NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech Programme

GID-HTE10080 Surgical mesh for treatment of primary ventral hernias

Final scope

1. Introduction

The technologies included in this NICE HealthTech evaluation are surgical mesh for treatment of primary ventral hernias.

The technologies will be assessed for existing use. Existing-use assessments consider HealthTech products that are already in established use within the NHS, to inform commissioning and procurement decisions.

This scope document describes the context and the scope of the assessment. The methods and process for the assessment follow the NICE HealthTech programme manual.

2. The condition

Ventral hernia occurs when tissue or an organ (often part of bowel) pushes through a weakened area in the abdominal wall, creating a visible bulge. This can be uncomfortable or painful. If not treated, a ventral hernia can lead to serious complications, such as incarceration (when tissue becomes trapped) or strangulation (when the blood supply is cut off), both of which require urgent medical attention.

Primary ventral hernia can develop because of a natural weak spot in the abdominal wall, often near the belly button (umbilicus). It is not caused by a previous surgical scar or injury. Some people are born with this weakness,

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meaning a primary ventral hernia can appear at any age. The risk increases with age and is higher in individuals who have chronic coughing, constipation, obesity, are pregnant, or regularly lift heavy loads, all of which place extra pressure on the abdominal wall.

Primary ventral hernia includes:

- Umbilical hernia: Occurs at the umbilical ring. Frequently seen in infants and young children, but adults can also develop them, often due to ongoing or repeated pressure on the abdomen.
- Epigastric hernia: Appears as a small bulge in the upper midline of the abdomen, between the breastbone and the belly button.
- Spigelian hernia: Occurs along the lower side of the abdominal wall, typically near or just below the level of the belly button.
- Lumbar hernia: Relatively rare and occurs in the lower back area, between the bottom rib and top of the hip bone.

European Hernia Society classifies primary ventral hernia by the location and size of the hernia (Muysoms FE et al., 2009). Primary ventral hernia is categorised to small (less than 2 cm), medium (2 to 4 cm) and large (more than 4 cm). By location, hernia is classified into midline (central) hernias including epigastric hernia and umbilical hernia, and lateral hernias including spigelian hernia and lumbar hernia.

There are around 100,000 hernia repairs undertaken in the NHS annually in England (Pawlak M, 2020), and some clinicians suggest around 10,000 to 40,000 people undergo ventral hernia repair. Among ventral hernia repairs performed annually, approximately 18,000 cases involve umbilical hernias with mesh being used in around 50% of cases and roughly 7000 cases involving other abdominal wall hernia with mesh being used in over 55% of cases (Pawlak M, 2020).

In primary ventral hernia repair, the risk of postoperative wound complications is influenced by the condition of the surgical field at the time of repair. A clean

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field refers to hernia repair performed under absence of infection, no bowel opened and minimal presence of bacteria. An infected or contaminated field involves active infection at the time of repair. The modified Ventral Hernia Working Group (VHWG) classification incorporates these elements by stratifying individuals into 3 grades based on their risk of surgical site occurrences (SSO). Surgical site occurrences is an umbrella term for complications at the operation site, including surgical site infection, seroma, haematoma). These are Grade 1 (low risks, clean field), Grade 2 (comorbidities or prior wound infection) and Grade 3 (contaminated or infected field), and the grade guides risk assessment in primary ventral hernia repair (Kanters AE et al., 2012).

3. Current practice

There is no single national care pathway for hernia repair. The management of primary ventral hernias in the NHS is informed by guidelines from European Hernia Society, American Hernia Society and local clinical commissioning policies. British Hernia Society (BHS) signposts to the guidelines developed by European Hernia Society and American Hernia Society. The relevant guidelines are:

Guidelines for treatment of primary ventral hernia in rare locations or special circumstances from the European Hernia Society and Americas Hernia Society, 2019.

Guidelines for treatment of umbilical and epigastric hernias from the European Hernia Society and Americas Hernia Society, 2019.

Updated Guidelines for laparoscopic treatment of ventral and incisional abdominal wall hernias from the International Endohernia Society (IEHS), 2019.

Guidelines for Laparoscopic Ventral Hernia Repair from the SAGES Guidelines Committee, 2016.

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NICE has not published any guidance on primary ventral hernia repair.

3.1 Referral

People with suspected primary ventral hernia are referred from primary care to secondary care based on symptoms, perceived risk of hernia and concerns about complications such as incarceration or strangulation. In secondary care, if a hernia is symptomatic (causing pain, discomfort or limiting normal daily activities), an elective surgical referral is made. If there are signs of strangulation or incarceration, then an emergency referral is made for surgical assessment. Asymptomatic or minimally symptomatic hernias may be managed with watchful waiting without surgical assessment.

3.2 Diagnosis

Diagnosis is based on history and physical examination. Imaging typically using CT scan or ultrasound is used if there is no palpable hernia (an atypical presentation), as well as in people with obesity, to accurately determine the treatment plan. Diagnosis also assesses the size and location of hernia. Surgeons commonly use the European Hernia Society classification of primary ventral hernia to classify by location and size to aid treatment planning.

3.3 Treatment

For symptomatic primary ventral hernias, surgical repair is the definitive treatment. Prior to surgery, people with modifiable risk factors such as obesity, smoking or comorbidities are offered preoperative optimisation to improve wound healing and minimise recurrence risk.

Surgery can be laparoscopic, robotic or open. The choice depends on size and location of the hernia, individual's health status and comorbidities. Except for small hernias (1cm to 2cm), most primary ventral hernia repairs require mesh reinforcement to reduce the risk of hernia recurrence. According to clinical experts, permanent synthetic mesh, typically polypropylene, is the

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most commonly used type of mesh for this repair. The choice of mesh and its anatomical placement are determined by the risk of contamination and patient related factors. Common mesh placement technique includes: onlay (mesh is placed on top of the abdominal muscle, just beneath the skin), retromuscular or preperitoneal (mesh is placed behind the muscle but outside the abdominal cavity) and intraperitoneal (mesh is placed inside the abdominal cavity, directly against the peritoneal lining).

3.4 Current NHS market for the technologies

Surgical meshes are primarily purchased through NHS Supply Chain surgical mesh framework agreement, under medical and surgical consumables. At present, there are 21 suppliers on the NHS Supply Chain framework offering 3 categories of mesh: synthetic, biological and specialist mesh, with more than 1,100 products available. The framework offers a National Pricing Matric to facilitate discounted pricing based on value or volume commitments with 8 suppliers currently offering this commitment. The current framework reflects a competitive market with two new suppliers entering and four suppliers being delisted at the start of the new framework agreement.

NHS Supply Chain information indicates that the pricing of mesh varies widely based on material types and marketed benefits. For example, inclusive of 20% VAT, a synthetic hybrid or synthetic shaped mesh can range from less than £100 to approximately £10,000 depending on the factors such as shape, size, thickness, absorbable versus non-absorbable components, with or without reinforcement, and other design features. Biological meshes are more expensive and prices can range from less than £200 to approximately £19,000, similarly influenced by shape, size and other features of the products.

Based on expert advice, about 70% of mesh procurement goes through the NHS Supply Chain, while 30% is purchased independently by NHS Trusts by securing their own deals directly with manufacturers, often leading to a default choice based on cost-saving deals.

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4. The technologies

This section describes the purpose and features of surgical meshes based on information provided to NICE by manufacturers and experts, and publicly available information. NICE has not carried out an independent evaluation of these descriptions.

4.1 Purpose of the technologies

NHS Supply Chain defines surgical mesh as a woven sheet which is used as either a permanent or temporary support for organs and other tissues during surgery. In hernia repair, surgical mesh is used to reinforce weak tissue and lower recurrence rates. When implanted, the mesh acts as a support structure, promoting tissue ingrowth that integrates it into the body's internal scar tissue, providing long-term structural support. Based on source of material used, mesh can be broadly categorised into:

- Synthetic: Made from polymer materials and broadly categorised into:
    - Permanent synthetic meshes composed of non-absorbable polymers such as polypropylene (PP), polyester, polytetrafluoroethylene (PTFE) and expanded polytetrafluoroethylene (ePTFE). Permanent synthetic meshes are most commonly used in clean wounds and elective hernia repairs due to their ability to provide long-term strength. These non-absorbable meshes remain in the body indefinitely and offer permanent mechanical strength. However, their use may be associated with complications such as chronic pain, infection, adhesions, and fistula formation
    - Absorbable synthetic meshes are newer generation of synthetic mesh that is made of polymers such as polyglycolic acid, polyglactin and polydioxanone (PDO). These meshes degrade over time and provide temporary support. They are often considered in contaminated or high-risk surgical fields where permanent mesh implantation may not be appropriate. This category also includes biosynthetic mesh which is a

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slowly absorbable synthetic mesh which integrates into tissues over 6 to 18 months.

- Composite meshes combines two or more materials, most commonly a synthetic polymer (such as polypropylene, polyester, or polytetrafluoroethylene) with range of additional components or coatings, including absorbable barriers (e.g. monocryl), anti-adhesive substances (e.g. hyaluronate), or surface coatings such as titanium.

Within these categories, further distinctions exist based on mesh weight (heavyweight, midweight and lightweight), pore size (macroporous versus microporous) and filament type (monofilament versus multifilament).

- Biological: Derived from animal (commonly bovine or porcine) or human tissues. The tissue undergoes decellularisation to remove all the living cells, leaving a natural extracellular matrix scaffold. Often used in complex hernia repairs and contaminated surgical fields where synthetic mesh may pose a higher risk of complications such as infection, or reaction against foreign body. However, it can have exhibit variable resorption and a potential for increased hernia recurrence.

- Hybrid: Combines synthetic polymers such as polypropylene for long-term strength with biological materials such as collagen or extracellular matrix to promote tissue growth and reduce inflammation.

4.2 Basic technology requirements

Mesh design has evolved over time, with adjustments in weight, pore size, and material composition leading to a wide variety of available options. For example, lightweight meshes with large pores were developed to minimise excessive scar formation while maintaining sufficient strength repair (Brown CN et al., 2010). More recently, biosynthetic meshes have been introduced to address the limitations and complications associated with both synthetic and biological mesh.

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For this evaluation, a “benchmark” mesh will be used, for innovative features of mesh to be identified in comparison to it. Basic requirements of this benchmark mesh include:

- Weight: Characterised by mesh material weight per unit area (g/m2). For example, synthetic mesh can be classified as ultra-lightweight (less than 35 g/m2), lightweight (35 to less than 70 g/m2, standard (70 to less than 140 g/m2), or heavyweight (140 g/m2 or greater) (Coda A et al., 2012).
- Tensile strength: Mesh must be able to withstand physiological abdominal wall pressure of at least 180mm Hg without failure. In the case of permanent mesh, it should maintain long-term structural integrity.
- Filament structure: For example, synthetic meshes can be monofilament consisting of a single continuous fibre, or multifilament composed of multiple fibres woven or twisted together.
- Porosity: Large pore sizes typically promote improved soft tissue ingrowth and greater flexibility by reducing granuloma bridging. Permanent synthetic meshes are most commonly macroporous, with pore sizes greater than 75 microns, allowing infiltration by macrophages, fibroblasts, blood vessels and collagen. Microporous meshes, such as those made from expanded polytetrafluoroethylene (ePTFE), have pore sizes less than 10 microns and permit minimal tissue ingrowth.
- Elasticity: Mesh should have sufficient elasticity to accommodate abdominal wall dynamics. Lightweight meshes demonstrate 20-35% elasticity at 16 N/cm. Heavyweight meshes generally exhibit lower elasticity, approximately 4 -16% at 16 N/cm.
- Biocompatibility: Mesh must be chemically stable. While the body will recognise it as a foreign material, the material should not cause an excessive toxic or allergic reaction.
- Resistance to material degradation: Meshes should be resistant to shrinkage. In the case of permanent meshes, they must not break down over decades. Most standard permanent synthetic meshes are hydrophobic in nature.

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4.3 Innovative aspects

Surgical mesh would typically be classified as potential incremental innovations, continuous improvements or copycat devices under the Department of Health and Social Care's medical technology innovation classification framework. Manufactures tend to add in innovations that fall into category of incremental improvement rather than fundamentally changing mechanism of action.

Additional or innovative features include:

- Radiopaque markers for postoperative visibility.
- Long term durability or ageing resistance.
- Better biocompatibility (integration with host tissue, providing long-term support without excessive inflammation, fibrosis, or allergic responses).
- Enhanced cellular adhesion behaviour.
- Structural or mechanical innovation such as dynamometric elasticity, positional stability.
- Use of advanced materials and biochemical engineering such as polyvinylidene fluoride (PVDF), titanium-coated polypropylene, tailored resorbability.
- Optimised textile engineering such as advanced pore size, knit patterns and filament structure to improve integration and flexibility.
- Infection or safety innovation such as antimicrobial surfaces.
- Advance surface engineering such as anti-adhesive, self-gripping, thin film or nanocoating technology.
- Extra-lightweight construction.

It is important to note that the features and potential innovations listed in this section are not exhaustive and other distinguishing or innovative features may be identified for assessment.

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5. Comparator

The comparator for this assessment is surgical mesh that meets basic technology requirements (see section 4.2 of the scope) but does not have additional or innovative features. Permanent synthetic mesh is the most commonly used type of mesh for primary ventral hernia repair. Other comparators will be considered relevant to the assessment if the value of innovative features is able to be assessed.

6. Patient and healthcare professional preferences

People who undergo hernia repair value shared decision making and clear information about mesh options. Most expect their surgeons to explain the benefits and risks of various types of mesh before their operation (East B et al., 2021). Evidence suggests that perception about mesh is influenced by media coverage, with more negative attitudes observed among individuals with higher media exposure (Miller M.P. et al., 2019, AlMarzooqi R et al., 2020). Positive views on mesh safety are more common among men, people with higher socioeconomic status, and those with personal experience of mesh repair, while aversion is more frequently reported by women and by individuals who have heard about mesh-related complications, wound problems, or chronic pain (AlMarzooqi R et al., 2020, Elhage SA et al., 2021). Patients conducting their own research were also likely to report concerns about mesh safety and outcomes (Elhage SA et al., 2021).

In submissions made by people with lived experience, individuals also emphasised the importance of clear communication and informed consent throughout the care pathway, including accessible information on mesh type, surgical approach, risks, recovery, and long-term outcomes. Confidence in the surgeon's judgement, effective pain management, physiotherapy support, and appropriate postoperative follow-up were seen as essential to recovery and quality of life. The need for acceptable waiting times, good preoperative

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preparation, accurate documentation, and meaningful choice in treatment options were also highlighted.

Healthcare professionals, mostly surgeons, make the choice about mesh product. This is based on the individual's medical history, risk factors, hernia size, wound contamination, mesh features and its suitability for the selected surgical approach, anatomical location and availability of evidence. Factors related to the individual surgeon such as familiarity with specific mesh products, level of expertise, training background and access to training for newer mesh products can further influence mesh selection. Additionally, the range of meshes available to surgeons may be limited by local policies, procurement arrangements, and cost considerations.

7. Potential equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with protected characteristics (Equality Act 2010) and others.

Access to specialist hernia services can vary by region leading to differences in waiting time and treatment options. People living in the most deprived areas are more than twice as likely to experience wait of over a year for elective surgery compared with those in the least deprived areas (Jefferies D, 2023). People from more deprived socioeconomic groups are also more likely to have comorbidities such as obesity, smoking, or diabetes (Madigan CD et al.,2025), which may delay surgery due to preoperative optimisation requirements and impact surgical outcomes.

The choice of surgical mesh can be influenced not only by clinical factors but also by the procurement policies of local Integrated Care Bodies (ICB) and individual NHS Trusts. Access to specialised or higher cost meshes may be restricted to centres where these products are included in procurement agreements. As a result, individuals with the same diagnosis and clinical need treated in different geographical areas may be offered different mesh options

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based on local purchasing decisions rather than clinical need. This variation in access can contribute towards regional disparities in care and healthcare inequality.

Additionally, biological meshes derived from animals may raise cultural, religious or ethical concerns if the source of mesh is not disclosed. People may potentially avoid animal derived meshes due to cultural or religious beliefs (Koshy RM et al., 2020).

Evidence also suggests that women report worse quality of life and higher level of pain one year after hernia repair (EK Arhos et al., 2024). They are also at greater risk of postoperative complication after hernia repair compared to men (Schoel LJ et al., 2025). For women of childbearing age, elective hernia repair is generally recommended after completion of last pregnancy, because pregnancy can increase the risk of hernia recurrence. Additionally, hormonal changes associated with menopause may affect connective tissue, wound healing and abdominal wall strength, potentially influencing postoperative outcomes.

Furthermore, people with visual or hearing difficulties, cognitive impairment, problems with manual dexterity, a learning disability, people who are unable to read or understand health-related information (including people who cannot read English), or neurodivergent people may need additional support to understand information about mesh types, benefits and risks of different available options. Mental health concerns, including anxiety about mesh safety may also influence individual's ability to engage in shared decision making for hernia repair.

8. Guidance type

The surgical mesh for ventral hernias is proposed to be assessed for existing use. This approach to guidance development is proposed because:

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- the assessed group of technologies (interventions) comprise similar technologies, at least some of which would be considered established practice in the NHS (NICE HealthTech programme manual provides more detail on how established practice is determined)
- the technologies are potential incremental innovations, continuous improvements or copycat devices, as defined by the Department of Health and Social Care's medical technology innovation classification framework
- there is likely to be variation in price between alternative technologies in the assessed group of technologies.

9. Decision problem

The key decision questions for this assessment are:

- Do differences in clinical and cost-effectiveness between alternative surgical meshes justify price variation?
- Are there other factors that can inform decisions about which surgical mesh to purchase?

Table 2: Decision problem

Proposed type of assessment	Existing use
Population	Use of surgical mesh for primary ventral hernia repair in adults.
Interventions	Surgical mesh for ventral hernia available for purchase in the NHS including: • Synthetic mesh • Biological mesh • Hybrid mesh These surgical meshes should meet basic technology requirements and have one or more additional or innovative features.
Comparator	Surgical mesh that meets basic technology requirements but does not have innovative features.
Setting	Secondary care setting

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Outcomes and costs (may include but are not limited to)	Intermediate outcomes:
	• Postoperative pain
	• Postoperative complications
	• Readmission within 30 to 90 days
	• Time to return to normal activities
	
	Clinical outcomes:
	• Surgical site occurrence (SSO)
	  - Surgical site infection
	  - Seroma
	  - Hematoma
	  - Wound dehiscence
	  - Skin or soft tissue necrosis
	  - Cellulitis
	  - Chronic wound
	• Hernia recurrence
	• Mesh related complications:
	• Mesh infection
	  - Chronic pain
	  - Chronic foreign body sensation
	  - Mesh migration
	  - Mesh shrinkage or contraction
	  - Mesh failure
	  - Erosion into bowel or other organs
	  - Fistula formation
	  - Adhesion to bowel
	• Long term morbidity
	• Bowel and sexual function
	• Fertility outcomes
	• Reoperation or reintervention
	• Ileus
	• Small bowel obstruction
	
	Patient-reported outcomes:
	• Health-related quality of life
	• Pain and discomfort
	• Anxiety
	• Satisfaction
	• Body image

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	• Cosmetic outcome • Impact on daily life Costs and resource use: • Cost of surgical mesh • Cost of fixation materials • Staff training cost • Imaging cost • Operating room time including staff time and anaesthesia cost • Cost of surgical approach • Hospitalisation and perioperative resource use (length of hospital stay, readmission rates, emergency department visit, medication and postoperative imaging) • Cost of treating mesh related complication including treatment of SSI or SSO, infection, mesh removal, management of adhesion or erosion • Cost of treating recurrence • Monitoring costs and follow-up visits User preference and non-clinical outcome measures will be based on the prioritisation of outcomes as part of the user preference assessment.
Economic analysis	A health economic model will be developed comprising a cost utility or cost-comparison analysis. Costs will be considered from an NHS and Personal Social Services perspective. Sensitivity and scenario analysis should be undertaken to address the relative effect of parameter or structural uncertainty on results. The time horizon should be long enough to reflect all important differences in costs or outcomes between the technologies being compared.

10. Other issues for consideration

10.1 Factors affecting choice of mesh

The choice of mesh used may depend on various patient-related, hernia-related, and surgical factors. Patient factors include the individual's health status, future pregnancy plans, and the presence of comorbidities such as diabetes, smoking status, and Crohn's disease. Hernia characteristics such as

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size, location, and risk of contamination may also affect choice of mesh. Additionally, surgical factors including emergency versus elective repair, and operative technique may influence the selection of mesh for primary ventral hernia repair.

10.2 Evidence

The British Hernia Society maintains a hernia mesh registry, launched in November 2024, which may offer real-world evidence. It aims to collect information on all hernia repairs in the UK (both elective and emergency), including patient-reported outcomes and long term follow up, as well as details of mesh removal procedures.

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