INSTRUCTIONS FOR USE
ENDOPUMP
TUBING FOR FLUSHING PUMPS COMPATIBLE WITH DIGESTIVE ENDOSCOPY

In accordance with Directive 93/42/ECC
Date of CE marking: 12 May 2021
Notice version 2 dated 24/05/2021

Please read the following information carefully.
Non-observance of the precautions for use could have a detrimental effect on the patient.

Important note:
This document provides assistance when using tubing for flushing pumps for endoscopes. No reference is made to a specific medical technique. The manufacturer accepts no responsibility for any issues resulting from improper use of the device.

Symbols used

Caution		Use-by date		24h	Dispose of after 24 hours of use
Temperature limits		Do not use if the packaging is damaged		NON STERILE	Non-sterile
Store away from sunlight	CE	0459	CE in accordance Directive 93/42/ECC and update 2007/47/EC		Manufacturer
Protect from moisture		Latex-free			Refer to the operating instructions
LOT Batch code		DEHP-free		REF	Catalogue reference
QTY Quantity					

Classification rules vary from country to country. In accordance with European Directive 93/42, tubing for flushing pumps for endoscopes is **class IIa**.

- Refer to the operating instructions for the endoscopy device concerned, as well as to those for its accessories to be used, prior to use of this device.
- Do not use any tubing that presents a risk for the patient.
- **ADVANCE MEDICAL INTEGRATION SYSTEMS SAS** cannot be held liable for any incidents that occur in the event of non-compliance with the rules for installation and use stipulated in these instructions for use.

I – INDICATION/IDENTIFICATION/SCOPE OF APPLICATION

INDICATION
ENDOPUMP is intended for use with irrigation pumps in endoscopy.

IDENTIFICATION:
ENDOPUMP enables irrigation with sterile water towards the main endoscopes present through the irrigation pump during the endoscopy.
ENDOPUMP is compatible with all sterile water bottles available on the market. The device may be used for 24 hours after opening.

SCOPE OF APPLICATION:
ENDOPUMP connects to most sterile water bottles on the market on one side and, on the other side, to a specific port on the endoscope to be used for irrigation through a specific connection.
There are five models to respond to the main stakeholders on the market:

- **50100** is compatible for single use with Olympus® endoscopes from the 140, 160, 180, 190 series and EMED irrigation pumps.
- **50200** is compatible for use with Pentax® and Fujifilm® endoscopes and EMED irrigation pumps.
- **50110** is the device compatible for use with 140, 160, 180, 190 Olympus® endoscopes and Olympus irrigation pumps®.
- **50120** is the device compatible for use with 140, 160, 180, 190 Olympus® endoscopes and ERBE irrigation pumps.
- **50210** is the device compatible for use with Pentax® and Fujifilm® endoscopes and ERBE pumps.

II – STORAGE/PACKAGING

STORAGE:
The storage conditions for **ADVANCE MEDICAL INTEGRATION SYSTEMS SAS** tubing for flushing pumps are the following:

Room temperature: +10 to +50°C

PACKAGING:
The tubing for flushing pumps for endoscopes is packaged individually and then in boxes of 20.
Once removed from its packaging, the tubing must be used within 24 hours.

III – WARNINGS AND PRECAUTIONS

WARNINGS AND PRECAUTIONS:

ENDOPUMP must be used within 24 hours of the packaging being opened. After this time, the device must be disposed of as waste in compliance with the country regulations in force.
ENDOPUMP must never be connected or reconnected to an endoscope that has not been subject to the wash cycle recommended by the manufacturer.
ENDOPUMP may not be re-treated after being used for 24 hours.
ENDOPUMP is only to be used by individuals authorised to work in endoscopic departments.
ENDOPUMP must not be used if, visually, the product is damaged, or if the individual sachet is open. The product must be destroyed.
Any establishment or legal entity that uses this device improperly shall be liable for the effectiveness of this device and for the safety of both users and patients.
When a water bottle is changed, upon disconnection of the system between two patients, or during any other manipulations, authorised personnel must respect the appropriate techniques in order to avoid contamination of the **ENDOPUMP** system.
Ensure that no leaks from the connector are observed in order to avoid flooring from potentially becoming wet and leading to medical staff slipping and falling.

COMPATIBILITY:
ADVANCE MEDICAL INTEGRATION SYSTEMS SAS makes a document that can be downloaded from its website (https://www.advance-medical-integration-systems.com/) available to its clientele; this document includes information on the compatibility of the device, along with any associated technical information.

MECHANICAL INTEGRITY:
In order to ensure the tubing's good mechanical resistance, **ADVANCE MEDICAL INTEGRATION SYSTEMS SAS** has used high-quality, high-reliability materials.

ALLERGENICITY:

The **ENDOPUMP** does not come into direct contact with the patient.

IV – INSTALLATION/USE/ MAINTENANCE/HYGIENE/STERILISATION

INSTALLATION
For optimal installation and use of your **ENDOPUMP**, please follow the instructions below:
(Also refer to the instructions for use for this endoscopy device and any associated accessories)

As a reminder, the tubing for flushing pumps is fitted with a connector which has an anti-return valve so that the tubing can be used several times within a 24-hour period.
If the tubing is used for longer than 24 hours, bacteria may develop due to stagnant water in the tubing.
This product is manufactured such that it does not contain latex.
It is important to become familiar, and carry out a test, with the device prior to any clinical use.

1. Open a bottle of sterile water (25 cl, 50 cl or 100 cl).
2. Open the packaging and remove the product.
3. Insert the tubing into the bottle of sterile water and tighten the cap.
4. Open the pump head of the irrigation pump and insert the tubing, then close the pump head again.
5. Power-up the irrigation pump and prime the system prior to carrying out any procedures.
6. Connect the anti-return valve to the auxiliary channel of the endoscope or to the side connector of the biopsy valve.
7. If the bottle of sterile water needs to be replaced, use the appropriate techniques to change it.
8. Once the procedure is complete, disconnect the system.

Ensure that the device is properly disposed of within 24 hours of the packaging being opened. A traceability label is supplied for this purpose.
Comply with the regulations and techniques in force in the country when disposing of this device.
The device is fitted with a **male Luer** connector. In normal conditions of use, the tubing is intended for use a distance away from the patient, close to the endoscopy column.

However, particular care must be taken in order to ensure that the connector is not inadvertently connected to an approach present on the patient and fitted with a female connector.

CONTRAINDICATIONS:
The contraindications are those specific to any endoscopic intervention.
If the tubing is used for longer than 24 hours, bacteria may develop due to stagnant water in the tubing.

MAINTENANCE:

- There is no maintenance for this product.
- If the packaging is damaged, do not use the tubing.

V – GUARANTEE/RESPONSIBILITY

Any unused tubing, kept in its original packaging, and that has not suffered any apparent damage, is guaranteed against any manufacturing defects for three months by **ADVANCE MEDICAL INTEGRATION SYSTEMS SAS**.
ADVANCE MEDICAL INTEGRATION SYSTEMS SAS guarantees the compliance of the device with the specifications of the safety and performance standards currently in force and applicable to it.

NB:

Refer to the operating instructions for the electro-medical device concerned, as well as to those for its accessories to be used, prior to use of this device.
ADVANCE MEDICAL INTEGRATION SYSTEMS SAS cannot be held liable for any incidents that occur in the event of non-compliance with the rules for installation and use stipulated in these instructions for use.