AMIS
Advance Medical Integration Systems

In accordance with Directive 93/42/ECC
Date of CE marking: 12 May 2021
Notice version 3.1 dated 1/02/2024

INSTRUCTIONS FOR USE
ENDOBOTTLE
WASH BOTTLE FOR FLUSHING PUMPS COMPATIBLE WITH DIGESTIVE ENDOSCOPY

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 wash bottles 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	04 59 CE in accordance Directive 93/42/ECC and update 2007/47/EC		Manufacturer
	Protect from moisture	LATEX	Latex-free		Refer to the operating instructions
LOT	Batch code	DEHP	DEPH-free	REF	Catalogue reference
QTY	Quantity	MD	Medical devices		

In accordance with **European Directive 93/42/ECC** (Appendix IX, rule II, part 1), 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
Irrigation and insufflation tubing for endoscopes is intended to ensure irrigation with sterile water and to provide air (through an air insufflator) or CO_2 (through a CO_2 insufflator) at the same time as sterile water during endoscopy examinations.

IDENTIFICATION:
Certain tubing is intended to be used with an air or CO_2 source or pump, along with a sterile water source in order to supply an endoscope with air or CO_2 and with sterile water during endoscopic interventions.
ENDOBOTTLE is tubing to be used within 24 hours which connects any sterile water bottle on the market to the endoscope with its direct connector.

SCOPE OF APPLICATION:
ENDOBOTTLE is designed to supply the endoscope with air and water during endoscopic interventions. It is compatible with most sterile water bottles on the market. **ENDOBOTTLE** is a device that may be used for 24 hours after opening.
There are four **ENDOBOTTLE** models to respond to the main stakeholders on the market:

- **60100** is the device compatible for use with Olympus endoscopes®.
- **60200** is the device compatible for use with Pentax endoscopes®.
- **60300** is the device compatible for use with Fujifilm 500, 600® and earlier endoscopes.
- **60400** is the device compatible for use with Fujifilm® 700 endoscopes.

ENDOBOTTLE + CO_2 Luer is designed to supply the endoscope with air or carbon dioxide (CO_2) and water during endoscopic interventions. **ENDOBOTTLE + CO_2** is compatible with sterile water bottles on the market. **ENDOBOTTLE + CO_2** is to be used within 24 hours of opening.
There are four models to respond to the main stakeholders on the market:

- **60150** is the device compatible for use with Olympus endoscopes®.
- **60250** is the device compatible for use with Pentax endoscopes®.
- **60350** is the device compatible for use with Fujifilm 600® and earlier endoscopes.
- **60450** is the device compatible for use with Fujifilm® 700 endoscopes.

The **70100** and **70200** models are designed to connect the CO_2 insufflator and **ENDOBOTTLE + CO_2** tubing. This tubing is fitted with a hydrophobic antibacterial filter.

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ENDOBOTTLE Hybrid is designed to supply the endoscope with air or carbon dioxide (CO2) and water during endoscopic procedures and a tubing designed to supply the endoscope with carbon dioxide (CO2) via a CO2 insufflator. This last tubing is connected on one side to the insufflators intended for endoscopy equipped with a "Luer male or Female" connector and on the other side to the 2 or 3 way valve of the ENDOBOTTLE + CO2 range thanks to its "Luer female" connector.
ENDOBOTTLE Hybrid is compatible with commercially available sterile water bottles.
ENDOBOTTLE Hybrid should be used within 24 hours of opening.

ENDOBOTTLE Hybrid has eight references to meet the needs of the main market players:

- 60160 is the compatible device for use with Olympus® endoscopes and insufflators with "luer specific" connector.
- 60260 is the compatible device for use with Pentax® endoscopes and insufflators with "luer specific" connector.
- 60360 is the compatible device for use with Fujifilm® 600 and front endoscopes and insufflator with a "specific luer" connector.
- 60460 is the compatible device for use with Fujifilm® 700 and insufflator endoscopes with "luer specific" connector.
- 60170 is the compatible device for use with Olympus® endoscopes and insufflators with "luer female" connector
- 60270 is the device compatible for use with Pentax® and insufflator endoscopes with "luer female" connector
- 60370 is the device compatible for use with Fujifilm® 600 and earlier endoscopes and insufflator with "female luer" connector
- 60470 is the device compatible for use with Fujifilm® 700 endoscopes and insufflator with "luer female" connector

II – STORAGE/PACKAGING

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

- **Room temperature: +10 to +50°C**

PACKAGING:

The tubing **ENDOBOTTLE et ENDOBOTTLE + CO2** for wash bottles for endoscopes is packaged individually and then in boxes of 20.

The tubing **ENDOBOTTLE Hybrid** for wash bottles for endoscopes is packaged individually and then in boxes of 15.

Once removed from its packaging, the tubing must be used within 24 hours.

III – WARNINGS AND PRECAUTIONS

WARNINGS AND PRECAUTIONS:
ENDOBOTTLE 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.
ENDOBOTTLE must never be connected or reconnected to an endoscope that has not been subject to the wash cycle recommended by the manufacturer.
ENDOBOTTLE is a device that may not be re-treated after being used for 24 hours.
ENDOBOTTLE is only to be used by individuals authorised to work in endoscopic departments.
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.
The water level of the bottle must be monitored during the intervention and the water bottle must be changed when the water level drops below the tubing in the water bottle.
When a water bottle is changed, upon disconnection of the system between two patients, or during any other manipulations, the authorised personnel must respect the appropriate techniques in order to avoid contamination of the **ENDOBOTTLE** 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.
ENDOBOTTLE Hybrid must be used with an insufflator equipped with a filter.

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.

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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:
ENDOBOTTLE does not come into direct contact with the patient.

IV – INSTALLATION/USE/ MAINTENANCE/HYGIENE/STERILISATION

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

USE:
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 tubing.
3. Insert the tubing into the bottle of sterile water and tighten the cap to ensure watertightness.
4. Check that the clamp is in the open position.
5. Connect the air/water connector to the endoscope.
   Connect the hydrophobic tubing to the CO2 system and then to the insufflator if applicable.
6. Switch on the processor's light source.
7. Before starting the procedure, ensure proper functionality by priming the air/water channel on the endoscope. If there is a malfunction, check that the water bottle is watertight and that the endoscope is properly connected.
8. If the bottle of sterile water needs to be replaced, use the appropriate techniques to change it.
9. Once the procedure is complete, clamp and disconnect the system.
10. You can then switch the processor off once the system has been disconnected.

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.

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

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.
Any tubing that is unused, kept in its original packaging, and that has not suffered any apparent damage is guaranteed up to its expiry date indicated on the label by **ADVANCE MEDICAL INTEGRATION SYSTEMS SAS.**

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.

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