

MEDIVATORS™
**ENDO
SMART BOTTLE™**

Rinse and Insufflation System

Reorder No. ESB-145

**ENDO SMART BOTTLE Rinse and Insufflation System for OLYMPUS®140/240, 160/260, 180/280, 190/290
Series GI Endoscopes**

INSTRUCTIONS FOR USE

GEBRAUCHSANWEISUNG

MODE D'EMPLOI

INSTRUCCIONES DE USO

ISTRUZIONI PER L'USO

GEBRUIKSINSTRUCTIES

BRUGSANVISNING

BRUKSANVISNING

INSTRUÇÕES DE UTILIZAÇÃO

BRUKSANVISNING

ИНСТРУКЦИЯ ПО ПРИМЕНЕНИЮ



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Intended Use:

ENDO SMART BOTTLE™ rinse and insufflation system is intended to be used with an air or CO₂ source and / or pump along with a sterile water source to supply air or CO₂ and sterile water to an endoscope during endoscopic procedures.

Warnings and Precautions:

- Guidelines for Preventing Cross Contamination:
 - ALWAYS prime the air / water channel prior to inserting the GI endoscope into the patient.
 - NEVER attach or reattach ENDO SMART BOTTLE system to a GI endoscope that is / was inside the patient and has not been reprocessed.
 - NEVER turn off the air processor / CO₂ while ENDO SMART BOTTLE system is attached to a GI endoscope.
 - ALWAYS remove the colonoscope from the light source before removing the adapter from the colonoscope.
 - DO NOT RE-STERILIZE OR REPROCESS**
- If any of the above prevention guidelines were not followed, or if there is any reason to believe that ENDO SMART BOTTLE system was contaminated, immediately discard the entire ENDO SMART BOTTLE system. Replace with a new ENDO SMART BOTTLE system.
- ALWAYS inspect the GI endoscope's o-rings and gaskets (air / water button, endoscope connection, etc) for damage. Damaged components can result in less than optimal performance of ENDO SMART BOTTLE system.
- Sterility is not guaranteed if package has been opened or damaged. Do not use if packaging or product is damaged.
- ENDO SMART BOTTLE system is for 24 hour use (discard daily).
- This product contains DEHP (Bis(2-ethylhexyl)phthalate) and may be harmful to sensitive populations (children and pregnant/nursing mothers.)
- Due to the short duration of use and the slow migration rate of DEHP from leachable materials into aqueous fluid the residual chemical safety risk is deemed negligible. The risk and benefits of using this device shall be carefully evaluated by a clinician on a case-by-case basis.
- PRECAUTION:** If ENDO SMART BOTTLE system needs replacing during a procedure, refrain from depressing the air/water valve. A potential for backflow may occur if the air/water valve is depressed while no ENDO SMART BOTTLE system is connected to the GI endoscope. If this occurs, replace the ENDO SMART BOTTLE system immediately.
- Contact customer service for assistance.
- Federal (USA) law restricts the sale of this device by or on the order of a physician. **Rx ONLY**

Instructions for Use (by product number):

REF ESB-145





DO NOT RESTERILIZE

STERILE EO STERILIZED USING ETHYLENE OXIDE

24 HOUR USE (DISCARD DAILY)

DEHP CONTAINS DEHP (Bis(2-ethylhexyl)phthalate)

ENDO SMART BOTTLE Rinse and Insufflation System for OLYMPUS® 140/240, 160/260, 180/280, 190/290 Series GI Endoscopes

- Open the sterile peel pack and remove ENDO SMART BOTTLE system. Open a bottle of sterile water. Pour the sterile water into the ENDO SMART BOTTLE system using aseptic techniques and firmly tighten the cap to ensure a secure seal. The volume of sterile water within the ENDO SMART BOTTLE system should not exceed the fill line on the device. Write the date and time on the bottle.
 
- NOTE:** If CO₂ source is used, connect the ENDO SMARTCAP™ CO₂ source tubing (100551) to the ENDO SMART BOTTLE system. Follow instructions for use of the CO₂ insufflator per manufacturer's instruction.
- NOTE:** If air is used in place of CO₂, ensure the cap is on the CO₂ luer connection.
- Connect the ENDO SMART BOTTLE system to the air/water port of the GI endoscope with a firm pushing motion.
- Turn on the air processor or CO₂.
- 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.
- WARNING:** To prevent cross-contamination, always prime the air / water channel prior to inserting the GI endoscope into the patient.
- If water bottle needs to be refilled, use proper aseptic technique.
- When the procedure is finished, disconnect ENDO SMART BOTTLE system from GI endoscope. Turn off air processor/CO₂ at the conclusion of the procedure.
- Discard the ENDO SMART BOTTLE system daily, in accordance with local, state and federal regulations and laws.



WARNING:

After use, these products may be potential biohazards. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.