

ROMEDIS^{GMBH}

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. Do not use the knee sleeve further if there are fitting problems, as pressure marks and constriction of blood vessels and nerves from incorrect donning may occur.

Please read the instructions completely and attentively! 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. Store all documents for future accessibility.

2. Intended use

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

We emphatically recommend the usage of mechanical and electric vacuum pump systems and also for exhaust valve for this knee sleeve.

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

Due to the extremely thin material in the middle, which is folded over the knee, an optimal freedom of movement for vacuum socket systems is attained.

The advantages become very evident when sitting or bicycling.

Likewise, one notices the advantage of the possibility for controlling the prosthesis without resistance.



Carefully test your first steps with the new knee sleeve in order to get used to the new, free feeling.

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 nor compression in the popliteal area provide high wearing comfort, paired with a perfect vacuum fit of the prosthesis.

This knee sleeve has a new socket edge protection. This ensures high comfort in combination with longevity. 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	
		min. circumference	elastic to
SA801 1	S	23 cm	35 cm
SA801 2	M	27 cm	39 cm
SA801 3	L	31 cm	43 cm
SA801 4	XL	35 cm	47 cm

4. Handling the knee sleeve



Caution!

- Put on the knee sleeve only with clean hands, in order to avoid soiling the silicone.

- Incorrect or excessively tight fitting of the knee sleeve on the body may result in pressure marks and constriction of blood vessels and nerves.
- Keep the product away from fire, embers or other sources of heat to avoid injury (e.g. burns) due to melting of materials.
- Cleaning in the washing machine or dryer may cause damages.

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 length 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.



length 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.
- Cleaning in the washing machine or dryer can result in damages.
- 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 cleansing agent.

Step 3: Thoroughly dry the knee sleeve with a clean towel and lay it flatly on a clothes 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 an operating life of 3 months. During this time, the guarantee is valid for material defects, premature wear of singular materials and manufacturing flaws. The knee sleeve is a wear part which is subject to typical wear and tear.

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/EEG 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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