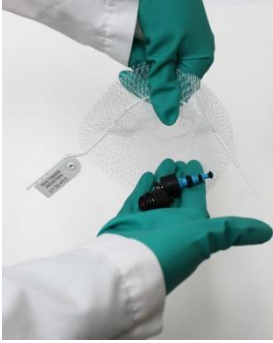
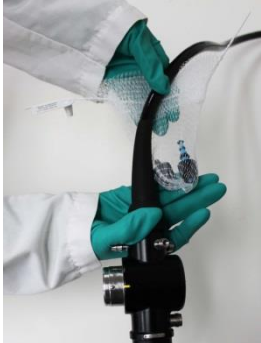

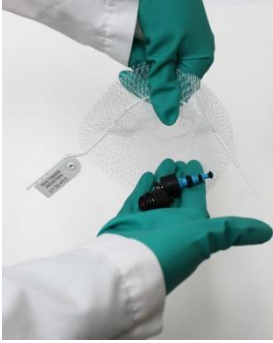
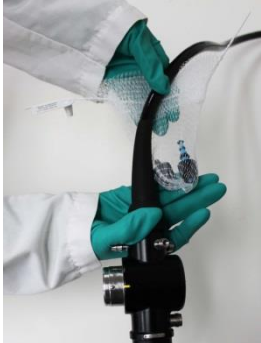

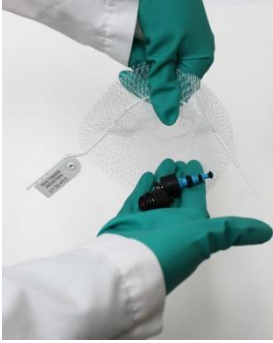
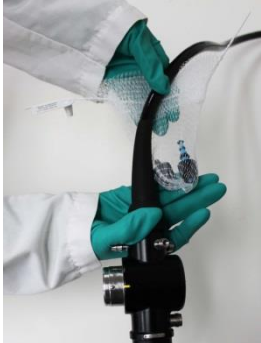





Instructions for Use: Secure Valve Bag

Brand Name of Product	Secure Valve Bag
Generic Name of Product	Endoscope Valve Bag
Product Code Number(s)	SVB604 WT, SVB604 WT CLN
Purpose of Product	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.
Range of Applications for Product	For valves that are a part of endoscopes.
Key specifications of product	<ul style="list-style-type: none"> ● Single-use – cannot be reused. <ul style="list-style-type: none"> ○ Tamper evident seal ensures lock is ‘broken’ and therefore prevents re-use. ○ Tamper Evident Seal marked “CLEAN” for clear communication. ○ Tamper Evident Seal marked with unique number that assists with tracking. ● Attaches onto the parent endoscope – without concealing any part. ● Takes multiple valves, including cleaning valves.. ● Large mesh openings, to allow solutions through. ● Designed to hold valves and accessories: <ul style="list-style-type: none"> ○ Air/water valve ○ Suction valve ○ Air/water cleaning adaptor ○ Biopsy cap (if not breached)

Shipping & Storage	
Shipping Conditions & Requirements	
Storage Conditions	
Packaging Conditions	
Shelf Life	

Instructions for Using Product							
Description of Use (s)	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.						
Preparation for Use							
Diagrams (drawings, pictures):	<table border="1" style="width: 100%; text-align: center;"> <tr> <td style="width: 33%;"></td> <td style="width: 33%;"></td> <td style="width: 33%;"></td> </tr> <tr> <td>a</td> <td>b</td> <td>c</td> </tr> </table>				a	b	c
							
a	b	c					

Steps for Use of Product	<ol style="list-style-type: none"> 1. Remove the valves from the endoscope. 2. Manually reprocess as recommended by the valve manufacturer. 3. Place the valves into the open Valve Bag. The chain of the A/W cleaning valve will fit as well (Picture a). 4. Close the top of the Valve Bag around the endoscopes umbilical cord (picture b), using the tamper evident seal to tighten (Pictures c & d). Do not over tighten. 5. Ensure that the valve bag is closed around the umbilical cord and not in the scope insertion tube. 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 & f) 7. Place the valves back with the endoscope. 8. Safely discard the Valve Bag and seal. Do not reuse.
Interpretation of Results	
Contraindications of Test Results	
Documentation This will need to be updated with Valve Bag study	<ul style="list-style-type: none"> • .AAMI ST91 recommends that the endoscope and accessories remain together as a unique set for infection control and tracking purpose
Special Warnings and Cautions	Ensure you are familiar with IFU, including intended purpose of use and do not modify or alter function of devices.
Disposal	Safely discard. Do not reuse.

Reprocessing Instructions	
Point of use:	
Preparation for decontamination:	
Disassembly Instructions:	
Cleaning – Manual:	
Cleaning – Automated: Update	
Disinfection:	
Drying:	
Maintenance, inspection, and testing:	
Reassembly Instructions:	
Packaging:	
Sterilization:	
Storage:	
Additional Information:	

Related Healthmark Products	
Other Product Support Documents	Prosys Brochure, Prosys Price List
Reference Documents	
Customer Service contact:	Healthmark Industries Company, Inc 33671 Doreka Fraser, MI 48026

	1-586-774-7600 healthmark@hmark.com hmark.com
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