



VIP and VIP Lock Instructions

Intended Purpose

The ALPS VIP and ALPS VIP-Lock are intended to be used as part of a lower limb external prosthetic leg.

The ALPS VIP is an elevated vacuum system, fabricated into the distal end of a socket similar to a distal end pad. The VIP is engineered out of a medical grade silicone polymer and two valves to control the airflow. Once the amputee dons the prosthesis and places a seal sleeve over the socket, the pump is activated from the user's weight during heel strike, and draws elevated vacuum after toe off during swing phase.

The ALPS VIP-Lock is a shuttle lock system fabricated into the distal end of a socket. The VIP-Lock is engineered out of a glass reinforced nylon with a hardened steel and nickel coated locking surface. The amputee will don the prosthetic leg by inserting the pin into the VIP-Lock. The pin is released by pushing the push button, exposed and accessible to the user, allowing the amputee to remove the residual limb from the prosthesis.

The ALPS VIP / VIP-Lock is an interchangeable prosthetic attachment systems allowing the prosthetist to switch from a pin locking system to a vacuum suspension system or vice versa.

Limitations and Contraindications

The ALPS VIP, being an elevated vacuum suspension, can be used only with a total contact socket. It is not indicated for residual limbs which conditions does not allow the patient's weight bearing (as neuromas).

Environment

The ALPS VIP and the ALPS VIP-Lock are not suitable to be used in shower or swimming prosthetic legs.



Warnings

Safety information for the end user

In case the pin is caught in the VIP-Lock mechanism, and you are unable to remove the pin from the locking mechanism, immediately contact a certified prosthetist. Ask for someone's help to release the residual leg.

Debris or lint can lead the VIP Pump to not working properly; this may bring to a loose fit, with greater stress on the skin and tissues, increasing risk of skin damages. Visually inspect the VIP daily, to remove visible debris or lints. If skin rashes or skin damage occur, discontinue the use and consult a certified prosthetist.

Safety information for the professional user

Elevated levels of vacuum will draw fluid to any voids in the socket where there is no contact: it is strongly recommended to make a check/diagnostic socket to verify there are no voids.

It is recommended to inspect the VIP and the VIP-Lock every 6 months and verify the suspension system is working properly. Inspect for debris, lint or impurities that may affect the functionality of the suspension system.

Clean the VIP as indicated in the "Cleaning the VIP" section.

Intended life

The VIP and the VIP-lock have been tested for 3,000,000 cycles, corresponding to approximately 2 years of use under normal conditions; the device have then to be inspected by a certified prosthetist to verify the suspension system is working properly and looking for signs of deterioration. It is also recommended to perform a local risk assessment based upon activity and usage.

Part Number	Description
VIP-DH	VIP Valve Integrated Pump, High Vacuum
VIP-DL	VIP Valve Integrated Pump, Low Vacuum
VIP1120-S	EZ VIP Lock - Small

Accessories and fabrication products

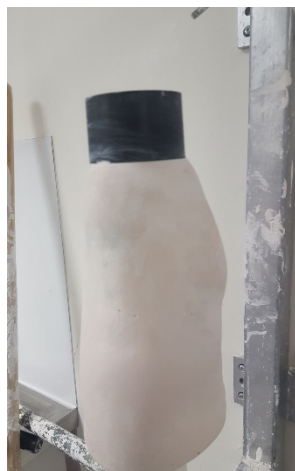
Part Number	Description
VE319-D	VIP Dummy (standard)
VE319-DS	VIP Dummy Short
VE819-P	VIP Mounting Plate
LMV-009	Mini valve Kit

Casting

(Note: Elevated levels of vacuum will draw fluid to any voids in the socket where there is no contact, due to the interchangeability of the VIP system care should be taken to reduce voids when fitting either unit.)

The patient should be casted in the method the CP is most comfortable casting or scanning. Ideally the socket is casted over a liner and fitted with a Total Contact Socket, not total weight bearing. Check sockets are critical to verify there are no voids within the fit to obtain optimal comfort to the end user.

Fabricating the VIP



Take cast as normal, reduce 5-7% proximally and reduce to 1% distally

Place VIP Dummy on distal end of the cast where the patient will weight bare

Select the short dummy if you are not using the VIP mounting plate.

Use either a plaster build up, or superglue to fasten the dummy to the cast.

Utilize a 4 hole socket adapter (such as ALPS VIP Mounting Plate, VE819-P**) with a center hole to allow for the air to evacuate. (In some high vacuum applications the unit may shift during the swing phase of the step to prevent this a one way valve (LMV-009) must be installed in the center hole to prevent this)

** When using the VE819-P, please note the center hole is beveled on one side. Be sure to place the beveled side facing down into the socket for use.

After the socket is pulled or laminated, a center hole must be drilled.

Ensure you have good contact with the seal all around the socket.

Removing the VIP from the socket may be difficult, we recommend using Vaseline on the seal for diagnostic fitting so ease removal for the manufacture of the definitive socket.

Note: Please use caution when using Vaseline or other oil based lubricants. Be sure to clean the definitive socket and remove any Vaseline or other oil based lubricants residue prior to introducing an ALPS Liners as these products will cause damage to the ALPS liner.





Fabricating the VIP-Lock

Take cast as normal, reduce 5-7% proximally and reduce to 1% distally

Place VIP Dummy on distal end of the cast where the patient will weight bare

Use either a plaster build up, or superglue to fasten the dummy to the cast.

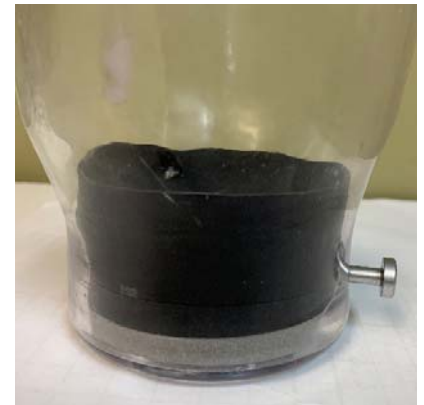
Use the ALPS VIP Mounting Plate VE819-P**, this has the correct holes for mounting the VIP-Lock in the socket

** When using the VE819-P, please note the center hole is beveled on one side. Be sure to place the beveled side facing down into the socket for use.

After the socket is pulled or laminated, a center hole must be drilled to allow the pin to pass through.

When mounting the VIP-Lock, place the VIP-Lock on top of the ALPS mounting plate and screw it down utilizing the 4 mounting screws.

Once in place mark the location of the push button hole and drill it out utilizing a 3/16” drill bit. Once in location screw the push button into the VIP-Lock



Cleaning the VIP

Wipe the exterior of the VIP with 50% alcohol and 50% water, being careful not to saturate the hole for the valve. Do not soak or saturate the VIP, fluid inside the pump may cause the pump to malfunction.

Note: If the patient is not obtaining elevated vacuum, the valves should be checked for any lint or debris. If an observable amount of lint is gathering in the distal end of the socket on the VIP, the patient is not receiving any distal contact, which will cause the pump to be inactive.

Warranty

30-day satisfaction guaranteed, no questions asked

6 month warranty against manufactures defects

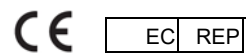
Symbol legend	
Medical device	
Single patient multiple use	
Manufacturer	

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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