Pelvic Prolapse

A Patient Guide to Pelvic Floor Reconstruction

Pelvic Prolapse

When an organ becomes displaced, or slips down in the body, it is referred to as a prolapse. Your physician has diagnosed you with a pelvic organ prolapse if part of the vagina has become weakened or displaced.

Women affected by pelvic prolapse sometimes refer to their “dropped bladder” or “fallen uterus.” In the medical profession, these conditions are referred to in more technical terms – such as “cystocele”, “uterine prolapse” or “rectocele”, which will be explained in this brochure.

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. For other women, diminished comfort and control in the bladder and/or the bowels can be an indicator of a worsening prolapse condition.

Vaginal prolapse can be treated in several ways, depending on the exact nature of the prolapse and its severity. You and your physician may discuss:

- Changes to your diet and fitness routine
- Considering a “pessary” – a rubber or plastic device, inserted vaginally and designed to relieve symptoms when in place
- Surgical procedures to improve the prolapse. Many surgical procedures have been developed for the correction of pelvic prolapse.

This patient guide will help discuss the various types of prolapse, and the surgical procedures that may help to improve your prolapse.

Please consult your physician to discuss the treatment options including post-operative care.

What is Pelvic Floor Reconstruction?

Pelvic prolapse repairs can be performed in a few basic ways:
(1) through vaginal incisions,
(2) through traditional abdominal incision, or
(3) through a laparoscopic approach.
Hospitalization and recovery times vary for each procedure type.

Surgical repairs for prolapse sometimes involve the placement of 'mesh' or 'graft' materials, to reinforce areas of weakened tissues.

Types of PROLAPSE*

Cystocele
The Bulging Bladder…

is often referred to as a dropped bladder. A cystocele forms when the normally flat upper vaginal wall loses its support and sinks downward. This allows the bladder, which is located right above the upper vaginal wall, to drop right along with it. When a cystocele becomes advanced, the bulge may become visible outside the vaginal opening. 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 vaginal bulging or pressure, slowing of the urinary stream, overactive bladder symptoms, and an inability to fully empty the bladder.

Rectocele
The Bulging Rectum…

is formed when the normally flat lower vaginal wall loses its support, allowing the rectum to bulge upward. This creates and extra pouch in the normally straight rectal tube.

Rectoceles cause symptoms related to incomplete emptying of the rectum. Even a minor rectocele bulge 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 in some cases incontinence of stool or gas. Those symptoms result from stool and air remaining within the rectocele pouch even after defecation, in contrast to the normal rectum, which fully empties. Larger rectoceles can bulge right through the vaginal opening and look like a cystocele, although this time it is the lower vaginal wall accounting for the bulge.

Enterocele
The Female Hernia…

occurs when intestines bulge downward into the top of the vagina. Enteroceles are similar to hernias that can develop in the abdominal and groin areas of both women and men: both involve bulging of the intestines into weakened supports nearby. In a man, hernias bulge through the abdominal wall; in a woman, enteroceles bulge into the top of the vagina. The symptoms can be vague, including a bearing down pressure in the pelvis and vagina, and perhaps a lower backache. They can exist alongside vaginal vault prolapse in women who have had a hysterectomy.

Uterine Prolapse
The Fallen Uterus …

is a weakening of the support structures at the top of the vagina (called the vault or apex). When this happens, the apex sinks downward towards the vaginal opening. This allows the uterus, which is located right above the vaginal apex, to drop right along with it. When the uterine prolapse becomes advanced the bulge may become visible outside the vaginal opening. The visible tissue is the weakened vaginal wall; the uterus is right behind the skin but cannot be seen. The symptoms caused by uterine prolapse include, but are not limited to, vaginal pressure, vaginal pain, pain during intercourse, recurrent bladder infections and difficulty with urination.

Vaginal Vault Prolapse…

is a weakening of the support structures at the top of the vagina (called the vault or apex), in women who previously had a hysterectomy. During the hysterectomy procedure, the apex was likely attached to supportive ligaments on either side of the pelvis. These attachments prevent the top of the vagina from bulging outward beneath the constant pressure of the abdominal contents. However if these attachments weaken and the vaginal apex drops, a bulge may form near the vaginal opening. This is called vaginal vault prolapse, a condition that only happens to women who have had a hysterectomy, and one that can cause severe pressure and bulging symptoms.

Considerations prior to Surgical Repair

If you are considering pelvic floor reconstruction surgery, your physician may ask you questions about your medical history, to ensure you are a candidate for this type of procedure. Some of the contraindications, warnings/ potential complications, and adverse events associated with pelvic floor reconstruction are listed on the following pages as a reference to you.

You should consult your physician for a complete understanding of this information and to determine whether this procedure is right for you.

INTENDED USE / INDICATIONS FOR USE

Mesh based transvaginal surgeries are indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended.

CONTRAINDICATIONS

- Synthetic mesh is contraindicated for use in any patient in whom soft tissue implants are contraindicated.
- Biologic mesh should not be used for patients with a known history of hypersensitivity of collagen or bovine products.
- Pregnant patients, or patients that are considering future pregnancies.
- The potential of future growth (e.g. infants, children)
- Any pathology, including known or suspected uterine pathology, which would compromise implant placement.
- Any pathology that would limit blood supply and compromise healing.
- Blood coagulation disorder.
- Autoimmune connective tissue disease.
- Renal insufficiency and upper urinary tract obstruction.
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before performing a repair.

WARNINGS / POTENTIAL COMPLICATIONS

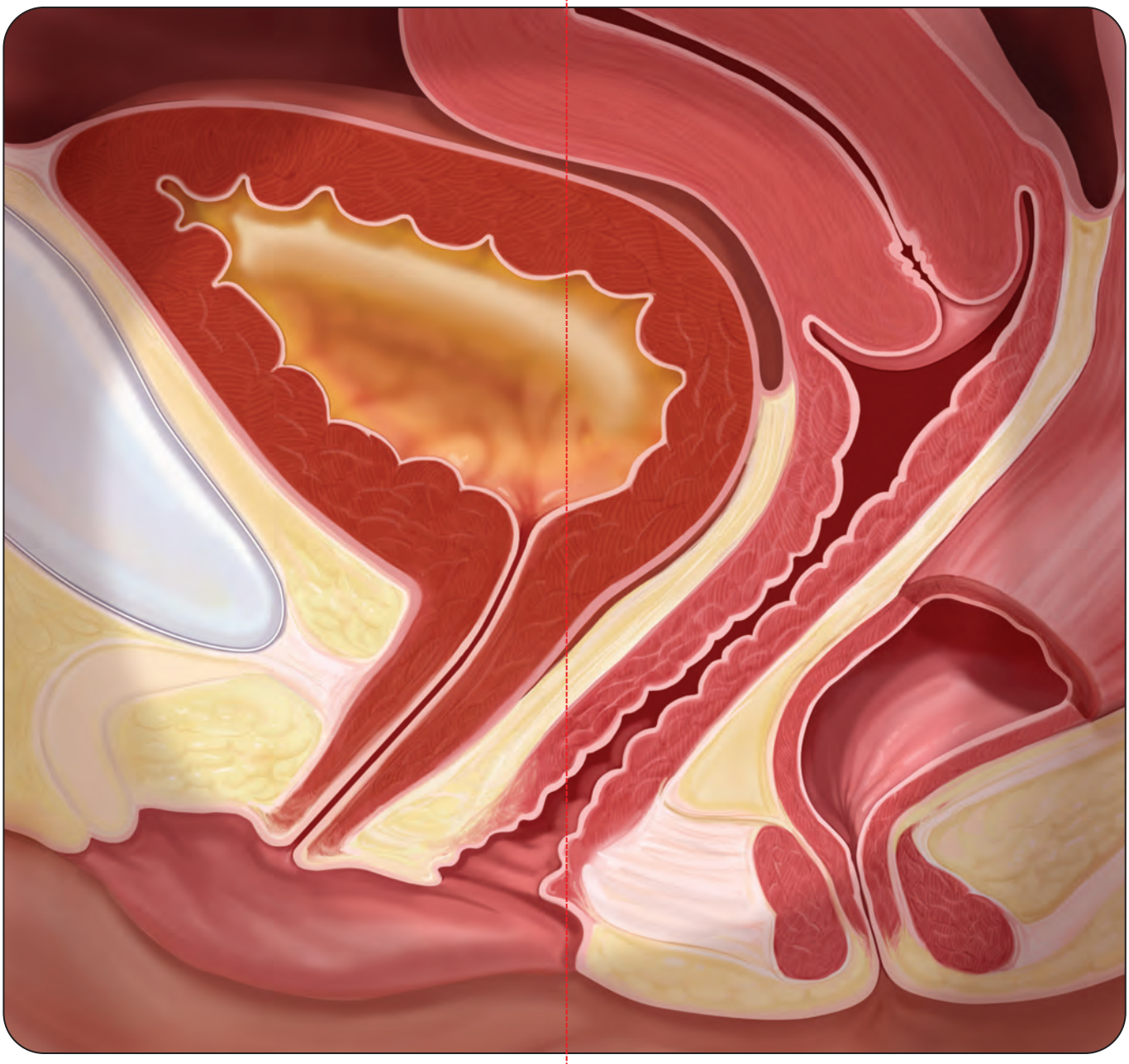
- Hysterectomy may be needed in the future; Use of mesh may make a future hysterectomy more difficult due to tissue in-growth and scarring
- Continued screening and surveillance for cervical and uterine disease may be required; Regular pelvic exam, Pap test and endometrial biopsies should be continued as medically indicated
- Should dysuria, bleeding or other problems occur, contact your physician immediately.
- Refrain from heavy lifting, exercise and intercourse for a minimum of six (6) weeks after the procedure. Your physician should determine when it is suitable for you to return to normal activities.
- In the event that infection presents post procedure, the entire mesh may have to be removed or revised.
- Like all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis.
- Tissue responses to the implant could include: local irritation at the wound site, vaginal erosion or exposure through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, foreign body reaction, and inflammation. The occurrence of these responses may require removal or revision of the mesh.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Mild to moderate incontinence may occur due to incomplete support.
- Known risks of surgical procedures for the treatment of prolapse include pain, infection, erosion/exposure, device migration, complete failure of the procedure resulting in recurrent or de Novo prolapse and/or incontinence.
- Punctures or lacerations of vessels, nerves, bladder, urethra, or bowel may occur during placement and may require surgical repair.
- Overweight women may be prone to interoperative and postoperative complications (weight parameters to be determined by your physician).

ADVERSE EVENTS

Potential adverse reactions that may be associated with surgically implanted materials include:

- Abscess formation/Foreign body reaction;
- Adhesion formation;
- Allergic, hypersensitivity or other immune reaction;
- Bruising, hematoma, hemorrhage;
- Constipation;
- Dehiscence and/or necrosis;
- Dyspareunia;
- Erosion/ extrusion;
- Fistula formation;
- Granulation tissue formation;
- Infection/ Sepsis potentiation;
- Inflammation (acute or chronic);
- Mesh and/or tissue contracture;
- Organ perforation;
- Pain, discomfort, irritation;
- Post-operative bleeding;
- Recurrent prolapse;
- Surgical site wound irritation, erythema, edema;
- Ureteric injury;
- Ureter obstruction;
- Urinary Incontinence;
- Urinary retention;
- Vaginal discharge;
- Vaginal shortening or stenosis;
- Vessel/Nerve injury/perforation;
- Wound dehiscence.

Notes



Glossary

Apex: The roof, or top of the vagina (also know as vault).

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

Enterocele: Condition in which weakened pelvic muscles cause the intestines to bulge downward into the vagina.

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

Pelvic Floor Reconstruction: The surgical correction, or improving, of prolapse and incontinence.

Pessary: Device for women that is placed in the vagina to provide support for pelvic descent or prolapse of pelvic organs.

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

Rectocele: Condition in which weakened pelvic muscles cause the rectum to bulge into the space normally occupied by the vagina.

Uterine Prolapse: Condition in which weakened pelvic muscles cause the uterus to drop from from it's usual position down into the apex of the vagina.

Vaginal Vault Prolapse: Condition in which weakened pelvic muscles cause the vaginal vault (apex) to drop towards the vaginal opening.

Vault: The roof, or top, of the vagina (also known as apex).

Boston Scientific

Delivering what's next.™

Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537
www.bostonscientific.com/gynecology

Individuals depicted are models and included for illustrative purposes only.

*Goldberg, Roger, M.D., M.P.H. "Ever Since I Had My Baby" (2003): 12-14

MVU6410 Rev. A 10M 11/08