



Seal™

Single Use Biopsy Valve

**Boston
Scientific**
Advancing science for life™

Refer to the device directions for use for complete instructions on device use.

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

Warning

Contents supplied NON-STERILE. Do not use if damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse or reprocessing may also create a 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Indications For Use

The Seal Single Use 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.

CONTRAINDICATIONS

Contraindications include those specific to any endoscopic procedure.

Adverse Events

None known.

Caution:

The biopsy valve cannot be used with ultrasonic endoscopes with UC in the model number, or with dual channel endoscopes with 2T in the model number.



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Warnings

- When irrigation is used, ensure proper techniques to avoid aspiration in the patient.
- Do not use a sharp or pointed object to prime the biopsy 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 can compromise leak management.
- If the lid of the Seal Single Use Biopsy Valve is opened while attached to the endoscope during a procedure, scope suction will be compromised and chances of leakage increase. Gauze should be used to cover the biopsy valve if the lid must be opened for any reason.
- 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.

All trademarks are the property of their respective owners.

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician.

Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.

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