



**Instructions for Use: Secure Valve Bag**

<b>Brand Name of Product</b>	Secure Valve Bag
<b>Generic Name of Product</b>	Endoscope Valve Bag
<b>Product Code Number(s)</b>	SVB604 WT, SVB604 WT CLN
<b>Purpose of Product</b>	Single-use valve bag for the safe storage of endoscope valves and to ensure that they remain as part of a unique set with the parent endoscope, as recommended by a number of national and international guidelines.
<b>Range of Applications for Product</b>	For valves that are a part of endoscopes.
<b>Key Specifications of Product</b>	<ul style="list-style-type: none"> <li>• Attaches onto the parent endoscope – without concealing any part.</li> <li>• Takes multiple valves, including cleaning valves.</li> <li>• Large mesh openings, to allow solutions through.</li> <li>• Designed to hold valves and accessories:             <ul style="list-style-type: none"> <li>○ Air/water valve</li> <li>○ Suction valve</li> <li>○ Air/water cleaning adaptor</li> <li>○ Biopsy cap (if not breached)</li> </ul> </li> </ul>

<b>Shipping &amp; Storage</b>	
<b>Shipping Conditions &amp; Requirements</b>	
<b>Storage Conditions</b>	
<b>Packaging Contents</b>	
<b>Shelf Life</b>	

**Instructions for Using Product**

<b>Description of Use (s)</b>	Single-use valve bag for the safe storage of endoscope valves and to ensure that they remain as part of a unique set with the parent endoscope with tamper evidence.		
<b>Preparation for Use</b>			
<b>Diagrams (drawings, pictures):</b>			
<b>Steps for Use of Product</b>	<ol style="list-style-type: none"> <li>1. Remove the valves from the endoscope.</li> <li>2. Reprocess as recommended by the valve manufacturer.</li> <li>3. Place the valves into the open Valve Bag. The chain of the A/W cleaning valve will fit as well</li> </ol>		

	<p>(Picture a).</p> <ol style="list-style-type: none"> <li>4. Close the top of the Valve Bag around the insertion tube (picture b), using the tamper evident seal to tighten (Pictures c &amp; d). Do not over tighten.</li> <li>5. Ensure that the valve bag is closed around the insertion tube.</li> <li>6. Pull the tear-off rod away from seal-tab and out of locking mechanism to open the Valve Bag and to release the valves (Pictures e &amp; f)</li> <li>7. Place the valves back with the endoscope.</li> <li>8. Safely discard the Valve Bag and seal. Do not reuse.</li> </ol>
<b>Interpretation of Results</b>	
<b>Contraindications of Test Results</b>	
<b>Documentation This will need to be updated with Valve Bag study</b>	<ul style="list-style-type: none"> <li>• AAMI ST91 recommends that the endoscope and accessories remain together as a unique set for infection control and tracking purpose</li> </ul>
<b>Special Warnings and Cautions</b>	Ensure you are familiar with IFU, including intended purpose of use and do not modify or alter function of devices.
<b>Disposal</b>	Safely discard. Do not reuse.

<b>Reprocessing Instructions</b>	
<b>Point of Use</b>	
<b>Preparation for Decontamination</b>	
<b>Disassembly Instructions</b>	
<b>Cleaning – Manual</b>	
<b>Cleaning – Automated</b>	
<b>Disinfection</b>	
<b>Drying</b>	
<b>Maintenance, Inspection, and Testing</b>	
<b>Reassembly Instructions</b>	
<b>Packaging</b>	
<b>Sterilization</b>	
<b>Storage</b>	
<b>Additional Information</b>	

<b>Related Healthmark Products</b>	
<b>Other Product Support Documents</b>	ProSys™ Brochure, ProSys™ Price List
<b>Reference Documents</b>	
<b>Customer Service Contact</b>	<p>Healthmark Industries Company, Inc.  18600 Malyn Blvd.  Fraser, MI 48026  1-586-774-7600  <a href="mailto:healthmark@hmark.com">healthmark@hmark.com</a>  hmark.com</p>