

Endo-Safier™

Single Use Endoscopy Button Valves Set Contains Air/Water, Suction & Biopsy Valve & Auxiliary Water Jet Connector Fitting For Olympus G.I. Endoscopes

Instructions for Use

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Made in China

<u>REF NUMBER</u>	<u>DESCRIPTION</u>
G-VS01M	Air/Water, Suction, Biopsy Valve -& Auxiliary Water Connectors
G-VS0101M	Air/Water, Suction & Biopsy Valves
G-VS0102M	Air/Water & Suction Valves
G-VS01SM	Suction Valve

Use Compatibility for Olympus® G.I. Endoscopes

OES40, EVIS 140, 145/ 160/165/ 180/ 190/ 240/ 260/ 290 Series Endoscopes

INTENDED USE

- Endo-Safier™ air/water valve is intended for single use to attach to air/water cylinder of Olympus® G.I. endoscopes for controlling of function of air/water delivery performance.
- Endo-Safier™ suction valve is intended for single use to attach to suction cylinder of Olympus® G.I. endoscopes for controlling of suction performance.
- Endo-Safier™ Biopsy valve is intended for single use to cover the open of Olympus® G.I. endoscopes to the biopsy/instruments channel of Olympus® G.I. Endoscopes. The Endo-Safier™ biopsy valve provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port and provides access for irrigation.
- Endo-Safier™ auxiliary water connector is intended for single use to attach to auxiliary water jet adaptor of Olympus® G.I. endoscopes as connector to Endo-Safier™ Irrigation tubing.

WARNINGS AND PRECAUTIONS

These devices are intended to be used with Olympus® G.I. Endoscopes ****EXCLUDING Olympus® echoendoscopes that utilize a balloon channel****

Use these button valves follow the instructions specified by Olympus® manual

Do not re-sterilized, reprocessed or reused. Suzhou GZM Medical Co., Ltd cannot verify that reprocessing can clean or maintain the structural integrity of these devices to ensure the safety of patients and users.

- It is only designed for single use.
- Endoscopic procedures should only be performed by persons well-trained about and familiarity with endoscopic techniques.
- Prior to perform endoscopy procedures, consult the medical literature relative to techniques, contraindications, complications and hazards prior to any endoscopic procedure.
- Before use these valves set the appropriate aseptic technique should be conducted.
- Endoscopic cleaning procedures should only be conducted by persons having skilled at or well trained with endoscope cleaning techniques.
- Do not attempt to reuse, reprocess, refurbish, remanufacture or re-sterilize this device. They aren't designed for intended to be reused, reprocessed, re-sterilized. Doing such activities on this single use medical device could presents a safety risk to patients.
- Use appropriate aseptic technique before using the products.

Prior to Use

- Prior to G.I. procedure use, inspect and familiarize yourself with the device. If there is evidence of damage (i.e. deformed, cracked/broken, damaged packaging), do not use this product, save for return, and contact your local Product Specialist.
- Inspect the package for shipping or handling damage. If damage is evident, DO NOT USE THESE DEVICES, SAVE THEM OR RETURN, AND CONTACT YOUR LOCAL PRODUCT SPECIALIST.

Biopsy valve:

- Peel open the pouch and take out the biopsy valve from the tray.
- Do not use a sharp or pointed object to prime the valve prior to use.
- Do not use if the damage and cracks are found to the biopsy valve.
- Do not leave a device hanging from the valve. Doing so can cause the creation of a larger valve slit/hole that may cause leakage.
- If the lid of the valve that attached on the endoscope is opened during the procedure, scope suction will be compromised and leakage may happen and cause biological contamination to user.
- If leakage occurs and for complete the endoscopic procedure a sterile gauze should be used to cover the valve.

Suction button valve:

- Peel open the pouch and take out the suction button valve from the tray.
- For optimal performance, please soak the suction button valve in the sterile water for one minute prior to use.
- Insert the suction button valve into suction cylinder of an Olympus® G.I. endoscope.
- Twist valve slightly to seat in properly with a right attachment to its cylinder.
- Confirm that the valve fits securely and correctly. There is no gap between the valve button and endoscope.

Note: If the attachment to the cylinder is correct, the suction valve can not be able to be rotated. Depress and release the button valve to check if it moves smoothly and freely to performance ON/OFF position.

Air/water button valve:

- Peel open the pouch and take out the air/water button valve from the tray.
- For optimal performance, please soak the air/water valve in the sterile water for one minute prior to use.
- Insert the air/water button valve into its cylinder of an Olympus® G.I. endoscope.
- Confirm that the valve fits securely and correctly. There is no gap between the valve button and endoscope.
- Note: If the attachment to the cylinder is correct, the suction valve can not be able to be rotated. Depress and release the button valve to check if the valve moves smoothly and freely returns to its ON/OFF position.

Auxiliary jet water connector:

- Before use for procedure, familiarize yourself with the device and read all the Instructions for Use.
- Peel open the pouch and take the connector out. Attach the connector to adaptor on the endoscope. When attaching the auxiliary water jet connector to the adaptor on endoscope, be careful to ensure that screwing auxiliary water connector is aligned to the adaptor and avoid over tightening. Otherwise, misalignment or excessive tightening possible to lead to the possibility of leakage during final irrigation procedure.
- Attached the irrigation tube to the luer-lock connector of Auxiliary Water Jet Connector. For the use of irrigation tubing, carefully read the instruction or use of it.

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- When replace the Auxiliary Water Jet Connector grip the clamp of irrigation tubing.
 - Discard the auxiliary water connector after each patient use.
- Protective garments (i.e. gloves, protective eyewear, gowns, etc) should be worn during the use of this device to protect against the risk of cross-contamination and injury.

Product Disposal:

After use, this product may be a potential biohazard. Handle and dispose of the product in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

DESCRIPTION OF SYMBOLS USED ON LABELS

	Do not re-sterilization		Instruction for Use
	Do Not Re-use		Quantity in package
	Manufacturing Date		Manufacturer
	Reference No.		Lot Number
	Use by		Keep Dry
	Authorized Representative in the European Community		Prevent from sun light
	Sterilized By Ethylene Oxide		Do not contains natural rubber
	Notify Body		Do not use if packaging is opened or damaged
	DEHP Free		Medical Device
	Temperature Limit		Prescription Only
	Humidity Limit		

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