their final configuration. The tube clamp pinch bolt is to be torqued to 10Nm and Use loctite 243. **DO NOT** over tighten. The Sensor Knee is now ready for cosmetic finish if so desired. When viewing the knee from the posterior aspect ensure that the clamp screw is inserted from the right hand side(4).

YIELD / LOCK SWITCH

Yield/Lock Switch option is used by the more experienced amputee who learns to negotiate more difficult terrain and consequently wants to switch between the two stance phase modes, lock and yield.

1. If the patient requires added security they would have the switch down, stance lock mode.
2. For the more experienced amputee the switch should be in the up position, stance yield mode.

COSMETIC FINISHING

The Sensor Knee can be finished with a single foam cosmesis.

NOTES FOR NEW USERS

It is important to bear in mind that the Sensor Knee is extremely versatile and in being so will be an appropriate device for a 'Primary' amputee with a prognosis of progression to a good level of capability. The limb can be set up to be virtually locked throughout gait but can still be flexed sitting (SAKL function). As the user progresses, the knee can then be used as a locking knee in stance, but free swinging during gait.

Ortho Europe provides both technical and practical support on this and all aspects of the knee. Engineers are available to discuss any particular technical or quality issues. An Amputee Demonstrator is available to provide practical help and support.



MAINTENANCE AND SERVICE

The Sensor Knee is designed as a low maintenance knee. For routine inspection please follow these guidelines:

1. Does the long lever operate without friction? If friction is found, is there dust build up in or around any of the moving parts?
2. Does any part appear dented or distorted?
3. Is there any visual damage or corrosion of the frame, cylinders, knee ball or any other parts that may compromise a good, reliable and safe function?
4. Is there any sign of hydraulic fluid leaking?
5. Are any controls knobs damaged?
6. If the knee malfunctions in any other way and if the problem cannot be remedied by the instructions above, please contact the manufacturer for technical support.

Services are recommended every 12 months. Loaner units are available during service period.

Standard Service

A complete overhaul will include changing the oil, replacing all seals, replacing any faulty bearings, valves and actuators.

Major Service

In addition to the items covered by the standard service, the major service will cover the cost of replacing high cost items such as cylinders, piston rod, knee ball etc.

REFIT OF SOCKETS AND REPLACEMENT OF PARTS

The Sensor Knee can be re-used where a new socket is being supplied. Where torqued and loctited interfaces are loosened, it is recommended to carefully clean the threads or use new grub screws. When replaced ensure that Loctite 243 is applied and all grub screws torque tightened correctly.

Reuse (UK Only)

The Sensor Knee may be reused providing it has been returned to, and assessed by Ortho Europe under the Reuse Scheme Policy. Ortho Europe reserves the right to decline recommendation for reuse.

RISK ASSESSMENT AND WARNINGS

This product has been tested to ISO 10328 to A125 rating, as well as in house tests on the reliability of the stance security.

The user should be informed that this product is a complicated product and needs professional care and maintenance. There is a risk of crushing, pinching or cutting of limbs (e.g. fingers) due to joint movement. DO NOT REACH INTO THE JOINT DURING USE.

No parts are to be greased or oiled by the user. Do not use spray cleaners containing white spirit e.g. WD40, as these will wash out any grease in the bearings and bushes.



NO ADJUSTMENT TO THE SENSITIVITY SCREW BY THE AMPUTEE IS PERMISSIBLE.

It is not recommended for first users to change the setting of the Black Yield Screw.

Where applicable the silver swing phase screw can be adjusted by the user to their requirements when the prosthetist is satisfied that the user understands the adjustment process.

Check List



1. Place knee in palm of left hand so you can see the BLACK (2) and SILVER (3) buttons, the Short Switch (1) on the left of the cylinder block and the Long Lever on the right of the knee.
2. Check position of Small Brass Plunger (4) found in between the Silver (3) and Black (2) buttons. If the button isn't protruding from the cylinder, activate the knee ball several times until the brass button (4) protrudes from the cylinder. If it doesn't protrude there may be a problem with the knee. Contact your prosthetist.
3. Turn Silver Button (3) fully anti-clockwise. Activate knee ball. Knee should move easily.
4. Turn Silver Button (3) half a turn clockwise. Activate knee ball. Knee should move with more resistance.
5. Turn Silver Button (3) back to starting position (fully anti-clockwise).
6. Put switch on left of cylinder block (1) into the down position. LOCK Mode.



7. With left thumb push Long Lever on right forwards and hold in position. Try to bend knee. Knee should be locked. Remove thumb from Long Lever and activate knee ball. Knee should move freely.
8. Put switch on the left of cylinder block (1) into the up position. YIELD Mode.
9. Turn BLACK Button (2) fully anti-clockwise.
10. With left thumb push Long Lever on right forwards and hold in position. Try to bend knee. Knee should move with some resistance. Remove thumb from Long Lever and activate knee ball. Knee should move freely.
11. Turn Black Button (2) half a turn clock-wise.
12. With left thumb push Long Lever on right forwards and hold in position. Try to bend knee. Knee should move with increased resistance. Remove thumb from Long Lever and activate knee ball. Knee should move freely.

RESTRICTIONS IN USE

Though most parts of the Sensor Knee are corrosion resistant, immersion in water is not recommended. If the Sensor Knee accidentally gets wet immediate drying is required, do not use soap to clean. The Sensor Knee can also be used for most sports activities, Consult the manufacturer for advice.

TERMS AND CONDITIONS

Storage

The Sensor Knee should be stored in a cool dry place.

Traceability

Each Sensor Knee is identified with a unique serial number for traceability and warranty purposes. Please find the serial number at the back of the Knee Ball on the frame.

Support

When you use the Sensor Knee in a prosthesis for a patient, please ensure that you are fully conversant with its fitting and adjustment. Ortho Europe Ltd will provide ongoing support to help you become fully conversant with the Sensor Knee.

Patient weight limit

The Sensor Knee is versatile in performance and highly adjustable to the amputees' needs. The Sensor Knee has been tested to cover amputees weighing up to 125kg/275lbs.

Warranty

This warranty is available for sellers of prosthetic devices and other buyers for re-sale, with the express exclusion of consumers. The warranty is limited to a period of 24 months from the date of fitting. The warranty applies to the Sensor Knee components against defects in parts and workmanship. This warranty does not cover:

1. Damage from force, abuse, accidents, improper use, modifications, bent, broken, corroded or damaged parts.
2. Components which have had their batch numbers removed or defaced.
3. Any secondary cost such as expenditures caused in connection with the exchange of the





unit to be repaired with a loaner or viceversa.

A loaner unit may be made available by Ortho Europe free of charge, at customer's risk, for a period not exceeding 60 days from shipping date. If the loaner unit has not been returned to Ortho Europe after 60 days from original shipping date the unit will be deemed to have been sold and will be invoiced. Ortho Europe shall not be liable for loss of use of the Sensor Knee, or other incidental or consequential costs, expenses or damages incurred by the purchaser or wearer.

During the warranty periods defective parts will be repaired, adjusted, reconditioned or replaced (at the discretion of Ortho Europe) without charge, when the unit is returned prepaid and insured to Ortho Europe.

When, due to Ortho Europe's commitment to continuous improvement, a unit has become dated during the warranty period, a new unit of a higher specification may (at the discretion of Ortho Europe) replace the unit sent for repair, under the terms of the warranty, however, the original purchase date remains in force for the purpose of warranty.

This warranty applies to the frame, knee ball, lever mechanisms, and the hydraulic unit only. Any distal shin extension and proximal socket interfacing are excluded. This warranty is in lieu of all other warranties, express or implied, including any implied warranty of merchantability or fitness for a particular purpose. The remedies provided are exclusive; in no event shall Ortho Europe be liable for any special, indirect or consequential damages.

If a repair becomes necessary after the 24 month warranty period has expired, Ortho Europe will perform the repair work. Any such repair work shall be warranted for a period of 6 months from the date of repair (subject to normal use and service) against defects in parts and workmanship. Any item returned under the 6 month warranty period must be accompanied by the original repair sheet. Under this policy no more than three repairs shall be carried out on any one unit.

Any unit sent for warranty claim must be addressed to:

The Returns Department
Ortho Europe Limited
Ability House
Nuffield Way
Abingdon
OX14 1RL

Tel: +44 (0)1235 552 895

Fax: +44 (0)1235 555004

Email: info@ortho-europe.com



(OE-IFU-W08 SENSOR KNEE VER 6.0)

www.ortho-europe.com • info@ortho-europe.com • +44 (0)1235 552 895

Ability House, Nuffield Way, Abingdon, OX14 1RL