

BullDog® Disposable Endoscope Valves Set

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

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REF Part Number Description

1203-91	Set of Air/Water, Suction & Biopsy Valve, Sterile (3-piece kit)
1203-92	Set of Air/Water, Suction & Biopsy Valve, & Auxiliary Water Jet Connector, Sterile (4-piece kit)
1203-93	Set of Air/Water, Suction & Biopsy Valve, Auxiliary Water Jet Connector and Air/Water Channel Cleaning Adapter, Sterile (5-piece kit)
1203-61	Air/Water Cleaning Adapter, Non-Sterile

For Fujifilm® 700 Series Endoscopes

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

The single use BullDog® Air/Water Channel Cleaning Adapter is intended as part of the precleaning process, to help clear the air/water channel of Fujifilm® GI endoscopes post procedure.

WARNINGS AND PRECAUTIONS

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

- Follow the Fujifilm® guidelines for air / water / suction use in the Fujifilm® 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.

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.)
- These devices should be discarded after being used on one patient. It should not be used on multiple patients.
- 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.

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.

BullDog® Air/Water Cleaning Adapter:

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

DIRECTIONS FOR USE

- Prior to clinical use, familiarize yourself with the device and read all the Instructions for Use.
- 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.**

BullDog® Suction Valve:

- Remove the suction valve from the tray.
- Insert the suction valve into suction cylinder of a Fujifilm® endoscope (see Figure 1 below).
- Twist valve slightly to seat in proper orientation within the cylinder.

- 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.
- 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 sterile water for one minute prior to use.

BullDog® Air/Water Valve:

- Remove the air/water valve from the tray.
- Insert the air/water valve into the air/water cylinder of a Fujifilm® endoscope (see Figure 1 below).
- Confirm that the air/water valve fits securely and that there is no gap between the air/water valve end cap and the endoscope.
- Depress and release the valve to check if the valve moves smoothly and freely returns to its OFF position.
Note: For optimal performance, please soak the air/water valve in the sterile water for one minute prior to use

BullDog® Biopsy Valve:

- If using the 3-piece, 4-piece or 5-piece valve kit (Figure 3, Figure 4 or Figure 5), attach the biopsy valve.
- Securely place the biopsy valve onto the biopsy/suction channel opening of a Fujifilm® endoscope (See Figure 1).
Note: This biopsy valve does not accommodate a luer-lock syringe without an irrigating adapter.
- Close the lid when there is not a need to pass a device through the channel.
- When the device diameter is over 3.2 mm, open the lid and pass the device through the hole into the biopsy/suction channel.

BullDog® Auxiliary Water Jet Connector (applicable to 1203-92 and 1203-93):

- If using the 4-piece or 5-piece valve kit (Figure 4 or Figure 5), 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.
- If there is any leakage due to misalignment or excessive tightening, replace with a new auxiliary water jet connector.
- Once the auxiliary water jet connector is attached to the auxiliary water port of the endoscope, attach irrigation tubing set to the auxiliary water jet connector. For use of the irrigation tubing, reference Instructions for Use.
- Discard the auxiliary water jet connector after each patient use.

BullDog® Air/Water Cleaning Adapter (applicable to 1203-61 and 1203-93):

- Turn off the airflow regulator on light source after initial rinsing of scope (per facility guidelines)
- Remove the air/water valve from the endoscope.
- Insert the air/water channel cleaning adapter into the air/water cylinder on the control body of the endoscope.
- Place the distal end of the scope into a basin of water.
- On the light source, turn on the airflow regulator and set it to a maximum output of "high".
- Depress the BullDog® Air/Water Channel Cleaning Adapter for 30 seconds.
Note: This flushes the air/water channel with water.
- Release the BullDog® Air/Water Channel Cleaning Adapter.
- Keep the distal end of the scope in the basin of water.
- Flush air for 10 seconds.
Note: Air bubbles will be seen in the basin of water.
- Turn off the airflow regulator on the light source.
- Remove distal end of the endoscope from the basin of water. Remove the BullDog® Air/Water Channel Cleaning Adapter from the endoscope after the precleaning step is completed.

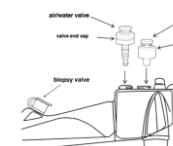


Figure 1
3-piece-valve kit



Figure 2
4-piece valve kit

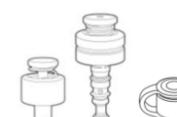


Figure 3



Figure 4



Figure 5

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. If two years have elapsed between this date and product use, the user should contact manufacturer 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.

Fujifilm® is a registered trademark of Fujifilm Corporation.

Diversatek™ Healthcare is a trademark of Diversatek Inc.

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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
	Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.