

1 in 3 women experience bladder leakage in their lifetime.¹

Do You?



*Reclaim
your life*

Your Resource Guide to Stress Urinary Incontinence (SUI)

Urinary Incontinence

Bladder leakage, also known as **urinary incontinence** is the loss of bladder control or involuntary loss of urine.





40%

In a clinical study of 131 women more than 40% reported urinary incontinence affected their work or other activities.²

There are several types of incontinence.

You may experience symptoms of more than one type:

STRESS INCONTINENCE

Leaking urine during physical activity like laughing, lifting, exercising, sneezing and coughing

URGE INCONTINENCE

Experiencing a sudden, intense need to urinate — even if you just went — but being unable to hold it long enough to reach a bathroom

MIXED INCONTINENCE

A combination of stress and urge incontinence

OVERFLOW INCONTINENCE

Leaking urine because your bladder never completely empties

FUNCTIONAL INCONTINENCE

A physical or mental impairment that stops you from getting to the toilet on time

What Causes Incontinence?

You may have wondered why your bladder is leaking urine. In women with stress urinary incontinence, pelvic muscles and tissue have caused the bladder and urethra (the canal that carries urine from the bladder) to relax from their normal positions.

As a result, sudden abdominal pressure from coughing, sneezing, laughing or simple lifting can cause accidental loss of urine.

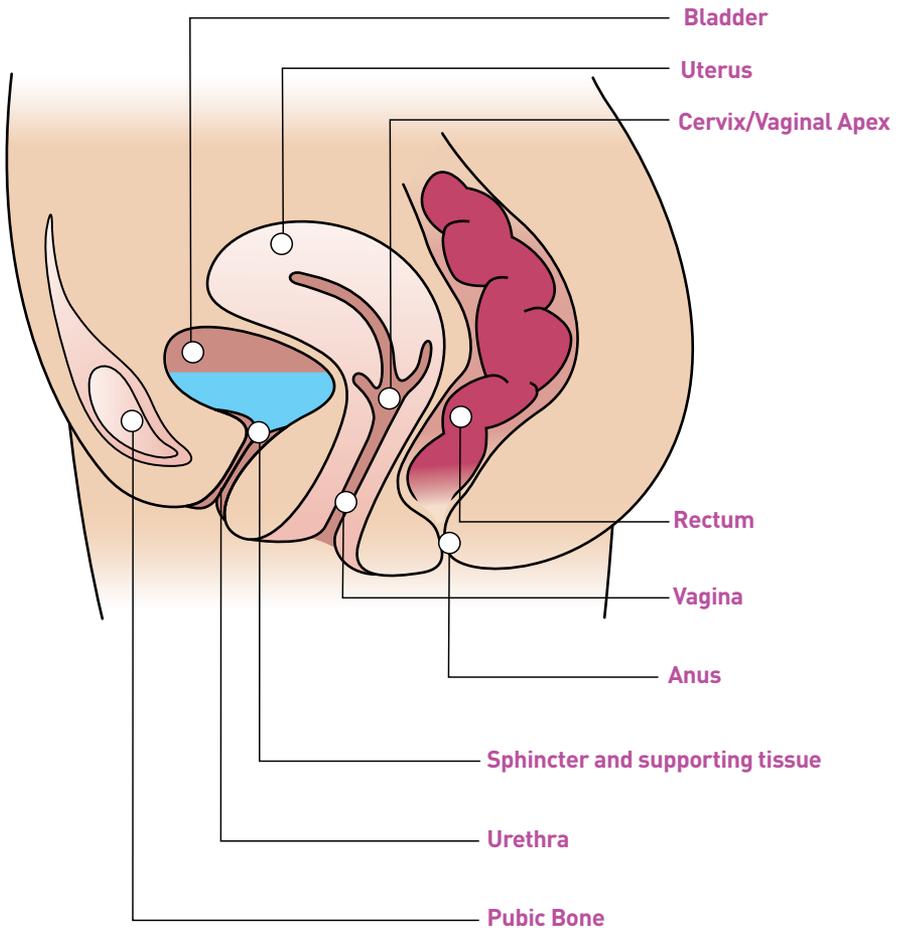
Muscles and tissue often are weakened by:^{3,4}

- Age
- Pregnancy
- Vaginal delivery
- Obesity/BMI
- Hysterectomy
- Physical activity
- Smoking
- Family history
- Diet
- Other medical conditions

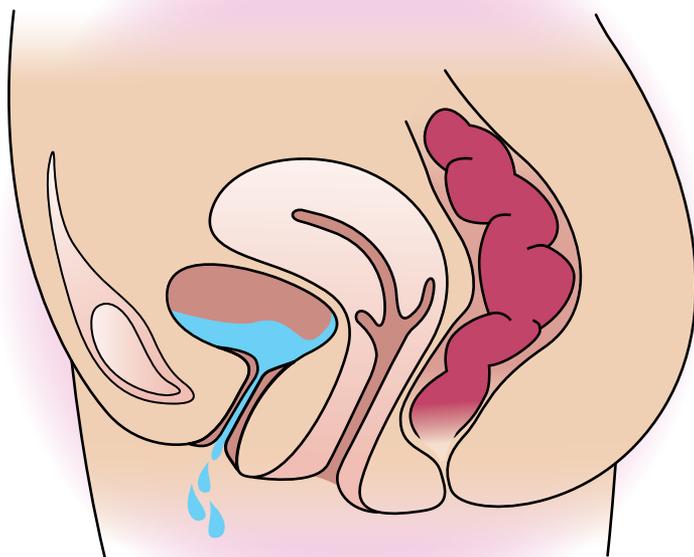


When sudden pressure is placed on your bladder, urine may escape past those weakened muscles, resulting in urinary incontinence.

If the muscles that hold your bladder in place (*pelvic floor muscles*) or the muscles that keep your urethra closed (*sphincter muscles*) are not working properly, the muscles may be unable to handle pressure put on the bladder from coughing, sneezing or laughing.⁵



Your Body with SUI



If the pelvic floor muscles or sphincter muscles are weakened or damaged, the urethra may relax from its normal position and not close completely. The result is urinary incontinence—urine escapes past the weakened muscles whenever pressure is placed on your bladder.

There are Potential Solutions for Stress Urinary Incontinence

There are treatment options for Stress Urinary Incontinence.⁶ A urethral sling is an effective treatment option.⁷

From time to time, women with SUI may rely on sanitary or incontinence pads or panty liners to help with accidental urine leakage.¹

Some patients may benefit from pelvic floor muscles training, bladder training or prompted voiding. Currently, no medications are approved to treat SUI.⁶

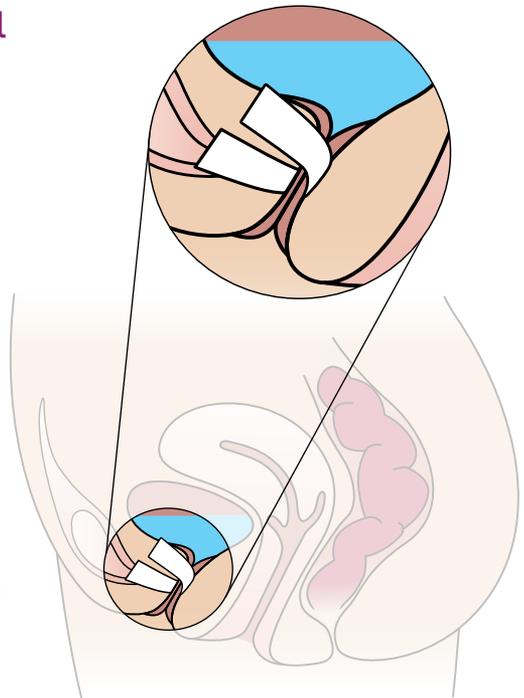
Urethral Support Sling

A urethral support sling is a minimally invasive procedure that can help correct incontinence with a soft material called “mesh” that supports the urethra.⁸

The sling functions much like a hammock on which your urethra rests and helps keep it closed.⁸

Mesh has been used to treat incontinence since 1968, and has been used in millions of patients worldwide.^{9,10}

Your body after sling repair



A urethral support sling made of soft synthetic mesh is placed under urethra to provide support and help it close more tightly

1 million

More than **1 million women** have received AMS™ slings.⁹

A Minimally Invasive Procedure

The type of urethral support sling your doctor chooses will affect certain aspects of the procedure.

Placement of a MiniArc™ Single Incision Sling, a Monarc™ Subfascial Hammock, a SPARC™ Self-Fixating Sling System or a RetroArc™ Retropubic Sling System is a minimally invasive procedure performed on an outpatient basis. Local, regional or general anesthesia can be used, depending on what you and your doctor choose.

In general, placing a sling involves the following steps:¹¹⁻¹⁴

- Small incisions may be made in the vagina, the abdomen or where the top of your thigh meets your pelvic area.
- The mesh is inserted through an incision and placed under the urethra (the canal that carries urine from the bladder) to form a cradle of support.
- The soft mesh sling is made of a narrow strip of loosely knitted strands of polypropylene. This material is light and porous so your body tissues can grow into it to provide support.
- The mesh is self-fixating and anchors itself to tissue and muscle in the space surrounding the urethra.
- Once the procedure is complete, the sling functions like a hammock on which your urethra rests and helps keep it closed.

Post-Operative Care

Follow your physician's instructions after your surgery. Below are some general guidelines.

- You should not do any heavy lifting, exercise, or have intercourse for a minimum of 4 weeks.
- You can return to other normal daily activities at your physician's discretion, often in 1 to 2 weeks.
- You should call your physician immediately if you have painful urination (dysuria), bleeding, severe pain or other problems occur.



Less than
50%

Less than 50% of women
with urinary incontinence
have discussed their
symptoms with a health
care provider.¹⁵

Risks

As with most surgical procedures, potential adverse reactions may occur. Some potential adverse reactions to surgical procedures to correct urinary incontinence include:

- Pain/Discomfort/Irritation
- Inflammation (redness, heat, pain, or swelling resulting from surgery)
- Infection
- Fistula formation (a hole/passage that develops between organs or anatomic structures that is repaired by surgery)
- Foreign body (allergic) reaction to mesh implant
- Adhesion formation (scar tissue)
- Urinary incontinence (involuntary leaking of urine)
- Urinary retention/obstruction (involuntary storage of urine/blockage of urine flow)
- Voiding dysfunction (difficulty with urination or bowel movements)
- Contracture (mesh shortening due to scar tissue)
- Wound dehiscence (opening of the incision after surgery)
- Nerve damage
- Perforation (or tearing) of vessels, nerves, bladder, ureter, colon, and other pelvic floor structures
- Hematoma (pooling of blood beneath the skin)
- Dyspareunia (pain during intercourse)
- Mesh erosion (presence of suture or mesh material within the organs surrounding the vagina)
- Mesh extrusion (presence of suture or mesh material within the vagina)

NOTE: Some of these adverse reactions are specific to procedures involving mesh repair (e.g. mesh extrusion).

ADDITIONAL INFORMATION on surgical mesh for Stress Urinary Incontinence (SUI) can be found at: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm>

Success Rate

Studies show that most patients are continent following the sling procedure and can resume normal, non-strenuous activities — including returning to work — within a few days.¹⁶

85-94%^{7,16-18}

Clinical data on AMS slings shows:^{7,16-18}

*In a MiniArc Single-Incision Sling study 90% of patients had a negative cough stress test and 85% had a 1-hour pad weight test less than 1 gm at 1 year.

*In a MiniArc Single-Incision Sling study 94% of patients had significant improvement in pad use at 1 year.

*In a Monarc Subfascial Hammock study 90% of patients had a negative cough stress test and improvement in pad use at 1 year follow-up.

*In a SPARC Self-Fixating Sling System study 88% of patients had significantly reduced symptoms according to the Kings Health Questionnaire at 1 year.



Is it Right for You?

Sling procedures require surgery and are not recommended for everyone. Slings cannot be implanted in patients who are pregnant. The Risks and benefits of sling procedures should be carefully considered if you have uncorrected bleeding disorders (blood coagulation disorders), a compromised immune system, poor kidney function (renal insufficiency) or blockage of the urinary tract (upper urinary tract obstruction).

Inflammation and irritation may occur after surgery, and future pregnancies can cause you to become incontinent again.

You should talk with your doctor about benefits and risks before moving forward with any treatment option.

If you are ready to talk with your doctor about urethral support slings, you can start with these questions:

- Would a urethral support sling help correct my incontinence?
- What are the benefits and risks of sling procedures?
- How many procedures have you done?
- Tell me about the results you've seen with the MiniArc™ Single Incision Sling, Monarc™ Subfascial Hammock, SPARC™ Self-Fixating Sling System and RetroArc™ Retropubic Sling System.
- Tell me about the procedure and the recovery period.
- When can I resume sexual intercourse?
- How long will a sling last?
- Is the sling procedure covered under my insurance plan?



AMS Family of Products

MINI Arc™
Single-Incision Sling System

monarc™
subfascial hammock

SPARC™
SELF-FIXATING SLING SYSTEM

RetroArc™
Retropubic Sling System

For more information and a list of frequently asked questions visit **www.PelvicHealthSource.com**

1. American Urological Association Foundation, Inc. 2011. Frequently Asked Questions About Stress Urinary Incontinence. Retrieved from http://www.urologyhealth.org/SUI/_documents/_pdf/AUAF_SUI_FAQs.pdf 2. Margalith I, Gillon G, Gordon D. Urinary incontinence in women under 65: quality of life, stress related to incontinence and patterns of seeking health care. *Quality of life research* Oct 2004 v. 13(8) pp. 1381-90. 3. Liou LS, Zieve D. Stress incontinence. MedlinePlus Medical Encyclopedia's Website. Available at: <http://www.nlm.nih.gov/medlineplus/ency/article/000891.htm> Accessed January 7, 2012. 4. Reynolds WS, Dmochowski RR, Penson DF. Epidemiology of stress urinary incontinence in women. *Curr Urol Rep*. 2011; 12:370-376 5. What I need to know about Bladder Control for Women. National Kidney & Urologic Disease Information Clearinghouse (NKUDIC)'s Website. Available at: http://kidney.niddk.nih.gov/KUDiseases/pubs/bcw_ez/index.aspx Accessed January 7, 2012. 6. Holroyd-Leduc JM, Straus SE. Management of urinary incontinence in women: clinical applications. *JAMA*. 2004 Feb 25;291(8):996-9 7. Pickens RB, Klein FA, Mobley JD 3rd, White WM. Single incision mid-urethral sling for treatment of female stress urinary incontinence. *Urology*. 2011;77(2):321-4. 8. Mayo Clinic Staff. Urinary incontinence. Treatment and Drugs. Mayo Clinic's Website. Available at: <http://www.mayoclinic.com/health/urinary-incontinence/DS00404/DSECTION=treatments-and-drugs>. Accessed January 7, 2012. 9. References available upon request. Data as of June 2012. 10. Moir, JC. The gauze-hammock operation. *J Obstet Gynecol Br Common* 1968;75(1):1-9. 11. Monarc Instructions for Use. Minnetonka, MN: American Medical Systems, Inc; 2011. 12. SPARC Instructions for Use. Minnetonka, MN: American Medical Systems, Inc; 2009. 13. MiniArc Instructions for Use. Minnetonka, MN: American Medical Systems, Inc; 2011. 14. RetroArc Retropubic Sling System Instructions for Use. Minnetonka, MN: American Medical Systems, Inc. 2013 15. Kinchen KS, Burgio K, Diokno AC, Fultz NH, Bump R, Obenchain R. Factors associated with women's decisions to seek treatment for urinary incontinence. *J Womens Health (Larchmt)*. 2003;12(7):687-98 16. Kennelly MJ, Moore R, Nguyen JN, Lukban JC, Siegel S. Prospective evaluation of a single incision sling for stress urinary incontinence. *J Urol*. 2010;184(2):604-9 17. Liapis A, Bakas P, Creatas G. Monarc vsTVT-O for the treatment of primary stress incontinence: a randomized study. *Int Urogynecol JPelvic Floor Dysfunct*. 2008;19(2):185-90. 18. Siddiqui K, Raj H., Flynn, R.J., Grainger R, Thornhill J. A. Minimally invasive treatment of female stress urinary incontinence: 100 cases using SPARC sling. *Ir J Med Sci*. 2008 Mar. 177(1):39-42.



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AMSUS/FC-00217(1)/February 2014 www.AmericanMedicalSystems.com 1-800-328-3881

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