Information from RACS and RANZCOG:
What you need to know as a clinician

All mesh MUS cases from Wednesday 23 August 2023 should be postponed.
Private surgeons will need to notify their patients.

Purpose of the pause

- To allow space for the implementation of measures to improve patient safety in the use of mesh midurethral sling (MUS) to treat stress urinary incontinence (SUI)

Duration of the pause

- The announcement is of a time-limited pause. We expect it to be between six and 12 months
- The pause will end when these measures are in place:
    - national credentialling of surgeons
    - introduction of a pelvic floor registry (work is underway to implement an Australasian registry)
    - structured informed consent process using a patient decision aid (HQSC are expected to finalise a decision aid in the next few months)
    - establishment of regional multidisciplinary meetings (Te Whatu Ora is working on this)

Implementation

- The pause is effective from 23 August 2023
- Patients booked on the Te Whatu Ora waiting list are being contacted by Te Whatu Ora
- Patients booked privately need to be contacted by their surgeon
    - Two resources have been prepared to support this and are attached:
        - A template letter you can use to contact patients
        - A Manatū Hauora Ministry of Health patient information sheet

With the pause on mesh MUS, use of other non-mesh urinary incontinence procedures are expected to increase so a high vigilance process has been put in place for all SUI procedures.

High vigilance for stress urinary incontinence procedures

- **During the pause a high vigilance process of peer review must be used for all SUI procedures** (outlined below)
- Surgeons are expected to provide patients with a range of nonoperative and operative options. This may require referral to credentialed surgeons for appropriate surgery that isn't offered by that surgeon.
- If you have patients already booked for non-mesh procedures, these can proceed. Any that can be put through the high vigilance process should be.
- Cases being changed from mesh to another procedure must go through the high vigilance process
- All SUI cases not yet booked must go through the high vigilance process
- Procedures that are subject to high vigilance are:
    - Fascial sling
    - Burch colposuspension
    - Periurethral bulking agents
    - Mesh MUS retropubic slings

High vigilance process

- The operating surgeon must be locally credentialed to perform the procedure or be operating with a fully credentialed surgeon
- The patient must have had a trial of pelvic floor muscle exercises
- The patient must have had a full preoperative assessment including urodynamic studies performed and interpreted by an appropriately skilled clinician
- The patient must have been through a shared decision-making and informed consent process consistent with the Code of Rights (right 7) including the use of a patient decision aid (for example, the NHS PDA which can be used until the Aotearoa New Zealand tool is available)
- A decision to proceed to surgery must be supported by a local or regional multidisciplinary meeting (MDM) after discussion and a detailed review
    - MDM participants must consist of at least two surgeons; ideally a urologist and a gynaecologist but may be two from the same speciality. There should also be two continence advisors or pelvic floor physiotherapists.
    - Meetings need to be minuted, with recommendations placed in the patients notes and provided to the patient.
- Patient data must be recorded in an agreed database pending availability of the Australasian Pelvic Floor Registry
- An appropriate follow up plan must be documented

Exceptions process for mesh MUS

- An exceptions pathway will be in place for rare cases where mesh MUS is the only appropriate option. An application to proceed must be submitted and approved before the procedure can proceed.
- **Before application the high vigilance process must be followed**
- Patient selection:
    - An exception may be approved where:
        - a patient-specific review suggests mesh MUS is the most appropriate surgery on the balance of risks versus benefits in a fully informed manner consistent with the high vigilance process
        - there is evidence of patient harm from delaying surgical treatment
        - surgeon or MDM advice is that a non-mesh procedure may carry additional risks (for example, difficulty harvesting fascia, a ‘hostile abdomen’ or overall patient morbidity)
    - The patient must be provided with the Manatū Hauora document *Considering surgical mesh to treat SUI (2019)*
- Application:
    - An application for formal approval for surgery must be made to a Mesh Exceptions Group chaired by Manatū Hauora
    - The Mesh Exceptions Group will have appropriate representation from the Royal Australasian College of Surgeons (RACS), the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), a non-surgical pelvic floor professional and a lay person
    - Details of how to apply for approval will be provided soon

Still have questions? Contact us College.NZ@surgeons.org.nz or ranzcog@ranzcog.org.nz and we will add your question and the answer to our FAQs.