



# AIR/WATER, SUCTION & BIOPSY VALVES

*Instructions for Use.*

*Read carefully prior to use.*



Manufactured for  
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<u>Part Number</u>	<u>Description</u>
EN10229PB	Single Use - Valves (Suction-/ Air-Water-/ Biopsy-Valve) Einmal-Ventile (Absaug-/ Luft-Wasser-/ Biopsie-Ventil)
EN10229P.2B	Single Use - Valves (Suction-/ Air-Water- Valve) Einmal-Ventile (Absaug-/ Luft-Wasser- Ventil)

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 thought the endoscopic procedure and provides access for irrigation.

## 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/CO<sub>2</sub> 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.

## 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 below).
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 below).
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. Please 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.

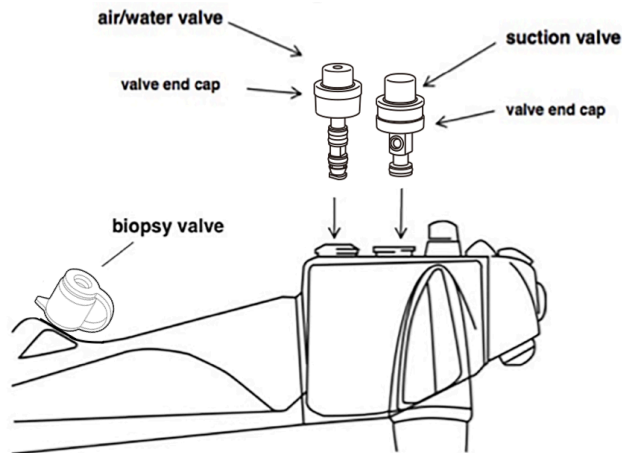


Figure 1

**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 the manufacturer to determine if additional information is available.

Pentax® is a registered trademark of Pentax Corporation.

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



Used by date



Batch or lot code



Manufacturer



Sterilized by Ethylene Oxide



Do not re-use  
Single use



Do not re-sterilize



Consult Instructions for Use



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.