

Life without POP is possible

Pelvic Organ Prolapse (POP)

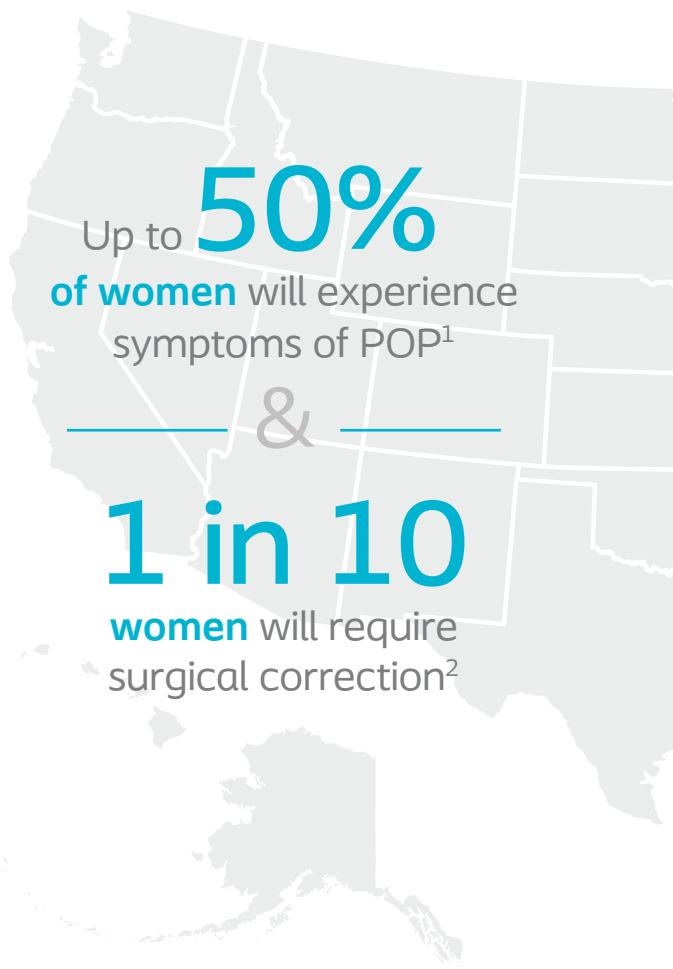
A Patient Guide



Coloplast

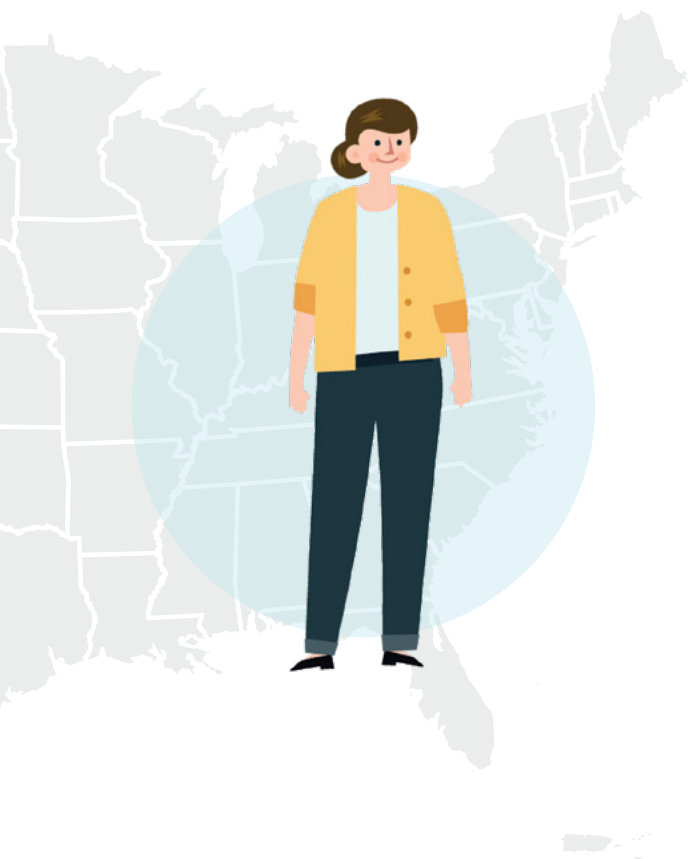
Pelvic organ prolapse (POP) is the dropping of the pelvic organs caused by the loss of normal support of the vagina.

This condition is common.



Up to **50%**
of women will experience
symptoms of POP¹

_____ & _____
1 in 10
women will require
surgical correction²



If you're experiencing heaviness or pressure in your pelvic region, vaginal pain or pressure, painful sex, or difficulty urinating or having a bowel movement, you may be experiencing **Pelvic Organ Prolapse (POP)**.

You're not alone

Keep reading to find out more about POP, the causes, the treatment options, and how to find a specialist. ***Instead of living with POP, live better without it.***



Find your path to prolapse relief

No two people walk the same path to a diagnosis or a solution. Every woman's experience with pelvic organ prolapse (POP) is different, their symptoms vary, making it difficult to know what next steps should be taken to address it.

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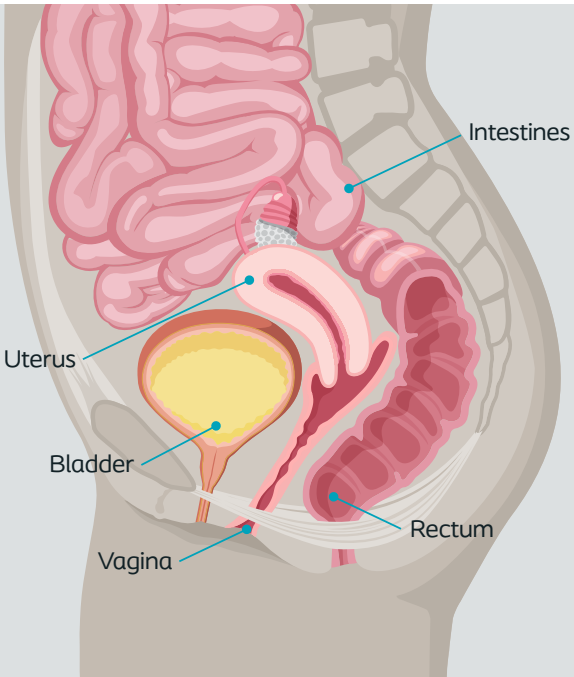
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- Before surgery and questions to ask
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What is prolapse?

Pelvic organ prolapse (POP) is the dropping of the pelvic organs caused by the loss of normal support of the vagina. It occurs when there is weakness or damage to the normal support of the pelvic floor causing pelvic organs (the vagina, cervix, uterus, bladder, urethra, intestines or rectum) to drop down. Women with POP may feel a bulge inside their vagina or see a bulge coming out of their vagina.³

Experiencing pelvic organ prolapse can be challenging — it can interfere with your activities, intrude on your personal life, and cause some serious discomfort.³



Female anatomy without prolapse



Living with POP is not only physically draining, but it also affects your mental health. Women with this condition are 3 times more likely to get depressed.⁴

*However, there are **solutions** to repair POP at the source, so you can **get back to living the life you want.***

Symptoms of prolapse

While it is not life-threatening, women with prolapse experience symptoms that impact their day-to-day lives and keep them from experiencing moments to the fullest. But these symptoms won't always seem obvious. As prolapse progresses, the symptoms may become more apparent and painful. If you are experiencing prolapse, you may feel:

- Pressure in the pelvic region, vaginal discomfort, pain or bleeding⁵
- Pulling or aching in the lower abdomen or pelvis, a bulge coming out of the vagina⁵
- Pain or discomfort during sex⁶
- Difficulty urinating or having a bowel movement⁵

POP is common.

Nearly

half of all women

between ages 50 and 79
say they have symptoms⁷



If you are suffering from any of these symptoms, you may have pelvic organ prolapse and should consult with a doctor. Although these signs and symptoms can alert you to a problem, they are not unique to prolapse, so it is important to **consult a doctor for the correct diagnosis.**



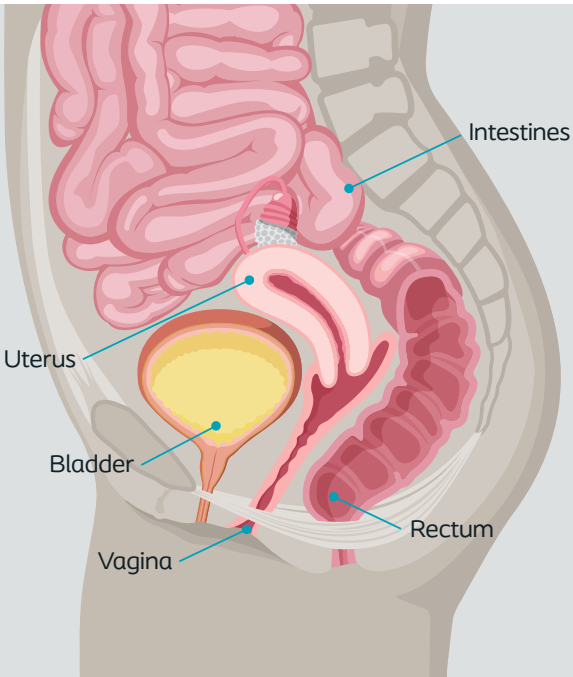
Find a
prolapse specialist.

<https://www.femalepelvicsolutions.com/prolapse/find-a-prolapse-specialist/>

What causes prolapse?

Pelvic organ prolapse can drastically impact your lifestyle. Things that can cause the muscles in the pelvis to become stretched or weakened include:

- Pregnancy and childbirth³
- Genetics³
- Smoking³
- Pelvic Floor Injury³
- Chronic constipation³
- Chronic coughing³
- Obesity³
- Menopause³
- Nerve and muscle diseases³



Female anatomy without prolapse

Types of prolapse

There are several different types of pelvic organ prolapse, with different names depending on the organs involved:⁸

- Cystocele
- Vaginal vault
- Uterine
- Rectocele
- Enterocele

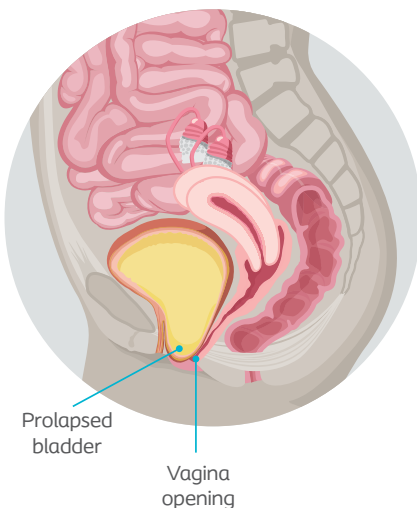
While you may have obvious symptoms of prolapse, only your doctor can confirm which type of prolapse you're currently experiencing.

Anterior vaginal wall prolapse

Cystocele prolapse occurs when there is a loss of support to the front wall of the vagina. The bladder drops down and may cause a bulge in the vaginal opening.

Cystocele

Prolapse of the bladder



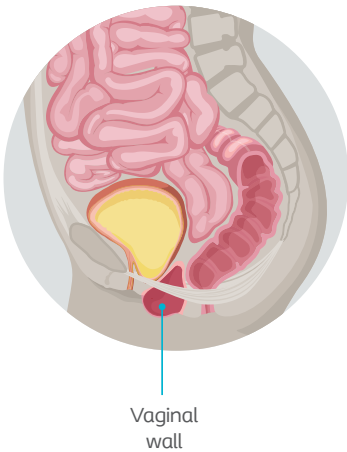
Do I have pelvic organ prolapse?

Apical prolapse

Vaginal vault or **uterine** prolapse occurs when there is a loss of support for the uterus and the top part of the vagina after a hysterectomy.

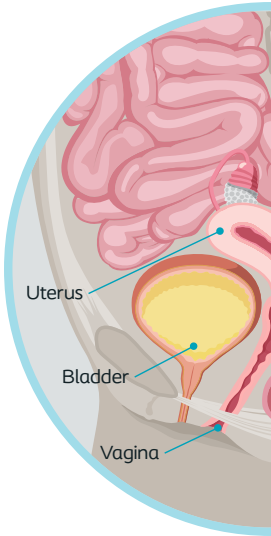
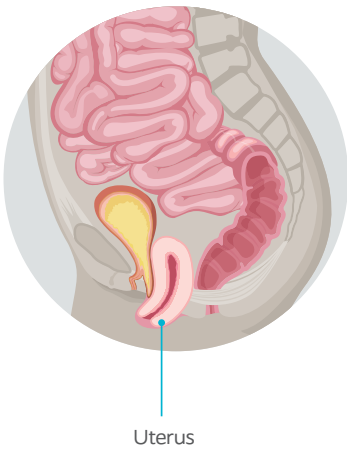
Vaginal Vault

Prolapse of the vaginal wall



Uterine

Prolapse of the uterus



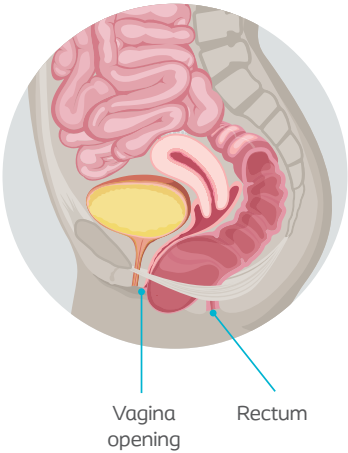
Female anatomy without prolapse

Posterior vaginal wall prolapse

Rectocele or **Enterocoele** prolapse occurs when there is a loss of support to the back wall of the vagina. The rectum or intestines drop down and may cause a bulge in the vaginal opening.

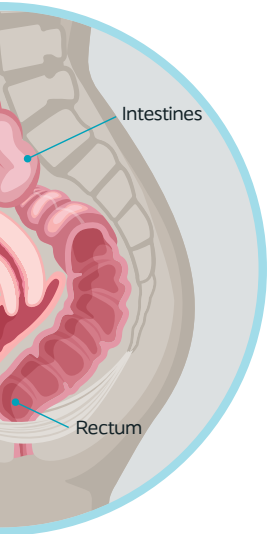
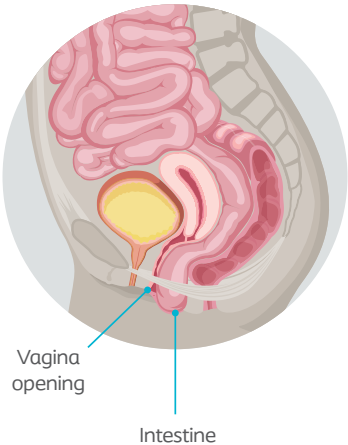
Rectocele

Prolapse of the rectum



Enterocoele

Prolapse of the intestine



Non-surgical treatment options

There's nothing simple about dealing with prolapse, but there are treatment options. Your physician may recommend some of these non-surgical options as a first step to relief:

Vaginal pessary: a removable device placed in the vagina to support the pelvic floor and support the prolapsed organ. Your physician will fit and insert the pessary, which must be cleaned frequently and may have to be removed before intercourse.⁹

Kegels: an exercise you can do on your own or with the guidance of a pelvic floor therapist to help strengthen your pelvic floor muscles.¹⁰

Biofeedback therapy: a technique that uses different types of devices to give information on how well pelvic muscles are contracting. This information can help improve awareness and control of pelvic floor muscles.¹⁰

Non-surgical options may involve long-term treatment, ongoing maintenance and continued expenses, and **may not fully resolve the underlying condition.**

Surgical solutions for prolapse

Restore your normal

Prolapse can be repaired rather than just managed. And following surgery many women ultimately realize, “I wish I would’ve done it sooner.” It’s time you choose a solution that treats the source of the problem, instead of masking its symptoms. It’s time to find lasting relief.

Reconstructive surgical solutions are effective in repairing POP. They fix the source of the symptoms, so you can get back to living the life you want.



Learn more
about surgical solutions
for **prolapse.**

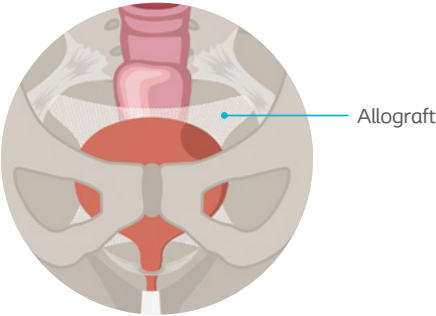
<https://www.femalepelvicsolutions.com/prolapse/how-surgical-options-for-prolapse-work/>



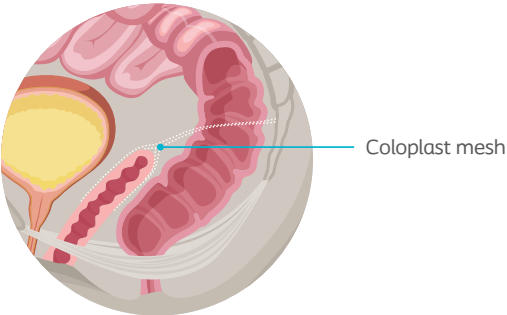
What are my treatment options?

Two approaches to POP repair

Your physician will recommend a procedure based on your type of prolapse and your medical history.



Through the vagina (Transvaginal): This approach includes various types of procedures where a surgeon corrects your prolapse through your vagina using your own tissue or a biologic graft, called an allograft (colpopexy).¹¹



Through the abdomen (Transabdominal): This approach corrects prolapse via incisions in the abdomen that allow surgeons to attach surgical mesh from the vagina to tissue at the sacrum (sacrocolpopexy). This procedure can be done using a surgical robot or laparoscopic instruments.¹¹

Coloplast Mesh

Coloplast's Restorelle® mesh allows for tissue ingrowth which combines with your body's natural collagen tissue to provide extra support. This strengthened support system maintains the organ's anatomical placement.¹²

Synthetic mesh has been shown studies to reduce the risk of recurrence of prolapse, as well as relieving the symptoms of prolapse.¹³ Your doctor will be able to provide more information about prolapse surgery and the different types of repair materials available.



What have others experienced?

Women experiencing POP deserve a clinically proven and effective solution that lasts. Prolapse repair procedures have effective outcomes such as:

88%

of patients were “satisfied” or **“very satisfied”**¹³

87%

of patients stated they would definitely **“do it all over again”** if they had the chance¹³

86%

stated they **“would definitely recommend to a friend”**¹³

How surgery helped Laurie get back to her normal

Laurie's gynecologist told her she had pelvic organ prolapse (POP) before her symptoms were even noticeable. Since Laurie wasn't experiencing any symptoms prior to her appointment, she and her doctor agreed that no action was needed yet. A year and a half later that changed. After sharing her symptoms with her gynecologist, she was referred to a pelvic floor specialist who recommended that she have surgical repair for POP.

Laurie's surgery went well. She experienced some typical post-op discomfort during recovery, but was able to return to her routine within a few weeks as directed by her physician.

Laurie has had no problems or symptoms of POP since her surgery.

I have no regrets. I highly recommend surgery for POP.

LAURIE

Actual patient not pictured.



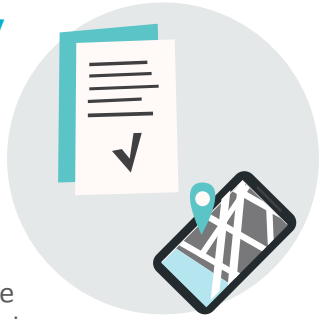
Patient story -
Surgery for pelvic organ prolapse.

<https://www.femalepelvicsolutions.com/prolapse/patient-story-surgery-for-pop/>

Before surgery

You will likely have a pre-op visit with your doctor and possibly with your anesthesiologist.

This is the time to ask questions you may have about your surgery and post-operative care. Your surgeon will review your medical history and recent experiences. You will have to provide a list of all medication and supplements you take. They will inform you of the correct preparations you should take prior to your procedure and medically clear you for your surgery.



Some physicians might recommend a “bowel prep” for the day before your procedure (a laxative or an enema). And if you are going to have anesthesia, you’ll be instructed not to eat or drink anything a minimum of six hours before your surgery.¹⁴

If you are considering surgery with the use of surgical mesh to repair your POP, ask your surgeon these questions before you agree to the procedure:

Are you planning to use mesh in my surgery?

Why do you think I am a good candidate for surgical mesh?

Why is surgical mesh being chosen for my repair?

Will my partner be able to feel the surgical mesh during sexual intercourse? What if the surgical mesh erodes through my vaginal wall?

If surgical mesh is to be used, how often have you implanted this particular product? What results have your other patients had with this product?

What can I expect to feel after surgery and for how long?

Which specific side effects should I report to you after the surgery?

If I develop a complication, will you treat it or will I be referred to a specialist experienced with surgical mesh complications?

What if the mesh surgery doesn't correct my problem?

If I have a complication related to the surgical mesh, how likely is it that the surgical mesh could be removed and what could be the consequences?

If a surgical mesh is to be used, is there patient information that comes with the product, and can I have a copy?

During surgery

During the surgery, your surgeon will place the synthetic graft (mesh) through an incision in your abdomen. If your surgeon uses a biologic graft (allograft), they will place it through an incision in the vagina.

If a synthetic mesh is used, your body's tissue will grow through the holes in the mesh and the mesh will slowly become part of your body. Biologic grafts are typically absorbed by your body within 6 to 9 months.¹⁵



After surgery

If you have surgery with mesh to repair your POP, you should:

Continue with your annual and other routine check-ups and follow-up care. There is no need to take additional action if you are satisfied with your surgery and are not having complications or symptoms.

Notify your health care provider if you have complications or symptoms, including persistent vaginal bleeding or discharge, pelvic or groin pain or pain with sex, that last after your follow-up appointment.

Let your health care provider know you have surgical mesh, especially if you plan to have another surgery or other medical procedures.

Talk to your health care provider about any questions you may have.

Insurance information

Most insurance plans, including Medicare, cover these procedures. Consult your insurance carrier to find out the specific criteria for coverage. The reimbursement specialist at your physician's office may also be able to help answer your insurance questions.

Healing and recovery

Although every pelvic organ prolapse patient's recovery process is different, there are general recovery guidelines that apply to most pelvic floor procedures.¹⁶

- It is common to spend one to four days in the hospital, depending on the type of surgery performed (outpatient or a brief stay in the hospital);
- Patients often can resume most normal activities two weeks after surgery or at the physician's discretion;
- Physical strain, sexual intercourse, and heavy lifting should typically be avoided for six weeks after surgery.

Your physician will provide recommendations for your recovery process that are specific to your individual needs.





Follow your physician's recovery directions carefully. Even though you may not be feeling much pain from your surgical procedure, your body needs time to heal properly from the surgery and allow the implant to incorporate within your body's natural tissue.

Contact your physician immediately if you have any problems after your surgery. It's important to tell them if you have excessive bleeding, pain, abnormal vaginal discharge or signs of infection occurring at any time during your recovery. Your physician will give you a more detailed list of possible adverse events that can happen. Continue with your annual and other routine check-ups and follow-up care.

Important safety information

The FDA has made a commitment to inform the public about urogynecologic surgical mesh for pelvic organ prolapse (POP) and maintains information on their website for patients about POP and the use of surgical mesh for repair of POP.

The information provided by the FDA for mesh used in the treatment of pelvic organ prolapse is not specific to any company or specific product line. To ensure you receive the full list of potential risks for any specific mesh device, please discuss with your healthcare provider.

The information below has been taken directly from the FDA’s website regarding urogynecologic surgical mesh. Please note that these excerpts include information on mesh used to treat stress urinary incontinence and pelvic organ prolapse.

Scan the QR codes below to access the latest from the FDA regarding urogynecologic surgical mesh.



Pelvic Organ Prolapse (POP)



Pelvic Organ Prolapse (POP): Surgical Mesh Considerations and Recommendations

Restorelle® Y, Y Contour™, M, L, and XL Polypropylene Mesh for Sacrocolposuspension/Sacrocolpopexy

Pelvic organ prolapse (POP) is a condition in which the muscles of a woman's pelvis become weak or damaged and can no longer support the pelvic organs (such as the bladder, uterus and rectum), causing them to push into the vagina. This condition can cause pain in the pelvis, discomfort while going to the bathroom and problems with having sex.

Pelvic organ prolapse can be treated with a surgical procedure in which mesh is implanted to support the pelvic organs. **Restorelle® Y, Y Contour™, M, L, and XL** mesh is a non-absorbable mesh that is surgically implanted through the abdomen (transabdominally) and once implanted into your body is permanent. The mesh is intended to act as a support to the weak or damaged pelvic muscles to prop up the muscles while new tissue grows into the mesh to provide strength and support, preventing the pelvic organs from pushing into the vagina. A mesh is implanted inside the abdomen to support the internal organs. The operation to place a mesh is considered major surgery.

Restorelle Y, Y Contour, M, L, and XL is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (transabdominal placement via laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Restorelle Y, Y Contour, M, L, and XL is not for females who have the following: are pregnant or desire for future pregnancy, potential for further growth (e.g., adolescents), pre-existing local or systemic infection, taking blood thinning medication (anti-coagulant therapy), any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement, and sensitivity/allergy to polypropylene.

Check with your Physician on the warnings, precautions and risks associated with the use of this mesh.

The effectiveness of **Restorelle Y, Y Contour, M, L, and XL** has not been validated by a prospective, randomized clinical trial.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh procedure.

Check with your Physician on:

- Alternative pelvic organ prolapse treatments that may be appropriate
- The reason for choosing transabdominal mesh
- The postoperative risks and potential complications of transabdominal mesh surgery
- The mesh to be implanted is a permanent implant
- Some complications associated with the implanted mesh may require additional surgery; repeat surgery may not resolve these complications
- Serious adverse tissue responses or infection may require removal of parts of the mesh, or the entire mesh, and complete removal of the mesh may not always be possible
- Individuals who have varying degrees of collagen laydown that may result in scarring
- Certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events, as with all surgical procedures

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using **Restorelle Y, Y Contour, M, L, and XL** should be considered in all patients, taking into account patients with the following underlying conditions:

- Age-related underlying conditions
- Autoimmune disease
- Coagulation disorder
- Connective tissue disorder
- Debilitated or immunocompromised state
- Diabetes
- Pelvic radiation therapy or chemotherapy
- Physical characteristics (e.g., body mass index)
- Smoking-related underlying conditions
- Urinary tract anomalies

Any future pregnancy could negate the benefits of this mesh surgical procedure. You should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Adverse events are known to occur with transabdominal synthetic mesh procedures and implants.

Adverse events following mesh implantation may be new onset (de novo), persistent, worsening, transient, or permanent.

Potential complications include, but are not limited to: abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, bowel obstruction, constipation and/or defecatory dysfunction, fecal incontinence and/or anal sphincter incompetence, ileus, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, mesh migration, necrosis, new onset (de novo) and/or worsening painful intercourse (dyspareunia), neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., ligaments, muscles, nerves, vessels), structures, or organs (e.g., bowel, rectum, bladder, urethra, ureters, vagina), seroma, suture erosion, bladder storage dysfunction

(e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), de novo or worsening prolapse in untreated compartment, granulation tissue formation, palpable mesh (patient and/or partner), recurrent prolapse, sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring, tightening, rigidity, shortening and/or contracture.

The occurrence of these events may require one or more revision surgeries, including removal of the mesh.

Complete removal of the mesh may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh explantation.

This treatment is prescribed by your physician. Discuss the treatment options with your physician to understand the risks and benefits of the various options to determine if mesh is right for you.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Minneapolis, MN
PM-07280 02/19/2019

Axis™/Tutoplast®

Axis™ Tutoplast® Processed Dermis is processed from donated human tissue. The US FDA regulates Axis Tutoplast Processed Dermis as a human cell and tissue product and restricts it to homologous use.

Homologous use means Axis Tutoplast Processed Dermis can be used by a qualified healthcare professional to repair, replace, reconstruct or supplement soft tissue. For your procedure this may

include supplemental support and reinforcement of soft tissue, such as graft placement below the urethra (suburethral) in stress urinary incontinence (SUI) procedures, and support and reinforcement of fascial structures (a type of connective tissue) in the pelvic floor in pelvic organ prolapse procedures. The implant is provided sterile.

Warnings – The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. Discuss the associated risks and potential complications of this procedure with your physician. As with any human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant. Successful treatment is dependent upon the patient's host tissue response. In order for this procedure to be successful, Axis Tutoplast Processed Dermis will need to be integrated and remodeled with your own tissue.

Precautions – Axis should only be used by a qualified physician familiar with the implant and the surgical procedure. Please let your doctor know if you are not feeling well since poor general health or any conditions such as limited blood supply, compromised healing, or an active infection should be considered before use.

Tutoplast is a registered trademark of Tutogen Medical GmbH.

PM-25857 05/2023



Take back your normal FemalePelvicSolutions.com

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