



Seal™ Single Use Biopsy Valve

Rx ONLY

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.

DEVICE DESCRIPTION

The Seal Single Use Biopsy Valve is an endoscopic biopsy valve that fits on the working channel port of endoscopes to facilitate device passage and maintain insufflation during endoscopic procedures. The attached cap should remain closed during the endoscopic procedure unless larger devices need to be passed. The Seal single use biopsy valve is used to cover the opening to the biopsy/suction channel inlet of Olympus™ and Fujinon™ G5 series gastrointestinal endoscopes.

CONTENTS

Package contents include: (1) Seal Single Use Biopsy Valve

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.

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.

ADVERSE EVENTS

None known.

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OPERATIONAL INSTRUCTIONS

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.

The Seal™ Single Use Biopsy Valve is designed to allow passage of a 3.2 mm device with a closed cap and once the device is removed to seal securely.

1. Remove the Seal Single Use Biopsy Valve from the pouch.
2. Place the Seal Single Use Biopsy Valve on the endoscope channel inlet.
3. Insert devices as needed through the Seal Single Use Biopsy Valve by aligning the device with the endoscope inlet and advancing slowly in a straight manner.

Caution: If the diameter of the accessory is greater than 3.2 mm open the cap for instrumentation.

4. Remove and discard the Seal Single Use Biopsy Valve after each procedure prior to reprocessing the endoscope.
5. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

HOW SUPPLIED

The device is supplied non-sterile and intended for single use only. The packaging and device should be inspected prior to use. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place. See product label for expiration date.


WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument.

This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or sterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Olympus is a trademark of the Olympus Corporation and Fujinon is a trademark of the Fujinon Corporation.

REF Catalog Number

 Consult instructions for use.

 Contents

EC REP EU Authorized Representative

 Legal Manufacturer


LOT Lot


 Recyclable Package

 Use By

AUS Australian Sponsor Address

ARG Argentina Local Contact

 For single use only. Do not reuse.

 Do not use if package is damaged.

 Non-Sterile

 Keep Away from Sunlight

 Date of Manufacture

EC REP **EU Authorized Representative**

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG **Argentina Local Contact**

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

 **Legal Manufacturer**

Manufactured for:
Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

 **Do not use if package is damaged.**

 **Recyclable Package**

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