

Learning Notice: 05/18

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Learning Notice Concerning Mesh Devices in Uro-Gynaecological Procedures

Actions required By Whom: Hospital Group CEOs, Hospital CEOs and Managers, Clinical Directors, Gynaecology Clinicians in all Directorates and Hospitals.

By When: For **IMMEDIATE ACTION** in Maternity Hospitals and Acute Hospitals with Gynaecological Units/Services. Please ensure that this is brought to the attention of all relevant staff.

Learning: Controversy about the use of mesh devices is not unique to Ireland and has occurred in many jurisdictions. This notice is been issued subsequent to a meeting held on the 14th June between the Minister for Health and patients who have suffered from complications of mesh implantation to correct Stress Urinary Incontinence (SUI). The Chief Medical Officer is currently preparing advice for the Minister on this issue. Bearing this mind, and not wishing to anticipate any conclusions, the following should be noted:

1. Patient Selection

Mesh procedures for stress incontinence should be reserved for patients who have been assessed in an appropriate uro-gynaecological / urological setting and in whom conservative measures have failed. Surgeons must ensure they have appropriate facilities and training plus the ability to either treat the patients who develop complications themselves or an approved, appropriate pathway to refer on to another.

2. Consent and Information

Adequate information must be available to patients pre-operatively. The current NHS information leaflet extends to 16 pages. A national consent form is being prepared, however, prior to its introduction patients should be made aware of the following:

- The mesh is a non-absorbable material. Post-operative complications may necessitate full/partial mesh removal which can be extremely difficult.
- In obtaining consent **both** the common complications (mesh erosion, procedure failure, temporary bladder emptying difficulty, etc) and the uncommon complications (erosion into bladder, long term pain, etc) should be stated and explained.

3. Complications

All Surgeons inserting mesh for Urodynamic Stress Incontinence (USI) are capable of treating the minor complications. A significant cause of patient dissatisfaction is the difficulty in accessing services should serious complications develop. Such patients have a firmly held conviction, that their needs are not being addressed to their satisfaction in Ireland. A Response Group has convened to address and propose remedies to these issues. Further information will be circulated in due course.

To facilitate information gathering, complications should be noted to the HPRA.

For more information please contact: Aideen Quigley, Risk & Quality Project Manager, National Women & Infants Health Programme: aideen.quigley@hse.ie.

<https://www.hse.ie/eng/about/who/acute-hospitals-division/woman-infants/>