HSE National Patient Safety Alert (NPSA)
Date of issue 24 November 2023 ***Unique ID*** HSENPSA 004/2023

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Risk of patient harm from medical device: Olympus Insufflation Unit-UHI-4

WHO needs to take action?

Following the publication of an urgent Field Safety Notice (FSN) from Olympus Ireland (Ref: QIL FY24-EMEA-19-FY24-OMSC-19 UHI-4 Overpressure), this is a safety critical HSE National Patient Safety Alert.

This alert is for action by all HSE Services that are using Olympus High Flow Insufflation Unit UHI – 4 (see Appendix A). UHI – 4 is used 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

WHAT is the safety issue?

This alert highlights a FSN that the medical device company Olympus has issued after it became aware of patients experiencing complications from over insufflation where UHI-4s were used, including arrythmias, gas embolism and one death. These complications may have been due to over insufflation of the abdominal cavity resulting from use of the UHI-4 during the procedures. This includes events where the device was reported to 'not alarm' or otherwise notify the user and events where the device did not relieve the over insufflation to the set pressure.

HOW to take action?

1. Circulate this HSE NPSA to relevant staff including but not limited to Clinical Directors, Surgeons, Anaesthetists, operators of the device, staff working in theatres and endoscopy units, managers of those areas and medical device engineers.
2. Alternative devices should be used where available
3. In the absence of an alternative device, the HSE recommends that extreme caution is exercised in the continued use of the Olympus UHI-4 device. Heightened vigilance is required through careful physiological monitoring for signs of complications.
4. If using a UHI-4 device the lead surgeons should conduct a call out – **'insufflation commencing – please be extra vigilant ….'** to the attending anaesthetist during insufflation of the peritoneal cavity to allow hyper-vigilance to observe for bradycardias etc.
5. Please refer to pg.4 of the attached FSN for the action steps to be taken by end user
6. The risks associated with insufflation, with reference to the FSN should be included in the consent process.
7. Report any incident/near miss related to medical devices onto the National Incident Management System (NIMS), to the device manufacturer and the HPRA

WHEN does action need to be completed?

Please circulate this HSE NPSA to relevant staff by latest **27th November 2023.**

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Why is this action required?

The medical device company Olympus became aware of patients experiencing complications from over insufflation during surgical procedures where UHI-4s were used. Olympus conducted a health hazard assessment, including an examination of adverse events and complaints. The assessment indicated that over insufflation may lead to various patient harms during a procedure, which may include gas embolism, arrythmias (bradycardia, asystole, or cardiac arrest), pneumothorax, kidney or urinary problems, hypoxia, subcutaneous emphysema, delay to treatment, more complex procedures. These complications could potentially lead to death.

A HSE Serious Incident Management Team [SIMT] was convened to review the FSN. The SIMT determined mitigating actions to reduce the likelihood of harm occurring based on a risk assessment, albeit, the root cause of the issue has not being determined yet. The decision to continue with the use of the UHI-4 at this time was taken due to absence of alternative devices and the greater risk of cancelling surgeries and procedures that involved use of a UHI-4 device.

References

- Olympus Field Safety Notice (see attached)
- HSE Consent policy

What evidence supports this HSE NPSA?

The Olympus health hazard assessment indicates that over insufflation may lead to various patient harms during a procedure which could potentially lead to death. Olympus is continuing a broader investigation for a root cause of over insufflation of the abdominal cavity in procedures which used the UHI-4. This includes concomitant devices, patient conditions and the specifics of the reported events, including an event 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. Olympus will update the HSE upon the conclusion of these investigations, including any further corrective actions necessary.

What stakeholders were involved in issuing this HSE NPSA?

This alert was developed collaboratively by the following:

- HSE/RCSI Clinical Programme in Surgery
- College of Anaesthesiologists of Ireland
- HSE National Quality and Patient Safety Directorate
- HSE Acute Operations
- HSE Capital and Estates, National Medical Devices Office
- Input from Health Products Regulatory Authority
- HSE National Patient Safety Alerts Committee

Where can I get further information?

For queries on this alert or other HSE National Patient Safety Alerts please visit www.hse.ie/pst or email patientsafetytogether@hse.ie

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Appendix A

According to the inventory list received from Olympus Ireland, the following hospitals are affected:

- Beaumont Hospital
- Cherry Orchard Hospital
- Connolly Memorial Hospital
- Letterkenny University Hospital
- Louth County Hospital
- Mater Misericordiae University Hospital
- Mayo University Hospital
- Mercy University Hospital
- Midland Regional Hospital Mullingar
- Midland Regional Hospital Portlaoise
- Midland Regional Hospital Tullamore
- Naas General Hospital
- Our Lady of Lourdes Hospital Drogheda
- Our Lady's Hospital Navan
- Roscommon University Hospital
- Rotunda Hospital Dublin
- Royal Victoria Eye & Ear Hospital
- Sligo University Hospital
- St Columcilles Hospital
- St James's Hospital
- St Lukes Hospital Clonmel
- St Lukes Hospital Kilkenny
- St Michael's Hospital
- St Vincent's University Hospital
- Tallaght University Hospital
- Tipperary University Hospital
- University Hospital Waterford
- Wexford General Hospital