

1. STANDARD SET LIST

This package includes the following items:

- Ruhof Disposable Endoscope Valve Set
- Instructions for Use



NOTE:

- Read this manual before operating.
- Failure to read and thoroughly understand the information presented in this manual, as well as those developed for other endoscopic equipment, may result in serious injury to the patient and/or user. Furthermore, failure to follow the instructions in this manual may result in damage to, and/or malfunction of, this equipment.
- It is the responsibility of each medical facility to ensure that only well-educated and appropriately trained personnel, who are competent and knowledgeable about endoscopic equipment, antimicrobial agents/processes, and hospital infection control protocol be involved in the use of these medical devices.
- Known risks and/or potential injuries associated with flexible endoscopic procedures include, but are not limited to, the following: hemorrhage, perforation, and infection.

2. INTENDED USE

- Disposable Air/Water Valves:

This device intended to be fitted to an endoscope air/water channel to enable the operator to control inflow of medical gases and water, whilst preventing backflow.

- Disposable Suction Valves:

The device intended to be fitted to an endoscope suction channel to enable the operator to control suction whilst preventing inflow of air.

- Disposable Biopsy Valves

This device is intended to be fitted to an endoscope biopsy port to enable access for/exchange of endoscopic devices while maintaining insufflation and minimizing leakage of bio material during an endoscopic procedure.

⚠ CAUTION:

Never use this device for any purpose other than that for which it has been designed. Since endoscopic accessories are designed to be used in conjunction with other medical devices, the effectiveness of an accessory is dependent upon a number of factors, including the condition of the endoscope.

WARNING:

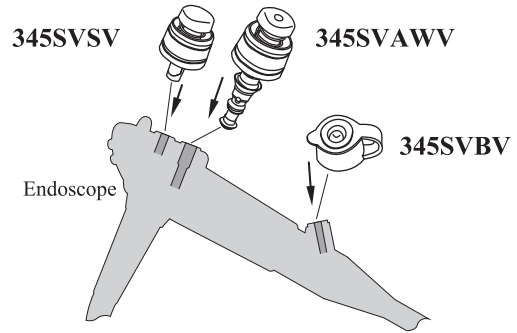
- This device has been ETO sterilized for single patient use. Never reuse, reprocess, or re-sterilize. Reuse, reprocessing, or re-sterilization may lead to device failure, patient injury, and/or illness. Reuse, reprocessing, or re-sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection. Contamination of the device may lead to injury and/or illness of the patient.
- Never attempt to repair or modify this device. The use of a repaired or modified device may result in patient injury.

3. CONTRAINDICATION

Do not use these devices for any purpose other than that for which they are intended.

4. NOMENCLATURE

- The Disposable Endoscope Valve Set contains 345SVAWV Air/Water Valve, 345SVSV Suction Valve and 345SVBV Biopsy Valve.



Set	Component	Model	Quantity	Endoscope Model
A	Air/Water Valves	345SVAWV	1	Compatible with Olympus 140/160/180/190/240/260 series endoscopes
	Suction Valves	345SVSV	1	
	Biopsy Valves	345SVBV	1	

* The above product specifications are only partial, just for reference.

5. PREPARATION AND INSPECTION BEFORE USE

⚠ CAUTION:
Wear sterile surgical gloves when performing the pre-use inspection.

- 1) Prior to use, the endoscope with which this device will be used must be carefully and thoroughly inspected for cleanliness and proper function to determine that it is appropriate for patient use. Please refer to the manual supplied with the endoscope.
- 2) Confirm that the devices are compatible with the endoscope.

⚠ CAUTION:
Use of this device with an incompatible endoscope can result in endoscope and/or accessory damage/failure.

- 3) Check the sterilization expiration date printed on the package/ labeling and confirm that the product has not expired. Make sure that there are no signs of abnormalities such as stains, wetness, tears, or any other indications that the packaging has previously been opened or compromised.

WARNING:
Do not use this device if it is expired or if the sterilization package is opened, damaged, or displays any abnormalities. In such cases, sterility can't be guaranteed, and clinical use of the device can result in patient infection or allergic reaction.

- 4) Remove the device from the packaging.
- 5) Make sure that there are no abnormal conditions such as holes, dents, cracks, tears, edges, deformation etc. within or on the device.

⚠ CAUTION:
As a precaution, always have an extra device available for use in the event that the original device becomes inoperable and/or unsafe for patient use. If a spare device is used, the above preparation and inspection steps should be followed.

WARNING:

Do not use a device that shows any signs of damage or operational difficulty. Any malfunction of the device during a patient procedure can result in serious injury to the patient.

WARNING:

Store the packaged device in a clean and dry place. Avoid storage areas with high humidity, high temperature, and exposure to direct sunlight.

6. OPERATION**WARNING:**

- The user must carefully read and follow all instructions in the operating manuals supplied with all related equipment. The equipment should be carefully and thoroughly inspected to determine that it is appropriate for patient use.
- Technical criteria, clinical applications, and accompanying risks must be well understood before using this device.
- Physicians and assistants should wear personal protective equipment such as gloves, gowns, face masks, goggles, etc. to minimize the risk of cross contamination.

- 1) Push the Air/Water Valves down on to its holder and then rotate it into the slot, until the Air/Water Valves snap into place.
Push the Suction Valves down on to its holder until it snaps into the place.
Push the Biopsy Valves down on to the instrument channel port until it snaps into the place.

 **CAUTION:**

At low temperature, the device may become stiff and difficult to be attached.

- 2) Use a finger to block the cover vent on the Air/Water Valves, thus delivering the air. Use a finger to block the cover vent on the Air/Water Valves while pressing it all the way down, thus delivering the solution.

 **CAUTION:**

While delivering the air, Do not press down the Air/Water Valves.

- 3) Press the Suction Valves all the way down, thus aspirating the solution.
- 4) Open the Biopsy Valves cover, insert a syringe and hold it perpendicular to the Biopsy Valves and then press the plunger to feed the solution.

 **CAUTION:**

Angled or incomplete insertion may cause leakage of the solution from the Biopsy Valves.

- 5) Insert the Endo-Therapy Accessory through the slit of the Biopsy Valves. After use, slowly withdraw the Endo-Therapy Accessory.

 **CAUTION:**

Inserting the Endo-Therapy Accessory straight into the Biopsy Valves.

- 6) Remove the endoscope Valves set from the Air/Water Valves Holder, Suction Valves Holder and Instrument Channel Port.

7. CARE AFTER USE**WARNING:**

This device is for single patient use. Never reuse or resterilize the device. For disposal, follow the applicable protocol at your medical facility, as well as local or national regulations.



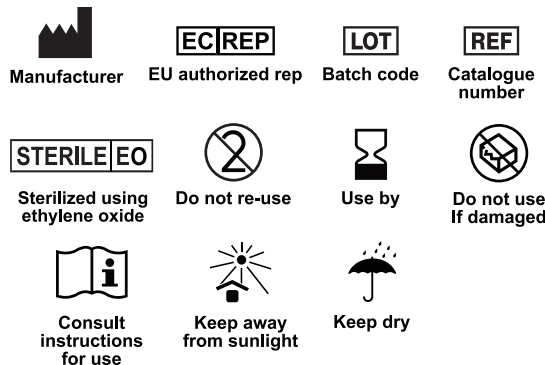
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USA

Federal (USA) law restricts this device to sale by or on the order of a physician or other appropriately licensed medical professional.