Reference: 2023-008M

25 September 2023

URGENT - FIELD SAFETY NOTICE

To all users of Olympus High Flow Insufflation Unit **UHI-4 (All serial numbers)**

Re: Amendment to the Instruction for Use.

Attention: **Endoscopy Department, Surgical, Gynecology and Urology Department; Risk Management Department**

Dear Health Care Practitioner,

This Safety Notice pertains to the Olympus HIGH FLOW INSUFFLATION UNIT **UHI-4** and is to inform you of an amendment to the instructions for use.

The UHI-4 is intended to facilitate laparoscopic and endoscopic observation, diagnosis, and treatment. It is used to insufflate the abdominal cavity and colon and provides automatic suction and smoke evacuation.

HIGH FLOW INSUFFLATION UNIT - UHI-4

Olympus has become aware of patients suffering complications from over insufflation including arrythmias reported as “short cardiac arrests,” gas embolism, and death during surgical procedures where UHI-4s were used.

These events may have been due to an over insufflation of the abdominal cavity resulting from use of the UHI-4 during the procedures. This includes events where the user stated that the device did not alarm or otherwise notify the user and did not relieve the over insufflation to the set pressure. As a result, you should take the following actions:

If you notice the unit is over insufflating the operative field, i.e., the pressure in the cavity exceeds the set pressure without resolution, then discontinue use of that unit, replace the equipment with an alternative, and notify Olympus.

In addition, the instructions for use has been updated with the following Warning:

“It is recommended to use the lowest intraabdominal pressure allowing adequate visualization of the operative field for each procedure to help reduce risk of complications related to over insufflation. Complications related to over insufflation include: air embolism, arrhythmias (bradycardia, asystole, or cardiac arrest), prolonged or more complex procedures, delay to treatment, pneumothorax, hypoxia, subcutaneous emphysema, kidney or urinary problems, and potentially death. “

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
Unit T2-L05-1, PJ33, No. 3, Jalan Professor Khoo Kay Kim, Section 13, 46200 Petaling Jaya, Selangor, Malaysia
Tel: (603) 7650 8990 Fax: (603) 7650 8999

Risk to Patient Health:

Olympus conducted a health hazard assessment, including an examination of adverse events and complaints. The assessment indicates that over insufflation may lead to various patient harms during a procedure, which may include air embolism, arrythmias (bradycardia, asystole, or cardiac arrest), pneumothorax, kidney or urinary problems, hypoxia, subcutaneous emphysema, delay to treatment, more complex procedures, and potentially death.

Actions to be taken by the end user

Our records indicate that your facility has purchased one or more of the Olympus UHI-4.
Olympus **requires you to take the following actions:**

1. Carefully read the content of this Field Safety Notice as well as the attached "Addendum". The Addendum provides information on the updated information on warning of complications related to over insufflation.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this letter.
3. Olympus requests that you acknowledge receipt of this letter return the 'Response Form' to us.
4. If you have further distributed this product, identify your customers, forward them this notification, and appropriately document your notification process.

Olympus requests that you report complaints, including any injuries associated with over insufflation during the procedure with UHI-4, to Olympus. Please report complaints including 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 and Quality Assurance Department
Email : 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
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Hideki Nagai
Managing Director
Olympus (Malaysia) Sdn. Bhd.

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Addendum – Instructions for use

Model; UHI-4

1. Instructions

The sections below provide updated information on warning of complications related to over insufflation. 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.

Warning in "Important Information — Please Read Before Use"

WARNING

Excessive flow rates and/or pressures may result in an excessive absorption of CO2 and/or gas embolism. The cavity can be adequately distended using a maximum pressure of 20 mmHg. It is seldom necessary to use a cavity pressure greater than 20 mmHg. Little intravasation should occur at these levels. Pressures over 20 mmHg are rarely necessary and will increase the amount and the rapidity of intravasation of gas. Adequate respiration helps avoid problems related to CO2.
It is recommended to use the lowest intraabdominal pressure allowing adequate visualization of the operative field for each procedure to help reduce risk of complications related to over insufflation. Complications related to over insufflation include: air embolism, arrhythmias (bradycardia, asystole, or cardiac arrest), prolonged or more complex procedures, delay to treatment, pneumothorax, hypoxia, subcutaneous emphysema, kidney or urinary problems, and potentially death.

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Response Form

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

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs
Fax/Email : (603) 7650 8999 / mes-ra.oml@olympus.com
From : _____ [Facility Name] Contact no.:_____
Date : _____
Ref : 2023-008M

URGENT - FIELD SAFETY NOTICE

Re: Amendment to the Instruction for Use.

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 condemned or discarded.

☐ I DO have the affected devices, which I will adhere to the FSN.

MODEL NO.	SERIAL NUMBERS
HIGH FLOW INSUFFLATION UNIT **UHI-4**	

Name: _____

Designation: _____

....
Signature & Company Stamp Date

OLYMPUS (MALAYSIA) SDN. BHD. (200101010901)
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2023-008M FSN - Customer Letter

Final Audit Report 2023-09-25

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