LINER

Fig. 1

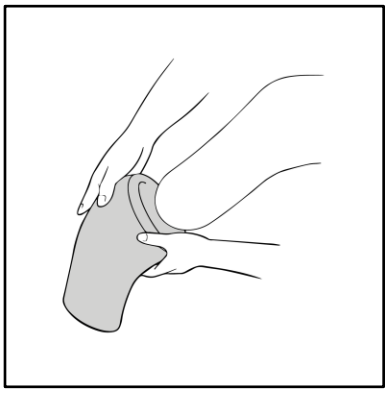


Fig. 2

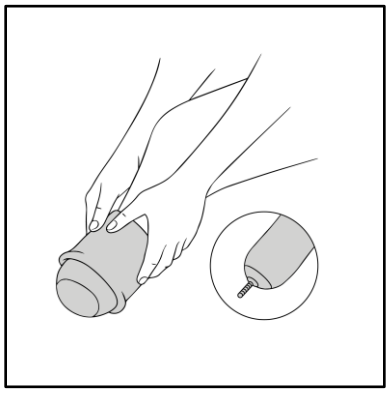


Fig. 3

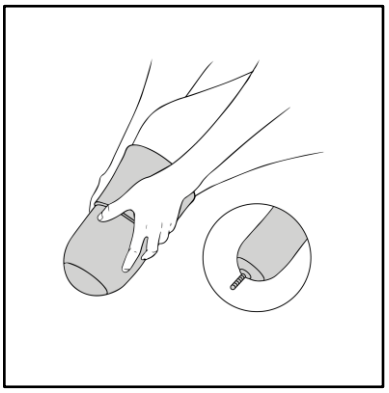


Fig. 4

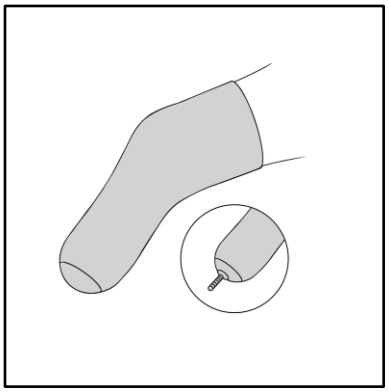


Fig. 5

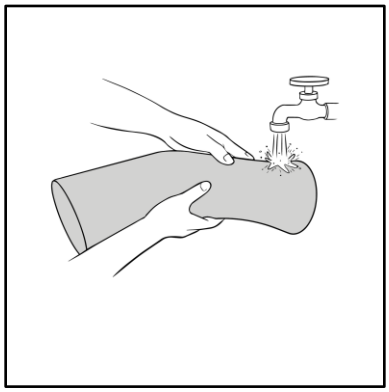
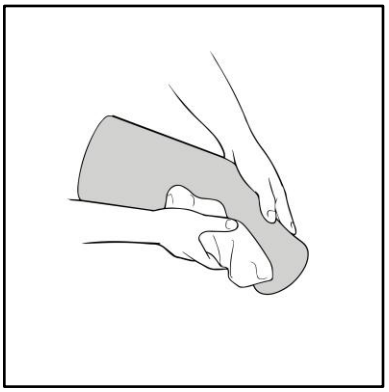


Fig. 6



ENGLISH

READ THE FOLLOWING INSTRUCTIONS CAREFULLY IN THEIR ENTIRETY BEFORE USING THE DEVICE AND OBSERVE THE SAFETY INSTRUCTIONS. CORRECT INSTALLATION IS ESSENTIAL FOR THE PROPER FUNCTIONING OF THE DEVICE.

DEVICE DESCRIPTION :

The device is a silicone liner worn over the residual limb to provide a comfortable and protective interface inside the prosthetic socket. It also helps secure the limb to the prosthesis.

There are two main types of liners:

1. Locking liner (-L-): Includes either a built-in or interchangeable distal attachment that connects directly to the prosthesis for suspension.
2. Cushion liner (-C-): Has no distal attachment and therefore requires the use of a separate suspension sleeve to create suction or vacuum and hold the prosthesis in place.

INTENDED USE :

The device is a prosthetic interface designed to help suspend and secure a lower-limb prosthesis. It is intended to be used as part of a complete prosthetic system after limb loss.
A qualified healthcare professional must evaluate whether this device is appropriate for the patient and the specific prosthesis. The device must be fitted and adjusted by a trained healthcare professional.

INFORMATIONS :

1. Please read this entire document carefully before using the device and follow the safety instructions.
2. A healthcare professional must instruct the patient or the caregiver how to use this device safely.
3. Contact the manufacturer, or your healthcare professional if you are a patient or a caregiver, if you have any questions about the device or if you experience any problems or complaints or incidents including any worsening medical conditions.
4. Please keep this document.

MATERIALS :

List of materials per Liner SKU

Liner SKUs	**Material**
LNR-SIL-L-3-XX-30	Medical Grade Silicone
LNR-SIL-C-3-XX-30	Medical Grade Silicone
LNR-SIL-L-6-XX-30	Medical Grade Silicone
LNR-SIL-C-6-XX-30	Medical Grade Silicone
LNR-SIL-L-3-XX-40	Medical Grade Silicone
LNR-SIL-C-3-XX-40	Medical Grade Silicone
LNR-TF-SIL-L-2-XX-40	Medical Grade Silicone
LNR-GEL-L-X-X-X	Thermoplastic Elastomer
LNR-GEL-C-X-X-X	Thermoplastic Elastomer

USE OF SYMBOLS

Symbols	Symbols titles	Explanatory text
	**Country of manufacturing**	**Indicates the country of manufacturing**
	**Importer**	**Indicate the importer informations**
	**CE Mark**	**Indicate that the medical device is compatible with the European regulations.**
	**Packaging integrity**	**Indicates to not use the device if the packaging is damaged.**
	**Batch code**	**Indicates the manufacturer's batch code so that the batch or lot can be identified.**
	**Catalog #**	**Indicates the manufacturer's catalog # so that the medical device can be identified.**
	**Quantity**	**Indicates the # of units per package.**
	**Consult instructions for use**	**Indicates the need for the user to consult the instructions for use.**
	**Medical device**	**Indicates that the item is a medical device.**
	**Single patient - Multiple use**	**Indicates that the medical device can be used multiple times, but only on one patient.**
	**Caution**	**Indicates that caution is necessary when operating the device to avoid undesirable outcomes.**

Symbols source : ISO 20417:2021

SAFETY INSTRUCTIONS:


If the device is too tight, it may cause blisters, pressure spots, or numbness.
If the device is too loose, it can cause friction, skin irritation, and increased sweating.


Check the device daily for wear and damage and have the prosthesis checked at least every 6 months, the patient should stop using the device and contact a healthcare professional if the device is damaged. We also strongly recommend wearing 2 devices in alternance.


Please do not leave the device in a hot place where temperatures may exceed 65°C for a long time period. Exposure to excessive heat may alter the material's stated hardness and properties.


Using a lower-limb prosthetic device involves a natural risk of falling, which may result in injury. The healthcare professional is responsible for reviewing this entire document with the patient and making sure the patient understands all safety information and instructions for proper use of the device.


The device must be kept free from foreign particles. Simply washing the device may not remove these contaminants. If the device comes into contact with any foreign substances or chemicals, stop using it and return it to your healthcare professional for evaluation.


This device is intended for use by one patient only and must not be shared.


Wearing time must be determined together with your clinician or doctor.


Do not wear the liner while sleeping.


Do not apply lotions, oils, or petroleum jelly (e.g., Vaseline) immediately before putting on the liner, as this can reduce adhesion and irritate the skin.


Always wear a residual limb/prosthetic sock over the liner to protect the outer fabric.
If your limb volume changes throughout the day, adjust by adding or removing socks.


Avoid damage to the liner caused by fingernails or sharp objects.
Ensure that the locking pin (if present) does not rub against the liner.


Examine your skin daily for irritation, redness, or injury.
Do not wear the liner if the skin is damaged.


This liner may be used with other prosthetic components only if they are properly selected and fitted by a qualified healthcare professional.

All serious incidents related to the device shall be reported to the manufacturer and the competent authority.

INSTRUCTIONS FOR USE:

Putting On the Device:

1. Ensure the residual limb is clean, dry, and free of any soap or lotion.
2. Turn the liner inside out (Fig.1).
3. Position the distal end of the liner directly against the end of the residual limb, making sure the locking pin (if present) aligns straight with the limb (Fig. 2).
4. Roll the liner up slowly and evenly toward the top of the limb (Fig. 3-4). The printed logo/marking should face the front.
5. Check that no air pockets are trapped between the liner and the skin.

Taking Off the Device:

1. Roll the liner off gently from the top downward, do not pull it off.

The product is intended for use on one patient only and cannot be reused on another patient.

MAINTENANCE, CLEANING AND STORAGE INSTRUCTIONS:

Daily Cleaning

1. Wash the device with warm water and a pH-neutral cleanser (Fig. 5-6).
2. Gently clean the inside using a soft towel, do not scrub or rub (Fig. 6).
3. Rinse thoroughly with plenty of water (Fig. 5).
4. Pat dry with a clean towel and allow the liner to air dry completely before use.

Weekly Disinfection

1. Lightly moisten a soft cloth with a small amount of cleansing alcohol.
2. Wipe the inside of the liner gently.
3. Follow all safety instructions provided by the cleaning product manufacturer.

Do Not:

- Do not use chlorine bleach.
- Do not use solvents such as acetone, benzene, or similar chemicals.
- Do not iron.
- Do not wash or dry the liner in a washing machine or tumble dryer.

Storage

- To avoid creases and facilitate drying, the device is best stored standing on a liner stand.

COMBINATION WITH OTHER PRODUCTS

The device is intended to be used together with other components as part of a complete lower-limb prosthetic system. It must be combined with a custom-made, full-contact prosthetic socket and an appropriate suspension or locking system. If the device is used with a pin suspension system, it may only be combined with pins that have an M10 threaded connection. All components must be selected, fitted, and adjusted by a qualified healthcare professional.

CONTRAINDICATIONS

Use of the device may not be appropriate in the following situations:

1. When residual limb weight-bearing is not possible, or when there are painful or sensitive neuromas.
2. When there is knee joint instability.
3. With certain residual limb shapes, such as very short limbs, strongly conical shapes, or limbs with very thin distal soft tissue.
4. For patients who are unable to follow proper donning, cleaning, and hygiene instructions.
5. For very high-activity users (e.g., K4 level or individuals participating in impact or high-load sports), the increased mechanical stress may exceed the device's intended performance. Suitability must be evaluated by a healthcare professional on a case-by-case basis.

To consider while choosing the correct liner for the patient:

1. Softer material liners (LNR-SIL-L-3-XX-30, LNR-SIL-C-3-XX-30, LNR-SIL-L-6-XX-30, LNR-SIL-C-6-XX-30) must be only used with low activity level patients such as K1 and K2, healthcare professional must evaluate the use of the softer material liners for activity level patient K3 and K4 on case-by-case basis.
2. The transfemoral liners (LNR-TF-SIL-L-2-XX-40) are suited for patient having an activity level of K1 to K3.
3. Firmer material liners (LNR-SIL-L-3-XX-40, LNR-SIL-C-3-XX-40) can be used on every type of activity level patients.

5. WASTE DISPOSAL :

The product must be disposed of with household waste in accordance with national regulations.

6. LEGAL INFORMATION

All legal conditions are subject to the local and other applicable law and may vary accordingly.

Responsibility

The manufacturer accepts no liability for damages resulting from failure to comply with this document, in particular from improper uses, unintended uses, uses outside the devices specified use conditions or unauthorized modification of the device. The device must be maintained in accordance with the operating instructions. Abuse or improper use of the device may result in decreased functionality. The manufacturer cannot be held responsible for damage resulting from improper maintenance or caused by components not authorized by the manufacturer. The manufacturer's distribution company responsible in your country will provide you with further information on the conditions of the commercial guarantee.

Commercial Warranty

The manufacturer grants a commercial warranty for this device from the date of fitting. The warranty period is 6 months. The commercial warranty covers proven defects in material, workmanship or construction. These defects must be reported to the manufacturer within the period of validity of the commercial warranty. Further information on the warranty terms and conditions can be obtained from the manufacturing company.

Note: While all advanced techniques have been used to achieve the maximum level of compatibility of function, strength, durability and comfort, there is no guarantee that the use of this device will prevent injury.