

Pelvic Organ Prolapse

Your Guide to

Pelvic Floor Reconstruction



Upsylon™ Y-Mesh

What is Pelvic Organ Prolapse?

When an organ becomes displaced, or slips down in the body, 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 by certain genetic factors.

What are Some of the Symptoms?

Symptoms of Pelvic 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.

You are
Not Alone

Glossary

Apex – The roof, or top of the vagina (also known as vault).

Biologic Graft – Tissue derived from a human or animal source for use in tissue support.

Cystocele – Condition in which weakened pelvic support tissues cause the base of the bladder to drop from its usual position down into the vagina.

Enterocele – Condition in which weakened pelvic support tissues cause the base of the intestines to bulge downward into the vagina.

Laparoscopic Surgery – A minimally invasive technique in which procedures are performed through small incisions in the abdomen through which a camera and instruments are inserted.

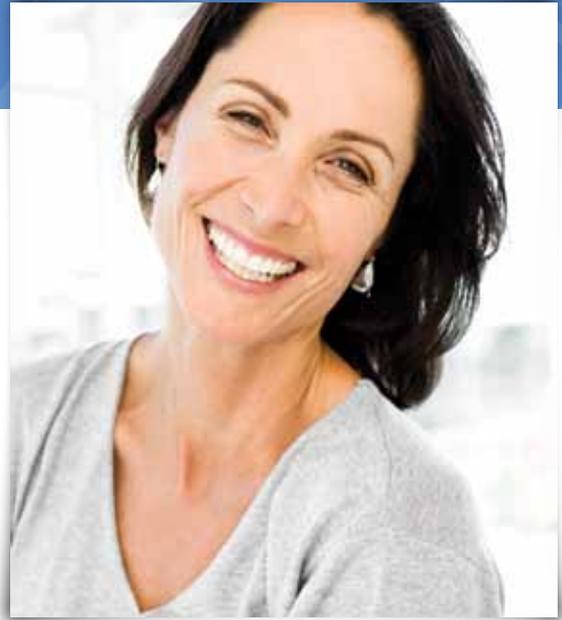
Minimally Invasive Surgery – A procedure that is less invasive (smaller incisions) than open surgery used for the same purpose.

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

Pelvic Floor – The muscles and ligaments at the base of the pelvis that support the uterus, bladder, urethra, and rectum.

Pelvic Floor Reconstruction – The surgical repair of prolapse and incontinence.

Pessary – A removable plastic device that is placed in the vagina to hold prolapse organs in place.



Prolapse – When one of the pelvic organs descends abnormally. Types of prolapse include: cystocele, enterocele, rectocele, uterine prolapse and vaginal vault prolapse.

Rectocele – Condition in which weakened pelvic support tissues cause the rectum to bulge into the vagina.

Robotic Surgery – Surgery facilitated by robotic arms controlled by a physician.

Uterine Prolapse – Condition in which weakened pelvic support tissues and/or ligaments cause the uterus to drop from its usual position out through the vaginal opening.

Vaginal Vault Prolapse – Condition in which weakened pelvic support tissues and/or ligaments cause the vaginal vault (apex) to drop towards or through the vaginal opening.

Vault – The internal end of the vagina (also known as the apex).

What type

of Prolapse do I have?

Cystocele

- A cystocele forms when the upper vaginal wall loses its support and sinks downward. This allows the bladder, which is located above the vagina, to drop. When a cystocele becomes advanced, the bulge may become visible outside the vagina. The visible tissue is the weakened vaginal wall; the bladder is right behind the skin but cannot be seen. The symptoms caused by cystoceles can include pressure, slowing of the urinary stream, overactive bladder and an inability to fully empty the bladder.

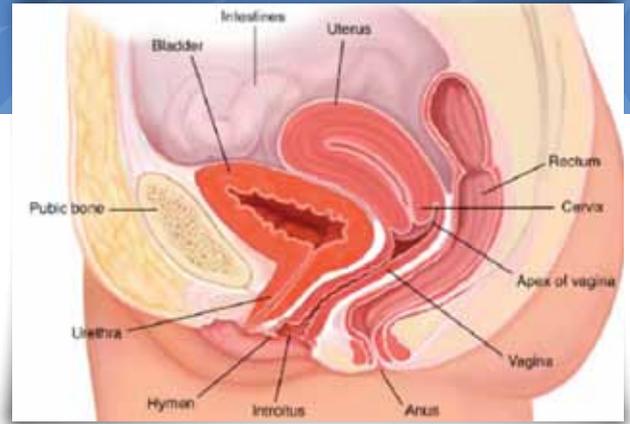


Rectocele

- A rectocele forms when the lower vaginal wall loses its support, allowing the rectum to bulge into the vagina. This creates an extra pouch in the rectal tube. Larger rectoceles can bulge beyond the vaginal opening. Rectoceles may cause difficulty with bowel movements—including the need to strain more forcefully, a feeling of rectal fullness even after a bowel movement, increased fecal soiling and incontinence of stool or gas. Some patients have to push on the back of the vagina to have a bowel movement.



Your physician will be able to assess which type of pelvic organ prolapse you may have and review potential treatment options.



Normal Anatomy

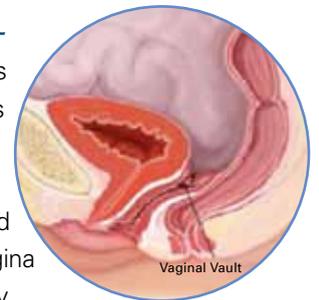
Enterocele

- An enterocele typically forms when the intestine bulges through the top of the vagina after a hysterectomy. In some women the intestine may slide between the back of the vagina and the rectum as shown in this picture with a uterus. The symptoms can be vague, including a bearing down pressure in the pelvis and vagina, and perhaps a lower backache.



Vaginal Vault Prolapse

- Vaginal vault prolapse occurs when the support structures holding the upper part of the vagina are weakened. If the uterus has been removed and the upper part of the vagina is dropping down it is usually referred to as apical or vaginal vault prolapse. When the uterus is present this is called uterine prolapse. When the apical prolapse becomes advanced, the bulge may become visible outside of the vaginal opening. The symptoms may include: pressure, pain, bladder infections and difficulty urinating.



What are some treatment options?

You don't have to live like this. Vaginal wall 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 a normal anatomical position.

You have Options



You and your physician may discuss:

Non-Surgical Options:

- Changes to your **diet** and fitness routine.
- Use of a **"Pessary"**, a rubber or plastic device, inserted vaginally and designed to relieve symptoms when in place
- **Physical therapy** such as Kegel exercises designed to increase strength and maintain elasticity in the pelvis.

Surgical Options:

- **Transvaginal graft** – Place a piece of biologic or synthetic mesh over the weakened connective tissue. This patch is placed through an incision in the vagina.
- **Sacrocolpexy/
Sacrocolposuspension** with an open, laparoscopic or robotic approach. Involves abdominal incisions for the attachment of a graft between the vaginal apex and tailbone. May require hysterectomy dependent on technique.
- **Native tissue repair** – A type of repair where suture(s) are used to sew weakened vaginal wall tissue back together.



Sacrocolpexy

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

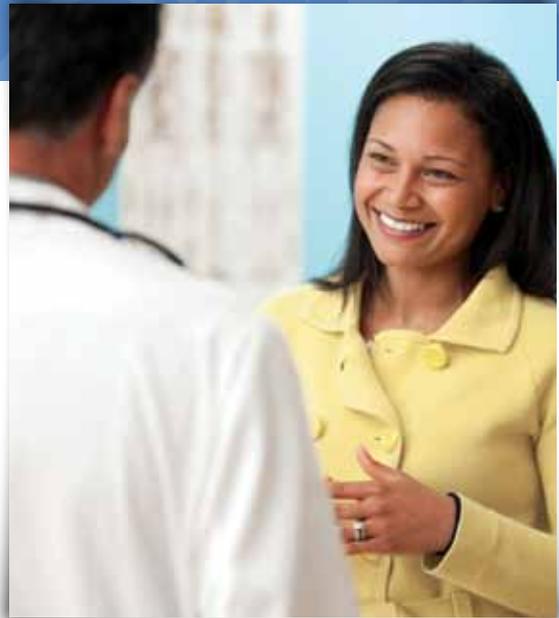
What questions

do you have about surgery?

What types of materials may be used in surgery and what are the risks?

There are several surgical materials which could be used to facilitate your repair. In a sacrocolposuspension/sacrocolpopexy procedure a thin, light synthetic Y shaped mesh is used. This material will be used to reinforce the vaginal wall back into place and stabilize your pelvic support structures. Risks associated with implanting synthetic mesh in pelvic organ prolapse procedures include those associated with general anesthesia and other risks generally associated with any open, laparoscopic or robotic procedure.

Risks associated with implanting permanent synthetic mesh in pelvic organ prolapse procedures include pain, bleeding, injury to blood vessels or nerves, scarring, inflammation and infection. Also there are risks of urinary incontinence or retention, recurrent prolapse, vaginal narrowing or shortening, fistula formation (abnormal connection between organs and/or mesh) injury to bladder, ureter, or bowel which 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). The safety and effectiveness of the Upsilon™ Y Mesh has not been studied in a randomized controlled clinical trial. Your physician can discuss with you the anticipated probability of any of these complications and their experience with the procedure.



What should I expect after surgery?

After the procedure you will likely stay in the hospital overnight. Before your discharge from the hospital, you may be given a prescription for an antibiotic and / or pain 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.

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 FDA can be found online: <http://www.fda.gov/medical-devices/safety/alertsand-notices/ucm262435.htm>

INTENDED USE Upsilon™ Y-Mesh is intended for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

CONTRAINDICATIONS Upsilon Y Mesh is contraindicated for use in any patient in whom soft tissue implants are contraindicated. These patients include those with:

- Pathology of the soft tissue into which the synthetic mesh is to be placed.
- Pregnant patients, the potential of future growth or patients that are considering future pregnancies.
- An anatomy that compromises device implant or pathology that limits blood supply or compromises healing.
- Autoimmune connective tissue disease.
- Pre-existing local or systemic infection.
- Blood coagulation disorder.

WARNINGS

- The implant procedure carries risk of infection and bleeding, inherent with open or laparoscopic procedures.
- In the event of post procedure infection, the entire mesh may have to be removed.
- Perforations or lacerations of vessels, nerves, bladder, urethra or bowel may occur during placement and may require surgical repair.
- As with all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis.

PRECAUTIONS

- Physicians should be trained in the placement of surgical mesh devices for treatment of pelvic floor disorders and in management of complications resulting from these procedures.
- An assessment of each patient should be made to determine their suitability for a synthetic mesh procedure.
- Aseptic technique must be adhered to throughout procedure.
- Do not use product if past the date of expiration.
- It is recommended that patients be counseled to refrain from heavy lifting, exercise, and intercourse for a minimum of six (6) weeks after the procedure. Follow physician's recommendations.
- It is recommended that patients be counseled to contact their physician in the case of post-operative bleeding, dysuria or other problems.

ADVERSE EVENTS Adhesion formation, Allergic reaction (hypersensitivity), Constipation, Dehiscence, Dyspareunia, Erosion or extrusion, Fistula formation, Granulation tissue formation, Hemorrhage, Infection, Inflammation (acute or chronic), Injury to ureter, Mesh and or tissue contracture, Necrosis, Nerve injury, Pain, Organ Perforation, Prolapse, Urinary and or fecal incontinence, Urinary retention, Vaginal shortening or stenosis.

Upsilon is a registered or unregistered trademark of Boston Scientific Corporation or its affiliates.

CAUTION Federal Law (USA) restricts this device to sale by or on the order of a physician trained in performing mesh procedures for surgical repair of pelvic organ prolapse. Refer to package insert provided with these products for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products.