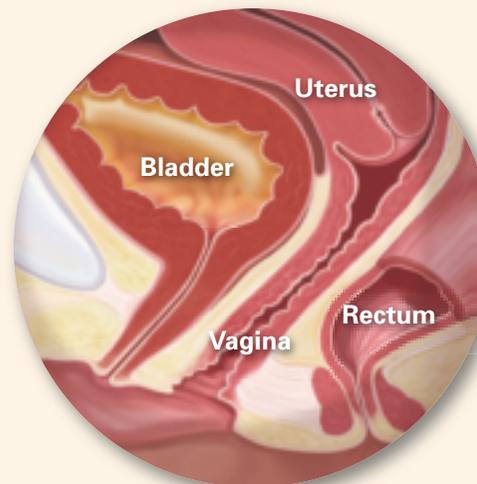


Selected Pelvic Organ Prolapse Treatment Options

Please be sure to request a copy of our Pelvic Prolapse Patient Guide to pelvic floor reconstruction from your physician. There are several treatment options available to address your pelvic organ prolapse. Please consult with your physician to discuss the various treatment options including post operative care.

The Pinnacle® Pelvic Floor Repair Kits and the Uphold™ Vaginal Support System are surgical treatment options designed to correct vaginal wall prolapse utilizing vaginal incisions. They were developed by Boston Scientific, a leader in pelvic floor reconstruction solutions. Each kit contains a thin, light, synthetic mesh and an intra-vaginal delivery device for a minimally invasive approach. Your physician may use the synthetic mesh assembly to reinforce the vaginal wall back into place and stabilize your pelvic support structures. At the discretion of a physician, most patients resume normal activities within six to eight weeks.



Normal Female Anatomy

What can I expect after my surgery?

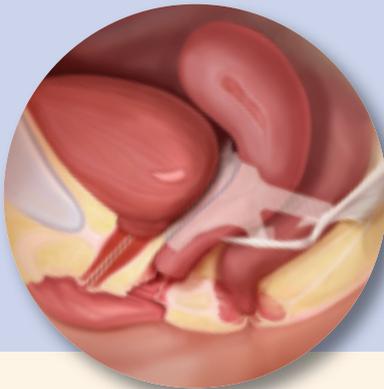
Your physician will provide specific post-operative guidance. The following points are designed to offer general patient information that we recommend you review with your physician.

- Avoid constipation and straining with bowel movements
- Avoid driving until you can safely and comfortably operate a car
- Limit lifting objects during the recovery process
- You may experience light vaginal bleeding for up to 2-4 weeks after surgery
- You may have vaginal discharge for up to 6 weeks after surgery
- You may feel some discomfort after surgery when sitting
- See next page for a more complete list of potential complications and adverse events

The four sample illustrations below demonstrate the placements for the Pinnacle Pelvic Floor Repair Kits and the Uphold Vaginal Support System.

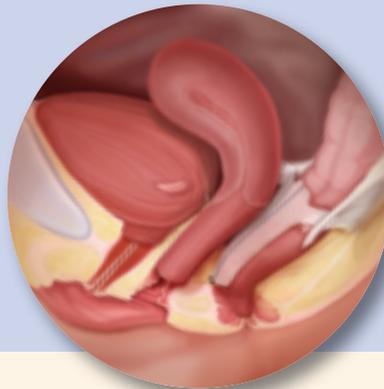
Pinnacle Pelvic Floor Repair Kits

Anterior /Apical



for reinforcement of the vaginal wall near the bladder

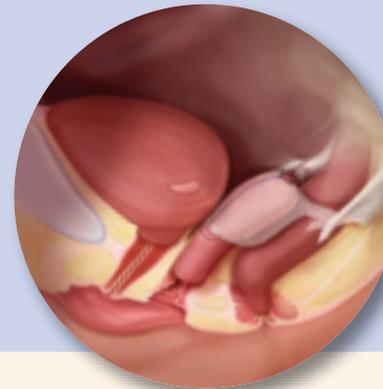
Posterior



for reinforcement of the vaginal wall near the rectum/intestines

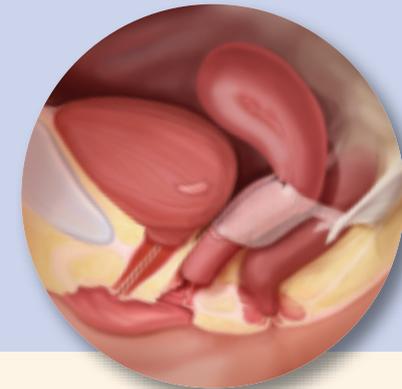
Uphold Vaginal Support System

shown in
Post-hysterectomy Anatomy



for reinforcement of the vaginal wall at the vaginal apex

shown in
Natural Anatomy



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 the 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 a future hysterectomy 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, contact your physician immediately.
- Refrain from heavy lifting, exercise and intercourse for a minimum of six (6) weeks after the procedure. Your physician should determine when it is suitable for you 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 your 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 these devices to sale by or on the order of a physician.

**Boston
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Delivering what's next.™

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