

SESLHD PROCEDURE COVER SHEET



Health
South Eastern Sydney
Local Health District

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FUNCTIONAL GROUP(S)	Clinical Governance
KEY TERMS	Mesh, pelvic floor surgery, credentialling of senior medical officers
SUMMARY	Use of mesh in gynaecological procedures is restricted to appropriately trained and credentialled gynaecologists. There are specific requirements to ensure the appropriate clinical governance of these procedures.

COMPLIANCE WITH THIS DOCUMENT IS MANDATORY

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Use of mesh in sacrocolpopexy and related procedures**SESLHDPR/747****1. POLICY STATEMENT**

The use of mesh in pelvic floor surgery is restricted to appropriately credentialled gynaecologists who act in accordance with appropriate governance standards based on TGA guidelines and the RANZCOG position paper on sacrocolpopexy. The use of mesh for vaginal prolapse via transvaginal approach is not permitted in SESLHD.

2. BACKGROUND

The use of mesh in pelvic floor surgery is an established standard of care. Following a series of class actions in Australia the use of mesh in pelvic floor surgery is restricted to appropriately credentialled gynaecologists in SESLHD who have appropriate Therapeutic Goods Administration Special Access Scheme (SAS) approval. Mesh is used in pelvic floor surgery throughout the world. Other surgical options for the management apical vaginal prolapse are less effective.

3. RESPONSIBILITIES

- 3.1 Gynaecologists will:** operate in accordance with their approved scope of practice. Ensure all patients have received appropriate clinical information regarding the risks and benefits of the procedure in advance of obtaining consent for a gynaecological procedure utilizing a mesh product. Only use mesh products in gynaecological procedures in accordance with TGA requirements, noting that this may include via application to the Special Access Scheme.
- 3.2 Admission Office & Operating Theatre List Managers will:** ensure that only appropriately credentialled gynaecologists book cases for sacrocolpopexy and related procedures. Advise the Director of Medical Services (DMS) immediately should any uncredentialled gynaecologists seek to book sacrocolpopexy or other mesh requiring procedures.
- 3.3 Operating Theatre staff will:** ensure mesh is only provided to appropriately credentialled gynaecologists who have Special Access Scheme (SAS) approval to utilise mesh for gynaecological procedures.
- 3.4 Directors Medical Services will:** ensure the use of mesh in gynaecological procedures is consistent with this procedure via an audit schedule. Facilitate any requested changes to Clinical Privileges

4. PROCEDURE**Who can undertake pelvic floor procedures utilising mesh in SESLHD?**

While mesh for gynaecological procedures is restricted by the Therapeutic Goods Administration, only gynaecologists who have sought Special Access Scheme (SAS) approval can obtain TiLOOP mesh for gynaecological procedures. TiLENE and other forms of mesh cannot be used.

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Having obtained SAS approval the following groups of gynaecologists may undertake pelvic floor procedures that utilise mesh:

- Specialist gynaecologists credentialled by SESLHD as subspecialist Urogynaecologists in a SESLHD facility;
- Specialist gynaecologists credentialled by SESLHD as Level 6 laparoscopic gynaecologists in a SESLHD facility;
- Specialist gynaecologists credentialled by SESLHD to undertake sacrocolpopexy or other mesh requiring procedures as individual procedures.

Consistent with the NSW State Scope of Clinical Practice Unit model scope for Obstetrics & Gynaecology all gynaecologists wishing to undertake vaginal mesh procedures must be specifically credentialled for vaginal mesh surgery regardless of any other scope of clinical practice they may hold.

Any gynaecologist seeking privileges to undertake mesh procedures should apply for a change of scope of practice using the standard change of scope of practice process outlined in [SESLHDPR/624 - Credentialing & Re-credentialing of Senior Medical & Dental Practitioners - Process](#).

All privileges for mesh pelvic floor procedures in SESLHD are conditional upon compliance with this procedure including agreement to enter all instances of the use of mesh for pelvic floor surgery in the Australasian Pelvic Floor Procedures registry and comply with any reporting requirements stipulated by the TGA.

Consent for gynaecological procedures using mesh

Consent for all gynaecological procedures utilising mesh should be documented using the standard NSW Health consent form.

The discussion of the risks associated with mesh for pelvic procedures should be carefully documented. Patients should be provided with a suitable patient information sheet such as those available from the Urogynaecological Society of Australasia or the International Urogynecological Association.

As part of the consent process, it should be documented that the mesh utilised for the procedure is provided under the Special Access Scheme.

Provision of the relevant form to the patient should be documented in the patient record.

Booking of patients and release of mesh

Sacrocolpopexy and other mesh requiring gynaecological procedures can only be booked in the name of appropriately credentialled gynaecologists, as per the SESLHD Scope of Clinical Practice Database. If there is any doubt as to whether an individual gynaecologist is appropriately credentialled the facility DMS should be consulted. All operating theatres should have local procedures to ensure that mesh is only released to gynaecologists who are credentialled as per the SESLHD Scope of Clinical Practice Database and who have approval under the Special Access Scheme.

Recording of the use of mesh in gynaecological procedures

The use of mesh should be documented in accordance with usual operation documentation standards. Relevant batch and other product identification references should be included in the operative record.

In addition, all gynaecological procedures utilising mesh should be recorded in the Australasian Pelvic Floor Procedures registry.

Complications arising from the use of mesh products in gynaecological procedures in SESLHD

In cases where complications arise following the use of mesh in gynaecological procedures the case should be considered as part of routine Morbidity & Mortality meeting discussions.

An insurance notification should be made in accordance with the treating gynaecologist's hospital indemnity arrangements (VMOIRS for VMOs and IMS+ for Staff Specialists and Clinical Academics) for all public patients experiencing complications after a mesh procedure.

5. DOCUMENTATION

Not required.

6. AUDIT

All sites where mesh is used for sacrocolpopexy or other gynaecological procedures should undertake regular audits to ensure only appropriately credentialed gynaecologists are using mesh in SESLHD.

7. REFERENCES

- [SESLHDPR/624 - Credentialing & Re-credentialing of Senior Medical & Dental Practitioners - Process](#)

8. REVISION AND APPROVAL HISTORY

Date	Revision No.	Author and Approval
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December 2022	DRAFT	Draft for Comment period
February 2023	DRAFT	Final version approved by Executive Sponsor. Tabled at SESLHD Clinical and Quality Council for approval.
March 2023	1	Approved at SESLHD Clinical and Quality Council.
June 2023	2	Minor review. Additional wording to provide clarity in Section 1 and terminology updated in Section 4. Approved by Executive Sponsor.