

SOLUTIONS FOR LIFE® American Medical Systems has been active in pelvic health since 1972 when it developed a cure for urinary incontinence. More than 30 years later, we remain a leader in offering cures for female incontinence and other female conditions including prolapse and excessive menstrual bleeding. AMS also offers products that treat incontinence, erectile dysfunction and benign prostatic hyperplasia (BPH) in men.

For a complete list of indications, contraindications, warnings and precautions, consult your doctor. If you have questions regarding the currency of this information please contact AMS.



A total transvaginal procedure for prolapse repair with a single incision.

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Solutions for Life®

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elevate.
PROLAPSE REPAIR SYSTEM

A GUIDE TO CORRECTING
**PELVIC ORGAN
PROLAPSE**



AMS
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RESTORE YOUR BODY

Pelvic organ prolapse occurs when pelvic structures, like the bladder or rectum, bulge or protrude into the vaginal wall.

TALKING ABOUT PROLAPSE

An estimated 34 million women worldwide are affected by prolapse —yet studies show that women are reluctant to discuss it, with each other and even with a doctor.¹

As a result, a silence persists that leaves most women unaware that they do not have to live with this health issue.

Statistics confirm how common this condition is: 1 out of 2 women over age 45 suffer from pelvic organ prolapse.

LEARNING ABOUT TREATMENTS

This brochure will provide you with information on a prolapse repair system from American Medical Systems (AMS) called Elevate[®] that offers a minimally invasive option for treating this condition.

HOW DO I KNOW IF I HAVE PELVIC ORGAN PROLAPSE?

Symptoms common to pelvic organ prolapse include:

- A bulge or lump in the vagina
- The vagina protruding from the body
- A pulling or stretching feeling in the groin area
- Difficult or painful sexual intercourse
- Vaginal pain, pressure, irritation, bleeding or spotting
- Urinary and fecal incontinence
- Difficulty with bowel movements
- Delayed or slow urinary stream

¹Mouritsen L, Larsen JP. Symptoms, bother and POPQ in women referred with pelvic organ prolapse. *Int Urogynecol J* 2003 v. 14 p. 122-127.

Prolapse is caused by muscles and ligaments that have been weakened or damaged. The most common causes of prolapse include:

Childbirth: Often, the stresses and strains of childbirth (especially multiple, large, or difficult childbirth) can weaken or damage pelvic muscles and ligaments, and eventually, causes vaginal prolapse.

Previous Surgery: Surgeries, especially in the pelvic area, may affect your muscles and other supportive tissue, potentially leading to vaginal prolapse.

Hysterectomy: Because important, supportive ligaments may be removed during your surgery, you may face an increased risk of prolapse after hysterectomy (vaginal vault prolapse).

Obesity: Added weight can strain muscles in the pelvic area, and over time, this can weaken muscles, which can lead to vaginal prolapse.

Age: Because aging can weaken pelvic muscles and ligaments, the risk of vaginal prolapse increases – in fact, it doubles with each decade of life – and affects half of women over age 45.

Ethnicity: Studies suggest that vaginal prolapse may occur more often in women of Northern European descent, and less frequently in women of African-American descent. Hispanic and Asian women may have an increased risk of developing cystocele (a form of prolapse).

Genetics: Research suggests vaginal prolapse may also run in families—a women with a mother or sister who has had a prolapse may be more likely to develop prolapse.

Other: Women who experience repetitive straining, such as with chronic constipation, or with jobs that involve heavy lifting, may be at an increased risk for vaginal prolapse. In addition menopause may also be a factor in the onset of prolapse.

YOUR BODY BEFORE AND AFTER PROLAPSE

TREATMENT OPTIONS FOR PROLAPSE

Treatment may vary depending on the type of prolapse. The treatment chosen will depend on the severity of the condition as well as the woman's general health, age, and desire to have children.

NON-SURGICAL OPTIONS

Exercise – Special exercises, called Kegel exercises, can help strengthen the pelvic floor muscles. This may be the only treatment needed in mild cases of uterine prolapse. For Kegel exercises to be effective they need to be done daily.

Vaginal Pessary – A pessary is a rubber or plastic device used to support the pelvic floor and maintain support of the prolapsed organ. A health care provider will fit and insert the pessary, which must be cleaned frequently and removed before sexual intercourse.

Estrogen Replacement Therapy (ERT) – Taking estrogen may help to limit further weakness of the muscles and other connective tissues that support the uterus. However, there are some drawbacks to taking estrogen, such as an increased risk of blood clots, gallbladder disease and breast cancer.

SURGICAL OPTIONS

Surgical options are used to help return prolapsed organs to a more normal anatomical position and to strengthen structures around the prolapsed area to maintain support. Surgical options can be done abdominally or vaginally, although vaginal usually involves less pain and the potential for a shorter recovery period.

The FDA has established an on-line list of voluntary reports on medical devices which may have malfunctioned or caused death or serious injury. This information is located on the Manufacturer and User Facility Device Experience Database (MAUDE).

Surgical mesh procedures for pelvic organ prolapse can be searched using the product codes FTM or FTL.

Be sure to discuss all treatment options with your physician.

HEALTHY PELVIC AREA

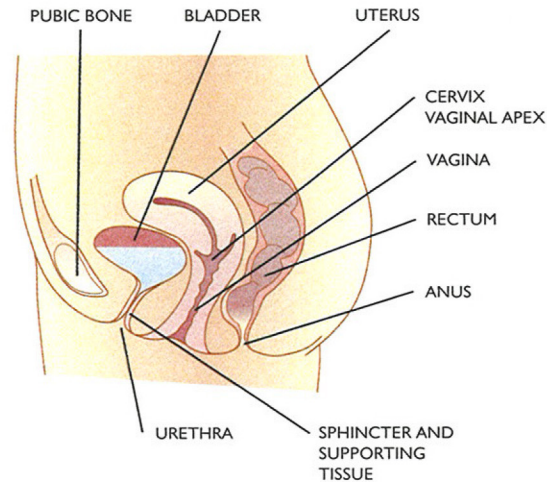


Figure 1: The bladder, vagina and rectum are well supported by pelvic muscles and ligaments when prolapse is not present.

VAGINAL VAULT PROLAPSE

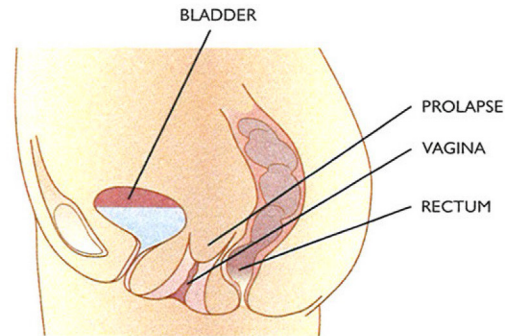


Figure 2: Vaginal vault prolapse occurs when the upper portion of the vagina (the apex) descends into the vaginal canal.

YOUR BODY BEFORE AND AFTER PROLAPSE

UTERINE PROLAPSE (PROCIDENTIA)

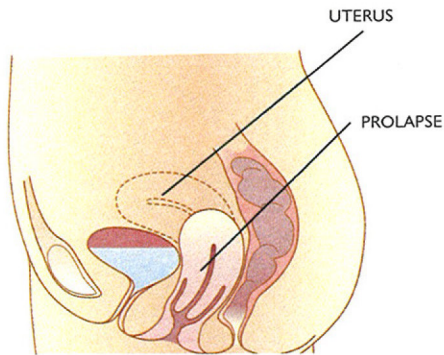


Figure 3: (procidentia, pronounced "pro-sid-entsha") – the uterus falls into the vagina.

BLADDER PROLAPSE (CYSTOCELE)

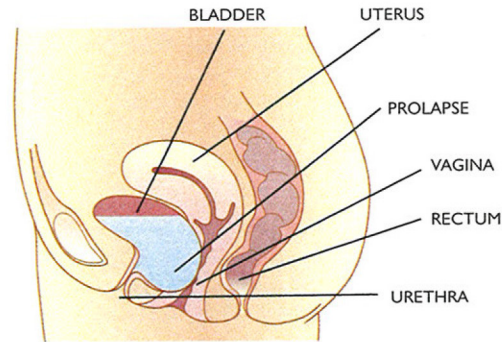


Figure 5: A cystocele is formed when the bladder bulges or herniates into the vagina.

SMALL BOWEL PROLAPSE (ENTEROCELE)

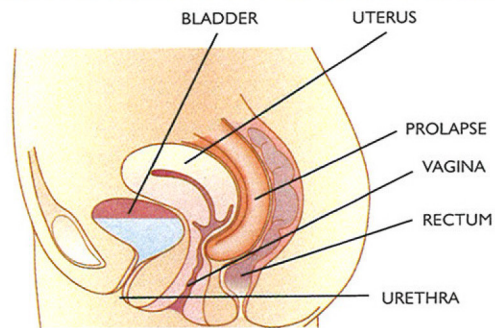


Figure 4: (enterocele, pronounced "enter-o-seal") – the small bowel bulges (herniates) into the vagina.

RECTAL PROLAPSE (RECTOCELE)

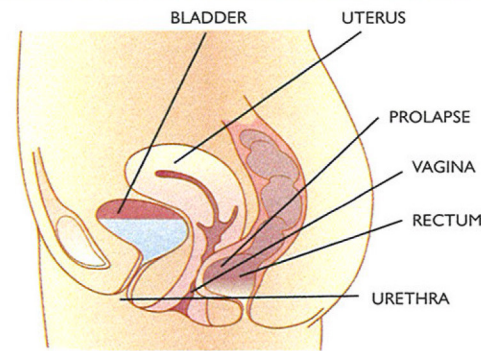


Figure 6: A rectocele is formed when the rectum bulges or herniates into the vagina.

HOW ELEVATE WORKS

The Elevate procedure uses a soft synthetic or biologic mesh to restore normal anatomy.

Vaginal vault prolapse occurs when the apex, or upper portion of the vagina, collapses and descends into the vaginal canal. This sometimes occurs after a hysterectomy, causing the vagina to turn inside out. For women who have had a hysterectomy the normal support from the uterus is no longer in place and prolapse can occur. The Elevate mesh is placed at the vaginal apex to provide support. (See Figure 2, page 5)

Uterine prolapse (procidentia) occurs when the muscles and ligaments are weakened and the woman still has a uterus, the uterus can descend into the vagina. The Elevate mesh is placed between the upper portion of the vagina, the apex. (See Figure 3, page 6)

Small bowel prolapse (enterocele) occurs when the intestine bulges into the vagina. Enteroceles can occur from the front, back or top. Figure 4 shows an enterocele from the back. The Elevate mesh is placed between the vaginal wall and the bowel in order to prevent herniation (bulging) of the bowel. (See Figure 4, page 6)

Bladder prolapse (cystocele) occurs when the wall between the bladder and the vagina weakens, causing the bladder to bulge or herniate into the vaginal wall. The Elevate mesh is placed between the bladder and vaginal wall. This corrects the herniation of the bladder into the vaginal wall. (See Figure 5, page 7)

Rectal prolapse (rectocele) occurs when the rectum bulges or herniates into the vagina. The Elevate mesh is placed between the vaginal wall and the wall of the rectum to provide reinforcement and correct the bulging of the wall of the rectum into the vaginal wall. (See Figure 6, page 7)

PROVIDING A FRAMEWORK OF SUPPORT

Depending on your needs and type of prolapse, your doctor can choose either a synthetic polypropylene mesh or a biologic graft material to repair the prolapse. It is possible for your doctor to repair more than one type of prolapse during the same surgery.

It can be reassuring to learn that the use of mesh for reinforcement is not new — it has been used extensively in surgery since 1960. Today surgical mesh is used in more than 1 million procedures annually.*

ELEVATE — BENEFITS TO PATIENTS

Elevate is designed to:

- Offer a minimally invasive solution.
- Minimize tissue trauma.
- Restore normal anatomy with a faster recovery than open abdominal approaches.
- Minimize pain compared to more invasive procedures.



AMS mesh is soft and pliable. It conforms to your body to provide additional support. (synthetic mesh shown)

"The safety and effectiveness of synthetic mesh or film support in transvaginal surgical procedures to treat pelvic organ prolapse have not been evaluated in a prospective, randomized clinical study."

*Data on file at AMS.

IS IT RIGHT FOR YOU?

Ask your doctor about prolapse repair systems and if Elevate will work for you.

You should only have surgery to repair pelvic organ prolapse if you no longer desire to have children. Pregnancy can compromise the effects of the procedure. Your doctor can provide you with a complete list of warnings, precautions and contraindications.

A MINIMALLY INVASIVE SURGERY

Depending on the type of prolapse you are experiencing, the Elevate procedure will, in general, follow these steps:

- A small vaginal incision is made.
- The mesh is inserted through an incision and placed in the body.
- The mesh is secured in the body through the use of self fixating tips attached to the mesh that are inserted into the ligament or muscles to secure the mesh until natural tissue ingrowth occurs.
- The incision is closed.

YOUR RECOVERY

Your hospital stay will be determined by your doctor. Your incision will be small and should heal quickly. Depending on the nature of your work, you may be able to return to work after one to two weeks. You will need to refrain from sexual intercourse, heavy lifting and rigorous exercise for six to eight weeks. Your doctor will provide you with additional information on how to care for yourself after surgery.

Mesh is a permanent medical device implant. There is not enough data from scientific studies to know whether the benefits outweigh the risks. Therefore, you should carefully discuss the warnings and precautions with your doctor before you decide to undergo a procedure to implant mesh to treat this condition.



QUESTIONS TO ASK YOUR DOCTOR

How does the Elevate procedure treat pelvic organ prolapse?

The Elevate prolapse repair system surgically places a strip of mesh-like material in your body. The mesh is intended to restore your anatomy (organs) to its natural position and strengthen the structures around your vagina to maintain support.

How will the procedure be performed?

The Elevate procedure is a minimally invasive procedure which is generally performed under general anesthesia.

A small vaginal incision will be made. A piece of mesh is inserted through the incision and placed in the pelvic area where the repair is needed. The mesh is secured in your body through the use of self-fixating tips attached to the mesh that are inserted into the ligament or muscles to secure the mesh in place until the natural process of tissue in-growth can occur.

After the mesh is secured the vaginal incision is closed. The Elevate procedure does not involve any external incisions.

What can I expect after the procedure?

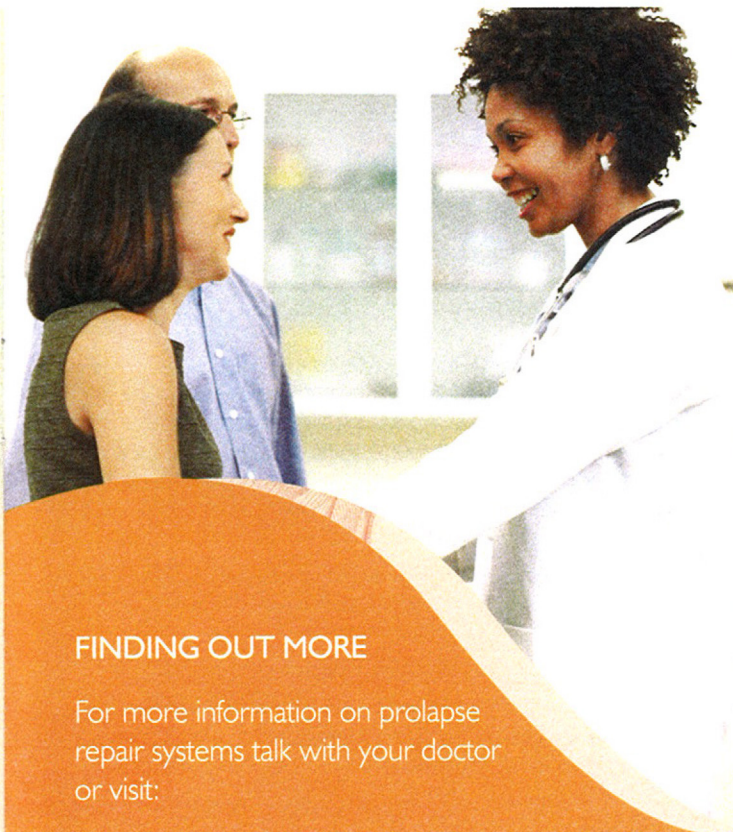
Your hospital stay will be determined by your doctor. Your incision is not external and should heal quickly. Depending on the nature of your work, you may be able to return to work after one to two weeks. You will need to refrain from sexual intercourse, heavy lifting and rigorous exercise for six to eight weeks. Your doctor will provide you with additional information on how to care for yourself after surgery.

When will I see results?

Most women will see results immediately following the procedure or a short time after. Talk with your doctor so you understand the results you can expect.

What is my next step?

If you are ready to learn more about correcting your prolapse, ask how you might benefit from the Elevate Prolapse Repair System. You can also refer to pages 13-14 in this brochure to learn about additional resources available.



FINDING OUT MORE

For more information on prolapse repair systems talk with your doctor or visit:

www.amswomenshealth.com



PELVIC HEALTH POINT

The median age of women seeking care for pelvic floor disorders was 61 years. Half of the women seeking care were aged 30 to 60 years.

(Luber KM, Boero S, Choe JY. The demographics of pelvic floor disorders: current observations and future projections. Am J Obstet Gynecol 2001 v. 184 p. 1496-503.)

The following clinical articles contain detailed information on the surgical repair of prolapse using surgical mesh:

Altman D, Vayrynen T, Ellstrom-Eng M, Axelsen S, Falconer C. Short-term Outcome After Transvaginal Mesh Repair of Pelvic Organ Prolapse, *International Urogynecology Journal* 2007; 10.1007/s00192-007-0526-2.

Abdel-fattah M, Ramsey I, Retrospective Multicentre Study of the New Minimally Invasive Mesh Repair Devices for Pelvic Organ Prolapse; *BJOG*, 2008; 22-30.

Gauruder-Burnester A, Koutouzidou P, Rohne J, Gronewold M, Tunn R, Follow-up After Polypropylene Mesh Repair of Anterior and Posterior Compartments in Patients with Recurrent Prolapse, *International Urogynecology Journal* 2007; 10.1007/s00192-006-0291-7.

Nguyen J N, Burchette R J, Anatomy and Visceral Function After Anterior Vaginal Prolapse Repair: A Randomized Controlled Trial, *Journal of Pelvic Medicine and Surgery*, July/August 2008; 14 (4):238.

Heubner M, Hsu Y and Fenner DE, The Use of Graft Materials in Vaginal Pelvic Floor Surgery, *International Journal of Gynecology and Obstetrics*, 2006; 92: 279-288.

A database of adverse event reports can be accessed at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.cfm>.

(use product codes FTM or FTL)

WARNINGS AND PRECAUTIONS

As with most surgical procedures, potential adverse reactions may occur. Some potential adverse reactions to surgical procedures to correct pelvic prolapse include:

- Pain/Discomfort/Irritation
- Inflammation (redness, heat, pain, or swelling resulting from surgery)
- Infection
- Mesh erosion (presence of suture or mesh material within the organs surrounding the vagina)
- Mesh extrusion* (presence of suture or mesh material within the vagina)
- Fistula formation (a hole/passage that develops between organs or anatomic structures that is repaired by surgery)
- Foreign body (allergic) reaction to mesh implant
- Adhesion formation (scar tissue)
- Urinary incontinence (involuntary leaking of urine)
- Urinary retention/obstruction (involuntary storage of urine/blockage of urine flow)
- Voiding dysfunction (difficulty with urination or bowel movements)
- Recurrent prolapse (return to your original prolapse)
- Contracture (mesh shortening due to scar tissue)
- Wound dehiscence (opening of the incision after surgery)
- Nerve damage
- Perforation (or tearing) of vessels, nerves, bladder, ureter, colon, and other pelvic floor structures
- Hematoma (pooling of blood beneath the skin)
- Dyspareunia (pain during intercourse)

* Extrusion of the mesh into the vagina is one of the most common adverse events. Most often, you may be able to be treated in your doctor's office. In some cases, treatment may occur in the operating room. If left untreated, this complication may interfere with sexual intercourse.