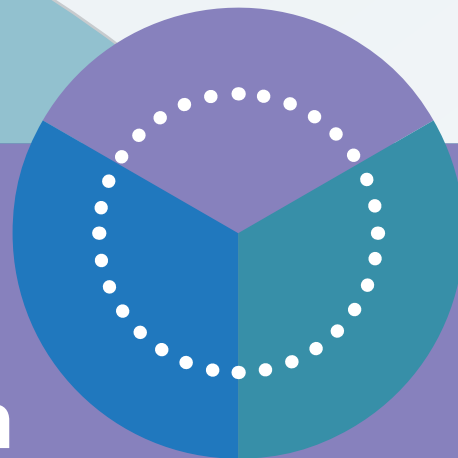


TREATMENT OPTIONS FOR

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 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 Australia 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 Australia where the intended purpose is solely for the treatment of pelvic organ prolapse. This is due to concerns about its safety in this procedure.

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

What are complications of transvaginal mesh?

Women have experienced a range of outcomes after treatment using transvaginal mesh.

Some women have experienced complications and others have not.

If you have mesh implanted and are not experiencing any troublesome symptoms, 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 mesh implant, it is important that you have a comprehensive assessment by a team of highly-skilled, specialised clinicians. Most health departments in Australia have or will soon have, a specialised service to assist you.

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.



Information for consumers

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

What are the symptoms of complications?

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

- 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
- Vaginal bleeding
- Being able to feel the mesh in the vagina or having pain or a prickly feeling
- Having blood in the urine due to erosion of the mesh into the bladder or urethra (urine tube)
- 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
- A 'foreign body response' (wound breakdown, extrusion, erosion, exposure, fistula formation and/or inflammation)

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

Many Australian women who have experienced transvaginal mesh 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.

How are complications assessed?

If you have symptoms of transvaginal mesh complications, you 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.

Health departments in most states and territories are planning or have established assessment and treatment services for women who experience complications following treatment with transvaginal mesh. These services 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.

These services should be able to do a comprehensive assessment of your mesh history and symptoms.

This may involve questionnaires to carefully 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.

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

- Continence nurse
- Dietitian
- General practitioner (GP)
- Occupational therapist
- Pain specialist
- Physiotherapist
- Psychiatrist
- Psychologist
- Social worker
- Surgeon including urogynaecologist, urologist, gynaecologist, plastic and reconstructive surgeon, orthopaedic surgeon and colorectal surgeon.

Further information on these health professionals is on page 7.

In addition, you can also seek support and advice from the peer support groups listed on page 8.



Understanding the risks of transvaginal mesh

In January 2018, the 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). The TGA also removed mini-slings (single-incision anchored mesh slings) for treating stress urinary incontinence.

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 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.

Information about these changes can be found at 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.



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

You can contact the Translating and Interpreting Service (TIS National) on 131 450 or at www.tisnational.gov.au for assistance with translating and interpreting services.

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:**

- Physiotherapy and other physical therapies
- Pain management
- Medications
- Surgery

Combinations of these treatments are usually recommended.

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.

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 (for example, 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 of a mood disorder, such as disturbed sleep, anxiety or depression, some medications might be recommended, along with counselling or psychotherapy.

Surgery

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 all of your symptoms. 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.

Mesh removal surgery requires specific expertise. Not all urologists, urogynaecologists or gynaecologists have this experience and expertise. You should ask your doctor about their experience and credentials in this area. (see *Questions to consider asking your doctor* on page 6).

If you are contemplating mesh removal surgery, these are some important things to know:

- Seek advice on the impact of this type of surgery from your health professional before consenting to surgery
- The service where the removal surgery is planned should have experience in mesh removal
- Mesh removal should only 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 and pelvic floor physiotherapists
- A full assessment should be undertaken including diagnostic ultrasound capacity, comprehensive urodynamic testing, psychiatry, psychology and pain services

- Surgery to remove mesh will not necessarily resolve all of your symptoms. You and your treating doctor should develop a plan for pre- and post-operative care, including longer term management of existing and any new symptoms
- A known problem with transvaginal mesh is chronic infection caused by contamination of the device when inserted through a non-sterile passage (the vagina).

Other surgeons may also be involved in your treatment, including plastic surgeons and orthopaedic surgeons. Only a small number of hospitals in each state or territory have the full range of these specialists and services available.

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.

Substantial surgical removal of transvaginal mesh compared to adjustments to mesh

Substantial removal is where a surgeon is able to remove most or all of the mesh from the body. However, substantial removal is not always possible or safe for many women with mesh complications. Sometimes, only some of the mesh may be surgically removed.

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 substantial 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.

A surgeon may recommend only removing mesh that is currently causing a problem.

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

Further information on services in the states and territories is available from the Commission's website at www.safetyandquality.gov.au/publications-and-resources/resource-library/service-model-framework-transvaginal-mesh-complications-and-removal

Questions to consider asking your doctor

Removal of mesh should only be done by a surgeon who is credentialed by the hospital where the surgery will be performed, and who is experienced in mesh removal procedures. Each hospital has its local processes to consider credentialing of health professionals.

- ? Do you have the necessary approvals and credentials from the hospital where you would perform my procedure?
- ? Can the type of mesh I have be removed?
- ? How many removals have you undertaken for my type of mesh and what were the outcomes?
- ? What are the surgical options, what are you recommending and why?
- ? If I have the surgery, what is my expected recovery period?
- ? Will my symptoms go away if the mesh is removed?
- ? What will happen if I don't have the procedure? Are there other options available?
- ? How much mesh are you planning to remove? If you are not removing all of the mesh can you explain why?
- ? What does the procedure involve?
- ? How will you perform the removal – vaginally, abdominally, laparoscopically - and why?
- ? What are the possible benefits for me?
- ? 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?

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

ARTG

Australian Register of Therapeutic Goods.

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 within their scope of practice.

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.

TGA

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

Who may be involved in my care?

You may have quite a few health professionals involved in your care. These might include:

- **Continence nurse** A registered nurse with specialist training and skills in managing problems associated with difficulty passing urine (including incontinence) or using the bowels.
- **Dietitian** 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.
- **General practitioner (GP)** A doctor who is based in the community and treats minor and chronic conditions and refers those with serious health conditions to other specialised health workers. GPs focus on the health of the whole person, combining physical, psychological and social aspects of care.
- **Occupational therapist** A health professional who assists in managing 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 specialist** A doctor with specialist training in the evaluation and treatment of different types of pain. The pain specialist assesses and manages chronic pain.
- **Physiotherapist** 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 transvaginal 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** A doctor who specialises in mental health problems including anxiety and depression that can occur with chronic illness.
- **Psychologist** A health professional who provides 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 worker** 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.
- **Surgeon** A doctor with pelvic surgery expertise include urogynaecologists (specialised in assessing and treating problems affecting the female pelvis); urologists (surgeons who specialise in urinary problems, some of whom also specialise in female functional urology); gynaecologists (surgeons who specialise in the female reproductive system), plastic and reconstructive surgeons, and colorectal surgeons (surgeons who specialise in bowel problems).

In addition, you can also seek support and advice from peer support groups listed on page 8.

About this guide

The safety and clinical aspects of using transvaginal mesh products to treat pelvic organ prolapse and stress urinary incontinence has been reviewed by the Australian Commission on Safety and Quality in Health Care.

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*.

Two other resources have been developed to help women discuss treatment options with their doctor and other health professionals, and share decisions about the treatment of pelvic organ prolapse and stress urinary incontinence.

Further 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* and the Government Response

www.aph.gov.au/Parliamentary_Business/Committees/Senate/Community_Affairs/MeshImplants

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists has some useful resources related to transvaginal mesh

www.ranzcog.edu.au/news/Use-of-mesh-for-the-surgical-treatment-of-vaginal

UroGynaecological Society of Australasia has a web page dedicated to urogynaecological-related information

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

Urological Society of Australia and New Zealand (USANZ) Submission to the Senate Inquiry into TransVaginal Mesh Implants

www.usanz.org.au/info-resources/position-statements-guidelines/vaginal-mesh-complications

Consumer resources

Australian Commission on Safety and Quality in Health Care

www.safetyandquality.gov.au/our-work/health-conditions-and-treatments/transvaginal-mesh/resources-consumers-clinicians-and-health-service-organisations-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

Australian Physiotherapy Association

<https://choose.physio/your-lifestage/motherhood/women's-health>

Dietitians Association of Australia

daa.asn.au/what-dietitians-do/dietitian-or-nutritionist

HealthDirect provides information on chronic pain

www.healthdirect.gov.au/chronic-pain

Mesh Injured Australia is a consumer organisation run by women with complications from mesh surgery

www.meshinjuredaustralia.org.au

The Australian Pelvic Mesh Support Group is a social network-based peer support group for women with transvaginal mesh

www.facebook.com/groups/AustralianPelvicMeshSupportGroup/

The Continence Foundation of Australia provides information on incontinence, prolapse, referral and products to manage these conditions

www.continence.org.au

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

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