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Instructions for Use: Shaver Leak Tester

Brand Name of Product	Shaver Leak Tester
Generic Name of Product	Shaver Leak Tester
Product Code Number(s)	SLT-MR, SLT-STK, SLT-STK SMJ, SLT-DYO, SLT-C-L, SLT-ART, SLT-PUMPCS
Intended Use	To test the seal of the fluid pathway within arthroscopic shavers.
Range of Applications for Product	Checks for performance of interior seal and, if any, leaks are present.
Key Specifications of Product	**Testing Stop** • AED-SLT Stryker® Formula - Stop: SLT-STK-SMJ • AED-SLT Midas Rex® - Stop: SLT-MR • AED-SLT Stryker® Formula - Stop: SLT-STK • AED-SLT Dyonics - Stop: SLT-DYO • AED-SLT ConMed® Linvatec - Stop: SLT-C-L • AED-SLT-Arthrex® - Stop: SLT-ART • AED-SLT PUMP: SLT-PUMPCS

Shipping & Storage	
Shipping Conditions & Requirements	N/A
Storage Conditions	N/A
Packaging Contents	N/A
Shelf Life	N/A

Instructions for Using Product	
Description of Use(s)	To test the seal of the fluid pathway within the arthroscopic shavers.
Preparation for Use	N/A
Diagrams (drawings, pictures)	 AED-SLT Styker® Formula SLT-STK-SMJ

Figure 1

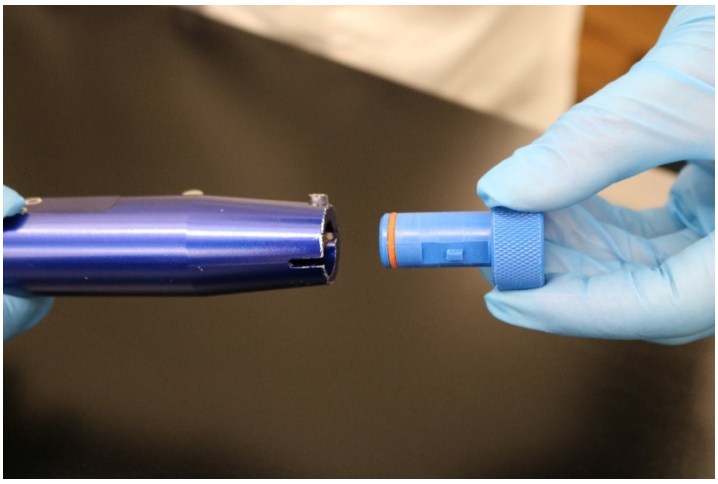

Figure 2

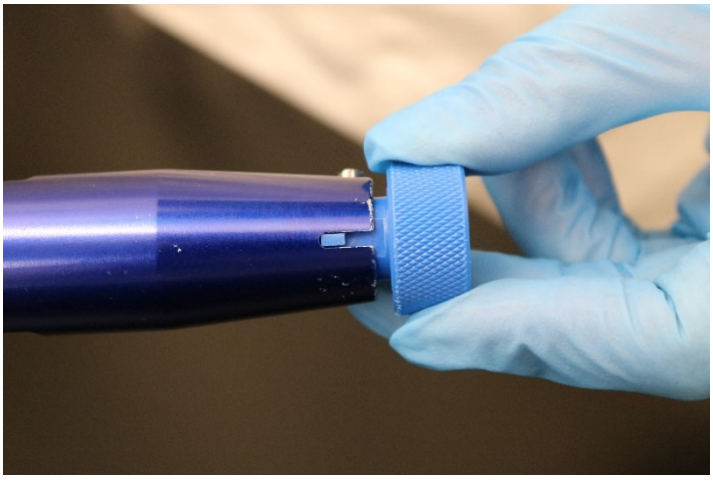

Figure 3

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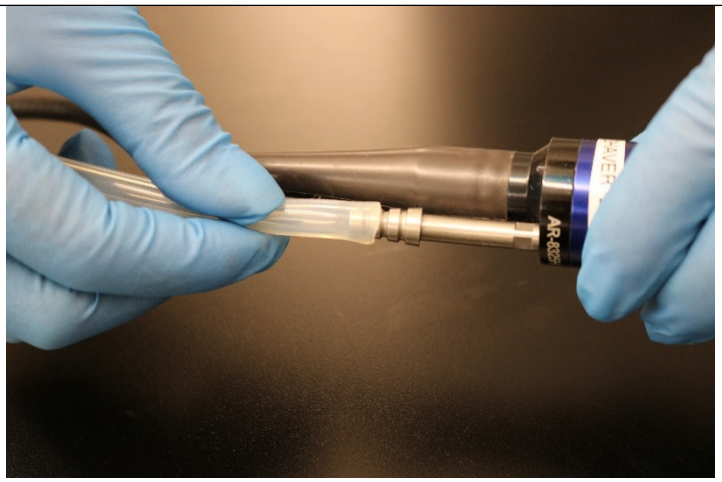

Figure 4

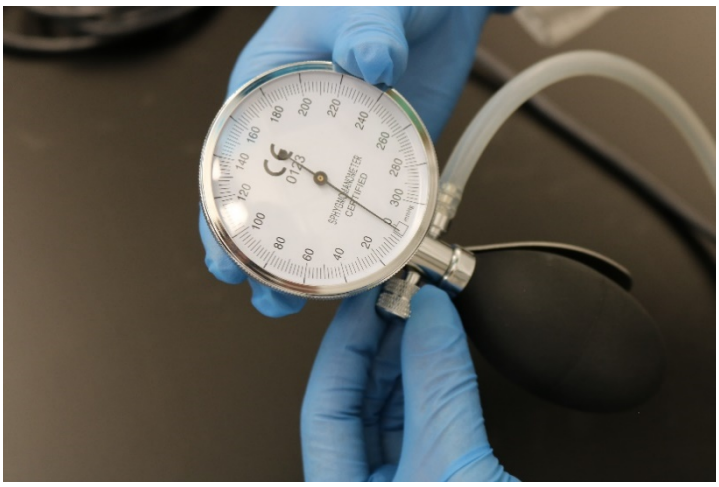

Figure 5

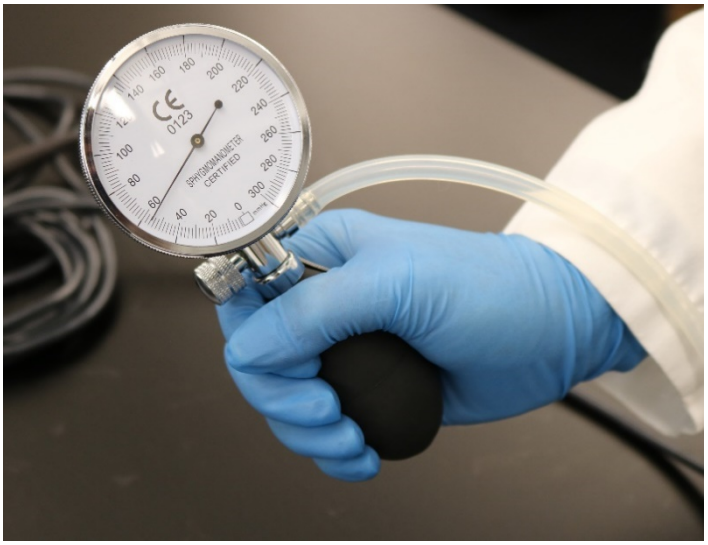

Figure 6
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<td>Steps for Use of Product</td>
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1. Place the shaver to be tested on a clean flat surface to avoid accidental damage.
2. Select the appropriate testing stop based on the brand of the shaver being tested. Each stop is brand-specific and is not interchangeable (Fig. 1)
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	3. Hold the shaver securely in one hand and the proper testing stop in the other (**Fig. 2)** 4. Insert the testing stop into the distal end of the handpiece until it is fully seated. Align keyed stop(s) with the corresponding slot on the handpiece (**Fig. 3)** **NOTE:** Some shaver models may require the engagement of a push-button latch to allow the stop to seat fully. 5. Connect the open end of the silicone tubing, attached to the pressure gauge, to the stainless-steel discharge port located at the proximal end of the handpiece. Push together to create an airtight seal (**Fig. 4)** 6. Ensure the pressure relief value of the hand pump is turned fully clockwise to the closed position (**Fig. 5)** 7. Use the bulb of the hand pump to apply pressure: a. No more than 1 to 2 pumps of the bulb will be necessary b. Observe that the pressure gauge displays and maintains a positive value c. Positive static pressure on the pressure gauge confirms no leaks in the fluid pathway and considered a passing result (**Fig.6)** **NOTE**: Proceed to Step 8 if pressure is not maintained 8. Remove testing stop and disconnect silicone tubing from the discharge port of the handpiece **NOTE**: Inspection, function verification, and sterilization of the shaver can now continue per the manufacturer's IFU. 9. If pressure gauge does not maintain static positive value: a. Re-verify all connection points and ensure the pressure relief value is sealed/closed b. Apply additional pressure using the hand pump c. Observe the pressure gauge i. If pressure is not holding statically, then shaver is leaking internally ii. The inability to maintain positive pressure is considered a failing result. (Remove all test stops and disconnect tubing from the handpiece) 10. Remove failed handpiece from service and identify for repair.
Interpretation of Test Results	N/A
Contraindications of Test Results	N/A
Documentation	N/A
Special Warnings and Cautions	Leak testing with Shaver Leak Tester should only be performed after cleaning and before sterilization of the shaver. **CAUTION:** Please refer to the steps outlined here for proper leak testing techniques. Always review OEM instruction manuals for your device.
Disposal	N/A

Reprocessing Instructions	
Point of Use	N/A
Preparation for Decontamination	N/A
Disassembly Instructions	N/A
Cleaning – Manual	**Shaver Leak Testing Stops:** 1. Rinse excess soil from the stop 2. Using a soft brush, apply detergent (as specified by the manufacturer's IFU) to all surfaces, ensuring complete coverage 3. Rinse thoroughly under running water 4. Apply a small amount of surgical grade lubricant to maintain the O-ring's integrity and help ensure proper seal

Cleaning – Automated	**Shaver Leak Testing Stops:** 1. Load testing stops loosely in a wire basket or similar 2. Select the *instrument cycle* of the automated washer 3. When unloading, check for the complete removal of any visible soil. If necessary, repeat the cycle or perform manual cleaning 4. A small amount of surgical grade lubricant will maintain the O-ring's integrity and help ensure proper seal.
Disinfection	**Shaver Leak Tester Stops and Pump**: • Remove any visible soil using disposable disinfecting wipe • Thoroughly wipe unit for a minimum of 60 seconds and allow to thoroughly dry before use
Drying	N/A
Maintenance, Inspection, and Testing	N/A
Reassembly Instructions	N/A
Packaging	N/A
Sterilization	**Shaver Leak Testing Stops (as desired)** **Steam sterilization temperature:** • 132 °C (270 °F) for 4 minutes, 135 °C (275 °F) for 3 minutes. Maximum temperature 135 °C (275 °F) for 30 minutes **NOTE:** The hand pump is not compatible with sterilization methods.
Storage	N/A
Additional Information	N/A
Related Healthmark Products	N/A
Other Product Support Documents	ProSys™ Brochure, ProSys™ Price List
Reference Documents	N/A
Customer Service Contact	Healthmark Industries Company, Inc. 18600 Malyn Blvd. Fraser, MI 48026 1-586-774-7600 healthmark@hmark.com hmark.com