PATIENT INFORMATION GUIDE

Waitematā District Health Board
Best Care for Everyone

Female Pelvic Medicine and Reconstructive Surgery

# Managing Complications of Stress Urinary Incontinence and Pelvic Organ Prolapse Treatments

## (with options for mesh removal)

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*Assessment and treatment for complications of treatment for stress urinary incontinence and pelvic organ prolapse should only be done by a doctor who is credentialed by the hospital where the surgery will be performed, and who is experienced in the procedure. Waitematā DHB has a robust process to credential our health professionals. You can ask your doctor to confirm that they or the surgeon performing your surgery are credentialed.*

**This guide is designed to help you discuss the treatment options for complications of treatment for stress urinary incontinence and pelvic organ prolapse with your health professional, and to share decisions about your care.**

**This guide will cover the following:**

# Understanding the risks and benefits of treatment

### Be informed

Before making a decision about your health care, it is important that you fully understand the risks and benefits of any medical test, treatment and procedure recommended to you by your doctor.

Asking your doctor or other health care provider questions about your tests and treatment options will help you make better decisions together. These discussions also support the consent process.

You can discuss the details of the different treatments with your doctor to better consider how these options may apply in your case.

### Second opinions

You may also consider getting more than one opinion on surgical treatments if you feel this would be of assistance. You can request your doctor to refer you to another specialist.

### Your rights

You have a right to be informed about services, treatment, options and costs in a clear and open way and be included in decisions and choices about your care.

### Support person

You may find it helpful to take a family member or friend for support when discussing your options and the next steps with your doctor.

### Pre-surgery Tests

Prior to any surgery you may require urodynamic or other specialised tests. This helps your surgeon determine if you are suitable for surgery and the most appropriate operation, if any, for your symptoms.

### Further questions

Some questions you may wish to ask your doctor are contained on page 23 of this patient information guide.

The content of this resource has been informed by Treatment Options for Transvaginal Mesh (including options for mesh removal) developed by the Australian Commission on Safety and Quality in Health Care. Sydney: ACSQHC; 2018

## Accessing care and getting help

Many New Zealand women who have experienced transvaginal mesh complications and other complications have reported that they had difficulty accessing the care they needed. This is because their doctors did not understand or believe that the transvaginal mesh may have been causing their symptoms, or did not believe that their symptoms were as severe as reported.

These symptoms can contribute to physical impacts and affect your quality of life. Women have also reported various forms of emotional and psychological distress, broken relationships and unemployment following a transvaginal mesh procedure.

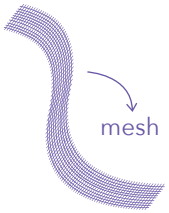
Some women report experiencing autoimmune diseases following treatment with transvaginal mesh. At present there is no scientific evidence to support a link to autoimmune disease.

Waitematā DHB offers assessment and treatment services for women who experience complications following treatment with transvaginal mesh. This involves assessment and treatment by a multidisciplinary team in a specialised service for treatment of mesh complications. This team may include medical, nursing and allied health professionals such as surgeons, pain specialists, physiotherapists, continence specialists, occupational therapists, nurse specialists, social workers, psychologists and psychiatrists. This team will make a comprehensive assessment of your mesh history and symptoms.

This may involve questionnaires to assess pelvic function and continence, pain, occupational and sexual function, quality of life, and psychological distress.

Additional tests may be performed such as bladder function tests (urodynamics), examination under general anaesthetic, cystoscopy (a camera to look inside the bladder), specialised ultrasound and/or magnetic resonance imaging. The decision about which tests to perform will be made by the clinical team in discussion with you, and will depend on your individual circumstances.

## What is transvaginal mesh?

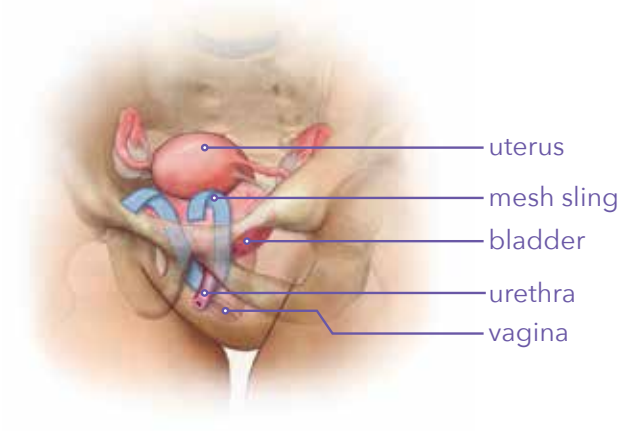



Transvaginal mesh is a manufactured, net-like product that has been used to treat pelvic organ prolapse and stress urinary incontinence in women. The mesh is intended to provide extra support to weakened tissues in the pelvis. It has been used worldwide for many years and in New Zealand for over 15 years.

Transvaginal mesh is intended to be permanent once placed in the body. This affects your options for removal in the event of complications.

Transvaginal mesh products are no longer used in New Zealand where the intended purpose is solely for the treatment of pelvic organ prolapse. This is due to concerns about its safety and success in this procedure.

A range of surgical and non-surgical treatment options are available for stress urinary incontinence in women.




**Source:** Reproduced with permission from Treatment Options for Transvaginal Mesh (including options for mesh removal), developed by the Australian Commission on Safety and Quality in Health Care. Sydney: ACSQHC; 2018

## What are the complications of transvaginal mesh, non-mesh prolapse, and incontinence procedures?

Women have experienced a range of outcomes after treatment for prolapse and incontinence.

Some women have experienced complications, but most have not. If you are not experiencing any troublesome symptoms after your treatment procedure, there is no need to be concerned.

Complications can occur immediately after your operation or even some years later. For women who have experienced complications, the symptoms range from mild to debilitating, and have significantly affected their quality of life.

! *If you experience symptoms that may be related to your procedure, it is important that you have a comprehensive assessment by a team of highly skilled, specialised clinicians.*

There are a variety of treatments available to treat complications, depending on outcomes of your assessment. Your treatment team will discuss the options with you to help make an informed decision about the best treatment for you.

# Understanding the risks of transvaginal mesh

In January 2018, Medsafe removed transvaginal mesh products from sale in NZ, *where sole use* is the treatment of prolapse via transvaginal implantation (through the vagina).

Medsafe has followed the actions of Therapeutic Goods Administration (TGA), Australia, who reviewed published international studies and an examination of the clinical evidence for each product included in the Australian Register of Therapeutic Goods (ARTG) and supplied in Australia. Based on this new information, and since the publication in 2014 of the results of a review into urogynaecological surgical mesh implants, the TGA decided that the risks posed to patients outweigh the benefits of using transvaginal mesh products in the treatment of prolapse.

# What are the symptoms of complications?

Women who report complications from mesh and non-mesh procedures for prolapse and incontinence treatments have described a range of symptoms, including:

## Pain-related Symptoms

- Chronic pain in the pelvis, lower back, hip and thigh, or a combination of these
- Becoming aware of the mesh during intercourse or experiencing pain during sex for the woman or her partner
- Being able to feel the mesh in the vagina or having pain or a prickly feeling

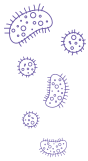
## Bleeding-related Symptoms

- Vaginal bleeding
- Having blood in the urine due to erosion of the mesh into the bladder or urethra (urine tube)

## Urinary-related Symptoms


- Obstruction of the urethra causing bladder symptoms such as retention (being unable to urinate when your bladder is full), incontinence, urge incontinence (sudden and strong need to urinate) and poor urinary flow
- Recurrent urinary or vaginal infection

## Foreign Body Response



- A 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)

## Prolapse-related Symptoms

- New onset of prolapse after burch colposuspension

"Don't be afraid to ask questions about all the treatment options, and ask them to tell you what the risks and complications are for each of those options."

– From a woman who has been through this before

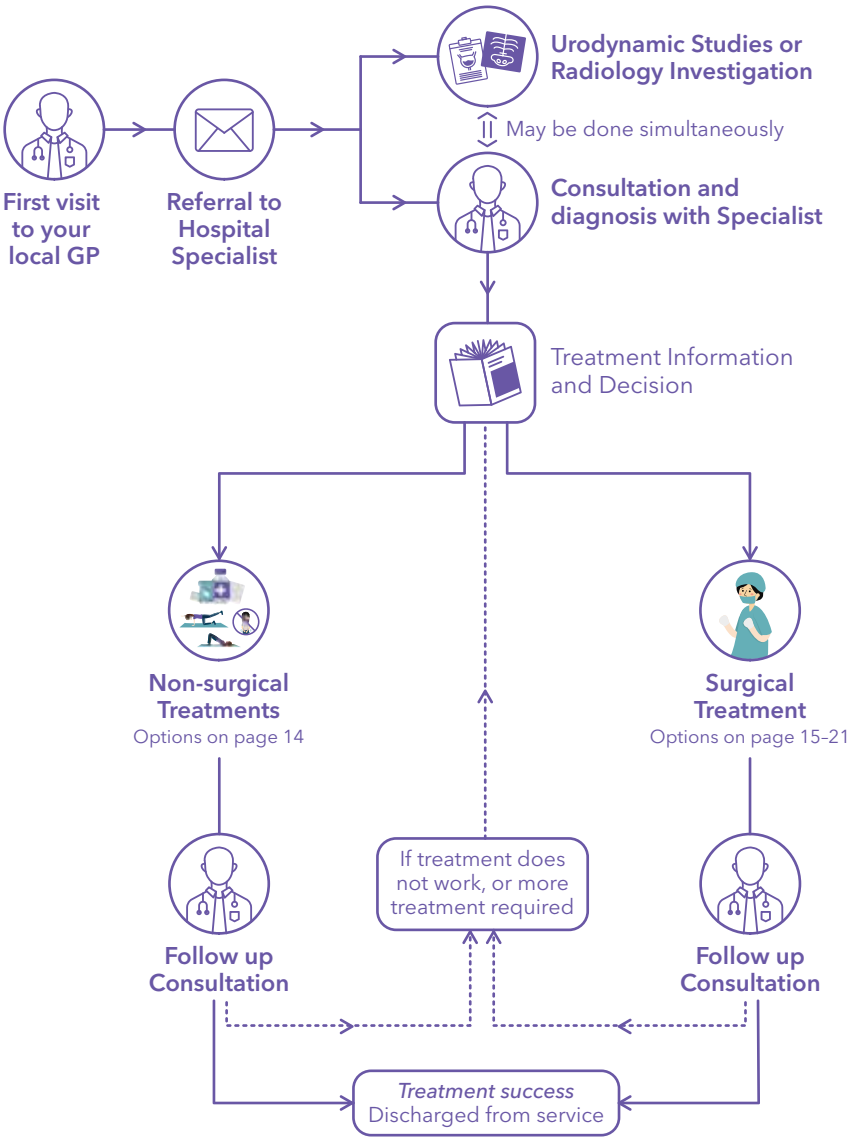
"If you can take along a support person when attending appointments, a second set of ears is excellent for a sounding board when making a decision. Also they might hear something you didn't hear in the appointment."

– From a woman who has been through this before

"Deciding to go ahead with mesh removal is probably one of the best decisions I've ever made, my groin pain disappeared immediately and hasn't returned in the 18 months since. Taking this step has enabled me to return to a normal life."

– From a woman who has been through this before

# Your Treatment Journey



## What are my treatment options?

The treatment you receive for mesh complications depends on your individual circumstances, the findings of the comprehensive assessment, and your personal preference.

There are different ways that your complications can be treated. Your options include:

1 **Non-surgical Treatments**
Conservative treatment options include physiotherapy and other physical therapies, pain management, and medications.

2 **Surgical Treatment**
It might be possible to remove or adjust the mesh, or release non-mesh repairs depending on the position of the mesh in your body, and the scar tissue around it. Every woman's situation is different. Your doctor will discuss your situation with you, and decide together what will be the best treatment option for you.

Your options are highlighted on page 13. Each of these options is explained in more detail on the following pages.

The decision you make about which treatment option is best for you will depend on a number of things:

- why you are seeking treatment
- how severe or troublesome your symptoms are
- how well you understand the treatment options
- your lifestyle and values

*We recommend that you consult your doctor until you are confident and fully understand your options before going ahead with treatment.*

# OVERVIEW OF TREATMENT OPTIONS

## 1 CONSERVATIVE OPTIONS
Page 14

Pain Management
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Physiotherapy and other Physical Therapies
Page 14

Medications
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## 2 SURGICAL INTERVENTIONS
Pages 15-21

### MESH

Mesh Adjustment
Page 16

Partial or Total Mesh Removal
Pages 17-19

### NON-MESH

Urethrolysis
Page 20

Release of Scar Tissue
Pages 21

Release or Removal of Sutures
Pages 20

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# Non-surgical Treatments

### Physiotherapy and other physical therapies

Physiotherapy can be very useful for some women. This may involve a number of treatments by health professionals with expertise in the anatomy of the female pelvis. These include massage techniques, bladder retraining, movement therapies, electrical stimulation and exercises to relieve chronic pain. Occupational therapies such as aids and equipment to help with activities of daily living may also be offered.

Pelvic floor physiotherapy is successful in treating muscular dysfunction – a common cause of pelvic pain.

### Pain management

If you are experiencing chronic pain, a pain management specialist can work with you to develop the right pain treatment plan for you.

### Medications

There are a range of medicine-based treatments for pain, incontinence and for problems with mood and sleep. Medications for pain include common analgesics (such as ibuprofen and paracetamol), anti-depressants, anticonvulsants, and muscle relaxants. There are also more invasive treatment options such as radiofrequency ablation, nerve blockers and steroid injections. Opioids (e.g. codeine, oxycodone and morphine) are only recommended for treatment of acute pain, active cancer pain or palliative care.

Medication-based therapies to treat continence and problems with urinating include different types of muscle relaxants. A specialised urologist or urogynaecologist can work with you to determine if medication is suitable for you.

If you are experiencing symptoms such as disturbed sleep, anxiety or depression, some medications might be recommended, along with counselling or psychotherapy.

2

# Surgical Treatment Options for Mesh Complications

Surgery to remove the mesh may not be possible if the position of the mesh in the body, or the scar tissue around the mesh, makes it unsafe to remove. ***Every woman's situation is different.***

If surgical removal is possible, it may not address or resolve all of your symptoms. You and your doctor should develop a plan for pre- and post-operative care, including longer term management of existing and any new symptoms. In some circumstances, removal surgery can make symptoms such as pain, incontinence and prolapse worse.

## Assessment

A full assessment should be undertaken and may include diagnostic ultrasound capacity, comprehensive urodynamic testing, psychiatry, psychology and pain services.

Other surgeons may also be involved in your treatment, including orthopaedic and colorectal surgeons.

Not all women who have had mesh placed are aware it is present. If you are having repeat surgery following a prolapse repair, discuss your previous surgery with your surgeon.

## Credentialed Specialists

At Waitematā DHB we have credentialed specialists in mesh removal. ***Only*** these specialists can perform mesh removal surgery.

# Mesh Adjustment

Occasionally mid-urethral slings require adjustment, especially if patients are having difficulty passing urine. Adjustment is usually carried out within a week of insertion and may require a brief anaesthetic. Adjustments to slings differ from removal as the mesh remains intact.

**Treatment Procedure**

On average this is a 60 minute operation.* This procedure involves a cystoscopy to check the bladder and urethra, and adjusting the mesh sling.

**Risks / Complications**

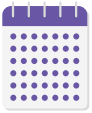
**Other risks:**

- Reoccurrence of stress incontinence
- Mesh exposure

* Additional 30 minutes required for prep and post surgery.

**Recovery Time**

**Day case or overnight stay** in hospital



**6 weeks** recovery at home with the following milestones

- Driving (1 wks)
- Work (2 wks)
- No high impact exercise (6 wks)

# Partial or Total Surgical Mesh Removal

A surgeon may recommend only removing mesh that is currently causing a problem. They may be able to remove most or all of the mesh from the body. However, removal is not always possible or safe for many women with mesh complications. Sometimes, only some of the mesh may be surgically removed.

## Risks of Removing Mesh

Removing mesh can have serious risks, including damage to the body's internal organs, nerves and blood vessels. This is because the body forms scar tissue around the mesh that fixes it in place.

The risks associated with partial or full mesh removal depend on your general health, the type and amount of mesh product implanted, and the length of time it has been inside your body. For women who have had their surgery in the last six weeks, scar tissue has not completely formed around the mesh, and the mesh may be easier to remove.

Mesh products for treatment of pelvic organ prolapse can be more difficult to remove than mesh products for stress urinary incontinence. This is because mesh products for prolapse are made from large sheets of synthetic mesh, while products for stress urinary incontinence are made from smaller pieces of mesh and not firmly attached inside the body.

## Your Treatment Options

Your surgical options for partial or total mesh removal will depend on the procedure used to insert mesh in your original treatment. Refer to the following pages based on your original treatment procedure:

**Retropubic Mid-urethral Sling**
Page 18

**Transobturator Mid-urethral Sling**
Page 18

**Vaginal Mesh (POP)**
Page 18

**Sacrocolpopexy Mesh**
Page 18

**Burch Colposuspension**
Page 20

**Fascial Sling (Native Tissue)**
Page 21

# Removal of Pelvic Mesh

**Treatment Procedure**

On average this is a 60–240 minute operation.* This procedure removes part or all of the mesh, including mesh or non-mesh.

## Risks / Complications

**Other risks:**

- Ureteic damage
- Nerve damage
- Bleeding
- Fistula
- Ongoing pain
- Reoccurence of prolapse/ incontinence

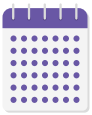
## Considerations

*This treatment may not be right for you if you have the following history. Please discuss this with your doctor.*

- Difficult to access mesh
- Significiant other medical problems
- Previous partial mesh removal

## Recovery Time

**Day case or 1–5 night stay** in hospital

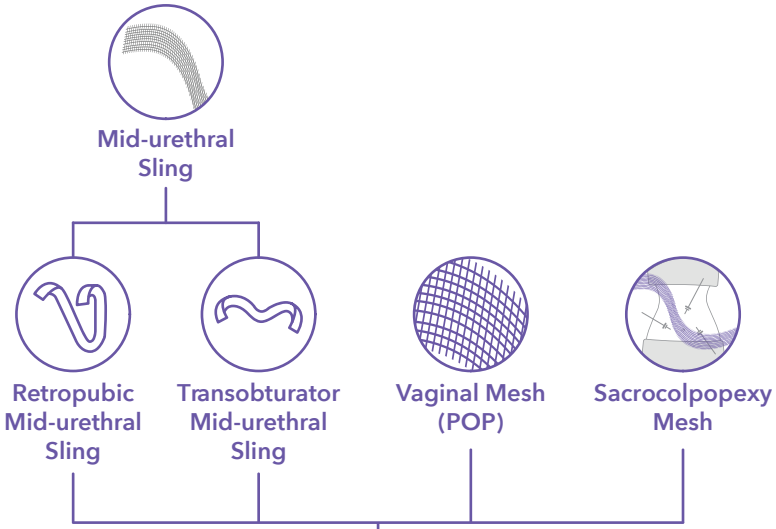


**2–6 weeks** recovery at home with the following milestones

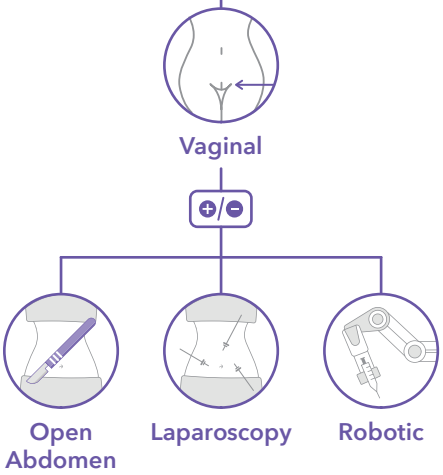
- Driving (2–6 wks)
- Work (2–6 wks)
- No high impact exercise (6 wks)
- Sexual intercourse (6 wks)

* Additional 30 minutes required for prep and post surgery.

Method of Mesh Insertion for your Original Treatment




Treatment Options for Mesh Removal



# Abdominal Urethrolysis

**Treatment Procedure**

On average this is a 90–120 minute operation.* This procedure cuts and removes sutures from colosuspension.

## Risks / Complications

**Other risks:**

- Damage to urethra
- Bleeding
- Persistence of difficulty urinating
- Damage to bowel

* Additional 30 minutes required for prep and post surgery.

## Recovery Time

**1–2 day stay** in hospital

**6 weeks** recovery at home with the following milestones

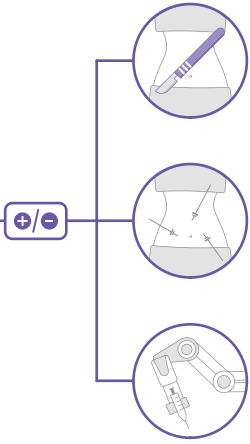
- Driving (2 wks)
- Work (2–4 wks)
- No high impact exercise (6 wks)
- Sexual intercourse (6 wks)

## Method of Mesh Insertion For Your Original Treatment

Burch Colposuspension

## Treatment Options for Mesh Removal

Urethrolysis



# Vaginal Urethrolysis

**Treatment Procedure**

On average this is a 45–60 minute operation.* This procedure divides scar tissue from a native tissue sling.

## Risks / Complications

**Other risks:**

- Urethral damage
- Fistula
- Persistence of difficulty urinating

* Additional 30 minutes required for prep and post surgery.

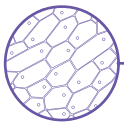
## Recovery Time

**Day case or overnight stay** in hospital

**6 weeks** recovery at home with the following milestones

- Driving (2 wks)
- Work (2–4 wks)
- No high impact exercise (6 wks)
- Sexual intercourse (6 wks)

## Method of Mesh Insertion For Your Original Treatment



Fascial Sling (Native Tissue)

## Treatment Options for Mesh Removal

Vaginal Urethrolysis

## A special note about transvaginal mesh

The Ministry of Health has reviewed evidence on the use of transvaginal mesh for stress urinary incontinence. The Ministry have decided that scientific evidence supports using mid-urethral slings for stress urinary incontinence and abdominal implantation of mesh for prolapse. Mid-urethral slings are different devices to single incision mini-slings. Single incision mid-urethral slings are not used in New Zealand.

Information about these changes can be found on the Ministry of Health's website – https://www.health.govt.nz/our-work/hospitals-and-specialist-care/surgical-mesh

The Ministry of Health has developed information for patients on surgical treatment of stress urinary incontinence and pelvic organ prolapse with mesh which includes an explanation of levels of risk for those surgical procedures that you may find useful.

## Questions to consider asking your doctor

- ? What are the risks or side effects? How likely are they? Make sure you are fully aware of the risks before you undertake removal surgery.
- ? What happens if the procedure doesn't work or something goes wrong?
- ? What are the possible benefits of surgery for me?
- ? Have you successfully performed mesh removal in the past?
- ? How many removals have you undertaken for my type of mesh and what were the outcomes?
- ? Have you recognised and managed complications of colosuspension and fascial sling?
- ? How much mesh are you planning to remove? If you are not removing all of the mesh can you explain why?
- ? Are you able manage and treat a fistula?

! *It can be helpful to take a support person with you when you talk to your doctor. You may wish to ask the doctor to explain some answers again.*

## A space for your notes, thoughts or questions...

## My Personal Plan:

*Your doctor will use this page to discuss your personal plan with you.*

# A special note for women following surgery

**In addition to the discharge information about post-operative care, here's what you can do if you have any new symptoms.**

If you experience an onset of new symptoms that do not improve with rest or simple pain relief within a day, please see:

- Your GP in the first instance
- The Emergency Department (ED) at your local hospital if you feel you require immediate treatment

**You should expect the following after your surgery:**

Pain should gradually improve over 6 weeks

You can urinate properly (emptying and normal flow) by 1 week

## A space for your notes, thoughts or questions...

## Further Information

The following websites contain helpful information, on occassion websites may change the location of information which can affect the links supplied below. To make sure you have the latest link, you can access them on our Waitematā DHB website here: **www.waitematadhb.govt.nz/healthyliving/fph/resources**

**More information can be found on the following websites:**

Information and documents from the Ministry of Health on surgical mesh www.health.govt.nz/our-work/hospitals-and-specialist-care/surgical-mesh

Useful resources for mesh
www.ranzcog.edu.au/Mesh-Resources

Urogynaecological-related information
www.ugsa.org.au/pages/patient-information.html

**Consumer resources:**

Australian Commission on Safety and Quality in Health Care
www.safetyandquality.gov.au/our-work/transvaginal-mesh/consumer-forums-to-discuss-transvaginal-mesh

Top Tips for Safe Health Care to help consumers, their families, carers and other support people get the most out of their health care. www.safetyandquality.gov.au/publications/top-tips-for-safer-health-care

# Explanation of Terms


### Credentialing
A process used by health service organisations to verify the qualifications and experience of a medical practitioner or other clinician to determine their ability to provide safe, high quality health care services within a specific health care setting and role.

### Cystoscopy
A look inside the bladder with a telescope.

### Erosion
Where a mesh implant is partly exposed inside the vagina, bladder or rectum. The synthetic mesh has worked its way outside the vaginal wall and can cause injury to surrounding structures, especially the bladder, bowel and urine pipe or urethra.

### Extrusion
Where the synthetic mesh used during surgical repair erodes through the skin and tissues and becomes exposed through the vaginal skin.

### Synthetic mesh
A man-made, net-like product that is placed in and attached to your pelvis, sometimes with ‘anchors’ to support your prolapsed organs. Polypropylene is the most common material that mesh is made from. Other terms used for mesh to repair prolapse include tape, ribbon, sling and hammock. Sometimes the term ‘mesh kit’ is used to refer to packages prepared by manufacturers that include pieces of mesh and anchors.

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