CO2 SOURCE / EXTEND TUBING WITH LUER CONNECTOR

Instructions for Use.
Read carefully prior to use.

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

Not Made with natural rubber latex.
Does not contain DEHP

Part Number	Description
GAR047	CO_2 Source Tubing with Luer Connector (Non Sterile)

INTENDED USE

The **VACUTORE® CO_2 Source / Extend Tubing with Luer Connector** is intended to be used with an air or carbon dioxide (CO_2) source with the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is a 24-hour multi-patient use device.

WARNINGS AND PRECAUTIONS

- This consumable medical device is 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.
- Never attach or reattach the CO_2 Source / Extend Tubing to an endoscope that is/was inside the patient and has not been reprocessed. If multiple endoscopes are used during a procedure and possible contamination is expected on the connections, discard the device after the procedure and before the next patient.
- 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.
- When using the CO_2 Source / Extend Tubing, it is recommended that an insufflator or supply tubing with a flow control device be used to prevent over pressurization of the water bottle.
- 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 CO_2 Source / Extend Tubing during device setup, replacement of water bottles and between patient uses.
- Do not attempt to reuse, reprocess, refurbish, remanufacture or resterilize this device. GA Health Company Limited did not design this device nor is it intended to be reused, reprocessed, refurbished, remanufactured, or resterilized. Performing such activities on this disposable medical device presents a safety risk to patients (i.e. compromised device integrity, cross-contamination, infection).

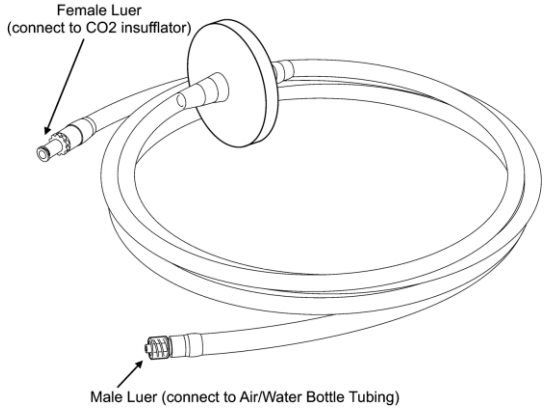
DIRECTIONS FOR USE

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 pouch and remove the CO_2 Source / Extend Tubing.
4. Connect the male luer of CO_2 Source / Extend Tubing (see Figure 1) to the luer connection of Vacutore® Air/Water Bottle Tubing.
5. Connect the female luer of the CO_2 Source / Extend Tubing to the CO_2 insufflator.
6. Turn on the CO_2 insufflator. Verify that the air supply from the GI endoscopic system is turned off.
7. Prime the channel and test for gas and water flow prior to insertion of GI endoscope. If the 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.*

8. When procedure is completed, close the pinch clip on the Vacutore® Air/Water Bottle Tubing and disconnect from the GI endoscope.
9. Turn off CO_2 insufflator.
10. Discard the CO_2 Source / Extend Tubing daily. A label is provided with the device.

GAR047



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

Batch or lot code


Manufacturer


Date of Manufacture

Medical Device

Catalogue number
Product Code

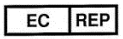

EC Conformity Quality Assurance

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.