

# Stress Urinary Incontinence

*-Stress No More-*



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# Introduction

If you are reading this monograph because you have **Stress Urinary Incontinence (SUI)**, you are by no means alone. It is a very common medical condition that one in three women will experience at some point during their lifetimes.

SUI is defined as a spurt-like leakage of urine during moments of physical activity, such as coughing, sneezing, laughing, jumping or exercise. It can even happen with walking, changing position from sitting to standing, or with sexual activity.

Despite its prevalence, many women with SUI are reluctant to seek medical help because of embarrassment, the misconception that it is an expected occurrence with aging, or lack of awareness that remedies ARE available. Many turn to pads to manage this problem, resigning themselves to living unhappily with this debilitating yet very treatable problem. SUI is far more than just a medical problem, often affecting the emotional, psychological, and social well being of patients as well. Many fear participating in activities that trigger the SUI, sometimes resulting not only in social isolation, but also in avoiding exercise that can result in weight gain and a loss of physical fitness.

Reading this booklet will provide you with basic education about SUI, including how it is properly evaluated and treated. The most important point of this monograph is that *help is available!* There are urologists, such as myself, who specialize in the treatment of SUI and have at their disposal state-of-the-art diagnostic methods and treatments to diagnose and cure the problem, so that a healthy, productive, and active lifestyle can be pursued.

After a thorough evaluation including a history and physical examination, a urinalysis, and other specialized diagnostic tests, the underlying cause of the SUI can be pinpointed and the course of treatment determined. It may involve one or more of the following treatments: lifestyle changes, behavior modification, pelvic muscle-conditioning exercises, biofeedback, or minimally invasive surgery.

My goal as a urologist who specializes in this condition is threefold: to educate you so that you have a thorough knowledge and understanding of SUI; to provide the proper testing and evaluation to determine the precise nature of the problem; and, lastly, to treat you in order to restore your quality of life and render you pad-free so that you can engage in any activity without fear of SUI.

# The Urethra

The *urethra* is the short, straw-like tube that connects the bladder to the outside world. It runs from the bladder neck to an opening near the vagina, functioning to conduct urine out from the bladder during urination and to help store urine at all other times. When functioning well, its presence is taken for granted—it's only when things go awry that you appreciate what you once had.

In reality, the urethra is not straw-like at all. In cross-section, it appears like a snowflake with lots of convolutions and infoldings of its innermost layer. This inner layer is surrounded by a rich, spongy layer that has an abundance of vascular (blood vessel) tissue that is encased in a fibrous and elastic sheath. This anatomy allows for *urethral coaptation*—a water-tight seal similar to a washer in the sink. The urethra is nourished by *estrogen*, the female hormone. After menopause, with loss of estrogen, the urethra tends to atrophy, and the washer tends to become a bit more brittle.

Simplistically, there are two *sphincters* that contribute to our continence. The *bladder neck sphincter*, located at the junction of the bladder and the urethra, is an involuntary muscle that is contracted (squeezed) at all times when we are storing urine and relaxes in order to allow urinating. The *striated sphincter*, located in the mid-urethra, is a voluntary auxiliary muscle that contracts in reflex-like fashion when we cough.

Just as important as the anatomy of the urethra and the sphincters is the anatomy of the support tissue of the urethra. The urethra is located in between a “sandwich” of connective tissue that anchors and supports it. The *urethro-pelvic ligament* forms the top of the sandwich and the *peri-urethral fascia* forms the bottom of the sandwich. Together, these two layers envelope the urethra, and provide a hammock-like support to the urethra and anchorage of the urethra to the pelvic sidewall.

The *pelvic floor muscles (PFM)* are hammock-like muscles that provide support to the bladder, urethra, and other pelvic organs. The pubococcygeus and perineal muscles are the muscles that comprise the PFM. These muscles not only contribute to the support of the bladder and the urethra but also to the maintenance of continence.

# ***Stress Urinary Incontinence (SUI) 101***

In Europe, SUI is referred to as *exertional* incontinence, since some form of physical exertion usually triggers the event. This is less confusing than the American term *stress incontinence* since the word ‘stress’ has multiple meanings. In the context of SUI, *stress* means *a sudden increase in abdominal pressure* and not *emotional strain or tension*.

Most women with SUI have it on the basis of weakened or lax support tissues of the urethra. This allows for the urethra to be displaced down out of its normal position at times of sudden increase in abdominal pressure, a condition called *urethral hyper-mobility*. Oftentimes this occurs with sneezing, coughing, lifting, laughing, walking, running, jumping, exercising, or changing position. Triggers that consistently induce SUI in women who have the problem are *vertical deceleration activities*—jumping up with a sudden stop as one’s feet touch down on the ground— typified by doing jumping jacks, trampoline or jumping rope.

The main **inciting** factor for SUI is the process of pregnancy, labor and delivery, particularly, traumatic vaginal deliveries of large babies. SUI is rare in women who have not delivered a child or in women who have had elective Caesarian sections. However, *emergency* Caesarian section confers a similar risk for SUI as does vaginal delivery.

**Promoting** factors for SUI are aging, menopause, weight gain, prior gynecological surgery including hysterectomy, and any condition causing a chronic increase in abdominal pressure including cough (often from smoking), asthma, constipation, weight training and occupations that require heavy labor. Chronic constipation is a major promoting factor because of the need for pushing and straining on a daily basis, cumulatively causing the same weakening of the support of the urethra as does being in labor.

Some women experience SUI after childbirth and it persists until it is fixed, while others find that it improves dramatically and often resolves within 6 months after delivery. Many others will not experience SUI until years after childbirth, after many of the promoting factors discussed above have kicked in. SUI is most common in young and middle-aged women, although it can happen at any age.

The specific activities that provoke the SUI and the severity of the leakage can vary tremendously from woman to woman. Some females only experience SUI with extreme exertion, such as with serving a tennis ball or accompanying a huge sneeze. Others experience SUI with minimal exertion such as walking or turning

over in bed. Some women don't wear any protective pads or liners, but simply change their panties as necessary, whereas others wear many pads per day. Some women are significantly bothered by even a minor degree of SUI, while others are accepting of experiencing many episodes of SUI daily, which they manage by changing their pads numerous times.

On occasion, SUI may be due to a weak or damaged sphincter, a condition called *sphincter deficiency*. The main risk factors for this are prior surgery for incontinence, radical pelvic surgery, damage to the nerve supply to the urethra, radiation and pelvic trauma. SUI due to sphincter deficiency causes severe urinary leakage with minimal activities and can also cause *gravitational* incontinence, which is urinary leakage resulting from positional changes such as standing up.

**Pseudo SUI** is defined as leakage of urine with physical activity that is not on the basis of genuine SUI from urethral hyper-mobility or sphincter deficiency. It can masquerade as genuine stress incontinence and it is critical to distinguish pseudo SUI from genuine SUI since the treatments are very different. This is one reason a thorough evaluation of SUI is so important. Pseudo SUI may be on the basis of *failure to empty the bladder*; the presence of a *urethral diverticulum*; *vaginal voiding*; or *stress-induced bladder over-activity*.

*Failure to empty* the bladder can occur for a variety of reasons, including obstructive and neurological issues. When the bladder is full, it is easy to understand why a sudden increase in abdominal pressure can provoke leakage. The treatment is to facilitate bladder emptying. An extension of this is that if your bladder is full and you leak a small amount with jumping or laughing, it is not necessarily pathological, but just means that you need to urinate before engaging in such activities.

*Urethral diverticulum* is a small sac-like out-pouching from the urethra that can fill up with urine and leak urine during physical activities. The treatment is surgical removal of the diverticulum.

*Vaginal voiding* occurs in a small percentage of women who have their urethral opening internally recessed to some extent. When they urinate, some of the voided urine pools in the vagina. Upon standing and physical exertion, the urine can then leak out.

*Stress-induced bladder over-activity* is a condition in which an involuntary bladder contraction is triggered by a stress maneuver such as a cough.

# ***Evaluation of SUI***

## ***History and Physical Exam***

The starting point of the evaluation of SUI is a thorough history and physical examination. The history will determine the duration and the severity of the SUI. The specific trigger factors that precipitate SUI will be ascertained. Other lower urinary tract symptoms including *obstructive symptoms* (blockage-type symptoms such as weak stream and prolonged emptying time) and *irritative symptoms* (urgency, frequency, urgency incontinence) will be determined.

Medical problems and their treatment, especially the presence of diabetes and neurological disease, are essential knowledge. Surgery, especially incontinence surgery, radical pelvic surgery, and gynecological procedures, is fundamental information. A complete list of all medications taken is important to review. An obstetric and gynecological history is very relevant.

Physical exam is focused on a thorough pelvic examination. Visual inspection will determine the presence or absence of atrophic changes that can accompany menopause and the aging process. A small catheter is placed in the bladder after you have urinated to determine the amount of residual urine remaining in the bladder. The catheter is also used to measure the angle of the urethra at rest and with strain, to determine the degree of urethral hyper-mobility. A single-bladed speculum exam is done to assess the appearance of the urethra at rest and with strain and then to gauge the presence and extent of pelvic organ prolapse; specifically, a bladder that descends into the roof of the vagina, a rectum that ascends into the floor of the vagina, or a cervix that descends into the apex of the vagina. The pelvic floor muscle tone is evaluated on a scale of 0-5 by asking you to contract your pelvic muscles. Finally, a bimanual pelvic exam is done to check for the presence of pelvic masses.

Beyond the history and physical exam, additional tests will often need to be done; these might include some of the following:

## ***Lab Tests***

*Urinalysis* is an exam of the urine that will test for sugar (possibly indicating diabetes), protein (possibly indicating kidney disease), pus cells and bacteria (often indicative of a urinary tract infection); and the presence of blood (which may indicate an abnormality in the urinary tract).

*Urine culture* is a test to see if bacteria are present in the urine, and if so, what particular type of bacteria.

*Urinary cytology* is a “Pap smear” of voided urine in which a pathologist will examine the urine under a microscope to detect early cancers of the bladder.

**Voiding diary** is a twenty-four hour record of urination in which the time of urination and the volume of urination is recorded by the patient. This is a simple and objective means of documenting the frequency of urination as well as the bladder capacity.

**Urodynamics** is an important test of bladder function that evaluates both bladder storage and emptying.

*Uroflowmetry* involves urinating into an electronic device that records the force of the urinary flow.

*Filling cystometry* measures the pressure and volume relationship of the bladder. A special catheter is placed into the bladder and the residual volume is measured. The bladder is slowly filled with water and an electronic device records both the volume and the pressure. This test gives information on bladder sensation, capacity, compliance (elasticity) and the presence or absence of involuntary bladder contractions.

*Leak point pressure* is the precise measured pressure in the abdomen that causes SUI. It is determined by having you cough and strain after the bladder is filled to a certain extent. It is helpful to distinguish between urethral hyper-mobility and sphincter deficiency.

*Voiding cystometry* (Pressure–Flow Study) is done after the bladder is filled to capacity. You are asked to urinate and flow rate and bladder pressure are recorded. This test is useful to distinguish between a weak bladder muscle and an obstructed urethra, and is also helpful to document satisfactory bladder contractility prior to surgery to correct SUI.

*Pelvic floor electromyography* uses patch electrodes placed near the anus to measure the activity of the pelvic floor muscles.

### ***Dynamic Bladder Imaging***

A standing cystogram is an x-ray of the bladder and urethra obtained during rest, strain and cough. The idea is to replicate the SUI and observe the anatomical changes that occur in the urethra and bladder. You can watch along and clearly witness what happens in real time when you experience SUI.

**Cystoscopy** is an anatomical test in which a narrow, lighted instrument is inserted to directly visualize the urethra, bladder neck, and bladder after anesthetic jelly

is placed in the urethra. The urethra is observed in both rest and strain modes and you can watch the entire procedure on a monitor.

**Marshall test** observes the urethra during rest, strain and cough. With the bladder filled to a certain extent, you are asked to cough and strain to try to replicate the SUI. The urethra is then gently supported by placing a finger in the vagina under the mid-urethra and you are again asked to cough and strain. If gentle support of the mid-urethra abolishes the SUI, this indicates the likely success of a mid-urethral sling.

## ***Non-Surgical Management of SUI***

**Treatment of the inciting conditions:** SUI is often provoked by increases in abdominal pressure, particularly when asthma causes wheezing; seasonal allergies cause sneezing; or cigarette smoking, bronchitis, sinusitis, or post-nasal drip cause coughing. By properly managing the provoking condition, incontinence can be avoided.

**Fluid moderation:** Although not always true, SUI will often not occur until a “critical” urinary volume is reached. By being prudent with drinking fluids, it will take a longer time to reach this critical volume. Caffeine and alcohol increase urinary output, so it is best to limit their intake. Caffeine is present in tea, coffee, cola, and chocolate. Additionally, many foods—particularly fruits and vegetables—have lots of hidden water content, so moderation applies best here as well.

**Timed voiding:** Urinating by the “clock” and not by your own sense of urgency will keep your bladder as empty as possible. By emptying the bladder before the “critical” volume is reached, the SUI can be controlled. Voiding on a two-hour basis is usually effective, although the specific timetable has to be tailored to the individual. Such “pre-emptive” voiding has been proven to be a useful strategy since *voluntary* urinary frequency is more desirable than *involuntary* SUI.

**Pelvic floor muscle (PFM) exercises:** By exercising the pubococcygeus and perineal muscles to increase their strength and tone, SUI can be improved. The PFM is a sling muscle that when contracted, tightens the urethra, vagina, and rectum. The PFM is NOT the muscle of the abdominal wall, the buttocks or the thighs. A simple means of recognizing the PFM is to put a finger inside your vagina and to squeeze down until the vagina tightens around your finger. An alternative means of identifying this muscle is to abruptly stop the urinary stream; if you are capable of doing so, you are contracting the PFM properly. PFM exercises can be done anywhere and at any time and in various positions

such as lying down, sitting, or standing. These exercises can be integrated into your daily activities. “Down time,” such as sitting in your car at red lights or waiting in line at the supermarket checkout, is convenient to exercise your PFM.

For maximum benefit, three sets of these exercises should be done daily. During each set, 25 repetitions should be performed. For up to 5 seconds, if possible, this muscle should be contracted, and then for 5 seconds relaxed. After completion of 25 repetitions of alternating “squeeze, relax” etc., the set is completed.

Gradually, the strength and tone of the PFM will increase. Given the potential success of these exercises, they are well worth your effort. You may notice some soreness in the PFM at first. The benefits of these exercises will continue only so long as you do them. “Use it or lose it” applies here. As in any muscle-conditioning program, it may take 6-12 weeks of exercising before you notice improvement in the SUI.

Pay close attention to those activities that trigger the SUI. By actively “pulsing” the PFM—doing a few vigorous cycles of contraction/relaxation of the PFM just before and during these activities—the SUI can often be lessened or precluded.

To access my educational videos on PFM, please see our website: [www.BergenUrological.com](http://www.BergenUrological.com).

***Pelvic floor physical therapy*** is a niche specialty of physical therapy that you can be referred for if you are having trouble getting the hang of the PFM exercises.

***Biofeedback*** is the use of electronic instrumentation to relay auditory or visual feedback information about PFM contractility. This can be of use to help learn the proper technique of doing PFM exercises.

***Exercise*** can go a long to help maintain general fitness and avoid SUI. That stated, there are women who are exercise enthusiasts in stellar physical shape who nonetheless will experience SUI. In general, exercises that emphasize the core muscles, particularly Pilates and yoga, are most helpful for SUI.

***Weight loss:*** The burden of extra pounds can worsen SUI; even a modest weight loss may improve it.

***Smoking cessation:*** The use of tobacco will often cause bronchial irritation and coughing that can provoke SUI. By eliminating tobacco, the SUI can be significantly improved.

***Avoidance of constipation:*** A full rectum can put mechanical pressure on the bladder and contribute to SUI. Chronic straining at bowel movements—similar to being in labor every day—can have a cumulative effect that can be instrumental to the development of SUI. Bowel regularity may thus be of aid in improving SUI and preventing it from progressing further.

***The tampon trick:*** If your SUI occurs under very predictable circumstances—for example, during tennis, golf or jogging—a strategically placed tampon can be your friend. By positioning the tampon directly under the urethra, it can act as a space-occupying strut that can provide a backboard of support to the urethra. For the purpose of helping with the SUI, the tampon does not need to be placed as deeply as it would for menstruation, as the urethra is only about 3 cm in length. Similar to what the supportive finger in the Marshall test accomplishes, this temporizing device just might allow you to pursue your activities without the need for a pad.

## ***Surgical Treatment of SUI***

If you are suffering with SUI and the non-surgical management has not proven effective, it is time to think about getting the problem fixed. The surgical treatment of SUI has evolved significantly over the past several decades. The current procedure represents an evolution of surgical technique that has merit because of its effectiveness, durability, relative simplicity, and need for only tiny incisions.

### **Mid-Urethral Sling**

The purpose of a sling procedure is to cure, if not vastly improve, the SUI. (It is also oftentimes performed in conjunction with bladder prolapse repair to prevent the occurrence of SUI that may be unmasked as a result of the cystocele repair.) The sling is positioned directly beneath the urethra, the tubular channel that leads from the bladder to the urinary opening.

The sling procedure works to stabilize and provide hammock-like support to the urethra. After sling placement, when a trigger of SUI occurs, the urethra will be compressed into the sling which will provide *coaptation* (closure of the urethra). The sling placed underneath the urethra recreates the natural “backboard effect” that is no longer working properly.

A sling is an outpatient procedure commonly done under a light general anesthesia. It typically takes less than 30 minutes to place the sling, which is

done using a small vaginal incision and two tiny groin punctures. A long-acting local anesthetic is used on these sites to minimize pain for the first few hours after surgery. The vaginal incision is closed with dissolvable stitches and the groin punctures with skin glue.

After completion of the surgery, the vagina will be gently packed with gauze that is removed in 1-2 hours. You will be discharged as soon as you are awake and alert, have eaten a snack, and have urinated. On occasion, a patient needs to be sent home with a catheter; if so, it is generally removed the following morning. You will be sent home with a short course of oral antibiotics to prevent a urinary or pelvic infection and a narcotic to be used as needed for pain relief. Many women do not need a narcotic for sling surgery, and do perfectly well with an anti-inflammatory over-the-counter medication such as ibuprofen 400 mg. This is actually preferable, as it does not have many of the side effects of the narcotics, including nausea, queasiness and constipation.

It is likely that you will experience groin discomfort for a few days following the sling; many describe it as a “charley horse” sensation that you might experience a day or two after a vigorous workout. You may have bruising of the groin area and vaginal bleeding for a few days. After the bleeding resolves, you may experience minor vaginal discharge until the stitches have fully dissolved.

Your regular diet and medications can be resumed immediately. You can pursue many of your normal activities the day following surgery. In fact, walking and stair climbing are desirable as rapid return to activities facilitates recovery. You may bathe or shower. Any non-strenuous activity is permissible as long as pain is not experienced. Avoid heavy lifting, strenuous exercise, straining at bowel movements and sexual intercourse for about four to six weeks after the sling placement.

### ***Benefits and Potential Risks of the Sling***

#### *Benefits:*

- 90% cure/improvement of stress urinary incontinence
- 65% of patients with pre-existing urgency incontinence that accompanies the stress urinary incontinence will have resolution/improvement of the urgency incontinence

#### *Potential Adverse Effects:*

- Failure of the procedure to cure the SUI in 10% of patients
- New onset of difficulty urinating, urinary frequency, urgency and possibly

- urgency incontinence in a small percentage of patients
- Change in voiding pattern with a less forceful or splayed urinary stream
- Inability to urinate in less than 1% requiring self-catheterization or takedown/revision of the sling
- Injury to the urethra, bladder, bowel, or vascular structures: extremely rare
- Failure of the sling material to incorporate properly: extremely rare

### ***Mid-urethral sling***



### ***Sling tensioning***

Precise sling tension is of paramount importance to the success of surgery to correct SUI. As a general rule, slings should be free of tension, except under unusual circumstances. To reiterate, the purpose of the sling is to create a backboard of support that the hyper-mobile urethra can be compressed into to allow urethral coaptation at the time of stress maneuvers. Essentially, the urethra will get pinched between the pressure from above and the sling from below. What is needed is support, not lift—similar to the purpose of a running bra. Too little tension and the SUI persists; too much tension and you can be hypercontinent such that it can be difficult to urinate; just the right amount of tension and voilà—the SUI is just a memory. There are three factors that I use to decide the proper tension: *degree of urethral mobility, magnitude of incontinence, and leak point pressure.*

*Degree of urethral mobility:* The more hyper-mobile your urethra is, the less sling tension that is necessary. I judge urethral hyper-mobility by placing a small catheter in the urethra and asking you to strain, measuring the angle of the urethra at rest and strain—the greater the angulation, the more movement of the

urethra, the less sling tension necessary. So, a woman with 90-degree mobility will need less tension than a woman with 20-degree mobility.

*Magnitude of incontinence:* The greater the volume of leakage and the more pads necessary for protection, the greater the sling tension required. So, a woman who wears a pad only when attending Zumba class or when she has a bad cold will likely need a sling with less tension than a woman who wears six pads per day who has large-volume leakage with low-impact activities.

*Leak point pressure:* This is a measurement of the abdominal pressure it takes to cause SUI, determined during the urodynamic evaluation. After the bladder is filled with a certain volume of water, you are asked to strain until leakage is noted, and this pressure is recorded. The higher the leak point pressure, the less sling tension necessary.

### ***Sling material***

Polypropylene is the “gold” standard sling material for SUI. This material is used by general surgeons for hernia repair and wound closure and by urologists for pelvic reconstruction. This synthetic material is strong, flexible, supple and durable. The sling acts as a scaffold and achieves incorporation in the body by way of tissue in-growth through the pores of the sling. After the sling is completely integrated, it becomes fully covered by human tissue, similar in appearance to a chain-link fence that becomes overgrown with ivy.

Several years ago there were a number of slings that did not have the proper design features necessary to promote satisfactory incorporation and integration in the body—specifically the *IVS sling* (Tyco) and the *ObTape* (Mentor) were two that failed to pass muster. I was one of the first surgeons to publicize the unfavorable results with use of these ill-designed and problematic slings:

Siegel, A, Kim, M, Goldstein, M, Levey, S, and Ilbeigi, P: “High Incidence of Vaginal Mesh Extrusion Using the Intra-Vaginal Slingoplasty (IVS) Sling,” *JOURNAL OF UROLOGY* 174: 1308, October 2005

Siegel, A: “Vaginal Mesh Extrusion Associated With Use of the Mentor Trans-Obturator Sling,” *UROLOGY* 66: 995-999, November 2005

These slings were ultimately withdrawn from the market. All of the newer slings have the favorable qualities necessary to promote proper incorporation and integration. These qualities are set forth in the following passage excerpted from a letter to the editor that I wrote, published in *NEUROUROLOGY AND URODYNAMICS*:

*“Those slings with the most favorable biomechanical properties and greatest likelihood of biocompatibility and successful integration are either a non-synthetic sling or alternatively, an elastic, macro-pored, monofilament polypropylene sling.”*

(Siegel, A: “What to do about new age slings,” *NEUROUROLOGY AND URODYNAMICS* 25:98, 2006)

Three factors are integral to proper sling integration: *sling* factors, *patient* factors and *surgeon* factors. The gold standard sling is a piece of large-pored, elastic, monofilament polypropylene—any other synthetic can result in integration issues. Patient considerations are very important as risk factors for inferior integration include: compromised or deteriorated vaginal tissues; diabetes; patients on steroids; immune-compromised patients; radiated tissues; etc. Foremost, a well-trained, experienced surgeon should be the one doing the sling implantation.

The surgeons most skilled at this type of surgery are those who have undertaken fellowship training in female pelvic medicine and reconstructive surgery after completion of their urology or gynecology training. It is sensible to check if your surgeon is specialized, and if not, at least has significant clinical experience doing sling procedures.

It is important that the surgeon performing the sling implant is capable of taking care of any complications that may arise. Many of the problems that have occurred are not intrinsic to the sling itself, but are potentially avoidable issues that have to do with either the surgical technique used to implant the sling or to patient selection. Complications such as sling exposure do occur in a small percentage of patients, but are most often manageable.

## **Urethral Bulking Agents**

Bulking agents are alternative treatments for sphincter deficiency in which a special material is injected into the tissues around the bladder neck and urethra. This “plumps up” the bladder neck and urethra to help close the urethra, resulting in improved urinary control. The procedure is simple to perform and is generally done on an outpatient basis. Several treatments may be necessary for lasting results. Bulking materials include the following: carbon-coated beads (Durasphere); calcium hydroxylapatite (Coaptite); and silicone microparticles (Macroplastique).

# Appendix

## ***Preparation for Urodynamic Testing***

Kindly complete the *bother questionnaire*, the *symptom questionnaire* and *voiding diary* and bring them in with you to the urodynamic study. The test takes about 30 minutes. **The only preparation is taking an oral antibiotic prior to the procedure and arriving with your bladder reasonably full so that you will be able to empty your bladder into a special commode that records the urinary flow.** The entire test will be recorded on a computer, and you may wish to watch it on the screen, as it is occurring. Everything will be explained to you during the test as it is being performed.

After the evaluation has been completed and all the data stored in the computer has been examined, the results will be reviewed in detail with you. Urodynamics provides the information needed in order to initiate an appropriate treatment plan. Whether it comes down to non-surgical or surgical interventions to manage your specific problem, you can rest assured that your SUI will be addressed in the simplest and most expedient means available.

# ***Urinary Incontinence Bother Questionnaire***

## ***Circle statements relevant to you:***

1. I worry about wetting myself.
2. I feel embarrassed talking about my incontinence with others.
3. I have to watch how much I drink because of my incontinence.
4. I worry about coughing or sneezing because of my incontinence.
5. I have to be careful standing up after I've been sitting down because of my incontinence.
6. I worry about where toilets are in new places.
7. I feel depressed because of my incontinence.
8. Because of my incontinence, I do not feel free to leave my home for long periods of time.
9. Having incontinence hurts my self-esteem.
10. I feel frustrated because my incontinence prevents me from doing what I want.
11. I worry about others smelling urine on me.
12. Incontinence is always on my mind.
13. It is important for me to make frequent trips to the toilet.
14. I avoid laughing because of my incontinence.
15. I feel ashamed because of my incontinence.
16. Because of my incontinence, it is important to plan every detail of my day in advance.
17. I worry about my incontinence getting worse as I grow older.
18. I have a hard time getting a good night of sleep because of my incontinence.
19. I worry about being embarrassed or humiliated because of my incontinence.
20. I avoid hugging others because of my incontinence.
21. My incontinence makes me feel like I am not a healthy person.
22. My incontinence makes me feel helpless.
23. I get less enjoyment out of life because of my incontinence.
24. I worry about not being able to get to the toilet on time.
25. I feel like I have no control over my bladder.
26. My incontinence limits my choice of clothing.
27. I worry about having sex because of my incontinence.

***If you were to spend the rest of your life with your urinary condition just the way it is now, how would you feel about that?***

- Completely satisfied
- Mostly satisfied
- Mixed feelings; about equally satisfied and dissatisfied
- Mostly dissatisfied
- Unhappy
- Completely miserable

# Incontinence Symptom Questionnaire

**Instructions:** Please answer the following questions about your urine leakage.

1. How long have you leaked urine? \_\_\_\_\_

2. Since you began leaking urine, has the amount you leak each time:

- Increased       Decreased       Stayed the same

3. Has the number of times you have leaked urine each day, week, or month:

- Increased       Decreased       Stayed the same

4. Please place a check next to the word that best describes how often each of the following activities causes you to leak urine.

	Never	Sometimes	Often
a) Exercising, including running and participating in other high-impact sports	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
b) Sneezing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
c) Coughing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
d) Laughing	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
e) Lifting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
f) Changing position from sitting or standing up	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
g) Bending down	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
h) Reaching	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
i) Walking or rushing to the toilet	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
j) Seeing or hearing running water	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
k) Washing hands	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
l) Feeling nervous or stressed	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
m) Being out in cold weather	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
n) Unlocking the front door	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5. Do you have strong urinary urges that you cannot always control?

- Yes       No

6. Once your bladder feels full, how long can you hold your urine?

- As long as I want  
 Less than a minute  
 A few minutes  
 Cannot tell when bladder is full

7. How often do you leak urine?

- Once a week at most       2 or 3 times a week  
 About once a day       Several times a day  
 Continuously

8. When does the leakage occur?

- Mainly during the day       Mainly at night  
 Both day and night

9. Do you ever find yourself wet or damp without realizing that you've leaked urine?

- Never       Sometimes       Always

10. Do you wake up in the night to urinate?

- |   |  |
|---|--|
| <input type="checkbox"/> Never or rarely    | <input type="checkbox"/> 2-3 times per week        |
| <input type="checkbox"/> Almost every night | <input type="checkbox"/> 1 time per night          |
| <input type="checkbox"/> 2 times per night  | <input type="checkbox"/> 3 or more times per night |

11. Please indicate how much urine you usually leak.

- A small amount (leaves you slightly damp)  
 A moderate amount (1 or 2 tablespoons)  
 A large amount (more than 2 tablespoons)

12. How much does leaking urine interfere with your everyday life?

Please circle a number between 0 (not at all) and 5 (a great deal)

0    1    2    3    4    5

13. If you avoid any of the following activities because you might leak urine, please check them below.

- |  |   |
|--|---|
| <input type="checkbox"/> Exercising                  | <input type="checkbox"/> Playing sports |
| <input type="checkbox"/> Dancing                     | <input type="checkbox"/> Traveling      |
| <input type="checkbox"/> Dating                      | <input type="checkbox"/> Shopping       |
| <input type="checkbox"/> Working outside of the home | <input type="checkbox"/> Having sex     |

14. Has urine leakage stopped you from doing any other activities during the past 5-10

years? If so, please list those activities below.

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15. Please check anything listed below that has occurred when you urinate.

- Difficulty in getting urine started  
 Very slow stream or dribbling  
 Discomfort, burning or pain  
 Blood in urine  
 Feeling that your bladder did not empty completely  
 Loss of urine in sudden, large amounts  
 Stopping and starting urine stream  
 Urinate, stand up, urinate again to empty bladder  
 Lose urine as you walk away from toilet

16. Did you wet the bed as a child?

- Yes                       No

If so, until what age? \_\_\_\_\_ How often? \_\_\_\_\_

17. If you have been treated for bladder leakage, urgency, or frequency before, please check all of the treatments that you have received in the past.

- |  |  |
|--|--|
| <input type="checkbox"/> Acupuncture                               | <input type="checkbox"/> Surgery                 |
| <input type="checkbox"/> Medications                               | <input type="checkbox"/> Pelvic muscle exercises |
| <input type="checkbox"/> Electrical stimulation                    | <input type="checkbox"/> Bladder training        |
| <input type="checkbox"/> Biofeedback                               | <input type="checkbox"/> Collagen injections     |
| <input type="checkbox"/> Urethral inserts/incontinence pessaries   |  |
| <input type="checkbox"/> Other treatments? Please list them below. |  |

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18. In the chart below, please place a check next to the medications you have used or are currently using to treat incontinence, and indicate whether or not they have improved your condition.

Medication	Used (✓)	Was the medication helpful?	
Detrol <sup>®</sup> (tolterodine)	<input type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Ditropan <sup>®</sup> (oxybutynin)	<input type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Enables <sup>®</sup> (darifenacin)	<input type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Vesicare <sup>®</sup> (solifenacin)	<input type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Sanctura <sup>®</sup> (trospium)	<input type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Tofranil <sup>®</sup> (imipramine)	<input type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
DDVAP <sup>®</sup> (desmopressin)	<input type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Gelnique	<input type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No
Toviaz	<input type="checkbox"/>	<input type="checkbox"/> Yes	<input type="checkbox"/> No

19. Have you ever had to use a catheter to drain your bladder?

Yes  No

20. Please check all of the “self-help” techniques you have used to deal with urine leakage.

- Wear panty liners
- Wear sanitary napkins or incontinence pads
- Wear adult pads or briefs designed for urine control
- Wear other protective underclothes
- Put toilet paper/paper towels inside briefs
- Drink less fluids
- Go to the toilet often
- Stay near a bathroom
- Use a bedside commode or bedpan

21. Have you used any other self-help techniques? Please list them below.

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22. How often do you have a bowel movement?

- Once a day
- More than once a day
- 2-3 times a week
- Less than once a week

23. If you have had any of the problems listed below, please check them.

- Straining on more than 1 out of 4 bowel movements
- Using enemas or laxatives (not fiber or bulk) to relieve constipation more than once a month
- Diarrhea (how often? \_\_\_\_\_)
- Bloody stool
- Change in the pattern of your bowel movements over the past year
- Uncontrolled loss of stool

24. a) Are you sexually active now?

Yes  No

b) If so, do you have trouble/pain urinating after intercourse?

Yes  No

c) Do you have discomfort/pain with intercourse?

Yes  No

25. What changes would you like to see in your symptoms as a result of your treatment here?

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# Voiding Diary

For a 24-hour period, every time that you urinate, record the *time of day* and the *volume voided* by using a measuring cup calibrated in ounces. Please bring this completed diary with you at the time of your urodynamic evaluation.

TIME OF DAY	VOLUME VOIDED
Void #1	
Void #2	
Void #3	
Void #4	
Void #5	
Void #6	
Void #7	
Void #8	
Void #9	
Void #10	
Void #11	
Void #12	
Void #13	
Void #14	
Void #15	
Void #16	
Void #17	
Void #18	
Void #19	
Void #20	

# The New York Times

MAY 5, 2009

## Women Sue Over Device to Stop Urine Leaks

By RONI CARYN RABIN

It was the promise of a quick fix that appealed to Amber Suriani.

She had just turned 40 and was very fit, but whenever she went running or practiced karate — she was working on a black belt — she leaked a bit of urine.

The diagnosis was stress urinary incontinence, and her surgeon recommended a simple procedure to plug the leak by inserting a hammock made of a strip of synthetic meshlike material, called a vaginal sling, under her urethra.

“It was supposed to be a simple ‘in one day and out the next’ kind of thing,” said Ms. Suriani, now 43, who lives in a suburb of Syracuse. And so it seemed, at least at first. The surgery went smoothly, and the leakage stopped. But several months later, Ms. Suriani developed a persistent, painful and often bloody vaginal discharge.

She was convinced that she had cancer. It did not occur to her that the sling was the source of the problem until a piece of the meshlike tape started working its way through her vaginal wall.

Since then, she has had five operations, each one removing bits of the sling but not the entire thing; another operation is scheduled. She still has chronic discharge and says her sex life with her husband has been affected. She relies on Motrin to get through the day and a sleeping pad to get through the night.

“I feel like I’m never going to be the same again,” Ms. Suriani said, adding: “I’m beginning to feel like this has ruined my life. Not just ruining my life, as in ‘It will get better,’ but ruined, as in ‘I’m stuck with this for the rest of my life.’ I try to stay positive, but it’s getting harder and harder.”

Ms. Suriani's lawyer, Matthew Metz of Seattle, said she was one of dozens of women suing the maker of the vaginal sling, called ObTape.

The company, Mentor Corporation, based in Santa Barbara, Calif., and recently acquired by Johnson & Johnson, stopped selling ObTape in 2006 but says there is nothing wrong with the product, which was cleared for sale by the Food and Drug Administration.

John Q. Lewis of Cleveland, a lawyer with the firm Jones Day, which represents Mentor, said that there were risks to any surgical procedure and that doctors should have warned patients. He noted that early European studies reported low rates of complications with ObTape.

"It's very unfortunate when anyone reports a complication," Mr. Lewis said. "That being said, these are complications that are well known, that patients are warned about, and are inherent to a surgical procedure that has helped thousands and thousands of people live a better life."

He continued, "The overall benefits of the procedure and this product outweighed the potential risks."

The lawsuits raise new questions about the process by which the F.D.A. reviews new medical devices. While it "approves" drugs, it merely "clears" medical devices with minimal testing if they are deemed "substantially equivalent" to devices already in use.

The process has been criticized by the agency's scientists and in a recent Government Accountability Office report concluding that most devices on the market have never been proved safe and effective.

In ObTape's case, the chain of similarity claims can be traced back to an older product that caused so much harm it was taken off the market. That recall did not stop the F.D.A. from clearing a new generation of vaginal slings whose only claim to safety was their similarity to the flawed device.

A reverse chronology, put together with help from plaintiffs' lawyers and researchers at Public Citizen's Health Research Group, a nonprofit consumer advocacy group, illustrates the pitfalls of the process.

In 2003, Mentor asked the food and drug agency to clear ObTape for the United States market, saying there was essentially no difference between its product and two other vaginal slings already widely in use — Johnson & Johnson’s Tension Free Vaginal Tape System and American Medical Systems’ Sparc Sling System.

Those slings had been cleared earlier, based on claims that they, too, were much like earlier products — in Johnson & Johnson’s case, the Protegen sling, made by Boston Scientific. But that sling had been recalled in 1999, four years before ObTape made its appearance. At the time, the F.D.A. called the Protegen sling an “adulterated and misbranded” product.

Officials at the F.D.A. declined requests for an interview, providing only answers to e-mailed questions. Asked why the agency would clear a product based on a recalled predecessor, they replied, “Any legally marketed device can serve as a predicate for a premarket submission.”

In fact, there were significant differences between ObTape and the earlier slings, and once Mentor had cleared ObTape for marketing based on its similarity to other devices, the company promoted its unique features. It obtained a patent and emphasized to surgeons that its new design, based on a European product called Uratape, allowed for a surgical approach that reduced the risk of puncturing the bladder.

Dr. Andrew L. Siegel, a urologist in Hackensack, N.J., who now serves as an expert witness for the plaintiffs suing ObTape, was one of the first surgeons to start using the device. “I was delighted about it,” Dr. Siegel said. “It was a great innovation.”

But ObTape was different from earlier slings in another way, which became clear only later and had to do with the type of material it was made of.

Many experts say the sling was too dense — not porous enough to allow tissue and capillaries to grow through it so it is fully incorporated in the body, rather than becoming encapsulated and expelled.

Reports of adverse events linked to ObTape soon started pouring in to the F.D.A. — 266 in all, starting in 2004, many of them describing problems similar to Ms. Suriani’s complaints.

Surgeons like Dr. Siegel started publishing case reports in medical journals and reporting negative experiences with the device. Several described the “malodorous discharge” patients developed after surgery, and said the tape started extruding.

In 2006, doctors at the Virginia Mason Medical Center in Seattle reported in *The Journal of Urology* that they had stopped using ObTape after observing a 13.4 percent rate of vaginal extrusion.

But Mr. Lewis, the lawyer for Mentor, said the material was tested by company engineers as part of an extensive premarketing process. The 266 reported adverse events represent a small fraction of the 16,000 ObTape slings implanted in the United States, he added, and he pointed to studies finding high complication rates for other slings.

Indeed, the F.D.A. alerted health care providers last year that it had received more than 1,000 reports of complications from nine surgical mesh manufacturers about devices for incontinence and organ prolapse. “Physicians should inform patients about the potential for serious complications and their effect on quality of life, including pain during sexual intercourse, scarring” and other complications, the notice said.

Mr. Lewis said clinical data from Europe supported the ObTape sling’s safety and efficacy, and suggested that American surgeons’ lack of familiarity with the new surgical technique was responsible for any problems. He noted that in California, a jury recently rejected a claim of negligence against Mentor by Lisa Ann Seeno, now 51, who was hospitalized with an abscess shortly after the device was implanted. (She has requested a new trial.)

Another plaintiff, Suzanne Crews, 69, of Washington State, said she was suing Mentor to spread the word about the risks of trying to repair what was, in hindsight, a problem she could have lived with — minor leaking when she coughed too hard or laughed too loud.

Ms. Crews said she has undergone four operations to remove portions of the tape.

“I’m not like I’m supposed to be,” she said. “I just really would be happier if more and more people knew about the problem, and didn’t just sit back and say, ‘Oh my gosh, I don’t know what’s happening.’”

## **About the Author**

Andrew Siegel received his medical degree from the Chicago Medical School, where he was elected to the AOA Honor Medical Society. He completed a residency in general surgery at the North Shore University Hospital, an affiliate of Cornell University School of Medicine and pursued residency training in urology at the University Of Pennsylvania School Of Medicine. Thereafter, he did fellowship training in incontinence, voiding dysfunction and female pelvic reconstructive surgery at the UCLA School of Medicine prior to joining Bergen Urological Associates in Hackensack, New Jersey, where he has been in practice since 1988.

Dr. Siegel is a diplomate of the American Board of Urology and a member of the American Urological Association, the New York Section of the American Urological Association, the Society for Urodynamics and Female Urology, the International Continence Society and the American Uro-Gynecologic Society. He has authored chapters in textbooks including *Current Operative Urology* and *Interstitial Cystitis*, and has published articles in numerous journals including: *Urology*, *Journal of Urology*, *Urology Clinics of North America*, *Postgraduate Medicine*, *Radiotherapy and Oncology*, *Neuro-Urology and Urodynamics*, and *International Urogynecology Journal*.

He has presented papers at professional meetings for many medical societies including the Philadelphia Urological Society, the American Academy of Pediatrics, and the American Urological Association, both nationally and internationally. Dr. Siegel serves as a Clinical Assistant Professor of Urology at the University of Medicine and Dentistry of New Jersey, actively involved in medical student and resident education.

Dr. Siegel is an avid believer in remaining young, healthy and fit through the practice of exercise, nutritional conscientiousness and intelligent lifestyle choices. He is the author of *FINDING YOUR OWN FOUNTAIN OF YOUTH: The Essential Guide to Maximizing Health, Wellness, Fitness and Longevity*, published in 2008. His second book, *PROMISCUOUS EATING— Understanding and Ending Our Self-Destructive Relationship with Food*, was published in 2011. He is passionate and enthusiastic about public health issues and wellness advocacy and his goal is educating the community about healthy lifestyles and preventative measures that help ensure maximum fitness, nutrition, disease avoidance and longevity.

Dr. Siegel resides in Ridgewood, New Jersey, with his wife, daughter and English Springer Spaniel. His son graduated New York University Film School in 2006 and daughter attends Tulane University. Dr. Siegel is an avid reader and writer and enjoys photography, tennis, cycling, golf, yoga, Pilates and fitness training.

### ***My Typical Patient with Stress Incontinence***

*"I am a 49-year-old woman who experiences incontinence when I sneeze, run or jump. This has been happening for the past 2 years or so, gradually worsening. I am very active physically and it gets in the way of my participation in sports. It also happens with walking downhill, coughing, laughing and even with sex. I use Poise pads to protect myself."*

Medical history: tonsillectomy; removal of ganglion cyst; cervical polyp removal; 2 vaginal deliveries

Pelvic exam: no atrophy; good tone; 4/5 PFM strength; urethral mobility: -10 degrees resting +80 degrees straining; no cystocele or rectocele; well-supported uterus; no pelvic masses

Catheterized post-void residual volume: 15 ml

Urinalysis, cytology and culture: normal

24 hour voiding diary: 9 voids, range 25-375 ml; total 1550 ml; average 170 ml

Marshall test: SUI with strain aborted with gentle support

Urodynamics: normal sensation, capacity, compliance; no bladder over-activity; excellent contractility; straining and cough leak point pressures: 100cm

Cystoscopy: hyper-mobile urethra; otherwise normal

Assessment: SUI due to urethral hyper-mobility

Treatment: Sling procedure performed at ambulatory center

Follow-up: Voiding well; no further SUI; Has returned to all activities, including kick-boxing

