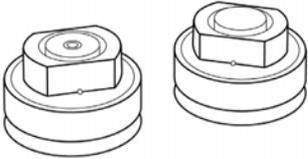




Part Number	Description
P12-320-1000	GREEN DOT TOTAL CONTACT SUCTION VALVE, STAINLESS STEEL, MANUAL EXPULSION



1. Grease Valve dummy threads thoroughly with petroleum jelly and screw firmly into valve housing and the plug. Wipe off excess.
2. 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.
3. Apply a disk of clear package sealing tape over the center of the pilot hole and puncture a hole through the tape and PVA.
4. Fill the slight depression in the bottom of the valve housing against the internal face of the plug with clay.
5. Attach the valve housing to the model at the pilot hole using the wood screw and washer provided. Clay will be forced out both under the valve housing and into the center hole void as the screw is tightened. Tighten down securely and remove excess clay.
6. Fill the remaining center hole in the plug over the screw head and the slot with clay.
7. Lay up the socket and laminate in the usual manner.
8. When the lamination is complete, remove laminate from the valve plug face. Go completely around the perimeter with a cast cutter at a level slightly below the bottom of the slot.
9. Remove clay from the hole and slot and remove the screw and washer. The socket may be blown off with compressed air through the hole.
10. Unscrew the plug from the valve housing. The slot may be used to facilitate removal.
11. Remove excess laminate from the distal face of the valve housing in the usual manner.



QUESTIONS

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Trulife has appointed Medical Device Safety Service (MDSS) of Hannover, Germany to act as our EU authorized representative. They may be contacted at:

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30175 Hannover

Germany

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LIMITED WARRANTY

Trulife warrants that the PRODUCT will be free from defects in material and workmanship for the PRODUCT from the date of installation.

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 a 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 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.

