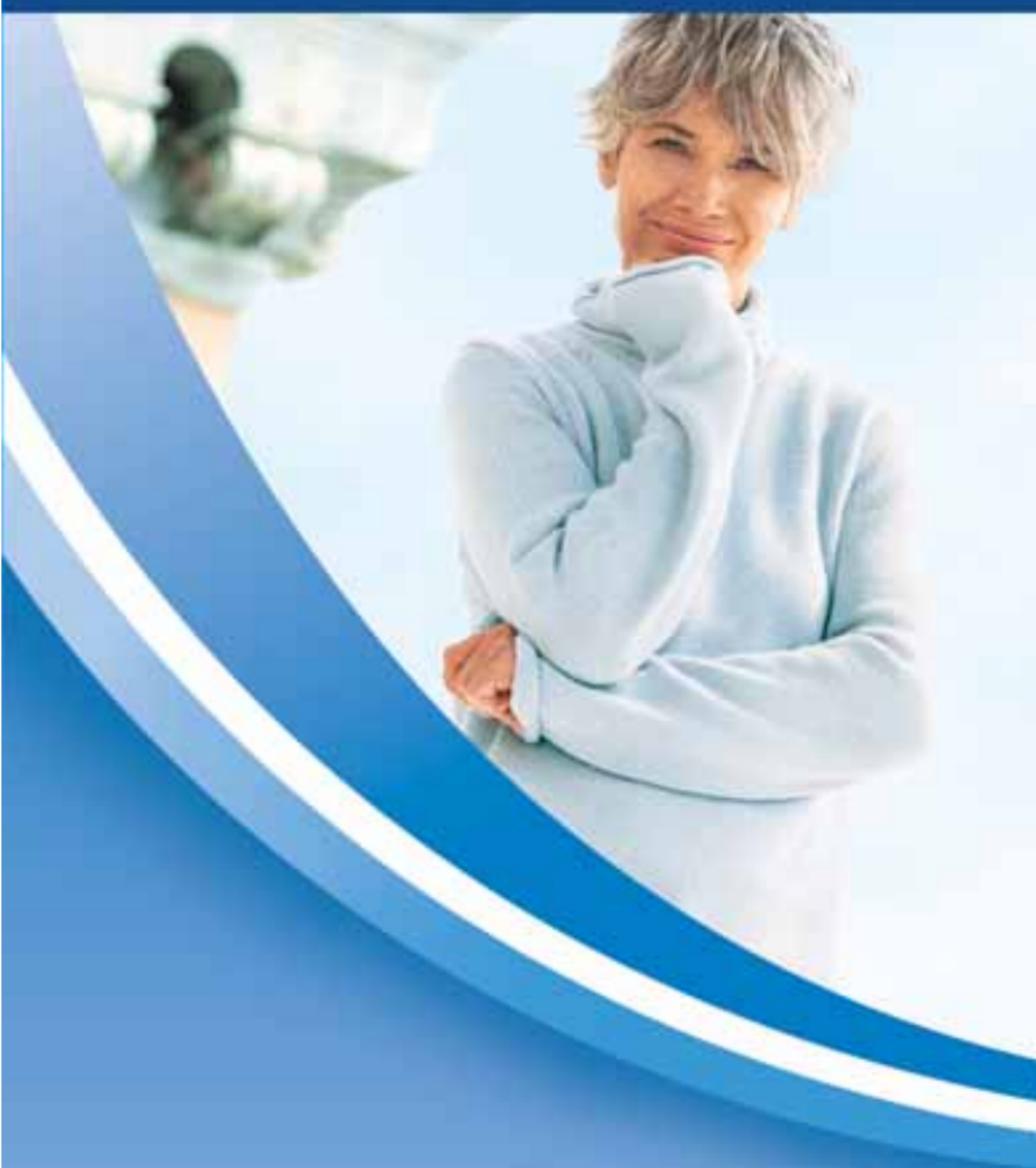


Stress Urinary Incontinence in Women



*What YOU can
do about it...*

Gynecare 
WOMEN'S HEALTH SOLUTIONS



Stress Urinary Incontinence in Women:

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

Would it surprise you...

To learn that more than 3 million women in the United Kingdom have urinary incontinence or loss of bladder control at some point in their lives? That it's not necessarily a "normal" part of getting older that a woman just has to accept? That it can affect women of all ages, for all kinds of reasons?

If this is surprising, it is probably because urinary incontinence is one of those things no one finds easy to talk about. It can be embarrassing. It can be uncomfortable. Urinary incontinence can be severe enough that it slows you down and limits your life. You may restrict or avoid activities you love, like exercise, travel or even social relationships.



It doesn't have to be that way...

You don't have to suffer with it. You can do something about urinary incontinence, at any age and no matter how hectic your life is. Today you have choices — there are safe and effective minimally invasive procedures that can help you control this condition, stay active, and be confident. These procedures often can deliver the most reliable, permanent results. The best news is that these procedures are simpler, much less invasive than traditional surgical procedures that require large incisions and several days in the hospital.



Use this brochure to gain a better understanding of urinary incontinence in women and what some of your treatment options are, and then...

Take the next step. Talk with your doctor or other healthcare professional about urinary incontinence, and what you can do about it.



But first, it's important to know what type of urinary incontinence do I have?

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

Stress urinary incontinence: the unintentional release or leakage of urine during sudden movements such as coughing, sneezing, laughing and exercising.

Urge Incontinence: the sudden, intense urge to urinate, followed by a loss of urine. 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 deals with 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 sudden urine loss, 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.

Any movement that puts pressure on the bladder (such as a sneeze) causes the urethra to lose its seal and allows urine to escape.



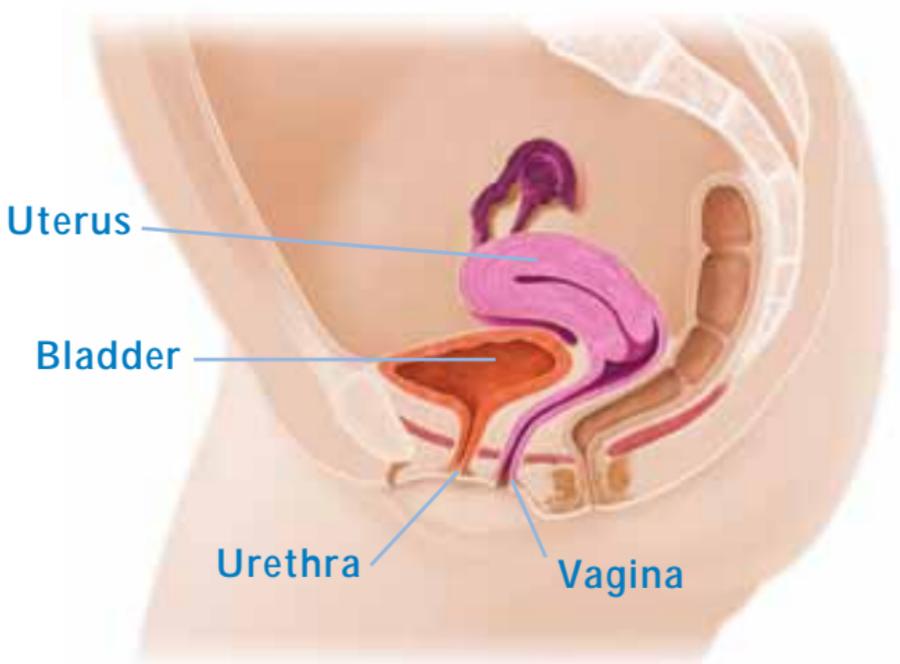
So why doesn't my urethra function properly?

There are two primary reasons why the urethra tube fails to maintain its seal during stress activity. The most common is poor support of the urethra normally provided by the underlying muscle and connective tissue of the vagina. Less commonly the urethral sphincter could be deficient.

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 or estrogen deficiency*
- *Obesity*

Pelvic Anatomy



Could I have stress urinary incontinence?

Initially at least, you are the person who knows better than anyone whether urinary incontinence is a problem for you. Perhaps it's something you've been living with for a while, and now you're frustrated at how incontinence complicates your life and limits the things you feel comfortable doing. Perhaps it's something that has just started to bother you – you've just had a baby or notice that bladder control is becoming a problem at the same time you are coping with other major changes in your life, such as menopause.

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

- Do you experience unplanned, sudden urine loss while laughing, sneezing, coughing or exercising?*
- Do you wear pads to absorb urine leakage?*
- Do you limit or avoid any activities to prevent leakage?*
- 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 your doctor or other healthcare professional.

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 – incontinence is a medical condition that can be treated, after all – but it's easy to feel uncomfortable.



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

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

What treatments are available to me?

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

Behavioural/Muscle Therapy: For women with stress urinary incontinence, the first line of therapy is usually Kegel exercises to help strengthen the pelvic floor muscles.

Depending on the severity of your condition, however, Kegels may not bring sufficient relief. Other therapies that may be used alone or in combination with Kegel exercises include:

Biofeedback – a process that helps you gain control over bodily functions by making you more aware of them.

Electrical stimulation – which aids pelvic floor exercises by isolating the muscles involved.

Medication - Some types of urinary incontinence can be treated with medications or hormone therapy (if incontinence is associated with estrogen deficiency, for example). At this time, however, drug therapy is not available to treat stress urinary incontinence.

Today's minimally invasive procedures offer safe and effective ways to treat sudden urine loss.

GYNECARE TVT* Tension-free Support for Incontinence is an innovative, minimally invasive 30-minute, outpatient treatment with proven results for the effective treatment of stress urinary incontinence.

How is GYNECARE TVT different from other surgical alternatives?

Recovery is quick – GYNECARE TVT can be performed under local anaesthesia. You'll be back to your normal routine in just a day or two.

GYNECARE TVT is the **only** treatment of its type with demonstrated long-term clinical results. It's clinically proven, safe and effective:

98% of women treated with GYNECARE TVT are still dry or report significantly less leakage seven years after treatment. Few patients experience complications.

Worldwide, more than 500,000 women have been treated with GYNECARE TVT — ten times the number of women who've been treated with the next treatment of its type.

GYNECARE TVT is also the only treatment for Stress Urinary Incontinence to be specifically recommended by The National Institute for Clinical Excellence which is the authority responsible for evaluating the quality of treatments.



How does GYNECARE TVT work?

GYNECARE TVT stops urine leakage the way your body was designed to – by supporting your urethra.

Normally, the urethra is supported by the pelvic floor muscle to maintain a tight seal and prevent involuntary urine loss. In women with SUI, the weakened pelvic floor muscle and connective tissue can't support the urethra in its normal position.

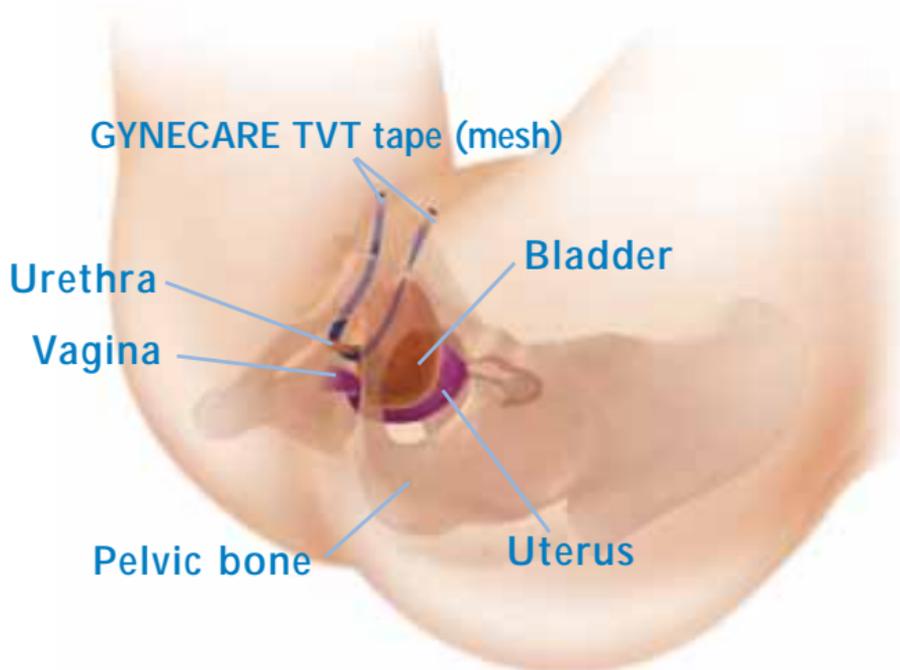
To correct this using GYNECARE TVT, your doctor will insert a ribbon-like strip of mesh under the urethra to provide support whenever you stress this area (such as during a cough or sneeze). This allows the urethra to remain closed, when appropriate, preventing involuntary urine loss.

The unique elastic properties of the GYNECARE TVT, more so than similar products, prevent the mesh from affecting normal voiding. Lastly, the ribbon-like mesh is made from a permanent material that will be well tolerated by your body. It will be there to help support your urethra for the rest of your life.

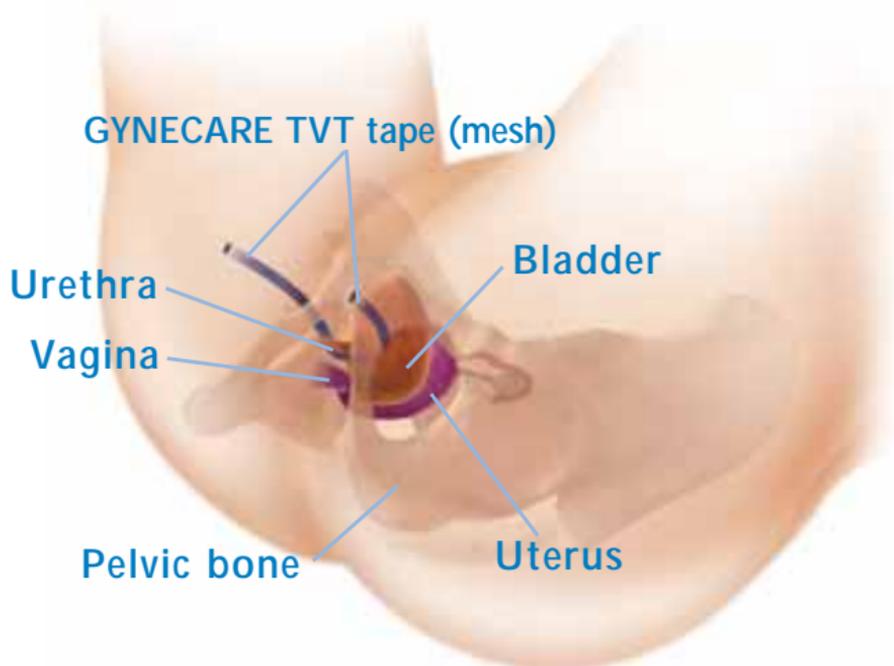
What can I expect during the procedure?

The procedure is short – it usually takes just 30 minutes. The GYNECARE TVT procedure can be performed under local, regional or general anaesthesia. You will be comfortable and may be asleep during the procedure. With local, epidural or spinal anaesthesia you will be awakened briefly in order to cough with a full bladder. Your doctor can then adjust the setting of the mesh. This cough test helps your doctor set the mesh “just right” for you. You will have two tiny incisions either just above the pubic area or near the creases on the thighs. Your doctor will monitor your ability to pass urine before you go home.

The GYNECARE TVT mesh will be placed in one of two possible configurations, based on your doctor's assessment.



The mesh is placed under the urethra and exits the abdomen just above the pubic bone.



The mesh is placed under the urethra and exits near the creases of the thighs.

The anatomy in these photos is shown with the woman in the gynecological exam position.

Is GYNECARE TVT right for me?

The best way to determine if you are a candidate for this procedure is to ask your doctor. GYNECARE TVT is appropriate for many types of patients. As with any procedure of this kind, GYNECARE TVT should not be considered if you are pregnant or if you plan to be in the future.

What can I expect after I go home?

At your doctor's discretion, you may be able to go home as early as a few hours after your procedure and return to a relatively normal schedule of activities the next day. There will be very little or no discomfort after the procedure. If you need it, your doctor may suggest taking an over-the-counter pain reliever. Your doctor will advise you to avoid heavy lifting and intercourse for four to six weeks.

What are the risks?

All medical procedures present risks. Although rare, complications include difficulty urinating, injury to blood vessels of the pelvic sidewall and abdominal wall, and bladder and bowel injury. For a complete description of risks, see the adverse events section of the attached product information.

Talk with your doctor about whether GYNECARE TVT is the right choice for you. If it is, be certain your doctor is giving you GYNECARE TVT, the No. 1 doctor-preferred treatment of its type.

To find a doctor in your area who has treated incontinence with GYNECARE TVT, call 0845 6023384.

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

SUMMARY OF PACKAGE INSERT

INDICATIONS

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.

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 these devices for patients who are on anti-coagulation therapy.
- Do not use these devices for patients who have a urinary tract infection.
- Users should be familiar with surgical technique for urethral suspensions and should be adequately trained in these procedures before employing these devices.
- Acceptable surgical practice should be followed for these procedures as well as for the management of contaminated or infected wounds.
- These procedures should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to patient anatomy and correct passage of the device will minimise risks.
- Bleeding may occur postoperatively. Observe for any symptoms or signs before releasing the patient from hospital.
- Do not remove the plastic sheaths until the tape has been properly positioned.
- Ensure that the tape is placed with no tension under the midurethra.
- PROLENE mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- Do not perform these procedures if you think the surgical site may be infected or contaminated.
- Since no clinical information is available about pregnancy following a suburethral sling procedure with these devices, the patient should be counselled that future pregnancies 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 these procedures, in case of pregnancy delivery via caesarean section should be considered.**
- **Postoperatively, 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 intercourse for one month. The patient can usually return to other normal activity after one or two weeks.**
- **Should dysuria, bleeding or other problems occur, the patient is instructed to contact the surgeon immediately.**
- **All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected.** Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following these procedures. To minimise this risk, make sure to place the tape tension-free in the midurethral position.
- Do not contact the PROLENE mesh with any staples, clips or clamps as mechanical damage to the mesh may occur.
- Do not resterilise any single-use devices or components. Discard opened, unused devices.
- Prophylactic antibiotics can be administered according to the surgeon's usual practice.

WARNINGS AND PRECAUTIONS – additional for **GYNECARE TVT / GYNECARE TVT** with abdominal guides

- The abdominal guide should not be used to pull the interlocked system upward toward the abdomen.
- Ensure there is a snug connection between the guide and coupler and the coupler and TVT needle.
- Cystoscopy should be performed to confirm bladder integrity or recognise a bladder perforation.
- The rigid catheter guide should then be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley catheter.
- When removing the rigid catheter guide, open the handle completely so that the catheter retains properly in place.

WARNINGS AND PRECAUTIONS – additional for **GYNECARE TVT** Obturator System

- Although bladder injury is unlikely to occur with this technique, cystoscopy may be performed at the discretion of the surgeon.
- Transient leg pain lasting 24-48 hours may occur and can usually be managed with mild analgesics.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during needle 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 minimise the risk of contamination.
- Over correction, i.e. too much tension applied to the tape, may cause temporary or permanent lower urinary tract obstruction.

You're not alone, and support is just a phone call away.

Millions of women across the country also experience stress urinary incontinence. A number of nationwide organisations have been set up to provide emotional support, helpful suggestions and more detailed information.



For further information about WellBeing please contact 020 7772 6400
or visit www.wellbeing.org.uk



For advice from specialist nurses call 0845 345 0165
(Mon-Fri, 9.30am-1.00pm), or write to: The Continence Foundation
307 Hatton Square, 16 Baldwins Gardens, London EC1N 7RJ.
www.continence-foundation.org.uk

GYNECARE, a division of Johnson & Johnson Medical Limited, 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 can weigh their options and, along with their surgeons, make informed decisions.

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



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