

andorate®

AIR/WATER, SUCTION & BIOPSY VALVES

Instructions for Use.
Read carefully prior to use.

Manufactured by :

Smartdata Suzhou Co., Ltd.
F4, Building 7, 198 Jinshan Road,
215011, Suzhou, Jiangsu,
PEOPLE'S REPUBLIC OF CHINA
Tel +86-512-6598 3722
e-mail: sales@smartdatamedical.com
www.smartdatamedical.com

Made in China

Not Made with natural rubber latex.

<u>Part Number</u>	<u>Description</u>
GAR004	Set of Air/Water, Suction & Biopsy Valve - Olympus® (3-piece kit)
GAR004C	Set of Air/Water & Suction Valve - Olympus® (2-piece kit)
GAR004A	Suction Valve - Olympus®
GAR004B	Air/Water Valve - Olympus®
GAR065	Set of Air/Water, Suction & Biopsy Valve - Olympus® (3-piece kit, metal shaft)

For Olympus®

EVIS 140/ 160/ 180/ 190/ 240/ 260/ 290

INTENDED USE

The single use **ANDORATE® air/water valve** is used to control the air / water function of an endoscope during GI endoscopic procedures.

The single use **ANDORATE® suction valve** is used to control the suction function of an endoscope during GI endoscopic procedures.

The single use **ANDORATE® biopsy valve** is used to cover the opening to the biopsy/suction channel of Olympus® gastrointestinal endoscopes. The **ANDORATE®** biopsy valve provides access for endoscopic device passage and exchange, helps maintain insufflation, minimizes leakage of biomaterial from the biopsy port thought the endoscopic procedure and provides access for irrigation.

WARNINGS AND PRECAUTIONS

These devices are intended to be used with Olympus® GI Endoscopes **EXCLUDING Olympus® echoendoscopes that utilize a balloon channel**

(Follow the Olympus® guidelines for air/water/suction use in the Olympus® endoscopes)

- Smartdata Medical did not design these devices to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of these devices to ensure patient and/or user safety.
- These disposable medical devices are not intended for reuse. Any institution, practitioner, or third party, who reprocesses, refurbishes, remanufactures, reesterilizes, and or reuses these disposable medical devices must bear full responsibility for their safety and effectiveness.
- Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.
- Consult the medical literature relative to techniques, contraindications, complications and hazards prior to any endoscopic procedure.
- When handling these devices use appropriate aseptic technique.

ANDORATE® air/water & suction valves:

- Make sure the holes in the air/water and suction valves are not clogged or blocked. (This could cause continuous air/CO₂ flow, or inadequate suction.)

ANDORATE® biopsy valve:

- Do not use a sharp or pointed object to prime the 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 may cause leakage.
- If the lid of the valve is opened while attached to the endoscope during a procedure, scope suction will be compromised and leakage may occur.
- If leakage occurs, a sterile gauze should be used to cover the valve.

DIRECTIONS FOR USE

1. Prior to clinical use, familiarize yourself with the device and read all the Instructions for Use.
2. Inspect the package for shipping or handling damage. If damage is evident, **DO NOT USE THESE DEVICES, SAVE THEM OR RETURN, AND CONTACT YOUR LOCAL PRODUCT SPECIALIST.**

ANDORATE® suction valve:

3. Remove the suction valve from the tray.
4. Insert the suction valve into suction cylinder of an Olympus® endoscope (see Figure 1 below).
5. Twist valve slightly to seat in proper orientation within the cylinder.
6. Confirm that the valve fits securely and that there is no gap between the valve end cap and the endoscope.
Note: The valve should not be able to be rotated once it is fully inserted into the cylinder.
7. Actuate the valve by pressing and releasing a few times to confirm smooth function.

Note: For optimal performance, please soak the suction valve in the sterile water for one minute prior to use.

ANDORATE® air/water valve:

8. Remove the air/water valve from the tray.
9. Insert the air/water valve into the air/water cylinder of an Olympus® endoscope (see Figure 1 below).
10. Confirm that the valve fits securely and that there is no gap between the valve end cap and the endoscope.
11. Actuate the valve by pressing and releasing a few times to confirm smooth function.

Note: For optimal performance, please soak the air/water valve in the sterile water for one minute prior to use.

ANDORATE® biopsy valve:

12. If using the 3-piece kit (See Figure 2), attach the **ANDORATE® biopsy valve**.
13. Securely place the biopsy valve onto the biopsy/suction channel opening of an Olympus® endoscope (See Figure 1).
Note: This biopsy valve does not accommodate a luer-lock syringe without an irrigating adaptor.
14. Close the lid when there is not a need to pass a device through the channel.
15. When the device diameter over 3.2mm, please open the lid and pass the device through the hole into the biopsy/suction channel.

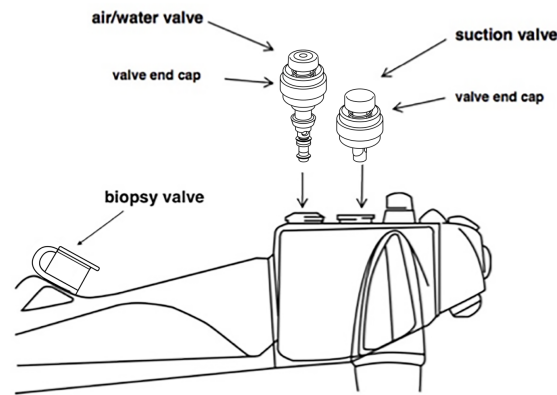


Figure 1

3-Piece Kit

ANDORATE® biopsy valve:

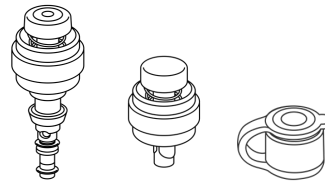


Figure 2

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.

WARNING

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

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

Olympus® is a registered trademark of Olympus corporation.

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.

EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE

EXP	Use-by date
LOT	Batch or lot code
MFD	Date of Manufacture
STERILE EO	Sterilized by Ethylene Oxide
	Notified body TÜV SÜD
	Do not re-use Single use
	Do Not Re-Sterilize
	Latex Free
	Consult Instructions for use
EC REP	Authorized Representative in the European Community
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight