

Diversatek Healthcare BullDog® Biopsy Valves

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

Caution: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.



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DIVERSATEK HEALTHCARE BULLDOG® BIOPSY VALVES

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INTENDED USE

The single use BullDog Biopsy Valve is used to cover the opening to the biopsy/suction channel of Olympus® and Fujinon® or Pentax® gastrointestinal endoscopes. It provides access for endoscopic device passage and exchange, helps maintain sufflation, minimizes leakage of biomaterial from the biopsy port throughout the endoscopic procedure, and provides access for irrigation.

<u>Part Number</u>	<u>Description</u>
1203-00	Biopsy Valve, Olympus®/Fujinon® compatible, non-sterile, 100/cs
1203-05	Biopsy Valve, Olympus®/Fujinon® compatible, bulk non-sterile, 200/cs
1203-10	Biopsy Valve, Olympus®/Fujinon® compatible, sterile, 100/cs
1203-20	Biopsy Valve, Pentax® compatible, non-sterile, 100/cs
1203-50	Irrigating Adaptor, 50/cs

WARNINGS AND PRECAUTIONS

1. The BullDog Biopsy Valve part number selected by the clinician must accommodate the type/manufacturer of gastrointestinal endoscope utilized. Selection is determined in accordance for use with Olympus® and Fujinon® gastrointestinal endoscopes, or for use with Pentax® gastrointestinal endoscopes.
Note: The 1203-00, 1203-05 and the 1203-10 parts are not compatible with Fujinon endoscopes older than the G5 Series.
2. Model/Part Numbers 1203-00, 1203-05 and 1203-20 are sold non-sterile. Model/Part Number 1203-10 is sold sterile. It is the responsibility of the end user to choose the appropriate model/part number for the procedure.
3. When irrigation is used, ensure proper techniques to avoid aspiration in the patient.
4. Do not use a sharp or pointed object to prime the biopsy valve prior to use.

5. Do not leave a device hanging from the valve. Doing so can cause the creation of larger valve slit / hole that can compromise leak management.
6. If the lid of the BullDog Biopsy Valve is opened while attached to the endoscope during a procedure, scope suction will be compromised and chances of leakage increase. Sterile gauze should be used to cover the biopsy valve if the lid must be opened for any reason.
7. Exposure to bodily fluids may occur during connection or disconnection of these devices; adherence to Body Substance Isolation protocols is the responsibility of the user.
8. Products marked “single-use” are for single-use only. Do not reuse, reprocess, or resterilize single-use products. The materials used in the manufacture of the device may not withstand repeated reprocessing. The device may not perform as intended by the manufacturer if it is reused. This may lead to failure of the device to perform as intended and/or material degradation, which may result in patient injury, illness or death. Reuse, reprocessing, or resterilization may also increase the risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

DIRECTIONS FOR USE

1. BullDog Biopsy Valve, Olympus®/Fujinon® compatible, non-sterile - Part# 1203-00
 - a. This model/part number is non-sterile. It is the user's responsibility to choose an appropriate model for the procedure.
 - b. Securely place the Biopsy Valve onto the biopsy/suction channel opening of an Olympus® or Fujinon® gastrointestinal endoscope.
 - c. Make sure the lid of the biopsy valve is closed.
 - d. The biopsy valve does not accommodate a luer-lock syringe without an Irrigating Adaptor (Part# 1203-50; sold separately).
 - e. At the end of the procedure, remove the biopsy valve from the endoscope prior to reprocessing the endoscope and discard the biopsy valve.

2. BullDog Biopsy Valve, Olympus®/Fujinon® compatible, bulk non-sterile - Part# 1203-05
 - a. This model/part number is non-sterile. It is the user's responsibility to choose an appropriate model for the procedure.
 - b. Securely place the Biopsy Valve onto the biopsy/suction channel opening of an Olympus® or Fujinon® gastrointestinal endoscope.
 - c. Make sure the lid of the biopsy valve is closed.
 - d. The biopsy valve does not accommodate a luer-lock syringe without an Irrigating Adaptor (Part# 1203-50; sold separately).
 - e. At the end of the procedure, remove the biopsy valve from the endoscope prior to reprocessing the endoscope and discard the biopsy valve.
3. BullDog Biopsy Valve, Olympus®/Fujinon® compatible, sterile - Part# 1203-10
 - a. Open the sterile peel pack and remove the biopsy valve using aseptic technique.
 - b. Securely place the Biopsy Valve onto the biopsy/suction channel opening of an Olympus® or Fujinon® gastrointestinal endoscope.
 - c. Make sure the lid of the biopsy valve is closed.
 - d. The biopsy valve does not accommodate a luer-lock syringe without an Irrigating Adaptor (Part# 1203-50; sold separately).
 - e. At the end of the procedure, remove the biopsy valve from the endoscope prior to reprocessing the endoscope and discard the biopsy valve.
4. BullDog Biopsy Valve, Pentax® compatible, non-sterile - Part# 1203-20
 - a. This model/part number is non-sterile. It is the user's responsibility to choose an appropriate model for the procedure.
 - b. Securely place the Biopsy Valve onto the biopsy/suction channel opening of a Pentax® gastrointestinal endoscope.
 - c. Make sure the lid of the biopsy valve is closed.
 - d. The biopsy valve does not accommodate a luer-lock syringe without an Irrigating Adaptor (Part# 1203-50; sold separately).
 - e. At the end of the procedure, remove the biopsy valve from the endoscope prior to reprocessing the endoscope and discard the biopsy valve.
5. BullDog Irrigating Adaptor - Part# 1203-50
 - a. Attach the Irrigating Adaptor to a luer-lock or slip tip syringe (syringe not included).
 - b. Fill syringe with institutionally approved irrigation fluid (e.g. sterile water).

- c. Gently place distal tip of Irrigating Adaptor/syringe assembly into the biopsy valve and depress the syringe plunger until the desired irrigation effect is achieved. Repeat as needed.

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.

DESCRIPTION OF SYMBOLS USED ON LABELS



Non-Sterile Device (Part# 1203-00, 1203-05, 1203-20, and 1203-50)



Sterilized Using Ethylene Oxide (Part# 1203-10 only)



Caution, Consult Accompanying Documents



Do Not Re-Use



Do Not Re-Sterilize



Do Not Use if Package is Damaged



Not Made with Natural Rubber Latex



Use By Date

Olympus® is a registered trademark of Olympus Optical Co., Ltd.

Fujinon® is a registered trademark of Fujinon Inc.

Pentax® is a registered trademark of Asahi Kogaku Kogyo Kabushiki Kaisha.

BullDog® is a registered trademark of Diversatek Healthcare.

Diversatek™ is a trademark of Diversatek, Inc.