

BullDog® Disposable Bronchoscope Valves Set

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

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REF	Part Number	Description
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1203-40	Set of Suction & Biopsy Valves (2-piece Kit)
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For Olympus® 160/180/190/260/290 Series Bronchoscopes

INTENDED USE

The single use **BullDog® Biopsy Valve** is used to cover the opening to the biopsy/suction channel of the endoscope. The biopsy valve provides access for endoscopic device passage and exchange and minimizes leakage of biomaterial from the biopsy port during the endoscopic procedure.

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

WARNINGS AND PRECAUTIONS

These devices are intended to be used with Olympus® Bronchoscopes

- Follow the Olympus® guidelines for suction use in the Olympus® 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® 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.

BullDog® Suction Valve:

- Make sure the holes in the suction valve are not clogged or blocked. (this could cause continuous inadequate suction.)
- Storage and transportation temperature limit: ≤ 40°C (104°F)

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 there is evidence of damage,
DO NOT USE THESE DEVICES. SAVE THEM AND RETURN TO MANUFACTURER AND CONTACT YOUR LOCAL PRODUCT SPECIALIST.

BullDog® Biopsy Valve:

- Remove the biopsy valve from the tray.
- Securely place the biopsy valve onto the biopsy / suction channel opening of the endoscope.
- 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® Suction Valve:

- Remove the suction valve from the tray.
- Insert the suction valve into the suction cylinder of an Olympus® endoscope.
- Twist valve slightly to seat in proper orientation within the cylinder.
- Confirm that the valve fits securely and that there is no gap between the valve end cap and the endoscope.
- 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.

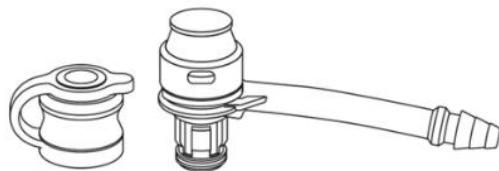


Fig. 1

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 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.

Olympus® is a registered trademark of Olympus Corporation. Diversatek™ Healthcare is a trademark of Diversatek Inc. BullDog® is a registered trademark of Diversatek Healthcare.

EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE

	Use-by-date
	Manufactured for
LOT	Lot number/batch code
STERILE EO	Sterilized using ethylene oxide
	Do not re-use
	Do not re-sterilize
	Not made with natural rubber latex
REF	Part number
	Consult Instructions For Use
	Do not use if package is damaged
	Store at controlled room temperature
	Keep dry
	Keep away from sunlight
Rx Only	Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.