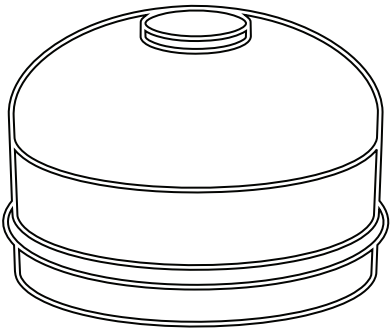
ALPS



INSTRUCTIONS FOR USE

FOR PRODUCTS:

Vacuum Integrated Pump (VIP-DL | VIP-DH)
VIP Lock (VIP-1120-S)

THIS MANUAL IS INTENDED OR USE BY A CERTIFIED PROFESSIONAL PROSTHETIST

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 helps 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 intended life is 2 years of use under normal conditions; the device has 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.

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

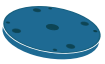
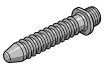
SYMBOL LEGEND	
Medical device	
Single patient multiple use	
Manufacturer	

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PRODUCT NAME	PART NUMBER	VISUAL REFERENCE
VIP Valve Integrated Pump, High Vacuum	VIP-DH	
VIP Valve Integrated Pump, Low Vacuum	VIP-DL	
EZ VIP Lock - Small	VIP1120-S	

Accessories and fabrication products

PRODUCT NAME	PART NUMBER	VISUAL REFERENCE
VIP Dummy (Standard)	VE319-D	
VIP Dummy (Short)	VE319-SD	
VIP Mounting Plate	VE819-P	
Mini Valve Kit	LMV-009	
VIP Pin 1.9 inch	VIP-92L	
VIP Pin 1.2 inch	VIP-92S	

Casting

The patient should be casted in the method the Clinician/Tech 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.

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.

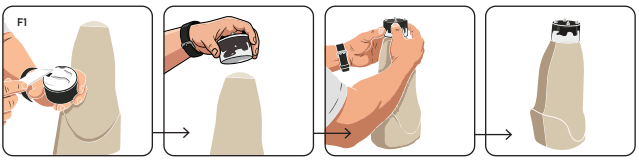
Instructions: Fabricating the VIP check socket

1. Take cast as normal, reduce 5-7% proximally and reduce to 1% distally
2. Place the VIP Dummy on the distal end of the cast through the weight center of the cast. The dummy should be placed with a neutral setup.

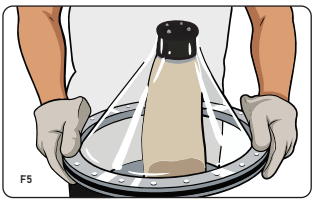
> **VERY IMPORTANT. DO NOT SKIP THIS STEP.**
> Proper dummy selection will ensure correct VIP compression during use.
> **Refer to the following chart before moving foward:**

ARE YOU USING A MOUNTING PLATE DIRECTLY BELOW THE VIP?	DUMMY TYPE TO USE	PART NUMBER
☒ NO	SHORT DUMMY	VE319-SD
☑ YES	STANDARD DUMMY	VE319-D

3. When using the standard dummy, align the dummy with a pair of the studs aligned in the anterior direction to orientate the 4-hole adapter. (F1)
4. Use either a plaster build up, or superglue to fasten the dummy to the cast. The dummy can also be affixed using the center hole. (F1)

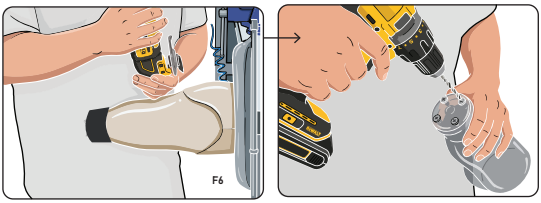


5. Using the manufacturer recommendations, heat your selected plastic and pull the check socket over the prepared cast. Ensure a good vacuum is maintained while the plastic cools. (F5)



6. After the check socket has cooled, knock out the cast and drill holes for mounting adapter and center vent hole for the VIP unit* (F6)

*If using a Red VIP (VIP-DH) an LMV-009 is suggested. This can be utilized by drilling a ½" hole for the center vent hole to place the grommet and inserting the valve. Refer to page 9 for further steps.



7. Trim, finish and assemble the check socket for use* (F7)

*Ensure the VIP unit is firmly seated within the socket for a tight, secure fit.

8. Have the patient don their ALPS liner and the prosthesis, to check fit and function. **Max vacuum will be achieved within 10-15 steps.** (F8)



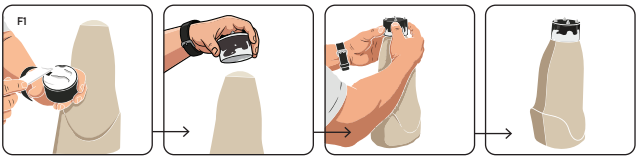
Instructions: Fabricating the VIP definitive socket

1. Take cast as normal, reduce 5-7% proximally and reduce to 1% distally
2. Placethe VIP Dummy on the distal end of the cast through the weight center of the cast. The dummy should be placed with a neutral setup.

> **VERY IMPORTANT. DO NOT SKIP THIS STEP.**
> Proper dummy selection will ensure correct VIP compression during use.
> **Refer to the following chart before moving foward:**

ARE YOU USING A MOUNTING PLATE DIRECTLY BELOW THE VIP?	DUMMY TYPE TO USE	PART NUMBER
☒ NO	SHORT DUMMY	VE319-SD
☑ YES	STANDARD DUMMY	VE319-D

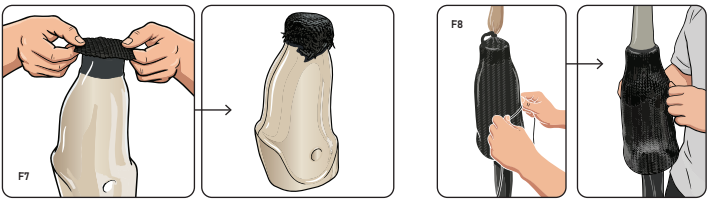
3. When using the standard dummy, align the dummy with a pair of the studs aligned in the anterior direction to orientate the 4-hole adapter. (F1)
4. Use either a plaster build up, or superglue to fasten the dummy to the cast. The dummy can also be affixed using the center hole. (F1)



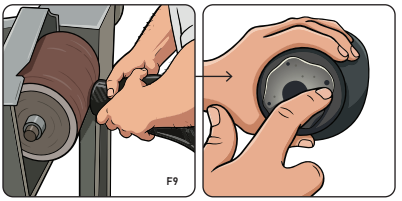
5. Place a nylon over the cast to ensure a good vacuum. This can be tied off at the base of the dummy and reflected down the cast to ensure a proper sealing surface. (F5)
6. Pull a PVA bag over the cast to prepare the definitive socket layup. When tying the PVA bag, the knot can be pushed into the dummy hole to keep a flat bottom in the socket. (F6)



7. Apply the desired socket layup over the prepared cast. (F7)
8. Proceed with the lamination following standard procedures. Ensure adequate resin has penetrated and saturated the layup. (F8)



9. After the socket has cured sufficiently, grind the outside of the distal end flat for the 4-hole adapter just enough so that the tips of the dummy studs are visible. This will leave a ¼" of socket thickness at the bottom. (F9)



10. Remove the cast and dummy. (F10)
11. Enlarge the holes for the mounting plate with a 7mm or 9/32" drill bit. (F11)
12. Drill the ¼" expulsion hole in the center of the socket* (F12)

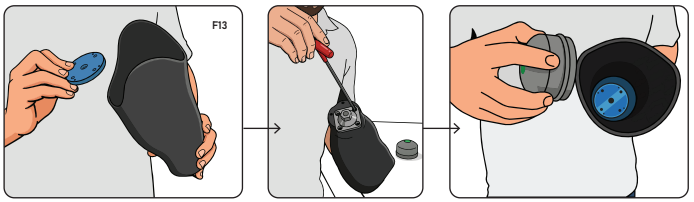






*If using the RED VIP (VIP-DH), it is suggested to either laminate in the LMV-009 (Mini Valve) into the center of the distal end of the socket where the vent would be or drill a ½" hole as the center vent for installation after the definitive socket is made. Refer to page 9 for information regarding the LMV-009.

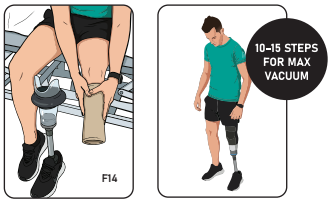
13. Assemble the socket with mounting plate (**ONLY** if using the standard dummy), 4-hole adapter, and VIP unit. (F13)



Insert Mounting Plate | Screw in Four-Hole Adaptor | Insert VIP*

*Ensure the VIP unit is firmly seated within the socket for a tight, secure fit.

14. Have the patient don their ALPS liner and the prosthesis, to check fit and function. Max vacuum will be achieved within 10-15 steps.(F14)



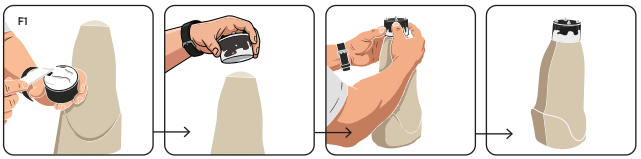
Instructions: Fabricating the VIP using a flexible inner

1. Take cast as normal, reduce 5-7% proximally and reduce to 1% distally
2. Place the VIP Dummy on the distal end of the cast through the weight center of the cast. The dummy should be placed with a neutral setup.

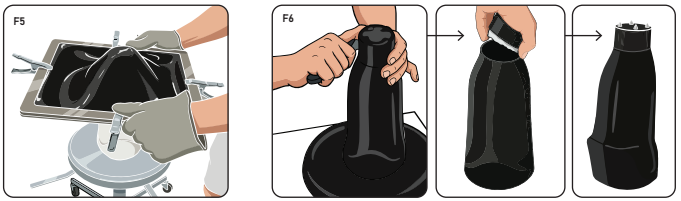
> **VERY IMPORTANT. DO NOT SKIP THIS STEP.**
> Proper dummy selection will ensure correct VIP compression during use.
> **Refer to the following chart before moving foward:**

ARE YOU USING A MOUNTING PLATE DIRECTLY BELOW THE VIP?	DUMMY TYPE TO USE	PART NUMBER
☒ NO	SHORT DUMMY	VE319-SD
☑ YES	STANDARD DUMMY	VE319-D

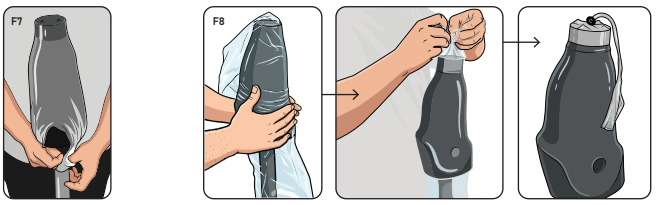
3. When using the standard dummy, align the dummy with a pair of the studs aligned in the anterior direction to orientate the 4-hole adapter. (F1)
4. Use either a plaster build up, or superglue to fasten the dummy to the cast. The dummy can also be affixed using the center hole. (F1)



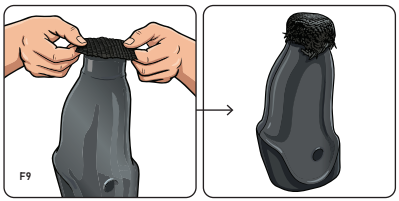
5. Using the manufacturer's recommendations, heat your selected plastic and pull the flexible inner over the prepared cast. Ensure a good vacuum is maintained while the plastic cools. (F5)
6. Once cooled trim the flexible inner so that roughly a ½" covers the dummy. **The VIP unit will be sealed off on the definitive socket.** (F6)

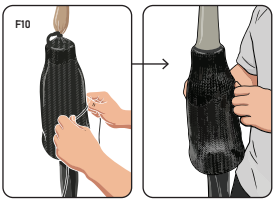


7. Place a nylon over the flexible inner. This can be tied off at the base of the dummy and reflected down the cast to ensure a proper sealing surface. (F7)
8. Pull a PVA bag over the cast to prepare the definitive socket layup. When tying the PVA bag, the knot can be pushed into the dummy hole to keep a flat bottom in the socket. (F8)

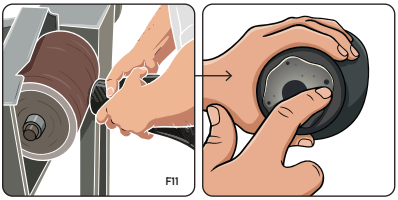


9. Apply the desired socket layup over the prepared cast. (F9)
10. Proceed with the lamination following standard procedures. Ensure adequate resin has penetrated and saturated the layup. (F11)



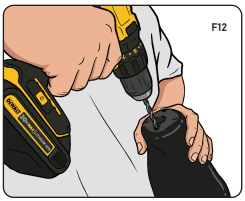


11. After the socket has cured sufficiently, grind the outside of the distal end flat for the 4-hole adapter just enough so that the tips of the dummy studs are visible. This will leave a ¼" of socket thickness at the bottom (F11).



12. Once the points are visible, enlarge the holes with a 7mm or 9/32" drill bit. (F12)

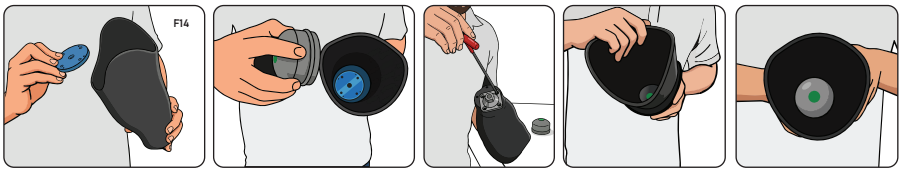
13. Drill the ¼" expulsion hole in the center of the socket* (F13)





*If using the RED VIP (VIP-DH), it is suggested to either laminate in the LMV-009 (Mini Valve) into the center of the distal end of the socket where the vent would be or drill a ⅛" hole as the center vent for installation after the definitive socket is made. Refer to page 9 for information regarding the Mini Valve.

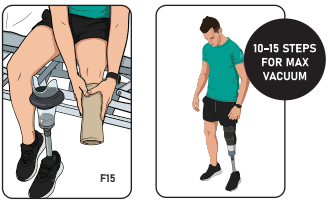
14. Assemble the socket with mounting plate (**ONLY** if using the standard dummy), 4-hole adapter, VIP unit and flexible inner. (F14)



Insert Mounting Plate | Insert VIP* | Screw in Four-Hole Adaptor | Insert Flexible Inner | **Completed View**

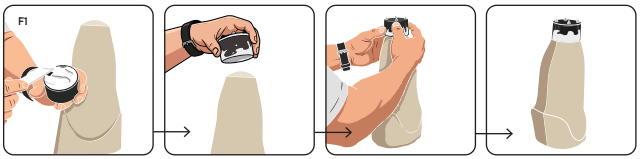
*Ensure the VIP unit is firmly seated within the socket for a tight, secure fit.

15. Have the patient don their ALPS liner and the prosthesis, to check fit and function. Max vacuum will be achieved within 10-15 steps. (F15)



Instructions: Fabricating the VIP Lock

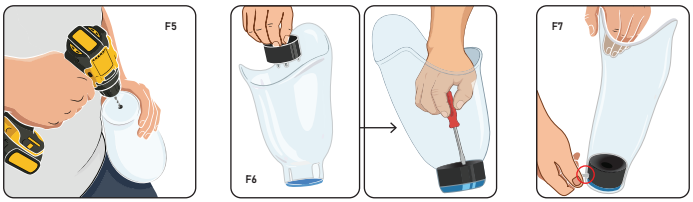
1. Take cast as normal, reduce 5-7% proximally and reduce to 1% distally
2. Place the VIP Dummy on distal end of the cast where the patient will weight bare. (F1)
3. Use either a plaster build up, or superglue to fasten the dummy to the cast. (F1)



4. 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.

5. After the socket is pulled or laminated, a center hole must be drilled to allow the pin to pass through. (F5)
6. 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. (F6)
7. 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. (F7)



Instructions: Inserting the Mini Valve (LMV-009)

When inserting the valve into a completed socket:

1. Drill a ½" hole for the bushing to be inserted into the socket
2. Ensure the location has enough thickness to accommodate the mini valve and allow for actuation of the valve
3. Insert the bushing with the flange on the outside and use a silicone based adhesive to adhere it to the socket
4. Push the mini valve into the bushing hole with the O-ring side towards the exterior of the socket

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.

Disposal

The device and packaging must be disposed of in accordance with local or national environmental regulations. Please verify your local and national environmental regulation and dispose accordingly.

SCAN FOR VIP VIDEO TUTORIALS

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