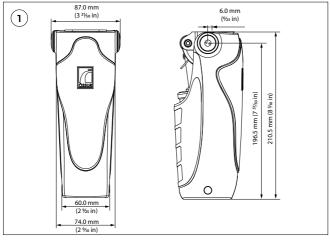


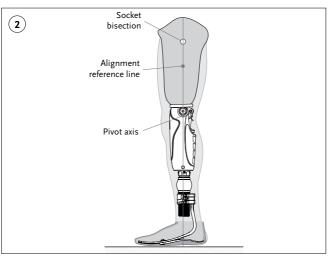


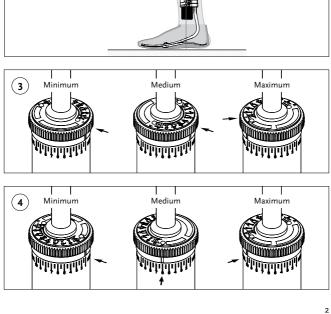
Instructions for Use

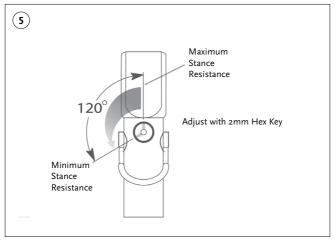
MAUCH® KNEE PLUS

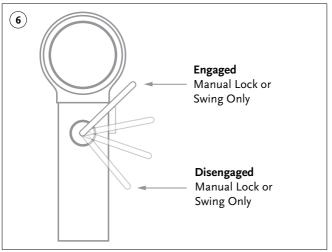
36 Months Warranty

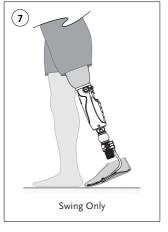


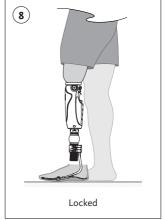












ENGLISH

Product no:

MKN71660	SNS
MKN71661	SNS – LOW RESISTANCE
MKN71662	SWING ONLY
MKN71663	THRU HOLE – SNS
MKN71664	THRU HOLE SNS – LOW RESISTANCE
MKN71665	THRU HOLE – SWING ONLY
MKN71666	SNS – HIGH STANCE RESISTANCE
MKN71667	THRU HOLE SNS – HIGH STANCE RESISTANCE

Description:

APPLICATION

The Mauch® Knee Plus is exclusively used for lower limb prosthetic fittings.

TECHNICAL SPECIFICATIONS

- · Maximum weight 166kg (366lbs).
- Net weight = 1210g (2.67lbs).
- 125° knee flexion available.

FUNCTION & DESIGN

- Single-axis hydraulic knee system with swing control (S) or swing and stance control (SNS).
- · Designed for multispeed ambulation.
- · Yielding stance control (with SNS package).
- Mode selector switch allows for manual locking and free swing functions (with SNS package).
- The frame is constructed of aircraft-grade aluminum optimized for strength.
- Universal 4-hole mounting patterns for versatile adapter options.
- · Through hole configuration as optional.
- Side load spherical bearings at knee axis and high-tech bearings ensure:
 - Smoother motion.
 - Reduced play.
 - Increased durability.

CAUTION

IMPORTANT: All components (adapters, screws and bolts), used with Mauch Plus Knee must be rated to 166kg (366lbs). Failure to comply may result in an injury and void the warranty.

Care should be taken with some component arrangements and / or alignment. It can limit knee flexion and cause damage to the knee frame or the cylinder, and may void the warranty as a result.

Össur recommends:

Össur Standard Adapters:

· Rated to 166kg (366lbs) High Impact.

ALIGNMENT: (Figure 2)

The alignment reference line is equal to the weight line.

- · Establish a vertical pylon.
- · Establish the knee center height.

- Establish the appropriate socket angles. 5 degrees of socket flexion is recommended.
- Position the socket so that the alignment reference line bisects the lateral wall at the ischial level of the socket and falls through or slightly posterior to the knee axis.
- · Establish the correct length of the prosthesis.

NOTES:

- The pyramid is shifted 6mm in an anterior direction from the knee axis.
- If the weight line is too far anterior to the knee axis, the knee may require more effort to create a hyperextension moment that will disengage the stance control and allow for fluid initiation of the knee flexion.
- Premature knee flexion may result from a weight line position too posterior to the knee axis.

SWING PHASE

The Mauch system is designed to provide variable hydraulic resistance to flexion and extension during swing phase based on changes in the user's walking speed. The resistance settings can be adjusted by rotating the cap atop the control cylinder.

FLEXION RESISTANCE: (Figure 3)

Turn the cap relative to the indicator mark for flexion.

- · Extreme left arrow indicates minimum resistance.
- Arrow at "A" indicates medium resistance.
- Extreme right arrow indicates maximum resistance.

EXTENSION RESISTANCE: (Figure 4)

Turn the cap to either extreme to move the indicator mark.

- 1 is minimum resistance.
- 5-6 is medium resistance.
- 10 is maximum resistance.

STANCE PHASE: (Figure 5)

The Mauch stance control system is designed to provide hydraulic yielding resistance to knee flexion when the prosthesis is loaded. This assists the user in descending stairs foot over foot and in stumble recovery. The stance resistance or yielding rate can be adjusted using the screw near the U-Lever on the piston rod.

- Full clockwise rotation sets the minimum yielding rate (maximum stance resistance).
- One-third rotation counterclockwise sets the maximum yield rate (minimum stance resistance). DO NOT EXCEED ONE-THIRD ROTATION.

SPECIALIZED MODES OF OPERATION

U-Lever (Mode Selector Switch): (Figure 6)

The Mauch system is designed to provide the user with a manual lock and a Swing Only mode of operation. These functions are engaged and disengaged through the U-Lever or mode selection switch located near the top of the piston rod. The manual lock may be useful when the user requires additional safety. Swing Only mode is useful during rowing, running, or cycling activities.

• Manual Lock or Swing Only mode engaged. U-Lever in up position.

Manual Lock or Swing Only mode disengaged. U-Lever in down position.

PROCEDURE FOR ENGAGING SWING ONLY MODE: (Figure 7)

- · Hyperextend the knee.
- · Raise the U-Lever.
- · Stance resistance is eliminated.

PROCEDURE FOR ENGAGING MANUAL LOCK: (Figure 8)

- DO NOT hyperextend.
- · Raise the U-Lever.
- · Unit is locked against flexion.

MAINTENANCE

- Cylinders **CANNOT** be replaced in the field. For cylinder replacement and/or repairs, send the knee joint in for service.
- Knee joints must be stored upright. Storing cylinders or knee joints on their side will cause the cylinder to draw in air. Air can be bled from the system by engaging Swing Only mode and cycling the cylinder until all of the air has been eliminated.
- Clean the extension stops regularly to prevent dirt buildup that may compromise the cylinder release. Use a blunt instrument and be careful not to scratch the contact areas.

DO NOT disassemble the knee joint or attempt your own repairs. If a problem should arise, send the knee joint in for service.

CLEANING

Wipe the knee with a soft cloth moistened with a small amount of kerosene

DO NOT use compressed air to clean the knee. Air will force pollutants into the bearings which may cause malfunctions and early deterioration. **DO NOT** use any solvents stronger than kerosene. Do not immerse the whole knee or pour solvent over the knee, which would damage the bearings and seals.

COSMETICS

DO NOT use talcum powder to eliminate noise in the cosmetic cover. It reduces lubrication, which may lead to malfunctions and early deterioration of mechanical parts. Use silicone spray instead.

WARRANTY

Product No:

Össur offers 36 months limited warranty on manufacturing faults.

CAUTION! Avoid placing hands or fingers near moving joints.

MAUCH® KNEE ACCESSORIES

MKA01361	KNEE BALL, SCREW, BTN HEAD
MKA01362	COVER, FRONT
MKA01363	COVER, REAR
MKA01364	PLUG, SIDE
MKA01365	EXTENSION STOP, SOFT
MKA01366	EXTENSION STOP, HARD

Description:

LIABILITY

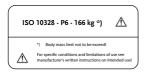
The manufacturer recommends using the device only under the specified conditions and for the intended purposes. The device must be maintained according to the instructions for use. The manufacturer is not liable for damage caused by component combinations that were not authorized by the manufacturer.

CE CONFORMITY

This device meets the requirements of the 93/42/EEC guidelines for medical devices. This device has been classified as a class I device according to the classification criteria outlined in appendix IX of the guideline.

COMPLIANCE

This component has been tested according to ISO 10328 standard to three million load cycles. Depending on the amputee's activity this corresponds to a duration of use of three to five years. We recommend carrying out regular yearly safety checks



EN – Caution: Ossur products and components are designed and tested according to the applicable official standards or an in-house defined standard when no official standard applies. Compatibility and compliance with these standard is achieved only when Ossur products are used with other recommended Ossur components. If un-usual movement or product wear is detected in a structural part of a device at any time, the patient should be instructed to immediately discontinue use of the device and consult his/ her clinical specialist. This product has been designed and tested based on single patient usage. This device should NOT be used by multiple patients. If any problems occur with the use of this product, immediately contact your medical professional.

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