YOUR GUIDE TO UNDERSTANDING

Pelvic Organ Prolapse







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 risks 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.²

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 intercourse³

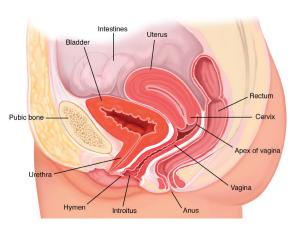
What type of Pelvic Organ Prolapse do I have?3

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 symptoms caused by cystoceles can include pressure, slowing of the urinary stream, overactive bladder and an inability to fully empty the bladder.

Vaginal Vault Prolapse - Vaginal vault prolapse occurs when the uterine or vaginal 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 Vaginal vault referred to as 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.

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

Enterocele – An enterocele typically forms when the small 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.



Normal Anatomy

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:

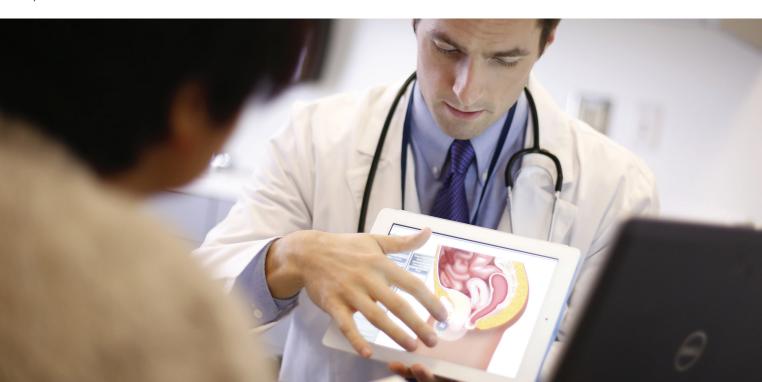
Non-Surgical Options:

- · Changes to your diet and fitness routine4
- 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.⁵
- Physical therapy such as Kegel exercises, designed to increase strength and maintain elasticity in the pelvic muscles⁴

Surgical Options:

- Transvaginal graft repair A biological graft is placed over the weakened connective tissue and sutured to correct the prolapsed area.⁶
- 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.⁷
- Native tissue repair The physician uses sutures to sew the weakened vaginal wall tissue back together⁸

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.



Frequently asked questions about surgical mesh

What is surgical mesh and what are the risks?

There are several surgical materials that could be used to facilitate your repair. These include a synthetic polypropylene mesh or biologic grafts made of dermis. Risk associated with implanting synthetic mesh in pelvic organ prolapse procedures can be found below and on the back of the brochure.

Potential adverse events, any of which may be ongoing, include but are not limited to: Abscess (swollen area within the body tissue, containing a buildup of pus), Adhesion formation (when a scar extends from within one area to another), Allergic reaction (hypersensitivity) to the implant, Bruising, Bleeding, Constipation, Dehiscence (opening of the incision after surgery), De novo detrusor instability (involuntary contraction of the bladder wall leading to an urge to urinate), Dyspareunia (pain during sexual intercourse) that may not resolve, Sexual dysfunction (difficulty with sexual response, desire, orgasm or pain); including the inability to have intercourse, Erosion into organs; exposure/extrusion into vagina (when the mesh goes through the vagina into other organs or surrounding tissue), Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Fistula formation (a hole/passage that develops through the wall of the organs) which may be acute or chronic, Foreign body reaction (body's inflammatory response to the implant) which may be acute or chronic, Granulation tissue formation (reddish connective tissue that forms on the surface when a wound is healing), Hematoma formation (a pool of blood under the skin/bruising), Hemorrhage (profuse bleeding), Infection, Inflammation (redness, heat, pain or swelling at the surgical site as a result of the surgery) which may be acute or chronic, Injury to ureter (the duct that urine passes from the kidneys to the bladder), Scarring/scar contracture (tightening of the scar), Mesh contracture (mesh shrinkage), Tissue contracture (tightening of the tissue) Necrosis (death of living tissue in a small area), Nerve injury (injury to the nerve fiber), Organ perforation (a hole in or damage to these or other tissues that may happen during placement), Pain: pelvic, vaginal, groin/thigh, dyspareunia-which may become severe, Perforation or laceration of vessels, nerves, bladder, or bowel (a hole in or damage to these or other tissues that may happen during placement), Post-operative bowel obstruction (blockage that keeps food or liquid from passing through the small or large intestines), Prolapse/recurrent prolapse (complete failure of the procedure), Vaginal shortening or stenosis which may result in Dyspareunia and/ or Sexual Dysfunction, Voiding dysfunction: incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention (involuntary leakage of urine or reduced or complete inability to empty the bladder). The occurrence of one or more of these complications may require treatment or surgical intervention. In some instances, the complication may persist as a permanent condition after the surgical intervention or other treatment. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

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.



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.

Enterocele – 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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Please consult your physician to discuss the associated risk and complications for the specific surgical material you receive. Below is a list of potential adverse events for Boston Scientific's pelvic organ prolapse surgical material.

Potential adverse events, any of which may be ongoing, include but are not limited to: Abscess (swollen area within the body tissue, containing a buildup of pus), Adhesion formation (when a scar extends from within one area to another), Allergic reaction (hypersensitivity) to the implant, Bruising, Bleeding, Constipation, Dehiscence (opening of the incision after surgery), De novo detrusor instability (involuntary contraction of the bladder wall leading to an urge to urinate), Dyspareunia (pain during sexual intercourse) that may not resolve, Sexual dysfunction (difficulty with sexual response, desire, orgasm or pain); including the inability to have intercourse, Erosion into organs; exposure/extrusion into vagina (when the mesh goes through the vagina into other organs or surrounding tissue), Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Fistula formation (a hole/passage that develops through the wall of the organs) which may be acute or chronic, Foreign body reaction (body's inflammatory response to the implant) which may be acute or chronic, Granulation tissue formation (reddish connective tissue that forms on the surface when a wound is healing), Hematoma formation (a pool of blood under the skin/bruising), Hemorrhage (profuse bleeding), Infection, Inflammation (redness, heat, pain or swelling at the surgical site as a result of the surgery) which may be acute or chronic, Injury to ureter (the duct that urine passes from the kidneys to the bladder), Scarring/scar contracture (tightening of the scar), Mesh contracture (mesh shrinkage), Tissue contracture (tightening of the tissue) Necrosis (death of living tissue in a small area), Nerve injury (injury to the nerve fiber), Organ perforation (a hole in or damage to these or other tissues that may happen during placement), Pain: pelvic, vaginal, groin/ thigh, dyspareunia-which may become severe, Perforation or laceration of vessels, nerves, bladder, or bowel (a hole in or damage to these or other tissues that may happen during placement), Post-operative bowel obstruction (blockage that keeps food or liquid from passing through the small or large intestines), Prolapse/recurrent prolapse (complete failure of the procedure), Vaginal shortening or stenosis which may result in Dyspareunia and/or Sexual Dysfunction, Voiding dysfunction: incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention (involuntary leakage of urine or reduced or complete inability to empty the bladder). The occurrence of one or more of these complications may require treatment or surgical intervention. In some instances, the complication may persist as a permanent condition after the surgical intervention or other treatment. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

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