



AIR/WATER BOTTLE TUBING

Instructions for Use.

Read carefully prior to use.



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Not Made with natural rubber latex.

Does not contain DEHP

<u>Part Number</u>	<u>Description</u>
GAR088EC	Air/Water Bottle Tubing (For EU Market)
GAR088US	Air/Water Bottle Tubing (For US Market)
GAR088CO2EXTEC	Air/Water Bottle Tubing with CO ₂ Extend (For EC Market)
GAR088CO2EXTUS	Air/Water Bottle Tubing with CO ₂ Extend (For US Market)

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

For Fujifilm® 500/600 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. This device is intended to be used for not more than 24 hours.

WARNINGS AND PRECAUTIONS

- Sterility is not guaranteed if package has been opened or damaged. Do not use if packaging or product is damaged.
- This disposable medical device is 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.
- Never attach or reattach the air/water bottle 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 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 disposable 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.

For GAR088EC and GAR088US, 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 GAR088CO2EXTEC and GAR90CO2EXTUS, 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
GAR088EC and GAR088US

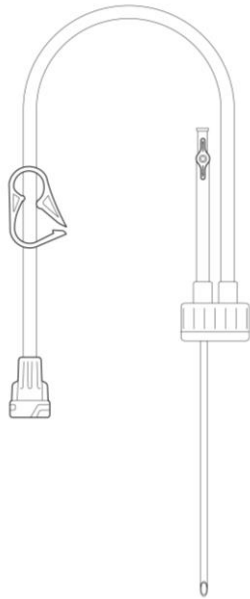
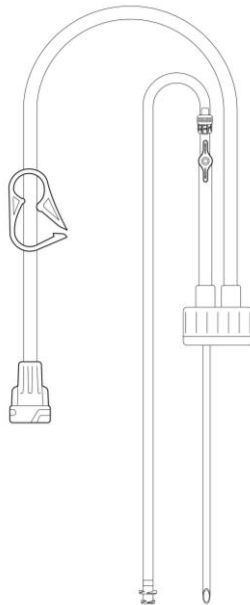


Figure 2
GAR088CO2EXTEC and GAR088CO2EXTUS



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.

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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-sterilize
-  Product not made with natural rubber latex
-  Does not contain DEHP
-  24 Hour 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
-  Federal law (U.S.A.) restricts this device to sale,
distribution and use by or on the order of a
physician.