







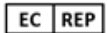






INSTRUCTIONS FOR USE

CO₂ Insufflator tubing set with hydrophobic filter (for connection between the disposable water bottle tubing EndoFlow and a CO₂ endoscopic insufflator)

The CO₂ insufflator tubing set is intended to be used for 24 hours and then disposed of.
The CO₂ insufflator tubing set is supplied non sterile.

SYMBOL LEGEND :

							
Manufacturer	Do not use if pack is opened or damaged	Consult Instructions for Use	Non Stérile	Date of manufacture	Use by date	Product reference number	Lot number
							
EC Rep	Medical device	CE Mark	Not made with Natural rubber latex	Not made with DEHP			

PRODUCT CODES AND DESCRIPTIONS

Product Code	Description
PFE551	CO ₂ insufflator set with hydrophobic filter
PFE552	CO ₂ Insufflator set with hydrophobic filter
PFE555	CO ₂ Insufflator Adapter

INTENDED USE

The CO₂ insufflator set is designed to be used in conjunction with CO₂ endoscopic insufflators. Each CO₂ insufflator tubing set contains 180cm tubing and 0.2 micron hydrophobic filter.

INSTRUCTIONS FOR USE

Read all of the instructions for use for the disposable water bottle tubing as well as the instructions for use for the CO₂ insufflator tubing set with hydrophobic filter carefully before use.

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

Please refer to CO₂ endoscopic insufflator operator's manual for additional instructions for use

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) Remove the CO₂ insufflator tubing set with hydrophobic filter from its packaging.
- 2) Peel off the 24h00 sticker from the packaging label. Write the date and time on the sticker before attaching it to the tubing. .
- 3) Connect the CO₂ insufflator tubing to the ScopeFlow disposable water bottle tubing
- 4) Connect the CO₂ insufflator tubing to the CO₂ endoscopic insufflator.
- 5) Ensure the tubing is not obstructed in any way
- 6) Initiate the endoscopic system by turning on the light source and video processor.

7) Turn on the CO₂ endoscopic insufflator system.

8) If you are insufflating CO₂, ensure that the air supply is turned off from the endoscopic system

9) Before commencing the procedure, and whatever the chosen insufflation, check the correct functioning by activating the air/water channel or CO₂ on the endoscope. In case of malfunction, check the fitting of the screw cap on the sterile water bottle and tighten if necessary as well as the correct connection of the tubings to the different devices/insufflator.

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

11) When the procedure is completed, turn off the CO₂ endoscopic insufflator

12) Dispose of the CO₂ insufflator tubing set with hydrophobic filter after 24 hours

NOTE: If using an Olympus CO₂ Insufflator, then you will need the PFE555 CO₂ Insufflator Adapter which is a reusable product and connects to the Insufflator via a simple screw thread. (Twist the luer locks to connect both ends)

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 CO₂ insufflator tubing with hydrophobic filter 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.

CONTRAINDICATIONS

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

The CO₂ insufflator tubing set with hydrophobic filter should not be re-sterilized for further use.

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.

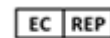
Packaging :

The CO₂ insufflator tubing sets with hydrophobic filter are supplied in an individual non sterile package in a box of 10 units.

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



Partners for Endoscopy Limited, Hartley House, Galveston Grove, Fenton, Stoke on Trent, ST4 3PE, GB



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

Instructions for use v5 July 2024