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 these contraindications, warnings/potential complications, and adverse events associated with pelvic floor reconstruction are listed below 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 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 future hysterectomies 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, the patient should be instructed to contact the physician immediately
- Patients should be counseled to refrain from heavy lifting, exercise and intercourse for a minimum of six (6) weeks after the procedure. Physician should determine when it is suitable for each patient 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 the 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

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effect, Warnings and Precautions prior to using this product.

Individuals depicted, other than Jonnie, are models and included for illustrative purposes only.

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WHAT ARE SOME TREATMENT OPTIONS?

You don't have to live like this. Vaginal wall prolapse can be treated in several minimally-invasive 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
- A "pessary" — a rubber or plastic device, inserted vaginally and designed to relieve symptoms when in place
- Physical therapy
- Surgical procedures to improve the prolapse
  Many surgical procedures have been developed for the correction of pelvic prolapse.

Please consult your physician to discuss the treatment options including the potential adverse reactions/ complications and postoperative care.

You are on your way!

What types of materials may be used in surgical repairs?

There are several surgical materials which could be used to facilitate your repair. Types of materials include a thin, light synthetic mesh, tissue or soft graft replacement. These materials will be used to reinforce the vaginal wall back into place and stabilize your pelvic support structures. Your physician will recommend the material which is right for you.

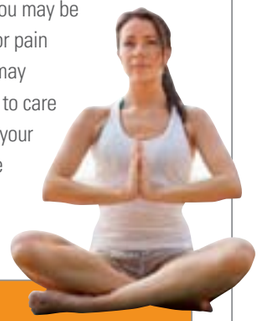
How will my surgery be performed?

Your pelvic prolapse repair can be performed in a few basic ways:

1. through minimally-invasive vaginal incisions
2. through traditional abdominal incision
3. through a laparoscopic approach

Hospitalization and recovery times vary for each procedure type.

What should I expect after surgery?



Before your discharge from the hospital, you may be given a prescription for an antibiotic and/or pain 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.

Glossary

Apex – The roof, or top of the vagina (also known 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 base of 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 its usual position down into the apex of the vagina.

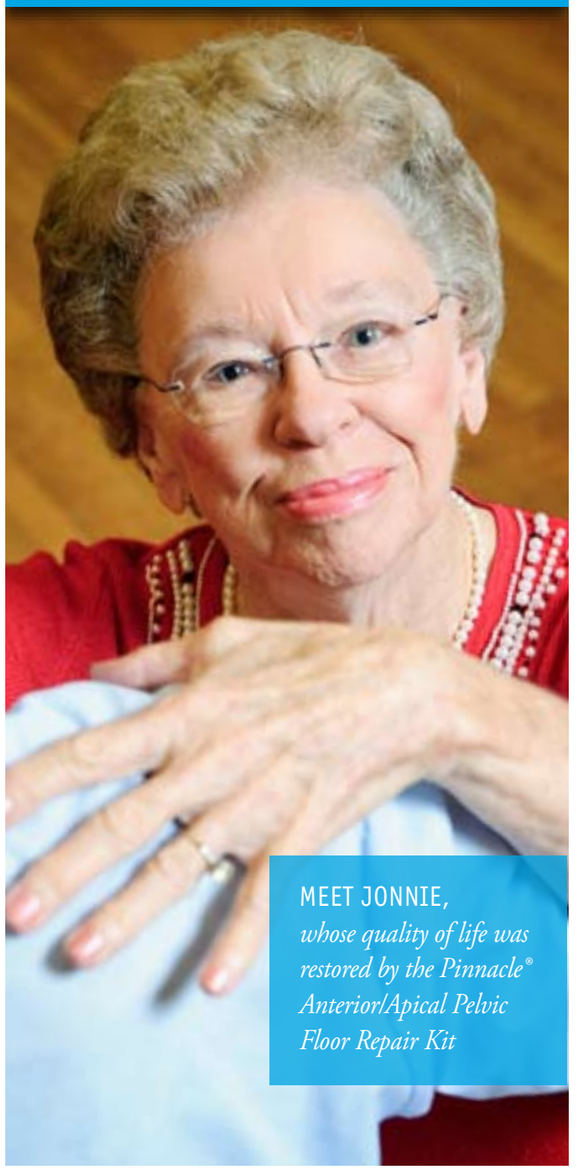
Vaginal Vault Prolapse – Condition in which weakened pelvic muscles cause the vaginal vault (apex) to drop towards the vaginal opening.

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

Visit www.supporting-women.com for additional educational resources.

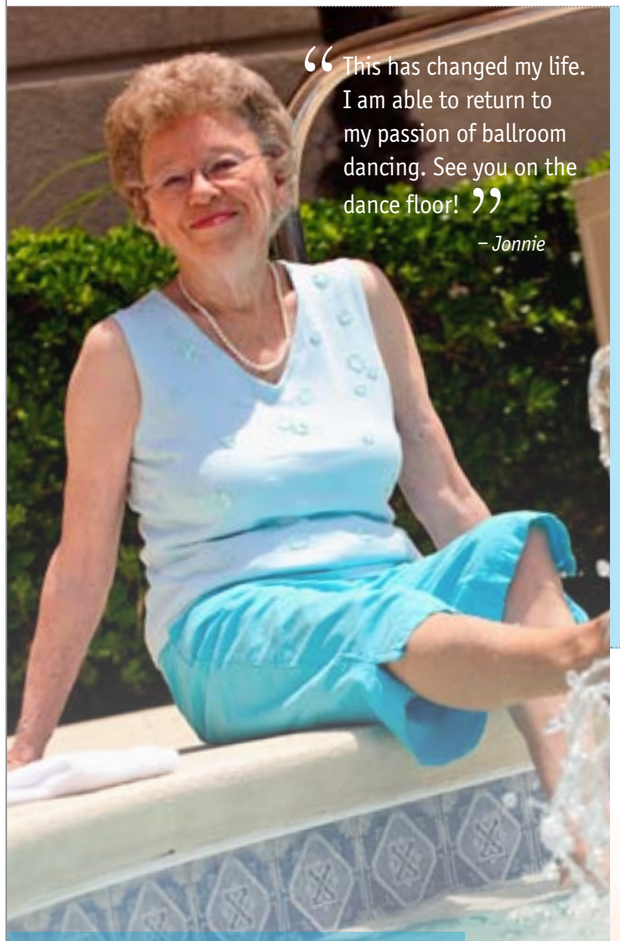
pelvic prolapse

YOUR GUIDE TO PELVIC FLOOR RECONSTRUCTION



MEET JONNIE,
whose quality of life was restored by the Pinnacle® Anterior/Apical Pelvic Floor Repair Kit

commonly asked questions, down-to-earth answers



"This has changed my life. I am able to return to my passion of ballroom dancing. See you on the dance floor!"

– *Jonnie*

Jonnie's condition kept her from ballroom dancing—her greatest passion. Not only has she returned to the dance floor, but she also has regained a freedom she hasn't enjoyed in years.

What is Pelvic Prolapse?

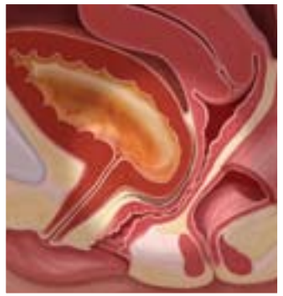
When an organ becomes displaced, or slips down in the body, it is referred to as a prolapse. You may have heard women refer to their "dropped bladder" or "fallen uterus." This problem afflicts over 3 million women in the United States. You are not alone.

What are some of the symptoms?

Symptoms of pelvic prolapse can include:

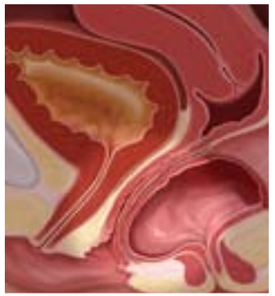
- pressure or discomfort in the vaginal or pelvic area, often made worse with physical activities such as prolonged standing, jogging or bicycling.
- diminished control in the bladder and/or the bowels.

WHAT TYPE OF PROLAPSE DO I HAVE?



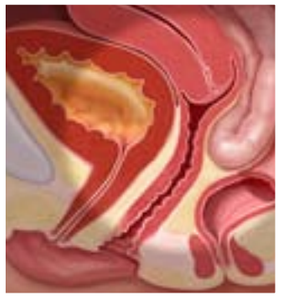
CYSTOCELE

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 bladder is right behind the skin but cannot be seen. The symptoms caused by cystoceles can include pressure, slowing of the urinary stream, overactive bladder and an inability to fully empty the bladder.



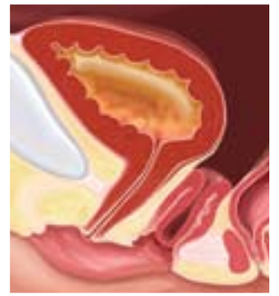
RECTOCELE

A rectocele forms when the lower vaginal wall loses its support, allowing the rectum to bulge upward. This creates an extra pouch in the rectal tube. Larger rectoceles can bulge right through the vagina. 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.



ENTEROCELE

An enterocele forms when intestines bulge downward 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.



APICAL PROLAPSE

Apical prolapse is a weakening of the support structures at the top of the vagina (called the vault or apex). For women who have their uterus intact, this is referred to as uterine prolapse. When this happens, the apex sinks downward toward the vaginal opening. When the apical prolapse becomes advanced, the bulge may become visible outside the vaginal opening. The symptoms may include pressure, pain, bladder infections and difficulty urinating.

"Over the past several years, my prolapse got increasingly worse, making my ballroom dance routine harder." – *Jonnie*