



Hydra™ Irrigation Tubing System

Prescriptive Information

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.

Warning

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

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.

Within 24 hours, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Warnings

- If any contamination is suspected, replace all involved items.
- Do not insert this device into the patient. The device should be attached with an appropriate connector to the auxiliary water port or biopsy channel of a flexible gastrointestinal endoscope and an irrigation source.
- Exposure to bodily fluids may occur during use of this device. The user is responsible for adhering to body substance isolation protocols.
- This medical device is intended to be used for no more than 24 hours after the package has been opened and should be discarded within this time period regardless of the number of, procedures in which it is used.

Intended Use/Indications for Use

The Hydra Irrigation Tubing System (tubing and accessories to accommodate various endoscopes and irrigation pumps) is intended to provide irrigation via sterile water supply during GI endoscopic procedures when used in conjunction with an irrigation pump.

Contraindications

Contraindications include those specific to any endoscopic procedure.

Precautions

- Compatible with specified irrigation pumps.
- Review the endoscope and irrigation pump Directions for Use.
- Use proper aseptic techniques to avoid contamination of the Hydra™ Irrigation Tubing System during device setup, replacement of water bottles and between patient uses.
- Use the appropriate irrigation scope connector when attaching the irrigation tubing to the auxiliary water channel or biopsy channel of the endoscope.

Adverse Events

Potential contamination