

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

PATIENT INFORMATION AND CONSENT BOOKLET

Patient
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Patient Information and Consent Booklet

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

Disclaimer:

This booklet contains information and consent form put together by the Scottish Government Short Life Working Group and Committee Members of the Scottish Pelvic Floor Network (SPFN), with reference to national guidance. The authors cannot be held responsible for errors or any consequences arising from the use of the information contained. The committee members will review and consider updating this booklet every two years. Please make sure you are reading the up-to-date document.

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About this booklet:

This booklet 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, National Institute of Health and Clinical Excellence. It is, therefore, a reflection of best practice in Scotland. 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 (see pages 14-15) to discuss with your surgeon prior to signing the consent form (see page 16).

Explanation of Terms

Tape: A tape is a type of prosthesis. It is a sling implant (a flat strip of material made from a synthetic polypropylene mesh) that is surgically inserted for the management of Stress Urinary Incontinence (SUI).

Mesh: A network fabric or structure; open spaces or interstices between the strands of the net.

What is Stress Urinary Incontinence?

Your bladder and urethra (water-pipe/outlet of urine) are supported by your pelvic floor muscles and ligaments. If this support is weakened by childbirth, you may experience stress urinary incontinence. This means that urine leaks with coughing, sneezing, laughing or with lifting and exercising. Lack of hormones after the menopause may cause the tissues to become even weaker.

Alternative Options

There are several non-surgical and surgical treatment options for women with stress urinary incontinence, for example physiotherapy, colposuspension, slings made from non-artificial material as well as injections. Please ask your doctor about leaflets which cover these options and familiarise yourself with the pros and cons. The leaflets are available on the following websites.

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

The most effective non-surgical treatment is **pelvic floor muscle exercises**. Many women who have undergone training supervised by a physiotherapist will not require surgery. Drug treatment using Duloxetine may also be a suitable option on occasion to treat SUI.

Other alternatives are:

- **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.

If non-surgical treatment options have not been successful, or are not appropriate, then surgical intervention may become necessary.

What is the Synthetic Vaginal Mesh Tape Procedure?

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

Intended benefits

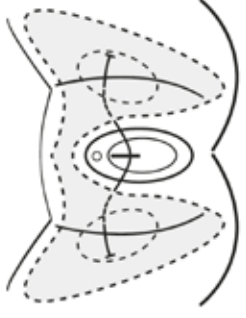
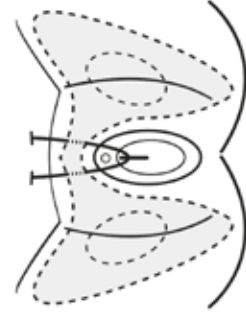
- Published studies have shown similar success results in achieving cure or improvement of stress urinary incontinence to non-tape surgical procedures.
- The procedure is not intended to improve symptoms of an overactive bladder (urinary frequency, urgency or waking up at night to pass urine).

During the procedure

- 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.
- The procedure is usually performed in the Day Surgery Unit of your hospital and most patients go home the same day. A synthetic sling is inserted through a small (1-2 cm) cut in the vagina, to support the urethra. 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 sling through them. The *single-incision** procedure is similar to the transobturator one but there are no cuts outside the vagina.
- The procedure takes around 20-30 minutes. A cystoscopy (camera looking into bladder) will be performed to ensure your bladder has not been injured during this process. The mesh tape is meant to **remain in place permanently**, i.e. remain inside the body for life.

*Single-incision or Mini Slings are recommended for use only within research context.

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

Transobturator tape		In the groin area eg Obturator/TVT-O	Similar success rate in the short and medium-term	Lower risk*	Lower risk*	Higher risk*
Retropubic tape		In the lower abdomen above the pubic bone eg Retropubic/TVT	Evidence of longer-term success rates	Higher risk*	Higher risk*	Lower risk*
Comparison		Outside cuts	Success rate	Bladder injury during surgery	Bladder emptying problems	Chronic pelvic pain

*Please see below for details of the risks and complications

After the procedure

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 straightaway on return from theatre. You will have 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 (tube that goes into your bladder) may need to be used for some time. There may be slight vaginal bleeding (like the end of a period) for a few days. You may have a vaginal gauze placed in your vagina to help control any bleeding.

Light activities may be resumed after two weeks, normal activities after four weeks. More strenuous tasks and heavy lifting should be avoided for six weeks. 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.

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. It is important to continue with the physiotherapy advice you have been given prior to your procedure.

A follow-up appointment will be made in 2-4 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:

<http://www.rcog.org.uk/files/rcog-corp/Mid-urethralSlingRecoveringWell0710.pdf>

Possible Risks of this Procedure

The tables below are designed to help you understand the risks associated with this type of surgery (based on the RCOG Clinical Governance Advice, Presenting Information on Risk). The terms used to denote the degree of risk in the main table are explained here:

Term	Equivalent numerical ratio	Equivalent environment
Very common	1/1 to 1/10	One person in a family
Common	1/10 to 1/100	One person in a street
Uncommon	1/100 to 1/1000	One person in a village
Rare	1/1000 to 1/10 000	One person in a small town
Very rare	Less than 1/10 000	One person in a large town

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 small but it can happen with any operation.
- **Infection:** The risk of infection at any of the wound sites is common, and you will receive antibiotics in theatre to reduce such risk. One in ten women will need a course of antibiotic to treat a urine infection. 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 day-surgery (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.

Specific Complications and Risks*

Complication	Risk
Mesh exposure (erosion) into the vagina	Common. The vaginal skin over the sling may not heal properly or get infected. 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 sling or to partly remove it (please see below).*
Recognised damage to the bladder or urethra during the procedure	Common, especially with the retropubic approach. When discovered during the procedure, the sling is removed and replaced correctly. Long-term problems following this complication are unlikely.
Failure of the procedure to stop urine leakage	Common. Persistence or recurrence of urinary leakage after some time. This can happen years after the sling has been inserted even if it cured your symptoms originally. 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 are managed with physiotherapy and/or drug treatment.

Temporary problems emptying bladder fully	Common. May require short-term home catheterisation (indwelling or intermittent) for few days or weeks.
<i>Temporary</i> pain in the pelvic area or at the site of the sling insertion (the groin area or inner thigh in transobturator procedure) or during sexual intercourse.	Common. Often resolves spontaneously or with painkillers.
<i>Chronic</i> pain in the pelvic area, at the site of the sling insertion or during sexual intercourse (due to vaginal scarring)	Common with transobturator tape, affecting the groin area and/or inner thigh. Could be due to nerve damage/irritation. Uncommon with retropubic tape. Repeat procedures to remove the sling may be necessary (see below).*
Persistent problems emptying bladder fully with recurrent urinary tract infections	Uncommon. May require further surgery to release, cut or remove the sling.* Urine leakage may return and you may need further surgery.
Mesh extrusion (erosion) into the urethra or the bladder	Rare. This may lead to fistula formation and can occur years after surgery. Could be due to spontaneous sling displacement or unrecognised damage to the bladder or urethra during the procedure. Requires further surgery to remove the sling (see below).
Injury to other organs such as bowel and major blood vessels	Rare. An abdominal operation may be necessary to resolve the problem.
Chronic problems emptying bladder fully	Rare. May require long-term self-catheterisation for months/years.
Death	Very rare.

*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.

*Risks if the mesh tape is to be removed

Repeat procedures may be necessary and complete sling removal may not be possible to do safely. Referral to a different hospital (with a mesh removal team) may be required and, even after complete removal, symptoms may persist. Partial or complete removal of the mesh sling may result in the operation no longer working so you may need further surgery for incontinence.

Risks of not having this procedure

(Doctor to document in space provided)



Further notes on risks

- The risks of any surgical procedure are increased above the average risks if you have any significant medical conditions, if you are over-weight or if you have previously had surgery for a similar problem.
- The National Institute for Health and Clinical Excellence has produced further information regarding the risks of vaginal slings in August 2013. You are able to access this using the following link: <http://publications.nice.org.uk/urinary-incontinence-cg171/recommendations>
- The Medicines and Healthcare products Regulatory Agency (MHRA) produced further information regarding the risks of vaginal slings in November 2012. You are able to access this using the following link: <http://www.mhra.gov.uk> – go to search box and type ‘synthetic vaginal slings’.
- The sling is a synthetic **mesh permanent** implant and **it is strongly recommended you consider this procedure only after your family is complete**. There is an anticipated increased risk of failure following pregnancy and childbirth. Please discuss with your GP and surgeon if you intend to have more children.

Is there any research being carried out in this area?

Your surgeon or specialist/research nurse will inform you about any relevant research studies taking place in the hospital. All surgical procedures, even those not currently the subject of active research, should be subjected to rigorous clinical audit so that we can analyse our results to inform future practice. In this way, we can learn how to improve our techniques and our results; this means that our patients will get the best treatment available.

If your hospital is running a research project in this field, you may be asked if you wish to participate and, if you agree, to sign a special consent form to this.

Information and support

- Continence Services
Telephone:
Opening hours:
- Gynaecology Inpatient Ward
Telephone:
Opening hours:
- Your GP

Useful Resources

- The British Association of Urological Surgeons
www.baus.org.uk
- The British Society of Urogynaecology
www.bsug.org.uk/patient-information.php
- The Royal College of Obstetricians and Gynaecologists
www.rcog.org.uk/files/rcog-corp/Mid-urethralSlingRecoveringWell0710.pdf
- International Urogynaecological Association
www.iuga.org/resource/resmgr/brochures/eng_sui.pdf
- Bladder and Bowel Foundation
www.bladderandbowelfoundation.org
Telephone: 08453 450165

Variant Creutzfeldt Jakob Disease (CJD)

We ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of CJD. This helps prevent the spread of CJD to the wider public. Please let your surgeon know if you have received a corneal transplant, a neurosurgical dural transplant, injections of human-derived growth hormone or similar substance/implant. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

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 slings available?
- What happens if surgery does not work?
- Do you perform at least 20 of these procedures a year, as recommended by NICE?
- Have you looked at your results?
- What are your success and complication rates?

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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 pads/protection.
- Be able to exercise or do sport regularly.
- Be dry and stop using pads/protection.
- Be more socially confident.
- Enjoy sexual life in general.

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Consent Form

Date:

Patient
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Synthetic Vaginal Mesh Mid-Urethral Tape Procedure for the Surgical Treatment of Stress Urinary Incontinence in Women

A. Statement of health professional (details of treatment, risks and benefits)

I confirm I am a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the hospital's consent policy. I have explained the procedure to the patient. In particular, I have explained:

- a) The proposed approach: Retropubic/Trans-obturator
(please delete as necessary) and device name:
..... (please complete)
- b) The above intended benefits of the procedure as follows:
To cure or improve stress urinary incontinence. This is not intended to improve symptoms of an overactive bladder (urinary frequency, urgency or waking up at night to pass urine).
- c) **The possible risks involved as discussed above in details**
(including those specific to the patient).
- d) The benefits and risks of any available alternative treatments
(including no treatment) and any particular concerns of the patient.
- e) Any additional procedure(s) that might become necessary during surgery such as:
☐ Blood transfusion other procedure (please state)
.....
.....

f) Any competing interests I may have regarding the device used in this procedure.

.....
.....

This procedure will involve: (tick all that apply)

- ☐ General and/or regional anaesthesia
☐ Local anaesthesia
☐ Sedation

Consultant or other responsible health professional

Signed (health professional): Date:

Name (PRINT): Time (24 hr):

Designation:

Contact/page no:

GMC number:

B. Consent of patient/person with parental responsibility

I confirm that I have read and understood all the information in the booklet including the risks, benefits and alternatives of this procedure. All information has been discussed with me and my questions have been answered to my satisfaction and understanding.

I acknowledge that the doctor has explained:

- ☐ the anaesthetic required for this procedure. I understand the risks, including the risks that are specific to me.
☐ my expected outcome and the risks of not having the procedure.
☐ that no guarantee has been made that the procedure will improve my condition even though it has been performed with due professional care.
☐ other relevant procedure/treatment options and their associated risks.
☐ that a qualified doctor undergoing training may perform the procedure under the supervision of my consultant.
I agree ☐ I disagree ☐
☐ the right to change my mind at any time, including after I have signed this form.

On the basis of the above statements:

I have listed below any procedures that **I do not wish to be carried out without further discussion.**

I have read and understood all the patient information in the booklet about this procedure. **I understand all the possible risks and I agree** to the procedure.

Signed (Patient): Date:

Name of patient (PRINT):

Statement of the interpreter:

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe she can understand.

Signed (Interpreter): Date:

Name of interpreter (PRINT):

Address:

.....

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signed (Witness): Date:

Name of witness (PRINT):

Address:

.....

C. Confirmation of consent

Confirmation of consent (where the treatment/procedure has been discussed in advance). On behalf of the team treating the patient, I have confirmed with the patient that she has no further questions and wishes the procedure to go ahead.

Signed (Health professional): Date:

Name (PRINT):

Job title:

Consent Form

Date:

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☐ Blood transfusion other procedure (please state)

f) Any competing interests I may have regarding the device used in this procedure.

.....
.....

This procedure will involve: (tick all that apply)

- ☐ General and/or regional anaesthesia
☐ Local anaesthesia
☐ Sedation

Consultant or other responsible health professional

Signed (health professional): Date:

Name (PRINT): Time (24 hr):

Designation:

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Signed (Witness): Date:

Name of witness (PRINT):

Address:

.....

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Name (PRINT):

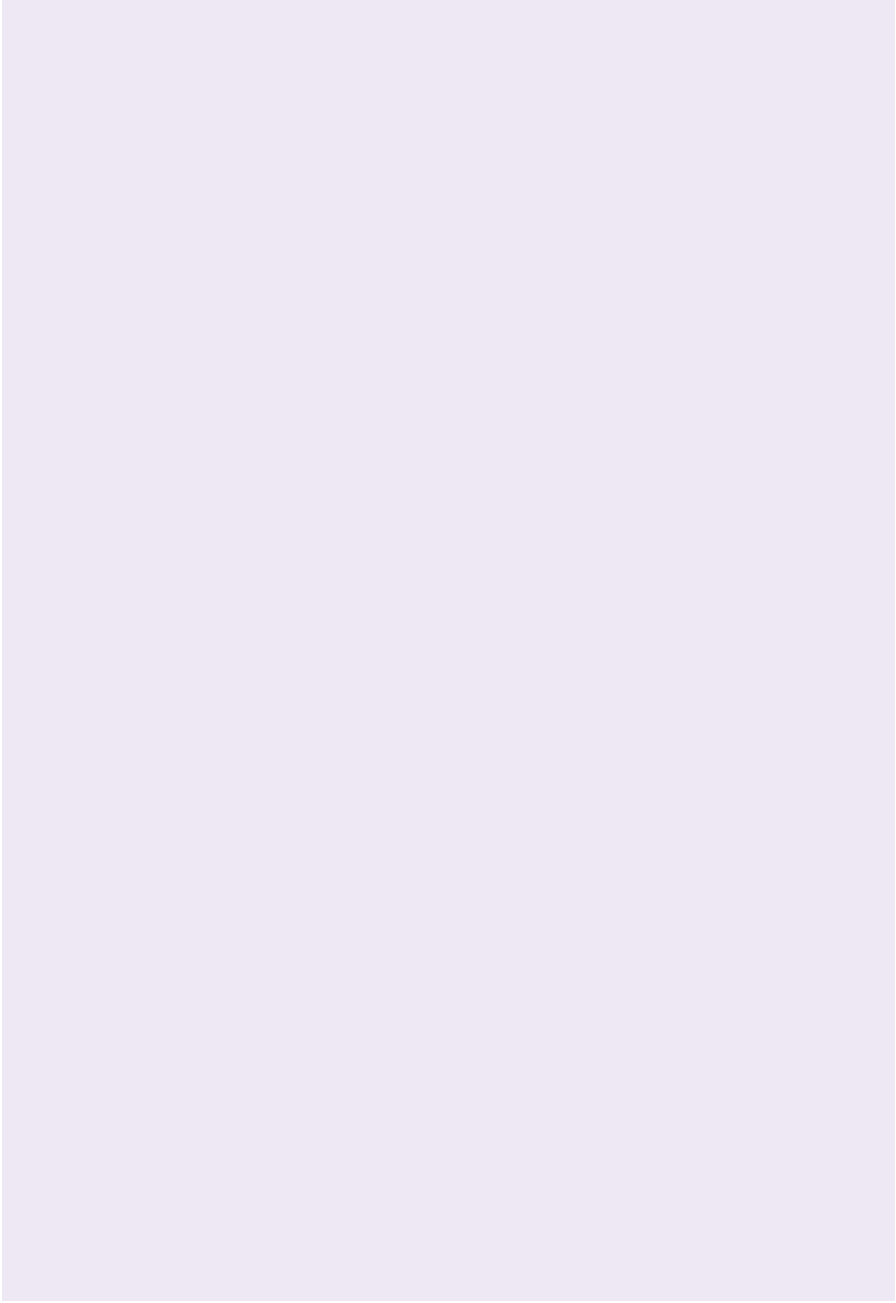
Job title:

Notes

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www.scotland.gov.uk

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