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Bulkamid treatment for urinary incontinence

What is Bulkamid?

Bulkamid hydrogel is a transparent polyacrylamide gel consisting of 97.5% non-pyrogenic water and 2.5% cross-linked polyacrylamide. It is bio-compatible, non-re-absorbable, migration resistant, non-allergenic and micro-article free. Tissue hardening is unlikely to occur.

What problems does it fix or improve?

There are many causes or types of urinary incontinence. Some people with stress incontinence have a urethra which is open at rest even when the bladder is only partly full. In this condition, exertion can cause urine to fall or spurt through the urethra. These leakages are not always felt when they occur but can be demonstrated by tests called fluoroscopic urodynamics.

Women or men with stress incontinence may respond to this treatment. It is very common to improve with Bulkamid injections, but only particular sub-types are likely to have a response which gets rid of their leakage entirely. The sub-type is determined with urodynamic testing and Prof O'Connell and staff will inform you of the probability of it being effective in your case.

How does it help exertion-related leakage (also known as stress incontinence)?

The goal of therapy is to bring about an effective seal of the inner lining of the urethra so that all surfaces on the inner aspect of the urethra are closed or "coated". Normally, the urethra is closed at rest and only opens when the bladder contracts. This latter process is generally not affected by injection into the top part of the urethra just below the bladder neck.

You may have other urinary problems that also require treatment or need to be considered separately such as medications for an overactive bladder or antibiotics for infection.

Where is the procedure performed?

The procedure takes place in the Day Procedure Unit at Melbourne Private Hospital under local anaesthetic. No fasting is required and there are no restrictions to activities afterwards.

If you are taking anti-coagulation medication (e.g. Warfarin), you should cease this five days prior to the Bulkamid treatment. It is important that you discuss this with the doctor who prescribes this medication for you.

What is involved during the procedure?

Using a cystoscopic set specifically engineered for Bulkamid injections, a small cystoscope (a very small flexible telescope approx 3mm in diameter) is passed into the bladder. You will be able to watch your treatment on the television monitor. In addition to the anaesthetic gel that has been given, a precise pinpointed injection of local anaesthetic is placed in the urethral wall. At this location, when you are comfortable (within a few seconds), the Bulkamid is placed. A dose of antibiotic will also be given prior to the procedure to prevent infection.

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How long does the procedure take?

The procedure takes approximately 15 minutes, however, allowing time for admission and discharge from the Day Procedure Unit, you should allow approximately 1.5hrs.

Are there any complications?

After any telescopic procedure, there can be a little bleeding. Thus, there may be a slight amount of blood in the urine. This settles within a day or two. Some minor discomfort may also be associated but significant discomfort is rare. Occasionally urgency or even urge incontinence occurs after a Bulkamid injection. This usually settles spontaneously although sometimes treatment is required, this is almost always short term.

Can I exercise after the procedure?

It is recommended to avoid vigorous exercise for at least 24 hours following the procedure. This allows time for the injection side at the urethra to heal.

How many injections will I have to stop the problem?

It is possible to predict how many injections will be required to some extent and the effect that is likely. You will be given guidance about this at the time of consent with Prof O'Connell. Typically, patients require between one and two separate treatments.

What is the follow up after an injection?

You will be given a questionnaire at the time of the procedure which you are asked to complete and return to Prof O'Connell four weeks post-treatment. Upon receipt of this information, the practice nurse will assess your progress and will be contacted should there be any recommendation.

If unexpected ill effects occur after the procedure, please contact Prof O'Connell's rooms or the Day Procedure Unit should be notified.

TREATMENT OPTIONS FOR

Stress Urinary Incontinence



What is stress urinary incontinence?

Stress Urinary Incontinence (SUI) is the leaking of urine during activities that increase pressure inside the abdomen and push down on the bladder, such as coughing, sneezing, running, or heavy lifting.

There are several causes of SUI including pregnancy, childbirth (particularly where forceps were needed), weight gain, and chronic straining or coughing.



Information for consumers

This guide is designed to help you discuss treatment options for stress urinary incontinence with your health professional and to share decisions about your care.

Types of incontinence

Incontinence is any accidental or involuntary loss of urine from the bladder – urinary incontinence – or bowel motion, faeces or wind from the bowel – faecal or bowel incontinence.

There are different types of urinary incontinence, each with different causes and treatments, which include:

- Stress incontinence – this type of incontinence is the focus of this information resource
- Urge incontinence – urinary incontinence preceded by a sudden and strong need to urinate
- Incontinence associated with chronic retention – when the bladder is unable to empty properly and frequent leakage of small amounts of urine occurs as a result
- Functional incontinence – due to medications or health problems that make it difficult to reach the bathroom in time
- Continuous incontinence – where your bladder cannot store any urine at all, resulting in either passing large amounts of urine constantly, or passing urine occasionally with frequent leaking.

Sometimes women have more than one type of incontinence. Specialised tests will help diagnose the type of incontinence you have and which treatment options are right for you. These tests may include a urodynamic study or a cystoscopy.



About this guide

The Australian Commission on Safety and Quality in Health Care 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 to discuss treatment options with their doctor and other health professionals, and share decisions about 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.

This guide has considered the decision by the Therapeutic Goods Administration, to remove transvaginal mesh single-incision mini-slings, from the Australian Register of Therapeutic Goods (TGA) from 4 January 2018.

What are my treatment options?

Stress urinary incontinence can be embarrassing and distressing. Your treatment really depends on how much it affects you and what you feel you can cope with, as well as your general health. Your options fall into three categories:

1 Do nothing

Manage your symptoms with continence aids

2 Non-surgical treatments

Lifestyle changes, pelvic floor exercises, continence pessaries

3 Surgical treatments

Pubovaginal sling, colposuspension, retropubic mid-urethral sling, transobdurator mid-urethral sling, urethral bulking agents.

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.

After considering the less-invasive, non-surgical options, it is your decision if you wish to proceed with surgical treatment.

Some surgical options use transvaginal mesh in a mid-urethral sling. The Royal Australian and New Zealand College of Obstetricians and Gynaecologists recommends mid-urethral sling surgery for SUI in routine cases. The Royal Australasian College of Surgeons also recommends that you understand your options before proceeding with treatment.

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Non-surgical treatment options

Non-surgical treatments are recommended as the first line of treatment by the Royal Australian and New Zealand College of Obstetricians and Gynaecologists and the Urological Society of Australia and New Zealand (part of the Royal Australasian College of Surgeons).

You may be able to improve some symptoms without surgery. The following treatment options are safe, and a combination of these options may give you good results. However, they may not work for everyone and you may still have symptoms that affect your quality of life.

Lifestyle changes

Reducing weight, avoiding heavy lifting, avoiding constipation and chronic coughing, stopping smoking and doing lower impact exercises are all non-surgical options that should be considered. Each of these options can help increase control over your bladder and contribute to overall good health.

These changes need consistent effort, over the long term as it takes time for lifestyle changes to work. Support from a health professional, such as a dietitian or your general practitioner may be helpful, as well as support from family and friends to assist in making these lifestyle changes.

Pelvic floor exercises

Pelvic floor exercises are intended to strengthen the pelvic floor, over time, through actively tightening and lifting the muscles at regular intervals. Involvement of a health professional, such as a physiotherapist with a special interest in pelvic floor dysfunction or continence nurse, is important to give instruction and assist in improving the outcomes of these exercises.

These exercises can reduce symptoms or the need for surgery and help increase control over your bladder. They need to be done correctly and consistently over time; these exercises are not a “quick fix”. If muscles are very weak, there are other additional treatments that may help to improve pelvic floor function. A physiotherapist with a special interest in pelvic floor dysfunction may suggest biofeedback or electrical stimulation.

An internal examination and some specialised tests may also need to be performed to assess whether you are doing the exercises correctly and whether they are helping improve your pelvic floor strength.

Information about pelvic floor exercises, continence nurses and physiotherapists with a special interest in pelvic floor dysfunction is available from the Australian Physiotherapy Association www.physiotherapy.asn.au/APAWCM/Physio_and_You/Pelvic_Floor.aspx or the National Continence Helpline on 1800 33 00 66 or the Continence Foundation of Australia at: www.continence.org.au/pages/pelvic-floor-women.html

Continence pessary

Your doctor or a physiotherapist with a special interest in pelvic floor dysfunction can fit you with a removable device called a pessary. This is inserted into your vagina to compress your urethra against your pubic bone and lift the neck of your bladder. Pessaries are made from a variety of materials including vinyl, silicone and latex. You may need to try a few types and sizes of pessaries to find what works for you. The material that the pessary is made of may cause a reaction in some women – for example, if you have a latex allergy.

More studies are needed to determine how beneficial pelvic floor exercises, lifestyle changes and pessaries are in treating SUI.

1

Do nothing – no treatment

After speaking with your doctor and considering information about SUI, you may choose not to have any treatment, particularly if your symptoms are mild or very mild.

Absorbent products do not reduce the symptoms of SUI, but you may find that leakage of urine can be sufficiently managed with pads and other absorption aids. See the Continence Foundation of Australia website www.continence.org.au for more information on incontinence, pelvic floor exercises, referral and products to manage the conditions.

You may be eligible for a subsidy for continence products.

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What are my treatment options?

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Surgical treatment options

If non-surgical treatments do not work for you, and your symptoms are severe and continue to disrupt your life, you might consider surgery. Surgery is intended to improve support of the urethra and bladder so that loss of urine is minimised.

If you choose to have surgery, the next decision is whether to have a repair using:

- your own tissue
- a biological graft
- synthetic mesh
- a combination of the above
- urethral bulking agents.

Surgery for SUI can be performed through either the vagina or abdomen, or both. Your surgeon will work with you to determine the best approach for you. Biological grafts are only approved for use in abdominal surgery. All surgery has risks including not fixing your SUI, damage to nearby organs, infection and life-threatening bleeding.

The main other surgical treatment options are:

- pubovaginal sling
- colposuspension
- retropubic mid-urethral mesh sling
- transobdurator mid-urethral mesh sling.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists has stated that mid-urethral sling surgery using synthetic mesh is a recommended surgical procedure for SUI in routine cases.

Urethral bulking agents

Urethral bulking involves an injection into the wall of the urethra usually of a water-based gels or silicone substance, to help strengthen the muscle around it. Urethral bulking is not a first-line treatment for SUI.

It is most commonly used in women where other procedures have not worked and the urethra is fixed or severely scarred. It is a minor procedure and is normally done as a day-procedure or 24-hour stay. Recovery time is short and the risk of complications is low. The success rate is not as good as for surgical procedures for SUI. Incontinence does not always improve after the procedure, and you may need repeat injections.

The potential benefits and considerations of each type of surgery are summarised in the table on page 5.



Potential benefits

Considerations

Pubovaginal or fascial sling

Uses your own fascial tissue from your abdomen
May be used for all forms of SUI including complex reconstruction after other procedures have failed
Long-term success rate of 85%

- Comparable risk of recurrent stress incontinence is 1 in 10 compared with other surgical treatments
- Involves a combination of vaginal and abdominal surgery Only some specialised surgeons perform this type of surgery.
- Involves a longer operation, post-operative hospital stay (2-3 days) and recovery period than mid-urethral sling,
- Complications include: wound related (such as infection and risk of hernia where the fascia was removed from) and difficulty emptying the bladder which may require self-catheterisation or re-operation
- Serious complications are rare

Colposuspension

Uses your own tissue and sutures (stitches) to re-support the bladder outlet and suspend the vagina from ligaments on the public bone
Long-term success rate of at least 70%

- May be performed by either abdominal or laparoscopic surgery
- A range between 1 in 10 and 3 in 10 risk of developing urinary incontinence after the operation
- Involves a longer operation, post-operative hospital stay (2-3 days) and recovery period than mid-urethral sling
- Complications include: wound related (such as infection), difficulty emptying the bladder which may require self-catheterisation or re-operation and may be difficult to correct
- Higher risk of vaginal prolapse compared to MUS in long term
- Serious complications are rare

Retropubic mid-urethral sling – polypropylene mesh repair

The incisions to insert the mesh with special needles are made in the vagina and just above the pubic bone. See image over page.

Mid-urethral sling is the recommended surgical treatment for SUI, and is highly effective in the short and medium term
Minimally invasive procedure
Large, long-term studies show women are satisfied in the long-term with this operation and the improvement in their SUI symptoms
More data about this than any native tissue repair
Rarely associated with major abdominal organ or major blood vessel damage
Decreased operating time, inpatient time (mostly performed as a day procedure), recovery time and lower rates of urinary retention and post-operative complications compared with surgery where mesh is not used

- Mesh is intended to remain in the body permanently
- Comparable risk of recurrent stress incontinence is 1 in 10 compared with other surgical treatments
- Difficulty with bladder emptying may require reoperation
- Rarely associated with major abdominal organ or major blood vessel damage
- Discomfort with intercourse may occur, sometimes with other pelvic pain syndromes, following mesh repair
- Removal of part, or all, of the sling may be necessary in the case of a complication such as the mesh affecting the vaginal wall and becoming exposed or eroding into the bladder or urethra. Complete removal may be difficult or impossible and multiple surgeries may be needed
- Long-term pain can be difficult to treat
- Women who have severe complications may experience significant personal and mental wellbeing effects. Higher rate of bladder perforation, major blood vessel injury, blood loss and longer hospital stay compared to transobturator surgery (see below)
- Bladder emptying difficulty may occur and require an adjustment after the operation
- Rarely associated with major abdominal organ or major blood vessel damage
- Discomfort with intercourse may occur, sometimes with other pelvic pain syndromes, following mesh repair
- Serious complications are rare

What are my treatment options?



Potential benefits

Considerations

Transobturator mid-urethral sling – polypropylene mesh repair

The incisions to insert the mesh with special needles are made in the vagina and the groin
See image below

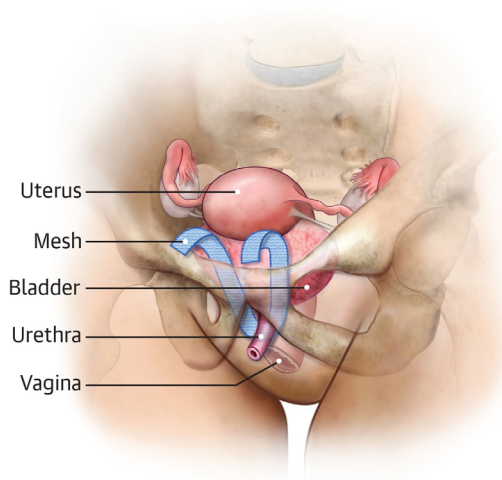
Mid-urethral sling is the recommended surgical treatment for SUI, and is highly effective in the short and medium term
Long-term studies show women are satisfied in the long-term with this operation and the improvement in their SUI symptoms
Minimally invasive procedure
Decreased operating time and inpatient time, recovery time and lower rate of urinary retention and post-operative complication compared with surgery where mesh is not used

- Less likely to have bladder emptying difficulty than retropubic approach, but more likely to have chronic pelvic pain
- Comparable risk of recurrent stress incontinence is 1 in 5 compared with other surgical treatments
- May be a preferable approach where there has been considerable abdominal surgery in the past
- Mesh is intended to remain in the body permanently
- Removal of part, or all, of the sling may be necessary in the case of a complication such as the mesh affecting the vaginal wall and becoming "exposed" or eroding into the bladder or urethra
- Complete removal may be difficult or impossible and multiple surgeries may be needed
- Long term pain can be difficult to treat
- Discomfort with intercourse may occur, sometimes with other pelvic pain syndromes, following mesh repair
- Women who have severe complications may experience significant personal and mental wellbeing effects
- Thigh, groin and pelvic pain and difficulties walking are not predictable. They may occur many years after otherwise uneventful surgery
- Serious complications are rare

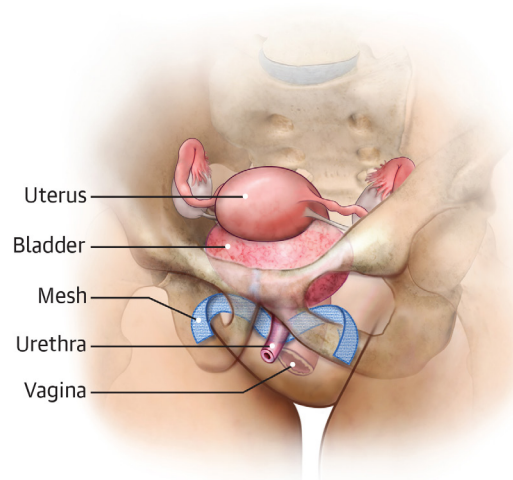
Urethral bulking agents

A useful option for recurrent SUI with a well-supported urethra and for women who wish to delay consideration of other types of surgery
This is usually offered as a day procedure or as a 24-hour stay and some clinicians offer this under local anaesthetic
Recovery time is short and the risk of complications is low
Low risk of difficulty with bladder emptying compared to other surgical procedures

- Urethral bulking is not generally used as a first-line treatment for SUI
- Success rate is around 4 in 10 to 5 in 10 after two years
Success is better with well supported urethra and satisfactory urethral closure function
- Rarely, a localised infection (abscess) can form in the urethral wall where the bulking agent was injected
- There may be temporary difficulty emptying the bladder after the procedure
- May require repeat injections for some patients
- Serious complications are rare



Retropubic Midurethral Sling (TVT)



Transobturator Midurethral Sling (TOT)

You can discuss these details with your doctor to better consider how these options may apply in your case. 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. You may also consider getting more than one opinion on surgical treatments if you feel this would be of assistance.

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

Some questions you may wish to ask your doctor are contained on page 8 of this resource.



A special note about transvaginal mesh

The Therapeutic Goods Administration (TGA) has reviewed evidence on the use of transvaginal mesh for SUI. It has decided that the scientific evidence supports using mid-urethral slings for SUI. Mid-urethral slings are different devices to single incision mini-slings.

Single incision mini-slings, which are inserted via a single incision in your vagina, have been removed from the Australian Register of Therapeutic Goods. The TGA considers that there is not enough adequate scientific evidence to understand if the benefits of single incision mini-slings for the treatment of SUI outweigh their risks. They should only be offered as part of a clinical trial, with the appropriate approvals.

Information about these changes can be found at www.tga.gov.au/alert/tga-actions-after-review-urogynaecological-surgical-mesh-implants.

The NHS England has developed information for patients on surgical treatment of SUI with mesh which includes an explanation of levels of risk for those surgical procedures that you may find useful. See: www.england.nhs.uk/publication/synthetic-vaginal-mesh-tape-procedure-for-the-surgical-treatment-of-stress-urinary-incontinence-in-women.



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 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 by your doctor.

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

Questions to consider asking your doctor

-
- ? What are the chances that my incontinence will worsen if I don't do anything?
-
- ? What non-surgical options are there to treat my incontinence?
-
- ? Will I be able to improve my incontinence by doing pelvic floor exercises and using a pessary?
-
- ? What are the benefits and problems of using a pessary?
-
- ? What are the surgical options for incontinence?
What are the risks and benefits of these options for me?
-
- ? Are you planning to use synthetic mesh in my surgery?
-
- ? If you are considering a single incision mini-sling for my surgery, have you obtained the necessary approvals from the hospital where my surgery will be done and the TGA, and what are the risks?
-
- ? Are you credentialed by the hospital where my surgery will be done to use mesh for treatment of SUI?
-
- ? Do you receive payments or other benefits from the manufacture, distribution or implanting of synthetic mesh products?
-
- ? If I develop a complication, will you be able to treat me, or will you refer me to another specialist?
-
- ? What can I expect to feel after surgery? What specific symptoms should I report to you after the surgery?
-
- ? Based on your experience, how long will I have pain after surgery?
-
- ? Could I please have a copy of the synthetic mesh product information and the product number at the time of the surgery?
(This will help in any future treatment of your incontinence.)
-
- ? Who will perform all, or parts, of my surgery?
-
- ? Will there be any people from the mesh company in the operating theatre during my procedure?
-
- ? If I develop a complication a long time after the surgery, what should I do?

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.



Explanation of Terms

ARTG

Australian Register of Therapeutic Goods

Biological graft

A sheet of absorbable biological material commonly made from cow, pig or human tissues and that is used to reinforce your damaged tissues. Such tissues are highly processed so that only a clean fibrous material remains. Biological grafts are only approved for use in abdominal surgical repairs, not in transvaginal repairs.

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.

Fascia

Tissue from the abdomen from which a sling can be made.

Native tissue

Tissue from your own body.

Pelvic floor

The muscles and ligaments at the base of your pelvis that support your womb (uterus), bladder, bladder opening (urethra) and bowel.

Pessary

A removable device that is placed in the vagina to compress your urethra against your pubic bone and lift the neck of your bladder so urine doesn't leak.

Retropubic mid-urethral sling

A mesh sling is inserted through an incision in the vagina using a trocar, a needle-like instrument about as wide as a pencil. The mesh is positioned in a U shape under and around the urethra; its ends—which are attached to needles—are guided up between the bladder and the pubic bone (the retropubic space) and out through tiny incisions in the abdomen above the pubic bone.

TGA

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

Transobturator mid-urethral sling

Mesh is inserted through the vagina and the ends are brought out through tiny incisions between the labia and the creases of the thighs.

Synthetic mesh

Synthetic mesh is a man-made, net-like product that is placed in and attached to your pelvis. Mesh is most commonly made of polypropylene. Other terms used for mesh 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.

Urethra

The water-pipe from the bladder to the outside of the body.

Urodynamic study

A series of tests conducted in an outpatient clinic that evaluates the function of the bladder, including how completely the bladder, sphincter and urethra are storing and releasing urine. This is particularly important for severe continence problems.

Further information

More information on the use of mesh for the surgical treatment of SUI:

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

Urogynaecological Society of Australasia has a web page dedicated to urogynaecological-related information www.ugsa.com.au/home-2/patient-resources/

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

Consumer resources:

Australian Commission on Safety and Quality in Health Care <https://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 Government Senate Inquiry – 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

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

Health consumer organisations in Australian states and territories may be able to assist you to find information about peer support for women who have experienced complications

Dietitians Association of Australia website daa.asn.au/what-dietitians-do/dietitian-or-nutritionist

The Continence Foundation of Australia provides information on incontinence, pelvic organ prolapse, referral and products to manage these conditions www.continence.org.au

Therapeutic Goods Administration TGA www.tga.gov.au/behind-news/results-review-urogynaecological-surgical-mesh-implants

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