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Hydra™

Disposable Auxiliary Water Jet Connector

Rx ONLY

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 use only. Do not reuse, reprocess or resterilize. Reuse, 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. Reuse, 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The Hydra Disposable Auxiliary Water Jet Connector is a disposable auxiliary irrigation port connector for endoscopes which is used in conjunction with Hydra irrigation tubing. The Hydra Disposable Auxiliary Water Jet Connector is comprised of a female luer connection, a backflow prevention check valve, and a threaded endoscope connection.

User Information

Endoscopic procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.

Contents

Package contents include:

- (1) Disposable Auxiliary Water Jet Connector

INDICATIONS FOR USE / INTENDED USE

The Hydra Disposable Auxiliary Water Jet Connector is used in conjunction with Hydra irrigation tubing (tubing and accessories) to accommodate various endoscopes and irrigation pumps) and 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.

WARNING

- This medical device is intended for single patient use only.

WARNINGS

- Never attach or reattach the Hydra Disposable Auxiliary Water Jet Connector to an endoscope that is/was inside the patient and has not been reprocessed.
- Exposure to bodily fluids may occur during the connection or disconnection of this device. The user is responsible for adhering to Body Substance isolation procedures.
- Do not insert this device into the patient. The device should be attached to the auxiliary water port of a flexible gastrointestinal endoscope and to an irrigation source.

PRECAUTIONS

- 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 during device setup.
- Always prime the auxiliary irrigation port prior to inserting the endoscope into the patient.
- The Hydra™ Disposable Auxiliary Water Jet Connector is intended for use with Hydra Irrigation Tubing only. Use of this device with any other irrigation tubing could potentially impact performance.

HOW SUPPLIED

The device is supplied sterile and intended for single use only. The packaging and device should be inspected prior to use. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place. See product label for expiration date.

OPERATIONAL INSTRUCTIONS

- Prior to clinical use, familiarize yourself with the device.
- Open the sterile pouch and attach the Hydra Disposable Auxiliary Water Jet Connector to the endoscope's auxiliary water jet port.
- After the Hydra Disposable Auxiliary Water Jet Connector is connected to the endoscope's auxiliary water jet port, connect the appropriate irrigation tubing set to the Hydra Disposable Auxiliary Water Jet Connector.
- After connecting the system (Hydra Disposable Auxiliary Water Jet Connector and appropriate irrigation tubing) to the endoscope and prior to inserting the endoscope into the patient, ensure that the tubing, water jet connector, and endoscope channel are primed by activating the foot pedal for water flow.
- When the procedure is completed turn off the irrigation pump before disconnecting the Hydra irrigation system from the endoscope.
- Discard the Hydra Disposable Auxiliary Water Jet Connector after each patient use.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

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Catalog Number



Consult instructions for use.



Contents



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For single use only. Do not reuse.



Do Not Resterilize



Do not use if package is damaged.



Sterilized using ethylene oxide.



EU Authorized Representative

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