# IRRIGATION TUBING

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

Manufactured for Ruhof Corporation
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***Not made with natural rubber latex.***

***Contains or presence of phthalate:***
***bis (2-ethylhexyl) phthalate (DEHP)***

| Part Number | Description |
|---|---|
| GAR083 | Irrigation Tubing |

For Olympus® OFP, Endo Stratus™ EGA-500 and Endogator™ EGP-100 Irrigation Pump

## INTENDED USE

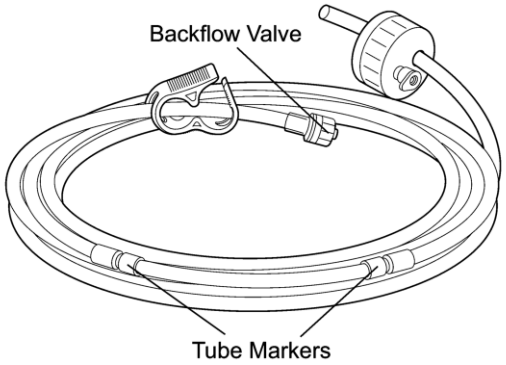
The 24 hour use **AquaPulse® Irrigation Tubing** (tubing and accessories to accommodate various GI endoscopes and irrigation pumps) is intended to provide irrigation via a sterile water bottle during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump.

## WARNINGS AND PRECAUTIONS

- **Guidelines for Preventing Cross Contamination:**
  - ALWAYS prime the auxiliary water channel prior to inserting the GI endoscope into patient.
  - NEVER attach the **AquaPulse® Irrigation Tubing** directly to the biopsy channel without also using a secondary backflow valve.
  - DO NOT REMOVE THE BACKFLOW VALVE. Backflow valves are permanently attached to the irrigation tubing.
  - The backflow valve attached to the irrigation tubing must be in place. If the backflow valve is missing, then discard the entire irrigation tubing, accessories and water bottle.
  - Ensure that tubing and irrigation flow is functioning properly.
- If any of the above prevention guidelines were not followed, or there is any reason to believe that the system was contaminated, immediately discard the entire irrigation tubing, accessories and water bottle. Replace with new irrigation tubing, accessories, and unopened sterile water bottle.
- Sterility is not guaranteed if package has been opened or damaged. Do not use if packaging or product is damaged.
- The irrigation tubing is for 24-hour use (discard daily).
- Never attach or reattach the irrigation tubing to an endoscope that is/was inside the patient and has not been reprocessed.
- 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.
- This medical device is not intended for reuse. Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, resterilizes, and/or reuses this medical device 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.
- Use proper aseptic techniques to avoid contamination during device setup.
- The device is not intended to be used with cautery unit.
- Contraindications include, but are not limited to, those specific to any endoscopic procedure.

## DIRECTIONS FOR USE

1. Prior to clinical use, familiarize yourself with the device and read all the Instructions for Use.
2. Open the sterile peel pack and remove the **AquaPulse® Irrigation Tubing**. Open a bottle of sterile water. Drop the tube into the sterile water bottle and firmly tighten the bottle cap to ensure a secure seal. Remove the label from the pouch and apply it to the tubing. Write the date and time on the label.
3. Open pump head, insert the irrigation tubing and close pump head. (Note: Ensure that tubing is placed in between tube markers.)
4. Connect the backflow valve (distal tip of the tubing) to the intended **AquaPulse® Auxiliary Water Connector** or **AquaPulse® Biopsy Irrigator** accessory.
5. Prime the tubing prior to use by activating the foot pedal; flush water through the entire GI endoscope.
6. **WARNING:** To prevent cross-contamination, always prime the auxiliary water channel prior to inserting the GI endoscope into patient.
7. If the water bottle needs to be replaced, use proper aseptic technique.
8. When the procedure is finished, turn off the pump unit before disconnecting the irrigation tubing.
9. Discard the irrigation tubing daily.




**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 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.

**AQUAPULSE®** is a registered trademark of GA Health Company Limited.

Olympus® is a registered trademark of Olympus Corporation.
Endo Stratus™ is a trademark of Cantel Medical Corporation.
Endogator™ is a trademark of Cantel Medical Corporation.

**EXPLANATION OF SYMBOLS USED ON LABELS AND INSTRUCTIONS FOR USE**

| | |
|---|---|
| | **Use-by date** |
| LOT | **Batch or lot code** |
| | **Manufacturer** |
| | **Date of Manufacture** |
| MD | **Medical Device** |
| REF | **Catalogue number**<br>**Product Code** |
| STERILE EO | **Sterilized using Ethylene Oxide** |
| CE 0123 | **Notified body TÜV SÜD** |
| 2 STERILIZE | **Do not re-sterilize** |
| PHT DEHP | **Contains or presence of phthalate:**<br>**bis (2-ethylhexyl) phthalate (DEHP)** |
| LATEX | **Product not made with natural rubber latex** |
| | **24 Hour Use**<br>**(Discard Daily)** |
| | **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** |
| Rx ONLY | **Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.** |