

BullDog®

Disposable Endoscope Valves Set

Instructions for Use.

Read carefully prior to use.

For Pentax® 90 / i10 / i10c Series Endoscopes

Diversatek™ Healthcare

102 E. Keefe Ave.

Milwaukee, WI 53212 USA

800.558.6408 | 414.265.7620

sales@diversatekhc.com

DiversatekHealthcare.com

| REF | Part Number | Description |
|-----|-------------|-------------|
|-----|-------------|-------------|

| | |
|---------|---|
| 1203-81 | Set of Air/Water, Suction & Biopsy Valve, Sterile (3-piece kit) |
| 1203-82 | Set of Air/Water, Suction, Biopsy Valve, & Auxiliary Water Jet Connector, Sterile (4-piece kit) |

INTENDED USE

The single use **BullDog® 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 channel may cause contamination to the air/water system.

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

The single use **BullDog® Biopsy Valve** is used to cover the opening to the biopsy/suction channel of Pentax® gastrointestinal endoscopes. The **BullDog® Biopsy Valve**

provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure and provides access for irrigation.

The single use **BullDog® Auxiliary Water Jet 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 **BullDog® Auxiliary Water Jet Connector** is manufactured with a one-way valve to minimize the risk of cross-contamination of the irrigation system.

WARNINGS AND PRECAUTIONS

These devices are intended to be used with Pentax® GI Endoscopes

(Follow the Pentax® guidelines for Air / Water / Suction use in the Pentax® endoscopes)

- This disposable medical device is intended for single patient use only.
- These devices were not designed 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, reesterilizes, 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.

BullDog® 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 and Suction valves are intended for single patient use only. These devices should be discarded after being used on one patient. It should not be used on multiple patients.

BullDog® Biopsy Valve:

- Do not use a sharp or pointed object to prime the Biopsy

Valve prior to use.

- Do not leave a device hanging from the Biopsy Valve. Doing so can cause the creation of a larger valve slit/hole that may cause leakage.
- If the lid of the Biopsy 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 Biopsy Valve.
- The device should be discarded after being used on one patient. It should not be used on multiple patients.

BullDog® Auxiliary Water Jet Connector:

- Never attach or reattach the Auxiliary Water Jet 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.
- 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.

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 and handling damage. If damage is evident, **DO NOT USE THESE DEVICES, SAVE THEM OR RETURN, AND CONTACT YOUR LOCAL PRODUCT SPECIALIST**

BullDog® 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 Suction Valve slightly to seat in proper orientation within the cylinder.
7. Confirm that the Suction Valve fits securely and that there is no gap between the valve end cap and the endoscope.
Note: The Suction 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.

Note: For optimal performance, please soak the suction

valve in the sterile water for one minute prior to use.

BullDog® 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 Air/Water 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 Air/Water Valve moves smoothly and freely returns to its OFF position.

BullDog® 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 adapter.
15. Close the lid when there is not a need to pass a device through the channel
 16. Upon reattachment of the lid, ensure the lid is tightly fixated into position by slightly compressing the edge of the Biopsy Valve and ensure no distortion is visible.
 17. When the device diameter is over 3.2 mm, open the lid and pass the device through the hole into the biopsy/suction channel.

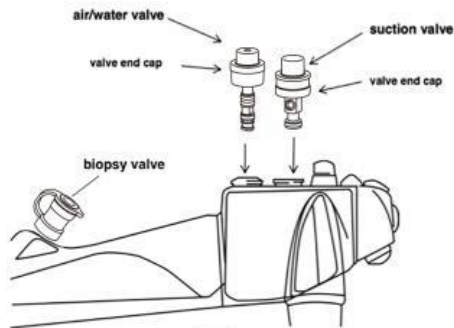


Figure 1

BullDog® Auxiliary Water Jet Connector:

(applicable to 1203-82 only):

18. Attach the **BullDog® Auxiliary Water Jet Connector** to the Irrigation Tubing. For use of the Irrigation Tubing, reference the specified Instructions for Use.
19. Attach the Auxiliary Water Jet Connector to the auxiliary water port by screwing it onto the port (See Figure 2). When attaching the Auxiliary Water Jet Connector to the port, take care to ensure that the Auxiliary Water Jet Connector is aligned to the port and avoid excessive tightening. Misalignment or excessive tightening of the Auxiliary Water Jet Connector could lead to the possibility of leakage. Once

the Auxiliary Water Jet Connector is attached to the auxiliary port of the endoscope, attach the irrigation tubing to the Auxiliary Water Jet Connector.

20. In the case there is any leakage due to misalignment or excessive, replace with a new Auxiliary Water Jet Connector.
21. Discard the Auxiliary Water Jet Connector after each patient use.

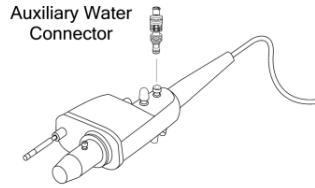


Figure 2

3-piece Valve Kit

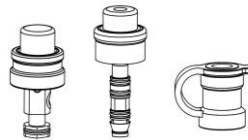


Figure 3

4-piece Valve Kit



Figure 4

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 Diversatek Healthcare to determine if additional information is available.

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

Pentax® is a registered trademark of Pentax Medical. Diversatek™ Healthcare is a trademark of Diversatek Inc.

BullDog® is a registered trademark of Diversatek Healthcare.

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.

EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE

| | |
|--|--------------------------------------|
| | Use-by-date |
| | Manufactured for |
| | Lot number/Batch code |
| | Sterilized Using Ethylene Oxide |
| | Do Not Re-Use |
| | Do Not Re-Sterilize |
| | Not made with natural rubber latex |
| | Part number |
| | Consult Instructions For Use |
| | Do not use if package is damaged |
| | Store at controlled room temperature |
| | Keep dry |
| | Keep away from sunlight |