

SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No:	1758
Service	Specialised services for women with complications of mesh inserted for urinary incontinence and vaginal prolapse
Commissioner Lead	<i>For local completion</i>
Provider Lead	<i>For local completion</i>

1. Scope

1.1 Prescribed Specialised Service

This service specification covers the multi-disciplinary team management and complex vaginal mesh removal surgery of women who have complex vaginal mesh complications consequent to mesh insertion vaginally or abdominally for urinary incontinence and prolapse. The multi-disciplinary team (MDT) and surgery are provided by a designated Specialised Mesh Removal Service (Mesh Service)

1.2 Description

Mid urethral tape mesh is commonly used to treat stress urinary incontinence in women whilst vaginal mesh is occasionally used to treat prolapse. A small number of women can develop complications from vaginal mesh surgery. These complications may include:

- Vaginal exposure
- Erosion into the urinary tract
- Erosion into the bowel
- Infection
- Pain
- Fistulae
- Mesh shrinkage
- Organ perforation
- Nerve or vascular injury
- Sexual difficulty

All women with mesh complications must be discussed by the Mesh Service's Multi-Disciplinary Team (Mesh MDT).

For vaginal mesh erosion into adjacent organs, this always requires removal of the mesh and a referral must be made to the Mesh MDT, members of whom who will carry out the surgery.

For none complex mesh complications, (lump, sinus or discharge or exposure of a small amount of mesh <1cm in the vagina) mesh removal may not always be required. However, if following discussion and agreement with the Mesh MDT, simple localised excision of minor mesh erosion can be performed by the Specialised Complex Urogynaecology/ Female Urology Conditions MDT.

For mesh complications with pain but with no erosion, input from a pain specialist and/or neurologist will be necessary. If mesh removal is advised a referral will need to be made to the Mesh Service. If following discussion and agreement with the Mesh MDT, simple localised excision for mesh for pain is indicated, surgeons in a Specialised Urogynaecology/ Female Urology Conditions Centre can perform it.

1.3 How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners

Clinical Commissioning Groups commission primary surgical treatment for urge urinary incontinence, primary surgery for stress urinary incontinence and primary surgery for pelvic organ prolapse.

2. Care Pathway and Clinical Dependencies

2.1 Care Pathway

This service specification covers the Mesh MDT management of women with complications of mesh inserted for urinary incontinence and vaginal prolapse and the provision of complex mesh removal surgery.

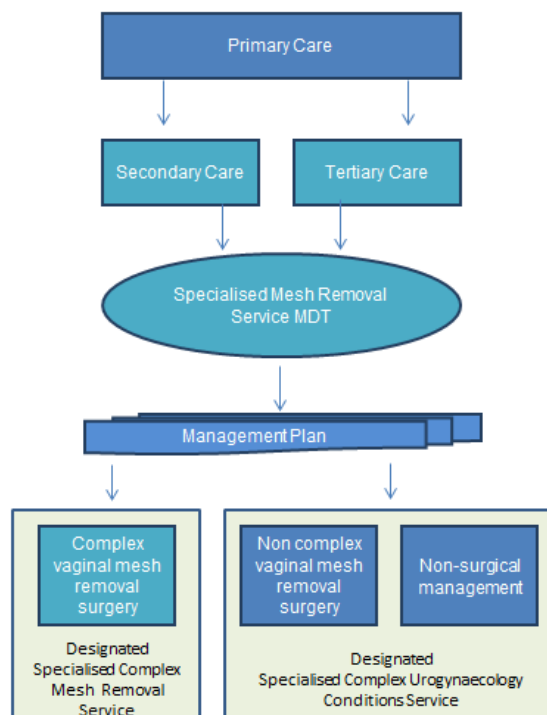
All women with complications of vaginal mesh are managed in specialised centres and the management will vary depending on the type of complication. Appropriate management will be determined by the Mesh MDT and the referring Specialised Urogynaecology/ Female Urology Conditions MDT (Uro-MDT).

There must be good joint working between the Mesh MDT and the Uro-MDT in order to manage women with vaginal mesh complications.

All women with complications relating to mesh must be discussed by the Mesh MDT. The Mesh MDT and the referring Uro-MDT will agree a treatment plan for all women referred. Specialised Complex Urogynaecology/ Female Urology Conditions Services can perform simple localised excision of minor erosion if that has been agreed by the Mesh MDT.

For complex vaginal mesh complications women will:

- Be referred from secondary or tertiary care.
- Be assessed in the outpatient setting by a named specialist gynaecologist or specialist urologist.
- Have appropriate investigations of lower urinary tract and gastrointestinal tract function. If these investigations have already been done by the referring centre they must be made available.
- Have an anaesthetic review and appropriate investigations at their referring centre to ensure that they are fit for operative intervention.
- Have their case discussed at a Mesh MDT meeting
- Be offered complex mesh removal surgery as recommended by the Mesh MDT.
- Be returned to the care of the referring Uro-MDT with a plan of management if complex mesh removal surgery is not indicated or declined by the patient.



Management by category

Mesh complications are classified by the anatomical location which helps to determine how these are managed.

All mesh complication must be classified using the joint International Urogynaecological Association (IUGA)/International Continence Society (ICS) classification system. <https://www.ics.org/complication>

IUGA/ICS Classification

- Vaginal: no epithelial separation-Include prominence (e.g. due to wrinkling or folding), mesh fibre palpation or contraction (shrinkage)
- Vaginal: smaller \leq 1cm exposure
- Vaginal: larger $>$ 1cm exposure (or any extrusion)
- Urinary Tract-Compromise or perforation. Including prosthesis (graft) perforation, fistula and calculus
- Rectum or Bowel-Compromise or perforation. Including prosthesis (graft) perforation and fistula
- Skin and / or musculoskeletal-Complications including discharge pain lump or sinus tract formation
- Patient compromise -Including hematoma or systemic compromise

MDT

Mesh MDT core membership:

- Consultant Urogynaecologists (Formally accredited subspecialist in urogynaecology)
- Consultant Urologist specialised in Female Urology
- Colorectal Surgeon specialised in pelvic floor disorders
- Consultant Radiologist with a special Interest in Female Urology/Urogynaecology

The extended Mesh MDT membership includes:

- Continence Nurse Specialist AND/OR
- Pelvic Floor Physiotherapist
- Multidisciplinary Team Administrator
- Consultant in Chronic Pain management
- Plastic Surgeon
- Neurologist
- Psychological support
- Psychosexual support

Outpatient Appointments

Following the Mesh MDT discussion, utilising all previous imaging and investigation results, any additional investigations will be requested at the Mesh MDT. A summary of the Mesh MDT discussion will be sent to the patient and they will be offered an outpatient appointment to discuss their diagnosis and management options with the Mesh MDT or their care will take place at their Specialised Urogynaecology Conditions Centre.

Investigations

Many of the investigations will have already been performed by the referring Uro-MDT and should be made available to the MDT prior to the initial outpatient appointment. However, further or repeat investigations may be required and these can include:

- Urodynamics
- Videourodynamics
- Ambulatory urodynamics
- Ultrasound – pelvic floor and endoanal
- Anorectal studies
- Magnetic Resonance Imaging (MRI)
- Computed Tomography (CT)
- MAG3 Renogram scan
- Barium or MR defecating proctogram
- Bowel motility studies

The investigations will allow for an extended or advanced assessment of the anatomical and functional problems which may include assessment of:

- Anatomical disruption
- Urinary function
- Bowel function
- Sexual function

Outpatient appointment

The Mesh MDT will review the patient. They will discuss their problems, the results of the investigations and the outcomes of the Mesh MDT. The patient will be offered surgical intervention and will decide which treatment options they would like to pursue. If they decide on surgery they will be counselled and consented, and contacted to offer a date and pre-assessment.

Second outpatient appointment (telephone call)

A second outpatient appointment (telephone call) will be made (at a minimum of 4 weeks after the initial outpatient appointment) to discuss any new concerns and to confirm their consent for surgical intervention.

Surgical Procedures

Diagnostic procedures or procedures undertaken at the start of the complex mesh removal surgery

Cystoscopy M25

Retrograde Assessment of Upper Tracts M11.3 M30.1

Endoscopic insertion of Stent M29.2

Endoscopic catheterisation of ureter M30.2

All procedures will contain the following codes

Complete Removal of tension free vaginal tape (TVT) M53.4

Partial Removal of TVT M53.5

Removal of TVT –O M53.7

Codes relating to urethral complications of mesh

Closure of urethrovaginal fistula P25.2

Urethroplasty M73.6

Urethral Reconstruction M73.4

Buccal Mucosal Graft S38.8 Y69.8 Z25.8

Martius Labial Fat Pad Interposition Y69.8 Z44.3 PO5.9 S25.2

Codes relating to bladder complications of mesh

Omental flap T36.5 S25.2

Closure of vesicovaginal fistula P25.1

Partial excision of bladder M35.8

Clam Cystoplasty M31.1 M31.2 M31.3

Open removal of foreign body from bladder M39.2

Martius labial fat pad interposition Y69.8 Z44.3 PO5.9 S25.2

NB Fistula repair can be vaginal, abdominal or laproscopic

Codes relating to ureteric complications of mesh

Ureteric Reimplantation Bilateral M20.1

Unilateral M20.2

Direct reimplant to bladder wall M21.1

Anastomosis to bladder using bladder flap M21.2

Ileal replacement of ureter M20.3

Omental flap T36.5 S25.2

Codes relating to bowel involvement

Colectomy HO7.8 HO8.8 HO9.8 H10.8 H11.8

Repair of bladder fistula M37.5

Closure of colovesical fistula M37.2

Closure of colovaginal fistula M25.3

Ileostomy G4.2 G74.3

Colostomy H15.1 H15.2

Codes relating to urinary diversion

Ileal conduit M19.1

Other Urinary diversion M19.2

NB all codes can be open or laparoscopic.

Codes used in follow up

Endoscopic removal of stent M29.3

Cystoscopy M25.5

Treatment Strategy

The Mesh MDT review will determine the treatment strategy and management of all vaginal mesh complications.

If conservative measures are recommended, the patient will be treated by the referring Uro-MDT. Simple localised excision of none complex mesh erosion can also be carried out by the referring Specialised Complex Urogynaecology/ Female Urology Conditions Service, if agreed by the Mesh MDT.

If at any time patients fail their conservative management or develop additional or new problems they will be discussed again at the Mesh MDT.

Follow up

All patients following complex Mesh removal surgery will have:

- A post-operative follow up visit with the Mesh Service
- A post discharge telephone follow up by a nurse specialised (2-4 weeks post-surgery)
- A face to face outpatient review (at 4 months and 12 months post-surgery)
- The majority of patients will be referred back to the referring MDT for annual telephone follow up reviews for up to 5 years post-surgery
- The referring Uro-MDT will update the Mesh MDT regarding patient outcomes after their annual telephone reviews
- On discharge from the Specialised Complex Urogynaecology/ Female Urology Conditions Centre (at 5 years) there will be clear instructions for the GP to refer back if there are any new issues.

Referral Processes and Sources

Referrals will be accepted from secondary and tertiary care Specialised Complex Urogynaecology/ Female Urology Conditions MDTs.

Data Management, Audit and Governance

- The management of mesh complications removal will take place in specialist Mesh Services that provide treatment by consultants working within a Mesh MDT structure
- The Mesh MDT must convene at least once each month. In order to be quorate, the Mesh MDT must always include a consultant urogynaecologist and a consultant urologist. If the case is relevant, the

consultant colorectal surgeon must also be included in the MDT to ensure quoracy.

- Individual Trusts providing complex Mesh removal services must use trust appraisal system to ensure surgeons: are appropriately trained and current in their practice; adhere to clinical guidance; comply with national data requirements; and report complications.
- All procedures should be recorded on a national database such as the British Association of Urological Surgeons (BAUS) or British Society of Urogynaecology (BSUG) databases or any subsequent data base endorsed by NHS England to record mesh insertions, complications and removals.
- All adverse incidents (AIs) must be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) including reporting retrospectively, regardless of whether the Mesh Service carried out the original procedure.
- All additional reporting requirements for individual patients also apply, for e.g. reporting to local incident systems, the National Reporting and Learning System (NRLS) and serious incidents to Strategic Executive Information System (StEIS).
- All surgeons undertaking Mesh surgery must submit their data to the BAUS Audit and/or BSUG database. This data must be submitted as an index procedure for their yearly appraisal. All trust Responsible Officers (RO) must ensure compliance with this.
- It is incumbent upon trust ROs and individual clinicians to ensure that these practices become embedded and are sustained long term.
- Specialist Mesh Services for complex removal will provide complex surgery in compliance with current NICE guidelines.
- All Specialised Complex Urogynaecology/ Female Urology Conditions Services hosting the Mesh MDT members must have members of the appropriate subspecialist society. All urogynaecologists must have BSUG membership. All female urologists forming part of the specialist MDT must have membership of the FNUU of BAUS with confirmed 100% entry onto BAUS database.
- There needs to be clear documented evidence that can demonstrate competency to perform complex vaginal mesh removal surgery. Advanced laparoscopic surgery and advance open surgery is not within the repertoire of most gynaecologists or urologists who perform primary surgery. Appropriately trained surgeons with expertise in complex pelvic surgery (specialist gynaecologist / specialist urologist +/- specialist colorectal surgeon) should only perform these techniques.
- All issues related to medical devices must be reported to the MRHA yellow card scheme.
- Providers will enter all procedures involving implants on a national registry along with organised follow up and an audit of outcomes.
- All specialised services performing complex and non-complex mesh removal surgery must meet annually in a clinical summit to present data and discuss outcomes.

The annual clinical summit will include clinical performance and outcomes including surgical and non-surgical outcomes and patient feedback.

Mesh Services for complex removal must always obtain patient legally informed consent in order to record the discussion between the clinician and patient about: the procedure; the alternatives; recommendations; and questions/understanding.

Reasonable time should be allowed once the patient has been given the information and the opportunity to ask questions before signing/confirming a consent form. The General Medical Council (GMC) guidance should be followed when obtaining consent.

2.2 Interdependence with other Services

In order to be able to provide a specialised service for women with complications of mesh inserted for urinary incontinence and vaginal prolapse including the provision of complex vaginal mesh removal surgery, centres must be a Complex Gynaecology Urinary Fistulae Service and a Specialised Complex Urogynaecology/ Female Urology Conditions Service.

Specialist gynaecology, specialist urology and colorectal surgery must be co-located. These must be subspecialist urogynaecologists, gynaecologists with a special interest and Female, Neuro-urological and Urodynamic Urologists (FNUU). In most units the gynaecologists would be a sub-specialist however, gynaecologists with a special interest may undertake further training to develop additional expertise to attain the correct skills. There must also be a co-located Consultant Radiologist with a Special Interest in Female Urology/Urogynaecology.

Adult critical care services, neurology, psychology, pain management and psychosexual support must also be co-located.

3. Population Covered and Population Needs

3.1 Population Covered By This Specification

This specification is specifically for women with complications relating to mesh insertion to treat simple or complex urinary incontinence and prolapse.

There is no specific age group for this intervention, however it is anticipated that most patients will be adult (over 18 years of age). If a case of a young person under the age of 18 requiring this intervention, their case should be discussed within a specialised MDT which includes a paediatric/ adolescent urologist and paediatric support staff to agree the appropriate treatment plan.

The service outlined in this specification is for patients ordinarily resident in England* or otherwise the commissioning responsibility of the NHS in England (as defined in Who Pays?: Establishing the responsible commissioner and other Department of Health guidance relating to patients entitled to NHS care or exempt from charges).

* Note: for the purposes of commissioning health services, this EXCLUDES patients who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES patients resident in Wales who are registered with a GP Practice in England.

3.2 Population Needs

15% of all women having any type of surgery for stress urinary incontinence will develop frequency and urgency which will require treatment.

20-30% will not have satisfactory treatment of their stress urinary incontinence following surgery.

1-4% will have long term difficulty emptying their bladder and will need to self-catheterise or have surgery to correct this.

1% of women will have chronic pain at surgical and pelvic sites following any surgery for stress urinary incontinence (this is more common in women with underlying chronic pain conditions such as ME and fibromyalgia.)

These complications are common to all stress incontinence operations and result in non-complex revision surgery.

Mesh specific complications are vaginal exposure (small and large) and extrusion of mesh into adjacent organs. Asymptomatic vaginal erosions of any size would require non-complex surgery whilst larger symptomatic vaginal exposure and all extrusions would require complex surgery.

It is estimated that the following number of patients will have non-complex and complex vaginal mesh complications:-

Non-Complex = 300-400

Complex = 50-100

3.3 Expected Significant Future Demographic Changes

No expected demographic changes

3.4 Evidence Base

- NHS England 'Mesh Oversight Group Report' July 2017
- NICE (2015) Urinary incontinence in women: management. CG171'
- NICE (2012) Urinary incontinence in neurological disease: assessment and management. CG 148
- NICE (2017) Extra urethral (non-circumferential) retro-pubic adjustable compression devices for stress urinary incontinence in women IPG576

- NICE (2016) Single-incision short sling insertion for stress urinary incontinence in women, IPG566
- NICE (2008) 'Surgical repair of vaginal wall prolapse using mesh, NICE Interventional Procedures Guidelines IPG267'
- NICE (2009) 'Infracoccygeal sacrocolpopexy using mesh for uterine prolapse repair, NICE Interventional Procedures Guidelines IPG280'
- NICE (2009) 'Infracoccygeal sacrocolpopexy using mesh for vaginal vault prolapse repair, NICE Interventional Procedures Guidelines IPG281'
- NICE (2009) 'Insertion of mesh uterine suspension sling (including sacrohysteropexy) for uterine prolapse repair, NICE Interventional Procedures Guidelines IPG282' NICE (2009) 'Sacrocolpopexy using mesh for vaginal vault prolapse repair, NICE Interventional Procedures Guidelines IPG283'
- NICE (2017) 'Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, IPG577'

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aim of Service

- To provide a Mesh MDT review for all patients with complications of mesh inserted for urinary incontinence and vaginal prolapse including vaginal mesh removal.
- To provide a treatment plan for local management as recommended by the Mesh MDT
- To provide complex vaginal mesh removal surgery, as recommended by the Mesh MDT

NHS Outcomes Framework Domains

Domain 1	Preventing people from dying prematurely	X
Domain 2	Enhancing quality of life for people with long-term conditions	X
Domain 3	Helping people to recover from episodes of ill-health or following injury	X
Domain 4	Ensuring people have a positive experience of care	X
Domain 5	Treating and caring for people in safe environment and protecting them from avoidable harm	X

4.2 Indicators Include: Please note that these indicators are still in development

Number	Indicator	Data Source	Outcome Framework Domain	CQC Key question
Clinical Outcomes				
101	Numbers of patients referred for complications of mesh insertion for urinary incontinence and prolapse	Provider	2,3,5	effective
102	% of patients treated by the specialist team	Provider	2,3,5	effective

103	% of patients treated by the referring specialist complex uro- gynaecological/ female urology service	Provider	2,3,5	effective
104	Types of repair	Provider	2,3,5	effective
105	% patients having abdominal surgery	Provider	2,3,5	effective
106	% patients having laparoscopic surgery	Provider	2,3,5	effective
107	Mean length of stay in hospital	Provider	2,3,5	effective
108	% patients with symptom relief post operatively at 4 weeks	Provider	2,3,6	effective
109	% patients with urinary continence post operatively	Provider	2,3,7	effective
Patient Experience				
201	Patients and carers are provided with information	Self-declaration	4	caring, responsive
202	Feedback from patients is reviewed and informs service development and improvements	Self-declaration	4	caring, responsive
203	Patients discuss treatment options with multi-disciplinary team	Self-declaration	4	caring, responsive
204	Patients are offered counselling/ psychological support	Self-declaration	4	caring, responsive
205	The service is collecting PROMS	Self-declaration	4	caring, responsive
Structure and Process				
001	<p>There should be specialist multidisciplinary team of named individuals designated for the care of patients with complications of mesh insertion. There should be a minimum of two consultants per speciality and should include:</p> <ul style="list-style-type: none"> - specialist urogynaecologist with expertise and training in complex pelvic surgery - urologist specialising in female urology and with expertise and training in complex pelvic surgery - colorectal surgeon specialised in pelvic floor surgery - specialist radiologist <p>In addition to the specialist team there should be named contacts for:</p> <ul style="list-style-type: none"> - specialist continence nurse - consultant pain specialist - neurology - psychological and psychosexual support 	Self-declaration	2,3,5	effective, safe

002	<p>All patients should be discussed at the specialist mesh MDT for decision on treatment and management planning.</p> <p>The MDT should include as a minimum to be quorate:</p> <ul style="list-style-type: none"> - one specialist urogynaecologist - one urologist specialising in female urology - colorectal surgeon specialised in pelvic floor surgery - specialist radiologist <p>THE MDT must be quorate, for 95% or more, of the meetings.</p>	Self-declaration	2,3,5	effective, safe
003	<p>There are clinical guidelines in place for the referral, investigation, treatment, discharge and follow up as detailed in the service specification.</p> <p>Where relevant these should reflect nationally and internationally agreed guidelines</p>	Self-declaration	2,3,5	effective, safe
004	<p>The service should agree with the relevant service providers and relevant commissioners, patient pathways for referral, assessment, investigation treatment, discharge and follow up, as detailed in the service specification</p>	Self-declaration	2,3,5	effective, safe
005	<p>All procedures should be recorded on a national database such as the British Association of Urological Surgeons (BAUS) or British Society of Urogynaecology (BSUG) databases.</p>	Self-declaration	2,3,5	effective, safe

4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C

4.4 Applicable CQUIN goals are set out in Schedule 4D

5. Applicable Service Standards

5.1 Applicable Obligatory National Standards

5.2 Other Applicable National Standards to be met by Commissioned Providers

- NICE (2015) Urinary incontinence in women: management. CG171'

- NICE (2012) Urinary incontinence in neurological disease: assessment and management. CG 148
- NICE (2017) Extra urethral (non-circumferential) retro-pubic adjustable compression devices for stress urinary incontinence in women IPG576
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- NICE (2017) 'Sacrocolpopexy with hysterectomy using mesh for uterine prolapse repair, IPG577'

5.3 Other Applicable Local Standards

Not applicable

6. Designated Providers (if applicable)

7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:

Multi-disciplinary Team (MDT).
 International Urogynaecological Association (IUGA)
 International Continence Society (ICS)
 Magnetic Resonance Imaging (MRI)
 Computed Tomography (CT)
 Tension free vaginal tape (TVT)
 British Association of Urological Surgeons (BAUS)
 British Society of Urogynaecology (BSUG)
 Adverse incidents (AIs)
 Healthcare Products Regulatory Agency (MHRA)
 National Reporting and Learning System (NRLS)
 Serious incidents to Strategic Executive Information System (StEIS)
 Serious Untoward Incident (SUI)
 Responsible Officers (RO)
 The General Medical Council (GMC)
 Female, Neuro-urological and Urodynamic Urologists (FNUU)
 National Institute for Health and Care Excellence (NICE)

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