



PELVIC ORGAN PROLAPSE (POP)

A Patient Guide



Coloplast

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Let's talk about it.
Pelvic organ prolapse.

Experiencing **pelvic organ prolapse** can be challenging — it can interfere with your activities, intrude on your personal life, and be just plain uncomfortable.¹⁰

Maybe you've heard other women talk about it — and now it's happening to you.

Over 3 million women in the United States suffer from Pelvic Organ Prolapse (POP) and 300,000 surgeries are performed annually for POP.⁶ This guide is designed to help you learn more about pelvic organ prolapse and the treatment options.

Review this guide to learn more
and then talk with your doctor.

Pelvic Organ Prolapse (POP): It's common and treatable⁶

Pelvic Organ Prolapse is a disorder in which one or more of the pelvic organs drop from their normal position. Pelvic organs that can drop include the bladder, uterus, rectum, vagina and the small intestine (bowel).⁶

Approximately **3.3 million women** in the U.S. suffer from pelvic organ prolapse⁶

Half of all women between ages 50 and 79 say they have symptoms⁷



1 in 3 women with POP
have multiple surgeries⁶

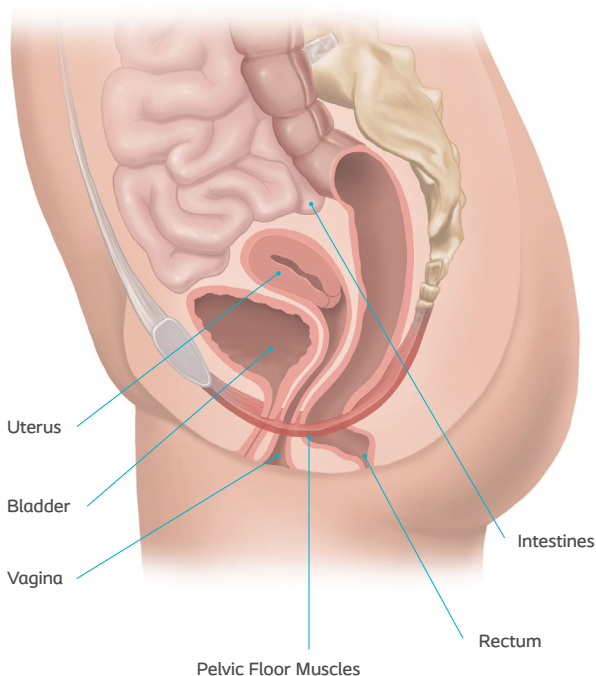
300,000
POP surgeries performed
in the U.S. each year⁶

- Many also have stress urinary incontinence (SUI)⁶
- May be a progressive condition, gradually getting worse and causing more severe symptoms⁸
- May require surgery for relief of symptoms³



The Pelvic Area and What Happens with Prolapse

The pelvic floor is a group of muscles that support the bladder and bowel and helps maintain continence. They are often described as being shaped like a hammock or sling.¹ Normally these muscles and surrounding tissues keep the pelvic organs in place.² Sometimes they can become too weak or stretched to continue to support your pelvic organs.²



Prolapse Causes

Certain risk factors increase your likelihood of experiencing pelvic organ prolapse:

- Vaginal childbirth⁶
- Menopause⁶
- Obesity²
- Chronic cough²
- Frequent constipation²
- Pelvic organ tumors²

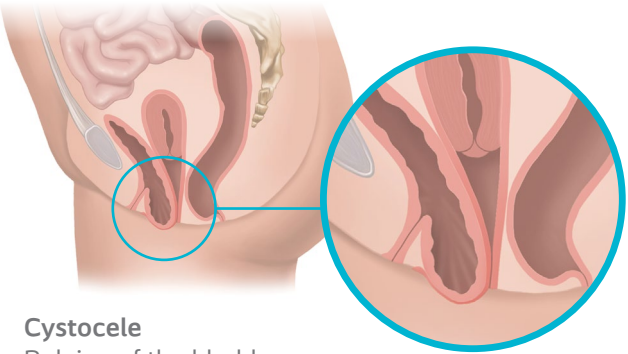
Prolapse Symptoms³

If you are experiencing prolapse, you may feel:

- Heaviness or pressure in the pelvic region
- Vaginal pain and/or pressure
- Pulling or aching feeling in the lower abdomen or pelvis
- Painful or uncomfortable sex
- Difficulty urinating or having a bowel movement

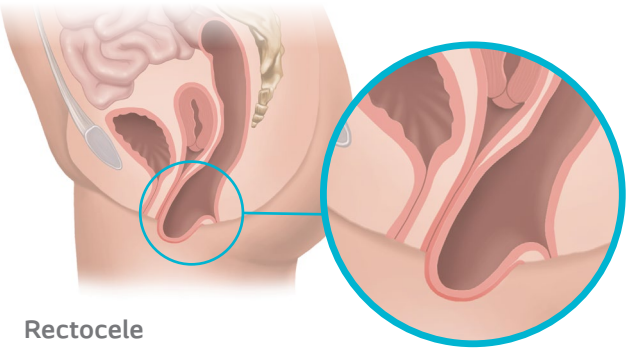


Types of Pelvic Organ Prolapse³



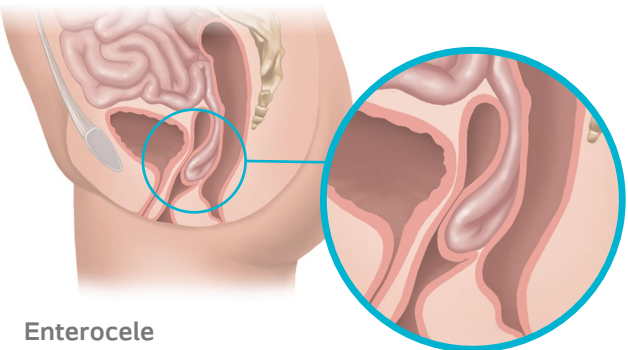
Cystocele

Bulging of the bladder into the vagina



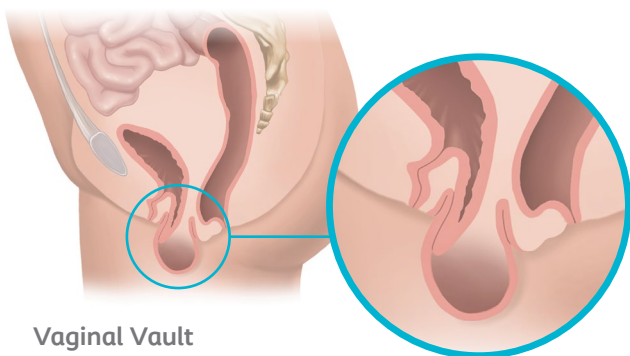
Rectocele

Bulging of the rectum into the vaginal wall



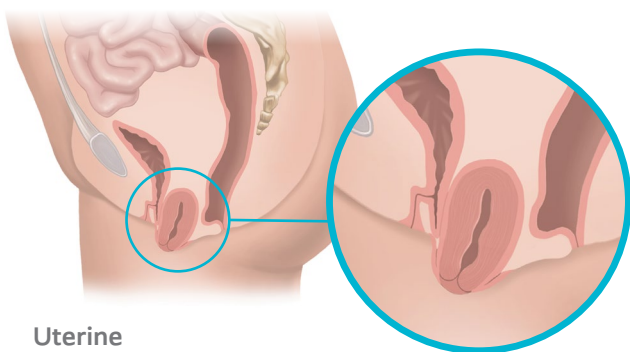
Enterocoele

Bulging of the intestine into the upper part of the vagina



Vaginal Vault

The top of the vagina loses its support and drops into or out of the vagina



Uterine

The uterus loses its support and drops into the vagina

Treatment Options⁹

There are different treatment options available and your doctor will be able to help you find the best solution for you. Treatment will depend on the type and cause of your prolapse as well as your plans for the future, such as whether you are planning to become pregnant.



Non-Surgical

Pelvic Organ Prolapse may be managed with vaginal pessaries, Kegal exercises, biofeedback and lifestyle changes. These options may involve long-term treatment, on-going maintenance, continued expenses and may not address the underlying condition.²

Surgical³

Reconstructive surgery reconstructs the pelvic floor with the goal of restoring the organs to their original position. Surgical repair can be done through the vagina or through the abdomen.

- Anterior or posterior colporrhaphy in which the wall of the vagina is strengthened with sutures so that it once again supports the pelvic organs.
- Surgery using vaginally placed mesh is done through an incision in the vagina. Surgical grafts include synthetic mesh or biologic tissue.
- Sacrocolpopexy and sacrohysteropexy are done through the abdomen to repair vaginal vault prolapse and uterine prolapse with surgical mesh.

Types of Surgical Grafts

- Synthetic mesh
- Biologic grafts

Coloplast Mesh

Coloplast's Restorelle® DirectFix and Restorelle Y Contour mesh allow for tissue ingrowth which combines with your body's natural collagen tissue to provide extra support. This strengthened support system maintains the organ's anatomical placement.¹ Synthetic mesh has been shown in many studies to greatly reduce the risk of recurrence of prolapse, as well as relieve the symptoms of prolapse.⁵ Your doctor will be able to provide more information about surgery for prolapse and the different types of repair materials available.

Restorelle DirectFix mesh is placed through a small incision in the vagina. To repair a cystocele prolapse the mesh is placed between the bladder and the vagina to prevent the bladder from protruding into the vagina. To repair a rectocele or enterocele, the mesh is placed between the vagina and the rectum to prevent your digestive tract from protruding into the vagina.

Restorelle Y Contour mesh is placed through small incisions in the abdomen. To repair a vaginal vault or uterine prolapse the mesh is placed on both sides of the vagina and then attached internally to lift the vagina.

Coloplast Biologic Grafts

Axis™ Dermis and Suspend™ Fascia Lata are preserved human tissue that have been purified through a vigorous sterilization process. These biologic grafts provide support to the body's natural regenerative process for the treatment of pelvic organ prolapse.



FDA Information

The FDA has made a commitment to inform the public about their continued assessment for safety and effectiveness of urogynecologic surgical mesh devices for pelvic organ prolapse (POP) repair. As such, the FDA maintains information for patients on its website. This information can be accessed electronically by visiting the following webpage:¹²

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm>

The FDA also provides Recommendations for Women with Pelvic Organ Prolapse which are printed below and can be found at the following webpage:¹³

<https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm345205.htm>



Recommendations for Women with Pelvic Organ Prolapse

It is important that women are aware of the risks associated with surgical mesh for transvaginal repair of pelvic organ prolapse (POP). Women who have mesh surgery may be at risk for needing additional surgery due to mesh-related complications. In a small number of patients, repeat surgery may not resolve complications.

Ask your surgeon about all POP treatment options, including surgical repair with or without mesh and non-surgical options, and understand why your surgeon may be recommending treatment of POP with mesh.

If you are considering surgery with the use of surgical mesh to repair your POP, ask your surgeon these questions before you agree to the procedure:

- Are you planning to use mesh in my surgery?
- Why do you think I am a good candidate for surgical mesh?
- Why is surgical mesh being chosen for my repair?
- What are the alternatives to transvaginal surgical mesh repair for POP, including non-surgical options?
- What are the pros and cons of using surgical mesh in my particular case? How likely is it that my repair could be successfully performed without using surgical mesh?
- Will my partner be able to feel the surgical mesh during sexual intercourse? What if the surgical mesh erodes through my vaginal wall?

- If surgical mesh is to be used, how often have you implanted this particular product? What results have your other patients had with this product?
- What can I expect to feel after surgery and for how long?
- Which specific side effects should I report to you after the surgery?
- If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?
- What if the mesh surgery doesn't correct my problem?
- If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?
- If I have a complication related to the surgical mesh, how likely is it that the surgical mesh could be removed and what could be the consequences?
- If a surgical mesh is to be used, is there patient information that comes with the product, and can I have a copy?



If you have surgery with mesh to repair your POP, you should:

- Continue with your annual and other routine check-ups and follow-up care. There is no need to take additional action if you are satisfied with your surgery and are not having complications or symptoms.
- Notify your health care provider if you have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after your follow-up appointment.
- Let your health care provider know you have surgical mesh, especially if you plan to have another surgery or other medical procedures.
- Talk to your health care provider about any questions you may have.

If you have had POP surgery but do not know whether your surgeon used mesh, ask your health care provider at your next scheduled visit.

Potential Risks with Mesh

Mesh reinforced prolapse repair may not be suitable for every patient, and a thorough discussion between you and your doctor will enable both of you to determine if this treatment is right for you. There are many considerations when deciding to place surgical mesh and these should be discussed before any surgery with your doctor.

Surgical mesh is not appropriate for every patient. Your medical and surgical history will help determine if a procedure with mesh is right for you. Potential complications from mesh surgery may include: pain, slow healing of mesh infection or non-healing, mesh extrusion from the vagina, mesh erosion into adjacent organs, nerve injury, recurrent prolapse, inflammation, adhesion formation, fistula formation, narrowing of the vagina, scarring, pain with intercourse, and mesh contraction.

As with any surgery, other potential complications can include bleeding, infection, injury to blood vessels, nerves, bladder, urethra or bowel injury during mesh placement and may require additional surgery to repair. Difficulty with urination or defecation can temporarily or permanently occur as well.

Talk to your doctor about these risks and reactions. It is important that you understand and consider the potential risks of a permanent mesh implant as well as the benefits when choosing the best treatment option for you.

Insurance Information

Most insurance plans, including Medicare, cover these procedures. Consult your insurance carrier to find out the specific criteria for coverage. The reimbursement specialist at your physician's office may also be able to help you with this.

Take the Next Step

Visit PelvicHealthID.com to review treatment options and find a physician who specializes in treating pelvic organ prolapse.



Notes

Feel confident and comfortable again. Take control of your pelvic organ prolapse today.

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