

**DRAFT**  
**Policy for the use of Biological  
Mesh.**

## Document Details:

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<b>Equality &amp; Diversity Impact Assessment</b>	

The CCG policy has been reviewed and developed by the Treatment Policies Clinical Development Group in line with the groups guiding principles which are:

1. CCG Commissioners require clear evidence of clinical effectiveness before NHS resources are invested in the treatment;
2. CCG Commissioner require clear evidence of cost effectiveness before NHS resources are invested in the treatment;
3. The cost of the treatment for this patient and others within any anticipated cohort is a relevant factor;
4. CCG Commissioners will consider the extent to which the individual or patient group will gain a benefit from the treatment;
5. CCG Commissioners will balance the needs of each individual against the benefit which could be gained by alternative investment possibilities to meet the needs of the community
6. CCG Commissioners will consider all relevant national standards and take into account all proper and authoritative guidance;
7. Where a treatment is approved CCG Commissioners will respect patient choice as to where a treatment is delivered; AND
8. All policy decisions are considered within the wider constraints of the CCG's legally responsibility to remain fiscally responsible.

## Category: Not Routinely Commissioned

### Surgical Mesh

Surgical mesh is a screen-like material that is used as a reinforcement for tissue or bone. It can be made of synthetic polymers or biopolymers.

Materials used for surgical mesh include:

- **Non-absorbable synthetic polymers** (polypropylene)
- **Absorbable synthetic polymers** (polyglycolic acid or polycaprolactone)
- **Biologic** (acellular collagen sourced from cows or pigs)
- **Composite** (a combination of any of the three previous materials)

Mesh implants may be used in a number of surgical procedures to provide additional support when repairing weakened or damaged tissue.

Over recent years attention has increased on complications that can occur with the use of this mesh in urogynaecological procedures to treat pelvic organ prolapse (POP) and stress urinary incontinence (SUI). These complications can include persistent pain, sexual problems, mesh exposure through vaginal tissues and occasionally injury to nearby organs, such as the bladder or bowel. There has been an acknowledgement from the NHS England mesh working group that there is a lack of comprehensive data on these complications. Work is ongoing to ensure that patients are encouraged to report complications and clinicians report adverse events.

Currently, the use of mesh in urogynaecological procedures to treat pelvic organ prolapse and stress urinary incontinence is not supported wider NHS review of the use of mesh means that at the current time the CCG does not support the use of mesh implants in these clinical circumstances.

However, surgical mesh implants (non-biological mesh) are routinely used across the NHS to address the clinical problem of hernia. These implants typically restore structural domain to the abdominal/pelvic wall and prevent extrusion of visceral contents. Surgery takes place either as an open or laparoscopic procedure.

#### Open surgery

The surgeon makes a single cut (incision) over the hernia. This incision is usually about 6 to 8cm long. The surgeon then places the lump of fatty tissue or loop of bowel back into your abdomen (tummy). A mesh is placed in the abdominal wall, at the weak spot where the hernia came through, to strengthen it. When the repair is complete, your skin will be sealed

with stitches. These usually dissolve on their own over the course of a few days after the operation.

If the hernia has become strangulated and part of the bowel is damaged, the affected segment may need to be removed and the 2 ends of healthy bowel rejoined. This is a bigger operation and you may need to stay in hospital for 4 to 5 days.

### Laparoscopic (keyhole) surgery

During keyhole surgery, the surgeon usually makes 3 small incisions in your abdomen instead of a single larger incision. A thin tube containing a light source and a camera (laparoscope) is inserted through one of these incisions so the surgeon can see inside your abdomen. Special surgical instruments are inserted through the other incisions so the surgeon can pull the hernia back into place.

There are 2 types of keyhole surgery.

1. Transabdominal preperitoneal (TAPP)

Instruments are inserted through the muscle wall of your abdomen and through the lining covering your organs (the peritoneum).

A flap of the peritoneum is then peeled back over the hernia and a piece of mesh is stapled or glued to the weakened area in your abdomen wall to strengthen it.

2. Totally extraperitoneal (TEP)

This is the newest keyhole technique and involves repairing the hernia without entering the peritoneal cavity.

Once the repair is complete, the incisions in your skin are sealed with stitches or surgical glue.

## Evidence Review

A review of the clinical evidence found mixed clinical review, with no strong basis for the use of biological mesh over standard mesh. Standard of the evidence reviewed comprised mainly of retrospective studies of low to moderate quality, but with hernia reoccurrence being higher following the use of biological mesh, but no significant difference was determined in the occurrence of wound and mesh infection. Therefore, in light of the currently available low quality evidence, to support the use of biological mesh over standard mesh, the use of biological mesh is not routinely commissioned.

## Eligibility Criteria

**Due to the currently available low quality evidence, to support the use of biological mesh over standard mesh, the use of biological mesh is not routinely commissioned.**

This means **(for patients who DO NOT meet the above criteria )** the CCG will **only** fund the treatment if an Individual Funding Request (IFR) application proves exceptional clinical need and that is supported by the CCG.

## Guidance

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