Stop Coping. **Start Living**

Talk to your doctor about pelvic organ prolapse and sacrocolpopexy
Did you know?

One in three women will suffer from a pelvic health condition in her lifetime. Four of the most common conditions are: abnormally heavy menstrual bleeding, uterine fibroids, incontinence and pelvic organ prolapse. Approximately 4 in 10 women over age 50 have some degree of pelvic organ prolapse.¹ Women need to know pelvic organ prolapse can be treated and that they don’t have to suffer.

What is pelvic organ prolapse?

Your vagina and uterus are secured to the pelvis by connective tissue that forms ligament-like structures around the vaginal walls. As pelvic floor muscles weaken, these connective structures give way, allowing the vagina to become displaced towards, and at times beyond, the vaginal opening. This can affect the bladder, bowel, and rectum, leading to the following symptoms:

- An uncomfortable feeling that something is bulging or dropping into the vagina
- Discomfort or lack of sensation with sexual intercourse
- Loss of bladder or bowel control
- Difficulty voiding
- Urinary frequency
- Problems with bowel movements, such as constipation and incomplete emptying
- Recurrent bladder infections
- Excessive vaginal discharge
- Back pain

Take the next step. Talk with your doctor or healthcare professional about pelvic organ prolapse and what can be done about it.
You are not alone. Pelvic organ prolapse affects millions of women
While it's rarely talked about, approximately 4 in 10 women over age 50 have some degree of pelvic organ prolapse. Pelvic organ prolapse can affect a woman's daily life, limiting physical activity and sexual intimacy.¹

Common causes
While aging is a dominant factor, there are many potential contributing causes to pelvic organ prolapse. They include loss of muscle tone, estrogen loss associated with menopause, multiple vaginal deliveries, obesity, family history, pelvic trauma or previous surgery, repeated heavy lifting, recurrent constipation, chronic coughing and certain medical conditions such as diabetes or connective tissue disorders.

There are several different types of pelvic organ prolapse
A prolapse occurs when organs drop from their naturally supported position and protrude into or outside of the vagina. There are several different types, which are simply defined according to which organ(s) have prolapsed into the vagina. Often a woman can have more than one type of prolapse.

Normal pelvic anatomy

![Diagram of normal pelvic anatomy](image)

This diagram shows normal positioning of the organs for the different types of prolapse

Organs that may be involved in pelvic organ prolapse include:

**Vagina:** For women who have had a hysterectomy and no longer have a uterus, the top of the vagina pushes into the lower vagina. This is called a vaginal vault prolapse.

**Small Bowel (Intestine):** Prolapse of the small bowel pushes the vagina towards the opening. This is called an enterocele.
**Bladder:** If the pelvic floor is weak, the bladder, which rests on this area of the vagina, can “drop” out of position. This defect is called a cystocele and is the most common type of pelvic floor defect. It is often referred to as a “dropped bladder.”

**Rectum:** As the back wall (or floor) of the vagina loses its support, the rectum can balloon up into, and sometimes out of, the vaginal opening. The rectum, which normally has the vagina as a backstop, can now protrude forward into the vagina, creating a “pocket” called a rectocele.

**Uterus:** Prolapse of the uterus into the vagina is called uterine prolapse.
Diagnosis
Pelvic organ prolapse is diagnosed by a thorough history and pelvic examination. Your doctor will also study your medical history, looking for factors that may have contributed to this condition. He or she may order diagnostic tests, such as a urodynamic study to evaluate bladder function or special imaging studies to visualize the prolapse.

Treatment options
If you have been told that pelvic organ prolapse is an inevitable part of getting older, you should know that you do not have to cope with it - there are treatment options for you. Pelvic organ prolapse can be treated with a variety of methods, including nonsurgical and surgical procedures, depending on the severity of the prolapse and the associated symptoms. Talk to your doctor about all treatment options.

Nonsurgical options

Behavioral/Muscle therapy: If symptoms are mild, therapy often starts with Kegel exercises, in which you contract and relax the pelvic floor muscles.

Pessary: This device is inserted into the vagina to support the pelvic area and help relieve symptoms of pelvic organ prolapse, including incontinence. Vaginal estrogen may be recommended in conjunction with the pessary. Also, it is important to ask your doctor how to remove, clean and reinsert the pessary device.

Biofeedback: In this method, the patient exercises the pelvic floor muscles while connected to an electrical sensing device. The device provides feedback to help you learn how to better control these muscles. Over time, biofeedback can help you use your pelvic muscles to decrease sudden urges to urinate and lessen certain types of pelvic pain.

Surgical options

Pelvic reconstructive surgery: The surgeon repositions the prolapsed organs and secures them to surrounding tissues and ligaments using either sutures or mesh.

Posterior and anterior colporrhaphy (pronounced kol-per'e-fe): These procedures repair the tears in the tissues on either the front (anterior) or back (posterior) wall of the vagina using sutures.

Hysterectomy: A hysterectomy, the removal of all or part of the uterus, may be done in combination with other pelvic floor repair procedures, depending on the type of pelvic organ prolapse.
Transvaginal synthetic mesh repair: Using incisions inside the vagina, the surgeon repositions the prolapsed organs and secures them to surrounding tissues and ligaments using mesh.

Sacrocolpopexy/Sacrocolposuspension synthetic mesh repair: This procedure is performed to address vaginal vault prolapse. It involves attaching the upper portion of the vagina to a piece of mesh which is then secured to a ligament at the bottom of the spine where it attaches to the tailbone. This procedure can be done either through an open abdominal incision or using a minimally invasive approach (laparoscopy or robotic surgery).

Talk to your doctor about pelvic organ prolapse
Remember, pelvic organ prolapse is common and treatable. Many women are understandably reluctant and embarrassed to talk to their doctors. You do not have to accept the limits that pelvic organ prolapse can put on your lifestyle, so talk to your doctor about treatment options.

The following types of questions will help you find out more information about your particular condition and the kinds of treatment that may be right for you. The more informed you are, the more comfortable and confident you will be with the decision you and your doctor make together.

Questions for your doctor

• If I have the sensation that something is “falling out”, could this be a sign of prolapse?
• Will treatment address any of my symptoms?
• What are my options?
• What course of treatment do you recommend for me?
• Can I do anything to strengthen the pelvic muscles?
• What factors contribute to prolapse?
• Will treatment affect my ability to have children?
• What are the risks associated with prolapse surgery and sacrocolpopexy?
• How soon after treatment can I resume my regular activities?
Who is a candidate for treatment?
You may be a candidate for treatment if you have been diagnosed with pelvic organ prolapse. As with any surgery of this kind, the procedure should not be performed on pregnant women, infants, or children. It should not be considered by women who plan a future pregnancy. Patient-specific factors may impair wound healing, which may increase the likelihood of complications.

What are the risks of treatment with sacrocolpopexy?
All surgical procedures present risks of complications. Although this brochure summarizes potential risks of sacrocolpopexy surgery and ARTISYN® Y-Shaped Mesh, you should speak to your doctor about what these risks mean and how frequently they occur, how they may affect your individual treatment decision, and your doctor’s experience with the use of mesh to treat prolapse. While this brochure is intended to introduce you to various treatment options for prolapse, only a thorough discussion with a properly trained doctor can best inform you as to which treatment option is right for you.

Complications associated with sacrocolpopexy and ARTISYN Mesh include those typically associated with surgery to repair pelvic organ prolapse and surgery using permanent synthetic implantable materials, including: bleeding, accidental urine loss, difficulty urinating, temporary or chronic pain, infection, opening of surgical wounds, nerve damage, recurrent prolapse, inflammation, internal scar tissue formation, development of artificial tissue tracks (fistula), excessive contraction of the tissue surrounding the mesh, mesh exposure into the vaginal wall, mesh erosion into surrounding organs, pelvic pain, vaginal pain, and pain with intercourse. The above complications may resolve with time; however some may persist and/or require additional treatment, including re-operation and removal of mesh.

For additional information on potential risks, see the Essential Product Information page of this brochure.

What should I expect after the sacrocolpopexy procedure?
After surgery, follow your doctor’s instructions and restrictions on your activities. During the recovery period, you will have to avoid heavy lifting, strenuous exercise and sexual intercourse until your doctor determines that you can return to normal activities. If you experience any complications, please notify your physician immediately.
ESSENTIAL PRODUCT INFORMATION

INDICATIONS
ARTISYN™ Y-Shaped Mesh is intended for use as a bridging material for sacrocolpopexy (laparotomy or laparoscopic approach) where surgical treatment for vaginal vault prolapse is warranted.

CONTRAINDICATIONS
- ARTISYN™ Y-Shaped Mesh should not be used in infants, children, pregnant women, or in women planning future pregnancies, because the mesh will not stretch significantly as the patient grows.
- ARTISYN™ Y-Shaped Mesh should not be used in the presence of active or latent infections or cancers of the vagina, cervix, or uterus.
- ARTISYN™ Y-Shaped Mesh must always be separated from the abdominal cavity by peritoneum.
- ARTISYN™ Y-Shaped Mesh must not be used following planned intraoperative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh which could lead to infection that may require removal of the mesh.

WARNINGS
- Patients who are on anticoagulation agents and undergoing surgery using ARTISYN™ Y-Shaped Mesh must have their anticoagulation therapy carefully managed.
- A digital rectal examination may be performed to detect possible rectal perforation.
- Cystoscopy may be performed to confirm bladder integrity or to detect possible bladder or ureteral perforation.
- Postoperatively, the patient should be advised to refrain from intercourse, heavy lifting, and/or exercise (e.g., cycling, jogging) until the physician determines when it is safe for the patient to return to her normal activities.
- Use ARTISYN™ Y-Shaped Mesh with care, and with attention to patient anatomy and to proper dissection technique, to avoid damage to vessels, nerves, bladder, bowel, and vaginal wall.
- The safety and effectiveness of this product has not been validated in clinical trials.
- Reuse of this device (or portions of this device) may create a risk of product degradation and cross-contamination, which may lead to infection or transmission of bloodborne pathogens to patients and users.

PRECAUTIONS
- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and synthetic meshes before employing ARTISYN™ Y-Shaped Mesh.
- Avoid placing excessive tension on the mesh implant during placement.
- This product should only be used under the prescription of a licensed healthcare practitioner.
- In patients with compromised immune systems or other conditions that could compromise healing, the risks and benefits should be weighed carefully.
- Vaginal or urinary tract infection should be treated and alleviated prior to implantation.

ADVERSE REACTIONS
- Potential adverse reactions are those typically associated with surgery employing implantable materials of this type, bleeding including hemorrhage or hematomata, urinary incontinence, urge incontinence, urinary frequency, urinary retention or obstruction, voiding dysfunction, acute and/or chronic pain, wound dehiscence, nerve damage, recurrent prolapse, inflammation, adhesion formation, fistula formation, contracture, scarring and mesh extrusion, exposure, or erosion into the vagina or other structures or organs.
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation.
- Potential adverse reactions are those typically associated with pelvic organ prolapse repair procedures, including pelvic pain or pain with intercourse, which in some patients may not resolve.
- Dissection for pelvic floor repair procedures has the potential to impair normal voiding for a variable length of time.
- Excessive contraction or shrinkage of the tissue surrounding the mesh, vaginal scarring, tightening and/or shortening may occur.
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, ARTISYN™ Y-Shaped Mesh may potentiate infection.
- Punctures or lacerations of vessels, nerves, structures or organs, including the bladder, urethra or bowel, may occur and may require surgical repair.
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur.
- These adverse reactions may require surgical treatment.
- As with any surgery, one or more revision surgeries may be necessary to treat these complications.
- ARTISYN™ Y-Shaped Mesh is a permanent implant that integrates into the tissue. In cases in which the ARTISYN™ Y-Shaped Mesh needs to be removed in part or whole, significant dissection may be required.

OTHER ADVERSE REACTIONS
- Seroma
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- Death

Consult your doctor to discuss the potential benefits and risks of your treatment options and whether ARTISYN™ Y-Shaped Mesh is appropriate for you.

ETHICON is dedicated to improving women's quality of life by providing innovative solutions for treating common pelvic health conditions.

Learn more: To speak with a nurse call 1-877-ETHICON (1-877-384-4266)

Reference

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