

Guide for Healthcare Professionals

Reporting of Vaginal Mesh Implant Adverse Incidents

The Health Products Regulatory Authority (HPRA) is the competent authority for medical devices in Ireland and maintains a medical devices vigilance system to protect the health and safety of patients, users and others. This is achieved by the evaluation of vigilance reports received from manufacturers, Healthcare Professionals and members of the public, providing information to users on the safe use of medical devices and where appropriate, evaluating an action for the market place e.g. device recall or device modification.

The following is a guide for Healthcare Professionals including consultants and general practitioners, as well as national mesh administrators to encourage the reporting of adverse incidents associated with vaginal mesh implants (for treatment of stress urinary incontinence and pelvic organ prolapse) to the HPRA.

What to report?

Specifically, in relation to vaginal mesh implants (for treatment of stress urinary incontinence and pelvic organ prolapse) the types of complications that should be reported and have been reported world-wide include (non-exhaustive list);

- Mesh related chronic pain
- Mesh erosion / exposure / extrusion through the vaginal epithelium
- Abscess
- Allergic reaction / 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)
- Abnormal vaginal bleeding / discharge due to mesh, for example due to erosion / extrusion
- De novo voiding or defecation dysfunction post mesh surgery
- Dyspareunia and/or pain to partner during intercourse from exposed mesh
- Mesh related recurrent UTIs / haematuria / infection / sepsis
- Mesh contraction / migration, or excessive contraction of the tissue surrounding the mesh
- Nerve or vascular injury
- Neuro-muscular damage in the pelvic area
- Mesh related abnormal vaginal scarring
- Visceral injury (e.g. bladder, urethra or bowel perforation)

The HPRA acknowledges that certain complications that are included in the above list can also occur in instances where the mesh implant is not considered to have been a contributory cause. In these instances, if a healthcare professional is satisfied that the implant is not a potential contributory cause of the complication(s), it is not necessary to submit an incident report to the HPRA.

When reporting adverse incidents associated with vaginal mesh implants to the HPRA, if possible, please indicate whether the mesh was used to treat stress urinary incontinence or pelvic organ prolapse. Please also include information on the timelines involved between surgery and onset of complications and any other information that you believe would be useful.

This guide is aimed specifically at Healthcare Professionals, however, members of the public are also encouraged to report adverse incidents associated with vaginal mesh implants. Receipt of adverse incident reports from Healthcare Professionals and members of the public assist the HPRA in effectively monitoring potential issues with medical devices.

The attached quick reference guide outlines how you can submit a report to the HPRA.

This guidance has been developed jointly by the National Women and Infants Health Programme and the HPRA.