

Gynecare TVT

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What you should
know about
Stress Urinary
Incontinence



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Have you ever leaked urine when you laughed, coughed or sneezed? You are not alone. Many women suffer 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, and to encourage an in-depth consultation with your doctor about your condition. This brochure is not intended to be medical advice or to substitute for a thorough discussion between you and your doctor about the potential benefits and risks of the various treatment options. Be sure to speak with your doctor about your treatment options and the best course of treatment for you.

What is Urinary Incontinence?

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

Stress Urinary Incontinence

Unintentional urine leakage during exertion, activity, or 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

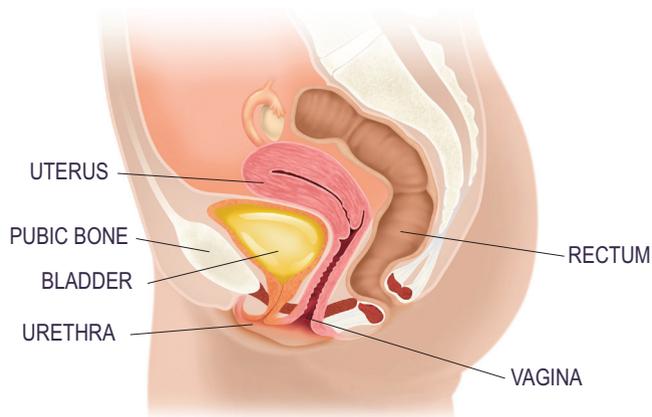
Occurs when the bladder doesn't completely empty. It may be caused by dysfunctional nerves or a blockage in the urethra that prevents the flow of urine.

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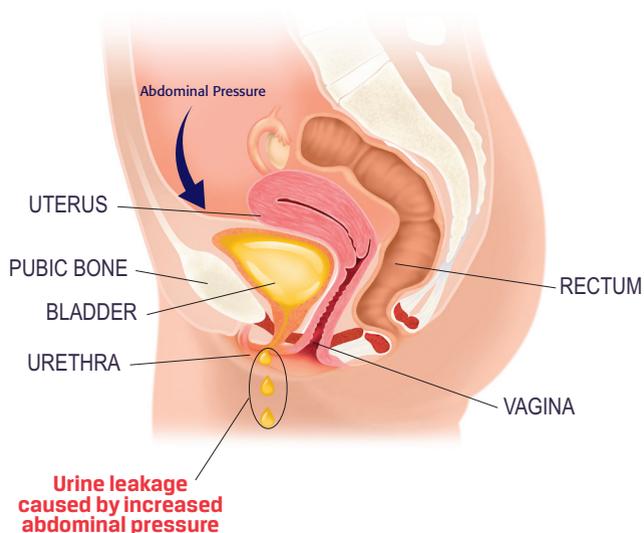
More about Stress Urinary Incontinence (SUI)

SUI occurs when urine leaks involuntarily during exertion, activity, or 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 urogynecologist, urologist, or gynecologist.

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.



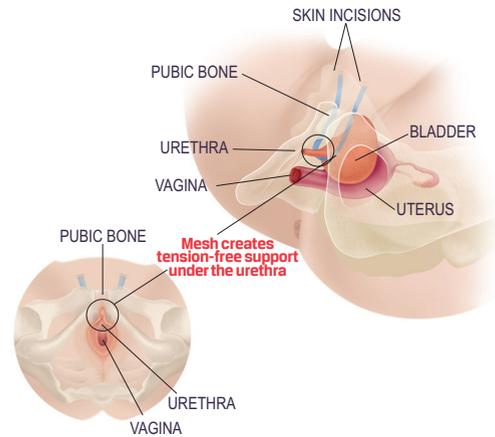
Minimally Invasive Surgical Sling Procedure:

Typically 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. In some patients, an inpatient procedure may be required.

The most common surgical techniques used to treat SUI are:

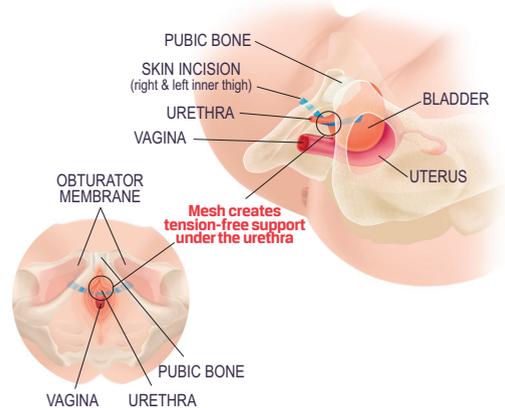
Retropubic Approach

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 obturator approach, represent the current standard of care for the surgical treatment of SUI. Multiple studies have been published supporting the clinical use of these approaches.

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.

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, other 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

Many women suffer from SUI without getting treated. Women should know that SUI is, in many cases, a treatable condition, and there are minimally invasive surgical options that can usually be done as an outpatient procedure. In some patients, an inpatient procedure may be required.

One such procedure uses GYNECARE TVT™ Tension-free Support for Incontinence. The procedure using GYNECARE TVT™ is the most commonly studied procedure using mesh for the treatment of SUI. A substantial number of clinical studies have been published to show evidence of safety and effectiveness. GYNECARE TVT™ is supported by over 17 years of clinical data – more than any other sling on the market.^{10*}

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 urogynecologist, urologist, or gynecologist. This procedure is covered by most insurance plans. You should check with your insurance company to determine if your specific procedure would be covered.

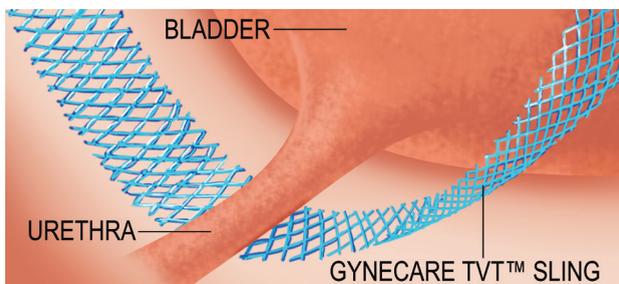
Information about surgical mesh procedures

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.[†]

How GYNECARE TVT™ Tension-free Support for Incontinence 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

- Typically a 30-minute procedure; in some patients, an inpatient procedure may be required
- 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

- Most 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™ Tension-free Support for Incontinence procedure is to consult with a doctor that is specifically trained to perform minimally invasive sling procedures such as a urogynecologist, urologist, or gynecologist. 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 child birth 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

^{*}Both retropubic and transobturator approaches have clinical studies showing long-term effectiveness. Individual results may vary; full details from these clinical studies may be found within the published clinical articles.

[†]"Considerations about Surgical Mesh for SUI," available at <http://www.fda.gov/medicaldevices/productsandmedicalprocedures/implantsandprosthetics/urogynsurgicalmesh/ucm345219.htm>

What are the risks?

Risks Common to All Pelvic Surgeries:

Risks for all pelvic surgeries include anesthesia risks, infection, inflammation, tissue contraction, vaginal scarring, pain (temporary or chronic), pain with intercourse, pelvic pain, development of urge urinary incontinence or voiding difficulties (such as urinary retention or frequency), bleeding, including hemorrhage, hematoma (collections of blood in the pelvis), seroma, injury to vessels, nerves, and organs including the bladder, urethra or bowel, wound healing problems, urinary tract infection, fistula (holes between bladder or bowel and the vagina), injury to ureters (tubes bringing urine from kidneys to bladder), pelvic abscess formation, nerve damage, neuro-muscular problems (including pain in the groin, thigh, leg, pelvic or abdominal area), adhesion formation, abnormal vaginal discharge, recurrent incontinence, and death. These complications may require additional medical treatment, hospitalization, or surgery. These complications may resolve over time or may be chronic.

Complications Associated with Synthetic Mesh to Treat SU:

There is a risk of the mesh material becoming exposed into the vagina (mesh exposure). 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 may require a return to the operating room. There is also a risk that the mesh material may erode into another organ such as the bladder or urethra (mesh erosion) and cause pain and additional problems. Mesh erosion would likely require additional surgery to remove the mesh from the organ. Synthetic mesh is a permanent medical device implant. 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.

Review the Essential Product Information provided in this brochure for more information on potential risks.

GYNECARE TVT™ Family of Products Essential Product Information

Indications

The GYNECARE TVT™ Tension-free Support for Incontinence, GYNECARE TVT EXACT® Continnence System and GYNECARE TVT™ with Abdominal Guides Tension-free Support for Incontinence, are intended to be used in women as pubourethral slings for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency. GYNECARE TVT™ Obturator System Tension-free Support for Incontinence and GYNECARE TVT ABBREVO® Continnence System are intended to be used in women as suburethral slings for the treatment of stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

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 in patients who are on anti-coagulation therapy
- Do not use the GYNECARE TVT Family of Products in 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 or GYNECARE TVT ABBREVO System 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

Patient factors

Physicians should use their surgical experience and judgment to determine if PROLENE Mesh is appropriate for certain patients. Patient-specific factors may impair wound healing, which may increase the likelihood of adverse reactions.

Adverse reactions

- Punctures or lacerations or injury of vessels, nerves, structures or organs, including the bladder, urethra, or bowel, may occur 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 temporary or permanent urinary tract obstruction
- Transitory local irritation at the wound site may occur
- As with any implant, a foreign body response may occur. This response could result in extrusion, erosion, exposure, fistula formation and/or inflammation
- Mesh extrusion, exposure, or erosion into the vagina or other structures or organs
- As with all surgical procedures, there is a risk of infection. As with all foreign bodies, PROLENE Mesh may potentiate an existing infection
- Acute and/or chronic pain
- Voiding dysfunction
- Pain with intercourse which, in some patients may not resolve
- Neuromuscular problems, including acute and/or chronic pain in the groin, thigh, leg, pelvic and/or abdominal area may occur
- Recurrence of incontinence
- Bleeding including hemorrhage or hematoma
- One or more revision surgeries may be necessary to treat these adverse reactions
- PROLENE Mesh is a permanent implant that integrates into the tissue. In cases in which the PROLENE Mesh needs to be removed in part or whole, significant dissection may be required

Other adverse reactions

- Seroma
- Urge incontinence
- Urinary frequency
- Urinary retention
- Adhesion formation
- Atypical vaginal discharge
- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- Death

Consult your doctor to discuss the potential benefits and risks of your treatment options and whether PROLENE mesh is appropriate for you.

REFERENCES **1.** Aigmueller T, Trutnovsky G, Tamussino K, et al. Ten-year follow-up after the tension-free vaginal tape procedure. *Am J Obstet Gynecol.* 2011 Nov;205(5):496e1-5. **2.** Olsson I, Abrahamsson AK, Kroon UB. Long-term efficacy of the tension-free vaginal tape procedure for the treatment of urinary incontinence: a retrospective follow-up 11.5 years post-operatively. *Int Urogynecol J.* 2010 Jun;21(6):679-83. **3.** Nilsson CG, Palva K, Aarnio R, Morcos E, Falconer C. Seventeen years' follow-up of the tension-free vaginal tape procedure for female stress urinary incontinence. *Int Urogynecol J.* 2013 Aug;24(8):1265-9. **4.** Serati M, Ghezzi F, Cattoni E, et al. Tension-free vaginal tape for the treatment of urodynamic stress incontinence: efficacy and adverse effects at 10-year follow-up. *Eur Urol.* 2012 May;61(5):939-46. **5.** Svenningsen R, Staff AC, Schiøtz HA, et al. Long-term follow-up of the retropubic tension-free vaginal tape procedure. *Int Urogynecol J.* 2013 Aug;24(8):1271-8. **6.** Heinonen P, Ala-Nissila S, Kiihola P, Laurikainen E. Tension-free vaginal tape procedure without preoperative urodynamic examination: long-term outcome. *Int J Urol.* 2012 Nov;19(11):1003-9. **7.** Cheng D, Liu C. Tension-free vaginal tape-obturator in the treatment of stress urinary incontinence: a prospective study with five-year follow-up. *Eur J Obstet Gynecol Reprod Biol.* 2012 Apr;161(2):228-31. **8.** Serati M, Bauer R, Comu JN et al. TVT-O for the treatment of pure urodynamic stress incontinence: efficacy, adverse effects, and prognostic factors at 5-year follow-up. *Eur Urol.* 2013 May;63(5):872-8. **9.** Laurikainen E, Valpas A2, Aukee P3, et al. Five-year results of a randomized trial comparing retropubic and transobturator midurethral slings for stress incontinence. *Eur Urol.* 2014 Jun;65(6):1109-14. **10.** Athanasiou S, Grigoriadis T, Zacharakis D, et al. Seven years of objective and subjective outcomes of transobturator (TVT-O) vaginal tape: why do tapes fail? *Int Urogynecol J.* 2014 eb;25(2):219-25.



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?
- What are the risks for my situation that are associated with the GYNECARE TVT™ procedure?
- How safe and effective is the procedure to implant the GYNECARE TVT™?
- How soon after treatment can I resume my normal activities?
- How is the procedure used to treat SUI different than the procedure used to treat pelvic organ prolapse with surgical mesh?

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

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