

















INSTRUCTIONS FOR USE

Auxiliary water jet connectors for flexible digestive endoscopes.

The auxiliary water jet connectors are intended for single use only.

A back flow valve is integrated in each auxiliary water jet connector, thus mitigating risks of cross contamination.

SYMBOL LEGEND :

							
Manufacturer	Do not use if pack is opened or damaged	Consult Instructions for Use	Sterilized using Ethylene Oxide	Date of manufacture	Use by date	Product reference number	Lot number
							
Medical device	CE Mark	Do not re-sterilize	Not made with Natural Rubber Latex	Not made with DEHP	Non Sterile	EC Rep	UKCA Logo

REFERENCE AND PRODUCT DESCRIPTION

Product code	Description	Endoscopes compatibility (Gastroscope – Colonoscope)
PFE241	Auxiliary water jet connector with back flow valve	Olympus®
PFE242	Auxiliary water jet connector with back flow valve	Pentax®
PFE126	Back flow valve	Fujinon®

INTENDED USE

The single use auxiliary water jet connectors are designed to be used with the EndoStream water irrigation tubings during digestive endoscopic procedures on a patient who has been indicated for an endoscopic procedure.

The auxiliary water jet connectors are designed to be compatible with Olympus®, Fujinon® and Pentax® flexible digestive endoscopes. These single use medical devices are intended to replace re-usable connectors with a single use patient alternative.

INSTRUCTIONS FOR USE

Read all of the instructions for use for auxiliary water jet connectors carefully before use.

Consult the instructions for use of the endoscope as well as the concerned accessories to be used before using these medical devices.

These medical devices must only be used by trained and qualified medical staff or authorized person familiar with endoscopy techniques and acquainted with the pathologies in question as well as their possible complications.

DIRECTIONS FOR USE

Product code PFE241 : Auxiliary water jet connector for Olympus® digestive endoscopes

- 1) Ensure packaging is not opened or damaged before using.
- 2) Remove the auxiliary water jet connector from its packaging.
- 3) Attach the single use auxiliary water jet connector to the GI endoscope's auxiliary water port by placing the threads and slowly turning the connector until a resistance is felt.
- 4) Firmly attach the auxiliary water jet connector to the backflow valve of the EndoStream water irrigation tubing via the luer lock connection.
- 5) Before the procedure, prime the tubing and GI endoscope with sterile water by activating the irrigation pump's footswitch.
- 6) Discard the single use auxiliary water jet connector after each procedure.

Product code PFE242 : Auxiliary water jet connector for Pentax® digestive endoscopes

- 1) The single use auxiliary water jet connector contains its own backflow valve and it is a disposable replacement for the Pentax® water jet check valve adapter OE-C12 and Pentax® irrigation tube OF-B113.
- 2) If the Pentax® water jet check valve adapter OE-C12 is installed onto the GI endoscope, remove it by unthreading it from the water port. DO NOT discard the OE-C12 as this component must be used during the reprocessing of the GI endoscope.
- 3) Ensure packaging is not opened or damaged before using
- 4) Remove the auxiliary water jet connector from its packaging.
- 5) Attach the single use auxiliary water jet connector to the endoscope's auxiliary water port by inserting the nozzle end into the port and engaging the threads while turning clockwise slowly until a firm resistance is felt.
- 6) Firmly attach the single use auxiliary water jet connector to the back flow valve of the EndoStream water irrigation tubing via the luer lock connection.
- 7) Before the procedure, prime the tubing and GI endoscope with sterile water by activating the irrigation pump's footswitch.

8) Discard the single use auxiliary water jet connector after each procedure.

Product code PFE126 : Backflow valve (compatible with Fujinon® digestive endoscopes)

- 1) Ensure packaging is not opened or damaged before using
- 2) Remove the back flow valve from its packaging
- 3) Attach the single use back flow valve to the GI endoscope's auxiliary water port by placing the threads and slowly turning the connector until a resistance is felt.
- 4) Firmly attach the back flow valve to the backflow valve of the EndoStream water irrigation tubing via the luer lock connection.
- 5) Before the procedure, prime the tubing and GI endoscope with sterile water by activating the irrigation pump's footswitch.
- 6) Discard the single use back flow valve after each procedure.

WARNINGS AND PRECAUTIONS

- The auxiliary water jet connectors must be used with the compatible endoscope according to the endoscope type and manufacturer.
- The manufacturer did not design this device to be reprocessed or used for more than one patient and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the device to ensure patient and/or user safety.
- Traceability stickers are provided.
- The auxiliary water jet connectors are intended for single use and must be disposed of after each procedure.
- The auxiliary water jet connectors must not be reprocessed or resterilized. Their re-use presents a risk of cross contamination of bodily fluids
- Do not attach or reattach an auxiliary water jet connector to an endoscope which has not been reprocessed.
- Do not use the product if packaging is damaged.

Any serious incident that has occurred in relation to this device should be reported to the manufacturer and Competent Authority.

CONTRAINDICATIONS

The contraindications are those which are specific to all endoscopic procedures.

STORAGE / PACKAGING

Storage :

In order to prevent any damage, products should be stored in their original packaging, away from sunlight in a cool dry place.

Packaging :

The auxiliary water jet connectors are supplied in an individual package in a box of 50 units.



PRODUCT DISPOSAL

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice.

Manufacturer:



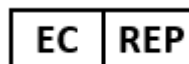
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Instructions for use v10 August 2023

Olympus® is a registered trademark of Olympus Optical Co., Ltd.

Fujinon® is a registered trademark of Fuji Film Co., Ltd.

Pentax® is a registered trademark of Pentax Medical



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