



# HSE National Patient Safety Alert

## Updated: Risk of patient harm from medical device: Insufflation Unit 001/2024

***What does it mean for me as a patient or service user?***

### About National Patient Safety Alerts

HSE *National Patient Safety Alerts* (NPSA) are high-priority communications about patient safety issues, which require HSE services and HSE funded agencies to take specific action within an identified timeframe. They are developed with relevant people including subject matter experts and patient representatives.

### What is the issue?



In November 2023, the HSE was notified of a concern regarding an Olympus Insufflation Units-UHI-4 medical device. In March 2024 a further issue was reported in relation to this device and the HSE has decided to remove all affected devices from use at the earliest opportunity. The HSE Medical Devices Office has been in direct contact with each hospital individually and provided advice and information on ordering replacement devices.

This medical device is used in surgical procedures, such as endoscopy, (a procedure to look inside your body, e.g. by passing a tube through your mouth) and laparoscopy (a procedure to check the organs in your abdomen). More information about endoscopy is available on the HSE website at <https://www2.hse.ie/conditions/endoscopy/>. The medical device works by insufflating (blowing air or gas) into the abdominal area and colon (lower bowel) so the surgeon can get a clear view of the area.

The manufacturer has informed the HSE about potential patient safety issues when using this device including: increased pressure in the abdomen, gas embolism (a bubble that becomes trapped in a blood vessel and blocks it), and arrhythmia (a problem with the rate or rhythm of your heartbeat).

### How will it affect me?



Some patient groups are at higher risk of over insufflation, including; people with obesity, those who are pregnant and people with cardiac disease. Paediatric (children), and geriatric (older people) patients are also more at risk.

The HSE has decided to remove all affected devices from use. Whilst, there are being replaced, and to prevent a potentially more serious risk to patients through the cancellation of surgeries and procedures, an individual hospital's decision to continue with the use of the device while waiting for a replacement device is supported by the HSE. While using the device staff will use extreme caution and use alternative ways to monitor patients for potential complications.

### What do I have to do?



As a patient you will not need to do anything.

If you require a procedure that uses the affected device, your healthcare team will have been provided with advice on how to proceed and look after you.

If you have any queries or concerns please speak with your doctor or healthcare team.



### Where can I get more Information?



For queries on this or any HSE NPSA visit [www.hse.ie/pst/](http://www.hse.ie/pst/) or email [patientsafetytogether@hse.ie](mailto:patientsafetytogether@hse.ie)

