

Instructions for Use: ScopeFlow™ Pure for use with Pentax endoscopes
















INDICATION FOR USE

The ScopeFlow Pure is intended to be used in conjunction with a flexible endoscope to insufflate air/CO₂ and supply sterile water during endoscopic procedures. The ScopeFlow Pure is compatible with the different sterile water bottles available. It is intended to be used for 24 hours and then disposed of.

CAUTION

Federal (United States) law restricts this device to sale by or on the order of a physician.

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
							
Keep away from sunlight	Keep dry	Biohazard	CE Mark with notified body identification	Do not re-sterilize	Not made with Natural rubber latex	Not made with DEHP	

PRODUCT CODES AND DESCRIPTIONS

Product code	Description	Endoscope compatibility (GI Endoscopes)
SFP160	Disposable water bottle tubing for Pentax®endoscopes	Pentax®
SFP160CO2	Disposable water bottle tubing for Pentax®endoscopes with Co2 tubing	Pentax® Olympus 100/130 200/230 series
SFP160CO2S	Disposable water bottle tubing for endoscopes	Pentax® Olympus 100/130 200/230 series with short Co2 tubing
SFP160CO21 HYBRID	Disposable water bottle tubing for Pentax®endoscopes with Co2 tubing and EndoStream™ PFE130	Pentax® Olympus 100/130 200/230 series
SFP160CO2 HYBRID	Disposable water bottle tubing for Pentax®endoscopes with Co2 tubing and EndoStream™ PFE230	Pentax® Olympus 100/130 200/230 series

DESCRIPTION OF USE

The ScopeFlow Pure functions by using a two parallel tubes configuration to supply air to the water bottle and provide water to the flexible endoscope.

The HYBRID configuration consists of the ScopeFlow Pure and the EndoStream units being used together with one single sterile water bottle.

DIRECTIONS FOR USE

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

Manufacturer :

Partnership Medical Ltd
Hartley House, Galveston Grove, Fenton, Stoke on Trent, UK

- 1) Open the sterile water bottle
- 2) Remove ScopeFlow Pure 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 Pure 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 tubing with one black joint directly to the processor
- 6) Connect the other distal extremity of the tubing with 2 black joints to the endoscope air/water connection.
- 7) Turn on the light source of the processor.
- 8) Test prior to endoscopic procedure for water flow, if the flow is slow, check the fitting of the screw cap on the sterile water bottle and tighten if necessary.
- 9) If using CO₂ insufflation, disconnect from the light source. Connect the ScopeFlow Pure to the CO₂ insufflator tubing. If air is required again reconnect the light source extension tubing
- 10) If using the Hybrid product, please refer to EndoStream Instructions for Use for connection of irrigation tubing to the endoscope and pump at point 6 – (enclosed)**
- 11) If the sterile water bottle should be changed during the procedure, consult trust guidelines on the correct technique in handling of the ScopeFlow Pure during the replacement of the sterile water bottle, setup of the device and between patients.
- 12) When the procedure is completed, close the pinch clamp and remove the ScopeFlow Pure from the endoscope. This will prevent water spillage.
- 13) Turn off the processor
- 14) Dispose of the ScopeFlow Pure 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 Pure 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 Pure to an endoscope which has not been reprocessed.

CONTRAINDICATIONS

The contraindications are those which are specific to all endoscopic procedures. The disposable water bottle tubings should not be re-sterilized. Only use with Sterile water bottles.

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 Pure, 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

Instructions for use **USA July V5 2019**

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