



PDS-Padsil™

Silicone Distal Pads



Intended Purpose

The ALPS Padsil™ is intended to be used as part of a lower limb external prosthetic leg. The Padsil adds additional cushioning and helps to maintain total contact in the socket.

Limitations and contraindications

Do not wear on injured skin or open wounds; protect the injured area with a suitable device before wearing.

Warnings



Skin rashes and irritations

ALPS Padsil is made of non-allergenic silicone.

If skin rashes or irritations occur when placing the Padsil in direct contact with the skin, discontinue the use and consult a certified prosthetist.

Integrity of the product

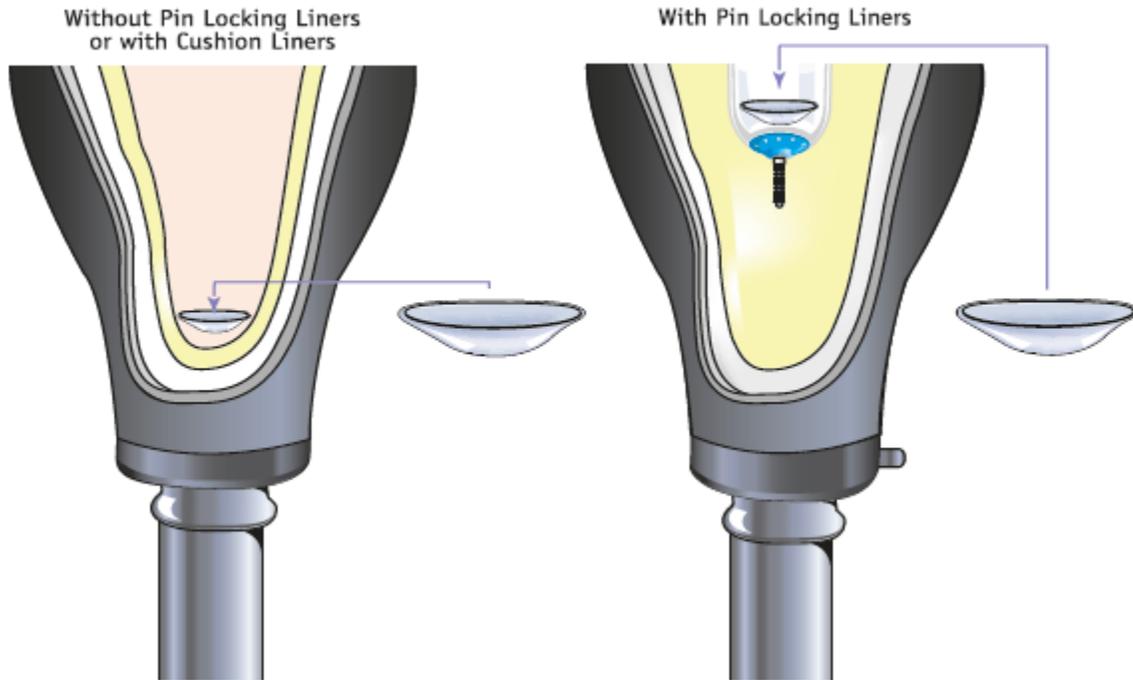
Discontinue the use of the Padsil if the material shows signs of creases, holes, degradation and consult a certified prosthetist.

Donning the Padsil

When used in combination with a cushion liner, the Padsil is placed at the distal edge of the prosthetic socket (outside the liner).

When used in combination with a locking liner, the Padsil is placed inside the liner

Please refer to the image below for appropriate positioning.



Sizing Instructions

Measure the circumference in cm at the beginning of the cylindrical section approximately 6 cm from the bottom of the distal end. This is the measured size.

Find the measured Size from Step 1 in the following chart. Read across to the find the recommended size.

Limb Circumference (cm)	Padsil
14-19 cm	S
20-23 cm	M
24-27 cm	L
28-31 cm	XL
32-35 cm	XXL

Cleaning the Padsil

Wash the padsil by hand with a mild soap; such as Alps Cleanser (PD 595). Allow them to dry before the next use. Be sure **not** to use any antibacterial or deodorant soap on the padsil for this may damage the product.

ALPS Satisfaction Guarantee

ALPS offers a no hassle return policy within **30 days** from date of purchase. If you are unsure of the proper size of Padsil to order, you can order two sizes from ALPS Customer Service. Once received, decide which size fits best. You can then call ALPS Customer Service for a Return Authorization Number and return the improper size for full credit of the product cost within 30 days from date of purchase (excludes freight charges).

Warranty

ALPS Padsils are warranted against manufacture's defects for **6 months** from the date of purchase. ALPS warrants only that its products will meet its specifications. **THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR USE, NOR ANY OTHER EXPRESS OR IMPLIED WARRANTIES.** The user's exclusive remedy and ALPS South LLC sole liability is limited to the replacement of any product shown to be otherwise than as warranted. ALPS South LLC. will not be liable for incidental or consequential damages of any kind.

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:

1. **Customer ID Number**
2. **Invoice Number**
3. **Date of Invoice**
4. **Nature of the return**

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

Any products returned to ALPS after 30 days without manufacturing defects will be subject to a 25% restocking charge.

Symbol Legend	
Medical device	
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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PDS



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