

Treatment Options for
Stress Urinary Incontinence

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Gynecare 

TVT™

Family of Products

Tension-free Support
for Incontinence



Stress Urinary Incontinence: Know Your Options

If you've ever leaked urine when you laughed or sneezed, you may have chalked it up as a simple accident, but for many women, leaks are a surprisingly common occurrence.

Maybe you find that pressure from coughing, picking up something heavy, or exercising causes recurring problems. Many women cope by wearing pantliners, pads or dark clothing, planning trips around restroom facilities, or even sticking closer to home – anything to shield themselves from embarrassment.

You may be struggling with symptoms of a common condition called urinary incontinence but you're not alone. Forty-five percent of U.S. women have some degree of urinary incontinence. You don't have to be one of them. Why keep planning your life around leakage if you don't have to? Use this brochure to gain a better understanding of urinary incontinence and learn about safe, effective, minimally invasive treatments.

Types of urinary incontinence

There are 4 types of urinary incontinence that are most common in women:

Stress Urinary Incontinence: the unintentional leakage of urine during sudden movements such as coughing, sneezing, laughing and exercising.

Urge Incontinence: the sudden, intense urge to urinate, followed by urine leakage. You may feel like you never get to the bathroom fast enough, 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.

The right treatment for you will depend on the type of urinary incontinence that you have. This brochure discusses stress urinary incontinence, the most common type in women. It affects women of all ages – and it's very treatable.

What is stress urinary incontinence?

Stress urinary incontinence, or SUI, is the sudden, unintentional release of urine during normal, everyday activities. You may have SUI if you lose urine when you:

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



You may also go to the bathroom frequently during the day to avoid accidents. If you are experiencing stress urinary incontinence, it means your urethra (the tube from the bladder through which urine exits the body) does not stay closed until it's time to urinate.

Common Causes

SUI occurs when pelvic muscles supporting the bladder and urethra have been damaged or weakened, so that they may not hold the urethra in its correct position. Sudden movements, like sneezing or jumping, put stress on the bladder, causing urine to leak out involuntarily.

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. And although common, SUI is not a normal part of aging. The weakening of the pelvic floor, connective tissues and muscle can happen as a result of:

- Pregnancy and childbirth
- Chronic heavy lifting or straining
- Menopause
- Obesity
- Smoking

The graphic on page 6 shows normal pelvic anatomy.

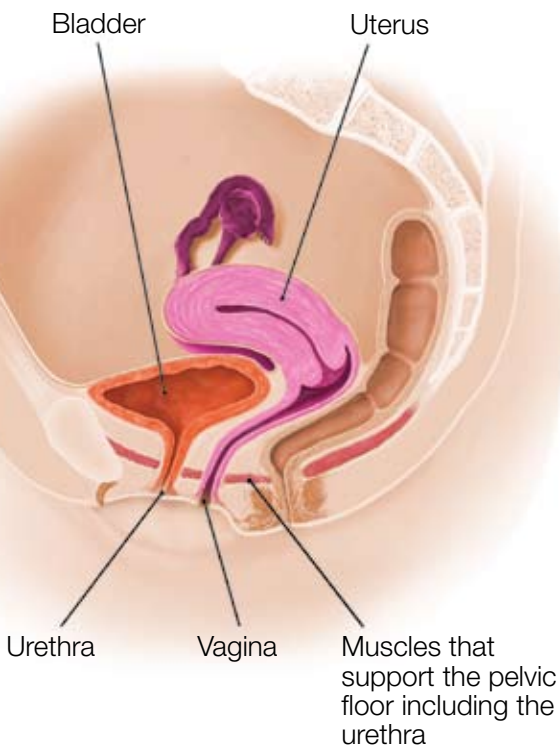
Common symptoms of stress urinary incontinence

If you are experiencing urine leakage, take a moment to ask yourself:

- 1 Do you experience urine leakage while laughing, sneezing, coughing or exercising?
- 2 Do you wear pantliners or pads to absorb urine leakage?
- 3 Do you limit or avoid any activities to prevent leakage?
- 4 When planning a trip, outing or event, does the availability of restroom facilities affect your decision?

If you answered “yes” to even one of these questions, take the next step and talk with a doctor or other healthcare professional.

Normal Pelvic Anatomy





Talking about it is the most important thing you can do to begin taking control. But for many women, it is often the most difficult step. It shouldn't be embarrassing – urinary incontinence is a medical condition that can be treated, after all.

Consider asking your healthcare professional the following questions to help make that conversation a bit easier:

- 1 What type of urinary incontinence do I have?
- 2 What treatments are available to help me regain bladder control? Which one is best for me?
- 3 Can you take care of this problem, or can you refer me to a doctor specializing in female urinary incontinence?

Diagnosis

SUI can often 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. Often your doctor will want to obtain special tests (such as 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.

Treatments

Stress urinary incontinence is treatable at any age. But not all approaches work for every person or for every type of incontinence. For SUI, your physician may suggest one or more of the following:

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

Biofeedback: In this method, the patient exercises the pelvic floor muscles while connected to an electrical sensing device. The device provides “feedback” to help you learn how to better control these muscles.

Over time, biofeedback can help you use your pelvic muscles to decrease sudden urges to urinate and lessen certain types of pelvic pain.

Electrical stimulation: This approach aids pelvic floor exercises by isolating the muscles involved.

Medication: Some types of urinary incontinence, like urge incontinence, can be treated with medications; however there is currently no medication approved to treat SUI in the U.S.

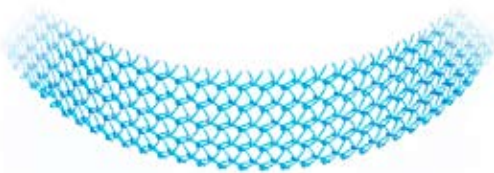
A minimally invasive surgical procedure may be right for you

Today's minimally invasive options mean you may be able to treat incontinence with an outpatient procedure. In one type of treatment, your surgeon inserts a ribbon-like strip of mesh through very small incisions in the abdomen or vagina to support the urethra. The mesh acts like a supportive sling, allowing the urethra to stay closed when appropriate preventing urine leakage. One such procedure uses GYNECARE TVT™ Tension-free Support for Incontinence in a minimally invasive 30-minute, outpatient procedure with proven results for effectively treating stress urinary incontinence. The procedure using GYNECARE TVT™ is covered by most insurance plans.*

How GYNECARE TVT™ Works

GYNECARE TVT™ is designed to stop urine leakage the way your body was designed to – by supporting your urethra. Normally, the urethra is supported by the pelvic floor muscles and ligaments to help maintain a tight seal and prevent involuntary urine leakage. Women with weakened urethras, pelvic floor muscles or connective tissue may suffer from SUI.

To correct this, your doctor will insert a ribbon-like strip of mesh under the urethra to provide support whenever you stress this area such as during a cough or sneeze. This allows the urethra to remain closed, when appropriate, preventing involuntary urine leakage.



GYNECARE TVT™ Mesh

*The information provided represents no statement, promise, or guarantee by ETHICON, INC. concerning coverage, levels of reimbursement, payment, or charge. Please consult your insurance company or other payor organization with regard to local or actual coverage and reimbursement policies and determination processes.



What to expect during the procedure

This procedure is short; it usually takes just 30 minutes. Your doctor inserts the mesh in an outpatient procedure under local, regional or general anesthesia. Depending on your specific needs, the procedure may be performed using very small incisions. Your doctor can tell you specifically what will happen during your treatment.



What to expect when you return home

Recovery is quick. Patients treated with GYNECARE TVT™ Tension-free Support for Incontinence usually return home the same day. The rate of complications is low and most patients expect a short recovery period. While recovering, you should be able to resume most daily activities quickly, however, your doctor may advise you to avoid heavy lifting and sexual intercourse for 4-6 weeks.

Most patients experience immediate results with significantly less or no leakage. Moreover, 97% of women surveyed following treatment with GYNECARE TVT™ were still dry or had significantly less leakage 11 years later! These women were so satisfied with the treatment that 97% said they would recommend the procedure with GYNECARE TVT™ to a friend.

With over 1 million women treated worldwide, GYNECARE TVT™ is clinically proven, safe and effective.

Is GYNECARE TVT™ right for you?

The best way to determine if you are a candidate for this procedure is to ask your doctor or find a doctor who specializes in treating female urinary incontinence. These procedures are appropriate for many types of patients, even those who have undergone surgical treatments for incontinence in the past. As with any procedure of this kind, treatment with GYNECARE TVT™ should not be considered if you are pregnant or if you plan to be in the future.



What are the risks?

All surgical procedures present some risks. Complications associated with the procedure include injury to blood vessels of the pelvis, difficulty urinating, pain, scarring, pain with intercourse, bladder and bowel injury. There is also a risk of the mesh material becoming exposed. Exposure may require treatment. For a complete description of risks, see the attached product information.

Synthetic mesh is a permanent medical device implant. Therefore, you should carefully discuss the decision to have surgery with your doctor and understand the benefits and risks of mesh implant surgery before deciding how to treat your condition.

GYNECARE TVT™ Family of Products Tension-Free Support for Incontinence Essential Product Information for Patient

INDICATIONS

The GYNECARE TVT™ Family of Products: GYNECARE TVT SECUR™, GYNECARE TVT™, GYNECARE TVT™ with abdominal guides, and GYNECARE TVT™ Obturator 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 System.
- 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.
- 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.
- Improper placement of the TVT device may result in incomplete or no relief from urinary incontinence or may cause urinary tract obstruction.



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

For more information or to find a doctor in your area who has treated stress urinary incontinence with GYNECARE TVT™, visit www.PelvicHealthSolutions.com/SUI or please call **1-888-GYNECARE** to speak to a nurse.

