

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 : GAR028 – Biopsy Valve for Olympus® / Fujinon® GI Endoscopes (Non-sterile)
GAR028-S – Biopsy Valve for Olympus® / Fujinon® GI Endoscopes (Sterile)
GAR018 / GABV02 – Biopsy Valve for Pentax® GI Endoscopes (Non-sterile)
GAR018-S – Biopsy Valve for Pentax® GI Endoscopes (Sterile)

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.
- Smartdata Suzhou Co., Ltd. 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 are intended for single patient use only. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, reesterilizes, and/or reuses this disposable device must bear full responsibility for its safety and effectiveness.
- The products are supplied sterile and non sterile. The sterile product is not designed for re-sterilized. With regards to the non-sterile biopsy valve, if an end user wishes to sterilize the device, ethylene oxide (EO) gas is compatible with the biopsy valve materials. However, all disinfection solutions and sterilization methods must be validated by the end user for safety and effectiveness.

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.



Smartdata Suzhou Co., Ltd.

F4, Building 7, 198 Jinshan Road, 215011, Suzhou, Jiangsu, PEOPLE'S REPUBLIC OF CHINA

TEL: +86-512-6598 3722 FAX: +86-512-8228 5160 sales@smartdatamedical.com www.smartdatamedical.com

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Instruction For Use – Biopsy Valve

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 Andorate® 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.













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 Smartdata Suzhou Co., Ltd. to determine if additional information is available.

8. Symbols

MFD	Date of manufacture		Do not use if package is damaged		Caution
EXP	Use-by date		Keep away from sunlight		EO Sterile
LOT	Batch or lot code		Keep dry		Non Sterile
	Consult instructions for use		Latex free		Do not re-use Single use
	Notified body TÜV SÜD 0123		EC Conformity Quality Assurance		Do Not Re-Sterilize

 Authorized Representative in the European Community

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.

ANDORATE® is a registered trademark of GA Health Company Limited.

Olympus® is a registered trademark of Olympus Corporation.

Fujinon® is a registered trademark of Fujinon Corporation.

Pentax® is a registered trademark of Pentax Corporation.



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