



PureFlo™ Single-Use Auxiliary Water Jet Connector

Instructions for Use

Read carefully prior to use.

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

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PUREFLO™ AUXILIARY WATER JET CONNECTOR

Instructions for Use

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Part Number	Description	Compatible Endoscopes	Consumable Description	Quantity
1195-21	PureFlo™ Single-Use Auxiliary Water Jet Connector, Sterile	Olympus® 160, 180, 190, 240, 260, 280, 290 Series Endoscopes, specifically those with an auxiliary water port connector.	Single-Use Device	100/CS

INTENDED USE

The Diversatek Healthcare PureFlo™ Auxiliary Water Jet Connector is used in conjunction with the PureFlo™ Irrigation Tubing and is intended to provide irrigation via irrigation fluids such as sterile water supplied during gastrointestinal endoscopic procedures when used in conjunction with an irrigation pump or electrosurgical unit.

INTENDED USER

The PureFlo™ Auxiliary Water Jet Connector should only be used by or under the supervision of physicians thoroughly trained in gastrointestinal endoscopy. Consult medical literature relative to techniques, complications, and hazards prior to the performance of any endoscopic procedure.

CONTRAINdications

Contraindications include those specific to any endoscopic procedure.

WARNINGS AND PRECAUTIONS

- **This disposable medical device is intended for single patient use only.**
- Never attach or reattach the PureFlo™ Auxiliary Water Jet Connector to an endoscope that is/was inside the patient and has not been reprocessed.
- Do not attempt to reuse, reprocess, refurbish, remanufacture or resterilizes this device. Diversatek Healthcare 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 safety risk to patients (i.e., compromised device integrity, cross-contamination, infection).
- Use proper aseptic techniques to avoid contamination during device setup.
- Exposure to bodily fluids may occur during the connection or disconnection of this device. The User is responsible for adhering to Body Substance Isolation protocols.
- Do not insert this device into the patient. The device should be attached to the auxiliary water port of a flexible gastrointestinal endoscope and an irrigation source.
- Use proper techniques to avoid risk of aspiration of a patient.
- Always prime the auxiliary water channel prior to inserting the endoscope into the patient.

INSTRUCTIONS FOR USE:

1. Prior to clinical use familiarize yourself with the device.
2. Open the sterile peel pack, remove the PureFlo™ Auxiliary Water Jet Connector (**Figure 1**) and attach it to the PureFlo™ Irrigation Tubing (Part #1195-01 or 1195-02) via the luer lock connection.
3. Attach the PureFlo™ Auxiliary Water Jet Connector to the GI endoscope's auxiliary water port by engaging the threads and turning slowly until resistance is felt.

NOTE: Ensure that the PureFlo™ Auxiliary Water Jet Connector is aligned to the port and avoid excessive tightening. Misalignment or excessive tightening could lead to the possibility of leakage. The PureFlo™ Auxiliary Water Jet Connector is manufactured with a one-way valve to minimize the risk of cross-contamination of the PureFlo™ Irrigation System.

4. Prior to the procedure, activate the footswitch and prime the PureFlo® Irrigation Tubing System and GI endoscope with sterile water.
5. If PureFlo™ Auxiliary Water Jet Connector is leaking, disconnect and replace with a new PureFlo™ Auxiliary Water Jet Connector.
6. **Discard the PureFlo™ Auxiliary Water Jet Connector after each patient use.**

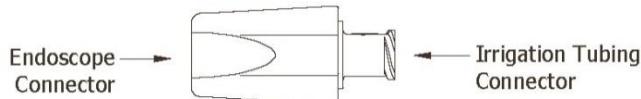


Figure 1
(1195-21)

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.

DESCRIPTION OF SYMBOLS USED ON LABELS

	Manufacturer
	Use-by date (YYYY-MM-DD)
LOT	Lot number
REF	Part number
STERILE EO	Sterilized using ethylene oxide
	Do not re-sterilize
	Consult instructions for use
	Do not use if package is damaged
	Not made with natural rubber latex
	Do not re-use

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