

INSTRUCTIONS FOR USE

IFU CODE: 49



**Liner Sealing
Membrane**
(LS-2 / LS-3 / LS-4 /LS-5)



Silicone Glue
(LS-R)

INFORMATION

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- Please read this document carefully before using the product.
- Instruct the user in the appropriate and safe use of the product.
- Follow the safety instructions to abstain injuries and damage to the product.
- Please keep this document in a safe place.

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1. LS

Liner Sealing Membrane

The LS (Liner Sealing Membrane) is a silicone ring which can be bonded in any position to almost all fabric-coated liners. Silicone Glue (LS-R) must be used for bonding. The LS can be used with active or passive vacuum systems. The LS can be used together with Locking Liners to eliminate rotation and longitudinal stroke. The advantage of the LS is that a vacuum is created between the stem and the liner, creating a hold of the prosthesis on the body without the need for a knee cap or locking liner.

2. Intended Use

The LS (Liner Sealing Membrane) is available in 4 sizes. It is intended for use only with upper and lower limb prostheses. The product is designed for use with almost all fabric-coated silicone, polyurethane, and TPE liners.

The LS forms the interface between the residual limb and the prosthetic socket.

The suitability of the product for both the patient and the prosthesis must be assessed by a qualified orthopedic technician.

The product must only be applied and fitted by a qualified orthopedic technician.

The product provides the following functions:

1. Provides prosthetic suspension using vacuum suspension technology.
2. Helps reduce rotation and longitudinal pistoning of the residual limb within the prosthetic socket.

2.1. Indication

The LS (Liner Sealing Membrane) is intended exclusively for prosthetic fitting of patients with lower limb amputation and/or congenital lower limb deficiency.

2.2. Contraindication

- severe circulatory disorders



Warning!

If you have severe diabetes and poor blood circulation, consult a doctor before use

3. Technical Specifications

3.1. Liner Sealing Membrane

Code	Circumference (cm)	Silicone Liner	Gel Liner
LS-2	18-22	18-21,5	S
LS-3	20-38	22-36	M-L
LS-4	30-48	32-45	XL
LS-5	40-55	>40	

3.2. Silicone Glue

Code	Content
LS-R	90 ml

- Use for bonding LS Sealing Membranes on the Liners.
- For sealing at the position of the Sealing Membrane.

4. Environmental Conditions

Acceptable Environmental Conditions
Temperature storage range: -20 °C to +55 °C
Store at room temperature in a dry place, protected from direct sunlight, when not in use for an extended period.

Unsuitable Environmental Conditions
Storage temperature below -20 °C or above +55 °C
Direct sunlight during long-term storage
Humid or wet storage conditions



WARNING

1. Do not expose the product to unsuitable environmental conditions.
2. If the product has been exposed to unsuitable environmental conditions, inspect it for damage before use.
3. Do not use the product if damage is visible or suspected.
4. If necessary, clean, replace, or have the product inspected by a qualified orthopedic technician.
5. Only use the product with prosthetic components that are intended and approved for compatible use.

5. Service Life

The product is a wearing part that is subject to normal wear and tear.

6. Limitations of Use

6.1. Single-Patient Use

Due to hygiene requirements and the need for fitting by a qualified orthopedic technician, this product is intended for use by one patient only.

6.2. Misuse

The product is intended exclusively for prosthetic fitting in accordance with its intended use and is not suitable for sports activities or any other unintended use.

7. General Safety Instructions



CAUTION!

Before each use, inspect the LS (Liner Sealing Membrane) for tears, cracks, or other visible damage. Damage to the sealing edge may impair the vacuum seal. If any damage is detected, discontinue use and consult a qualified orthopedic technician.

To avoid the risk of injury and product damage, do not use for longer than the service life of the product.

The suitability of the device to the patient and the prosthesis should be evaluated by a healthcare professional.

The device must be fitted and adjusted by a healthcare professional.

Avoid using this product in unsuitable environmental conditions. If the product has been exposed to unsuitable environmental conditions, check for damage.

Do not use the product that is damaged, has limited functionality or is in doubtful condition. Ensuring that appropriate measures are taken (e.g. control, cleaning, repair, replacement by the authorized workshop or manufacturer).

To prevent mechanical damage, be careful and caution when working the product.

Use the product for a single patient to avoid injuries and product damage.

Products should be used in appropriate combinations. Using the product with unsuitable combinations may result in possible injury.

8. Size Selection

8.1. How to choose the correct liner size

- a) Measure the circumference of the residual limb at the height at which the ring is to be attached to the liner, above the tightened liner. In the case of a transtibial liner, the knee should be slightly bent so that the soft tissue can hang down.
- b) Choose the ring size corresponding to this measurement or the next smaller size, respectively.
- c) Do not choose a ring whose size exceeds the measurement taken.
- d) Never reduce by more than one ring size in order to avoid unnecessarily high compression.

Choosing the right ring size is critical for comfort and safety.

- If the ring is too tight, this can lead to lifting, numbness and blistering.
- If the ring is too large and too loose, wrinkling may occur during bonding and subsequent sealing of the liner in the socket can no longer be guaranteed.



Caution!

The product must be thoroughly checked for defects before fitting.

9. Bonding with Silicone Glue (LS-R)

Determine the attachment height of the LS (Liner Sealing Membrane) on the liner **(Fig. 1)**. Use the plaster model of the die for this purpose.

If an air expulsion valve is already present in the prosthetic socket, make sure that the LS is above the valve seat and does not touch it. To do this, mark the seat of the valve through the valve hole in the prosthetic socket **(Fig. 2)**.

Tape above and below the LS with adhesive tape. A gap of approx. 3–5 mm should remain **(Fig. 3)**.

Remove the sealing lip from the liner and clean it with Acetone on the side to be bonded **(Fig. 4)**.

Apply Silicone Glue (LS-R) onto the fabric between the masking tape. Make sure that the seams are coated well as otherwise no vacuum can be created **(Fig. 3)**.

Position the LS (Liner Sealing Membrane) over the Silicone Glue (LS-R) and wipe off any excess silicone. Make sure that no air is trapped between the membrane and the adhesive. This causes air bubbles and reduces the service life of the LS **(Fig. 6)**.

Remove the adhesive tape and smooth out the bonding silicone at the edge of the membrane.

Allow the Silicone Glue to cure for at least 4–6 hours.

10. Use

The LS (Liner Sealing Membrane)

- can be bonded in any position to almost all fabric-coated liners
 - can be used with active or passive vacuum system
 - can be used with locking liners to eliminate rotation and longitudinal stroke
 - can be bonded to prosthetic stockings to create a sealing stocking
- The liner with bonded ring must be used according to the liner's instructions for use.

Caution:



The product must be thoroughly checked for defects before fitting.

11. Cleaning and Care

- Clean the product daily after use. Wash the bonded ring by hand in warm water (30°C) with neutral soap. Use only water and soap for this, but no other harsh cleaning liquids.
- Always return the product to its neutral position immediately after cleaning. Do not store the product in a turned state, as this may damage it.

Notice:



Using the wrong detergent may damage the product.

Do not use bleach, harsh chemicals or objects such as salt water, acids, dust or sand as this may damage the fabric on the outside of the liner or the silicone surface.

Caution:



When handling the LS, make sure that it is not damaged by your fingernails or sharp objects.

12. Maintenance

1. After the first 30 days of use, the prosthesis parts should be visually inspected and function checked.
2. Inspect the entire prosthesis for wear during normal consultations.
3. This prosthesis and its components should be checked for function by a prosthetist at regular intervals every six months. If the recommendations are followed properly, there is no risk.



CAUTION: Failure to follow the maintenance instructions
Risk of injury due to changes in or loss of product function,
as well as damage to the product.



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