



Stress urinary incontinence (SUI) is common, and treatment may help you get back to doing the things you enjoy most. Speak with your doctor or surgeon to discuss the best options for you.

### QUESTIONS FOR YOUR DOCTOR ABOUT STRESS URINARY INCONTINENCE

- What type of incontinence do I have?
- What are the least invasive treatment options you would recommend for me?
- Am I a candidate for treatment with GYNECARE TVT™ Tension-free Support for Incontinence?
- Will treatment affect my ability to have children?
- How safe and effective is the GYNECARE TVT™ procedure?
- How is the procedure used to treat SUI different than the procedure used to treat pelvic organ prolapse with surgical mesh?
- What are the risks for my situation that are associated with the GYNECARE TVT™ procedure?
- How soon after treatment can I resume my normal activities?

Ethicon, Inc. is dedicated to improving women's quality of life by providing innovative solutions for treating common pelvic health conditions, including stress urinary incontinence.

Learn more: [www.PelvicHealthSolutions.com](http://www.PelvicHealthSolutions.com)  
1-888-GYNECARE (1-888-496-3227)

**ETHICON**  
PART OF THE *Johnson & Johnson* FAMILY OF COMPANIES



STOP COPING.  
**START LIVING.®**

WHAT YOU  
SHOULD  
KNOW ABOUT  
**STRESS  
URINARY  
INCONTINENCE**



GYNECARE  
**TVT™**  
*Family of Products*



**Have you ever leaked urine when you laughed, coughed or sneezed? You are not alone. One in three women suffers from a common condition called stress urinary incontinence, or SUI.**

SUI is the most common type of urinary incontinence and can be the cause of some very embarrassing situations. You may be surprised to learn there are treatments that could reduce urine leakage or stop it altogether, so you can get back to doing the things you enjoy most.

This brochure is intended to help you understand the causes, symptoms and treatment options for SUI. Be sure to speak with your doctor to discuss the best course of action for you.

**WHAT IS URINARY INCONTINENCE?**

Urinary incontinence occurs when you experience accidental urine leakage. Forty five percent of women suffer from some type of urinary incontinence. There are 4 major types.

**Stress Urinary Incontinence**

Unintentional urine leakage during sudden movements, such as coughing, sneezing, laughing and exercising. This is also referred to as stress incontinence.

**Urge Incontinence**

The sudden, intense urge to urinate, followed by urine leakage. You may feel like you can never get to the bathroom fast enough, or you may wake several times a night with the strong urge to urinate.

**Mixed Incontinence**

Occurs when women have symptoms of both stress and urge incontinence.

**Overflow Incontinence**

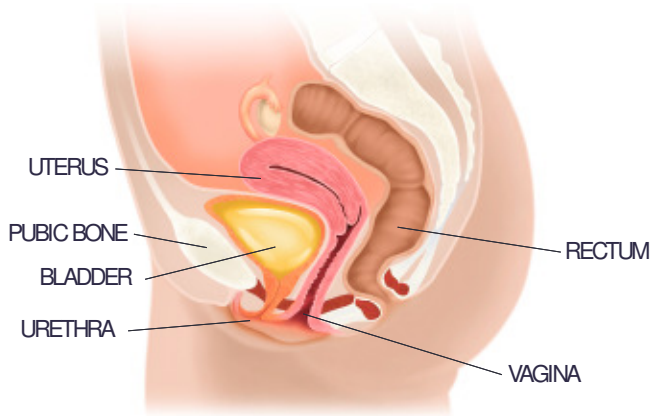
Occurs when the bladder doesn't completely empty. It may be caused by dysfunctional nerves or a blockage in the urethra that prevents the flow of urine.

**STOP COPING. START LIVING.®**

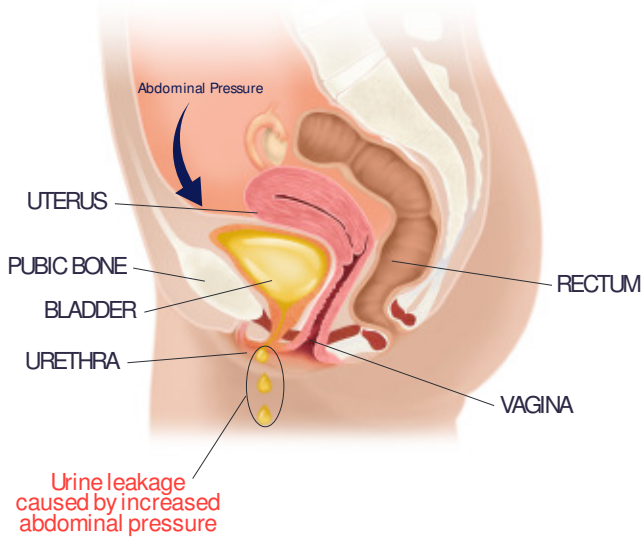
## MORE ABOUT STRESS URINARY INCONTINENCE (SUI)

SUI occurs when urine leaks involuntarily during sudden movements. This can be caused by weakening of the pelvic muscles that support the bladder and urethra.

### NORMAL PELVIC ANATOMY



### EFFECT OF SUI



## COMMON SYMPTOMS

You may have SUI if you leak urine when you:

- Cough, sneeze or laugh
- Walk, exercise or lift
- Engage in intercourse
- Get up from a seated or lying position

Many women make gradual changes to their lifestyle to avoid embarrassment from accidental urine leakage. Take a moment to ask yourself:

- Do you wear sanitary pads to absorb urine?
- Do you avoid or limit some activities to prevent accidents?
- Do you limit the amount of fluids you drink to avoid accidents?
- Do you go to the bathroom frequently to avoid accidents?
- When planning a trip, outing or event, does the availability of restroom facilities affect your decision?

If you have any symptoms or answered "yes" to any of these questions, take the next step and talk with a doctor that is specially trained to treat SUI, such as a gynecologist, urogynecologist or urologist.

## COMMON CAUSES

One of the myths about SUI is that it is a natural part of the aging process. In reality, it can affect women at any age. Although common, SUI is not a normal part of aging. Weakening of the muscles and supporting ligaments within the pelvis can occur as a result of:

- Pregnancy and childbirth
- Connective tissue disorders
- Chronic heavy lifting or straining
- Menopause
- Obesity
- Smoking
- Coexisting conditions such as pelvic organ prolapse

## DIAGNOSIS

SUI may be diagnosed based on the symptoms you describe to your doctor and a careful pelvic exam focused on your pelvic support. Your doctor may ask you to cough with a full bladder to observe leakage. Some doctors will want to conduct special bladder function tests (urodynamics) to evaluate your bladder and urethral function. These tests usually involve placing a small tube, called a catheter, into the bladder, which can measure bladder and urethral activity. Urodynamics may be useful in helping your doctor determine exactly what type of incontinence you have, as well as making a recommendation for treatment.

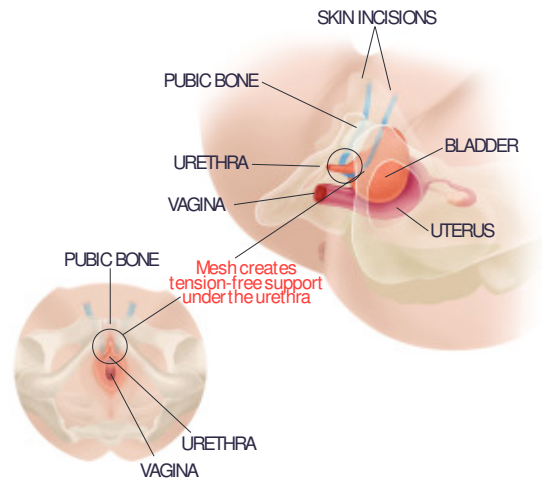




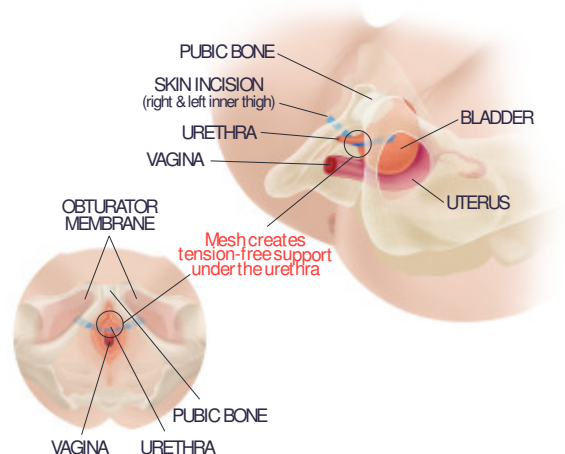
**Minimally Invasive Surgical Sling Procedure:** An outpatient procedure in which the surgeon places a thin piece of flexible, permanent surgical mesh under the urethra, like a sling, to prevent involuntary urine leakage.

The most common surgical techniques used to treat SUI are:

**Retropubic Approach** Mesh is inserted through a small incision in the vagina and exits through two small incisions in the abdomen.



**Obturator Approach** Mesh is inserted through a small incision in the vagina and exits through a small incision in each inner thigh.



Slings using synthetic mesh, placed by either the retropubic or approach, represent the current standard of care for the surgical treatment of SUI; and safety and efficacy is supported by 15 years of clinical experience.

## TREATMENTS

Stress urinary incontinence is treatable at any age, but not all approaches work for every person. Your doctor may suggest one or more of the following:

**Behavioral/Muscle Therapy:** Therapy often starts with Kegel exercises, which help strengthen the pelvic floor muscles. Depending on the severity of your condition, however, Kegels may not bring sufficient relief.

**Biofeedback:** While you exercise your pelvic floor muscles, you are connected to an electrical sensing device that provides “feedback”. Over time, biofeedback can help improve muscle control to prevent urine leakage.

**Electrical Stimulation:** This approach sends a mild electric current to the pelvic muscles or nerves that are involved in urination.

**Medication:** There is currently no medication approved to treat SUI in the U.S. However, some types of urinary incontinence, like urge incontinence, can be treated with medications.

**Bulking Agents:** Injectable therapy that is used to thicken the wall of the urethra in order to help control urinary flow.

## A MINIMALLY INVASIVE SURGICAL SLING PROCEDURE MAY BE RIGHT FOR YOU

Millions of women suffer from SUI without getting treated. Women should know that SUI is a commonly treated condition, and there are minimally invasive surgical options that are usually done as outpatient procedures.

One such procedure uses GYNECARE TVT™ Tension-free Support for Incontinence, which has demonstrated proven results for effectively treating stress urinary incontinence for over 11 years.

To find out if GYNECARE TVT™ is right for you, ask a doctor that is specially trained to perform minimally invasive sling procedures, such as a gynecologist, urogynecologist or urologist. This procedure is covered by most insurance plans. You should check with your insurance company to determine if your specific procedure would be covered.

## INFORMATION ABOUT SURGICAL MESH PROCEDURES

The mesh procedure used to treat stress urinary incontinence (SUI) is different than that used to treat another common women's health condition, pelvic organ prolapse (POP).

- Pelvic organ prolapse occurs when the supportive muscles and tissues of the pelvis become weak, which causes the organs inside the pelvis to “drop” from their natural position.

You may be aware that procedures using mesh to correct both POP and SUI were the subject of an FDA Safety Communication in July 2011.\*

After further review of the clinical studies for SUI, an FDA Panel concluded that the retropubic and obturator slings currently on the market have been extensively studied, and the safety and effectiveness of these devices is well-established. (See Page 4 of FDA Panel Summary, Sept. 2011: <http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM271769.pdf>)

The procedure using GYNECARE TVT™ Tension-free Support for Incontinence is the most commonly studied procedure using mesh for the treatment of SUI; and a substantial number of clinical studies have been published that show evidence of safety and effectiveness.

\*FDA Safety Communication, July 2011: <http://www.fda.gov/medicaldevices/safety/alertsandnotices/ucm262435.htm>



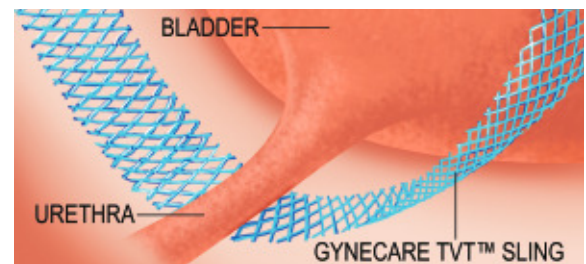
## GYNECARE TVT™ TENSION-FREE SUPPORT FOR INCONTINENCE IS THE GOLD STANDARD IN SUBURETHRAL SLINGS

- 15 years of clinical studies; more than any other sling on the market.
- 97% of women experience little or no leakage after a “retropubic” or “obturator” procedure.
- More than 2 million patients have been treated worldwide.

## HOW GYNECARE TVT™ WORKS

GYNECARE TVT™ is designed to stop involuntary leakage the way your body normally should – by providing support for the urethra.

- Your surgeon will place a thin piece of flexible, permanent mesh underneath the urethra. The mesh acts like a supportive sling, which helps prevent urine leakage.
- The body then naturally incorporates the mesh into the surrounding tissue, preventing future leakage.



## WHAT TO EXPECT DURING THE PROCEDURE

- 30-minute, outpatient procedure.
- Performed under local, regional or general anesthesia.
- Depending on the type of procedure, the mesh is inserted through a small incision in the vagina, and exits through two small incisions in the lower abdomen or inner thigh.

## WHAT TO EXPECT WHEN YOU RETURN HOME

- Patients usually return home the same day of the procedure and are able to resume most daily activities.
- Most women see results immediately following the procedure, with significantly less or no leakage.
- You may have minimal scarring and should not feel the mesh once it has been placed.
- Your doctor may advise you to rest for the first 24-48 hours.
- Your doctor may advise you to avoid heavy lifting and sexual intercourse for approximately 4 to 6 weeks.

## WHO IS A CANDIDATE FOR TREATMENT?

The best way to determine if you are a candidate for a GYNECARE TVT™ procedure is to consult with a qualified surgeon. GYNECARE TVT™ procedures are appropriate for many women, even those who have undergone surgical treatments for incontinence in the past.

- The procedure should not be performed on women who are pregnant or who are planning future pregnancies. Pregnancy and childbirth can cause the mesh to stretch and become ineffective against urine leakage.
- Women who smoke have a higher risk of mesh exposure. You should seriously consider smoking cessation before undergoing this surgery.

## WHAT ARE THE RISKS?

**Risks Common to All Pelvic Surgeries:** Risks for all pelvic surgeries include pain with intercourse, pelvic pain, development of urinary incontinence or voiding difficulties, hemorrhage (bleeding) or hematoma (collections of blood in the pelvis), injury to abdominal organs including bowel, urinary tract infection, bladder injury, wound healing problems, fistula (holes between bladder or bowel and the vagina), injury to ureters (tubes bringing urine from kidneys to bladder), pelvic abscess formation and nerve damage.

### Complications Associated with Synthetic Mesh:

There is a risk of the mesh material becoming exposed into the vagina. Mesh exposure can be associated with pain during intercourse for you and your partner. Exposure may require treatment, such as vaginal medication or removal of the exposed mesh, which may be performed in the office or operating room.

There is a risk of infection, inflammation, vaginal scarring and mesh contracture (mesh shortening due to scar tissue). Pelvic pain, or pain with intercourse, may occur and may resolve with time. There is a risk of developing urinary incontinence or difficulty urinating. Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss the decision to have surgery with your surgeon and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition.

## GYNECARE TVT™ FAMILY OF PRODUCTS ESSENTIAL PRODUCT INFORMATION

### INDICATIONS

The GYNECARE TVT™ Family of Products: GYNECARE TVT™, GYNECARE TVT EXACT® Continenence System, GYNECARE TVT™ with Abdominal Guides, GYNECARE TVT™ Obturator System and GYNECARE TVT ABBREVO® Continenence System are intended to be used in women as suburethral slings for the treatment of stress urinary incontinence (SUI).

### CONTRAINDICATIONS

- As with any suspension surgery, these procedures should not be performed in pregnant patients.
- Additionally, because the PROLENE™ Polypropylene Mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

### WARNINGS & PRECAUTIONS

- Do not use the GYNECARE TVT™ Family of Products for patients who are on anti-coagulation therapy.
- Do not use the GYNECARE TVT™ Family of Products for patients who have a urinary tract infection.
- Bleeding or infection may occur post-operatively.
- Transient leg pain lasting 24-48 hours may occur and can usually be managed with mild analgesics after a GYNECARE TVT™ Obturator or GYNECARE TVT ABBREVO® Procedure.
- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT™ Family of Products, the patient should be counseled that future pregnancy may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical information is available about vaginal delivery following sub-urethral sling procedure with the GYNECARE TVT™ Family of Products, in case of pregnancy, delivery via cesarean section should be considered.
- Post-operatively, refrain from heavy lifting and/or exercise (e.g. cycling, jogging) for at least three to four weeks and to refrain from intercourse for one month. The patients can usually return to other normal activity after one or two weeks.
- Contact your surgeon immediately if there is burning sensation during urination, unusual bleeding, problems voiding or other problems.

### ADVERSE REACTIONS

- Punctures or lacerations or injury to vessels, nerves, bladder, urethra, or bowel may occur during instrument passage and may require surgical repair.
- Improper placement of the GYNECARE TVT™ Family of Products devices may result in incomplete or no relief from urinary incontinence or may cause urinary tract obstruction.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This could result in extrusion, erosion, fistula formation or inflammation.

For more information, please consult your doctor or call 1-888-GYNECARE (1-888-496-3227).