


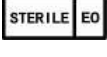













## INSTRUCTIONS FOR USE

**EndoStream : Disposable water irrigation tubing for irrigation pumps (direct connection between the endoscope and sterile water bottle via an irrigation pump).**

**The EndoStream 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	Non Sterile	EC Rep	

### PRODUCT CODES AND DESCRIPTIONS

Product code	Description	Examples of compatible irrigation pumps
PFE230 / SFP230 / PFE230s / SFP230s	Disposable water irrigation tubing for irrigation pumps	EGP-100E®, Olympus OFP-1®, Erbe™
SFP130/SFP130s	Disposable water irrigation tubing for irrigation pumps	Olympus® OFP-2, Pentax®, EndoStratus™, Scope Assist®
PFE330 / SFP330 / PFE330s / SFP330s	Universal Disposable water irrigation tubing	Olympus® OFP-2, Pentax®, EndoStratus™, Scope Assist®, EGP-100E®, Olympus OFP-1®, Erbe™

### INTENDED USE

The EndoStream tubing is designed to be used in conjunction with a peristaltic pump which attaches to a flexible endoscope to supply sterile water for irrigation during endoscopic procedures, on a patient indicated for an endoscopic procedure. The EndoStream tubing is compatible with Baxter, Versol and Fresenius Sterile water bottles.

*EndoStream is a tubing with a cap which directly screws onto a sterile water bottle. The tubing extremity connects to the endoscope via the pump head on a peristaltic irrigation pump.*

A back flow valve is integrated in the extremity of each EndoStream tubing ensuring the unidirectional flow from the sterile water bottle to the endoscope, mitigating the risks of cross contamination.

### INSTRUCTIONS FOR USE

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

Please refer to the peristaltic pump operator's manual for additional instructions for 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 EndoStream tubing from the sterile pouch.

3) Insert the tubing into the sterile water bottle and screw the plastic cap of the EndoStream 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) Open the peristaltic pump head and place the tubing (PFE230/SFP130/SFP230/PFE330/SFP330 ensuring that it is placed between the markers).

6) Close the peristaltic pump head

7) Connect the extremity of the EndoStream tubing to the auxiliary channel connector or to the lateral connexion of a biopsy valve.

8) Prime the tubing before use by operating the peristaltic pump until sterile water flows through the digestive endoscope.

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

10) When the procedure is completed, remove the EndoStream tubing.

11) Dispose of the EndoStream tubing after 24 hours.

### WARNINGS AND PRECAUTIONS

- Always prime the auxiliary 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 Endostream 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 EndoStream 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 this product if the 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 irrigation 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.

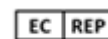
Packaging : The disposable irrigation tubings, EndoStream, are supplied in an individual sterile package in a box of 10 units.

### PRODUCT DISPOSAL

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



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