

Reference: 2023-003M

11<sup>th</sup> July 2023

## URGENT - FIELD SAFETY NOTICE

### AIR/WATER VALVE MAJ-1444 (Lot No: All lot numbers)

The Air/Water Valve is provided/used with the following Endoscopes:  
ULTRASONIC GASTROFIBERSCOPE, ULTRASONIC GASTROVIDEOSCOPE,  
GF-UC140P-AL5, GF-UE160-AL5, GF-UE260-AL5, GF-UCT260, GF-UCT180,

Attention: **Endoscopy Department,  
Risk Management Department**

Dear Health Care Provider:

Olympus has become aware of a matter that requires your attention. This Field Corrective Action notice pertains to the AIR/WATER VALVE MAJ-1444 (MAJ-1444). Our records indicate that your facility has purchased one or more of these models, and an Olympus OER automated reprocessing machine OER-AW. The MAJ-1444 enables the feeding of air/water during endoscopy procedures to remove any fluid or debris adhering to the objective lens, and for filling the balloon attached to the distal end of the scope with sterile water.

As a result of testing, Olympus discovered the MAJ-1444 may become damaged and result in loss of the one-way valve functionality by repeated automated endoscope reprocessing in Olympus OER machines. Specifically, when the MAJ-1444 is put into the washing case with other accessories of the ultrasonic endoscope, such as Suction valve MAJ-1443, which may collide against each other causing damage.

#### **Risk to Health**

If the MAJ-1444 loses one-way valve functionality, body fluid could backflow into the air/water channel of the ultrasonic endoscopes during the procedure. There is no check that can be performed by users which evaluates one-way valve functionality.

Therefore, a risk to patient health exists: 1) if the body fluid remains in the channel of the ultrasonic endoscopes following reprocessing, and 2) if the contaminated ultrasonic endoscope is used for the next patient without realizing the body fluid during the inspection, then a contaminated ultrasonic endoscope channel can cause transmission of infection.

#### **Actions to be taken by the end user:**

Our records indicate that your facility has purchased one or more of the MAJ-1444 valves. Olympus **requires you to take the following actions:**

1. Inspect your inventory for the referenced devices and identify any device with the model names specified above. Please check all areas of the hospital and include a copy of this letter and addendum with any of these devices remaining in inventory.

2. Carefully read the content of this Medical Device Field Corrective Action as well as the attached “Addendum” for valve inspection instructions and updated MAJ-1444 reprocessing instructions:  
To avoid the MAJ-1444 damage, available reprocessing method for MAJ-1444 are as follows:
  - Disinfect the MAJ-1444 in the OER by placing the MAJ-1444 individually in the washing case of the endoscope reprocessor, with no other accessories.
  - Steam sterilization (autoclaving)
  - Manual disinfection
3. Ensure all personnel are informed on valve inspection requirements and to **cease use and dispose of any valves suspected of having an abnormality.**
4. Olympus requests that you acknowledge receipt of this letter and return the ‘Response Form’ to us.
5. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

**Actions to be taken by the company:**

Olympus is updating the MAJ-1444 Instructions for Use to reflect the information found in the attached addendum. MAJ-1444 valves will be shipped with the Addendum until the Instructions for Use are updated.

Olympus requests that you report complaints, including any injuries associated with the use of MAJ-1444, and adverse events experienced with the use of this product to Olympus.

Olympus regrets any inconvenience caused and fully appreciates your cooperation in this matter. Please do not hesitate to contact us for any additional information or support concerning this matter.

**Contact for enquiries**

Regulatory Affairs Department

Email : [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)

Tel : (603) 7650 8990

Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

*Hideki Nagai* .....

Hideki Nagai

Managing Director

Olympus (Malaysia) Sdn. Bhd.

## Addendum – Instructions for use

### Affected product: AIR/WATER VALVE MAJ-1444

#### 1 Instructions

The sections below provide sample images of the damaged MAJ-1444 and additional information on the reprocessing procedure.

Changes are summarized below and are denoted by underlined text in the subsequent sections of this Addendum. Other parts of the instruction manual are not changed.

#1 Sample images of the damaged MAJ-1444 are added in Chapter 3, “3.2 Inspection of the valve”.

#2 Information on the reprocessing of MAJ-1444 with an endoscope reprocessor recommended by OLYMPUS is added in Chapter 7 Cleaning and Disinfection Equipment.

#### 2. Instructions in Chapter 3.2 Inspection of the valve

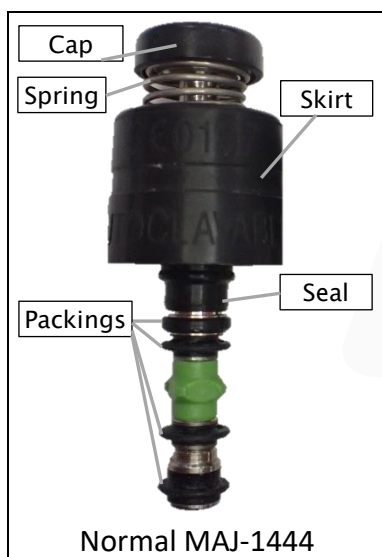
While referring to Chapter 2, “Instrument Nomenclature”, visually inspect the valve and all of its components visually as follows:

- Confirm the hole is not blocked.
- Confirm that the valve is not deformed or cracked.
- Check for excessive scratching or tears in the seal and packings.
- Confirm that the seal or packing is not peeled off.

Sample images as an example of the damaged MAJ-1444 are below.

#### NOTE

The following sample images are only an example and the MAJ-1444 should not be used if any abnormality is suspected, please use new one.



## **WARNING**

- Never use the valve on a patient procedure if an abnormality is suspected.

Damage or irregularity in the instrument may compromise patient or user safety and may result in more severe equipment damage.

## **3. Information on the reprocessing with an endoscope reprocessor in Chapter 7 Cleaning and Disinfection Equipment**

## **WARNING**

- Thoroughly clean the endoscope as described in Chapter 6, “Cleaning, Disinfection and Sterilization Procedures” before cleaning and disinfection of a valve in an endoscope reprocessor. If the endoscope reprocessor is used with an endoscope with a large amount of debris attached to it, cleaning and disinfection may pose an infection-control risk to the patients and/or operators who perform the next procedure with it. Note that cleaning of the valve becomes difficult if debris is allowed to solidify because of a delay before cleaning following the procedure. Refer to the instruction manual of endoscope reprocessor for details

- When the MAJ-1444 is cleaned and high-level disinfected by the endoscope reprocessor, place the MAJ-1444 individually in the washing case of the endoscope reprocessor.

If the MAJ-1444 is put into the washing case with other accessories and reprocessed repeatedly with the endoscope reprocessor, the MAJ-1444 may be damaged and the damage may lead to lost one-way valve function integrity.

- Olympus confirms validation of the endoscope reprocessors recommended by Olympus only. If using endoscope reprocessor that are not recommended by Olympus, the endoscope reprocessor manufacturers are responsible for validation of the endoscope reprocessor with the valve. If using an endoscope reprocessor, confirm that it is capable of reprocessing the valve. If the valve cannot be cleaned and high-level disinfected by the endoscope reprocessor, have to undergo manual cleaning and high-level disinfection or sterilization must be performed as described in Chapter 6, “Cleaning, Disinfection and Sterilization Procedures”. Otherwise, insufficient cleaning and disinfection or sterilization of the valve may pose an infection control risk to the patient and/or operators performing the next procedure with the valve. If you are uncertain as to the ability of your endoscope reprocessor to clean and high-level disinfect the valve, contact the endoscope reprocessor supplier for specific instructions.

## Response Form

Please send the complete and signed Response Form to Regulatory Affairs Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs  
Fax/Email : (603) 7650 8999 / [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)  
From : \_\_\_\_\_ [Facility Name] Contact no.: \_\_\_\_\_  
Date : \_\_\_\_\_  
Ref : 2023-003M

### **URGENT - FIELD SAFETY NOTICE**

**Re: AIR/WATER VALVE MAJ-1444**

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I understand that I need to undertake the action(s) listed in the FSN.

Check the applicable boxes below:

- I DO NOT have affected devices remaining. All have been used or discarded.
- I DO have the affected devices, which I will adhere to the FSN.

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

.....  
Signature & Company Stamp

.....  
Date