



Instructions for Use – Biopsy Valve

1. Intended Use

Biopsy Valve are intended to cover the opening of the biopsy/suction channel inlet of Olympus®, Fujinon® or Pentax® endoscopes providing access of endoscopic devices through it and helps maintaining insufflation and minimizing leakage of biomaterial from the biopsy port during a procedure.

2. Product Description

The device is made of a main part that can be attached to the biopsy/suction channel of the endoscope and of a lid to properly close the channel. Select the appropriate model depending on the endoscope brand.

Product code: EN10233 – Biopsy Valve for Olympus® / Fujinon® GI Endoscope (Sterile) /
Biopsie-Ventil für Olympus® / Fujinon® GI Endoskope (Steriler)
EN10234 – Biopsy Valve for Pentax® GI Endoscope (Sterile) /
Biopsie-Ventil für Pentax® GI Endoskope (Steriler)

3. Warnings and Precautions

- Please read carefully and follow all safety operating instructions and warnings before first application of the device.
- A previous knowledge regarding handling and operation is required and essential.
- Unpack the instrument carefully and examine the devices for any possibility of damage. In case of any damage or missing items, please contact your distributor immediately.
- Flexible endoscopy procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, complications and hazards prior to the performance of an endoscopic procedure.
- The Manufacturer did not design this device to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the device to ensure patient and/or user safety.
- The biopsy valve is intended for single patient use only. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, resterilizes, and/or reuses this disposable device must bear full responsibility for its safety and effectiveness.
- The products are supplied in sterile. The sterile product is not designed for re-sterilized.

4. Handling and Operation

- Carefully open the package and refer to the label to check the compatibility with your endoscope brand.
- 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 larger valve slit / hole that can compromise leak management.
- If the lid of the 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.

5. Directions for use

- Prior to clinical use, inspect and familiarize yourself with the device. If there is evidence of damage, do not use this product and contact your local distributor.
- Attach the valve to the biopsy/suction channel of the endoscope.
- Close the lid when there is not a need to pass a device through the channel.
- When the device diameter over 3.2mm, please open the lid and pass the device through the hole into the biopsy/suction channel.

KEY SURGICAL
8101 Wallace Road/ Eden Prairie, MN 55344/ USA
(US) PH: 800.541.7665 KEYSURGICAL.COM
(UK) TEL: +44(0) 1628 810626 KEYSURGICAL.CO.UK
(EU) TEL: +49 4363 905900 KEYSURGICAL.DE

Issued Date: 12-Dec-2019
Current Name: Biopsy Valve

Page: 1 of 2
Doc. No.: D2017040801 Rev 5



Instructions for Use – Biopsy Valve

6. Product Disposal

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.

7. Warning

An issued or revision date for these instructions is included for the user's information. In the event three years has elapsed between this date and product use, the user should contact the manufacturer to determine if additional information is available.

8. Symbols



Batch of lot code



Do not use if package is damaged



Do Not Re-Sterilize



Use-by date



Keep away from sunlight



Sterilized by Ethylene Oxide



Notified body TÜV SÜD



Keep dry



Do not re-use Single use



Consult Instructions for Use



Manufacturer



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



Authorized Representative in the European Community

Olympus® is a registered trademark of Olympus Corporation.

Fujinon® is a registered trademark of Fujinon Corporation.

Pentax® is a registered trademark of Pentax Corporation.



GA Health Company Limited

Unit 18, 21/F, Metropole Square, 2 On Yiu Street, Shatin, N.T., HONG KONG

Tel: +852 2833 9010 Fax: +852 2833 6560

www.andorate.com ken.mccabe@andorate.com

Manufactured for GA Health Company Limited

KEY SURGICAL

8101 Wallace Road/ Eden Prairie, MN 55344/ USA

(US) PH: 800.541.7665 KEYSURGICAL.COM

(UK) TEL: +44(0) 1628 810626 KEYSURGICAL.CO.UK

(EU) TEL: +49 4363 905900 KEYSURGICAL.DE

Issued Date: 12-Dec-2019

Current Name: Biopsy Valve

Page: 2 of 2

Doc. No.: D2017040801 Rev 5

The document is only controlled in electronic format by the QM