SCHEDULE 2 – THE SERVICES

A. Service Specifications

1. Service name	Specialised services for service users with complications of mesh inserted for urinary incontinence, vaginal or internal and external rectal prolapse (16 years and above) [Updated Summer 2023]
2. Service specification number	1758 – 230702S
3. Date published	1st August 2023
4. Accountable Commissioner	NHS England - Women and Childrens' Programme of Care Internal Medicine Programme of Care

5.	**Population and/or geography to be served**
5.1	**Population Covered** This service specification covers the multi-disciplinary team management of people with mesh complications consequent to mesh insertion, either vaginally or abdominally, where the clinical indication was urinary incontinence, vaginal prolapse, or rectal prolapse. A designated Mesh Service provides multi-disciplinary team assessment and treatments. The service outlined in this specification is for people ordinarily resident in England* or who are 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 people who, whilst resident in England, are registered with a GP Practice in Wales, but INCLUDES people resident in Wales who are registered with a GP Practice in England. **Population Needs** During their lifetime, approximately 1 in 3 women are affected by Stress urinary incontinence (SUI). It is estimated that an 18 year old woman has a 14% chance of having surgery for SUI during her lifetime. Prolapse of the vaginal wall and uterus are common conditions affecting up to 50% of women who have given birth. By the age of 80 years, 11% of women will undergo a surgical prolapse repair. The socio-economic, psychological and physical impacts of SUI and utero-vaginal prolapse are considerable.

	Approximately 15% of women who have had an operation to treat SUI will have persistent/recurrent urinary incontinence and require further surgery. Approximately 10% of women who have had surgery for prolapse, will develop symptoms and signs of recurrent prolapse in the same anatomical site. Between 2008/09 to 2016/17 194,107 people had urogynaecological procedures of which 96,286 were for utero-vaginal prolapse and 101,538 were for SUI. Some people underwent surgery for both indications. Some of these operations included the use of mesh, some did not. Overall the number of surgical procedures for SUI and utero-vaginal prolapse has reduced year on year from 25,416 people in 2008/09 to 17,349 people in 2016/17, a reduction of 32%. **Tape insertion procedures for stress urinary incontinence** • Between 2008/09 to 2016/17, 100,516 people had a reported tape insertion procedure for SUI. • In 2016/17 there were 7,245 people underwent a tape insertion procedure, a reduction of 48% from 2008/09 when 13,990 people were recorded. **Mesh insertion procedures for utero-vaginal prolapse** • Between 2008/09 to 2016/17, 27,016 people had a reported mesh insertion procedure for utero-vaginal prolapse. • In 2016/17 there were 2,680 people who had mesh insertion for prolapse, a reduction of 13% from 2008/09 when 3,073 people were recorded as undergoing this surgery. **People who have had removal procedures** The number of people that have had urogynaecological procedures that relate to the removal of material associated with tape and mesh has varied year on year. Increasing from 580 people in 2008/09 to 679 people in 2012/13 before decreasing to 502 people in 2016/17 an overall reduction of 13% between 2008/09 to 2016/17. **Mesh insertion and removal for rectal prolapse (Rectopexy)** The Cumberlege Report First Do No Harm (2020) identified the lack of data for mesh insertion for rectal prolapse (mesh rectopexy). The Pelvic Floor Society (PFS) collects data on a voluntary basis reporting 1,360 laparoscopic ventral mesh rectopexies (LVMR):1,301 in women and 59 in men, between 01/2009 and 11/2020. This data was considered the best indicator of the number of operations performed. The clinical indications for those operations were noted as 60% to treat rectal prolapse and 40% to treat Obstructed Defaecation Syndrome (ODS). Complications were reported as 10% having a recurrence of symptoms, 6% having recurrence of prolapse and 1.5% having specific mesh complications. The wider surgical literature reports mesh complications in 2% of surgeries. It is recognised that rectal mesh insertion procedures are poorly recorded, and some larger providers had not submitted data to the PFS.

	However, clinical estimates suggest that 80 cases of removal of mesh following rectopexy will be required over the next 5 years. **Expected Significant Future Demographic Changes** There are no expected significant demographic changes due to the high vigilance restriction on the use of surgical mesh / tape in certain treatments.
5.2	**Minimum population size** Not applicable
6.	**Service aims and outcomes**
6.1	**Service aims** This service specification covers the multi-disciplinary team management of people with mesh complications consequent to mesh insertion, either vaginally or abdominally, where the clinical indication was urinary incontinence, vaginal prolapse or rectal prolapse / Obstructed Defaecation Syndrome (ODS). The multi-disciplinary team and treatment, including surgery, are provided by a designated Specialised Mesh Complications Service (Mesh Service). Sub- urethral mesh tape has been used to treat SUI in women, vaginally placed mesh has been used to treat utero-vaginal prolapse, and abdominally placed mesh is used to treat vaginal and rectal prolapse / ODS. Complications following mesh surgery include: • Extrusion of the mesh into the bowel • Extrusion of the mesh into the urinary tract • Vaginal mesh exposure • Fistulae • Infection • Pain • Sexual dysfunction • Bowel incontinence • Bowel obstruction • Changes to bowel habits (diarrhoea or increased constipation) All people with mesh complications must be referred to a Mesh Service and discussed by the Mesh Service's Multi-Disciplinary Team (Mesh MDT). For mesh extrusion into adjacent organs, this usually requires removal of the mesh and a referral must be made to the Mesh MDT, members of whom will carry out the surgery. For non-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 exposure into the vagina is recommended, this surgery can be performed by the Specialised Complex Surgery for Urinary Incontinence and Vaginal and Uterine Prolapse Regional MDT (Regional (specialist) MDT) following discussion and agreement with the Mesh MDT. This is in line with the separate service specification in place for

specialised complex surgery for urinary incontinence and vaginal and uterine prolapse. [specification 1649]

The Mesh MDT will be able to advise whether surgery related to mesh complications from internal and external rectal prolapse can be done by the local colorectal team or whether it will require referral.

For mesh complications with pain but with no exposure, extrusion, infection or fistulae, input from a specialist in pain management with an expertise in pelvic pain will be necessary through the Mesh MDT.

6.2 Outcomes

NHS Outcomes Framework Domains & Indicators

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

Service defined outcomes/outputs

Applicable Obligatory National Standards

Clinical outcomes

Outcome Reference Number	Domain	Rationale	Name of Outcomes/ Description
101	2,3,5	Effective	Number of patients referred for complications of mesh insertion for urinary incontinence and urinary or rectal prolapse
102	2,3,5	Effective	Proportion of patients treated by the specialist team
103	2,3,5	Effective	Proportion of patients treated by the regional MDT with agreement by the Mesh MDT
104	2,3,5	Effective	Proportion of patients having abdominal surgery
105	2,3,5	Effective	Proportion of patients having laparoscopic surgery
106	2,3,5	Effective	Mean length of stay in hospital
107	2,3,5	Effective	Proportion of patients with symptom relief post operatively at 4 weeks

	108	2,3,5	Effective	Proportion of patients with urinary continence /ODS post operatively
	109	2,3,5	Effective	Proportion of patients who have received psychological support

Patient Outcomes

The service will collect interim patient reported outcome measures for service users with complications of mesh inserted for urinary incontinence, utero-vaginal prolapse, and rectal prolapse/ODS.

Quality Metrics

The service will complete / upload data for all listed quality metrics to the national specialised Services Quality Dashboard (SSQD). The full version of the quality metrics and their descriptions including the numerators and denominators can be accessed at https://www.england.nhs.uk/commissioning/spec-services/npc-crg/spec-dashboards/

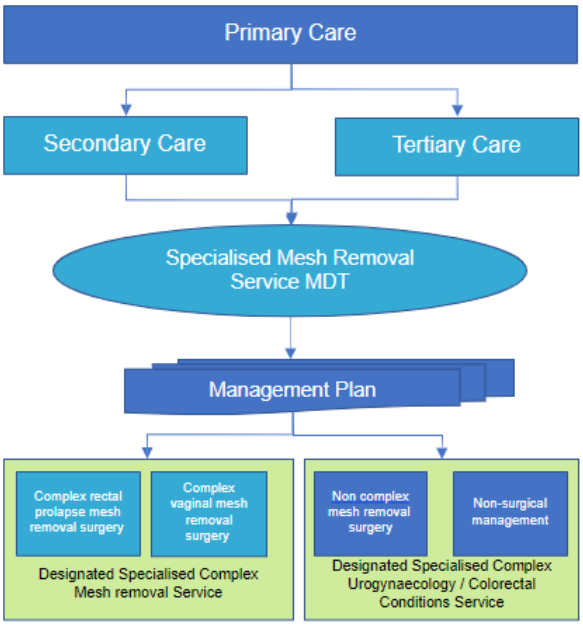
All specialised teams dealing with complications of mesh must meet annually in a clinical summit to present data and discuss outcomes.

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.

Other Applicable National Standards to be met by Commissioned Providers

Not Used

7.	**Service description**
7.1	**Service model** This service specification covers the Mesh MDT management of people with complications of mesh inserted for urinary incontinence, vaginal and rectal prolapse including the provision of mesh removal surgery and non-surgical options. The service will ensure the provision of specialist assessment, care and treatment for people aged 16 and over. People under the age of 16 years are unlikely to require this intervention, but if there is concern that a person under this age has complications of mesh, they should be referred to paediatric services including paediatric surgery/urology/gynaecology and a request for advice sent to one of the national centres for this service.
7.2	**Pathways** Overall patient pathway All people with complications of mesh are to be managed in specialised centres. Management will vary depending on the type of mesh complication. Appropriate management will be determined by the Mesh MDT.

	All people with complications relating to pelvic mesh must be discussed by the Mesh MDT and the Regional (specialist) MDT when applicable. Regional (specialist) MDTs can perform simple localised excision of minor mesh exposure if the MDT clinicians have the appropriate surgical expertise, and this has been agreed by the Mesh MDT. For mesh complications following surgery for vaginal or rectal prolapse people will: • Be referred by their GP, Local MDT and/or the Regional/specialist MDT to the Mesh MDT for discussion. • Be assessed in the outpatient setting by a consultant sub-specialist in urogynaecology and/or a consultant urologist with expertise in female urological conditions and/or a consultant colorectal surgeon with pelvic floor surgical expertise. • Where abdominal mesh placement has occurred and the rectum is considered at risk of involvement, assessment must include a consultant colorectal surgeon with pelvic floor surgical expertise. • 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 for review by the Mesh MDT. • Have an anaesthetic review and appropriate investigations at their referring centre to ensure that they are fit for operative intervention. • Discuss the treatment options and associated risks with the Mesh MDT and agree and consent to their preferred treatment plan. 

	Specialised patient pathway **Management by category** Mesh complications are classified by the anatomical location. This helps to determine how the complications 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 **Referral processes and sources** Referrals will be accepted from GPs/primary care, Local MDTs and Regional (specialist) MDTs. **Outpatient Appointments** Following the Mesh MDT discussion, any additional investigations will be requested at the Specialised Mesh Service. A summary of the Mesh MDT discussion will be sent to the person. They will be offered an outpatient appointment with a member of the Mesh MDT to discuss their diagnosis and treatment options (non-surgical and surgical). If they wish to proceed with treatment, the person will be counselled and consented. Prior to surgery an anaesthetic review will be performed. This should be at the time of consenting for and agreeing a date for surgery. If at any time conservative management is not successful or additional or new problems develop, the person will be referred back to the Mesh MDT for further discussion. **Second outpatient appointment** A second outpatient appointment will be made (at a minimum of 4 weeks after the initial outpatient appointment) to discuss any new concerns and to confirm consent for surgical intervention. **Treatment Strategy** The Mesh MDT review will determine the treatment and management strategy for all people with mesh complications including non surgical and surgical options. If conservative measures are recommended, the person can be treated by the referring Regional (Specialist) MDT with the agreement of the Mesh MDT. The referring Regional MDT can also carry out simple localised excision of minor mesh exposure into the vagina if that is also agreed by the Mesh MDT. **Follow up** All people following Mesh removal surgery will: • Have a post discharge follow up by a nurse specialist (2-4 weeks post-surgery)

	• Have a outpatient review (at 4 months and 12 months post-surgery) • Have follow up reviews for up to 5 years post-surgery. On discharge from the Specialised Mesh Service at 5 years, there will be clear instructions for the GP to refer the person back if there are any new problems.
7.3	**Clinical Networks** Local MDTs, Regional/specialist MDTs and Mesh MDTs will work within a clinical network arrangement. Specialised Mesh Services are responsible for ensuring that they deliver specialised treatment as part of an established network. The Mesh Services must ensure that the Local MDTs and Regional (specialist) MDTs within its network are working to: - • jointly agreed guidelines and pathways • referral guidelines and protocols • guidelines and protocols for patient follow up Integrated Care Systems commission non-specialised gynaecology and female urology services and Local Multi-Disciplinary Teams (Local MDT) to provide non-specialised treatment for women with primary stress urinary incontinence, primary organ prolapse and commission colorectal services to undertake procedures for rectal prolapse, faecal incontinence and ODS. General Practitioners (GPs), Local MDTs and Regional (specialist) MDTs will refer people to Mesh Services for complications of mesh inserted for urinary incontinence, and utero-vaginal or rectal prolapse.
7.4	**Essential Staff Groups** The Mesh MDT must include: **Core members**: • Named consultant sub-specialist in urogynaecology, • Named consultant Urologist with expertise in female urological conditions, • Named consultant Colorectal surgeon with expertise in pelvic floor surgery, • Consultant Radiologist with expertise in pelvic floor imaging • A specialist in pain management with an expertise in pelvic pain • A specialist nurse (urogynaecology, urology or colorectal). **Other membership may include**: • A pelvic floor specialist physiotherapist • A plastic surgeon • A neurologist • A psychologist • A psychosexual counsellor • An occupational therapist • Access to a member of the care of the elderly team • A gastroenterologist • Other specialist imaging

	• A neurosurgeon • Stoma therapist. Administrative support for the MDT structure is required to co-ordinate the MDT meeting and to provide data entry. The outcome of the MDT meeting must be documented.
7.5	**Essential equipment and/or facilities** **Investigations** Many of the investigations will have already been performed by the referring Regional (specialist) MDT, local MDT or GP and must be made available to the Mesh MDT prior to the initial outpatient appointment. These investigations will allow for an extended or advanced assessment of both mesh and non-mesh related anatomical and functional problems and an assessment of urinary, bowel and sexual function. However, further or repeat investigations may be required and these can include*: • Ambulatory urodynamics • Anorectal studies • Barium or MR defecating proctogram • Bowel motility studies • Computed Tomography (CT) • Contrast studies • Cystoscopy • Examination Under Anaesthetic • Diagnostic Laparoscopy • Flexible sigmoidoscopy / colonoscopy • MAG3 Renogram scan • Magnetic Resonance Imaging (MRI) • Ultrasound – pelvic floor and endoanal • Urodynamics • Videourodynamics **Note that the above is not an exhaustive list of investigations*
7.6	**Interdependent Service Components – Links with other NHS services** Specialist urogynaecology, specialist urology and colorectal surgery must be co-located within the same Trust. These services must include a consultant subspecialist in urogynaecology, a consultant urologist with expertise in female urological conditions and a colorectal surgeon specialist in pelvic floor disorders. Specialist nursing in urogynaecology, urology or continence and pelvic floor physiotherapy must also be co-located. There must also be a co-located Consultant Radiologist with expertise in pelvic floor imaging. There must also be access to adult critical care services. The following services should also be co-located or be available to the Mesh MDT: - • Gastroenterology • Neurology • Neurosurgery • Occupational therapy

	• Other specialised imaging • Plastic surgery • Psychology • Psychosexual counselling • Stoma care services • Care of the Elderly Team
7.7	**Additional requirements** **Data Management, Audit and Governance** • The Mesh MDT must convene at least once each month. The Mesh MDT is quorate if there are at least 3 core members in attendance. There must be at least a sub-specialist in urogynaecology and a consultant urologist with expertise in female urological conditions and the specialist nurse or the physiotherapist from the extended MDT. In addition, for all cases of abdominal placed mesh a colorectal surgeon with expertise in pelvic floor surgery must be present. • All NHS health care organisations undertaking pelvic floor procedures are required to submit data to the NHS Digital Surgical Devices and Implants Information System. Mandatory submission of this data commenced in April 2021. The Pelvic Floor Registry is part of the Surgical Devices and Implants Information System. It is designed to collect historical and current surgical device and implant data including outcome information, data submitted directly from people and outcome information regarding alternative procedures for pelvic floor surgery, from NHS and independent sector hospitals. • Specialised Mesh Centres must use Trust appraisal systems to ensure that surgeons are appropriately trained, current in their practice, adhere to clinical and NICE guidance, comply with Pelvic Floor Registry data requirements and report complications • All adverse incidents linked to mesh must be reported to the Medicines and Healthcare Products Regulatory Agency (MHRA) yellow card scheme including reporting retrospectively, regardless of whether the Mesh Service carried out the original procedure. • All additional reporting requirements for individual people also apply, e.g. reporting to local incident systems, the National Reporting and Learning System (NRLS) and serious incidents to the Strategic Executive Information System (StEIS). • All procedures must be recorded on the British Society of Urogynaecology (BSUG)/Pelvic Floor Society databases and the subsequent Pelvic Floor national database that will form part of the development of a national registry. • The Pelvic Floor Society have reinforced the need to report these complications to their members and have a link on their website to register complications; https://thepelvicfloorsociety.co.uk/qa-governance/reporting-adverse-mesh-complications-to-mhra/

	• All surgeons undertaking Mesh surgery must submit their data to the BAUS Audit and/or BSUG database and the national database/registry. 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. • All Specialist surgeons providing complex surgery for urinary incontinence and vaginal and uterine prolapse services hosting the Mesh Service and Mesh MDT, must be members of the appropriate subspecialist society. All urogynaecologists must have BSUG membership. All urologists taking care of female patients forming part of the specialist MDT must have membership of the Female, Neurlogical and Urodynamic Urology (FNUU) section of BAUS with confirmed 100% entry onto the BSUG / PFS database. • There needs to be clear documented evidence that can demonstrate competency to perform complex mesh removal surgery for all surgical members of the MDT. 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 urogynaecologist/specialist urologist +/- specialist colorectal surgeon) can only perform these techniques. • Providers will enter all procedures involving implants on the national registry along with organised follow up and an audit of outcomes. • All specialised teams dealing with complications of mesh inserted for urinary incontinence, vaginal and rectal prolapse 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 must provide people with information on all mesh and non-mesh treatment options, types of treatment and risks and allow them time to consider their options. They must always legally obtain patient informed consent and ensure that a record is kept of the discussions between the clinician and patient about the treatment procedure, the alternative treatment recommendations; and any questions raised and answers given and the understanding of the person being treated. Reasonable time should be allowed once the patient has been given the information and the opportunity to ask questions before signing and/or confirming a consent form. The General Medical Council (GMC) guidance should be followed when obtaining consent.
7.8	**Commissioned providers** Service providers have been appointed, following a provider selection exercise. This will ensure sufficient activity and adequate geographical coverage to develop and maintain appropriate clinical expertise. Providers listed to deliver the mesh complication service are:

	a. Newcastle Upon Tyne Hospitals NHS FT b. Sheffield Teaching Hospitals NHS FT c. Manchester University NHS FT d. Cambridge University Hospital NHS FT e. University College London Hospitals NHS FT f. University Hospitals of Leicester NHS Trust g. Nottingham University Hospitals NHS Trust h. University Hospital Southampton NHS FT i. North Bristol NHS Trust NHS England will agree with each individual Trust the full scope of service to be provided.
7.9	**Links to other key documents** **Evidence Base** • NICE (2019) Urinary incontinence and pelvic organ prolapse in women: management NG123 • NHS England 'Mesh Oversight Group Report' July 2017 • ICE (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 sacrolpopexy using mesh for uterine prolapse repair, NICE Interventional Procedures Guidelines IPG280' • NICE (2009) 'Infracoccygeal sacrolpopexy 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 • NICE (2018) 'Laparoscopic ventral mesh rectopexy for internal rectal prolapse' IPG618 The following abbreviations and acronyms have been used in this document: AIs Adverse incidents BAUS British Association of Urological Surgeons BSUG British Society of Urogynaecology CT Computed Tomography FNUU Female, Neuro-urological and Urodynamic Urologists (FNUU) GMC The General Medical Council

	GP General Practitioners ICS International Continence Society IUAG International Urogynaecological Association MDT Multi-disciplinary Team MHRA Medicine and Healthcare Products Regulatory Agency MRI Magnetic Resonance Imaging NICE National Institute for Health and Care Excellence NRLS National Reporting and Learning System ODS Obstructed Defaecation Syndrome PFS Pelvic Floor Society RO Responsible Officers StEIS Serious incidents to Strategic Executive Information System SUI Serious Untoward Incident TVT Tension free vaginal tape