



Patient
Label

Synthetic Vaginal Mesh Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women

PATIENT INFORMATION LEAFLET

About this leaflet:

This leaflet gives you detailed information about the operation being proposed and its alternatives. It includes advice from Scottish consensus panels, the relevant national organisations and other evidence-based sources, for example the Cochrane Collaboration and National Institute of Health and Clinical Excellence. It is, therefore, a reflection of best practice in the UK. The information is intended to supplement any advice you may already have been given by your GP or surgeon.

Please take your time to read it carefully, write down any questions and expectations on page 15, and discuss with your surgeon before you sign the Information Checklist on page 16.

Acknowledgement:

This leaflet contains information based on original booklets developed by The Scottish Government Working Group with input from representatives of the British Association of Urological Surgeons (BAUS), the Royal College of Obstetricians and Gynaecologists (RCOG), the Pelvic, Obstetric and Gynaecological Physiotherapy Professional Network of the Chartered Society of Physiotherapy, and patient support groups, with reference to national guidance.

Disclaimer:

The authors cannot be held responsible for errors or any consequences arising from the use of the information contained. As current evidence is incomplete and further evidence will be available in due course, the UK Mesh Working Group will review and consider updating this leaflet every two years. Please make sure you are reading the latest document.

Contents	Page
Explanation of Terms	4
What is Stress Urinary Incontinence?	5
What is Synthetic Vaginal Mesh Tape Procedure?	5
Alternative Options	8
Possible Risks of the Procedure	9
Useful Resources	14
Questions to my Surgeon	15
My Expectations from Surgery	15
Information Checklist	16

Explanation of Terms:

Catheter: temporary flexible tube which drains urine from the bladder following surgery.

Catheterise: to insert a catheter to drain urine from the bladder following surgery.

Fascia: A sheet of supporting fibrous tissue that holds body organs in their correct positions.

Mesh: A net-like fabric with open spaces or interstices between the strands of the net. It is a permanent implant usually made from the non-absorbable polypropylene (prolene) material.

Mesh erosion: An adverse event where mesh erodes into the bladder, urethra or bowel.

Mesh exposure: An adverse event where mesh is partly exposed inside the vagina.

Pessary: A removable device placed inside the vagina to support the pelvic organs.

Retropubic: This describes the space behind the pubic bone and in front of the bladder (the retropubic space); this is the route of tape passage in the most common form of mesh tape procedure.

Transobturator: This refers to an opening in the bones of the pelvis (the obturator foramen); this is the route of tape passage in an alternative form of mid-urethral tape procedure.

Tape: A tape is a permanent implant. It is a flat strip of mesh made from a synthetic material (polypropylene) that is surgically inserted for the management of stress urinary incontinence.

The word 'tape' in this leaflet will be used to refer to polypropylene (prolene) mesh tape.

Trocar: A pointed surgical instrument used to insert a material implant into the body.

Urethra: The water-pipe from the bladder to the outside.

What is Stress Urinary Incontinence?

Your bladder and urethra are supported by your pelvic floor muscles and ligaments. If this support is weakened, urine leaks with coughing, sneezing, laughing or with lifting and exercising.

What is the Synthetic Vaginal Mesh Tape Procedure?

This operation involves placing a piece of synthetic mesh material, like a sling, under your urethra to support it.

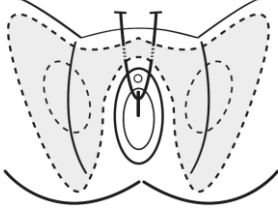
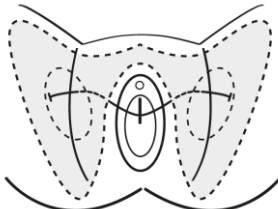
Intended benefits

- The main intended benefit of the tape procedure is to cure or improve stress urinary incontinence.
- Published studies have shown similar success results in curing or improving stress urinary incontinence to those gained by more traditional non-tape surgical procedures.
- The procedure is not intended to improve symptoms of an overactive bladder (urinary frequency, urgency, urgency incontinence or waking up at night to pass urine). This is a different condition that sometimes may improve following this type of surgery and sometimes may worsen.

During the procedure

- This is a relatively short operation and many patients go home the same day. You will be given a general, spinal or local anaesthetic and/or sedation. The type of anaesthesia will be discussed by your anaesthetist/surgeon and depends on the nature of your surgery, your health as well as your wishes.
- A synthetic mesh tape is inserted through a small (1-2 cm) cut in the vagina, to support the urethra (see table). The surgeon then makes 2 smaller cuts just above the pubic area (during a *retropubic* procedure) or on the inside of both thighs (during a *transobturator* procedure) and passes the synthetic mesh tape through them. The *single-incision** short mesh sling procedure is similar to the transobturator tape but there are no cuts outside the vagina. This procedure uses plastic anchors that can be very difficult to remove and *should be used only within a research setting*. All mesh tapes are meant to remain in place permanently, i.e. remain inside the body for life.
- A cystoscopy (telescopic examination of the bladder) will be performed.

There are two main types of vaginal mesh tape procedures commonly used for urinary incontinence:

Comparison	Retropubic tape	Transobturator tape
		
Outside cuts	2 small cuts in the lower abdomen above the pubic bone (Retropubic / TVT)	2 small cuts in the groin area (Transobturator / TVT-O/TOT)
Success Rate	Better evidence of long - term success rates	Similar success rate in the short and medium-term. Long term data (5 years and beyond) are awaited*.
Bladder injury** during surgery	Higher risk*	Lower risk*
Bladder emptying problems	Higher risk*	Lower risk*
Long-term pelvic pain	Lower risk*	Higher risk*

*Please see below for details of the risks and complications

**Trocars are required during surgery to insert the mesh tape. Organ damage, see risks table below, can happen due to the use of trocars.

There may be clinical reasons why your doctor recommends one method over the other. To enable a decision to be made, a multi-disciplinary team of health professionals will consider all relevant issues including your previous surgical history and your own wishes, in guiding the shared-decision with your surgeon.

Transobturator procedures are not routinely offered in Scotland. It is to be offered only if the patient condition suggests that the retropubic procedure is not possible. Such recommendation applies only to clinical practice in Scotland.

After the procedure

The first few hours:

- You will be taken back to the ward, where the nurses will look after you. Painkillers will be given as required and you may eat and drink shortly after return from theatre.
- You may or may not have a catheter inserted during the operation. After it is removed, your bladder emptying will be checked. This is done by a routine bladder ultrasound scan and once staff are happy that the bladder empties well, most women can go home on the same day. If not, a catheter may need to be re-inserted and used for some time.
- You may have a vaginal gauze pack placed inside the vagina to help control or prevent any bleeding. This will be removed later.

The first few days / weeks*:

- There may be slight vaginal bleeding (like the end of a period) and if you need to wear protection, use a sanitary pad/liner, not a tampon.
- You should not drive for 24 hours after a general anaesthetic, nor until you are free from the sedative effects of any pain relief.
- There is no restriction on undertaking light activities in a few days, if you feel able to do so, and after a few weeks resume normal activities, if you feel able to do so. More strenuous tasks and heavy lifting should be avoided for six weeks.
- To avoid discomfort during wound healing, you should refrain from sexual intercourse and inserting any creams or devices for six weeks following your procedure, unless recommended by your doctor.
- It is important that you avoid constipation by ensuring you drink plenty of fluid and eat fruit and vegetables. Laxatives may be required to help your bowels work better.
- Return to work will depend on the type of work you do. Please ask your doctor for his/her opinion and if you require a "Fitness for work" certificate.
- It is advisable to continue with the physiotherapy advice you have been given prior to your procedure**.
- A follow-up appointment will usually be made in 2-6 months time (in clinic or by phone).

*For more information on recovery, please ask your doctor for the detailed Recovery Leaflet or visit the following web link: <https://www.rcog.org.uk/en/patients/patient-leaflets/mid-urethal-sling-operation-for-stress-urinary-incontinence/>

**For more information on physiotherapy following your procedure, please ask your doctor or visit the following web link: <http://www.csp.org.uk/sites/files/csp/secure/pogp-ffsurgery1.pdf>

Alternative Options

There are several non-surgical and surgical treatment options for women with stress urinary incontinence.

- **Non-surgical treatment options:**

These options should be discussed with all women prior to considering surgery.

- **Pelvic floor muscle exercises** are the most effective non-surgical treatment. Many women who have undergone training supervised by a physiotherapist will not require surgery.
- **Weight loss** is an effective treatment option for overweight women with stress urinary incontinence. Please discuss further with your GP.
- **Drug treatment** (Duloxetine tablets) may also be a suitable option for some women.
- **Continence pessaries:** These and similar devices placed inside the vagina or urethra may occasionally be useful for managing urine leakage, such as during physical exercise.
- **Absorbent products** such as incontinence pants or pads may provide extra ways of managing urinary problems for some women.
- **Do nothing:** if the leakage is not troublesome, no treatment is an option.

- **Surgical treatment options*:**

If non-surgical treatment options have not been successful or are not appropriate/suitable, the following surgical procedures may be considered as alternatives to the mesh tape procedure described:

- **Colposuspension procedure:** Abdominal operation (open or key-hole) to lift the vagina underneath the water-pipe using permanent synthetic sutures.
- **Natural Tissue Sling procedure:** Abdominal operation (only open) to lift the urethra (waterpipe) using a natural sling (hammock-like) from your own abdominal wall 'fascia'.
- **Biological Tissue Sling procedure:** Uses biological material (of animal origin) instead of polypropylene mesh.
- **Urethral bulking agents:** Vaginal operation where a synthetic 'bulking' material (absorbable or permanent) is injected in or around the water-pipe to improve the seal.

Please ask your doctor about leaflets which cover the details of these options and familiarise yourself with the pros and cons on the following website:

www.nhs.uk/Conditions/Incontinence-urinary/Pages/treatmentoptions.aspx

*Please note your surgeon may not provide all of these procedures and referral to another surgeon or hospital may be required.

Possible Risks of Surgery*:

The tables below are designed to help you understand the risks associated with surgical procedures. The terms used to denote the degree of risk in the main table are explained here:

Term	Number of people	Size of group/area
Very common	1in1 to 1in10	One person in a family
Common	1in10 to 1in100	One person in a street
Uncommon	1in100 to 1in1000	One person in a village
Rare	1in1000 to 1in10 000	One person in a small town
Very rare	1in10 000 and above	One person in a large town

*Based on the RCOG Clinical Governance Advice, Presenting Information on Risk

A. General Risks of Surgery

Any surgical procedure has its risks and potential problems. The following are possible problems that you may experience:

- **Anaesthetic risks:** This is rare unless you have specific medical problems. Death is very rare. Your anaesthetist will discuss with you in detail.
- **Bleeding:** You should expect some vaginal bleeding after the operation. The risk of major bleeding, which is severe enough to need a blood transfusion, is uncommon but it can happen with any operation.
- **Infection:** The risk of infection with any surgery is common, and you will receive antibiotics in theatre to reduce such risk. The vagina is considered a 'clean but not sterile' surgical field which will not be fully clear of bacteria prior to surgery. Despite receiving routine antibiotics, a urine infection is common while a wound infection is uncommon. Serious hospital-acquired infections (e.g. MRSA and Clostridium Difficile) are rare.
- **Deep Vein Thrombosis (DVT):** A clot in the deep veins of the leg. While the overall risk is common (4-5%), the majority pass unnoticed and resolve spontaneously. It is rare for a clot to migrate to the lungs and cause serious problem following an operation that takes only a short time (less than 1% of those who get a clot). However, there have been deaths following such clots and, therefore, special stockings and/or injection to thin the blood are provided to all patients.

B. Specific Complications and Risks of the mesh tape procedure*

Complication	Risk
Mesh exposure (erosion**) in the vagina	Common. The vaginal skin over the tape may not heal properly or get infected. This could also be due to inflammation, foreign body reaction*** or unusual immune response. It can happen years after surgery. Further surgery may be required to cover the tape or to partly remove it (see further notes below).
Recognised damage to the bladder or urethra during the procedure	Common with the retropubic approach (bladder damage). When discovered during the procedure, the trocar / tape is removed and replaced correctly. No long-term problems have been found following this complication. Damage to the urethra is uncommon but may have long term consequences.
Failure of the procedure to stop urine leakage	Common. Persistence or recurrence of urinary leakage after some time. This can happen years after the tape has been inserted even if it cured your symptoms originally. Risk of failure of retropubic and transobturator procedures is similar in the first 3 years but is higher with the latter on the longer term. You may need further surgery for incontinence and success rates may be lower.
Problems with the need to pass water more often than normal or having trouble getting to the toilet in time	Common. Overactive bladder symptoms (urgency) may develop after surgery. These are managed with bladder retraining, physiotherapy and/or drug treatment.
Temporary problems emptying bladder fully	Common. May require short-term home catheterisation (indwelling or intermittent) for a few days or weeks. If necessary you will be offered training on how to self-catheterise.
<i>Temporary</i> pain in the pelvic area or at the site of the tape insertion (the groin area or inner thigh in transobturator procedure) or during sexual intercourse.	Common. Often resolves spontaneously or with painkillers. Referral to physiotherapy or pain management team may be helpful for pain relief.

<p><i>Long-term</i> pain in the pelvic area, at the site of the tape insertion or during sexual intercourse (due to vaginal scarring).</p>	<p>Common with transobturator tape, affecting the groin area and/or inner thigh. Could be due to nerve damage/irritation or muscle spasm following surgery. Referral to physiotherapy or pain management team may be helpful for pain relief.</p> <p>Uncommon with retropubic tape (in the pelvic area).</p> <p>Nerve and musculoskeletal damage and pain could be permanent and severe enough to be debilitating and affect leg movement (the evidence is unknown). Repeat procedures to remove the tape may be necessary (see further notes below).</p> <p>Where pain is experienced during intercourse, physiotherapy can help in the stretching of scar tissue and using ‘trigger-point techniques’ can relieve the pain or referral to a pain management team. Advice can be given regarding care of the vagina after surgery and, if necessary, referral for psychosexual counseling.</p>
<p>Persistent problems emptying bladder fully with recurrent urinary tract infections</p>	<p>Uncommon. May require temporary self-catheterisation or further surgery to release, cut or remove the tape. Urine leakage may return and you may need further surgery. Long term problems requiring self-catheterisation for months/years are rare. If necessary you will be offered training on how to self-catheterise.</p>
<p>Mesh erosion into the urethra or the bladder</p>	<p>Rare and can occur shortly or years after surgery. Could be due to either spontaneous tape displacement long after the procedure or unrecognised damage to the bladder or urethra during the procedure. Requires further surgery to remove the tape (see further notes below).</p>
<p>Injury to other organs such as urethra, bowel and major blood vessels</p>	<p>Rare. An abdominal operation may be necessary to resolve the problem.</p>
<p>Long-term problems emptying bladder fully</p>	<p>Rare. May require long-term self-catheterisation for months/years.</p>
<p>Death</p>	<p>Very rare.</p>

* All mesh-related adverse events are required to be reported to the medical device watchdog, the Medicines and Healthcare products Regulatory Agency (MHRA) through this web-link: <https://yellowcard.mhra.gov.uk/devices/?type=mop>

*The risk levels quoted are those reported in medical literature and confirmed /endorsed by the National Institute of Health and Clinical Excellence. Data from large relevant registries are not yet available at the time of writing this leaflet. **As current evidence is incomplete and further evidence will be available in due course, this booklet will be updated every two years. Please make sure you are reading the up-to-date version.**

**The term 'erosion' is not an accurate description of this complication; however it is the commonly used term for it. Please refer to the explanation of terms at the beginning of the document.

***Foreign body reaction to the mesh material could lead to inflammation, scarring, infection and mesh exposure. This could be due to an unusual immune response; however, there is currently no good evidence to support a link to autoimmune diseases, at the time of writing this document.

Further notes on risks:

- **Risks if the mesh tape is to be removed:**
Repeat procedures may be necessary and, as the mesh tape is meant to be a permanent implant, complete removal may not be possible to do safely. Complete removal of the transobturator mesh tape may not be possible in the short (after 4 weeks of surgery) or long term. As mesh removal procedures carry higher risks of organ and nerve damage, referral to a different hospital (with a surgical team experienced in mesh removal) may be required. Even after complete removal, symptoms may persist or worsen. Partial or complete removal of the mesh tape may result in the operation no longer working. You may then wish to consider further surgery for incontinence.
- **Your individual risk:**
The risks of any surgical procedure are increased above the average risks if you have any significant medical conditions (such as diabetes), if you smoke, are over-weight or if you have previously had surgery for a similar problem. Please discuss your own individual risks with your surgeon.
- **Pregnancy and Childbirth:**
The tape is a synthetic mesh permanent implant and it is highly advisable you consider this procedure only after your family is complete. While it will not affect your ability to become pregnant, there is an anticipated increased risk of failure of the tape procedure following

pregnancy and childbirth. A Caesarean section may be recommended to reduce such risk. Such recommendation applies to women following all types of surgery for stress urinary incontinence. Please discuss with your GP and surgeon if you intend to have more children.

**Risks of not having this procedure
(Doctor to document in space provided)**

.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....
.....

Is there any research being carried out in this area?

There may be national and local research studies in these areas and you may be invited to participate.

Information and support

- Continence Services
Telephone: _____ Opening hours: _____
- Gynaecology Inpatient Ward
Telephone: _____ Opening hours: _____
- Your GP
Telephone: _____
- Scottish Mesh Helpline
Telephone: 07824537938 Opening hours: Mon 16:30 to 18:30
Thurs 09:00 to 11:00

Useful Resources

- The British Association of Urological Surgeons - Synthetic Vaginal Tape Procedure: <http://www.baus.org.uk/search/?q=sling%20female%20synthetic>
- The British Society of Urogynaecology: www.bsug.org.uk/patient-information.php
- The Royal College of Obstetricians and Gynaecologists: Recovering from Tape Surgery: <https://www.rcog.org.uk/en/patients/patient-leaflets/mid-urethal-sling-operation-for-stress-urinary-incontinence/>
- International Urogynaecological Association: www.iuga.org/resource/resmgr/brochures/eng_sui.pdf
- Bladder and Bowel Foundation: www.bladderandbowelfoundation.org
- The Pelvic, Obstetric and Gynecological Physiotherapy Professional Network of the Chartered Society of Physiotherapy: pogp.csp.org.uk
- NHS Choices: Treatment Options for Women with Urinary Incontinence: www.nhs.uk/Conditions/Incontinence-urinary/Pages/treatmentoptions.aspx
- The National Institute for Health and Clinical Excellence urinary incontinence in women pathway: <https://pathways.nice.org.uk/pathways/urinary-incontinence-in-women/surgery-for-stress-urinary-incontinence-in-women#content=view-node%3Anodes-synthetic-tapes>
- The Medicines and Healthcare products Regulatory Agency (MHRA) - Risks of vaginal tapes (November 2012) www.mhra.gov.uk/home/groups/comms-ic/documents/websiteresources/con205383.pdf
- Reportable adverse events: www.bsug.org.uk/MHRA.php
- MHRA reporting of adverse incidents involving medical devices: <https://yellowcard.mhra.gov.uk/devices/?type=mop>
- Self-help groups in the UK:
www.scottishmeshsurvivors.com www.tvtinfo.wordpress.com
www.tvt-messed-up-mesh.org.uk www.patientopinion.org.uk

Note: If you do not have access to Internet, please ask your GP/Surgeon for paper copies of these leaflets.

Disclaimer: The NHS is not responsible for the content and does not necessarily endorse the information published in the above websites.

Questions to my Surgeon

Having read the leaflet, please write down any questions you may have to ask your surgeon.

Example questions:

- Is this type of treatment right for me?
- What are the pros and cons of the different tapes available?
- Is my own individual risk different from those mentioned in the leaflet?
- Are you adequately trained to do this procedure?
- Are your success and complications rates comparable to national figures?
- What happens if surgery does not work?
- What would happen if I had a complication?
- Is there anything I can do myself to help make my surgery more successful?
-

My expectations from surgery

What do you expect the operation to do to you?

What activity do you expect to be able to do again after surgery?

Example expectations:

- Have less urinary leakage and use less protection (e.g. pads).
- Be able to exercise or do sport regularly.
- Be dry and stop using pads/protection.
- Be more socially confident.
- Enjoy sexual life in general.
-
-
-

Mesh Device Information

Name of the proposed device:

Name of manufacturer of the proposed device:.....

Patient Label

Information Checklist*

Please read the following points and write your initials in the boxes next to each statement.

I confirm that I have read and understood, to the best of my ability, all the information in the booklet including:

The details of the procedure proposed and the desired outcome

All available alternatives of this procedure and their advantages and disadvantages

All information on possible risks including my own

All my questions were answered

Signatures

Signed (Patient):

Name of Patient (PRINT).....

Date:

Signed (Health professional)

Name (PRINT):

Designation:

Date:

***This is not a consent form.**

This information checklist ensures your understanding of all the important information regarding this procedure. Your surgeon will then obtain your consent to undergo the procedure by signing a separate document.