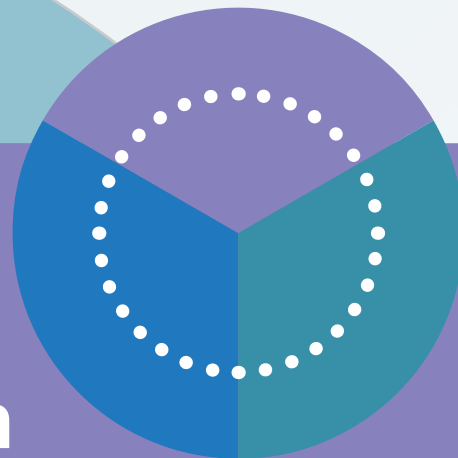


TREATMENT OPTIONS FOR

# Complications of transvaginal mesh (including options for mesh removal)



## 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 world-wide for a number of years, and in Australian women for over 15 years. The mesh provides extra support to weakened tissues.

Transvaginal mesh products are no longer available in Australia solely for the treatment of women with pelvic organ prolapse because of safety concerns about its use in this procedure. Transvaginal mesh remains a recommended surgical treatment option for stress urinary incontinence in women.

Transvaginal mesh is considered to be permanent once placed in the body.

## About this guide

The Australian Commission on Safety and Quality in Health Care (the Commission) has reviewed the safety and clinical aspects of the use of transvaginal mesh products for the treatment of pelvic organ prolapse and stress urinary incontinence, resulting in the development of some resources to support women in considering these procedures.

**Three resources have been developed to assist women discuss treatment options with their doctor and other health professionals, and share decisions about the treatment of:**

- pelvic organ prolapse
- stress urinary incontinence
- complications of transvaginal mesh (including options for removal)

This guide responds to the Recommendations of The Senate Community Affairs References Committee Report on the *Number of women in Australia who have had transvaginal mesh implants and related matters*.



## Information for consumers

This guide is designed to help you discuss the treatment options for complications and the removal of transvaginal mesh with your health professional and to share decisions about your care.

# What are the symptoms of complications of transvaginal mesh?

**While many women who have transvaginal mesh experience no complications, a number do.**

**Women can experience complications immediately after their operation or years later, and some of these will be due to transvaginal mesh.**

**Complications may range from mild to debilitating.**

Women who report complications from transvaginal mesh procedures have described a range of symptoms, including:

- Pain in the pelvis / lower back / thigh
- Awareness of the mesh during intercourse or painful sex for the woman or her partner
- A prickling feeling or pain in the vagina
- Vaginal bleeding
- Mesh can be felt in the vagina
- Recurrent urinary or vaginal infection

**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 treatment with transvaginal mesh.

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

The Therapeutic Goods Administration has listed the potential complications and adverse events that may be associated with urogynaecological meshes on its website at: [www.tga.gov.au/alert/urogynaecologicalsurgical-mesh-complications](http://www.tga.gov.au/alert/urogynaecologicalsurgical-mesh-complications).

# How are complications assessed?

Women who have transvaginal mesh complications may be assessed and treated by:

- The surgeon who implanted the transvaginal mesh
- Another specialist in the use of transvaginal mesh
- A multidisciplinary team in a specialised service for treatment of mesh complications.

Specialised services have been established by health departments in most states and territories for the assessment and treatment of women who experience complications following treatment with transvaginal mesh.

These services have teams of medical, nursing and allied health professionals including surgeons, pain specialists, physiotherapists, continence specialists, occupational therapists, nurse specialists, social workers, psychologists and psychiatrists. These teams are called multidisciplinary teams.

Teams conduct a comprehensive assessment of women's mesh history and symptoms.

- The team may use questionnaires to carefully assess pelvic function and continence, pain, social, 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 regarding which tests to perform is made by the multidisciplinary team or the treating doctor and depends on the woman's individual circumstances.

## Which types of health professionals may be in a multidisciplinary team or be seen by women independently for assessment and treatment of mesh complications?

The health professionals who may be involved in providing care to women who experience complications following treatment with transvaginal mesh include:

- **Continence nurses:** A registered nurse with specialist training and skills in managing problems associated with difficulty passing urine (including incontinence) or using the bowels.
- **Dietitians:** Dietitians provide advice to manage bowel problems and to manage weight. Women who experience mesh complications can have difficulties exercising due to pain or incontinence problems. This can lead to weight gain which worsens pelvic floor problems.
- **Occupational therapists:** A health professional who helps manage difficulties with everyday activities. Occupational therapists are able to assist in developing skills for living independently with a long-term health condition, provide advice regarding useful equipment or modifications in the home environment and teach alternative methods for everyday tasks and routines.
- **Pain specialists:** A doctor with specialist training in the evaluation and treatment of different types of pain. The pain specialist assesses and manages chronic pain. Review by a pain specialist requires completion of assessment questionnaires to enable pain levels to be monitored over time.
- **Physiotherapists:** A health professional who assesses and treats a range of problems, such as urinary and bowel problems and incontinence, pelvic pain and sexual dysfunction associated

with mesh complications. Treatments may include exercises, bladder and bowel retraining techniques, targeted massage, fitting of specialised pessaries and addressing chronic pelvic pain with different modalities.

- **Psychiatrists:** Doctors who specialise in mental health problems including anxiety and depression that can occur with chronic illness.
- **Psychologists:** Health professionals who provide emotional and mental health support. Psychologists can help women who have experienced mesh complications prepare emotionally for medical and surgical procedures; help to treat chronic pain; help with adjustment to their medical diagnoses and treatment; and treat anxiety and depression that can occur with chronic illness.
- **Social workers:** A social worker can assist with identifying social and support networks, advocate and negotiate on a woman's behalf and link women to other services and resources such as income support, employment support and disability support.
- **Surgeons:** Doctors with pelvic surgery expertise include urogynaecologists (described below), gynaecologists (surgeons who specialise in the female reproductive system), plastic and reconstructive surgeons, urologists (surgeons who specialise in urinary problems, some of whom also specialise in female functional urology) and colorectal surgeons (surgeons who specialise in bowel problems).
- **Urogynaecologists:** A doctor who has specialist training in assessing and treating problems affecting the female pelvis and in performing surgery of the female pelvis. They work with other surgeons with pelvic surgery expertise if the woman requires this, including colorectal surgeons, urologists and plastic surgeons.



## Understanding the risks of transvaginal mesh

In January 2018, the Therapeutic Goods Administration (TGA) removed transvaginal mesh products from the Australian Register of Therapeutic Goods (ARTG), where sole use is the treatment of prolapse via transvaginal implantation (through the vagina).

This action followed a review by the TGA of the latest published international studies and an examination of the clinical evidence for each product included in the ARTG and supplied in Australia. Based on this new information, and since the publication in 2014 of the *Results of review into urogynaecological surgical mesh implants*, the TGA has decided that the risks posed to patients outweigh the benefits of using transvaginal mesh products in the treatment of prolapse.

Information about these changes can be found at [www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants](http://www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants).

Complications have been attributed to the use of synthetic mesh inserted through the vagina, including mesh migration, extrusion or erosion; continual chronic pain; painful sexual intercourse; and nerve damage. These complications can be debilitating and life-altering.

# What are my treatment options?

Treatment of mesh complications depends very much on individual circumstances, the findings of the comprehensive assessment, and patient preference.

**There are different ways that complications can be treated. Your options fall into three categories:**

- 1 Physical therapy
- 2 Medications
- 3 Surgery

**Combinations of these treatments are usually recommended.**

## 1 Physical therapy

Physical therapy involves a number of different types of treatments. These include different massage techniques, bladder retraining, movement therapies, electrical stimulation, occupational therapies such as aids and equipment, and exercises to relieve chronic pain.

## 2 Medications

Medications can be used to treat continence problems, chronic pain and problems with mood and sleep.

### 3

## Surgery

Every woman's clinical situation is different. Mesh removal surgery 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.

If surgical removal is possible, it may not address all of the symptoms that a woman is experiencing. In some circumstances removal surgery can make symptoms such as pain, incontinence and prolapse worse.

For these reasons mesh removal may not be an appropriate treatment option for all women.

For women contemplating mesh removal surgery:

- The service where the removal surgery is planned should have experience in mesh removal
- Mesh removal should be carried out by an appropriately credentialed senior medical practitioner as part of a treatment program managed by a multidisciplinary team with access to specialists in urogynaecology, urology and colorectal surgery, pelvic floor physiotherapists, diagnostic ultrasound capacity, comprehensive urodynamic testing, psychiatry, psychology and pain services
- Other surgeons may also be needed including plastic surgeons and vascular surgeons. For these reasons, mesh removal surgery is usually carried out in a small number of large hospitals in each state/territory where the full range of these specialists and services is available.

## Substantial surgical removal of transvaginal mesh versus adjustments to mesh

Surgeons may be able to remove most or all of the mesh from the body (substantial removal). But for many women with mesh complications substantial removal is not always possible or safe. For these women only some of the mesh may be surgically removed.

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

The risks associated with substantial mesh removal depend on the woman's general health status, the type of mesh product implanted, the amount of mesh inserted and the time since the mesh was inserted.

Mesh products for treatment of pelvic organ prolapse are made from large sheets of synthetic mesh and are much more difficult to remove than mesh products for stress urinary incontinence, which are smaller pieces of mesh that are not firmly attached inside the body.

Risks associated with mesh removal also depend on the length of time the mesh has been inside the body. For women who have had their surgery recently (for example, in the last six weeks) scar tissue has not completely formed around the mesh and the mesh may be easier to remove.

For this reason a surgeon may recommend only removing the mesh that is currently causing a problem. For example, a surgeon may recommend removal of mesh where there is a small, painless exposure of the mesh into the vagina.

Further information on specialist clinics in states and territories are available from the Commission's website at [www.\(include link to the service model framework\)](#)



## Understanding the risks and benefits of treatment

**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.**

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

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



# Questions to consider asking your doctor

If you are offered mesh removal by a surgeon, make sure they are credentialed by the hospital where they will be performing the procedure, are experienced and have carried out the procedure before.

- ? Are you credentialed for mesh removal by the hospital?
- ? How many removals have you undertaken and what were the outcomes?
- ? What are the surgical options, what are you recommending and why?
- ? Can the type of mesh I have be removed?
- ? How much mesh are you planning to remove?
- ? What does the procedure involve?
- ? How will you perform the removal – vaginally, abdominally, laparoscopically - and why?
- ? What are the possible benefits? How likely am I to get them?
- ? 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 happens if I don't want the procedure? Are there other treatments available?
- ? Will my symptoms go away if the mesh is removed?

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.

## Terms used in this guide

### 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.

### 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 and bowel.

### 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.

### TGA

Therapeutic Goods Administration. The TGA is responsible for regulating the supply, import, export, manufacturing and advertising of therapeutic goods in Australia.

## Further information

### More information on the use of mesh for the surgical treatment of prolapse:

The Senate Community Affairs References Committee Report on the Number of women in Australia who have had transvaginal mesh implants and related matters [www.aph.gov.au/Parliamentary\\_Business/Committees/Senate/Community\\_Affairs/MeshImplants/~media/Committees/clac\\_ctte/MeshImplants/report.pdf](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants/~/media/Committees/clac_ctte/MeshImplants/report.pdf)

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists has some useful resources which can be accessed here: [www.ranzcog.edu.au/Mesh-Resources](http://www.ranzcog.edu.au/Mesh-Resources)

UroGynaecological Society of Australasia has a web page dedicated to urogynaecological-related information [www.ugsa.org.au/pages/patient-information.html](http://www.ugsa.org.au/pages/patient-information.html)

Urological Society of Australia and New Zealand (USANZ) Submission to Senate Inquiry into TransVaginal Mesh Implants [www.usanz.org.au/submission-senate-inquiry-mesh](http://www.usanz.org.au/submission-senate-inquiry-mesh)

### 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](http://www.safetyandquality.gov.au/our-work/transvaginal-mesh/consumer-forums-to-discuss-transvaginal-mesh)

Top tips for safe health care was designed by the Australian Commission on Safety and Quality in Health Care to help consumers, their families, carers and other support people get the most out of their health care. It is an aid to use when talking to your doctor and other healthcare providers, which also supports the consent process [www.safetyandquality.gov.au/publications/top-tips-for-safer-health-care](http://www.safetyandquality.gov.au/publications/top-tips-for-safer-health-care)

Australian Physiotherapy Association [www.physiotherapy.asn.au](http://www.physiotherapy.asn.au)

The Continence Foundation of Australia provides information on incontinence, prolapse, referral and products to manage these conditions [www.continence.org.au](http://www.continence.org.au)

Dietitians Association of Australia [daa.asn.au/what-dietitians-do/dietitian-or-nutritionist](http://daa.asn.au/what-dietitians-do/dietitian-or-nutritionist)

The Health Consumer Council in each Australian state and territory has a link on their website to information about peer support for women who have experienced complications.

Published by the  
Australian Commission  
on Safety and Quality  
in Health Care

Level 5, 255 Elizabeth Street  
Sydney NSW 2000  
Phone (02) 9126 3600  
Fax (02) 9126 3613

[mail@safetyandquality.gov.au](mailto:mail@safetyandquality.gov.au)  
[www.safetyandquality.gov.au](http://www.safetyandquality.gov.au)

OCTOBER 2018