















INSTRUCTIONS FOR USE

ScopeFlow : Disposable water bottle tubing for endoscopes (direct connection between the endoscopes and sterile water bottle)

The ScopeFlow tubing is intended to be used for 24 hours and then disposed of.

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 with notified body identification | Do not re-sterilize | Not made with Natural Rubber Latex | Not made with DEHP | EC Rep | | |

PRODUCT CODES AND DESCRIPTIONS

| Product code | Désignation | Endoscope compatibility (Gastroscope – Coloscope) |
|--------------|---|---|
| PFE165 | Disposable water bottle tubing for endoscopes | Fujinon® (except serie 700) |
| PFE165CO2 | Disposable water bottle tubing for endoscopes | Fujinon® (except serie 700) |

INTENDED USE

The ScopeFlow is designed to be used in conjunction with a flexible endoscope to insufflate air/CO₂ and supply sterile water during endoscopic procedures, on patients indicated for an endoscopic procedure. The ScopeFlow is compatible with Baxter, Versol and Fresenius sterile water bottles. It is intended to be used for 24 hours and then disposed of.

INSTRUCTIONS FOR USE

Read all of the instructions for use for the disposable water bottle tubing carefully before use.

Consult the instructions for use of the endoscope as well as the concerned accessories before using this medical device.

This medical device 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

- 1) Open the sterile water bottle
- 2) Remove ScopeFlow tubing from the sterile pouch and ensure the pinch clamp situated on the tubing is open.
- 3) Insert the tubing into the sterile water bottle and screw the plastic cap of the ScopeFlow to the sterile water bottle.

4) Peel off the 24h00 sticker from the packaging label. Write the date and time on the sticker before attaching it to the tubing.

5) Connect the distal extremity of the tubing ScopeFlow (endoscope adaptor) to the endoscope air/water connector.

6) Turn on the light source of the processor.

7) If using CO₂ insufflation, connect the CO₂ insufflator tubing to the connector of the ScopeFlow tubing.

8) Test prior to endoscopic procedure for flow, if the flow is slow, check the fitting of the screw cap on the sterile water bottle and tighten if necessary.

9) If the sterile water bottle should be changed during the procedure, consult trust guidelines on the correct technique in handling of the ScopeFlow during the replacement of the sterile water bottle, setup of the device and between patients.

10) When the procedure is completed, close the pinch clamp and remove the ScopeFlow from the endoscope. This will prevent water spillage.

11) Turn off the processor

12) Dispose of the ScopeFlow tubing after 24 hours.

WARNINGS AND PRECAUTIONS

- Always prime the air/water channel prior to inserting the digestive endoscope into the patient.
- The manufacturer did not design this device to be reprocessed or used for more than 24 hours once the packaging is opened, 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. A traceability sticker is provided.
- The ScopeFlow tubing is intended to be used for 24 hours after the packaging is opened. The product should be discarded within this time period regardless of numbers of use.
- Do not attach or reattach the ScopeFlow to an endoscope which has not been reprocessed.
- Only to be used with Sterile water bottles.
- Product must be discarded after it has been used in a procedure with vCJD.
- Do not use if product 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. The disposable water bottle tubings should not be re-sterilized.

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 disposable water bottle tubings, ScopeFlow, are supplied in an individual sterile package in a box of 10 units.

PRODUCT DISPOSAL

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



Partners for Endoscopy Ltd, Hartley House, Galveston Grove, Fenton, Stoke on Trent, UK



Advena Limited, Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013, Malta

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