



A L P S

Silicone Liner Instructions

Intended Purpose

ALPS Silicone Liners are intended to be used as part of a lower limb external prosthetic leg; it is worn on the residual limb to provide cushioning and protection. Alps Silicone Liners are a medical grade silicone liner with fabric available in Locking or Cushion Suspension. The locking version has a distal attachment for installation of the pin and is used in combination with a locking system to allow the suspension of the prosthetic leg.

Limitations and Contraindications

- Do not wear on injured skin or open wounds. Protect the injured area with a suitable device before wearing the liner /sleeve.

Environment

- The material is resistant to salt and chlorinated water. Consult a certified professional for using a prosthetic leg in water environment.

WARNINGS

Skin rashes and irritations

- The material used for Alps Silicone Liners is skin friendly and latex free.
- To prevent skin irritations, it is important to clean the residual limb and the liner/sleeve every day.
- After washing, rinse the surface of the residual limb to remove all traces of soap, which could cause rashes and irritations. Make sure the residual limb is completely dry before donning the prosthesis.
- If skin rashes or irritations occur, discontinue the use and consult a certified prosthetist.
- Please refer to “Washing the Liner” and “Washing the Residual Limb” sections.

Deterioration of the material

- When not in use, keep the liner away from direct source of heat; store in a cool area.
- Lying flat for long period may cause creases to develop; always keep the form insert in the liner when not in use.

Integrity of the product

- Discontinue the use of the liners if the material shows signs of creases, holes, degradation and consult a certified prosthetist.

Donning the Liner

- Remove any air pocket trapped between residual limb and the liner, to prevent pain
- If using a liner with a distal attachment (pin), check that the pin is properly aligned. Check that the locking mechanism is safely engaged before starting to walk with the prosthetic leg. Please refer to “Donning the liner” section.

Sizing

Measure the proximal circumference in cm at 6 cm above the distal end.

Find the recommended size under Sizing Column in the following chart.

Measurements taken 6cm from distal end.

Silicone Pro Liner

MEASURED SIZE (CM)	 LOCKING 3.0 MM UNIFORM	 CUSHION 3.0 MM UNIFORM
20-22 cm	LSL3.0-20	LSC3.0-20
22-24 cm	LSL3.0-22	LSC3.0-22
24-26 cm	LSL3.0-24	LSC3.0-24
26-28 cm	LSL3.0-26	LSC3.0-26
28-30 cm	LSL3.0-28	LSC3.0-28
30-32 cm	LSL3.0-30	LSC3.0-30
32-35 cm	LSL3.0-32	LSC3.0-32
35-38 cm	LSL3.0-35	LSC3.0-35
38-41 cm	LSL3.0-38	LSC3.0-38
41-44 cm	LSL3.0-41	LSC3.0-41
44-47 cm	LSL3.0-44	LSC3.0-44

SoftSil Liner

MEASURED SIZE (CM)	 LOCKING GRAY	 CUSHION GRAY	 LOCKING BEIGE	 CUSHION BEIGE	 LOCKING BROWN	 CUSHION BROWN
20-22 cm	SSGSL-20	SSGSC-20	PL-SSBGSL-20	PL-SSBGSC-20	PL-SSBNSL-20	PL-SSBNSC-20
22-24 cm	SSGSL-22	SSGSC-22	PL-SSBGSL-22	PL-SSBGSC-22	PL-SSBNSL-22	PL-SSBNSC-22
24-26 cm	SSGSL-24	SSGSC-24	PL-SSBGSL-24	PL-SSBGSC-24	PL-SSBNSL-24	PL-SSBNSC-24
26-28 cm	SSGSL-26	SSGSC-26	PL-SSBGSL-26	PL-SSBGSC-26	PL-SSBNSL-26	PL-SSBNSC-26
28-30 cm	SSGSL-28	SSGSC-28	PL-SSBGSL-28	PL-SSBGSC-28	PL-SSBNSL-28	PL-SSBNSC-28
30-32 cm	SSGSL-30	SSGSC-30	PL-SSBGSL-30	PL-SSBGSC-30	PL-SSBNSL-30	PL-SSBNSC-30
32-35 cm	SSGSL-32	SSGSC-32	PL-SSBGSL-32	PL-SSBGSC-32	PL-SSBNSL-32	PL-SSBNSC-32
35-38 cm	SSGSL-35	SSGSC-35	PL-SSBGSL-35	PL-SSBGSC-35	PL-SSBNSL-35	PL-SSBNSC-35
38-41 cm	SSGSL-38	SSGSC-38	PL-SSBGSL-38	PL-SSBGSC-38	PL-SSBNSL-38	PL-SSBNSC-38
41-44 cm	SSGSL-41	SSGSC-41	PL-SSBGSL-41	PL-SSBGSC-41	PL-SSBNSL-41	PL-SSBNSC-41
44-47 cm	SSGSL-44	SSGSC-44	PL-SSBGSL-44	PL-SSBGSC-44	PL-SSBNSL-44	PL-SSBNSC-44

Donning the Liner

- Although it is not necessary to apply any type of lubricant to the residual limb, you may use either talcum powder or a very small amount of ALPS SL108 silicone skin lotion.
- Remove any air pockets trapped between the residual limb and the liner.
- For residual limb volume loss, sheaths and socks can be donned, if substantial volume has been lost, an ALPS skin reliever can also be applied.
- Introduce the residual limb into the socket.

Washing the Liner

- Wash by hand with mild soap such as Alps Cleanser (PD 595). Lay flat to dry. Do not use antibacterial or deodorant soaps.

Washing the Residual Limb

- Wash the residual limb every evening with warm water and a pH-balanced soap (such as PD595, which is specially formulated for sensitive skin).
- After washing, rinse the surface of the residual limb to remove all traces of soap, which could cause rashes and irritations.
- Dry the residual limb with a clean towel.
 - o If washed in the morning, make sure that the residual limb is completely dry before donning the prosthesis.
- Avoid using petroleum based products and other oil based lubricants on skin.

Symbol Legend	
Liner 	Medical device 
Single patient multiple use 	Manufacturer 

F.A.Q.'s

Question: Should the patient expect any negative reactions due to the silicone construction?

Answer: The silicone construction is the main advantage of this product. Its non-toxic, non-allergic characteristics make it very compatible with skin and as a result the incidence of rejection is minimal.

Question: What other advantages does the liner have?

Answer: ALPS silicones have an extremely smooth surface, which maximizes holding power and minimizes dirt retention.

Question: What is recommended to ease the donning of the liner?

Answer: It is recommended that ALPS Silicone Skin Lotion (SL108) be used to lubricate before donning. The lotion should be applied in areas where relative movement between the silicone and the skin is expected, such as the patella, hamstring insertion and, sometimes, at the very proximal edge.

Warranty

30-day satisfaction guaranteed, no questions asked

12 month warranty against manufactures defects

To obtain an ALPS Return Authorization Number (RA#) call ALPS Customer Service between the hours of 8 am and 5 pm EST and provide an ALPS representative with the following information:

Customer ID # -- Invoice # -- Date of Invoice – Nature of Return

The RA# must be displayed on the exterior of the returned item box or it will be refused at the dock.

Warning: Specific exclusions from this warranty are cuts, holes, any rips due to hits, scrapes, etc.

CE Conformity

This product meets the requirements of the European Regulation EU2017/745 for medical devices. This product has been classified as a class I device accordingly to the classification rules outlined in Annex VIII of the regulation.

Reporting of serious incidents

In the unlikely event of a serious incident occurring in relation to this device, it should be reported to the manufacturer and your national competent authority.



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CAN #9985 Form #900161 Rev H

April 2023