

Pelvic mesh: Frequently Asked Questions

What support is available?

The SA Health **Pelvic Mesh Consumer Support Line: 1800 66 MESH** (1800 666 374) 9 am – 4 pm, Monday to Friday (except public holidays).

A **multidisciplinary Pelvic Mesh Clinic** is open at the Royal Adelaide Hospital, providing comprehensive health care for women experiencing major complications related to pelvic mesh implants.

Clinical experts are available at the clinic to assist the patients with specialist surgical advice, pain management, continence management, pelvic floor physiotherapy, urogynaecology, psychology and urology assessment as required.

A referral is required from a GP or specialist.

Each referral will be reviewed to determine the clinical urgency and appointments will be scheduled based on clinical need. Women found to have less complex complications during the assessment may be referred to a local gynaecology service. See the patient referral pathway for more details.

What is pelvic mesh?

Pelvic mesh, also known as transvaginal mesh as it is implanted in a surgical procedure via the vagina, is a woven synthetic netting usually made from Polypropylene. Other synthetic meshes can be implanted via laparoscopic procedure for intra-abdominal approach.

Pelvic mesh is implanted into the pelvis for a variety of conditions, usually pelvic organ prolapse and stress urinary incontinence.

- > **Pelvic organ prolapse** - a condition where a woman's vaginal walls and pelvic organs (uterus, bladder and bowel) lose natural support, which causes them to bulge down within, and sometimes outside of the vagina. For more information visit www.sahealth.sa.gov.au/pelvicmesh and see information on pelvic organ prolapse.
- > **Stress urinary incontinence** - a condition where the supporting tissues of the bladder neck and urethra lose their natural support, which causes an accidental loss of urine with physical activity such as coughing, sneezing or exercise. For more information visit www.sahealth.sa.gov.au/pelvicmesh and see information on stress urinary incontinence.

These two conditions are different but both may occur in the same woman, and the surgeries for the two conditions may be performed together. The mesh used in each condition is made from the same material, but the nature of the operation for each condition is quite different.

In most cases:

- > The recommended first line treatment for either condition is with a pelvic physiotherapist and urogynaecology nurse who are trained in pelvic floor problems, except in severe prolapse as outlined above.
- > Women can safely choose to have no treatment and prefer to manage with pads or other treatment / aids.
- > Treatment is usually only recommended if prolapse or incontinence symptoms are bothersome, or there is an extremely large prolapse creating bladder blockage, kidney blockage, vaginal ulceration or pelvic pain.
- > Women should consider conservative (non-surgical) treatment before considering surgical treatment.
- > Surgery for both prolapse and stress incontinence generally involve procedures that reinforce the weakened support tissues.
- > Many women choose to go on to surgery because they have not gained sufficient improvement with non-surgical treatments, and the condition is affecting their quality of life.

Are 'slings' and 'tapes' made from the same material as pelvic mesh?

A 'sling' or 'tape' used in pelvic procedures are produced from woven synthetic netting usually made from Polypropylene. This is the same product as those referred to as 'pelvic mesh'. Meshes are sometimes known as 'slings', 'tapes' or 'hammocks'. It can also be referred to as 'prolapse repair'.

The Therapeutic Goods Administration¹ decided on 28 November, 2017 to remove transvaginal mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the Australian Register of Therapeutic Goods.

In Australia at present 'Mesh' products are not restricted in the treatment of stress urinary incontinence.

If you have any concerns regarding the product that was been used in the surgery that you have undergone, you would benefit from requesting a copy of your Medical Record from the site where the surgery was performed and discussing your concerns with your GP or the treating surgeon to ascertain what, if any, product was used in your surgery/procedure.

What is the concern with pelvic mesh?

The majority of women have a good outcome from transvaginal mesh procedures; however, there are women who have suffered complications. Some of these are very serious and life changing, particularly for women who experience severe chronic pain, have had mesh exposure or erosion into the bladder, urethra or bowel, or recurrent vaginal exposure and infection.

In December 2017, the Therapeutic Goods Administration, Australia's regulatory authority for therapeutic goods, removed transvaginal mesh solely used for the treatment of most pelvic organ prolapse (such as bladder, bowel or uterine prolapse).

What are some of the possible mesh-related complications?

Transvaginal mesh products can cause significant and severe complications for some women including:

- > Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, requiring surgical repair.
- > Mesh extrusion, expulsion or erosion into the vagina or other structures or organs.
- > Acute and/or chronic pain; or neuromuscular problems.
- > Infection.

What symptoms might I notice if I have a pelvic mesh complication?

Symptoms that may be associated with pelvic mesh implant complications include:

- > Pain that is not improving - low abdominal, pelvic, groin, thigh or buttock pain
- > Poking / prickling sensation or spasms in the pelvic area
- > You or your sexual partner feeling the mesh through the vaginal wall
- > Pain (either you or your sexual partner) during sexual intercourse
- > Abnormal vaginal bleeding or discharge
- > Difficulty with bladder emptying
- > Pain associated with urination
- > Recurrent bladder infections
- > Abscess or swelling at the mesh insertion or exit sites.

¹ Therapeutic Goods Administration - www.tga.gov.au

What can be done about pelvic mesh that is causing symptoms?

Further assessment and any additional treatment should be undertaken by experienced Gynaecologists, Urogynaecologists or Urologists who specialise in pelvic surgery.

As part of the process, assessment and treatment options specific to your circumstances should be discussed and tailored to these concerns and problems.

ASSESSMENT

Common assessments which may be undertaken include a bladder assessment (urodynamic),-or a cystoscopy, where a thin tube with a camera is inserted into the urethra. A specialised ultrasound or other imaging such as a CT scan or MRI may be helpful. You and your doctor should decide whether imaging would be helpful, taking into account your circumstances.

TREATMENT

What can be done to help in these circumstances very much depends on what is found in your assessment, other medical factors and your expectations.

Treatment may include:

- > bladder and/or pain medications
- > expert physiotherapy (particularly for bladder/bowel dysfunction and down regulation of pelvic muscles; standard pelvic floor exercises are not appropriate and may lead to increased pain)
- > pain management strategies
- > psychological support
- > targeted partial removal of mesh (particularly for localised problems, such as a small painless vaginal exposure)
- > full removal of mesh (particularly for chronic pain).

Combinations of these management strategies are often recommended.

When considering mesh removal there needs to be an individualised balance struck between the risk of further complications associated with the mesh remaining, compared with the risk of complications from any removal procedure and also the possibility of complications remaining with the mesh removed.

You may wish to access your medical record from the hospital where you had the surgery. More details are available under 'How can I make a request for access to my medical records?'

The SA Health **Pelvic Mesh Consumer Support Line: 1800 66 MESH** (1800 666 374), can provide more information regarding access to your medical records.

What should I do if I think pelvic mesh is affecting my health?

If you are having symptoms visit your GP to determine if the symptoms are associated with a mesh implant.

If your GP does not have details of your operation you or your GP may ask for a copy from the hospital where you had your surgery to help establish a management plan for you.

If you are assessed as having major complications your GP may refer you to the Pelvic Mesh Clinic. Each referral will be reviewed at the clinic to determine the clinical urgency of your condition. Appointments will be scheduled based on clinical need.

Those women assessed with less complex complications may be referred to a local gynaecology service.

The SA Health **Pelvic Mesh Consumer Support Line: 1800 66 MESH** (1800 666 374), can provide more information regarding access to your medical records.

My referral to the pelvic mesh clinic has been declined, now what?

Your options will depend on the reason your referral was declined. The pelvic mesh clinic does not decline referrals for women who are having complications from mesh that was inserted vaginally.

Sometimes, after the pelvic mesh clinic staff have gathered all of the required information; it is found that no mesh was inserted. Under these circumstances you should discuss your condition further with your General Practitioner to determine the best plan for the management of your symptoms.

Some referrals received by the pelvic mesh clinic are for women who have had mesh inserted, but not in the pelvis. Mesh is commonly used in the repair of hernias. If this is the case, you should see your General Practitioner regarding management of this, which may include referral to a surgeon.

Some referrals are not for complications from the mesh, but for a recurrence of the condition for which the mesh was inserted, usually pelvic organ prolapse or urinary stress incontinence. These women do not need to be seen in the pelvic mesh clinic, but would best be managed by seeing a Gynaecologist who specialises in these areas. Your General Practitioner can provide you with an appropriate referral.

Who can I report my pelvic mesh problems and side effects to?

Consumers and health care professionals are strongly encouraged to report adverse events related to implanted medical devices directly to the Therapeutic Goods Administration (TGA).

Reporting adverse events (problems with medical devices) helps make medical devices safer for everyone.

If you think you may be experiencing problems in relation to pelvic mesh seek advice from your GP or the treating surgeon as soon as possible.

Information on how to make a report to the TGA can be accessed on their [Report a problem or side effect](#) webpage.

If you require assistance to report a medical device problem you can contact the TGA on 1800 809 361 (08:30 am to 5:00 pm, Monday to Friday) or email IRIS@health.gov.au.

Once you have made a report it is assessed and entered into the TGA [Incident Reporting and Investigation Scheme \(IRIS\)](#) where all reports of adverse events or problems associated with medical devices are managed.

I have been told to not do pelvic floor physio with a mesh implant – is this true?

Not every woman who has had pelvic surgery will suffer with the same health problems because of pelvic mesh and because everyone is different, you are encouraged to discuss your concerns with your GP who may refer you to a Physiotherapist who specialises in pelvic floor health.

I can't be intimate with my partner anymore and our relationship is breaking down, what can we do?

Pelvic mesh can significantly impact intimate relationships, especially when pain is present. Having access to advice from the right medical specialists and pelvic physiotherapists can help you navigate the physical challenges this brings, and psychological support can help you manage the stress that you and your partner may feel, as well as help you to strengthen your relationship in other ways. Intimacy is important to our relationships, and we believe it should be openly discussed.

If you have any concerns about your relationship it is important to try to be as open as possible and communicate with your partner. Some couples, especially those who have never really discussed their sexual behaviour, may struggle to accept and embrace change, and as a result, may harbour feelings of disappointment or loss. If this is the case, you may benefit from speaking to a relationship counsellor. Counselling can help you to:

- > Address specific issues in life
- > Improve self-confidence
- > Manage anxiety
- > Expand communication
- > Deal with differences and conflict
- > Cope with separation and losses
- > Overcome trauma and life challenges
- > Repair or strengthen your relationships.

Relationships Australia (www.rasa.org.au) provides counselling support that can provide you and your partner a chance to adjust repair and strengthen your relationship. Contact the Relationships Australia South Australia office on 1300 364 277 (cost of a local call) or 1800 182 325 (country callers).

Alternatively, call the Family Relationship Advice Line on 1800 050 321 or visit www.familyrelationships.gov.au.

What is being done about this problem for women in South Australia?

SA Health has developed a range of strategies to support for women who are 'mesh affected'. These strategies have been developed in conjunction with lead clinicians and from across South Australia and consumer advisors.

SA Health has established a multidisciplinary Pelvic Mesh Clinic, providing comprehensive health care for women experiencing major complications related to pelvic mesh implants. Each referral will be reviewed at the clinic to determine the clinical urgency of your condition. Appointments will be scheduled based on clinical need.

Those women assessed with less complex complications may be referred to a local gynaecology service.

The **Pelvic Mesh Consumer Support Line: 1800 66 MESH** (1800 666 374) remains in operation for consumers requiring information about transvaginal mesh, operating between 9 am and 4 pm Monday to Friday (excluding public holidays).

SA Health is supporting women in South Australia who are experiencing complications from pelvic mesh, and is waiving the Freedom of Information application fee and the associated charges.

Support for country residents

Patients living in a rural or remote area that need to travel more than 100 kilometres to see a specialist may be eligible for support through the Patient Assistance Transport Scheme (PATS).

For more information about PATS, visit www.sahealth.sa.gov.au/pats.

What can I do now?

If you are worried or have symptoms that may be related to your pelvic mesh surgery you are encouraged to discuss your concerns with your GP who may refer you to the Pelvic Mesh Clinic.

Each referral will be reviewed at the clinic to determine the clinical urgency of your condition. Appointments will be scheduled based on clinical need.

You may wish to call the SA Health **Pelvic Mesh Consumer Support Line on 1800 66 MESH** (1800 666 374) between 9 am – 4 pm, Monday to Friday (except public holidays) to discuss your issues.

If you require help in accessing the Pelvic Mesh Consumer Support Line the following services are available.

For those who speak languages other than English:

- > **Translation service:** phone (08) 8226 1990, then ask for 1800 666 374.

For those who are deaf, hearing impaired or speech impaired:

- > **TTY users:** 133 677 then ask for (08) 8226 6000.
- > **Speak and Listen users:** 1300 555 727 then ask for (08) 8226 6000.
- > **Internet relay users:** connect to the National Relay Service - <https://www.communications.gov.au/what-we-do/phone/services-people-disability/accesshub> then ask for (08)8226 6000.

What other support is available?

- > **Health Consumers Alliance of SA Inc.** – <https://www.hcasa.asn.au/>
- > **Continence Foundation of Australia** – <https://www.continence.org.au/>
- > **Australian Pelvic Mesh Support Groups** – Support groups are available on *Facebook* by searching 'Australian Pelvic Mesh Support Groups'. A moderator may need to approve you joining the group.

Is pelvic mesh the same mesh that they use for hernia repairs?

Pelvic mesh, also known as transvaginal mesh as it is implanted in a surgical procedure via the vagina, is a woven synthetic netting usually made from Polypropylene.

There are a wide range of products made from polypropylene that are commonly called mesh that are used in many different types of surgery. The mesh used for these surgeries is essentially the same mesh used by general surgeons to repair hernias and other abdominal wall defects.

If you have any concerns regarding the product that was been used in the surgery that you have undergone, you would benefit from requesting a copy of your Medical Record from the site where the surgery was performed and discussing your concerns with your GP or the treating surgeon to ascertain what, if any, product was used in your surgery/procedure.

Can pelvic mesh be removed?

If you have had pelvic mesh implanted to treat prolapsed organs and/or stress urinary incontinence resulting in complications, you may require surgery to remove all or part of the mesh.

Pelvic mesh removal surgery ranges from being relatively straight forward to complex, and because pelvic mesh is considered a permanent implant, surgery to remove the mesh can be difficult and may increase the risk of additional complications or symptoms.

The Australian Commission on Safety and Quality in Health Care makes note that if surgical removal of the mesh 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. This surgery 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. For these reasons, mesh removal may not be an appropriate treatment option for you².

The Pelvic Mesh Clinic at the RAH brings together clinical experts from various health backgrounds and disciplines to work together as a team to review your individual case.

These experts will assist you with specialist surgical advice, pain management, continence management, pelvic floor physiotherapy, urogynaecology, psychology and urology assessment as required.

² <https://www.safetyandquality.gov.au/wp-content/uploads/2018/12/Treatment-Options-Complications-Consumer-Info.pdf>

A full mesh removal procedure will require hours of surgery and can risk damage to nerves and nearby organs, including the bladder and bowel. The decision to undertake a full mesh removal procedure will not be taken lightly and only after considered consultation with the Pelvic Mesh Clinic multidisciplinary team.

Any recommended surgery will be customized to your needs and it will depend on the type of mesh and surgery that has already been performed. Following your assessment your surgeon may recommend only removing the part of your mesh that is currently causing a problem.

For more information contact the **SA Health Pelvic Mesh Consumer Support Line: 1800 66 MESH** (1800 666 374), or access the [Australia Commission on Safety and Quality in Health Care](#) website resources.

I am waiting to go in for a pelvic procedure but I am scared now.

If you have any concerns about your upcoming surgical procedure you would benefit from speaking to your doctor / surgeon so that you are fully informed before your procedure and what medical devices, if any are planned on being used in your procedure.

Contact the SA Health Pelvic Mesh Consumer Support Line on 1800 66 MESH (1800 666 374) if you require any assistance.

I had a sling put in for pelvic organ prolapse, is this pelvic mesh?

A sling could be one of a wide range of products made from 'polypropylene' that are commonly called 'mesh'. Other terms used for mesh to repair prolapse include tape, ribbon and hammock.

The Therapeutic Goods Administration decided on 28 November, 2017 to remove transvaginal mesh products whose sole use is the treatment of pelvic organ prolapse via transvaginal implantation from the Australian Register of Therapeutic Goods. In Australia at present, 'mesh' products such as a 'sling' are not restricted in the treatment of stress urinary incontinence.

If you have any concerns regarding a product used in your surgery, you may benefit from requesting a copy of your Medical Record from the hospital site where your surgery was performed. It would be advisable that you discuss your concerns with your GP or the treating surgeon.

I want all of my mesh removed, why can't I get this done in South Australia?

The report on the Australian Government Senate Inquiry - *Senate Community Affair Reference Committee: Transvaginal Mesh 2018 recommended that 'full mesh' removal should only be undertaken in an urogynaecology unit.* South Australia currently does not have a urogynaecology unit.

However, through the Pelvic Mesh Clinic available at the Royal Adelaide Hospital, clinicians are developing a referral pathway for women who require 'full removal of pelvic mesh'. It is hoped that this service may be available in South Australia in 2021.

Who owns my medical records?

Generally, the health service provider who creates a medical record owns that record. This doesn't interfere with your right to access your record, because ownership and access rights are separate.

Can I get access to my medical records?

SA Health agencies

If your medical records are held by a South Australian hospital you have a right to access those records.

SA Health is supporting women in South Australia who are experiencing complications from pelvic mesh and will waive the freedom of Information application fee and the associated charges.

The South Australian Freedom of Information (FOI) Act 1991³ gives members of the public a legally enforceable right to access information held by South Australian Government agencies, subject to certain conditions. For more information please refer to the *Pelvic Procedure: Request for Access to Health Records*⁴ fact sheet.

Applications for access to documents must be made in writing and lodged with the agency that holds the document. To apply for access to your personal medical records you can complete the *Pelvic Procedure: Freedom of Information Application Form*⁵, or access the relevant agencies (i.e. hospital) website and complete their FOI Form.

The **SA Health Pelvic Mesh Consumer Support Line: 1800 66 MESH** (1800 666 374) can provide more information regarding accessing your medical records.

If you believe you have been unfairly denied access to your medical record by the agency, you have the right to seek an internal review by the Principal Officer/Chief Executive of the agency. If access is still not granted then further rights to request a review exists, either to the Ombudsman⁶, or to the South Australian Civil and Administrative Tribunal⁷.

Ombudsman SA has the power to investigate and conduct an external review of determinations by agencies under the FOI Act. They may confirm, vary or reverse the determination made by the agency. They may also review the fees and charges levied by agency for access to documents under the FOI Act.

Private health service

If your medical records are held by a private sector organisation, such as a doctor in private practice or by a private hospital, as a general rule, you have a right to gain access to all the information held about you as prescribed in the Commonwealth Privacy Act⁸.

You may exercise this right in a number of ways (depending on, for example, the sort of information you have asked for, the type of organisation and the way the organisation holds its records) for example:

- > looking over the records
- > taking a copy of those records with you
- > having them explained to you.

In some cases, you may need to reach an arrangement about access with the organisation holding the records. There are some limitations on your right of access. These may apply for example, to:

- > where giving access would pose a serious threat to the life and health of anyone
- > where refusing access is required by law.

If you believe you have been unfairly denied access to your medical record by the 'private health service', you can make a complaint to the *Office of the Australian Information Commissioner*⁹.

Can my health service provider give my representative access to my medical records?

In some cases, an individual may need a representative to assist them in gaining access to their medical record. For instance, an individual may be unable to exercise their access rights because they lack the legal capacity to do so, but their guardian (if they have one) may seek access, if the guardian has the appropriate legal authority.

³ SA Freedom of Information Act 1991: www.legislation.sa.gov.au/lz/c/a/freedom%20of%20information%20act%201991.aspx

⁴ Pelvic Procedure: Request for Access to Health Records: <https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/resources/pelvic+procedure+request+for+access+to+health+records+fact+sheet>

⁵ Pelvic Procedure: Freedom of Information Application Form: <https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/resources/pelvic+procedure+freedom+of+information+application+form>

⁶ Ombudsman SA: www.ombudsman.sa.gov.au

⁷ South Australian Civil and Administrative Tribunal: www.sacat.sa.gov.au

⁸ Commonwealth Privacy Act: <https://www.legislation.gov.au/Series/C2004A03712>

⁹ Office of the Australian Information Commissioner: <https://www.oaic.gov.au/individuals/what-can-i-complain-about>

How can I make a request for access to my medical records?

When making an application for access to your medical records through the Freedom of Information process you will need to provide enough information to enable the correct documents to be identified.

SA Health agencies

Each SA Health agency operates separately for the purposes of Freedom of Information legislation.

Applications for access to documents must be made in writing and lodged with the agency that holds the document. To apply for access to your personal medical records you can complete the *Pelvic Procedure: Freedom of Information Application Form*⁴ or you can download an FOI form from the website of the site where the surgery was performed.

It is recommended that you read the *Pelvic Procedure: Request for Access to Health Records*³ fact sheet before completing and lodging your application.

The SA Health Pelvic Mesh Consumer Support Line: **1800 66 MESH** (1800 666 374) can provide more information regarding accessing your medical records.

N.B. SA Health is supporting women in South Australia who are experiencing complications from pelvic mesh, and is waiving the Freedom of Information application fee and the associated charges.

Private health service

Australian Privacy Principle 12 in the *Privacy Act*² deals with access to personal information (including health information). However, it doesn't set out any requirements for the way you should make an access request.

This means you can request access to your medical records simply by asking the health service provider holding the records. If the request is a complex one, for example the information comes from a number of different sources, it may be necessary to provide the request in writing. Your health service provider may need to establish your identity before providing you with access.

If you believe you have been unfairly denied access to your medical record by the 'private health service', you can make a complaint to the *Office of the Australian Information Commissioner*⁴.

How much time can an organisation take to meet my request for my medical records?

Health service providers should respond to a request for access to medical records within an appropriate time. What is **appropriate** will depend on a number of factors, which can include;

- > the amount of information requested,
- > the complexity of the organisation's functions and activities, and
- > the way the access is to be provided.

A request for access will be dealt with as soon as practicable, within 30 calendar days of it being received. In certain circumstances the agency may extend the timeframe for dealing with your application and should inform you if an extension is necessary, and why.

Can a health service provider refuse to give me access to my medical records because it would pose a threat to either my, or somebody else's, life or health?

Generally, health service providers are required to give you access to your health information.

However, in some situations, health service providers may refuse to give access. For example, health service providers can deny access if they reasonably believe letting a patient see their records would pose a serious threat to the patient's life, health or safety, or the life, health or safety of someone else (such as a relative, the health service provider or their staff).

The threat must be significant, for example where there is a serious risk the patient may cause self-harm or harm to another person if they saw the information.

The threat can be to physical or mental health safety, but does not need to be imminent — it can be a serious threat that could occur sometime after access is granted.

If you believe you have been unfairly denied access to your medical record by an 'SA Health agency', for example a public hospital, you have the right to seek an internal review by the Principal Officer/Chief Executive of that agency. If access is still not granted then further rights to request a review exists, either to the *Ombudsman*, or to the *South Australian Civil and Administrative Tribunal*.

If you believe you have been unfairly denied access to your medical record by the 'private health service', you can make a complaint to the *Office of the Australian Information Commissioner*.

For more information

Pelvic Mesh Consumer Support Line
Telephone: 1800 66 MESH (1800 666 374)
Email: Health.PelvicMeshSupportService@sa.gov.au
www.sahealth.sa.gov.au/pelvicmesh

