P36110
Below Knee Valve
Instructions and User Guide
28213-001 REV M 2022-05-23

CE

INTRODUCTION

The Below Knee Valve is an expulsion valve for use with a socket connector. By simply clearing the hole in the pyramid of resin following lamination and countersinking from the inside, allowance is made for valve installation. The valve provides escape for air as the user pushes into the socket. By use of a sleeve to seal the socket brim around the thigh, a secure suction suspension is created.

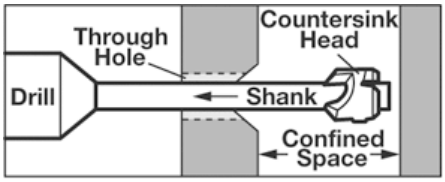
Model No.	**Description**
P36110	Below Knee Valve

INDICATIONS

Transtibial amputees.

INSTALLATION AND USE

Valve installation requires use of a 5/16” drill and countersink (McMaster Carr 3309A49 & 3309A35).



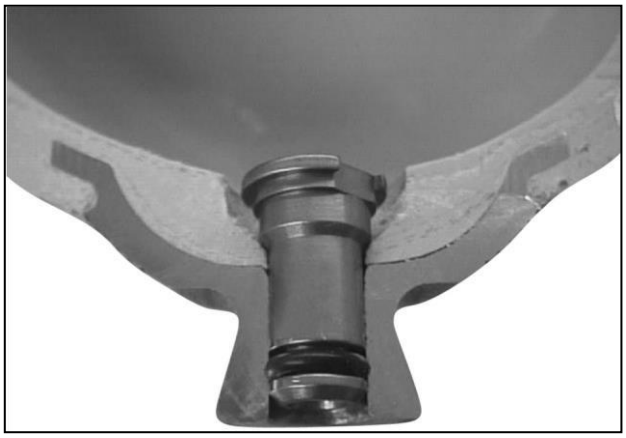
1. After completing the lamination following the instructions included with the connector, use a 5/16” drill to clear the residual resin from the hole in the pyramid by drilling completely through to the inside of the socket.
2. Insert the countersink through the hole from the inside and attach the end to a drill motor.
3. Countersink the hole until the countersink contacts the connector. **Note: The countersink is made to operate in the standard forward drill direction.**
4. Insert the valve into the countersunk hole in the distal socket.

Note: The valve is held in place and sealed against the hole by the small black O-ring that surrounds it.

Note: If installing this system in a molded block, the procedure is the same. Drill the 5/16” hole through the center of the block into the socket; countersink as above. There should be a sufficient gap between the distal block and the attached component to allow air to escape. If not, a small groove may be cut into the plastic to allow air flow.

Note: If necessary, use these additional instructions:

1. Drill a larger hole in the distal end of the socket to accommodate the head of the valve.
2. Fill in the void with epoxy.
3. Countersink fill and install valve.



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

CE

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.

Trulife
3225 Woburn St. Suite 160
Bellingham, WA 98226
USA
Phone (+1) 360 697 5656
Email supportop@trulife.com

EC REP
MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

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/repaired 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.