



YOUR GUIDE TO UNDERSTANDING
Pelvic Organ Prolapse

What is pelvic organ prolapse?

When a pelvic organ becomes displaced or slips down in the pelvis, it is referred to as a prolapse. You may have heard women refer to their “dropped bladder” or “fallen uterus.”

This problem afflicts over 3 million women in the United States.

You are not alone.

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 correct position in the pelvis. Potential causes include pregnancy and childbirth, aging and menopause, obesity, pelvic tumors, chronic coughing, chronic constipation, heavy lifting, prior pelvic surgeries, some neurological conditions and certain genetic factors.

What are some of the symptoms?

Symptoms of pelvic organ prolapse can include:

- Pressure or discomfort in the vaginal or pelvic area, often made worse with physical activities such as prolonged standing, jogging or bicycling
- Diminished control in the bladder and/or the bowels
- Painful intercourse

Frequently asked questions about transvaginal mesh

What is transvaginal mesh and what are the risks?

There are several surgical materials that could be used to facilitate your repair. In a transvaginal procedure, a thin, light synthetic mesh may be used. This material will reinforce the vaginal wall at the location of the pelvic organ prolapse. Risks associated with implanting synthetic mesh in pelvic organ prolapse procedures include those associated with general anesthesia and other risks generally associated with any vaginal procedure.

Risks associated with implanting a permanent synthetic mesh in pelvic organ prolapse procedures include pain, bleeding, injury to blood vessels or nerves, scarring, inflammation, allergy, hypersensitivity or other immune reaction, vaginal discharge, and constipation or defecatory dysfunction and infection. Also, there are risks of urinary incontinence, retention, frequency or urgency, recurrent prolapse, vaginal narrowing or shortening, fistula formation (abnormal connection between organs and/or mesh) injury to bladder, ureter or bowel that may require additional surgery to repair; mesh and/or tissue contracture and mesh exposure into the vagina or adjacent organs. Mesh exposure in the vagina has been associated with pain during sexual intercourse (also called dyspareunia). Your physician can discuss with you the anticipated probability of any of these complications and their experience with the procedure.

The FDA has issued a Safety Communication regarding serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse. Further information on the Safety Communication issued by the FDA can be found online: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/ucm262299.htm/

What should I expect after surgery?

Before your discharge from the hospital, you may be given a prescription for medication to relieve any discomfort you may experience. You will be instructed on how to care for your incision area. At the discretion of your physician, most patients resume moderate activities within 6 to 8 weeks, with no strenuous activity for up to 12 weeks to allow for healing.

For more specific information on what to expect following any of the prolapse surgical options please consult with your physician.



What are some treatment options?

You don't have to live with the symptoms of pelvic organ prolapse. Pelvic Organ Prolapse can be treated in several ways, depending on the exact nature of the prolapse and its severity. The goal of these treatments is to restore prolapsed organs to their normal anatomical positions.

You and your physician may discuss:

Non-Surgical Options:

- Changes to your **diet** and fitness routine
- Use of a "**pessary**," which is a device designed to relieve symptoms when in place by holding up the vaginal walls. It is inserted vaginally and is removable.
- **Physical therapy** such as Kegel exercises, designed to increase strength and maintain elasticity in the pelvic muscles

Surgical Options:

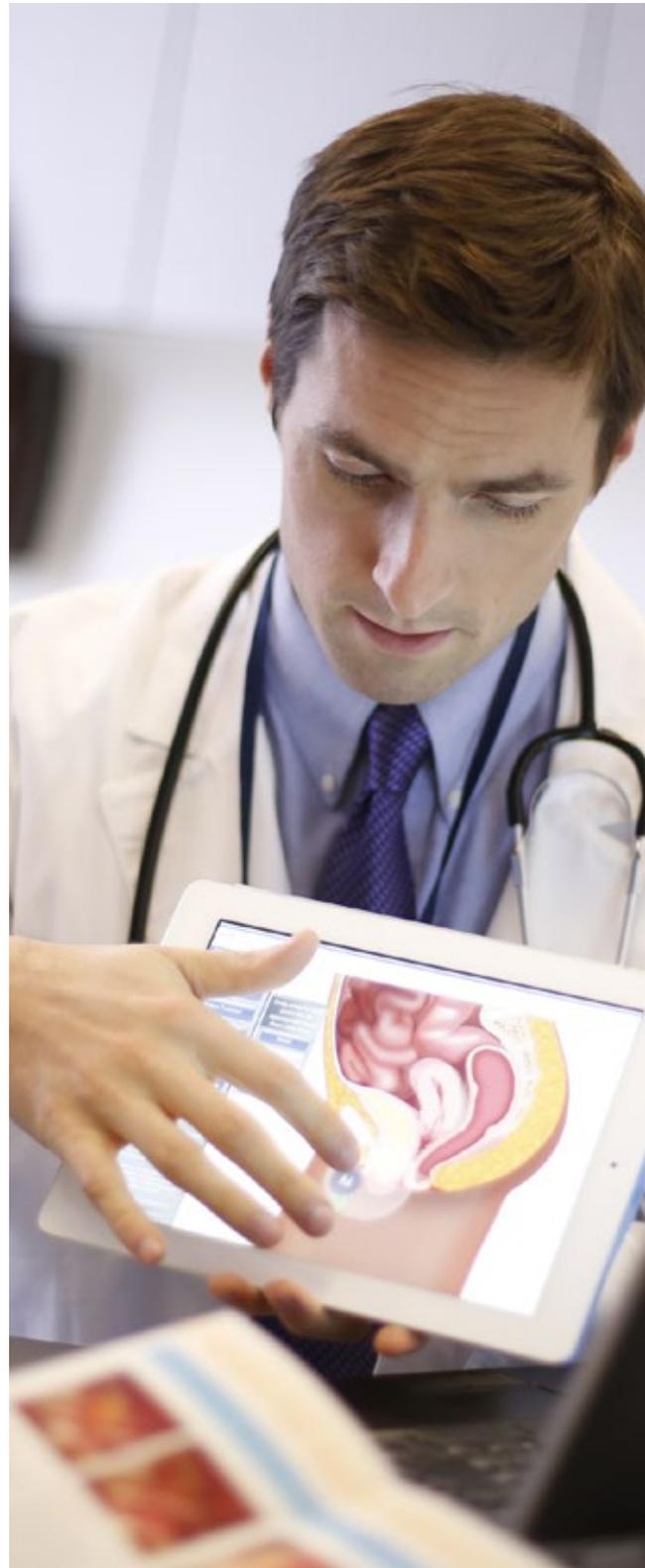
- **Transvaginal graft repair** – A piece of biological or synthetic mesh placed over the weakened connective tissue and sutured to correct the prolapsed area.
- **Sacrocolpopexy / sacrohysteropexy** – The physician uses an open, laparoscopic or robotic approach and attaches a graft between the vaginal apex and the tailbone. Depending on the technique used, a hysterectomy (removal of the uterus) may be required.
- **Native tissue repair** – The physician uses sutures to sew the weakened vaginal wall tissue back together

Many surgical procedures have been developed for the correction of pelvic organ prolapse. Please consult your physician to discuss the treatment options, including the potential adverse reactions/ complications and post-operative care.

Potential Complications of Surgery

The following are complications that are common to all prolapse surgeries except for erosions/extrusions/exposures which are only relevant to the use of graft materials. For a more comprehensive list of complications associated with use of graft materials please refer to specific product indications for use.

- **Pain**
 - Ongoing pain (pelvic, vaginal)
 - Dyspareunia (pain during sexual intercourse)
- **Discomfort / irritation**
- **Erosion** – Presence of mesh material within the pelvic organs
- **Extrusion / exposure** – Presence of mesh material within the vagina
- **Infection**
- **Bleeding or bruising**



Glossary

Apex

The top of the vagina (also known as vault).

Biologically Derived Graft

Tissue derived from human or animal source.

Cystocele

Condition in which weakness in pelvic support tissues causes the bladder to drop from its usual position down into the vagina.

Enterocoele

Condition in which weakness in pelvic support tissues causes the small intestine to bulge downward into the vagina.

Laparoscopic Surgery

A minimally invasive technique in which a procedure is performed through small incisions in the abdomen that are used to insert a camera and surgical instruments.

Minimally Invasive Surgery

A procedure that minimizes surgical incisions and reduces trauma to the body.

Native Tissue Repair

A type of surgical repair known as vaginal colporrhaphy, which uses sutures and the patient's own native vaginal tissue to repair the vaginal wall prolapse.

Open Surgery

A procedure that requires an incision through the skin large enough for the surgeon to gain access to the structures they are operating upon.

Pelvic Floor

A group of muscles that form at the base of the pelvis and support pelvic organs.

Pelvic Floor Reconstruction

The surgical repair of prolapse and incontinence. Surgical repair of pelvic support structures that can lead to pelvic organ prolapse and/or incontinence when weakened either via age-related changes or trauma.

Pelvic Organ Prolapse

A medical condition that occurs when normal support of the vagina is lost resulting in the "sagging" or "dropping" of pelvic organs.

Pessary

A removable plastic device that is inserted into the vagina to hold prolapsed organs back in place.

Rectocele

Condition in which weakness in pelvic support tissues causes the rectum to bulge into the vagina.

Stress Urinary Incontinence

The involuntary loss of urine during physical activity, which may include but is not limited to: coughing, laughing or lifting.

Synthetic

Permanent material used to repair tissue damage, can be used to supplement a pelvic organ prolapse repair.

Transvaginal Surgery

Surgery that is approached through an incision in the vagina.

Uterine Prolapse

Condition in which weakness in pelvic support tissues and/or ligaments causes the uterus to drop from its usual position into and through the vaginal canal.

Vaginal Vault Prolapse

Condition in which weakness in pelvic support tissues and/or ligaments causes the vaginal vault (apex) to drop into or through the vaginal canal.

Vault

The top of the vagina in the absence of a uterus.

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