



INTRODUCTION

The AEV350 and the MEV350 valves are intended for transfemoral prosthetic suction sockets. Both utilize the same two-part valve housing, which is ideal for use with flexible thermoplastic socket materials.

The AEV350 valve has automatic air expulsion function and manual push button to release suction.

The MEV350 valve has a push button used to manually expel air and to release suction.

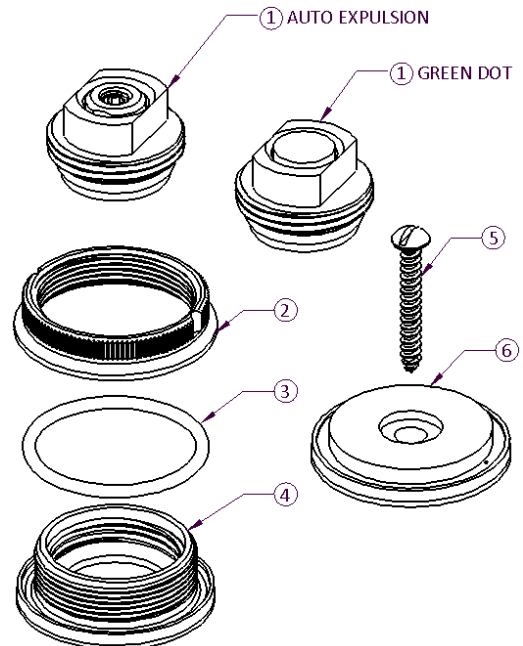
Both type valve inserts are removable to allow use of a pull-sock for donning the socket.

Both are furnished with valve key and necessary components to form the socket to accept the two-part valve housing.

Product Code	Description
AEV350	AUTO EXPULSION VALVE WITH TWO-PART HOUSING
AEV35i	AUTO EXPULSION VALVE INSERT ONLY
MEV350	MANUAL EXPULSION VALVE WITH TWO PART HOUSING
MEV35i	MANUAL EXPULSION VALVE INSERT ONLY

Accessories	Description
AEV35K	VALVE KEY

PRODUCT CONTENTS:			
ITEM	QTY	PART #	DESCRIPTION
1 (AEV350)	1	32201-001	AUTO EXPULSION VALVE INSERT ASSEMBLY
1 (MEV350)	1	32213-001	MANUAL EXPULSION VALVE INSERT ASSEMBLY (GREEN DOT)
2	1	32207-002	SOCKET OUTER HOUSING
3	1	32212-001	O-RING, SIZE -125
4	1	32208-001	SOCKET INNER HOUSING
FABRICATION / ADDITIONALCOMPONENTS :			
5	1	24437-001	SCREW, SIZE #8 X 1.25" LONG
6	1	32209-001	FORMING TOOL
7	1	19774-001	VALVE KEY ASSEMBLY (NOT SHOWN)



INDICATIONS

Transfemoral amputees who use flexible thermoplastic socket materials.

INSTALLATION AND USE

Recommended installation and use procedures must be followed for maximum safety and service life.

Socket Preparation:

- Determine valve location on the positive model. Flatten the region so the forming tool is flush. Mark the center hole location of the forming tool.
- Drill a $\varnothing 3.2\text{mm}$ ($\varnothing 1/8''$) pilot hole for the supplied screw.
- Drill a vacuum channel hole 12mm ($1/2''$) adjacent to the pilot hole with a long drill. This hole must extend through the model so that vacuum will draw at the forming tool site.
- Secure the forming tool to the model with the supplied screw, and positioning it so that one of the small holes in the forming tool is over the vacuum channel hole.
- Vacuum form the thermoplastic socket. Manually apply the necessary external pressure around the forming tool to help guide the softened thermoplastic to fully form around the tool.





6. After the socket has cooled, sand off excess plastic directly above the forming tool until the top surface of the forming tool is exposed.
7. Remove the socket from model. Use a sanding cone to carefully open up the hole if necessary so that the inner housing fits snug through the hole.
8. Clean the inside and outside of the formed pocket of anything that could prevent a good seal.

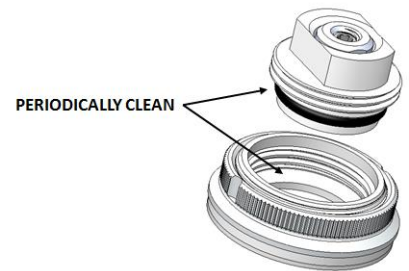
Final Assembly:

9. Make sure the large o-ring is seated in the groove of the flange of the inner housing and place components into the recess formed inside the socket.
10. On the outside of the socket, screw on the aluminum outer housing, and firmly hand tighten.
Tip: To facilitate a tight fit and a good seal, wet the o-ring and the threads of the housing components with water or isopropyl alcohol just prior to tightening.
11. Assemble the valve insert (auto expulsion or manual expulsion) by gently hand tightening clockwise until the o-ring on the outside of the valve insert makes contact with the sealing surface inside the valve housing.
Note: To prevent cross-threading, it is sometimes necessary to initially turn the insert counter-clockwise until the threads are aligned properly, and then tighten clockwise.
12. A valve key is provided to assist removal of the valve insert for individuals with limited hand strength or dexterity.

Disassembly and cleaning valve inserts:

Foreign debris such as dust, baby powder, and residue from lotions used for donning the socket can become lodged in the sealing surfaces of the valve overtime and may cause a decrease in vacuum performance.

Instruct patients to periodically wipe clean the outer o-ring and threads of the valve insert and the inner threads and sealing surface of the valve housing. Use water or isopropyl alcohol.

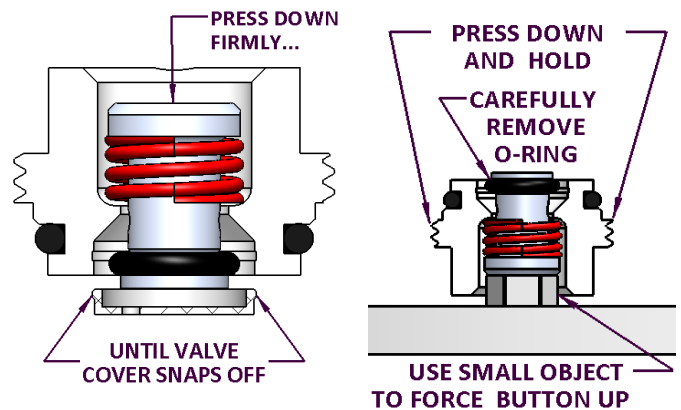


To disassemble the valve insert for more thorough cleaning, steps 1-4 pertain to both the auto expulsion and the manual expulsion valve inserts:

1. Remove the valve insert from the housing.
2. Firmly press down on the valve button until the valve cover snaps off.
3. Maintain downward force of the button, while carefully removing the inner o-ring.
 - This is made easier by using a small nut or other object on a flat, sturdy work surface.
 - Press the assembly down onto the small object so that the valve button lifts up from the inner seal surface.
 - While the valve button is lifted, use a pick to **CAREFULLY** remove the o-ring from the button.

DO NOT CUT OR DAMAGE THE O-RING!

4. Remove the button and spring from the valve body. Clean components with water and mild detergent, or isopropyl alcohol. Ensure all sealing surfaces are free of debris or residue.





Steps 5-7 pertain only to the auto expulsion valve insert:

5. Use a 3mm hex key to remove the set screw.
6. Carefully remove the small inner spring and rubber ball.
7. Clean components with water and mild detergent, or isopropyl alcohol. Ensure that the rubber ball and inner sealing surface of the button is free of any debris or residue.


Re-assemble valve inserts, steps 1-3 pertain to the auto expulsion version:

1. Lightly coat the rubber ball with petroleum jelly or synthetic lubricant.
2. Place the ball, followed by the small spring into the valve button.
3. Apply 1 drop of Loctite 242 or 243 (blue) to the threads of the set screw and screw it in until it stops.



Remaining steps apply to both the Auto-expulsion and the manual expulsion valves:

4. Place the large spring over the valve button, then press and hold it through the valve body while placing the small o-ring over the lip on the opposite side of the button to retain it in place.
5. Press the button a few times to ensure the o-ring is seated properly.
6. Position the valve cover over the lower opening of the valve and press firmly until it snaps into place.

 **Failure to follow the installation and use procedures set forth above may lead to failure of the components subjecting the user to a risk of serious personal injury.**



STORAGE AND USE

There are no identified restrictions on the temperature of storage and use.

DISPOSAL

There are no hazardous materials in the device. Comply with local and national laws and regulations.

LEGAL INFORMATION

MD The use of this class 1 medical device is subject to the respective national laws of the country of use and may vary accordingly. The user of this device should report any serious incident to Trulife and the competent authority of the country of use.



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LIMITED WARRANTY

Trulife warrants that the PRODUCT will be free from defects in material and workmanship from the date of installation for the warranty period stated on the PRODUCT warranty card.

This warranty will not apply if the PRODUCT has been damaged by misuse, abuse, neglect, improper care, failure to follow instructions, abnormal wear and tear, or in the event that the PRODUCT has been modified/repared by persons unauthorized by Trulife.

If a defect in material or workmanship is found during the warranty period, Trulife will, at Trulife's option, either repair or replace the product. If it is not possible to repair or replace the product, Trulife will be limited to refunding the purchase price.

Trulife will not be liable under any legal theory for any direct, indirect, special, incidental or consequential damages arising from the use of or inability to use this product.

The application guidelines for this Trulife product are for the use of and by a certified, qualified practitioner only. Patients are not to attempt to apply or adjust the item unless expressly instructed to do so by the practitioner responsible for the prescription and/or initial fitting of the device. All patient questions should be referred to the practitioner and not to the manufacturer. The manufacturer warrants only that the enclosed product has been inspected for quality and can be effective for certain indications, but final decisions and ongoing monitoring must be made by the medical professional(s) prescribing and/or fitting the device to determine its effectiveness for an individual patient. Patient compliance is an integral part of the entire protocol and must be adhered to in order to avoid potential problems and to maximize the effectiveness of the prescribed product.



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