

Symphonie Aqua Kniekappe



SA 801 1-4

DE Gebrauchsanleitung
EN User manual

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1. Safety instructions and warnings



Warning!

- Keep the product out of reach of children – danger of suffocation!
- Make sure that the knee sleeve is not worn on irritated or damaged skin! Possible consequences of doing so could result in skin irritations, formation of eczemas, or infection due to bacterial contamination.
- Inspect the knee sleeve for damages before each usage to avoid the risk of injury.
- For hygienic reasons, the product is intended for use by only one patient. Re-use is not permitted.
- Ensure that the knee sleeve is correctly donned and seated.
Discontinue use of the knee sleeve if there are fitting problems, as pressure marks and constriction of blood vessels and nerves from incorrect donning may occur.

Please read all instructions carefully! They contain important information regarding use and care of the knee sleeve.

The Romedis GmbH takes no liability for any claims that result from inobservance of this operating manual. Save all documents for future reference.

2. Intended use

The Romedis GmbH Symphonie Aqua knee sleeves are solely intended for prosthetic care of the lower extremities, to facilitate prosthetic suspension, and/or hermetically seal the interior space of the socket (e.g. for utilization of active vacuum systems.)

We recommend the use of mechanical or electric vacuum pump systems and /or expulsion valve for this knee sleeve.

The new knee sleeve consists of two materials. Proximal and distal sealing surfaces are crafted from silicone. This offers an optimal seal between the kneecap, socket and thigh.

ROM is maximized during all activities due to the extremely thin material in the middle, which comfortably folds over the knee.

Additionally, this design allows for improved prosthetic control without resistance from the knee sleeve.



Carefully test your first steps with the new knee sleeve.

Due to the folds in the knee area, it can take **up to 30 steps** – depending on the active or passive vacuum system and leg volume – until a full vacuum is reached and

therefore the connection between residual limb and the prosthesis is attained. **Please be careful during those first steps.**

The absence of tension over the patella and compression in the popliteal area maximizes comfort, paired with a perfect vacuum fit of the prosthesis.

This knee sleeve has a unique socket edge protection that ensures comfort and durability. The integrated socket edge protection is

individually cut to the corresponding prosthetic socket edge. It is recommended to leave an excess length of approximately 6 mm. This enables kneeling on clean surfaces without damaging the knee sleeve.

The Romedis GmbH knee sleeves can be deployed for mobility grades of 1-4.

Mobility grades:

Mob. 2	limited outdoor walkers
Mob. 3	unlimited outdoor walkers
Mob. 4	unlimited outdoor walkers with very high demands

3. Knee sleeve size chart

The Symphonie Aqua Knee Sleeve is available in four sizes.

Size chart:

Article No. Size Circumference at prosthetic socket MPT

Fits Limb Measuring

SA801 1 S 23 cm- 33 cm

SA801 2 M 27 cm- 37 cm

SA801 3 L 31 cm- 41cm

SA801 4 XL 35 cm- 45 cm

4. Handling the knee sleeve



Caution!

- Don knee sleeve with clean hands, in order to avoid soiling the silicone.

- Incorrectly sized or excessively tight fit of the knee sleeve may result in pressure marks and constriction of blood vessels and nerves.
- Keep the product away from fire, or other sources of heat to avoid injury (e.g. burns) due to melting of materials.
- DO NOT use washing machine or dryer as it may damage sleeve.

Step 1:

The Symphonie Aqua Knee Sleeve comes with an integrated edge protection function which must be cut to fit the individual form of the socket edge. Push the lower half of the knee sleeve outward, to expose the inner side.



Step 2:

Place the knee sleeve on the prosthesis edge and roll the inside-out half downward, over the socket.





Step 3:

Stretch the lower part of the knee sleeve over the socket edge so that the back part, which is at the flexor tendon area, is positioned low enough to allow the thin, airtight fabric on the back to sit

below the socket edge. (The knee sleeve is positioned on the socket.)



Step 4:

Now you can cut the socket brim. (Small, sharp, half-round scissors work best). Under no circumstances should you cut through the thin, black, airtight fabric. Cut the integrated socket edge protection at the brim, leaving approximately a 6 mm excess length over the shortened socket edge protector.





Step 5:

For donning the prosthesis, roll down the upper half.

Following that, roll the knee sleeve upward, over the knee.



To remove the knee sleeve, proceed in the reverse order.

Make certain that the elongation limitation straps are always located medially and laterally to the knee. The wrong placement (anterior/posterior) leads to damage of the knee sleeve and can injure the patient.



Elongation limitation
Strap

5. Care and cleaning of the Symphonie Aqua Knee Sleeve



Caution! Common problems and questions:

- Prior to initial use, the knee sleeve must be thoroughly washed.
- Clean the knee sleeve after each use with lukewarm water and pH-neutral soap.
- Be careful not to damage the silicone surface with sharp objects, such as rings or wristwatches.
- DO NOT use washing machine or dryer as this will damage sleeve.
- The application of powders and oils (baby powder, talcum, perfume, antiperspirant, deodorant, care oils, etc.) may lead to signs of disintegration on the knee sleeve and are therefore not recommended.

Step 1: Turn the knee sleeve to the left and rub soap and water over the entire surface, using the palm of your hand.

Step 2: Then, rinse the entire silicone surface with fresh water to remove the soap.

Step 3: Thoroughly dry the knee sleeve with a clean towel and lay it flat on drying rack. Do not wring out!

6. Usage restrictions



Warning!

- Kneeling on hard ground (pebbles, asphalt, and coarse sand) can lead to damages.

We recommend prosthetic socket care which allows for total surface weight bearing, using the Symphonie Aqua VC System.

The daily wearing period and the period of application are determined by the medical indication.

7. Guarantee / Operating life

This product has a 3- month warranty. During this time, the guarantee is valid for material defects, premature wear of singular materials and manufacturing flaws.

The guarantee begins when the knee sleeve is deployed, according to regulations.

Modifications of the knee sleeve – of any kind – result in the termination of the guarantee.

Romedis GmbH reserves the right, regarding the product guarantee:

- to repair the damaged product at its own option
- to provide a replacement, free of cost
- to issue a credit voucher for the net sales price.

For further information, contact the customer service at Romedis GmbH.
(www.romedis.de)

8. Disposal

Waste should be disposed at an appropriate disposal center, in accordance with applicable laws, regulations and product properties. Do not dispose with household waste!

9. CE Conformity

This product fulfills the requirements of legal guidelines (EU) 93/42/EWG for medical devices. Based on the Classification of Medical Devices, according to Appendix IX of the guideline, this product has been classified in Category 1. The declaration of conformity was therefore generated by the Romedis GmbH on its sole responsibility, according to Appendix VII of the guideline.



10. Legal Information

All legal conditions are subject to national laws applicable in the country and place of use and may vary, accordingly.

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