

## INSTRUCTIONS FOR USE

### Intended Use Air/Water Tubing with CO2 Extension Tubing Fitting for OLYMPUS® G.I. Endoscopes series 140/240, 160/260, 180/280, 190/290

Air/Water tubing with CO<sub>2</sub> input with extension tube is intended to be used with CO<sub>2</sub> source and / or pump along with a sterile water source to supply CO<sub>2</sub> and sterile water to the gastrointestinal endoscope during endoscopic procedures.

#### Warnings and Precautions

##### Guidelines for Preventing Cross Contamination:

- Prior to clinical use, inspect and familiarize yourself with the device. Always prime the air / water channel prior to inserting the G.I. endoscope into the patient.
- 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.
- Do not attach or reattach the tubing to an G.I. endoscope that is / was inside the patient and has not been reprocessed.
- Make sure the flow clamp is closed with two audible clicks before disconnecting tubing from the GI endoscope.
- Do not disconnect the CO<sub>2</sub> source or CO<sub>2</sub> source tubing while tubing is attached to an GI endoscope.
- Make sure the removing the endoscope from the light source before removing the tubing's adaptor from the endoscope adaptor.
- Dispose of the tubing after each procedure.
- Do not remove the one-way connector. One-way connector is permanently attached to the device.
- Do not use a product with back-flow valve missed. If the one-way connector is missing, then discard the entire tubing, adapter, and water bottle.
- Do no attempt to reuse, reprocess, or re-sterilize the product. GZM Medical 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.
- Do not close stopcock to shut off CO<sub>2</sub> flow on regulator or insufflator operating over 16 PSI.
- If any of the above prevention guidelines were not followed, or there is any reason to believe that tubing system was contaminated, immediately discard the entire tubing and water bottle. Replace with a new tubing and an unopened sterile water bottle.
- Do inspect the G.I. endoscopes air water button valve's seals(O-rings) and gaskets at all connection on endoscope for damage. Damaged components can result in less than optimal performance of tubing.
- Sterility is not guaranteed if package has been opened or damaged. Do not use if packaging or product is damaged or open.
- Tubing is for 24-hour use (Discard the tubing daily or within 24 hours after the package has been opened).
- PRECAUTION: If sterile water bottle needs replacing during a procedure, stop depressing the air/water valve. A potential for back flow may occur if the air/water valve is depressed while non sterile water bottle is connected to the tubing. If this occurs, replace the tubing immediately.

























#### Instructions for Use (1 Piece/Pouch; 10Pieces/Inner; 4Inners/Case)

1. Open the sterile pouch and remove tubing. Open a bottle of sterile water (250cc, 500cc, or 1000cc). Drop the end perforated water delivery tube into the sterile water bottle and firmly tighten the threaded bottle cap to ensure a secure seal. Remove the label from the pouch and apply it to the bottle of sterile water. Write the date and time on the label.
2. Attach the CO<sub>2</sub> extension tube end (female connector) to the CO<sub>2</sub> insufflator or CO<sub>2</sub> source tubing. Follow instructions from the CO<sub>2</sub> manufacturer.
3. Leave the flow clamp open.
4. Place tubing, connected to the bottle of sterile water with a firm seal, in the water bottle holder provided.
5. Connect the scope connector of air/water tubing to the adaptor on the G.I. endoscope with a firm pushing motion.
6. Turn the stopcock. Turn on the CO<sub>2</sub> insufflator.
7. Prime the channel and test for air and water prior to insertion of G.I. endoscope. If the water pressure is low, ensure that the water bottle is tightly closed.
8. **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 flow clamp on tube by two audible clicks and disconnect tubing from GI endoscope. Turn off air processor/CO<sub>2</sub> at the completion of the procedure.
11. Discard the tubing daily. (Within 24 hours after the package has been opened)

#### Product Disposal

**After use, these products may be potential bio-hazards. Handle and dispose of in accordance with accepted medical practice and applicable local state. Reuse, re-sterilize and reprocessing of products will cause cross contamination.**

#### Explanation of symbols used on Labels

 Expiry Date (Use By)	 Lot Number	 Reference Number	 Notify Body
 Authorized Representative in the European Community	 Discard within 24 hours after opening package	 Do not use if packaging or product is damaged or open	 Read instructions prior to using this
 Single Sterile Barrier Sterilized By Ethylene Oxide	 Manufacturer	 Do Not Re-sterilize	 Do Not Contain Natural Rubber
 Contains One-way Connector	 Do Not Contain Phthalates	 Quantity Inside	 Keep away from sunlight
 Humidity Limit	 Use with connection to endoscopes	 Prescription Only	 Keep Dry
 Temperature Limit	 Medical Device	 UK Authorized Representative	 Unique Device Identifier

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