



Regaining Control. Restoring Quality of Life.



Bard: Women's Health

## Pelvic Organ Prolapse and the Avaulta™ System





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### Pelvic Organ Prolapse Treatments

*New technologies lead to improved treatment options*

Throughout a woman's lifetime, her body undergoes tremendous stress. The strain of pregnancy. The effort of childbirth. Even the trauma of certain gynecologic surgeries like hysterectomies.

All of these stresses – accumulated over the years – can weaken the natural support structures of the pelvis, causing problems like vaginal prolapse: a feeling of vaginal fullness, chronic constipation and urinary incontinence. Any of these may require pelvic reconstructive surgery to repair. It's actually a very common problem, and it can affect women of many ages and health circumstances; in fact, almost half of women over the age of 50 are affected.

The symptoms of a weakened pelvic floor can range from mild to debilitating, and can affect your ability to lead an active life – and even maintain sexual intimacy.

With recent advancements in treatment, pelvic reconstructive surgery is highly successful in correcting the problems associated with pelvic organ prolapse, and in helping restore a better quality of life.

The Avaulta™ system represents the latest advancement in pelvic organ prolapse treatment, and can be the first step in returning you to an active and enjoyable lifestyle.

### What is Pelvic Organ Prolapse?

The vagina and its surrounding structures (bladder, rectum, etc.) are attached to the pelvis by connective tissues. These tissues help form walls around the vagina, and ensure that normal urinary voiding and bowel movements can occur. As the pelvic muscles become weak the connective tissues can fail, allowing pelvic structures like the bladder or rectum to bulge into the vaginal wall. This can cause the following symptoms:

- A feeling of vaginal fullness, heaviness, or even pain
- Pain or discomfort during intercourse
- Loss of bladder and/or bowel control
- Involuntary urination or inconsistent urinary stream
- Difficulty with bowel movements
- Recurrent urinary or bladder infections

### What causes pelvic organ prolapse?

Pelvic muscles and connective tissues which have been weakened with age are the primary cause, but many other factors may play a role. These may include vaginal childbirth, previous vaginal surgeries, menopause, smoking, diabetes, obesity, repeated heavy lifting, chronic coughing and chronic constipation. Sometimes pelvic organ prolapse can be caused simply by aging or genetic factors.



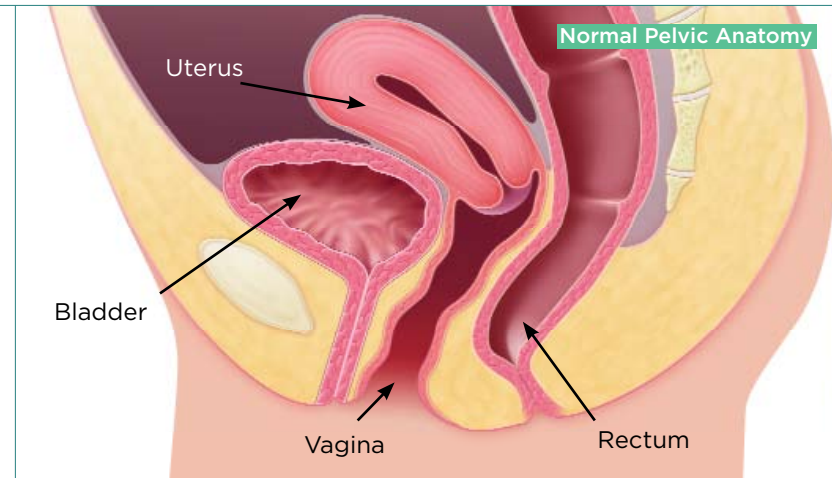
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### What are the different types of pelvic organ prolapse?

When vaginal prolapse occurs, an organ has dropped out of its normal position and can sometimes even protrude from the vagina. The definition of pelvic organ prolapse is different depending on which organ has prolapsed, and it is common to have more than one type of prolapse at a given time.

### Cystocele (pronounced “sis´to-sel”)

A cystocele is a hernia of the bladder into the vagina. As the connective tissue in the front wall (sometimes referred to as the roof) of the vagina fails, its attachment to the pelvis may be lost, allowing the bladder to drop into the vagina. This is the most common form of pelvic organ prolapse, and is often called a “dropped bladder”.





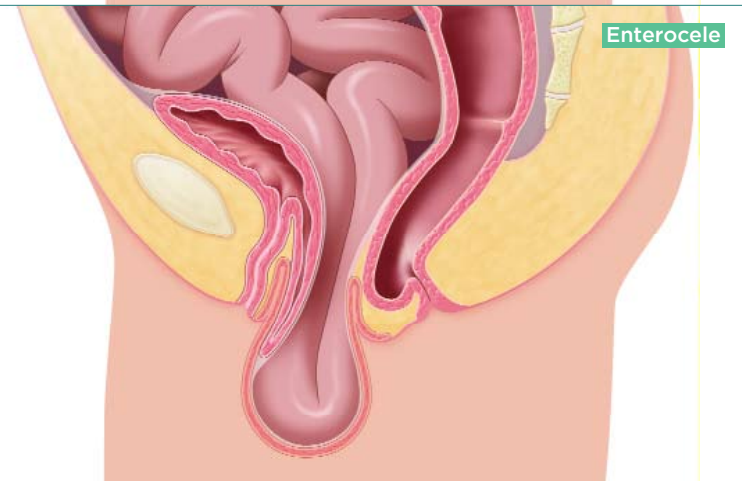
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### Rectocele (pronounced “rek´to-sel”)

A rectocele is a hernia of the rectum into the vagina. Similar to the cystocele, when the connective tissue in the rear wall (the floor) of the vagina fails, the rectum can then bulge into, or even out of, the vagina. As the rectum bulges upward, this can cause difficulty or pain during bowel movements.

### Enterocoele (pronounced “en´ter-o-sel”)

An enterocoele is a prolapse of the small bowel, which pushes the back of the vagina towards the opening.

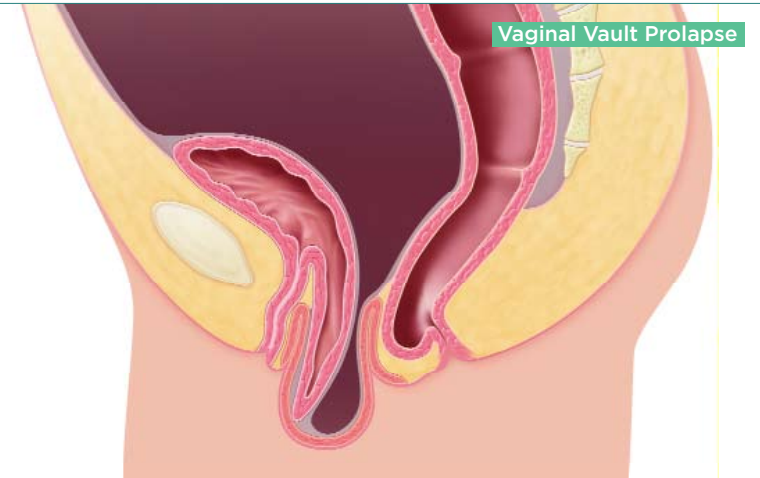




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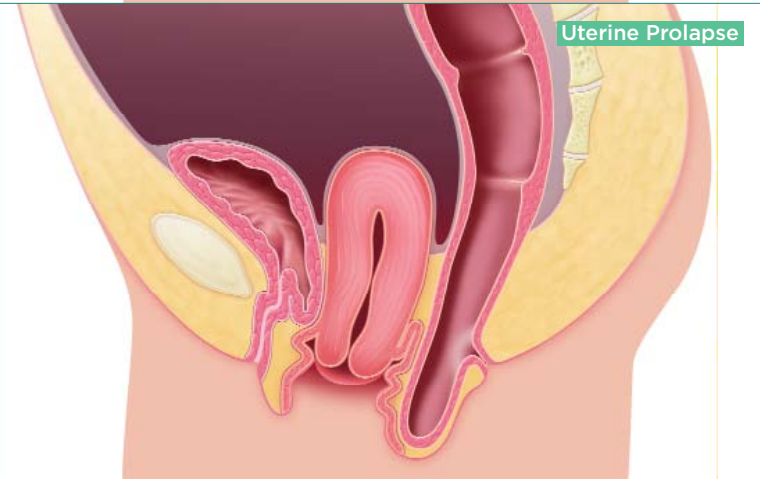
### Vaginal Vault Prolapse

In women who have had a hysterectomy and no longer have a uterus, the natural support structures in the vagina provided by the uterus no longer exist. The top portion of the vagina can then push down into the lower vagina, causing vaginal vault prolapse.



### Uterine Prolapse

For women who still have a uterus, the support structures holding the uterus in place can also be compromised, allowing the uterus to distend down into the vagina. This is called uterine prolapse.







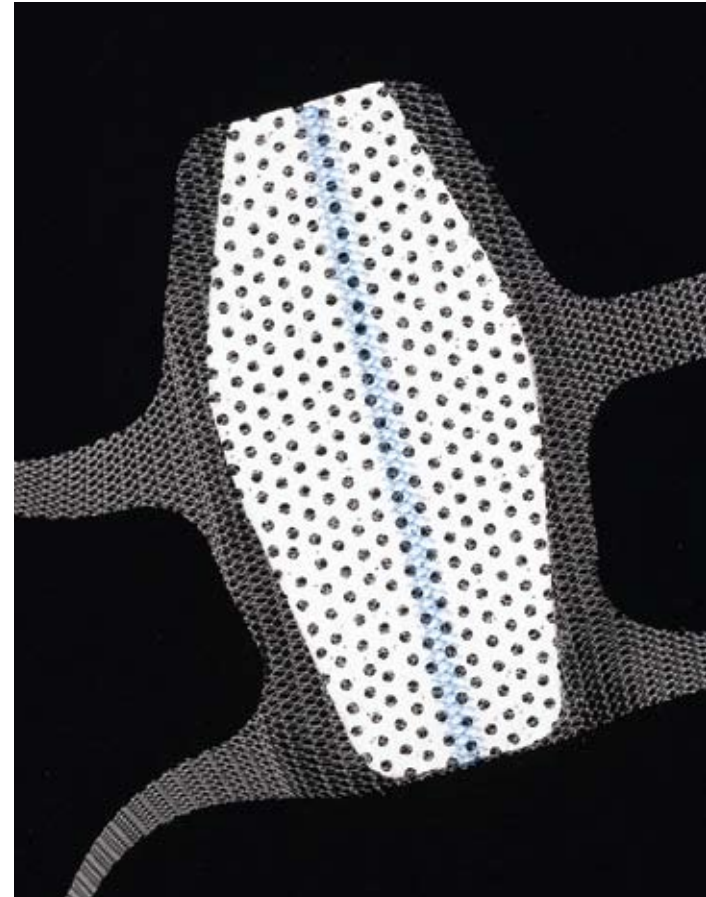
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### How is Pelvic Organ Prolapse Treated?

The best treatment for a specific type and severity of pelvic organ prolapse will vary from patient to patient. If the patient's symptoms are mild, the doctor may recommend lifestyle changes, Kegel exercises to strengthen pelvic muscles, or the use of a pessary to relieve the symptoms. When the symptoms are severe enough to affect the patient's quality of life, surgery remains the most definitive treatment.

### What is the Avaulta™ system?

The Avaulta™ system is a minimally invasive surgical procedure which places a special mesh material in the pelvis. The goal of the Avaulta™ system is to restore the strength and function in your weakened tissues so they can resume naturally supporting the organs in the pelvis. The Avaulta™ system mesh is placed by your doctor in the operating room, and is specifically designed to provide maximum pelvic muscle support with minimal procedure time.



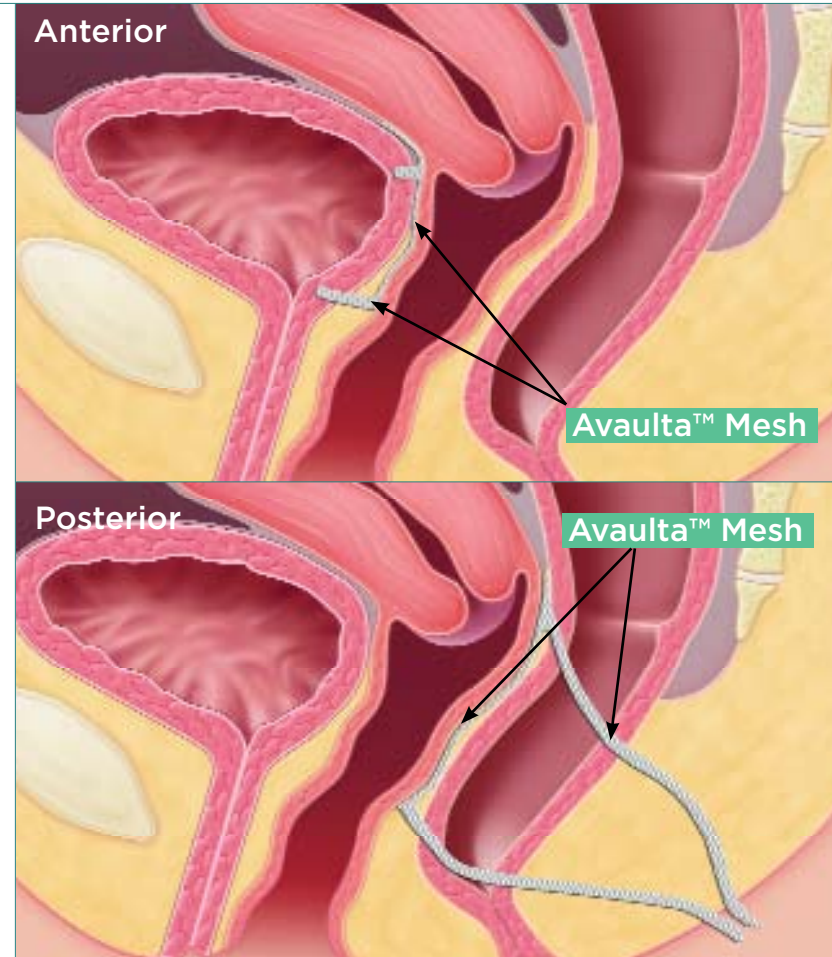


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### How is the Avaulta™ system used in treating pelvic organ prolapse?

Once the mesh and arms of the Avaulta™ system are placed in the pelvis, the natural healing processes of the body begin, causing the body's tissues to grow into the pores in the mesh. This rapid ingrowth locks the mesh into place and creates pelvic muscle support in the same way that a hammock holds your body when you lie down in one.

The mesh helps recreate the floor and/or ceiling of the vagina, resulting in a restoration of normal vaginal support and eventually relief from the patient's related symptoms.





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### How is the Avaulta™ system procedure performed?

The Avaulta™ system is placed through a vaginal incision and a few small skin incisions. The procedure is done in a hospital and usually takes between one and two hours. The surgery can be done under regional or general anesthesia, depending on what you and your doctor choose.

### What happens after the procedure, and how long will it take to heal?

Placement of the Avaulta™ system often requires a stay in the hospital lasting one night, and many patients are able to return home the next day. The body begins to incorporate the mesh early in the healing process, and many patients are able to resume normal activities in less than a week. By six weeks after surgery, the healing process in most patients will allow them to resume activities such as sexual intercourse, strenuous exercise, and the lifting of heavy objects. Your doctor will have specific instructions for your post-operative care based on your condition.

### Are there any risks with the Avaulta™ system procedure?

Like any surgical procedure, the Avaulta™ system procedure has the risk of certain complications. Your doctor can further explain specific risks for a given patient, and can provide a list of warnings and contraindications associated with the procedure. Synthetic mesh implants have been used safely in medical procedures for decades, but have the risk of extrusion, erosion, infection or inflammation.

### What makes the Avaulta™ system different from other surgical options?

The Avaulta™ system represents the latest technology in pelvic organ prolapse repair. It allows your doctor to perform the procedure in an outpatient environment using very small incisions and provides a permanent support for pelvic tissues.

There is no need to continue suffering through the debilitating effects of pelvic organ prolapse. With new products and procedures like the Avaulta™ system, patients can resume an active, fulfilling lifestyle.





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For more information on Bard's treatment options for Pelvic Organ Prolapse, visit

[www.bardurological.com/patient](http://www.bardurological.com/patient)  
and click on "Women's Health"

Be sure to speak with your doctor about today's treatment options and choosing the one that is right for you.



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