



**INTRODUCTION**

The P123401000 valve is intended for transfemoral prosthetic suction sockets. It utilizes a thermoplastic valve housing which is designed for use with semi-rigid thermoplastic socket materials such as Surlyn or Polyethylene.

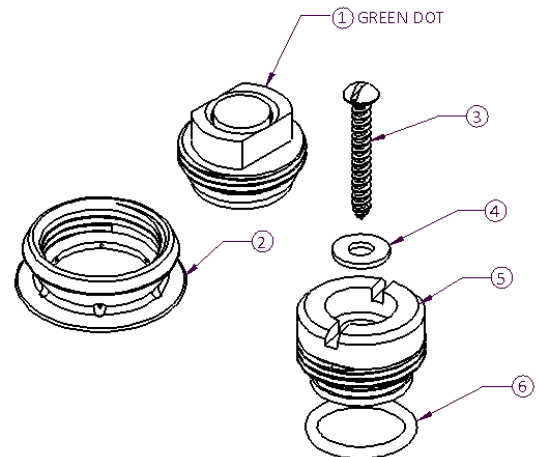
The valve has a push button to manually expel air and to release suction. The valve insert is removable to allow use of a pull-sock for donning the socket.

The valve is furnished with a valve key and the necessary components to embed the valve housing into the socket during the vacuum forming process.

Product Code	Description
P123401000	GREEN DOT VALVE WITH SFS HOUSING

Accessories	Description
AEV35K	VALVE KEY

PRODUCT CONTENTS:			
ITEM	QTY	PART #	DESCRIPTION
1	1	32213-001	GREEN DOT VALVE INSERT ASSEMBLY
2	1	19111-001	SFS VALVE HOUSING
FABRICATION / ADDITIONALCOMPONENTS :			
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 thermoformed 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  $\varnothing 3.2$  mm ( $\varnothing 1/8''$ ) pilot hole in the center.
2. Ensure the o-ring is installed onto the valve plug, and then screw it into the valve housing.
3. Thread a nylon stocking through the hole in the valve plug and tie a knot to prevent it from slipping off.
4. Pull the nylon stocking over the model, positioning the plug over the pilot hole. Temporarily displace the knot and secure the plug and housing to the model with the screw and washer provided.

**Note: If nylon stocking is not used, drill an air channel through the cast to provide vacuum at the valve site.**

5. Vacuum form the thermoplastic socket. Use a cord to manually apply the necessary external pressure around the valve housing to help guide the softened thermoplastic to form tight around the housing.
6. After the plastic is cool, remove excess plastic over the valve plug with a sharp utility knife.
7. Remove and discard the valve plug.





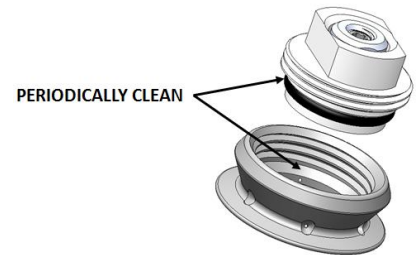
#### Final Assembly:

1. Assemble the valve insert 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.

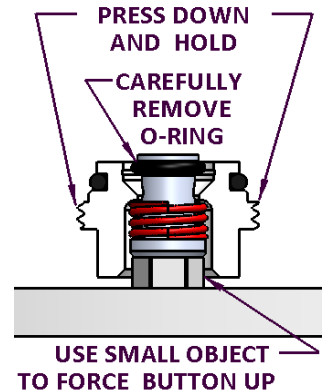
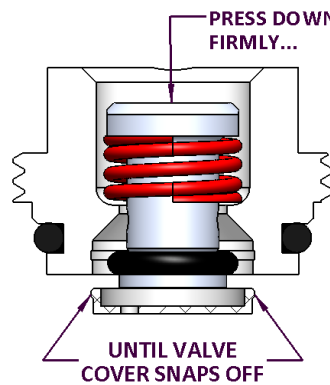


#### To disassemble the valve insert for more thorough cleaning:

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.



#### To re-assemble the valve insert:

1. 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.
2. Press the button a few times to ensure the o-ring is seated properly.
3. 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.



As a condition of the sale of any Trulife product, this product is restricted to a "Single Patient Use Only" by the originally fitted patient in order to protect the care provider and the patient against potentially adverse consequences of infectious disease transmission, material instability in adapting to the configuration of the original user and/or decrease in effectivity. Any express or implied warranties are voided if the product is reused or fitted to another patient. Additionally, a license of right to use under any relevant patents pertaining to the product is terminated with the cessation of use by the original patient. As with all Trulife products, this product must be prescribed and applied by a qualified practitioner to determine it meets the needs of the particular patient and accomplishes the desired results.