

Disposable Air/Water, Suction, Biopsy Valve & Auxiliary Water Connector Kit.

Instructions for Use

	Use-by date		Batch or lot code
	Manufacturer		Date of Manufacture
	Catalog number Product Code		Order number
	Sterilized using Ethylene Oxide		Do not re-use / Single use
	Single sterile barrier system with protective packaging inside		Product not made with natural rubber latex
	Does not re- sterilize		Consult Instructions for Use
	Do not contain DEHP		Keep dry
	Do not use if package is damaged		Packing Quantity
	Keep away from sunlight		Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.

IMPORTANT INFORMATION

Caution: Federal law restricts this device to sale by or on the order of a physician. Read all instructions carefully before use. They contain essential information on using this device safely and effectively. Keep these instructions in a safe, accessible location, as you may need to refer to them again. If you have any questions or comments about any information in these instructions, please contact Micro-Tech USA.

INTENDED USE

The single use **Air/Water Valve** is used to control the air / water function of an endoscope during GI endoscopic procedures. The air / water valve in the endoscopic system provides backflow prevention function to the air / water channel. Not using the air / water valve can cause potential contamination to the air / water system.

The single use **Suction Valve** is used to control the suction function of an endoscope during GI endoscopic procedures.

The single use **Biopsy Valve** is used to cover the opening to the biopsy/suction channel of Pentax® gastrointestinal endoscopes. The biopsy valve provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port through the endoscopic procedure and provides access for irrigation.

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 Pentax® GI endoscope during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump. The auxiliary water connector is manufactured with a one-way valve to minimize the risk of cross-contamination of the irrigation system.

WARNINGS AND PRECAUTIONS

- Follow the Pentax® guidelines for air/water/suction use in the Pentax® endoscopes.
- The manufacturer did not design these devices to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of these devices to ensure patient and/or user safety.
- These disposable medical devices are not intended for reuse. Any institution, practitioner, or third party, who reprocesses, refurbishes, remanufactures, resterilizes, and or reuses these disposable medical devices must bear full responsibility for their safety and effectiveness.
- 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 appropriate aseptic technique.

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.)
- The air/water valve and suction valves are intended for single patient use only. These devices should be discarded after being used on one patient. They should not be used on multiple patients.

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, a sterile gauze should be used to cover the valve.
- The device should be discarded after being used on one patient. It should not be used on multiple patients.

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 risk of aspiration by the patient.
- Always prime the auxiliary water channel or biopsy channel prior to inserting the endoscope into the patient.
- The device is part of distal irrigation system with a backflow prevention feature and is intended for single patient use only. The device should be discarded after being used on one patient. It should not be used on multiple patients.

Product Name:

Disposable Air/Water, Suction, Biopsy Valve & Auxiliary Water Connector Kit.

Production Date: See packaging

Shelf Life: 3 years

Contents supplied sterile.

This device is not made with natural rubber latex.

AW01-PEN4

Air/Water, Suction, Biopsy Valve & Auxiliary Water Connector Kit for Pentax® 90 / i10 / i10c Series Endoscopes

PREPARATION

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 THESE DEVICES. SAVE THEM AND RETURN TO MANUFACTURER AND CONTACT YOUR LOCAL PRODUCT SPECIALIST.**

INSTRUCTIONS FOR USE

Suction Valve:

3. Remove the suction valve from the tray.
4. Before inserting the suction valve to the suction cylinder, make sure the small locator on the suction valve is in alignment with the locating slot of the cylinder.
5. Insert the suction valve into suction cylinder of a Pentax® endoscope (see Figure 1).
6. Twist valve slightly to seat in proper orientation within the cylinder.
7. 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 cylinder.
8. With the thumb fully on the suction valve button, depress fully downward and release as required.

Air/Water Valve:

9. Remove the air/water valve from the tray.
10. Insert the air/water valve into the air/water cylinder of a Pentax® endoscope (see Figure 1).
11. Confirm that the valve fits securely and that there is no gap between the valve end cap and the endoscope.
12. Depress and release the valve to check if the valve moves smoothly and freely returns to its OFF position.

Biopsy Valve:

13. Remove the biopsy valve from packaging.
14. Securely place the biopsy valve onto the biopsy/suction channel opening of a Pentax® endoscope (See Figure 1).
Note: This biopsy valve does not accommodate a luer-lock syringe without an irrigating adaptor.
15. Upon reattachment of the lid, ensure the lid is tightly fixated into position by slightly compressing the edge of the valve and ensure no distortion is visible.
16. When the device diameter is over 3.2mm, open the lid and pass the device through the hole into the biopsy/suction channel.

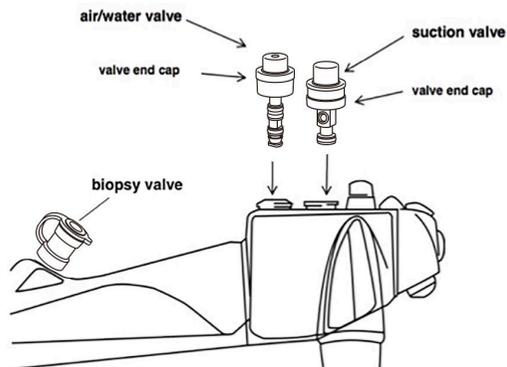


Figure 1

Auxiliary Water Connector:

17. For use of the Irrigation Tubing, reference Instructions for Use of it.
18. Attach the auxiliary water connector to the auxiliary water port 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 water port of the endoscope, attach Irrigation Tubing to the auxiliary water connector.
19. In the case there is any leakage due to misalignment or excessive tightening, please replace with a new auxiliary water connector.
20. Discard the auxiliary water connector after each patient use.

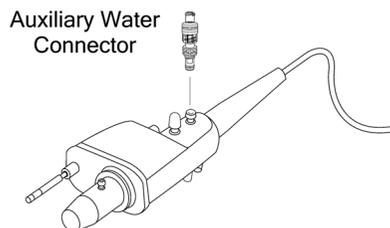


Figure 2

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.

WARNING

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 Micro-Tech USA to determine if additional information is available.

Report any serious incident that has occurred in relation to the device to the distributor or manufacturer or competent authority of the member state.

Pentax® is a registered trademark of Pentax Medical.

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