INSTRUCTIONS FOR USE
ENDOKIT
AIR/WATER PISTON AND BIOPSY VALVE KIT FOR 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 the air/water and aspiration piston with biopsy valve kit 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		Do not re-use
	Temperature limits		Do not use if the packaging is damaged		Do not sterilise
	Store away from sunlight		0459 CE in accordance Directive 93/42/ECC and update 2007/47/EC		Manufacturer
	Protect from moisture		Steam sterilisation		Refer to the operating instructions
	Batch code		Quantity		Catalogue reference
	Medical Device				

Classification rules vary from country to country. In accordance with European Directive 93/42, the air/water and aspiration piston with biopsy valve kit 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 a kit 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 – DESCRIPTION/INDICATION/SCOPE OF APPLICATION

DESCRIPTION:
The piston and valve kit for digestive endoscopy is for single sterile use.

INDICATION:

The air/water piston is for single sterile use and used to inject air or CO_2, and to enable the distal lens of the endoscope to be cleaned with water.

The aspiration piston is used for fluid aspiration in digestive endoscopy.

The biopsy valve is single sterile use, and is used to be positioned on the operating channel of the endoscope during a digestive endoscopy intervention. It enables the passage of medical devices, whilst ensuring insufflation and minimising the risk of any organic substance leakage through the operating channel during an endoscopy procedure.

SCOPE OF APPLICATION:

There are ten **ENDOKIT** models to respond to the main stakeholders on the market:

- **80120** Olympus® compatible aspiration and insufflation piston kit for single sterile use
- **80130** Olympus® compatible aspiration, insufflation piston and biopsy valve kit for single sterile use
- **80220** Pentax® compatible aspiration and insufflation piston kit for single sterile use
- **80230** Pentax® compatible aspiration, insufflation piston and biopsy valve kit for single sterile use
- **80320** Fujifilm® series 500/600 compatible aspiration and insufflation piston kit for single sterile use
- **80330** Fujifilm® series 500/600 compatible aspiration, insufflation piston and biopsy valve kit for single sterile use
- **80420** Fujifilm® series 700 aspiration and insufflation piston kit for single sterile use
- **80430** Fujifilm® series 700 aspiration, insufflation piston and biopsy valve kit for single sterile use
- **80600** Olympus®/Fujifilm® compatible biopsy valve for single sterile use
- **80610** Pentax® compatible biopsy valve for single sterile use

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II – STORAGE/PACKAGING

STORAGE:
The storage conditions for **ADVANCE MEDICAL INTEGRATION SYSTEMS SAS** air/water piston and biopsy valve kits are the following:

Valves and pistons must be stored in their original boxes away from light and at a temperature of between 10°C and 50°C. It is recommended that the medical equipment be stored flat, ensuring that it is not placed under a heavy load that may damage it.

Optimal temperature 20°C

PACKAGING:
The **ENDOKIT** is packaged individually and then in boxes of 120.

III – WARNINGS AND PRECAUTIONS

WARNINGS AND PRECAUTIONS:
Read the user manual prior to use.

ENDOKIT

Must be used immediately once the packaging has been opened.

Is a patient device for single sterile use not intended to be re-treated after being used.
Must be disposed of as medical waste in compliance with the country regulations in force.
Must never be connected to an endoscope that has not been subject to the wash cycle recommended by the manufacturer.
Do not reuse this device in order to minimise the risk of cross-infection.
Must only be used by trained medical personnel accustomed to endoscopic techniques who manage the pathological conditions concerned along with any foreseeable complications.

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.

DO NOT USE the equipment if its packaging has been opened or damaged, if it has been stored in poor conditions, if it has not been handled correctly, or for any other reasons that could impair its use.

ENDOKIT is exclusively for single sterile use. Reuse presents a risk of cross-contamination of organic fluids.

Always dispose of the pistons and valve after use.

Always check that the valves correctly adapt to the operating channel of the endoscope.

The pistons and valves may only be used in digestive endoscopy. Moreover, it is essential to check that the pistons and valves are compatible with the endoscope, in accordance with the type/manufacturer.

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 good mechanical resistance of the pistons and valve, **ADVANCE MEDICAL INTEGRATION SYSTEMS SAS** has used high-quality, high-reliability materials.

ALLERGENICITY:
The air/water and aspiration piston with biopsy valve kit for endoscopes does not come into direct contact with the patient.

IV – INSTALLATION/USE/ MAINTENANCE/HYGIENE/STERILISATION

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

USE:

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ENDOKIT is a patient device for single sterile use.
It is important to become familiar, and carry out a test, with the device prior to any clinical use.

Air/water piston

1. Open the packaging and remove the single sterile use air/water piston in compliance with asepsis rules.
2. Position the piston on the air/water port by pressing on it until the piston is held securely in the port.
3. Before starting the procedure, decompress the air/water piston in order to prime the air/water channel.
4. At the end of the examination, remove and dispose of the air/water piston.

2

Aspiration piston

1. Open the packaging and remove the single sterile use aspiration piston in compliance with asepsis rules.
2. Position the piston on the aspiration port by pressing on it until it is correctly inserted in the aspiration port.
3. Before starting the procedure, decompress the aspiration piston.
4. At the end of the examination, remove and dispose of the aspiration piston.

Valve for operating channel

1. Open the packaging and remove the single sterile use biopsy valve in compliance with asepsis rules.
2. Place the valve on the biopsy port of the endoscope.
3. Throughout the examination, check that the valve cap is closed.
4. At the end of the examination, remove and dispose of the biopsy valve.

TREATMENT OF THE PRODUCT AFTER USE:
After use, dispose of the product in its packaging by referring to the procedure in force in your establishment for the treatment of medical waste.

CONTRAINDICATIONS:
The contraindications are those specific to any endoscopic intervention.
Single use. Do not re-use.
Do not re-sterilise.
Reuse with another patient may lead to the risk of cross-contamination.

MAINTENANCE:

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

CLEANING, DISINFECTION, STERILISATION:
This is a single patient device in order to minimise the risk of cross-contamination.

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 air/water and aspiration piston with biopsy valve kits for endoscopes that are unused, kept in their original packaging, and have not suffered any apparent damage are guaranteed up to their 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.
- A patient device for single use not intended to be re-treated after being used.
- **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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