



AIR/WATER BOTTLE TUBING

Instructions for Use.

Read carefully prior to use.

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Manufactured for **GA Health Company Limited**

Not Made with natural rubber latex.

<u>Part Number</u>	<u>Description</u>
GAR090EC	Air/Water Bottle Tubing (For EU Market)
GAR090US	Air/Water Bottle Tubing (For US Market)
GAR090CO2EXTEC	Air/Water Bottle Tubing with CO ₂ Extend (For EC Market)
GAR090CO2EXTUS	Air/Water Bottle Tubing with CO ₂ Extend (For US Market)

Contains one cap fits for B. Braun, Fresenius and Baxter bottle.

For Fujifilm® 700 Series Endoscopes

INTENDED USE

The **Vacutore® Air/Water Bottle Tubing** is to connect an air/CO₂ source, a sterile water source (water bottle), and an endoscope to supply air/CO₂ 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, reesterilizes, 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.

DIRECTION 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. 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.
5. Connect the tubing with the metal tip of the air/water bottle tubing into the GI endoscope by twisting the tip while pushing firmly. The air/water valve should be installed prior connection of the air/water bottle tubing.

For GAR090EC and GAR090US, connect the stopcock of air/water bottle tubing to the CO₂ tubing. Follow instruction from the manufacturer of CO₂ source tubing (see Figure 1).

For GAR090CO2EXTEC and GAR090CO2EXTUS, connect the luer lock in extend tubing to the CO₂ source (see Figure 2).

6. Place the air/water bottle tubing, connected to the bottle of sterile water, in the water bottle holder.
7. Turn on the air processor or CO₂.
8. Prime the channel and test for air/CO₂ and water prior to insertion of GI endoscope. If the water pressure is low, ensure that the water bottle is tightly closed.
WARNING: To prevent cross-contamination, always prime the air /water channel prior to inserting the GI endoscope into the patient.
9. If water bottle needs to be replaced, use proper aseptic technique.
10. When the procedure is finished, close the pinch clip and disconnect the air/water bottle tubing from GI endoscope. Turn off air processor/CO₂ at the conclusion of the procedure.
11. Discard the air/water bottle tubing daily.

Figure 1
GAR090EC and GAR090US

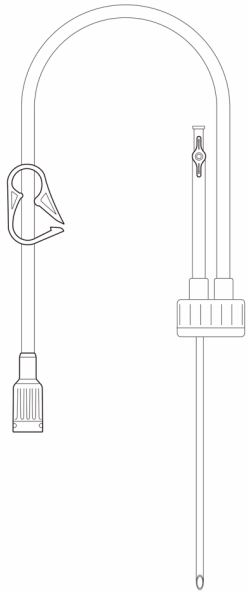
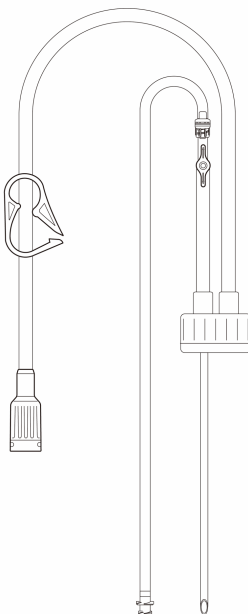


Figure 2
GAR090CO2EXTEC and GAR090CO2EXTUS



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.


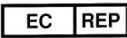

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Vacutore® is a registered trademark of GA Health Company Limited.

Fujifilm® is a registered trademark of Fujifilm 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

	Used by date
	Batch or lot code
	Notified body TÜV SÜD
	Do not re-use Single use
	Latex free
	Do Not Contain DEHP
	24 Hours Use (Discard Daily)
	Consult Instructions for Use
	Authorized Representative in the European Community
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight