

# *Pelvic Organ Prolapse*

ETHICON Women's Health & Urology, a division of ETHICON, INC., a Johnson & Johnson company, is dedicated to providing innovative solutions for common women's health problems and to providing valuable, easy-to-understand information so that women, along with their physicians, can weigh their options and make informed decisions.

ETHICON Women's Health & Urology is the leader in minimally invasive gynecological health solutions. Our clinically proven technologies have touched the lives of over 1.5 million women. ETHICON Women's Health & Urology offers minimally invasive solutions in several women's health categories: incontinence and pelvic floor repair, menstrual health, adhesion prevention and uterine surgery.



*Get the Facts,  
Be Informed,  
Make YOUR  
Best Decision*



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## Pelvic Organ Prolapse in Women:

### *It's Common. It's Treatable.*

#### *Would it surprise you...*

to learn that while it's rarely talked about, approximately one out of three women aged 45 or older has some degree of pelvic organ prolapse? By age 80, more than one out of every 10 women will have undergone surgery for prolapse. Pelvic organ prolapse can affect a woman's daily life limiting physical and sexual functioning. Depending on its severity, it can cause pressure-like discomfort, at times pain and almost always disturbances in normal bladder and rectal function.

The good news is that you don't have to suffer with it. You can do something about pelvic organ prolapse, and you have choices. The newest choice is GYNECARE PROLIFT\* Pelvic Floor Repair Systems, a revolutionary new minimally invasive surgical technique that offers promising long-term results for women with pelvic organ prolapse. During this procedure, the surgeon uses a soft synthetic mesh specially designed for placement through the vagina to support pelvic organs that have "dropped out" of their normal position (prolapsed).

Synthetic meshes, commonly used in abdominal wall hernia repair, are now being used in pelvic reconstructive surgery.



*Take the next step. Talk with your doctor or healthcare provider about pelvic organ prolapse and what you can do about it.*

### ***What is Pelvic Organ Prolapse?***

Normally the vagina and uterus are secured to the pelvis by connective tissue that forms ligament-like structures as well as a strong “envelope” 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. The bladder above and the rectum below the vagina are thereby affected, leading to the following symptoms.

### ***What are the symptoms?***

- Loss of bladder or possibly bowel control
- Difficulty voiding
- Urinary frequency
- Problems with bowel movements
- Feelings of pelvic or vaginal heaviness, bulging, fullness and/or pain
- Recurrent bladder infections
- Excessive vaginal discharge
- Discomfort or lack of sensation with intercourse

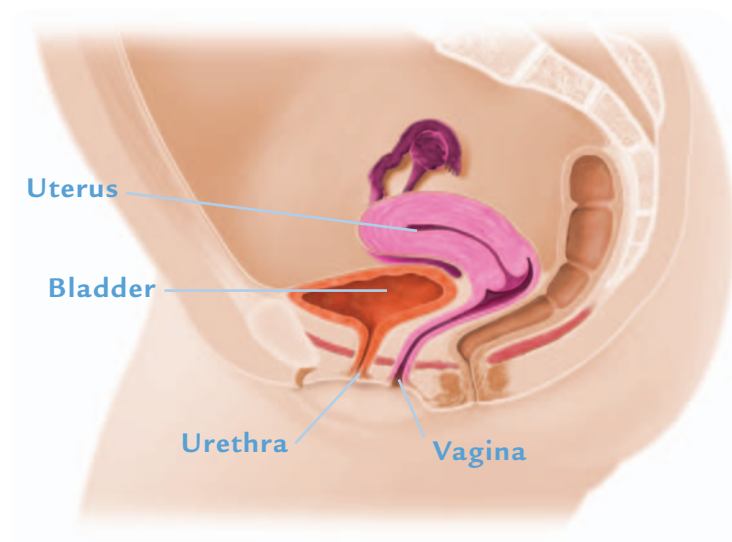
### ***What causes the condition?***

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

### ***How common is Pelvic Organ Prolapse?***

It is a very common disorder, particularly in older women. Half of all women over age 50 experience some degree of pelvic organ prolapse. By age 80, more than one in every 10 women will have undergone surgery for prolapse.

### ***Normal Pelvic Anatomy***



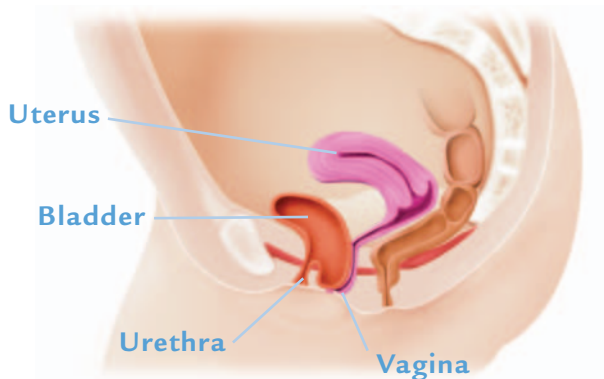
## Are there different types of pelvic organ prolapse?

A prolapse occurs when organs drop from their natural position and sometimes protrude. There are several different types, which are simply defined by what segment or area of the vagina is involved. Often a woman can have more than one type of prolapse.

Organs that may be involved in pelvic organ prolapse include the:

**Bladder** As the front wall (or roof) of the vagina stretches or loses its securement to the pelvis it drops, rotating down into and sometimes out of the vaginal opening. The bladder, which rests on this area of the vagina “drops” 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”.

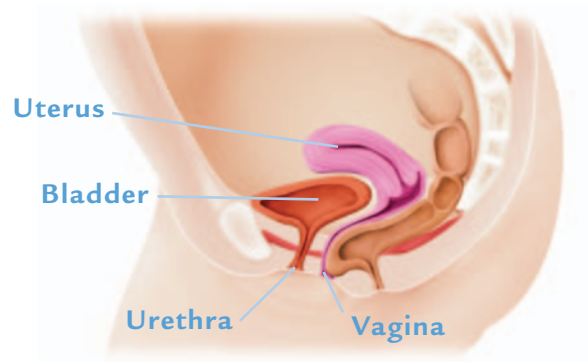
### Cystocele



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

**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 upward, creating a “pocket” called a rectocele.

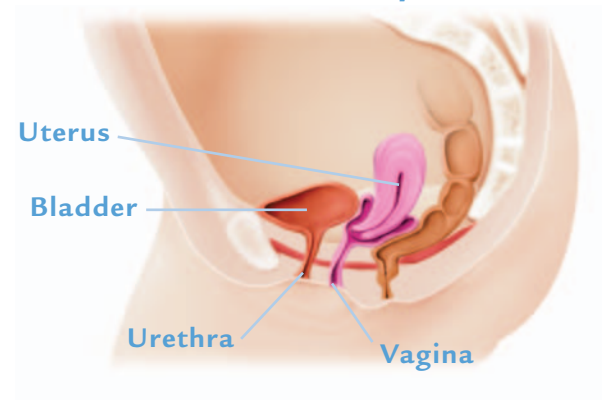
### Rectocele



**Small bowel** (intestine) Prolapse of the small bowel pushes the vagina towards the opening. This is called an enterocele.

**Uterus** Prolapse of the uterus into the vagina is called uterine prolapse

### Uterine Prolapse



## *How is it diagnosed?*

Pelvic organ prolapse is diagnosed by a thorough 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 bladder or rectum.

## *How is it treated?*

Not all women with pelvic organ prolapse have symptoms that require treatment. If a patient has symptoms that are compromising her quality of life, surgery is the most definitive treatment. However, patients who want to delay surgery or those with mild symptoms may be helped with the following:

**Kegel exercises** Contracting and relaxing the pelvic floor muscles may help a woman diagnosed with mild pelvic relaxation who is not currently experiencing any significant symptoms.

**Pessary** A device that is inserted in the vagina to help support the pelvic area may help to relieve mild symptoms of prolapse. A woman who selects this option may do best by learning how to remove, clean and reinsert the pessary. If she is unable to care for the pessary herself, she'll need to see a health care provider for regular check-ups and cleaning of the pessary. Sometimes vaginal estrogen is used with this option.

## *Pelvic Reconstructive Surgery*

Pelvic reconstructive surgery can be performed through the vagina or abdominally (via a traditional incision or through laparoscopy). During the procedure, the surgeon will reposition the prolapsed organ(s) and secure to the surrounding tissues and ligaments. The vaginal defect(s) will also be repaired, sometimes using a special synthetic material.

Prior to undergoing surgery, patients should undergo a thorough evaluation to ensure a proper diagnosis. For example, some women may have stress urinary incontinence and may require a sling procedure performed at the same time to correct urinary incontinence.



## *What is GYNECARE PROLIFT?*

A new and revolutionary minimally invasive surgical procedure using GYNECARE PROLIFT employs a specially designed supportive soft mesh placed in the pelvis to restore pelvic support. GYNECARE PROLIFT mesh is designed for placement utilizing a minimally invasive technique performed through very small incisions inside the vagina.

## *How is GYNECARE PROLIFT different from other surgical alternatives?*

It can be completed in less than half the time of traditional surgery. Patients may experience less pain, quicker recovery and go home the next day.

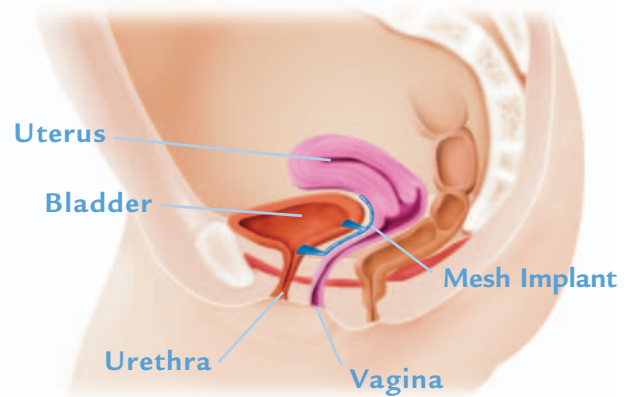
It allows for the restoration of sexual function by restoring normal vaginal anatomy.

Using this new surgical procedure there is often no need to perform a hysterectomy if the uterus itself is not diseased.

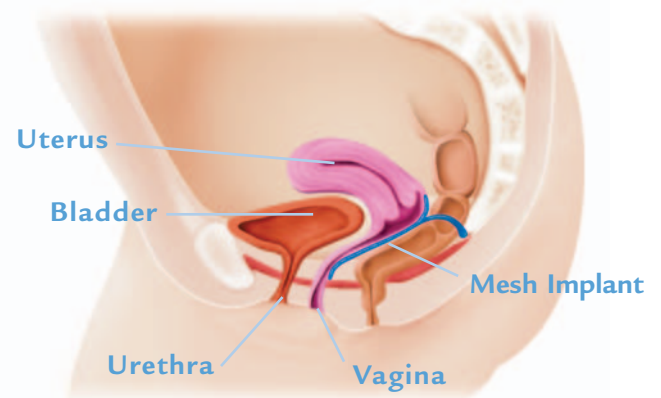
## *How does GYNECARE PROLIFT work?*

After insertion, the soft mesh is initially held in place by the friction created by long extension strap-like arms of mesh material weaved through the pelvis. The body tissues then quickly grow into the pores of the mesh, creating the final support. The strength of this tissue is greatly enhanced by the presence of the soft mesh. Despite which of the defects you are experiencing, repair with GYNECARE PROLIFT will correct these defects and restore normal support.

## *Cystocele Repair with GYNECARE PROLIFT*



## *Rectocele Repair with GYNECARE PROLIFT*



### *What can I expect during the procedure?*

The surgery takes only one to two hours and can be performed under regional (epidural or spinal) or general anesthesia.

### *What can I expect after I go home?*

After the surgery you will usually stay in the hospital for one night. Many patients return to normal daily activities within three to four days. Most completely recover in a two to three week period. During this time there should be very little interference with daily activities, although you will have to avoid heavy lifting, strenuous exercise and intercourse for up to six weeks.



### *What are the risks?*

All surgical procedures present some risks. Although rare, complications associated with the procedure include injury to blood vessels of the pelvis, nerve damage, difficulty urinating, bladder and bowel injury. There is also a small risk of the mesh material becoming exposed into the vaginal canal.



### *Is GYNECARE PROLIFT right for me?*

Pelvic floor repair procedures with GYNECARE PROLIFT are appropriate for almost all patients, including overweight patients, elderly patients, and even those who have undergone previous operations for pelvic organ prolapse or stress incontinence. As with any surgery of this kind, this procedure should not be performed on pregnant women, infants or children. It should also not be considered by women who plan a future pregnancy. Only a complete physical examination and consultation with your physician can determine which procedure is right for you.

**GYNECARE PROLIFT\*** Total Pelvic Floor Repair System

**GYNECARE PROLIFT\*** Anterior Pelvic Floor Repair System

**GYNECARE PROLIFT\*** Posterior Pelvic Floor Repair System

### **INDICATIONS**

The GYNECARE PROLIFT Total, Anterior, and Posterior Pelvic Floor Repair Systems are indicated for tissue reinforcement and long-lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

### **CONTRAINDICATIONS**

When GYNECARE GYNEMESH PS mesh is used in infants, children, pregnant women, or women planning future pregnancies, the surgeon should be aware that this product will not stretch significantly as the patient grows.

### **WARNINGS AND PRECAUTIONS**

- Users should be familiar with surgical procedures and techniques involving pelvic floor repair and nonabsorbable meshes before employing the GYNECARE PROLIFT Pelvic Floor Repair Systems.
- Acceptable surgical practices should be followed in the presence of infected or contaminated wounds.
- Post-operatively 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 suitable for the patient to return to her normal activities.
- Avoid placing excessive tension on the mesh implant during handling.
- Refer to the recommended surgical technique for the GYNECARE PROLIFT Pelvic Floor Repair System for further information on the GYNECARE PROLIFT procedures.

- The GYNECARE PROLIFT Pelvic Floor Repair Systems should be used with care to avoid damage to vessels, nerves, bladder and bowel. Attention to patient anatomy and correct use of the device will minimize risks.
- Transient leg pain may occur and can usually be managed with mild analgesics.
- Do not manipulate the GYNECARE PROLIFT Retrieval Device with sharp instruments or cut it to alter its length.

### **ADVERSE REACTIONS**

- Potential adverse reactions are those typically associated with surgically implantable materials, including infection potentiation, inflammation, adhesion formation, fistula formation, erosion, extrusion and scarring that results in implant contraction.
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during GYNECARE PROLIFT Guide passage and may require surgical repair.