

Refer to the device directions for use for complete instructions on device use.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Warnings

For single 24 hour use only. Do not reprocess or resterilize. Reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Intended Use/Indications for Use

The Hydra Water Bottle Cap System is intended to be used with an air or CO2 source for the purpose of supplying sterile water to the endoscope during endoscopic procedures. It is compatible with commercially available sterile water bottles.

Contraindications

Contraindications include those specific to any endoscopic procedure.

Warnings

- Never attach or reattach the system to an endoscope that is/ was inside the patient and has not been reprocessed as this may result in patient injury such as infection.
- This medical device is intended to be used for no more than 24 hours after the package has been opened. This device should be discarded within the time period regardless of the number of uses. Failure to do so may result in patient injury such as infection.
- Use proper aseptic techniques to avoid contamination of the system during device setup, replacement of water bottles and between patient uses. Failure to do so may result in patient injury such as infection.

Precautions

- When CO2 is used as the air source, turn off the air flow from the air processor to stop air feeding. If the air feeding is not in the 'off' position, a gas mixture of nonflammable gas will be insufflated into the body cavity of the patient. When CO2 is used as the air source, use only a CO2 insufflator intended for this purpose. Do not attempt to connect the device directly to a CO2 tank.
- Always prime the air/water channel prior to insertion of the endoscope into the patient.

Potential Adverse Events

Potential contamination

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CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device or at www.IFU-BSCI.com 2024 Copyright © Boston Scientific Corporation or its affiliates. All rights reserved.

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