

Disposable Endoscope Valve Sets

Model: SML001-PT

(For Pentax® 90/ i10 GI Endoscope)

INSTRUCTIONS FOR USE. READ CAREFULLY PRIOR TO USE.

REF	PACKAGE CONTENTS
SML001-PT01	4 Piece Valve Kit Suction Valve 1: 1 piece, Air/Water Valve: 1 piece Biopsy Valve: 1 piece, Auxiliary Water Connector: 1 piece
SML001-PT02	4 Piece Valve Kit Suction Valve 2: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece, Auxiliary Water Connector: 1 piece
SML001-PT03	4 Piece Valve Kit Suction Valve 3: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece, Auxiliary Water Connector: 1 piece
SML001-PT04	3 Piece Valve Kit Suction Valve 1: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece
SML001-PT05	3 Piece Valve Kit Suction Valve 2: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece
SML001-PT06	3 Piece Valve Kit Suction Valve 3: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece
SML001-PT07	2 Piece Valve Kit Suction Valve 1: 1 piece, Air/Water Valve: 1 piece
SML001-PT08	2 Piece Valve Kit Suction Valve 2: 1 piece, Air/Water Valve: 1 piece
SML001-PT09	2 Piece Valve Kit Suction Valve 3: 1 piece, Air/Water Valve: 1 piece
SML001-PT10	1 Piece Valve Kit Biopsy Valve: 1 piece
SML001-PT11	1 Piece Valve Kit Auxiliary Water Connector: 1 piece
SML001-PT13	5 Piece Valve Kit Suction Valve 1: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece, Auxiliary Water Connector: 1 piece, Air/Water Channel Cleaning Adapter: 1 piece
SML001-PT14	5 Piece Valve Kit Suction Valve 2: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece, Auxiliary Water Connector: 1 piece, Air/Water Channel Cleaning Adapter: 1 piece
SML001-PT15	5 Piece Valve Kit Suction Valve 3: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece, Auxiliary Water Connector: 1 piece, Air/Water Channel Cleaning Adapter: 1 piece
SML001-PT16	4 Piece Valve Kit Suction Valve 1: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece, Air/Water Channel Cleaning Adapter: 1 piece

SML001-PT17	4 Piece Valve Kit Suction Valve 2: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece, Air/Water Channel Cleaning Adapter: 1 piece
SML001-PT18	4 Piece Valve Kit Suction Valve 3: 1 piece, Air/Water Valve: 1 piece, Biopsy Valve: 1 piece, Air/Water Channel Cleaning Adapter: 1 piece
SML001-PT19	3 Piece Valve Kit Suction Valve 1: 1 piece, Air/Water Valve: 1 piece, Air/Water Channel Cleaning Adapter: 1 piece
SML001-PT20	3 Piece Valve Kit Suction Valve 2: 1 piece, Air/Water Valve: 1 piece, Air/Water Channel Cleaning Adapter: 1 piece
SML001-PT21	3 Piece Valve Kit Suction Valve 3: 1 piece, Air/Water Valve: 1 piece, Air/Water Channel Cleaning Adapter: 1 piece

--INTENDED USE--

The Disposable Endoscope Valve Sets is a collection of several sterile units. It is intended to be fitted to multiple endoscopes working channels/ports to control the flow of fluids, gases and other materials. It is only used for qualified physician or nurse, and includes an Air/Water Valve, a Suction Valve, a Biopsy Valve, an Auxiliary Water Connector and a Cleaning Adapter.

- The single use **Air/Water Valve** is used to control the air /water function of an endoscope during endoscopic procedures.
- The single use **Suction Valve** is used to control the suction function of an endoscope during endoscopic procedures.
- The single use **Biopsy Valve** is used to cover the opening to the biopsy/suction channel of gastrointestinal endoscopes.
- The single use **Auxiliary Water Connector** is used in conjunction with irrigation tubing, intended to provide irrigation via irrigation fluids such as sterile water supplied to the endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.
- The **Air/Water Channel Cleaning Adapter** is intended as part of the pre-cleaning process, to help clear the air/water channel of endoscopes post procedures.

--WARNINGS AND PRECAUTIONS--

These devices are intended to be used with Pentax® 90/ i10 Endoscopes
(Follow the guidelines for air/water, suction, Biopsy, Auxiliary Water Connector and air/water channel cleaning adapter use in the Pentax® 90/ i10 endoscopes)

NOTE: The product includes the backflow-prevention valves, and the Air/Water Valve and Auxiliary Water Connector have a backflow prevention feature.

- Not contain or presence of natural rubber latex.
- This disposable medical device is intended for single patient use only.
- These disposable medical devices are intended for single use only, do not resterilize or reprocess.
- 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.
- Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.
- Consult the medical literature relative to techniques, contraindications, complications, and hazards prior to any endoscopic procedure.
- When handling these devices use the appropriate aseptic technique.
- Never attempt to repair or modify this device. The use of a repaired or modified device may result in patient injury.
- Use of this device with compatible endoscopes, use with an incompatible endoscope can result in endoscope and/or accessory

damage/failure.

- Discard the used valves in accordance with local, state, and federal regulations.
- An issued or revision date for these instructions is included for the user's information. In the event that two years have elapsed between this date and product use, the user should contact to determine if additional information is available.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

Air/Water & Suction Valves:

- Make sure the holes in the air/water and suction valves are not clogged or blocked. (This could cause continuous air/CO₂ flow, or inadequate suction.)

Biopsy Valve:

- Do not use a sharp or pointed object to prime the valve prior to use.
- 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 is opened while attached to the endoscope during a procedure, scope suction will be compromised, and leakage may occur.
- If leakage occurs, sterile gauze should be used to cover the valve.

Auxiliary Water Connector:

- Never attach or reattach the Auxiliary Water Connector to an endoscope that is/was inside the patient and has not been reprocessed.
- Do not insert this device into the patient. The device should be attached to the auxiliary water port of a flexible gastrointestinal endoscope and an irrigation source. Use proper techniques to avoid the risk of aspiration of a patient.
- Always prime the auxiliary water channel or biopsy channel prior to inserting the endoscope into the patient.

Air/ Water Channel Cleaning Adapter

- Do Not Use the device during patient procedures. Continuous air flow could cause patient injury. In addition, insufficient aspiration and leakage cause cross-contamination.
- Endoscopic cleaning procedures should only be performed by persons having adequate training with endoscope cleaning techniques.

--DIRECTIONS FOR USE--

1. Prior to clinical use, familiarize yourself with the device and read all the Instructions for Use.
2. Inspect the package for shipping or handling damage. If damage is evident, DO NOT USE THIS DEVICE. Contact your local sales representative.

Suction Valve:

3. Remove the suction valve from the tray.
4. Insert the suction valve into the port of the suction channel of a Pentax® 90/ i10 endoscope (see Figure 1 below).
5. Twist valve slightly to seat in proper orientation within the port.
6. Confirm that the valve fits securely and that there is no gap between the valve end cap and the endoscope.
Note: The valve should not be able to be rotated once it is fully inserted into the port.
7. Actuate the valve by pressing and releasing it a few times to confirm smooth function.

Air/Water Valve:

8. Remove the air/water valve from the tray.
9. Insert the air/water valve into the port of the air/water channel of a Pentax® 90/ i10 endoscope (see Figure 1 below).
10. Confirm that the valve fits securely and that there is no gap between the valve end cap and the endoscope.
11. Actuate the valve by pressing and releasing it a few times to confirm smooth function.

Biopsy Valve:

12. Remove the biopsy valve from the tray.
13. Securely place the biopsy valve onto the port of the biopsy channel of a Pentax® 90/ i10 endoscope (See Figure 1). **Note:** This

biopsy valve does not accommodate a Luer-lock syringe without an irrigating adapter.

14. Close the lid when there is not a need to pass a device through the channel.
15. When the device diameter is over 3.2 mm, open the lid and pass the device through the hole into the biopsy channel.

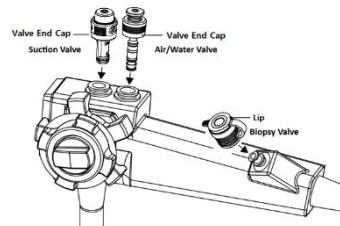


Figure 1

Auxiliary Water Connector:

16. Attach the Auxiliary Water Connector to the Irrigation Tubing. For use of the Irrigation Tubing, reference the specified Instructions for Use.
17. Attach the Auxiliary Water Connector to the port of auxiliary water by screwing it onto the port (See Figure 2). When attaching the Auxiliary Water Connector to the port, take care to ensure that the Auxiliary Water Connector is aligned to the port and avoid excessive tightening. Misalignment or excessive tightening of the Auxiliary Water Connector could lead to the possibility of leakage. Once the Auxiliary Water Connector is attached to the auxiliary port of the endoscope, attach the irrigation tubing to the Auxiliary Water Connector.
18. In the case there is any leakage due to misalignment or excessive tightening, replace it with a new Auxiliary Water Connector.
19. Discard the Auxiliary Water Connector after each patient use.

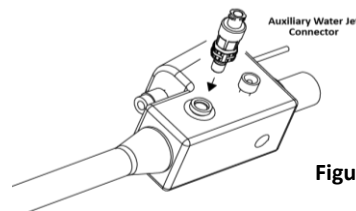


Figure 2

Air/ Water Channel Cleaning Adapter

20. Turn off the airflow regulator on the light source after initial rinsing of scope (per facility guidelines).
21. Remove the air/water valve from the endoscope.
22. Insert the air/water channel cleaning adapter into the air/water cylinder on the control body of the endoscope (See Figure 3).
23. Place the distal end of the scope into a basin of water.
24. On the light source, turn on the air pump and set it to highest pressure.
25. Press and hold the air/water channel cleaning adapter to supply water for 30 seconds.
26. Release the air/water channel cleaning adapter.
27. Remove distal end from the water and ensure that water is expelled from the distal end of the endoscope.
28. Release the valve of the air/water channel cleaning adapter for at least 10 seconds to completely expel the remaining water.
29. Press the pump button of the light source until the air supply indicator turns off.
30. Remove the air/water channel cleaning adapter from endoscope after pre-cleaning step is completed.

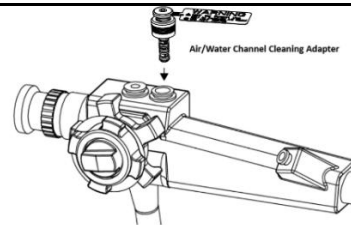


Figure 3

Remove and discard the Suction Valve, Air/Water Valve, Biopsy Valve, Auxiliary Water Connector, and Air/ Water Channel Cleaning Adapter after each use.

--PRODUCT DISPOSAL--

The Disposable Endoscope Valve Sets may be potential biohazards after use. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

-- STORAGE AND TRANSPORTATION --

Disposable Endoscope Valve Sets is sterilized by ethylene oxide in sterile packaging. The product shall be stored in a cool, ventilated and dry environment with a temperature of $\leq 40^{\circ}\text{C}$ and a humidity of $\leq 80\%$. The validity period of the product is three years.

-- PERFORMANCE CHARACTERISTICS --

The performance characteristics of the product have been verified and all meet the technical requirements. The performance characteristics are as follows:

- 1) For Suction Valve:
 - Endoscope Compatibility
 - Leakage
 - Suction Flow
 - Pressing Force
- 2) For Air/Water Valve:
 - Endoscope Compatibility
 - Leakage
 - Pressing Force
 - Water flow rate
 - Air flow rate
 - Backflow Performance
- 3) For Biopsy Valve:
 - Endoscope Compatibility
 - Leakage
 - Squeeze Leak
 - Backflow Performance
- 4) For Auxiliary Water Connector:
 - Endoscope Compatibility
 - Leakage
 - Water flow rate
 - Backflow Performance
- 5) For Air/Water Channel Cleaning Adapter
 - Endoscope Compatibility
 - Water flow rate
 - Air flow rate

--EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE--



Notified Body DQS for CE

Manufacturer

EU REP



Authorized representative in the European
Community/European Union

LOT

Date of manufacture



Lot Number or Batch Code

MD

Use-by date

REF

Medical Device

STERILE EO

Catalogue number



Sterilized Using Ethylene Oxide



Do Not Reuse or Single Use



Do Not Re-Sterilize



Do not use if package is damaged and consult
instructions for use



Consult Instructions for Use



Keep Dry

UDI

Keep Away from Sunlight



Unique device identifier



The Limit of Upper temperature $\leq 40^{\circ}\text{C}$



Humidity Limitation $\leq 80\%$

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