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HSE National Patient Safety Alert

Risk of patient harm from medical device: Insufflation Unit 004/2023

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?

The HSE was notified of a concern regarding an Insufflation Unit medical device. 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 been informed about patients experiencing complications as a result of possible over insufflation following the use of the device. Over insufflation can cause patient harm such as 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.

To prevent a more significant risk to patients through the cancellation of surgeries and procedures, the HSE is recommending that services continue to use this device if an alternative is not available or indicated based on site risk assessment. While using the device staff will use extreme caution and use alternative ways to monitor patients for potential complications.

The HSE is in continuous contact with the manufacturer and has put in place a number of measures to further reduce the potential risk to patients. Further guidance will be available once the manufacturer has resolved the issue.

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 email patientsafetytogether@hse.ie

HSE NPSA 004/2023/A Date of Issue: 01.12.2023