Coloplast

# Pelvic Organ Prolapse

## Transabdominal surgery

STRAIGHT Talk

The information in this guide is not intended to replace any discussion with your doctor, or any materials he or she may give you.

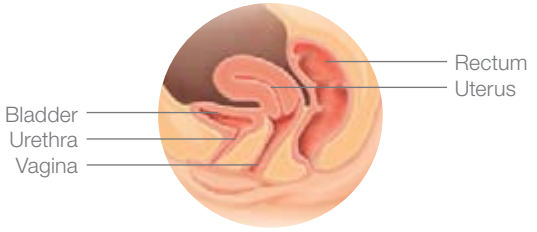
*It can be difficult talking about intimate health problems—pelvic organ prolapse is a condition that affects millions of women. Many women delay, or never seek treatment that could cure or drastically reduce their symptoms. Prolapse is not a fact of aging or something you need to live with; you are not alone and you have treatable options. This guide will help you learn effective solutions available to help cure or treat pelvic organ prolapse.*

# What is pelvic organ prolapse?

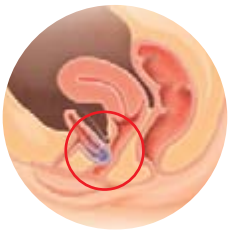
Pelvic organ prolapse occurs when the pelvic muscles and ligaments are weakened, making them unable to hold the pelvic organs in place. Consequently, the organs may fall, or shift down into the pelvic area.

Women with prolapse often have a sense of heaviness in the vagina or pelvis. They may complain of "sitting on a ball," may notice a bulge or mass protruding from the vaginal area while showering, or feel the heaviness of a bulge towards the end of the day, after working or standing all day. Other symptoms are described as a pulling or heavy sensation in your pelvic area, discomfort during intercourse, urinary incontinence, and bowel problems. Some women may attempt to push in the prolapsing organ to help urinate, but will often notice the pressure will reduce on its own when lying down at night. There are several types of pelvic organ prolapse, with different names depending on the organs involved.

# Types of pelvic organ prolapse




Normal pelvic floor

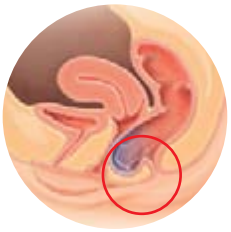


Cystocele

**Bladder prolapse –** a cystocele is when the bladder, which stores urine, slips and pushes against the front of the vagina.

**Urethra prolapse –** a urethrocele develops when the urethra, which transports urine from the bladder and out of the body, slips and pushes against the lower part of the front of the vagina.

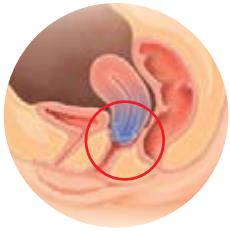
**Small bowel prolapse –** an enterocele occurs when the small intestine drops down between the back of the vagina and the rectum. This may occur at the same time as prolapse of the uterus or rectum.



Rectocele

**Rectum prolapse –** a rectocele is present when the rectum (the last section of the digestive tract which stores feces for elimination from the body) bulges into the back of the vagina.

**Vaginal vault prolapse –** a vaginal vault prolapse can be found when the top of the vagina falls in on itself. This can only occur if a woman has had a hysterectomy (an operation to remove the uterus).



Apical Vaginal Vault

**Uterus prolapse –** a uterine prolapse occurs when the uterus drops down into the vagina.

Your doctor will assess which type of prolapse affects you. It is possible that you may have more than one type at the same time.

# What causes pelvic organ prolapse?

Pelvic organ prolapse occurs when muscles and ligaments in the pelvic floor are stretched or become too weak to hold the organs in the pelvis. This is not life-threatening, but can cause pain and discomfort and have a major impact on your day to day quality of life.

**Potential causes that weaken and stretch the pelvis muscles include:**

- Pregnancy and childbirth
- Aging and menopause
- Obesity
- Fibroids or pelvic tumors
- Long-term (chronic) coughing
- Long-term (chronic) constipation
- Lifting heavy objects
- Certain genetic conditions
- Prior pelvic surgery
- Some neurological conditions or spinal cord injury

# How do I know if I have pelvic organ prolapse?

The signs and symptoms of pelvic organ prolapse vary from woman to woman depending on the type of prolapse and how far it has advanced.

Mild prolapse may result in pressure or dragging sensation in your pelvic area, particularly if you have been standing for a long time.

**As the prolapse becomes more severe, you may notice increasing discomfort and one or more additional symptoms including:**

- Problems controlling your bladder
- Difficulty emptying your bladder
- Leaking urine during everyday activities that put pressure on your abdomen (stress urinary incontinence)
- Constipation or other bowel problems
- Discomfort or pain in your lower pelvis
- Back pain
- A feeling that something is stuck or falling out of your vagina
- Discomfort or pain during intercourse
- A lump in your vagina
- Unusual bleeding or discharge

*Although these signs and symptoms can alert you to a problem, they are not unique to pelvic organ prolapse, so it is important to consult a doctor for the correct diagnosis.*

# Can pelvic organ prolapse be treated?

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. It is common for treatment to start with a non-surgical approach such as Kegel exercises, a pessary (a device worn in the vagina for support), estrogen supplementation or biofeedback. However, some pelvic organ prolapse may only be corrected with surgery.

This booklet explains a surgical treatment that can provide relief from pelvic organ prolapse. However, surgery is not suitable for everyone and you should discuss all treatment options with your doctor.

# Non-surgical options to repair the pelvic floor

**Exercise –** Pelvic floor muscle exercises, called Kegel exercises, can help strengthen the pelvic floor muscles. This may be the only treatment needed in mild cases of prolapse. For Kegel exercises to be effective, they need to be done daily.

**Vaginal Pessary –** A pessary is usually a silicone device placed in the vagina to support the pelvic floor and maintain support of the prolapsed organ. A healthcare provider will fit and insert the pessary, which must be cleaned frequently and removed before sexual intercourse.

**Estrogen Replacement Therapy –** Taking estrogen may help to limit further weakness of the muscles and other connective tissues that support the uterus, bladder or rectum. However, there are some side-effects to taking estrogen. Check with your doctor to see if you are an appropriate candidate for estrogen replacement therapy.

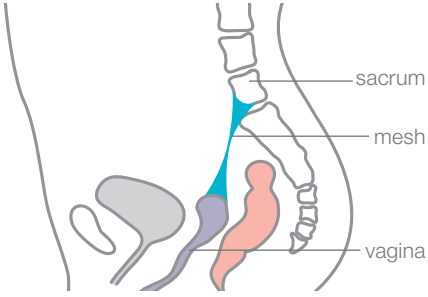
# Surgery to repair the pelvic floor

A surgical treatment option for pelvic organ prolapse involves reinforcing the prolapsing pelvic organs with a specially designed mesh. Restoring the normal anatomical position of the prolapsing organ can permanently relieve the symptoms of prolapse.

Coloplast offers a unique treatment solution for prolapse repair. Restorelle® Smartmesh® is created specifically for pelvic floor repairs and is composed of a very thin, light-weight mesh made from a soft synthetic polypropylene material. Restorelle Smartmesh allows for tissue ingrowth which combines with your body's natural tissue to provide support. This strengthened support system maintains the organ's anatomical placement. 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.[1] Your doctor will be able to provide more information about surgery for prolapse and the different types of repair materials available.

# What happens during surgery?

Surgery for pelvic organ prolapse is performed at a hospital under general anesthesia. Reconstruction to restore the pelvic floor to correct anatomical position is achieved using an open abdominal technique or with the use of minimally invasive surgery such as laparoscopy or robotic-assisted surgery. This type of surgery is called Sacrocolpopexy and is performed by creating a single incision, or 3 to 4 very small incisions, on the abdomen. These incisions allow a graft to be inserted into the pelvis and suspend the vagina from the sacral promontory (tailbone). The graft supports the organs and retains their proper anatomical position.




Sacrocolpopexy using mesh to repair a vaginal vault prolapse

# What happens after the surgery?

After the surgery, you may be required to stay in the hospital overnight. All surgical procedures carry some risk and you should ask your doctor to discuss this with you in more detail. It is normal to feel some discomfort and tiredness after the procedure. During your recovery, it is important not to lift anything heavy or have sexual intercourse so that your body can heal and the new graft material can bind with your own tissues.

It is usually possible to take part in your normal daily activities, including returning to work, within 4 to 6 weeks after the surgery, depending on your doctor's orders.

# Are there any 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.

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.

Your doctor can share with you the clinical data, safety, and efficacy of Restorelle® Smartmesh® and the use of Restorelle Smartmesh in sacrocolpopexy procedures. It is also recommended to speak with your surgeon about their success and complication rates using Restorelle Smartmesh and sacrocolpopexy procedures.

# FDA Information

On October 20, 2008, FDA issued a Public Health Notification on serious complications associated with surgical mesh placed through the vagina to treat pelvic organ prolapse and stress urinary incontinence. Subsequently, on July 13, 2011, FDA released a safety communication update on transvaginal placement of surgical mesh for Pelvic Organ Prolapse. http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm

The following information is directly from the FDA website. **Although this FDA notification does not include mesh placed transabdominally [for sacrocolpopexy]**, these questions should be discussed with your doctors.

## Before Surgery[2]

Be aware of the risks associated with surgical mesh for repair of pelvic organ prolapse. Know that having surgery with mesh may put you at risk for additional surgery due to mesh-related complications. In a small number of patients, repeat surgery may not resolve complications.

## Ask your surgeon these questions before you agree to have surgery in which surgical mesh will be used:[2]

- Why do you think I am a good candidate for surgical mesh?
- Why is surgical mesh being chosen for my repair?
- Are you planning to use mesh in my surgery?
- What are the alternatives to surgical mesh repair, 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?
- 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?

## After Surgery[2]

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 healthcare provider if you have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that lasts after your follow-up appointment.

# Talk to your doctor.

Ask about treatment options for pelvic organ prolapse and how Coloplast can make your life easier.

# Talking about pelvic organ prolapse

Many women find it difficult to speak about pelvic organ prolapse. Fortunately, it will become easier to discuss with time, especially now that you have discussed your symptoms with your doctor. Remember that it is a common problem and your doctor has seen many other patients with pelvic organ prolapse before.

# Notes / Questions for your doctor

Learn more about treatment options for pelvic organ prolapse and how Coloplast can make your life easier.

www.straighttalk.net
www.us.coloplast.com

## Coloplast – Your partner in women's health care

Coloplast is a Danish company, globally represented in 33 countries, with a 50-year legacy of listening and responding to the needs of our customers. We develop, manufacture and market medical devices and services in ostomy care, wound care, and surgical urology and continence care, striving to improve the quality of life for people. With a continuously evolving portfolio of women's health products, Coloplast is working to provide solutions that help improve quality of life for women globally.

[1] Hiltunen R, et al. Low-weight polypropylene mesh for anterior vaginal wall prolapse: a randomized controlled trial. Obstet Gynecol 2007;110(2):455-62.

[2] Source: 2011 FDA Transvaginal Safety Communication Update.

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Coloplast

Coloplast Corp.
Minneapolis, MN 55411
1.800.258.3476
usmedweb@coloplast.com
www.us.coloplast.com



M2446N 08.12