



AIR/WATER, SUCTION, BIOPSY VALVES & AUXILIARY WATER CONNECTOR

*Instructions for Use.
Read carefully prior to use.*

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Not Made with natural rubber latex.

<u>Part Number</u>	<u>Description</u>
EN10229P.1	Single Use - Valves (Suction-/Air-Water-/ Biopsy-Valve/ Auxiliary Water Connector) Einmal-Ventile (Absaug-/ Luft-Wasser-/ Biopsie-Ventil/ Jet-kanal-Adapter)

For Pentax® 90/ i10 GI Endoscope
Für Pentax® 90/ i10 GI Endoskope

INTENDED USE

The single use **air/water valve** is used to control the air / water function of an endoscope during GI endoscopic procedures.

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.
- GA Health Company Limited 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.)

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.

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 of a patient.
- Always prime the auxiliary water channel or biopsy channel prior to inserting the endoscope into the patient.

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 THESE DEVICES, SAVE THEM OR RETURN, AND CONTACT YOUR LOCAL PRODUCT SPECIALIST.**

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.
8. Depress and release the valve to check if the valve moves smoothly and freely returns to its OFF position.

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. Attach the **biopsy valve**.
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. Close the lid when there is not a need to pass a device through the channel.
16. When the device diameter over 3.2mm, please open the lid and pass the device through the hole into the biopsy/suction channel.

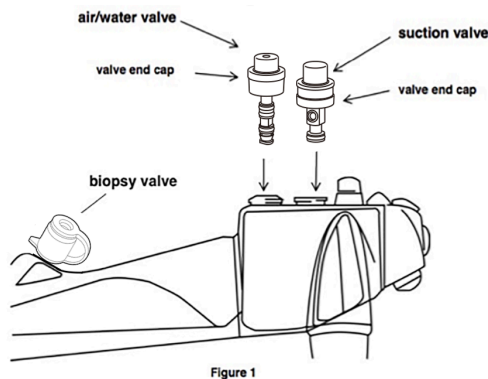


Figure 1

Auxiliary water connector:

17. Attach the auxiliary water connector to the Irrigation Tubing. 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.

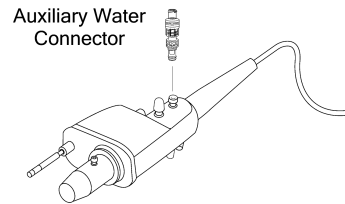


Figure 2


PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of 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 GA Health Company Limited to determine if additional information is available.

Pentax® is a registered trademark of Pentax Corporation.

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EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE

-  Used by date
-  Batch or lot code
-  Manufacturer
-  Sterilized by Ethylene Oxide
-  Notified body TÜV SÜD
-  Do not re-use
Single use
-  Do not re-sterilize
-  Consult Instructions for Use
-  Authorized Representative in the European Community
-  Do not use if package is damaged
-  Keep dry
-  Keep away from sunlight
-  Rx Only (U.S.A.)
Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.