



what's happening
down there
breaking the ice about SUI

Breaking the Ice About Stress Urinary Incontinence



The first time you leaked when you laughed or sneezed, you probably were surprised but didn't think much about it. Those things happen, right? But when it became clear that any pressure at all – exercise, bending, picking up something heavy, coughing – meant problems, you probably reacted the way most practical women do. You began wearing sanitary napkins, dark clothing – anything that would help you disguise what was becoming embarrassing, but that you may have worried was an inevitable part of getting older.

That's not so!

It's Called Stress Urinary Incontinence

It's a real medical condition that's very common because it's often a consequence of having babies, but it's not "normal"!

Despite what you may think, it's not necessarily associated with aging...it happens to women of all ages.

There's shame -- most women don't admit to it or try to have it cured.

It's not quite the same as what you see advertised on TV (that's urge incontinence, which actually is less common), and SUI can't be treated with a pill.*

But you don't have to live with it. Talk to a doctor: there are a number of treatments available.

Breaking the Ice About SUI

There's no doubt that talking about it can really be hard. Most women suffer three to ten years before broaching it to a doctor, which explains why more feminine pads are used for incontinence than menstruation...an astounding fact.

So what's happening down there? SUI occurs when pelvic muscles supporting the bladder and urethra have been damaged or weakened, often as a result of childbirth. Weakened pelvic muscles cannot hold the urethra in its correct position, causing the urethra to lose its seal and allowing urine to escape with any movement from the diaphragm that puts stress on the bladder, such as a sneeze.

*At publication date of this brochure, there is no U.S. FDA approved medicine to treat SUI.

Olympic Speed Skater
Bonnie Blair



Of course it doesn't help if you are overweight. Is there anything physical that doesn't seem to be affected by extra poundage? Don't despair!

Even those who are in great shape can be plagued by SUI. That's a chapter in the story of U.S. speed skater Bonnie Blair, who won many Olympic gold medals. If you could talk to Bonnie, she would speak very openly about SUI in the hope that you won't waste time putting up with it. After living with it for years after the birth of her first child, she overcame her embarrassment, talked to her doctor and found a solution.

Bonnie Blair's Story

"I first experienced SUI while I was exercising. After having my son, I was so excited to be able to run again -- until I found that my shorts were soaked not a block from home. Why had this happened to me? I was so embarrassed that I tried to hide it instead of doing something about it. I wore dark shorts, used feminine pads and limited my intake of fluids in a totally ineffectual attempt to cope.

"When I finally screwed up my courage and told my doctor, I was relieved to learn that most women who have urinary incontinence can do something to treat it. We discussed

options and tried different treatments, with little improvement until I had a simple minimally-invasive procedure called TVT. Within a day or two I was back to most of my normal activities and quickly resumed all that I had wanted to do.

"If you think you may have SUI, you don't have to suffer in silence and shame! Dealing with this problem has made me so much happier. Now I even can jump on the trampoline with my kids without fear of an accident."

For more information about SUI, please visit www.beatsui.com.



So What's GYNECARE TVT?

It's time for technical talk about what could be your solution. Why live with SUI?

When a woman has finished having children, a minimally-invasive treatment can fix SUI, allowing her to return to a full and active life.

GYNECARE TVT* Tension-free Support can stop urine leakage by supporting your urethra with a tape-like strip of mesh. Used in an approximately 10- to 30-minute outpatient procedure, it has shown proven results for the treatment of SUI. A clinical study shows that seven years after treatment, 81 percent of women who were treated with GYNECARE TVT remained dry and an additional 16 percent remained significantly improved. To date, more than one million patients worldwide have been treated.

Diagnosis is important.

There are different types of incontinence and different causes for the condition. To determine the right treatment for you, your doctor will seek to better understand your bladder and urethral function. To do this, your doctor may perform a pelvic exam focused on your pelvic support. Your doctor may ask you to cough with a full bladder to observe leakage or order special tests (urodynamics) to help him or her determine the treatment that is right for you.

What happens during the GYNECARE TVT procedure?

Your doctor inserts a strip of mesh-like tape under the urethra to create a supportive sling.

This provides support and allows the urethra to remain closed when appropriate, preventing urine loss during sudden movements or exercise.

The procedure is short -- it usually takes approximately 10 to 30 minutes -- and can be performed under local, regional or general anesthesia. You will be comfortable and may be asleep during the procedure. Depending on the method used, you may have two tiny incisions either just above the pubic area or near the creases on the thighs, or none at all.

What is recovery usually like?

Patients treated with GYNECARE TVT may be able to go home as early as a few hours after the procedure. Patients can expect a short recovery period. During this time, there should be little interference with daily activities; however, the patient may be advised to avoid

heavy lifting and intercourse for four weeks

Are there risks associated with a procedure using GYNECARE TVT?

All medical procedures present risks. Only your doctor can determine if GYNECARE TVT is right for you. For a complete description of risks, see the adverse reactions section of the product information that follows.

Is GYNECARE TVT right for me?

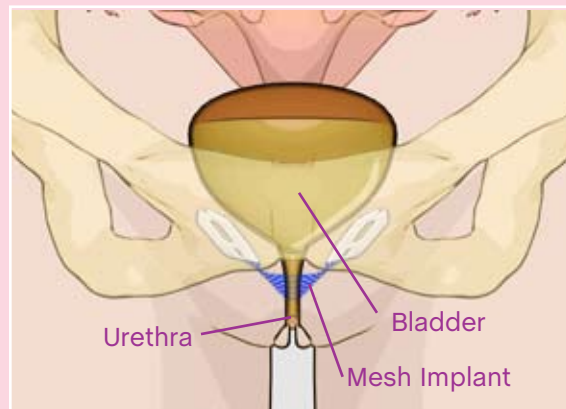
The best way to determine if you are a candidate for this treatment is to ask your doctor. It is appropriate for many types of patients. As with any surgery of this kind, this procedure should not be performed in pregnant patients. Additionally, because the mesh-like tape will not stretch significantly, GYNECARE TVT should not be used in women who plan future pregnancy.

The GYNECARE TVT SECUR* System

The technique allows for a new minimally-invasive approach that is designed for use under local anesthesia. It features a smaller mesh implant (the part left in your body) and eliminates the need for surgical exit incisions in your skin.

For more information about SUI?

- National Association for Continence; nafc.org; 1-800-BLADDER
- National Women's Health Resource Center; healthywomen.org; 1-877-986-9472
- womenshealth.gov
- Gynecare.com



GYNECARE TVT* Family of Products

GYNECARE TVT SECUR* System

GYNECARE TVT* Tension-free Support for Incontinence

GYNECARE TVT* with abdominal guides Tension-free Support for Incontinence

GYNECARE TVT* Obturator System Tension-free Support for Incontinence

Essential Product Information

INDICATIONS

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) resulting from urethral hypermobility and/or intrinsic sphincter deficiency. The GYNECARE TVT SECUR may be placed in either a "U" or "hammock" position under the midurethra. Placement orientation is per the surgeon's preference.

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 and Precautions

- Do not use GYNECARE TVT System for patients who are on anti-coagulation therapy.
- Do not use GYNECARE TVT System for patients who have a urinary tract infection.
- Bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Since no clinical information is available about pregnancy following sub-urethral sling procedure with the GYNECARE TVT SECUR, GYNECARE TVT, GYNECARE TVT with abdominal guides and GYNECARE TVT Obturator System, 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 SECUR, GYNECARE TVT, GYNECARE TVT with abdominal guides and GYNECARE TVT Obturator System, in case of pregnancy, delivery via cesarean section should be considered.
- Post-operatively, the patient should be advised to 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.
- The patient should be instructed to contact the surgeon immediately if dysuria, bleeding or other problems occur.

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 response could result in extrusion, erosion, fistula formation or inflammation.
- As with all foreign bodies, PROLENE mesh may potentiate an existing infection. The plastic sheaths initially covering the PROLENE mesh are designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

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