

22 September 2015

Attention – Chief Executive Officer
District Health Boards and Private Surgical Hospitals

Dear CEO

Surgical Mesh Devices for the treatment of POP and SUI

Medsafe, the New Zealand Medicines and Medical Devices Safety Authority, is writing to advise you of the latest information available about the use of surgical mesh, particularly for urogynaecological applications.

As you may be aware, a petition is currently before the Health Select Committee requesting an enquiry into the use of surgical mesh in New Zealand. This followed concerns expressed by some patients about the use and potential complications of surgical mesh used in the treatment of pelvic organ prolapse (POP) and stress urinary incontinence (SUI).

Since the first review in 2008, Medsafe has continued to monitor the use of surgical mesh by reviewing adverse event reports in New Zealand together with information available from ACC, and by considering recommendations from professional bodies and trusted overseas regulators. Based on this information, regulatory action is not considered appropriate at this time; however, clinicians should consider the information currently available and apply this to their practice.

Key messages for your clinicians and clinical teams involved with surgical mesh.

Clinicians should:

- consider research material and include it into their assessment and decision-making process with respect to examining and determining treatment options for patients under their care;
- communicate the treatment options with patients and discuss with them the evidence supporting the risks and benefits of the treatment option being proposed, in clear and simple terms to allow the patient to make an informed decision on their treatment.

Medsafe's advice is consistent with that of other regulators. In particular Medsafe draws your attention to two documents that have recently been published on this subject.

- A summary of the evidence on the benefits and risks of vaginal mesh implants, published by the MHRA, October 2014.
<http://webarchive.nationalarchives.gov.uk/20141205150130/http://www.mhra.gov.uk/home/groups/comms-ic/documents/news/con472715.pdf>
- Preliminary Opinion on The safety of surgical meshes used in urogynaecological surgery, published by the European Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), July 2015.
http://ec.europa.eu/health/scientific_committees/consultations/public_consultations/s_cenihr_consultation_27_en.htm

Further information about the use of surgical mesh is available from the Medsafe website at the link below:

<http://www.medsafe.govt.nz/hot/alerts/UrogynaecologicaSurgicalMeshImplants.asp>

Medsafe continues to monitor the use of surgical mesh in New Zealand and will consider additional data as it becomes available, such as the PROSPECT study (referred to in the links above).

Adverse events involving surgical mesh should be reported to Medsafe as well as the device supplier. Information on submitting an adverse event report to Medsafe can be found at:

<http://medsafe.govt.nz/regulatory/DevicesNew/safety-monitoring.asp>

Please ensure this information is provided to healthcare professionals who use surgical mesh in their practice or are involved with the care of patients who have had surgical mesh implanted.

Yours sincerely



Chris James
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Medsafe