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Instructions for Use: Valvesafe™

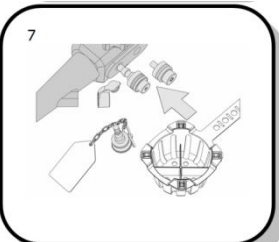

Brand Name of Product	Valvesafe™
Generic Name of Product	Endoscope Valve Basket
Product Code Number(s)	VS-002GRN, VS-002 BLU, VSH-022
Purpose of Product	Single-use valve cage for the safe storage of endoscope valves and to ensure that they remain as part of a unique set with the parent endoscope, as 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"> ○ “Smart-Click” technology ensures cage is ‘broken’ and therefore prevents re-use. • Locks onto the parent endoscope – without concealing any part. • Takes multiple valves, including cleaning valves. • Plastic construction to prevent ‘rust’ and prevent any microbiological growth. • Large openings, to allow solutions through. • Designed to take up to 4 valves: <ul style="list-style-type: none"> ○ Air/water valve ○ Suction valve ○ Air/water cleaning adaptor ○ Biopsy cap (if not breached) • Integrated opening for Air/water cleaning adaptor chain. • Holder sold separately

Shipping & Storage

Shipping Conditions & Requirements	
Storage Conditions	
Packaging Conditions	
Shelf Life	

Instructions for Using Product

Description of Use (s)	Single-use valve cage for the safe storage of endoscope valves and to ensure that they remain as part of a unique set with the parent endoscope.
Preparation for Use	
Diagrams (drawings, pictures):	

	 
Steps for Use of Product	<ol style="list-style-type: none"> 1. Remove the valves from the endoscope. 2. Manually clean as recommended by the valve manufacturer. 3. Place the valves into the open Valvesafe. The chain of the A/W cleaning valve should pass through a recess. 4. Close the top of the Valvesafe around the endoscope's umbilical cord, ensuring the four pins are fully located into the opposite housings. 5. Ensure that the Valvesafe is closed around the umbilical cord and not in the scope insertion tube. 6. Reprocess the endoscope, and place in drying cabinet if necessary. 7. Pull the "ring pull" to open the Valvesafe and to release the valves. 8. Place the valves back with the endoscope. 9. Safely discard the Valvesafe. Do not reuse.
Interpretation of Results	
Contraindications of Test Results	
Documentation	<ul style="list-style-type: none"> • Valvesafe™ Scientific data <ul style="list-style-type: none"> – The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK government agency which is responsible for ensuring that medicines and medical devices work, and are acceptably safe. – Released Medical Device Alert on the 9th May 2012 <ul style="list-style-type: none"> • Use of inappropriate accessory holders within an AER may lead to AER, endoscope and solution contamination by retained soil and corroded material • Fine mesh of some holders may trap contaminants • Inappropriate holders can deteriorate • Use only CE marked medical devices • The device must be specifically designed for decontamination • Must be compatible with AER and solutions • Gastrointestinal Nursing journal article • Launch Manual • Hospital Infection Research Laboratory paper • 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:	<p>The polymer used for the construction of Valvesafe is approved for endoscopy use. There should be no reaction with:</p> <ul style="list-style-type: none"> • Enzymatic detergents • Alkaline detergents
Disinfection:	Compatible with disinfectants typically used for endoscope reprocessing, including peracetic acid, glutaraldehyde, OPA, etc.
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	
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