



ALPS Instructions

Cleaning, Use, and Maintenance of ALPS Liners & Sleeves

Covered by one or more of the following patents:

1,076,089 | 6,454,812 | 7,709,570 | 8,226,732 | 8,246,694,
8,349,021 | 8,357,206 | 8,394,150 | 10,966,845

List of products covered by this instruction for use.

Gel Liners

NAME	PART #
Anterior Posterior Tapered Liner	APDT/APFR/PL-APDT/PL-APFR
Extreme Liner™	AKDT/AKDTHD/AKFR/AKFRHD/PL-AKDT/PL-AKFR
EcoLiner™	ECDTHD/ECFRHD
Easyliner®	ELDT/ELFR/ELFC/ELPX/PL-ELDT/PL-ELFR
EasyFlex Liner	EZF
General Purpose Liner	GPDT/GPFR/PL-GPDT/PL-GPFR
Private Label Liner	PLDT/PLDT-C/PLFR/PLFR-C
Proximal Sealing Liner	PSI
Superior Performance Liner	SPDT/SPDTHD/SPFR/SPFRHD/PL-SPDTHD/SPFRHD
Smart Seal Liner™	SAFR/SADT/SBFR
Thermoformable Liner	TFFC
Winters Gel Liner	WSL/WSDT/WSFR
White gel Liner	WFFC
ProFit Liner	PFBGDT/PFBGFR/PFBNDT/PFBNFR/PFGDT/PFGFR
UltraSeal Gel Liner High Ring	USHGL/USHGC
UltraSeal Gel Liner Low Ring	USLGL/USLGC
UltraSeal Gel Liner Ultra Low Ring	USUGL/USUGC

Gel Sleeves

NAME	PART #
Easysleeve™	SFR/SFS/SLE
Extreme Sleeve™	SFK
Superior Performance Sleeve	SFP/SFPHD
Superior Suspension Sleeve	SFB/SFBHD
Flex Sleeve	SFX
Reinforced Flex Sleeve	RFX
Reinforced Sleeve	RFS

Dear Valued Customer,

Thank you for selecting our ALPS product. Our Mission at ALPS is to make lives better one unique product at a time. To accomplish this we offer a variety of products to accommodate the most users possible.

Thank you for your Support,

ALPS Team

INTENDED PURPOSE

- Alps® Liners and Sleeves are intended to be used as part of a lower limb external prosthetic leg.
- The liner is worn on the residual limb to provide cushioning and protection.
- The sleeve helps maintain the suspension of the prosthetic leg by creating an airtight seal at the top of the prosthetic socket. The sleeve is used in combination with a cushion liner.
- Locking liners have a distal attachment for installation of the pin and are used in combination with a locking system to allow the suspension of the prosthetic leg.
- The Smart Seal/UltraSeal liner is used in combination with an expulsion valve to create an airtight seal on the rings area. To remove the Smart Seal/UltraSeal liner from the socket a release valve/function is needed.

LIMITATIONS AND CONTRADICTIONS

- 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.
- The material may deteriorate if exposed to high temperature for a prolonged time. Please refer to “warnings” and “storing the liner/sleeve” sections.

WARNINGS

Skin rashes and irritations

- The material used for Alps Gel Liners and Gel Sleeves 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.
- Please refer to “cleaning the residual limb” and “cleaning the liner/sleeve” sections
- If skin rashes or irritations occur, discontinue the use and consult a certified prosthetist.

Deterioration of the material

The material will delaminate if it comes into contact with oily substances. Avoid petroleum jelly and other oil-based lubricant on the skin. Wash the liner/sleeve with a hypoallergenic pH-balanced soap (as ALPS Cleanser PD595); do not use oil-based soap. Do not soak in acetone or you will dissolve the gel.

Please refer to “cleaning the residual limb”, “cleaning the liner/sleeve” and “tips to keep the product in good condition” sections

The material may deteriorate if exposed to high temperature for a prolonged time. When not in use, keep the liner away from direct source of heats; store in a cool area.

Lying flat for long periods may cause creases to develop: always keep the form insert in the liner/sleeve when not in use. Do not leave the liner/sleeve semi-inverted. When the prosthesis is not in use, separate the liner/sleeve from the socket.

If liner or sleeve is pulled too hard, the fabric will separate from the gel.

Please refer to “storing the liner/sleeve” and “tips to keep the product in good condition” sections.

Integrity of the product

- Discontinue the use of the liner/sleeve if the material shows signs of creases, holes, degradation and consult a certified prosthetist.
- Holes in the sleeve may bring to the loss of the suspension. Inspect the sleeve daily to verify there are no holes; discontinue the use and consult a certified prosthetist in case any holes have been found.

Donning the liner/sleeve

- 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” and “donning the sleeve” sections for a detailed explanation of the correct procedure.
- If you are using an Alps Anterior Posterior Tapered liner (APDT/APFR), for a proper fit, remember that the front side is thicker than the posterior side of the liner. The front side of the liner is indicated by the ALPS logo.

SIZING: LINERS

- Measure the stump circumference 6cm from the apex of the residual limb.
- Select a size inferior to the measured circumference.

ALPS Liner Reduction Rate

3-5% for most ALPS liners
5-8% for the ALPS Guardian liner
3-6% for the ALPS Smart Seal liner

DONNING LINERS

- Make sure the residual limb is completely dry.
- Invert the liner to fit so it firmly adheres to the surface of the distal end of the residual limb.
- Roll it up slowly to prevent air pockets from forming during this stage.
 - o Although it is not necessary to apply any lubricant, you may use a small amount of ALPS Silicone (SL108) to assist with any difficulties.
 - o For ALPS Guardian, Smart Seal™, and UltraSeal, you may lightly lubricate the raised gel bands with the ALPS Lubricant (PA604) or any other alcohol based lubricant, such as hand sanitizer. Be sure to allow the lubricant to dry in order to ensure no instability.
 - o **Petroleum jelly and other oil based lubricants should not be used to assist with donning. The gel will delaminate if it comes into contact with oily substances.**
- Remove any air pockets trapped between residual limb and liner.
- If using a liner with a distal attachment (pin), check that the pin is properly aligned.
- For residual limb volume loss, a sheath, sock or ALPS Skin Reliever (ENCP) may be used.



SIZING: SLEEVES

- Measure the stump circumference 10cm above patella of the residual limb.

DONNING SLEEVES

- Invert the sleeve so that the inside is facing out and don onto the socket.
 - For the V.I.V.A. be sure the valve is placed on the anterior aspect, proximal to the socket and just proximal to the patella. If the valve is not positioned correctly the air will not be expelled.
- Introduce the residual limb into the socket.
- Roll the sleeve onto the proximal end of the residual limb.
- For best results, verify the sleeve is placed properly.

For our complete product catalog and more information about specific sizing, please visit our website at www.easyliner.com

CLEANING THE RESIDUAL LIMB

- Wash the residual limb every evening with warm water and a pH-balanced cleanser (such as PD595, which is specifically 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.
 - 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.



CLEANING THE LINER / SLEEVE

- Do not use oil based soap.
- **Daily:** Hand wash the surface with warm water and hypoallergenic pH-balanced soap (such as ALPS Cleanser-PD595).
- Use a wash cloth to wipe the surfaces but do not rub/scrub or you may damage the product.
- Rinse well after washing.
- Wipe dry with a clean, dry towel.
 - Allow the product to dry thoroughly before use and do not dry on sources of direct heat.
- **Weekly:** Pour a small amount of rubbing alcohol on a soft, clean cloth. Wipe the liner/sleeve with the cloth; dry thoroughly with a towel. Do not soak the liner/sleeve in alcohol.
- To remove a stain on the fabric side, use a cloth dampened in acetone (nail polish remover) and rub until clean. **DO NOT SOAK IN ACETONE OR YOU WILL DISSOLVE THE GEL.**



STORING THE LINER / SLEEVE

- Always keep the foam insert in the liner/sleeve when not in use: lying flat for long periods may cause creases to develop.
- Do not leave the liner/sleeve semi-inverted.
- When the prosthesis is not in use, you should separate the liner/sleeve from the socket.

TIPS TO KEEP THE PRODUCT IN GOOD CONDITION

- Avoid using oil based products. The gel will delaminate if it comes into contact with oily substances. If the patient uses suntan lotion or other oil-based creams, the residual limb must be washed with a pH-balanced cleanser and rinsed thoroughly before putting the liner back on the limb.
- We recommend the use of ALPS Skincare Products, specifically formulated for the product. Should you need to use a different type of ointment, it should be applied when the prosthesis is not in use. Wash and rinse the residual limb thoroughly before putting the liner back on.

Question: My patient is using ALPS liner/sleeve for the first time and complained about excessive perspiration, is this normal?

Answer: Excessive perspiration is normal. It will gradually diminish over a period of two to six weeks. You also may use ALPS Anti-Perspirant (ATP008) to assist with perspiration in the meantime, but if a rash develops, discontinue its use.

Question: Do I trim the liner above the knee, just above the socket edge, or do I reflect the liner over the socket to provide suspension?

Answer: You can do all of the above. We recommend that you trim 1" above the edge of the socket. To trim, you may use scissors, a pizza roller or a hot knife for plastics (McMaster Carr's Part #2453A61, tel. 1-404-346-7000). If you choose to reflect the liner over the socket, make sure that the edge of the socket is well taped or a hole may develop in the liner. (In such a case, the warranty will not apply.)

For additional security, a small drop of instant adhesive on the seam directly below the trimmed edge may be used to help prevent the seam from unraveling.

Question: Do stains affect the performance of the liner/sleeve?

Answer: No, performance is not affected. If the stain cannot be removed with the procedures described in the Cleaning Section, it is recommended that the exposed portion of the liner/sleeve be covered with a 14" to 16" piece of stockinet.

Question: What is the cause of micro cracking on the surface of my liner/sleeve?

Answer: Micro cracking can take place either when:

a) Petroleum products or organic oils (including human fatty acids) come in prolonged contact with the liner/sleeve. Some patients' skin may be oily enough to induce micro cracking. In such cases the life expectancy of the liner is greatly reduced. The prosthetist will decide if the liner is appropriate for such patients.

b) The liner/sleeve is stretched over 100% of its original dimension and kept in a stretched position over a long period of time.

Question: How do I prevent the pin from unscrewing from the locking liner's distal end?

Answer: Use Loctite type thread locking compound 242 or equivalent.

Question: Does ALPS liner or sleeve contain latex?

Answer: No, all of ALPS liners and sleeves are latex free.

Please visit our website at www.easyliner.com
for our warranty policies.

To obtain an ALPS Return Authorization Number (RA#) for a warranty call ALPS Customer Service (727-528-8566) 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.

Symbol Legend			
Liner		Medical device	
Sleeve		Single patient multiple use	
		Manufacturer	

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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