



andorate®

BIOPSY IRRIGATOR

*Instructions for Use.
Read carefully prior to use.*



Manufactured for Ruhof Corporation
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**Not made with natural rubber latex.
Does not contain DEHP**

<u>Part Number</u>	<u>Description</u>
GAR015	Biopsy Irrigator

For Olympus® / Fujifilm® GI Endoscopes

INTENDED USE

The single use **ANDORATE® Biopsy Irrigator** is intended to enable simultaneous irrigation and instrumentation in the endoscope's biopsy channel.

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. It consists of a one-way valve to minimize the risk of cross-contamination of the irrigation system.

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.
- GA Health Company Limited 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 irrigator 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 device is part of distal irrigation system with a backflow prevention feature and is intended for single patient use only. The device should be discarded after being used on one patient. It should not be on multiple patients.

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 irrigator 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 irrigator 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 irrigator if the lid must be opened for any reason

DIRECTION FOR USE

1. 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.

2. Open the sterile peel pack and remove the Biopsy Irrigator. Position the Biopsy Irrigator to the biopsy port of the Olympus® or Fujifilm® Endoscope. (Figure 1)
3. Attach the irrigation tubing to the Biopsy Irrigator via the backflow valve. The Biopsy Irrigator is only to be used in conjunction with irrigation Tubing.
4. **CAUTION: DO NOT REMOVE THE BACKFLOW VALVE.** Backflow valves are permanently attached.
5. Slowly insert the instrument into the Biopsy Irrigator. If the diameter of the accessory is over 3.2mm, open the lid for instrumentation. NOTE: Lid must be closed for irrigation, suction, and insufflation.
6. Reduce irrigation pump setting when irrigating while utilizing biopsy instrumentation. Pump setting can vary depending on the biopsy channel size and the instrument size. The more obstructed the channel is, the lower the pump setting. If suctioning is affected, remove instrument from channel.
7. **WARNING:** Potential Patient Safety Risk: If the Biopsy Irrigator is leaking, the attached irrigation Tubing is potentially contaminated and must be discarded to ensure patient safety.
8. At the end of the procedure, remove and discard the Biopsy Irrigator and the irrigation Tubing.

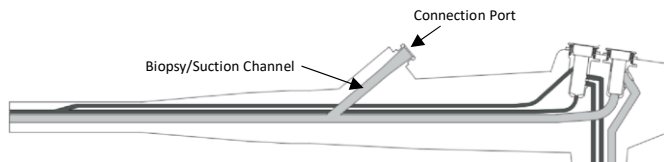


Figure 1

PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of the product 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 three years has elapsed between this date and product use, the user should contact GA Health Company Limited to determine if additional information is available. Report any serious incident that has occurred in relation to the device to the distributor or manufacturer or competent authority of the member state.

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

Olympus® is a registered trademark of Olympus Corporation.

Fujifilm® is a registered trademark of Fujifilm Holdings Corporation.

EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE

	Use-by date
	Batch or lot code
	Manufacturer
	Date of Manufacture
	Medical Device
	Catalogue number Product Code
	Sterilized using Ethylene Oxide
	EC Conformity Quality Assurance
	Do not re-use
	Single use
	Do not re-sterilize
	Product not made with natural rubber latex
	Does not contain DEHP
	Consult Instructions for Use
	Authorized representative in the European Community
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.