Health and Social Care

Vaginal Mesh

Frequently Asked Questions

1) **What conditions is vaginal mesh used to commonly treat?**

Vaginal mesh is used to treat **two different** health issues in women:

a) **stress urinary incontinence (SUI)**

The first is **stress urinary incontinence** (where urine leaks involuntarily from the bladder when coughing or running for example). A tension free **vaginal tape**, (also known as **sling**), usually made from **mesh** (a type of plastic), is used to support the water pipe (urethra) to prevent urine leaking from the bladder. Tapes are one of a number of surgical options to treat stress urinary incontinence recommended in the UK by NICE.

b) **pelvic organ prolapse (POP)**

The second is **pelvic organ prolapse** (a protrusion or feeling of something coming down through the vagina). A **vaginal mesh repair** for prolapse is when a **mesh** is inserted into the vagina to reinforce weak vaginal tissues and surrounding muscles.

Vaginal mesh repair is no longer recommended by NICE for routine surgery for pelvic organ prolapse due to an unacceptably high complication rate. It was not commonly used at any time in NI and has not been used in the last 2 years.

2) **Is there a difference between using mesh to treat stress urinary incontinence and pelvic organ prolapse?**

The same material (**Type 1 polypropylene mesh**) is used for both, but the operations are very different in the method and site of mesh placement, amount of mesh used and complication risks.

The amount of mesh used in a tape operation for stress urinary incontinence is much less than in vaginal mesh operations for prolapse. The risk of serious complications during insertion and after the operation is much higher with vaginal mesh for prolapse repairs than with tapes used to treat stress urinary incontinence.

The differences in complications mean that ***vaginally*** **placed mesh is no longer recommended by NICE in the treatment of pelvic organ prolapse**. It was not commonly used at any time in NI and has not been used in the last 2 years.

Mesh *tapes* for stress urinary incontinence and *abdominally* placed mesh for prolapse are still used in the UK in line with NICE recommendations. The abdominal mesh operation (sacrocolpopexy) for prolapse has been used for decades.

3) What are the different types of mesh procedures to treat stress urinary incontinence?

There are two types of tape to treat stress urinary incontinence with two different routes of insertion:

a. ***Retropubic tape*** – a mesh tape is introduced through a 1cm incision in the vagina, passed on either side of the urethra as a hammock and exits through the skin either side of the midline above the pubic hair line.
b. ***Transobturator tape*** – a mesh tape is introduced through a 1cm incision in the vagina, passed on either side of the urethra as a hammock and exits through the skin of the right and left inner thighs.

4) Are people still being treated with mesh for stress urinary incontinence?

Retropubic tape remains a safe and effective treatment option for women with stress urinary incontinence, so long as they are fully informed of the risks and complications and offered a 'non-mesh' alternative procedure such as colposuspension, autologous fascial sling or urethral bulking injections, all of which have their own risks and complications. Transobturator tape is more likely to cause long term pain and is less commonly used.

5) What are the different types of mesh procedures to repair pelvic organ prolapse?

a. ***Vaginally placed mesh*** – a sheet of plastic mesh is placed in the vagina to support weakened tissues. This may be inserted on the front or back wall of the vagina and is sometimes anchored to strong ligaments in the pelvis. These operations are no longer recommended by NICE for use in the UK.

b. ***Abdominally placed mesh*** – mesh can be used from above through the abdomen, rather than through the vagina, to pull up the vagina (sacrocolpopexy) or womb (sacrohysteropexy) toward the backbone to treat pelvic organ proplapse. The complication rate has been found to be lower than with vaginally placed mesh and these procedures are still performed in the UK line with NICE recommendations.

6) **How many mesh procedures have been carried out in Northern Ireland and how many have had complications?**

Between 2007 and 2015 in Northern Ireland, 5,255 women had tapes inserted for stress urinary incontinence, and there were 200 tape removals (3.8%).

Routinely available information tends to lag behind changes in clinical practice, and our information systems do not accurately differentiate between all types of mesh removal, making it difficult to give accurate figures for every kind of procedure. Most of the tape 'removals' will have been partial rather than total mesh removals.

There were 409 vaginal mesh implants for prolapse during the same period. We do not hold data for the removal of mesh implants for prolapse, because this is an emerging issue and we only started to collect data on it in 2017.

Vaginal mesh repair as opposed to abdominally placed mesh is no longer recommended by NICE for routine surgery for pelvic organ prolapse. It was not commonly used at any time in NI and has not been used in the last 2 years.

7) **How many women in Northern Ireland are likely to be affected by this?**

Several thousand operations using vaginal tapes and mesh have been performed in Northern Ireland, and most of these women are doing well with good results from their surgery. A small number of women experience problems immediately after the procedure, while others may do so many years later. All surgical procedures inherently carry risks, and these can vary depending on a number of factors.

It is therefore impossible to give exact figures, but reasonably accurate estimates tell us that approximately 4% of women having had a tape inserted for urinary incontinence in Northern Ireland have undergone some form of tape removal.

The number of women who have had vaginal mesh insertions for prolapse is a few hundred, and the number of removals is also small, but we cannot count them, because our information systems did not start collecting these data until 2017.

8) **Why has mesh continued to be used here, when the complications have been known for some time?**

All surgical procedures inherently carry risks and these can vary depending on a number of factors.

a) **Stress urinary incontinence**

The mesh complication rate for retropubic and transobturator tape is around 5%, much lower than the complication rate for vaginally placed mesh for prolapse. Some

women deem this level of risk acceptable, when they have been advised about the risks and success rates of 'non-mesh' alternatives. The transobturator tape procedure is more likely to cause long-term pain and is now less commonly performed.

b) Prolapse

In 2011, the United States Federal Drugs Agency recognised that complications from vaginally placed mesh for prolapse are 'not rare'. A number of reports reviewed the available evidence and made recommendations, but did not ban mesh for prolapse.

The PROSPECT study published in 2016 provided robust evidence that vaginal mesh procedures for prolapse do not provide any benefit over alternative operations like abdominal mesh procedures and 'non mesh' alternatives.

It was not commonly used at any time in NI and has not been used in the last 2 years.

9) Does the latest draft NICE guidance mean all mesh operations will be banned?

Some of the latest NICE guidance remains under consultation and refers to vaginally placed mesh used in pelvic organ prolapse and only. It does not suggest a change to existing practice for abdominally placed mesh for prolapse or mesh tape operations for stress urinary incontinence.

Vaginal mesh repair is no longer recommended for routine surgery for pelvic organ prolapse. It was not commonly used at any time in NI and has not been used in the last 2 years.

NICE has other guidance on how patients needing surgery involving mesh should be treated, and health and social care trusts in Northern Ireland follow this guidance.

All health and social care trusts, the Health and Social Care Board, the Public Health Agency and the Department of Health are working together to make better use of the skills and resources we have here through a Northern Ireland wide network to ensure every woman receives the best possible service regardless of where she lives.

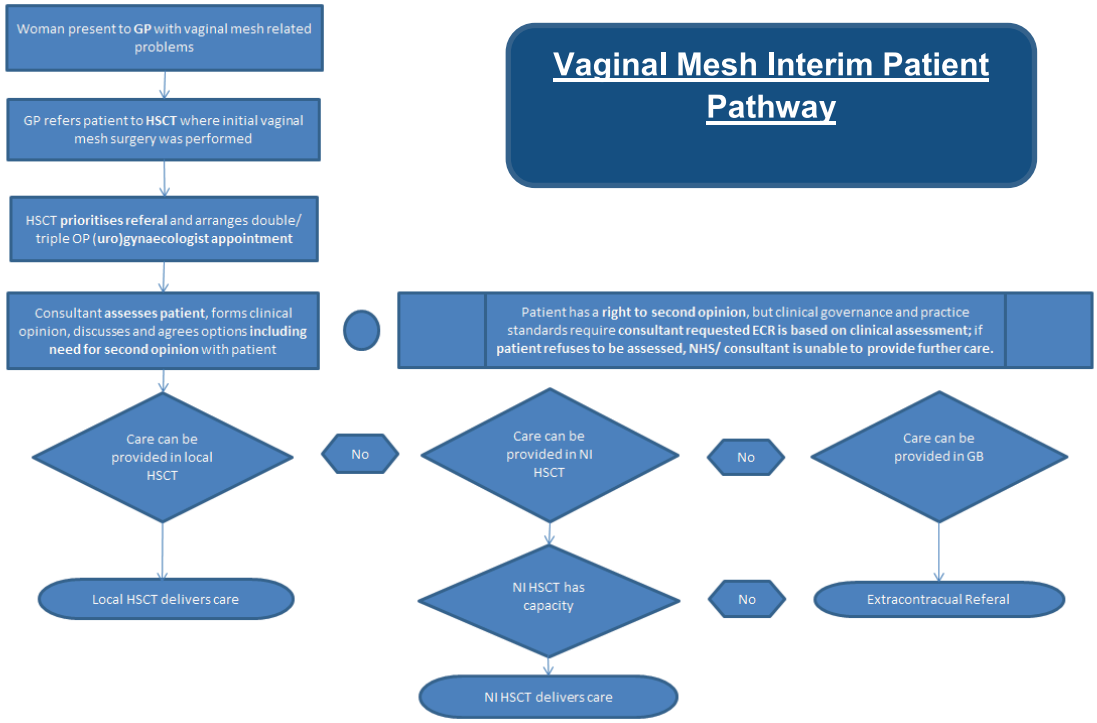
We have asked the Patient Client Council to help us identify women who can assist with this work, after which we will issue a report on our findings.

10) How do I know if I need my mesh removed?

The majority of women who have had any of these procedures do not experience complications. If you are not experiencing problems after your procedure, there is usually no need to do anything.

However, if you are among the small number of women who are experiencing complications, which you think may be caused in part or wholly by mesh, you need to be medically assessed by a consultant with experience in this area. This is available in every health and social care trust in Northern Ireland.

Depending on the outcomes of your assessment, and if a decision is made to remove the mesh, you can be treated in your local health and social care trust, another health and social care trust in Northern Ireland or at a hospital in Great Britain.



11) What does the assessment of whether I need my mesh removed or not involve?

The consultant will ask you about the problems you have and will review your medical record to get a full understanding of what has happened in the past. You need to be examined and, depending on the findings, tests will be done.

These may include keeping a record of your symptoms in a diary or on a chart, urine tests, imaging (ultrasound, CT or MRI), cystoscopy (looking into the bladder with a telescope), urodynamics (studying bladder movements) and nerve tests.

The results of these tests are usually discussed by your consultant at a multidisciplinary team meeting with colleagues to consider options for treating you. Based on this, you and your consultant agree next steps.

12) Is translabial ultrasound available in Northern Ireland?

Some consultants in Northern Ireland have used translabial ultrasound. Others are being trained, but equipment needs to be bought to ensure practice here is comparable to other mesh centres in Great Britain. It is another test amongst many available and is unlikely to change the way in which patients are treated.

13) Do we have the expertise in Northern Ireland to remove mesh partially and to remove mesh completely?

There are several specialists working in Northern Ireland health and social care trusts who can remove vaginal mesh.

Cutting or releasing tapes is relatively straightforward and can be done in every health and social care trust after a patient has been assessed and a conclusion reached that this will be the most appropriate procedure.

Partial removal of mesh is more complex but is performed in several Northern Ireland health and social care trusts by specialists who work with one another to achieve the best possible result for each patient.

Total mesh removal has been performed for a small number of women in Northern Ireland. Further expertise in total mesh removal is currently being developed in Northern Ireland, as it is in other mesh centres in the UK.

Northern Ireland now has a unit recognised by the Royal College of Obstetrics and Gynaecologists, which is able to see and treat women with mesh-related problems. This mesh centre has a multidisciplinary team (MDT) of experts in pelvic floor problems, who provide assessment and management of mesh complications and recurrent urinary incontinence. This team of specialists, nurses, physiotherapists and psychologists can provide a Northern Ireland-wide service including complex mesh removals and non-mesh surgical treatments for urinary and faecal incontinence.

We are developing a regional network and specialists from each health and social care trust contributes to it. The pathways of care are being developed to ensure that women in Northern Ireland have access to the most appropriate treatment for their condition either at their local hospital or at the mesh centre. More information about the mesh centre is available here: http://bsug.org.uk/budcms/includes/kcfinder/upload/files/Units%20with%20completed%20returns%20MASTER%20DEC%202017.pdf

14) What are the different types of mesh removal?

The type of mesh removal depends on the **reason for removing the mesh and type of complication**. Some operations for removal involve a **minor procedure** (revision, trimming, partial or release of tape) and others are more **complex operations** (complete removal/ partial removal of eroded mesh).

The most common reason for revision or removal of mesh is mesh that has eroded into the vagina and less commonly for removal of a tight tape, which protrudes into the vagina leading to painful sex or vaginal pain. On rare occasions, mesh can erode into a neighbouring organ such as the urethra, bladder or bowel, which makes removal necessary. There are different types of 'removal':

a. If a patient is unable to empty the bladder after a mesh tape has been used to treat stress urinary incontinence, it can be **cut or released** to reduce tension without removing any of it.
b. If a small piece of mesh has eroded into the vagina, the exposed part can be **trimmed or partially removed**. This is a simple day case procedure, which may be done under local or general anaesthesia.
c. If a piece of mesh has eroded into the urethra or bladder, then that part is removed **(partial / total removal of eroded mesh)**, which may involve complex surgery and the need for further operations.
d. In rare cases of long term pain, **complete removal of the vaginal portion of the mesh** may be necessary, and in very rare cases, **total removal of the entire mesh** can be performed. This surgery is very complex and makes up less than 5% of the removals undertaken in mesh centres in the UK. It has its own risks, with little evidence on the benefits of entire mesh removal, so a careful balance needs to be struck between trying to relieve existing problems and the risk of causing new ones.

Removal of vaginal mesh used to treat pelvic organ prolapse is the most technically difficult due to the larger amount of mesh used and its position close to important organs like the urethra, bladder and bowel. This to a lesser degree also applies to total removal of transobturator tape, which can be close to large blood vessels and nerves in the inner thigh, making removal difficult with potentially greater risk of complications. The removal of retropubic tape is technically more straightforward due its position behind the pubic bone.

For all types of removal, the original health problem that the mesh was used to treat might recur or get worse, regardless of whether the mesh is cut, partially or completely removed.

If a patient is in pain, the decision to cut or remove mesh must be considered very carefully and take into account every woman's individual circumstances. There are other causes for pelvic pain in women, many of which are more common than mesh

related ones, and it can be difficult to tell them apart. This is why a good assessment to identify and treat other problems if possible is so important.

15) If mesh is removed, what do you provide to replace it to ensure women are treated adequately for their original problem?

If the mesh was used to treat incontinence, and this recurs after mesh removal surgery, a 'non-mesh' operation may be offered such as colposuspension, fascial sling or urethral bulking injection, but each of these carries its own risks. Such surgery may be performed at the same time as the mesh removal or later.

If the mesh was used to treat prolapse, and this recurs after mesh removal, a hysterectomy or native tissue repair may be offered, or a non-surgical approach using a vaginal pessary may be an option.

Other non-surgical options include pelvic floor muscle exercises, which are effective and avoid the need for surgery in many women, especially if supervised by a physiotherapist, and weight loss for overweight women with stress urinary incontinence. Medication can also help, and some women might prefer to do nothing other than use incontinence pants or pads.

16) How often have surgeons been brought over from England to perform removals here?

No surgeons have been brought over from England to perform removals here, but surgeons from Northern Ireland have observed colleagues at work in England and are now reassured that the same level of expertise is available here to offer women the same level of service here as anywhere else in the UK.

It is likely that in future surgeons from England may visit their colleagues here to exchange examples of good practice and experiences of mutual benefit and to continually improve practice. Such UK wide collaborations are commonly used in many areas of clinical practice to continually improve services here and elsewhere.

17) What is an ECR?

An Extra Contractual Referral (ECR) becomes necessary when the Health and Social Care Board approves a consultant's request to transfer a patient temporarily to a colleague outside Northern Ireland for a second opinion, assessment or treatment, which the consultant considers necessary, but which is not available here.

This is normally to a service provider in Great Britain, but very rarely may also be outside the UK, where this is clinically justified.

Northern Ireland has a smaller number of people than many cities in Great Britain, so ECRs are made for a variety of patients and procedures. The process needs to work quickly, because many of these patients are very ill, but when patients are referred for a procedure that is clinically not as urgent, they join the waiting list of the consultant abroad in the same way as they would do here.

18) How many women have travelled to England to have their mesh removed?

Since June 2017, six ECRs made by consultants in Northern Ireland for women with mesh related problems living here have been approved. Our records indicate that none of these women have travelled to England yet, although we do not have information on patients who decide to travel and pay for treatment privately to avoid waiting lists.

19) If women want their mesh removed, how long will they have to wait for the procedure?

Women waiting for mesh-related and other gynaecological operations will be treated depending on how urgent the operation is and when they went on the waiting list. This applies in Northern Ireland as it does in Great Britain.

20) Are women who are affected by this being offered counselling and other support aside from surgery?

Those women needing support will be offered it either by their GP, their gynaecologists or by other members of the multidisciplinary teams that exist in every health and social care trust.

21) What are you doing for men who have experienced pain from mesh surgery?

Complications after mesh surgery in men are not often caused by the mesh itself, because it is used very differently in women compared with men. Surgery in men is usually done close to the surface of the body to strengthen the abdominal wall or other superficial structures. This makes it more straightforward and less likely to interfere with how the body functions after surgery. Any men who have problems after mesh surgery should consult with their GP and be directed to the health and social care trust where the surgery was performed if this is necessary to get the appropriate care and treatment.