AIR/WATER BOTTLE TUBING

Instructions for Use.
Read carefully prior to use.

Manufactured for Ruhof Corporation
393 Sagamore Avenue
Mineola, NY 11501
1-800-537-8463
www.ruhof.com

Not Made with natural rubber latex.
Does not contain DEHP

Part Number	Description
GAR025US	Air/Water Bottle Tubing
GAR025CO2EXTUS	Air/Water Bottle Tubing with CO_2 Extend

Contains one cap fits for B. Braun, Fresenius and Baxter bottle.
For Olympus®
140/ 160/ 180/ 190/ 240/ 260/ 290 Series Endoscopes

INTENDED USE

The **VACUTORE® Air/Water Bottle Tubing** is to connect an air/CO_2 source, a sterile water source (water bottle), and an endoscope to supply air/CO_2 and water during gastrointestinal endoscopic procedures. It is a 24-hour multi-patient use device.

WARNINGS AND PRECAUTIONS

- The air/water valve in the endoscopic system provide back-flow prevention function to the air/water channel. The use of air/water bottle tubing without using air/water valve can cause potential contamination to the air/water system.
- Sterility is not guaranteed if package has been opened or damaged. Do not use if packaging or product is damaged.
- This consumable medical device and the sterile water bottle are part of the proximal air/water system, intended to be used for no more than 24 hours after package has been opened. This device should be discarded within this time period regardless of number of uses. The air/water valve is part of the distal irrigation system that should be discarded or reprocessed after each endoscopic procedure.
- Never attach or reattach the air/water bottle tubing or the air/water valve 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 used more than the 24 hours period after the package has been opened, 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.
- Monitor the water level in the water bottle during the procedure. Water feeding will stop once the water level drops below the water bottle tubing.
- Any institution, practitioner, or third party who reprocesses, refurbishes, remanufactures, resterilizes, and/or reuses this consumable 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.
- Consult the medical literature relative to complications, hazards, and techniques prior to the performance of any endoscopic procedure.
- Use proper aseptic techniques to avoid contamination of the air/water bottle tubing during device setup, replacement of water bottles and between patient uses.

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.***
3. Open the sterile peel pack and remove the air/water bottle tubing.
4. **For GAR025US**
   please open a bottle of sterile water. Drop the water bottle tube into the sterile water bottle and firmly tighten the bottle cap to ensure a secure seal. Remove the 24 hours use label from the pouch and apply it to the tubing. Write the date and time on the label. If CO_2 source is used, connect the stopcock of air/water bottle tubing to the CO_2 tubing. Follow instruction from the manufacturer of CO_2 source tubing (see Figure 1).

   For GAR025CO2EXTUS
   Please open a bottle of sterile water. Drop the water bottle tube into the sterile water bottle and firmly tighten the bottle cap to ensure a secure seal. Remove the 24 hours use label from the pouch and apply it to the tubing. Write the date and time on the label. Connect the luer lock in extend tubing to the CO_2 source (see Figure 2).

5. Place air/water bottle tubing, connected to the bottle of sterile water, in the water bottle holder.
6. Connect the distal tip of air/water bottle tubing to the air/water channel of the GI endoscope with a firm pushing motion. The air/water valve should be installed prior connection of the air/water bottle tubing.
7. Turn on the air processor or CO_2.
8. Prime the channel and test for air and water prior to insertion of GI endoscope. If the water pressure is low, ensure that the water bottle is tightly closed.
9. **WARNING:** To prevent cross-contamination, always prime the air / water channel prior to inserting the GI endoscope into the patient.
10. If water bottle needs to be replaced, use proper aseptic technique.
11. When the procedure is finished, close the pinch clip and disconnect the air/water bottle tubing from GI endoscope. Turn off air processor/CO_2 at the conclusion of the procedure.
12. Discard the air/water bottle tubing daily.

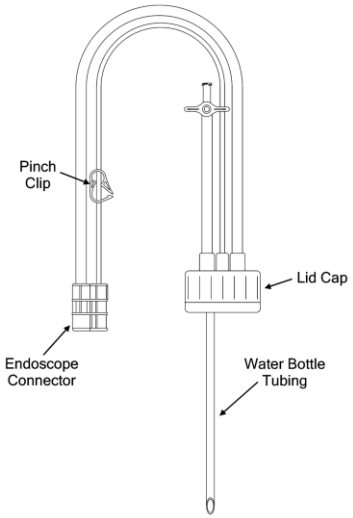

Figure 1
GAR025US

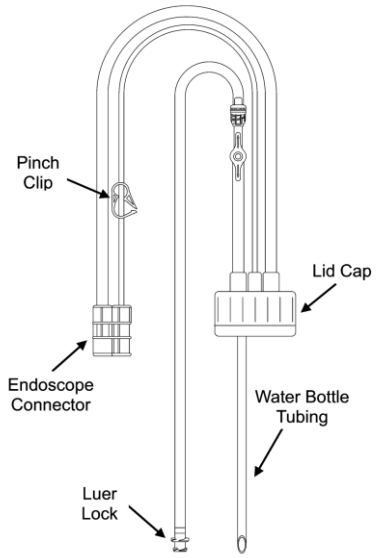

Figure 2
GAR025CO2EXTUS

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 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.

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** **Product Code**
STERILE EO	**Sterilized using Ethylene Oxide**
CE 0123	**EC Conformity Quality Assurance**
2 STERILIZE	**Do not re-sterilize**
LATEX	**Product not made with natural rubber latex**
PHT	**Does not contain DEHP**
	24 Hour Use **(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.**