

AEV320, MEV320
TOTAL CONTACT STAINLESS STEEL VALVE HOUSING,
AUTO AND MANUAL EXPULSION
Installation and User Guide

19879-001 REV N 2022-05-23



INTRODUCTION

The AEV320 and the MEV320 valves are intended for transfemoral prosthetic suction sockets. Both utilize a stainless steel valve housing which is ideal for use with laminated socket materials.

The AEV320 valve has an automatic air expulsion function and a manual push button to release suction.

The MEV320 valve has a push button to manually expel air and to release suction.

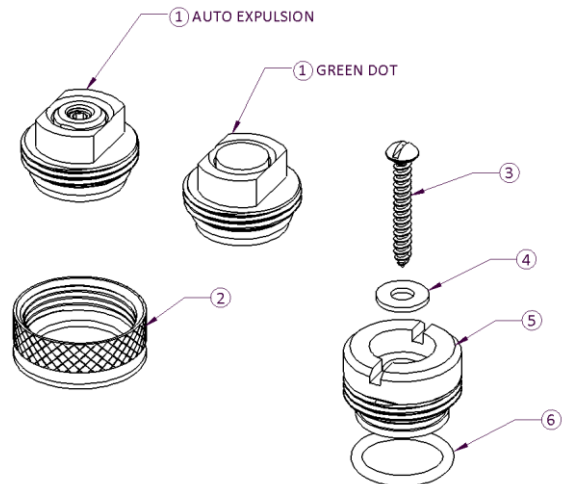
Both valve inserts are removable to allow use of a pull-sock for donning the socket.

Both are furnished with a valve key and the necessary components to embed the valve housing into the socket during the lamination process.

Product Code	Description
AEV320	AUTO EXPULSION VALVE WITH TOTAL CONTACT STAINLESS STEEL HOUSING
MEV320	MANUAL VALVE WITH TOTAL CONTACT STAINLESS STEEL HOUSING

Accessories	Description
AEV35K	VALVE KEY

PRODUCT CONTENTS:			
ITEM	QTY	PART #	DESCRIPTION
1 (AEV320)	1	AEV350i	AUTO EXPULSION VALVE INSERT ONLY
1 (MEV320)	1	MEV350i	MANUAL VALVE INSERT ONLY (GREEN DOT)
2	1	19334-001	STAINLESS STEEL HOUSING
FABRICATION / ADDITIONAL COMPONENTS:			
3	1	24437-001	SCREW, SIZE #8 X 1.25" LONG
4	1	24634-001	#10 FLAT WASHER
5	1	23974-001	VALVE PLUG
6	1	24785-001	O-RING, SIZE -116
7	1	19774-001	VALVE KEY ASSEMBLY (NOT SHOWN)



INDICATIONS

Transfemoral amputees who use lamination sockets.

INSTALLATION AND USE

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

Socket Preparation:

1. Sand a flat spot on the model at the determined valve location. Drill a 1/8" (3.2 mm) pilot hole in the center. Seal, cap and bag model in the usual manner.
2. Apply a disk of clear package sealing tape over the center of the pilot hole and puncture a hole through the tape and PVA.
3. Ensure the o-ring is installed onto the valve plug.
4. Thoroughly grease valve plug threads and o-ring with petroleum jelly, then screw firmly into valve housing. Wipe off excess.
5. Fill the slight depression in the bottom of the valve housing against the internal face of the plug with clay.
6. Attach the assembled valve housing and valve plug to the model at the pilot hole using the screw and washer provided. Tighten down securely and remove excess clay that is forced out.





7. Fill the remaining center hole in the valve plug with clay, making sure to cover the screw head and the slot.
8. Lay up the socket and laminate in the usual manner.
9. When the lamination is complete, remove resin from the valve plug face with a sander or cast saw.
10. Remove clay from the hole, and then remove the screw and washer. The socket may be blown off with compressed air through the hole.
11. Unscrew the plug from the valve housing and discard.
12. Remove excess resin from the outer face of the valve housing if required.

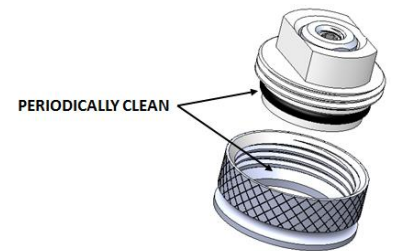
Final Assembly:

1. Assemble the valve insert (Auto-expulsion version or Green Dot version) 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.
2. 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.

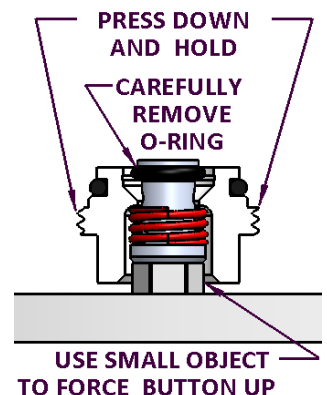
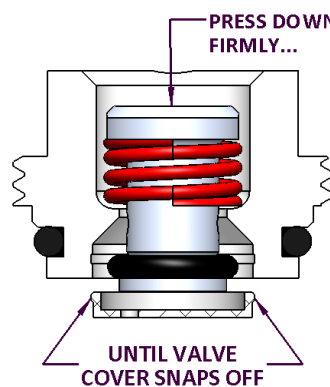


To disassemble the valve insert for more thorough cleaning, steps 1-4 pertain to both the Auto-expulsion and the Green Dot valve inserts:

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 Green Dot 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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