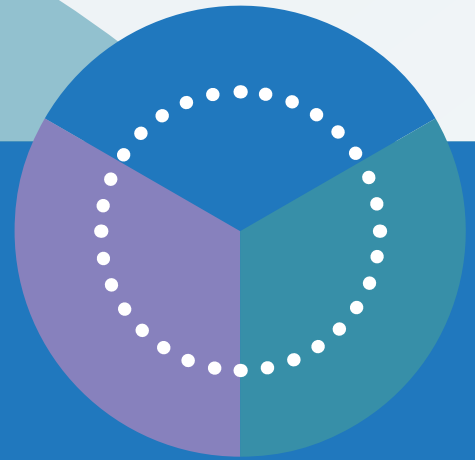


TREATMENT OPTIONS FOR

Pelvic Organ Prolapse



What is pelvic organ prolapse?

Pelvic organs include your bladder, womb (uterus) and rectum. Pelvic organ prolapse occurs when one or more of these organs bulges against, or sags down into the vagina and the muscles and ligaments in the pelvic floor become stretched, or too weak to hold the organs in the correct place.

Prolapse can occur in the front wall of the vagina (cystocele), back wall of the vagina (rectocele), uterus (uterine) or top of the vagina (vault). You can have prolapse of more than one organ at the same time. Types of prolapse are shown on page 6.

Vaginal prolapse is common, affecting up to half of adult women¹. Causes include pregnancy and childbirth, aging and menopause, obesity, chronic cough, chronic constipation, and heavy lifting. Prolapse can also occur following hysterectomy and other pelvic surgeries.

Prolapse is usually not life-threatening, but it can significantly affect your quality of life. It's your choice how you proceed.

¹ Lifetime risk of undergoing surgery for pelvic organ prolapse. Smith FJ, Holman CDJ, Moorin RE, Tsokos N, Obstet Gynecol 2010; 116,5:1096-1100

What are the symptoms of pelvic organ prolapse?

You might have:

- Pressure or bulging in your vagina, often made worse with physical activities
- Painful intercourse, or less sensation with intercourse
- Less control with your bladder or bowels
- Urinary problems such as retention (unable to urinate when your bladder is full), incontinence, and urinary tract infection
- In severe cases of prolapse obstruction of the ureters (the tubes which connect the kidneys to the bladder) and kidney function impairment can occur.

These symptoms can contribute to physical impacts and affect your quality of life. If you have no symptoms, or your symptoms don't affect your usual activities, you may safely choose to do nothing at all.



Information for consumers

This guide is designed to help you discuss treatment options for vaginal pelvic organ prolapse with your health professional and to share decisions about your care.



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 for 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 also considers the decision by the Therapeutic Goods Administration (TGA), to remove transvaginal mesh products where sole use is the treatment of prolapse via transvaginal implantation from the Australian Register of Therapeutic Goods (ARTG) from 4 January, 2018.

[See Understanding the Risks of Transvaginal Mesh on Page 7].

What are my treatment options?

There are different ways that prolapse can be treated. It depends on how much of a problem your prolapse is to your quality of life.

Your options fall into three categories:

- 1 Do nothing**
- 2 Non-surgical treatments**
Lifestyle changes, pelvic floor exercises, vaginal pessary, oestrogen cream
- 3 Surgical treatments**
Native tissue repair, synthetic mesh repair

Each of these three options is explained in more detail on the following pages.

1 Do nothing - no treatment

After considering information about your prolapse, you may decide not to have any treatment. The prolapse may worsen with time, but treatment can then be considered and undertaken later.

You might have both prolapse and incontinence present at the same time, but these are separate conditions and each needs to be assessed and specific treatment options for stress urinary incontinence should be considered. The Commission has another information resource to inform your options about stress urinary incontinence.

2

Non-surgical treatment options

You may be able to improve some symptoms without surgery with lifestyle changes, pelvic floor exercises, pessaries, and topical oestrogen cream. These treatment options are safe, and either alone, or in combination, may give you good results. However, these options may not work for everyone and you may still have symptoms that affect your quality of life. More studies are needed to understand how beneficial pelvic floor exercises, lifestyle changes and pessaries are in treating prolapse.²

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists recommends that you and your doctor discuss non-surgical treatment options.

Lifestyle changes

Non-surgical options that you should consider are reducing weight, avoiding heavy lifting, avoiding constipation and chronic coughing, stopping smoking and doing low impact exercises. Each of these options can help lessen your awareness of prolapse 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. It is important to involve a health professional specialising in the pelvic floor, such as a physiotherapist with a special interest in pelvic floor dysfunction or continence nurse,

to give instruction and assist in improving the outcomes of these exercises.

These exercises can reduce symptoms, or the need for surgery, and help decrease the awareness of prolapse and reduce the need for surgery. 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; 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 and women's health or 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.

Vaginal pessary

Your doctor or a physiotherapist with a special interest in pelvic floor dysfunction can insert a removable device, called a pessary. This is inserted into your vagina to support the walls of your vagina and/or uterus. Pessaries are made from materials such as vinyl, silicone or latex.

More studies are needed to understand how beneficial pelvic floor exercises, lifestyle changes and pessaries are in treating prolapse. However, it is safe to use pessaries, both short- and long-term. When

insertion is successful there may be improvement in prolapse symptoms and in bladder, bowel and sexual function.

You may need an internal examination and 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. Some types of pessaries are shown on page 4.

Topical oestrogen

Oestrogen cream can be applied to reduce vaginal dryness and improve tissue quality of a prolapsed vaginal wall. Where urinary infection has been a factor, this may be helpful.

² Genital Prolapse, Fact Sheet. 2011. <http://womhealth.org.au/sites/womhealth/files/public/documents/Genital%20prolapse.pdf>.



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.

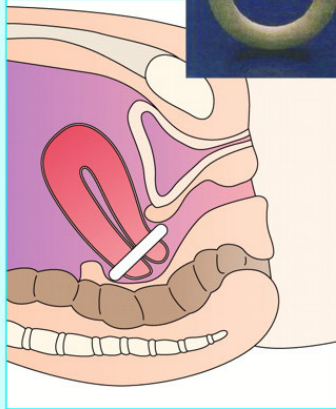
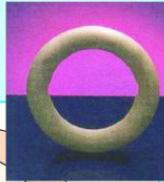
Asking questions about your testing and treatment options will help you and your doctor or other health care provider make better decisions together. These discussions also support the consent process.

What are my treatment options?

Types of pessaries

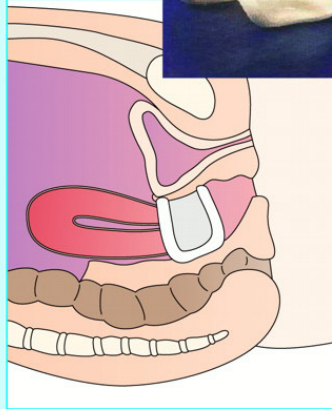
Support pessaries

Ring pessary



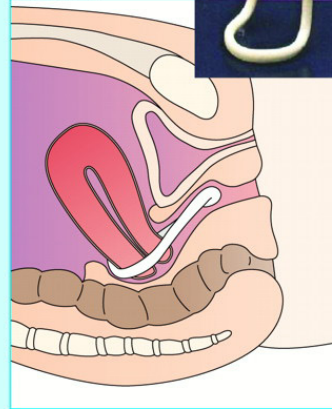
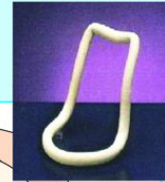
First and second degree uterovaginal prolapses
The most common pessary, and the easiest to use

Gehrung pessary



Cystoceles and rectoceles, with or without uterine collapse
Can be manually moulded. It rests along the anterior vaginal wall to straddle the bladder, and the lateral bars straddle the rectum, providing support via the legator sling

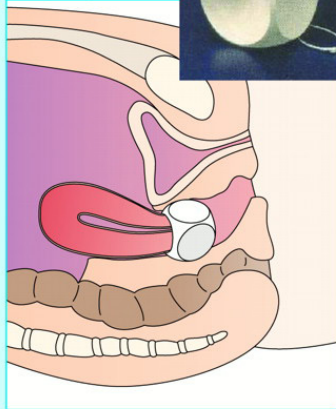
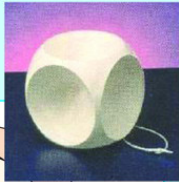
Hodge pessary



Mild cystoceles in women with a narrow pubic arch, and for correcting a retroverted uterus

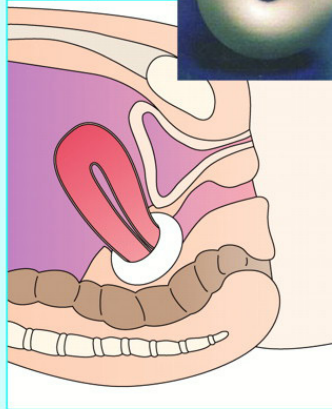
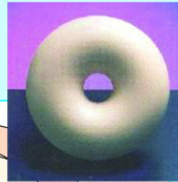
Space occupying pessaries

Cube pessary



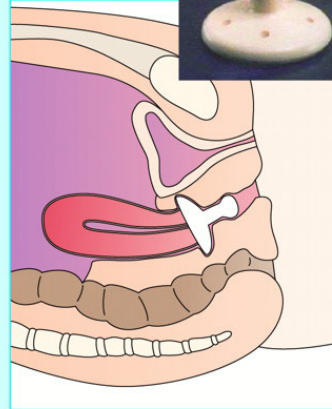
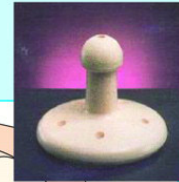
Third degree uterovaginal prolapse
Maintains its position by creating suction between itself and the vaginal wall. Has no area for drainage and has to be removed nightly

Donut pessary



Third degree uterovaginal prolapse
Remains in place by having a larger diameter than the genital hiatus. Usually latex, but an inflatable version allows for easy insertion and removal and an individualised fitting

Gellhorn pessary



Third degree uterovaginal prolapse with decreased perineal support
Concave surface fits against the cervix or vaginal cuff. Stem should be positioned just behind the introitus, so perineum must be intact

Source: Reproduced from [BMJ, Management of genital prolapse, Ranee Thakar, Stuart Stanton BMJ 2002;324:1258 www.bmj.com/content/324/7348/1258.1] with permission from BMJ Publishing Group Ltd

3

3 Surgical treatment options

If non-surgical treatments do not work for you and your symptoms are severe and disrupt your life, you may consider surgery. Surgery to repair the prolapse can involve use of either your own tissue (native tissue) or a biological graft (human or animal) or polypropylene mesh.

The repairs may be made by insertion of mesh through your abdomen or through your vagina using either dissolvable or permanent stitches. Biological grafts are only approved for use in abdominal prolapse repairs, not in transvaginal prolapse repairs.

You may find it helpful to take a family member or friend to support you in 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.

There is a risk that surgical procedures may not fix the prolapse. The risk of recurrent prolapse is higher following native tissue and biological graft repairs compared to polypropylene mesh repairs.

Some surgical options have involved the use of transvaginal mesh. Many women have had successful repairs of their prolapse using transvaginal mesh, however many have also experienced serious complications which are debilitating and affect their everyday lives. The number of women in Australia who have had transvaginal mesh implanted is not accurately known.

Mesh may also be inserted through the abdomen, which has been associated with fewer complications than transvaginal mesh, including lower re-operation rate and improved outcomes compared with both native tissue, biological graft and transvaginal mesh repairs. Mesh for use in this way is still included on the ARTG.

Complications of transvaginal mesh reported by some women include: mesh migration, extrusion or erosion resulting in lacerations of vessels and organs, including the bladder and vagina; continual chronic pain; painful sexual intercourse; and nerve damage. These complications can be debilitating and life-altering. The TGA website includes a comprehensive list of potential complications www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications.

Native tissue repair

This type of procedure involves reinforcing your damaged tissue by attaching them to your ligaments, with a graft of tissue from another part of your body (such as the lower abdomen) or with stitches. There are several types of native tissue repair operations, depending on the position of the prolapse. These include:

- anterior vaginal repair
- posterior vaginal repair
- vaginal colpopexy.

Information about the various types of repair surgery can be found on the Urogynaecological Society of Australasia website at: www.ugsa.org.au/pages/patient-information.html.

Your doctor should explain the approach that is best for the type of prolapse you have, considering your general health and fitness for surgery.

Native tissue repair has a higher risk of recurrent prolapse compared with synthetic mesh and, as for all types of prolapse repair, there is a risk of development of pelvic pain in the short and long term. If you do develop pelvic pain, it can be difficult to treat.

Synthetic mesh repair

Synthetic mesh is a man-made, net-like product that may be placed in, and attached to, your pelvis; sometimes with 'anchors' to support your prolapsed organs. Mesh and the anchors are most commonly made from polypropylene.

The mesh is intended to remain in the body permanently. If complications occur, additional surgery may be required. Complications may not completely resolve, even if the mesh is removed. Complete removal of the mesh is not always possible and multiple surgeries might be required.

Information about the various types of repair surgery using mesh inserted through the abdomen can be found on the Urogynaecological Society of Australasia website at: www.ugsa.org.au/pages/patient-information.html

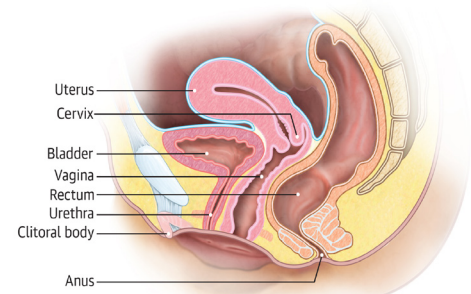
If your doctor suggests the use of mesh in this way you should discuss the risks and benefits of doing so.

Questions to consider asking your doctor

- ❓ What are the chances that the prolapse will worsen if I don't do anything?
- ❓ What non-surgical options are there to treat my prolapse?
- ❓ Will I be able to improve my prolapse 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 my prolapse? 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 transvaginal mesh, have you obtained the necessary approvals from the hospital where my surgery will be done and the TGA, and what are the risks?
- ❓ What are the potential risks of this treatment?
- ❓ If transvaginal mesh is proposed, are you credentialed by the hospital where my surgery will be done to use transvaginal mesh to treat prolapse?
- ❓ 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 might I have pain after surgery?
- ❓ Could I please have a copy of the synthetic mesh product information and the product number? (This may help in any future treatment of your prolapse.)
- ❓ 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?

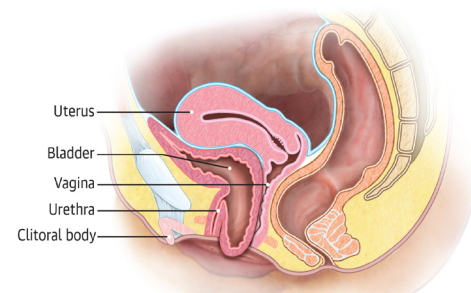
It can be helpful to take a support person with you when you talk to your doctor. You may wish to ask the doctor to explain some answers again.

Types of vaginal prolapse



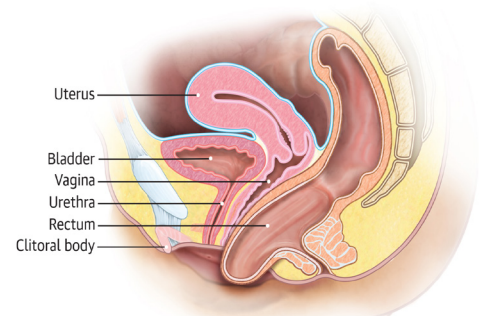
Normal Pelvic Organs

Normal Pelvic Organs



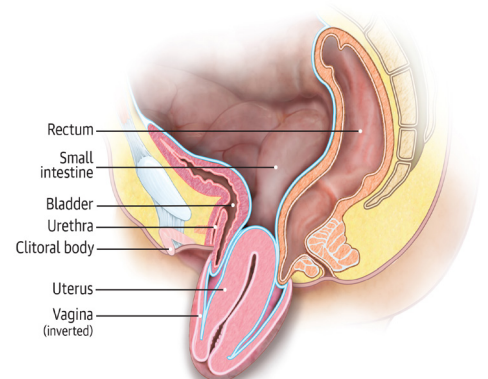
Cystocele

Prolapse of front wall of the vagina (cystocele)



Rectocele

Prolapse of back wall of the vagina (rectocele)



Prolapse of uterus (uterine)

Terms used in this guide

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 prolapse repairs, not in transvaginal prolapse repairs.

Colpopexy

An operation to repair prolapse by attachment of the vagina to the abdominal wall or the sacrum with stitches or synthetic mesh. Colpopexy may be performed through an incision in the lower abdomen (laparotomy) or as a keyhole procedure (laparoscopy).

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.

Ligament

A sheet or band of tough fibrous tissue that holds an organ in place.

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 hold prolapsed organs in place.

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.



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.

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.

Where transvaginal implantation of synthetic mesh to treat prolapse is proposed, specialised surgical skills are required and there are also special approvals required if your doctor is recommending you consider this surgery. You should ask your doctor if the necessary approval has been given by the TGA and the hospital and about the risks and benefits for you.

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.

The TGA has listed the potential complications and adverse events on its website at:

www.tga.gov.au/alert/urogynaecological-surgical-mesh-complications.

The NHS England has developed information for patients on surgical treatment of prolapse with transvaginal mesh which includes an explanation of levels of risk for transvaginal surgical procedures that you may find useful. The information is available at: www.england.nhs.uk/publication/surgical-procedures-for-treatment-of-pelvic-organ-prolapse-in-women.

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

mail@safetyandquality.gov.au
www.safetyandquality.gov.au

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Further information

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

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.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

Consumer resources:

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

Top tips for safe health care 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](http://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%E2%80%99s-health>**

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

Dietitians Association of Australia
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.

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