New Zealand Government

# Considering Surgical Mesh to Treat Stress Urinary Incontinence?

## Using permanent polypropylene (plastic) mesh tape in mid-urethral sling (MUS) operations

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MINISTRY OF HEALTH
MANATŪ HAUORA

## Disclaimer

The authors cannot be held responsible for errors or any consequences arising from using the information contained in this document.

Current evidence regarding the safety of these devices in the longer term (ie, five years or longer) is incomplete. The Ministry of Health continues to monitor the risk profile for the treatment of stress urinary incontinence (SUI) using mesh.

Please keep this document for your information and future reference.

The document will be reviewed and updated on a regular basis and/or as new information becomes available. Please make sure you are reading the latest version of this document, available at health.govt.nz

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# Introduction

This document gives you information about treating stress urinary incontinence with surgery involving mesh and alternative management options.

The information is intended to supplement any advice you may have already received from your doctor or surgeon.

Please take your time to read it carefully and write down your expectations and any questions or concerns that you wish to discuss with your surgeon.

# What is stress urinary incontinence?

Stress urinary incontinence (SUI) is accidental or involuntary leakage of urine when there is pressure on the bladder. This may be from coughing, sneezing, running, jumping and many other activities. Your bladder and the pipe through which urine drains from the bladder (urethra) are supported by your pelvic floor muscles and ligaments. If this support is weakened or not working properly then urine may leak during these activities.

SUI can be caused by a number of things, including pregnancy, childbirth, weight gain, or chronic straining or coughing. It can be embarrassing or distressing, and what treatment you choose, if any, will depend on how SUI affects you and your health.

This guide sets out the treatment options, both non-surgical and surgical, for women with SUI. Every option has pros and cons and some may not be appropriate in your case. You should discuss all these options with your doctor or surgeon to help you decide which is the best option for you.

## Non-surgical treatment options

It is important to try non-surgical treatments such as those listed in the table below before contemplating mesh surgery.

| Treatment | Explanation |
|---|---|
| Pelvic floor exercise | Pelvic floor muscle exercises are the most effective non-surgical treatment. Many women who have undergone training supervised by a continence service will not require surgery. |
| Weight loss | Weight loss is an effective treatment option for overweight women with SUI. Please discuss further with your doctor. |
| Continence pessaries | Pessaries are a soft removable device that are placed inside the vagina or urethra, and may be useful for managing urine leakage during physical exercise. |
| Protection | Absorbent products such as incontinence pants or pads may provide extra ways of managing urinary problems for some women. |
| Lifestyle | Lifestyle changes such as reducing high impact activities that cause the incontinence. |

# Surgical treatment options not involving mesh

If non-surgical treatment options have not been successful or are not appropriate, you and your doctor may consider the following surgical procedures.

| Treatment | Explanation |
|---|---|
| Colposuspension | Abdominal operation using either open or keyhole surgery to lift your vagina underneath your urethra using permanent synthetic stitches or sutures. |
| Natural tissue sling | Abdominal operation using open surgery to lift your urethra using a natural sling from your own abdominal wall called a fascia. |
| Biological tissue sling | Uses biological material of animal origin to lift your urethra. |
| Urethral bulking agents | Vaginal operation where a synthetic 'bulking' material is injected in or around your urethra to improve the seal. This material may be permanent or absorbed by your body. |

# Surgical treatment options involving mesh

The term ‘mesh’ refers to a permanent implant, usually made from a non-absorbable polypropylene (plastic) material. Mesh is sometimes referred to as tape, sling, patch, ribbon, graft or hammock. Mesh is used to prevent leakage by supporting your urethra and mimicking the ligaments that are not giving it enough support. All mesh is meant to remain inside the body permanently.

## What the procedure involves

This operation involves placing a piece of mesh material, like a sling, under your urethra to support it. This is sometimes referred to as a midurethral sling procedure.

There are two different ways that the mesh can be inserted:

- behind the pubic bone (the retropubic method)
- where the mesh comes out in the inner thigh on each side (the transobturator method).

In both methods, the mesh is inserted through a small 1–3 cm cut in your vagina. The surgeon then makes 2 smaller cuts just above your pubic area (during a retropubic procedure) or on the inside of both thighs (during a transobturator procedure) and passes the mesh through them. There may be clinical reasons why your doctor recommends one method over the other. Your surgeon will discuss this with you and consider all relevant issues, including your previous surgical history and your own wishes.

Long pointed surgical instruments called trocars are used in both methods of surgery to insert the mesh into the body. There are specific risks associated with the use of trocars, including that they could damage/puncture the bladder or other organs (see page 8).

You will be given a general, spinal or local anaesthetic and/or sedation before surgery. The type of anaesthesia will be discussed with you by your anaesthetist/surgeon and depends on the nature of your surgery, your health, as well as your preference. This is a relatively short operation and most patients go home within 24 hours.

Your surgeon will perform a telescopic examination of your bladder (cystoscopy) to ensure that it hasn’t been injured during your operation.

Once the mesh is in position, your tissues grow through the holes in the weave of the mesh and anchor it in position. This may take 3 to 4 weeks.

## Comparing mesh implant methods

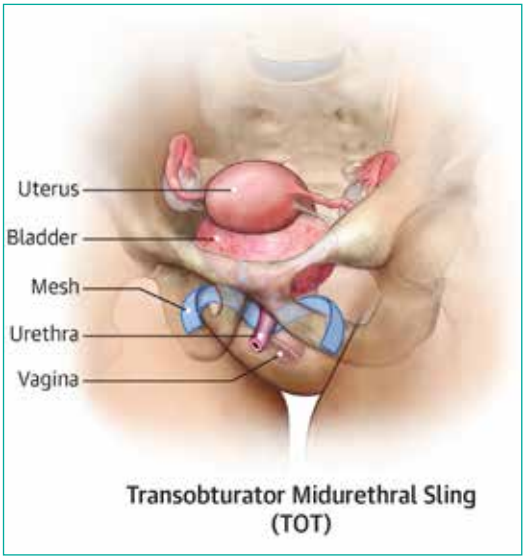
Retropubic Midurethral Sling (TVT)

### Retropubic

**Vaginal cut**
1–3 cm cut in the vagina

**Outside cuts**
2 small cuts in the lower abdomen above the pubic bone

**Success rate**
Better evidence of long-term success



Transobturator Midurethral Sling (TOT)

### Transobturator

**Vaginal cut**
1–3 cm cut in the vagina

**Outside cuts**
2 small cuts in the groin area

**Success rate**
Similar success rate in short and medium term. Long-term data (over 5 years) is awaited

## After the procedure

Immediately following your surgery you'll be taken back to the ward, where the nurses will look after you. You'll be given painkillers if you need them and you may eat and drink shortly after you 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 may be done by a bladder ultrasound scan. Once hospital staff are happy that your bladder empties properly, most women go home within 24 hours. If not, you may need a catheter re-inserted and used for some time.

The potential issue of long-term voiding dysfunction is covered in more detail on page 10.

You may have a vaginal gauze pack placed inside your vagina to help control or prevent any bleeding. This will be removed before you go home.

You will be offered a follow-up appointment.

For the first few days/weeks following your surgery, you may have slight vaginal bleeding (like the end of a period). If you need to wear protection, use a sanitary pad/liner, not a tampon.

If you feel able to do so, you should be able to carry out light activities after a few days. After a few weeks you may resume normal activities if you feel able to do so. Avoid more strenuous tasks and heavy lifting for four to six weeks. Talk to your doctor about how this affects your personal situation.

To avoid discomfort during wound healing, avoid sexual intercourse and inserting any creams or tampons for six weeks following your procedure, unless recommended by your doctor.

It is important that you avoid constipation and use laxatives if necessary.

Returning to work will depend on the type of work you do. Please ask your doctor for their opinion and if you need a medical certificate.

It is advisable to continue with any physiotherapy advice you were given before your procedure.

For more information on physiotherapy following your procedure, please ask your doctor or visit the following websites:

https://www.continence.org.nz/

https://www.yourpelvicfloor.org

## The intended benefits

The main intended benefit of the procedure is to cure or improve stress urinary incontinence.  Both retropubic and transobturator methods have been studied for effectiveness and are supported by evidence with an average success rate of 80% in the short to medium term (up to five years).

Improvement or cure of stress urinary incontinence following a mesh procedure is seen at rates similar to more traditional non-mesh surgical procedures.  Women considering surgery are encouraged to discuss their individual likelihood of success with their doctor.

These procedures are not intended to improve symptoms of an overactive bladder, such as urinary frequency, urgency, urge incontinence or excessive waking at night to pass urine, which may improve or worsen following this type of surgery.

## Possible complications and risks

The most common complications from mesh surgery to treat SUI, in descending order of frequency, include: pain, mesh erosion through the vagina (also called exposure, extrusion or protrusion), infection, urinary problems, recurrent incontinence, pain during sexual intercourse (dyspareunia), bleeding, organ perforation, neuromuscular problems and vaginal scarring. More detail about potential complications is provided in the following table.

Many of these complications require additional medical intervention, and sometimes require surgical treatment and/or hospitalisation. With the exception of mesh erosion, these complications can also occur following a non-mesh surgical repair for SUI.

# Specific risks associated with surgical treatment for SUI involving mesh

The table below describes the terms used in the following section. Note, it outlines the likelihood of the complication happening*, rather than how serious the complication might be.

| Term | Number of people | Size of group/area |
|---|---|---|
| Very common | 1 in 1 – 1 in 10 | one person in a family |
| Common | 1 in 10 – 1 in 100 | one person in a street |
| Uncommon | 1 in 100 – 1 in 1,000 | one person in a village |
| Rare | 1 in 1,000 – 1 in 10,000 | one person in a small town |
| Very Rare | 1 in 10,000 and above | one person in a large town |

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

| Complication | Risk* |
|---|---|
| Urinary tract infection (UTI) | **Very common** in the first year after mesh surgery. Requires antibiotic treatment. UTI may be recurring. |
| Mesh exposure in the vagina | **Common**. The vaginal skin over the mesh may not heal properly or may get infected. This could also be due to inflammation, foreign body response# or unusual immune response. Further surgery may be required to cover the mesh or to partly remove it. The symptoms of mesh exposure include vaginal discharge, bleeding, pain or discomfort to you and/or your partner during sexual intercourse.<br><br>It is important to note that this complication can begin years after surgery. |
| Recognised damage to the bladder or urethra during the retropubic procedure | **Common**. When discovered during the procedure, the trocar and mesh are removed and replaced correctly. No long-term problems have been found following this complication. |

| Complication | Risk* |
|---|---|
| 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 in the longer term for transobturator procedures. You may need further surgery for incontinence and success rates may be lower. |
| Needing to pass urine more often than normal or having trouble getting to the toilet in time | **Common**. Overactive bladder symptoms or urgency may develop after surgery. This can be managed with bladder retraining, physiotherapy and/or drug treatment. |
| Temporary problems emptying bladder fully | **Common**. May require short-term home catheterisation for a few days or weeks. If necessary you will be offered training on how to self-catheterise. Usually resolves spontaneously. |
| Short-term pain in the pelvic area or at the site of the tape insertion (the vagina, groin or inner thigh) | **Common**. Often resolves spontaneously or with painkillers. Referral to physiotherapy or pain management team may be helpful for pain relief. |
| Short-term pain during sexual intercourse | **Common**. May resolve spontaneously or with painkillers. It is recommended that you avoid sexual intercourse for 6 weeks following surgery. |

| Complication | Risk* |
|---|---|
| Long-term pain in the pelvic area, at the site of the mesh insertion | **Common** with both types of mesh procedure. With transobturator, pain can affect the groin area and/or inner thigh.<br><br>With retropubic, pain can occur more centrally affecting the lower abdomen and vaginal region. Most published research suggests lower rates of pain than with transobturator approach.<br><br>Nerve and musculoskeletal damage and pain can be permanent.<br><br>Regardless of the method used, if you have persistent groin or pelvic pain more than 8 weeks following mesh insertion, you should contact your surgeon to discuss timely mesh removal. You should be aware that even complete removal of the mesh does not guarantee relief from pain. |
| Long-term pain during sexual intercourse | **Uncommon** in women who experience no other complications.<br><br>**Common** in women who experience one or more complications and may have ongoing consequences. Physiotherapy may help relieve the pain. You may also need to be referred to a pain management team and counselling. If there is exposed mesh within the vagina then your male sexual partner may also experience discomfort. |
| Long-term problems emptying bladder fully (voiding dysfunction) | **Uncommon**. May require temporary self-catheterisation or further surgery to release, cut or remove the mesh. Urine leakage may return and you may need further surgery.<br><br>Long-term problems requiring self-catheterisation for months/years are rare. If necessary you will be offered training on how to self-catheterise. |

| Complication | Risk* |
|---|---|
| Mesh erosion^ into the urethra or bladder | **Rare**. Can occur years after surgery. Can be due to either spontaneous migration of the mesh after the procedure or unrecognised damage to the bladder or urethra during the procedure. You will require further surgery to remove the mesh. |
| Fistula | **Rare**. You may need an abdominal operation to fix the problem. |
| Injury to other organs such as the urethra, bowel and major blood vessels | **Rare**. You may need an abdominal operation to fix the problem. |
| Death | **Very rare**. |

* The risk levels quoted are those reported in medical literature and confirmed/endorsed by the UK National Institute of Health and Clinical Excellence. Data from large relevant registries were not available at the time of writing this document.

\# Foreign body response to the mesh could lead to long term inflammation, scarring, infection and mesh exposure.

^ 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 end of the document.

# Risks from any surgery

More generally, any surgical procedure has risks and potential problems. The following are possible problems that you may experience.

| Complication | Risk |
|---|---|
| Anaesthetic risks | These are rare unless you have specific medical problems. Death is very rare. Your anaesthetist will discuss these with you. |
| Bleeding | You should expect some vaginal bleeding after the operation. The risk of major bleeding severe enough to need a blood transfusion, is uncommon but it can happen with any surgery. |
| Infection | The risk of infection with any surgery is common, and you will receive antibiotics in theatre to reduce this risk. The vagina is considered a 'clean but not sterile' surgical field, which will not be fully clear of bacteria before surgery. Despite receiving routine antibiotics, a urine infection is common while a wound infection is uncommon. Serious hospital-acquired infections, such as MRSA and Clostridium Difficile are rare. |
| Deep vein thrombosis (DVT) | DVT is a clot in the deep veins of the leg. While the overall risk is common, the majority pass unnoticed and resolve spontaneously. It is rare for a clot to migrate to the lungs and cause a serious problem following short operations (fewer than 1% of those who get a clot). However, there have been deaths following such clots and, so you may be provided with special stockings. |

The risks of any surgical procedure are increased if you have any significant medical conditions (such as diabetes), if you smoke, are overweight, or if you have previously had surgery for a similar problem.

As mesh is a permanent plastic implant, it is highly advisable that you consider this procedure only after your family is complete. While it will not affect your ability to become pregnant, there is an increased risk of failure of the mesh procedure following pregnancy and childbirth. This recommendation applies to women following all types of surgery for stress urinary incontinence. Please discuss with your doctor and surgeon if you intend to have more children or become pregnant after this procedure.

## Risks if the mesh has to be removed

As the mesh is meant to be a permanent implant, complete removal may not be possible to do safely. Repeat procedures may be necessary but may not always fully correct the complications. Symptoms may persist or worsen and removal does not guarantee relief from pain.

As mesh removal procedures carry higher risks of organ and nerve damage, you may need to be referred to a different New Zealand hospital with a surgical team experienced in mesh removal.

Partial or complete removal of the mesh may also result in the return of your urinary incontinence. You may wish to consider further surgery for incontinence.

## Risks of not having this procedure

There are also risks associated with not doing anything, eg, continued incontinence. Discuss these with your doctor and write them below.

## Reporting complications

If you think you may have experienced an unexpected consequence from your mesh surgery, you should report this to Medsafe.
http://www.medsafe.govt.nz/regulatory/DevicesNew/9AdverseEvent.asp

Mesh-related complications can be reported to the New Zealand Accident Compensation Corporation (ACC) for consideration as a 'treatment injury'.
https://www.acc.co.nz/assets/provider/acc589-treatment-injury-help.pdf

# Questions to ask your surgeon

The different treatment options for SUI all have pros and cons and some may not be appropriate in your case. Your surgeon will be able to discuss them with you in more detail to help you reach a decision about the best treatment for you.

After you have read this document, please write down any questions about your personal situation you wish to ask your surgeon.

## Example questions

### About me

- Have I tried all of the non-surgical treatment options?
- Is this type of treatment right for me?
- Is my individual risk different to those mentioned in this document? If so, why?
- Why are you recommending a mesh procedure for me instead of the other options?
- Are my expectations realistic? (see expectations below)
- (Ask if relevant) I have allergies and/or auto immunity. Could this procedure make these symptoms worse?
- How long will you follow up my outcome of this surgery?
- Can I contact you with any more questions I have regarding the operation?

### About the mesh

- What are the pros and cons of the different methods of mesh implantation (retropubic/ transobturator)?
- What do you expect the success rate of this surgery to be for me?
- How many of the listed complications have your patients experienced?
- How could long-term complications impact on me?
- Is there a patient brochure for the mesh you are recommending and may I have a copy?

### About the surgeon

- Have you had specific training in this procedure and other types of incontinence surgery?
- How many mesh operations have you performed using this particular mesh?
- Can you explain the potential problems if you have to partially remove or cut the mesh and leave it in my body?
- If the mesh has been partially removed or cut, does this make it more difficult to remove the mesh later?
- If I have any complications, will you know how to fix it? If not, who would you refer me to?

### Planning ahead

- What happens if this surgery does not correct my incontinence problem?
- What side effects or unusual symptoms should I report to you?

# Your expectations from the surgery

- What results do you expect from receiving this surgery?
- What activities do you expect to be able to do after surgery?

## Example expectations

- Have less urinary leakage
- Cure urinary leakage
- Use less protection (eg, pads)
- Be able to exercise or do sport regularly
- Be more socially confident
- Quick recovery.

# Information and support

## Your GP

_____ Telephone: _____

## Hospital/Surgical team

_____ Telephone _____Ext: _____

# Information checklist

**This is not a legal consent form.** Your surgeon will obtain your consent to undergo the procedure by asking you to sign a separate form on the day of your operation.

Use this checklist to check that you understand all the important information about this procedure.

## Information Checklist

☐ I understand the details of the mesh procedure proposed and the desired outcome.

☐ I understand all the available alternatives to this procedure and their advantages and disadvantages.

☐ I understand all the information on possible risks.

☐ All of my questions were answered to my satisfaction.

| | |
|---|---|
| Signature of patient | Date |

| | | |
|---|---|---|
| Signature of surgeon | Print name of surgeon | Date |

# Explanation of words used in this document

| | |
|---|---|
| **Catheter** | A tube which is placed to drain urine from the bladder. |
| **Catheterise** | To insert a catheter to drain urine from the bladder eg, following surgery. |
| **Contraction** | Shrinkage of the mesh implant inside the body. |
| **Fascia** | A naturally-occurring sheet of supporting fibrous tissue that holds body organs in their correct positions. |
| **Fistula** | An abnormal connection between two surfaces such as blood vessels, intestines, or organs such as the bladder, urethra or bowel. Fistulas often result from injury or surgery but they can result from an infection, inflammation or cancer. |
| **Foreign body response (FBR)** | The foreign body response is the end-stage of the inflammatory and wound healing responses following implantation of a medical device such as mesh. |
| **Mesh** | A medical implant that is intended to be permanent, it resembles a net-like fabric with open spaces between the strands of the net. It is a permanent implant usually made from a non-absorbable polypropylene (plastic) material. Mesh is sometimes referred to as 'tape' or 'sling' or 'patch' or 'ribbon' or 'graft' or 'hammock'. |
| **Mesh erosion** | An adverse event where mesh erodes (enters) into the bladder, urethra or bowel. |
| **Mesh exposure** | An adverse event where mesh is exposed to inside the vagina. |
| **Pessary** | A removable device placed inside the vagina to support the pelvic organs. |
| **Perforation** | An adverse event where the organ has accidentally been punctured (urethra, bladder or bowel). |
| **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 is an alternative mid urethral surgical tape procedure and refers to the route of mesh passage which goes through the obturator foramen and comes out in the inner thigh on each side of the pelvis. |
| **Tape** | A mesh tape is a permanent implant. It is a flat strip of mesh made from a plastic material (polypropylene) that is surgically inserted into the body through the vagina for the management of stress urinary incontinence. |
| **Trocar** | Trocars are long pointed surgical instruments required during both methods of surgery to insert the mesh tape. There are specific risks associated with the use of trocars, including that they could damage/ puncture the bladder or other organs. |
| **Urethra** | The pipe through which the bladder empties urine to the outside. |

# Local and international links

Here is a list of local and international links relating to incontinence and mesh procedures that you may find useful.

## New Zealand

When you use a health or disability service in New Zealand, you have the protection of a **Code of Rights**: https://www.hdc.org.nz/your-rights/the-code-and-your-rights/

**Continence New Zealand:** http://www.continence.org.nz

**Physiotherapy New Zealand:**
http://physiotherapy.org.nz/your-health/how-physio-can-help/pelvic-floor-disorders/

**The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG):** https://www.ranzcog.edu.au/Mesh-Resources

**Urological Society of Australia and New Zealand (USANZ)**: https://www.usanz.org.au/

**Medsafe (Ministry of Health):**
https://medsafe.govt.nz/devices/Surgical%20Mesh/Landing.asp

**Health Navigator New Zealand:** https://www.healthnavigator.org.nz/health-a-z/b/bladder-control-problems-women/#Overview

**Accident Compensation Corporation report:**
https://www.acc.co.nz/assets/provider/1f2cb4d59b/surgical-mesh-report.pdf

**Ministry of Health:**
https://www.health.govt.nz/our-work/hospitals-and-specialist-care/surgical-mesh

**Mesh Down Under, patient advocacy and support group:** www.meshdownunder.co.nz

## International

**USA Federal Drug Administration statement:**
https://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/urogynsurgicalmesh/ucm345219.htm

**Australian Commission on Safety and Quality in Health Care:**
https://www.safetyandquality.gov.au/our-work/transvaginal-mesh/

**Pelvic Floor First, Australia:** http://www.pelvicfloorfirst.org.au

**Chartered Society of Physiotherapy, UK:**
http://www.csp.org.uk/your-health/conditions/incontinence

**International Urogynecological Association:** https://www.yourpelvicfloor.org/

**National Health Service, UK:** https://www.nhs.uk/conditions/urinary-incontinence/

**Scottish Independent review**: https://gov.scot/publications/scottish-independent-review-use-safety-efficacy-transvaginal-mesh-implants-treatment-9781786528711/pages/16/

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It includes advice from Scottish consensus panels, the relevant United Kingdom national organisations and other evidence-based sources, eg, the Cochrane Collaboration and National Institute of Health and Clinical Excellence.

Illustrations are used with the consent of Australian Commission on Safety and Quality in Health Care.

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# Sources and references

IUGA *Stress Urinary Incontinence A Guide for Women*: https://www.yourpelvicfloor.org/media/Stress_Urinary_Incontinence_RV1.pd

Extracted from the TGA list of Urogynecological surgical mesh complications: https://www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications

NHS Central Manchester University Hospital patient information: https://mft.nhs.uk/app/uploads/sites/4/2018/04/10-125-TVT-July-2014.pdf

NHS leaflet: MIS17-214-GD. *What matters to you when choosing surgery for stress urinary incontinence?* https://www.nhsaaa.net/media/3152/20171109stressincon.pdf

FDA Considerations about Surgical Mesh for SUI: https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345219.htm

Cochrane Database Syst Rev. 2017: https://www.ncbi.nlm.nih.gov/pubmed/26130017

Royal College of Obstetricians & Gynaecologists *Mid-urethral sling operation for stress urinary incontinence*: https://www.rcog.org.uk/en/patients/patient-leaflets/mid-urethal-sling-operation-for-stress-urinary-incontinence/

Australian Commission on Safety and Quality in Health Care *Treatment options for stress urinary incontinence information for consumers*: https://www.safetyandquality.gov.au/wp-content/uploads/2018/12/Treatment-Options-SUI-Consumer-Info.pdf