FEMALE URINARY INCONTINENCE

A Patient Guide
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Let’s talk about it.

Living with urinary incontinence (UI) can be challenging – it can interfere with your activities, intrude on your social life, and be just plain inconvenient and embarrassing.

Maybe you’ve heard other women talk about it — and now it’s happening to you.

Millions of other women who have experienced UI understand what you’re going through and have found a solution that works — and you can, too. This guide is designed to help you learn more about UI and how you can get back to your active lifestyle again. It’s your life and you can take it back from urinary incontinence.

Review this guide to learn more and then talk with your doctor.
Urinary Incontinence (UI): It’s common and treatable

Urinary incontinence (UI) is the involuntary loss of urine from the body. It can be frequent or occasional, a few dribbles to a total loss of control. It can be triggered by certain activities, or the result of certain risk factors. Most importantly, it can be treated!

Approximately 18 million women in the U.S. suffer from urinary incontinence. 1 in 4 women over age 18

80% of those affected can be cured or improved
2x more common in women than men\textsuperscript{6}

10% of adult women report weekly leakage\textsuperscript{3}

25-45% of adult women report occasional leakage\textsuperscript{3}

\textasciitilde6.5 years the average time women will wait to talk to their doctor about their UI\textsuperscript{5}
The Urinary System and How It Works

Bladder fills from the kidney.

Full bladder contracts and squeezes the urinary sphincter.

Empty bladder relaxes, stops contracting, and urinary sphincter closes.
What goes wrong with UI?¹

Urinary incontinence may be triggered by activities that cause extra pressure on the bladder like lifting, running, coughing, or even laughing.

It may also occur if the bladder muscles suddenly contract and the sphincter muscles aren’t strong enough to prevent urine from leaking.
Potential Causes of UI³

Risk of UI gradually increases each decade of life. However, age itself may not be the cause but rather other factors that are more likely present with increasing age:

- Obesity
- Childbirth
- Pelvic surgery
- Menopausal replacement therapy

Other Causes of UI³

- Co-morbidities such as diabetes, urinary tract infections, depression and heart disease
- Socioeconomic status
- High impact-exercise
- Medications such as estrogen replacement therapy
- Caffeine or alcohol consumption
Types of Urinary Incontinence and Their Symptoms

**Stress**
Bladder leaks during exercise, coughing, sneezing, laughing, or any body movement that puts pressure (stress) on the bladder.

**Urge**
Involves the sudden and unstoppable loss of urine – the sudden urge to go.

**Mixed**
Combination of stress incontinence (including muscle and sphincter related issues), and urge incontinence.

**Overactive Bladder (OAB)**
The urgent need to pass urine. Can result in urinating more than eight times a day, or more than once at night (urinary frequency) as well as a strong and sudden desire to urinate (urinary urgency).
Are You Showing Signs of Incontinence?

Below are some simple questions to help start a dialogue with your doctor:

Do you leak urine unexpectedly?
○ Yes  ○ No

What is the severity of leakage?
○ Mild (a few drops)
○ Moderate (wet undergarments)
○ Severe (wet clothing)

Do you leak urine when you:
○ Cough?  ○ Sneeze?  ○ Laugh?
○ Bend?  ○ Lift?
○ Change positions? (i.e. sitting or laying to standing)
○ Engage in sexual intercourse?

Do you leak urine continuously during the day?
○ Yes  ○ No

Do you leak urine while sleeping?
○ Yes  ○ No

Has urine leakage caused you to change your lifestyle?
○ Yes  ○ No

If yes, how has your lifestyle changed?
○ Limiting fluids  ○ Staying home
○ Limiting clothing to dark clothes
○ Stop exercising  ○ Other

If you answered yes to any of these questions incontinence may be preventing you from enjoying your life. Speak to your doctor to find the most effective treatment option for you.
Treatment Options:

**Urge Incontinence**

Non-Surgical
- Protective undergarments (pads)\(^7\)
- Medications\(^8\)
- Botox bladder injection\(^8\)

Surgical
- Implantable and non-implantable neuro-stimulation\(^8\)

**Stress Incontinence\(^4\)**

Non-Surgical
- Drinking less fluid
- Limiting caffeine
- Stopping smoking
- Losing weight
- Kegel exercises
- Physical therapy and Biofeedback
- Pessary

Surgical\(^1\)
- **Sling** – A piece of strong material (mesh) is placed beneath the urethra as a supporting “hammock” that corrects the poor anatomic support of the urethra and may additionally provide a degree of compression to the urethra.
Coloplast Slings

Coloplast offers various sling types, including the single-incision Altis® sling. These slings are made from polypropylene mesh. The combination of sling and tissue ingrowth under the urethra becomes the new substructure for urethral support.

Types of Sling Procedures for Stress Incontinence

There are several different surgical approaches to placing the sling. Your doctor will discuss with you the differences and why one type of procedure might be more appropriate for you.
FDA Information

The FDA has made a commitment to inform the public about urogynecologic surgical mesh for stress urinary incontinence (SUI) and maintains information for patients about SUI, use of surgical mesh for repair of SUI, and recommendations regarding SUI surgery on its website. This information can be accessed electronically by visiting the following webpage:

Recommendations Before Surgery:

Ask your surgeon about all SUI treatment options, including non-surgical options and surgical options that do and do not use mesh slings. It is important for you to understand why your surgeon may be recommending a particular treatment option to treat your SUI.

Any surgery for SUI may put you at risk for complications, including additional surgery. One complication that may occur when mesh slings are used is vaginal mesh erosion, which could require additional surgery to resolve.

If mesh erosion occurs through the vaginal tissue, it is possible that men may experience penile irritation and/or pain during sexual intercourse.

Ask your surgeon the following questions before you decide to have SUI surgery:

• What surgical or non-surgical treatment options are available and what do you recommend to treat my SUI?
• Have you had specialized training in the surgical treatment of SUI, and if so, what type of training have you had with this particular product and/or procedure?
• What can I expect after surgery and what is the recovery time?
• If I also have pelvic organ prolapse, will that change how you treat my SUI?

• What if the surgery doesn’t correct my problem?

• Which side effects should I report to you after the surgery?

• Are you planning to use a mesh sling in my surgery? If so:
  - How often have you performed this surgery using this particular product? What results have your other patients had with this product?
  - What are the pros and cons of using a mesh sling in my particular case? How likely is it that my repair could be successfully performed without using a mesh sling?
  - Are recovery times different for mesh sling surgery compared to non-mesh surgery?
  - Will my partner be able to feel the mesh sling during sexual intercourse?
  - If I have a complication related to the mesh sling, how likely is it that the complication can be resolved? Will you treat it or will I be referred to a specialist experienced with mesh sling complications?
  - Is there patient information that comes with the product, and can I have a copy?
Recommendations After Surgery:

- Physical strain, sexual intercourse and heavy lifting should be avoided for six weeks after surgery, but the patient may resume other normal activities after two weeks or at the physician’s discretion.
- Patients should contact physician to report any bleeding, pain, abnormal vaginal discharge or sign of infection occurring at any time.
- If infection occurs, partial or full sling removal or revision may be necessary, at the physician’s discretion.
General Risks Associated with Surgery for Stress Urinary Incontinence (SUI)\textsuperscript{4}

- Injury to the bladder, bowel, blood vessels, or nerves
- Bleeding
- Infection of the urinary tract or wound infections
- Urinary problems after the procedure (difficulty urinating or urgency symptoms)
- Problems related to the anesthesia used

Benefits and Risks of Sling Surgery\textsuperscript{4}

Benefits

- Short surgery time
- Outpatient procedure
- Recovery time generally is quicker than with other procedures for SUI

Risks

- Mesh erosion
- Infection
- Long-term pain
- Injury to the bladder or other pelvic organs by the instruments used to place the midurethral sling
Insurance Information

Most insurance plans, including Medicare, cover these procedures. Consult your insurance carrier to find out the specific criteria for coverage. The reimbursement specialist at your physician’s office may also be able to help you with this.

Take the Next Step

Visit PelvicHealthID.com to review treatment options and find a physician who specializes in treating female urinary incontinence.
Bring this brochure and the completed diary when meeting with your physician.
Voiding Diary
The voiding diary on the following pages is an important tool to help you and your physician better identify your condition and choose the best treatment for you. Please complete it as accurately as possible for four days (day and night).

How to complete:

• Each day, begin recording upon rising in the morning and continue for a full 24 hours.

• List all fluid intake.

• List each time you go to the bathroom to urinate, and record the amount of urine in ounces (any container can be used to measure output—but be consistent each time). If unable to measure, list as small, medium or large amount.

• In the “Leakage amount” column, write a 1, 2 or 3 to record the volume of leakage.

• If you changed a pad or any protective garments, mark that column with an “X”.

• In the “Activity” column, write down what you were doing when the leakage occurred. For example: coughing, sneezing, laughing, walking, sleeping, etc.
## Voiding Diary – Day 1

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<th>Time (A.M.)</th>
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Check with your Physician on:

- the warnings, precautions and risks associated with the use of this mesh sling.
- which could compromise implant or implant placement, and sensitivity/allergy to polypropylene.
- fistula, diverticulum), intraoperative urethral injury, any condition, including known or suspected pelvic pathology, infection in operative field, taking blood thinning medication (anti-coagulant therapy), abnormal urethra (e.g., fistula, diverticulum), intraoperative urethral injury, any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement, and sensitivity/allergy to polypropylene.

The Altis Single Incision Sling System is indicated for the treatment of female stress urinary incontinence (SUI) resulting from the urethra not closing properly (urethral hypermobility) and/or weakness of the urethral sphincter (intrinsic sphincter deficiency (ISD)).

The Altis Single Incision Sling System is not for females who have the following: are pregnant or have desire for future pregnancy, potential for further growth (e.g., adolescents), known active urinary tract infection and/or infection in operative field, taking blood thinning medication (anti-coagulant therapy), abnormal urethra (e.g., fistula, diverticulum), intraoperative urethral injury, any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement, and sensitivity/allergy to polypropylene.

Check with your Physician on:

- alternative incontinence treatments that may be appropriate
- the reason for choosing a mesh sling procedure
- the postoperative risks and potential complications of transvaginal mesh sling surgery
- the mesh sling to be implanted is a permanent implant
- some complications associated with the implanted mesh sling may require additional surgery; repeat surgery may not resolve these complications
- serious adverse tissue responses or infection may require removal of parts of the mesh sling, or the entire mesh sling, and complete removal of the mesh sling may not always be possible
- individuals who have varying degrees of collagen laydown that may result in scarring
- certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events, as with all surgical procedures

You should consider the risks and benefits of the Altis Single Incision Sling System. Any future pregnancy could negate the benefits of this mesh sling surgical procedure.

You should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

A mesh sling is implanted inside the vagina to support the urethra. The operation to place a mesh sling is considered major surgery.

A mesh sling procedure is a surgical solution that has risks such as: mesh extrusion, pelvic/urogenital pain, groin pain, hip pain, urinary retention, bleeding, new onset (de novo) urgency, delayed wound healing, painful intercourse (dyspareunia), inflammation, nausea, overactive bladder, pain, pelvic hematoma, reaction to antibiotic, slight discomfort upon return to work, urinary tract infection, urine stream decreased, and voiding dysfunction.

Additional potential complications include, but are not limited to: abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemmorhage or hematoma, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh sling into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, necrosis, new onset (de novo) and/or worsening painful intercourse (dyspareunia), neuromuscular symptoms (acute or chronic), pain, partner pain (acute or chronic) and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., muscles, nerves, vessels), structures, or organs (e.g., bone, bladder, urethra, ureters, vagina), seroma (pocket of fluid build-up), sling migration, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., painful urination (dysuria), urinary retention, incomplete emptying, straining, positional voiding, weak stream), granulation tissue formation, palpable mesh (patient and/or partner), sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring or tightening.

The occurrence of these events may require one or more revision surgeries, including removal of the mesh sling.

Complete removal of the mesh sling may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh sling explantation.

This treatment is prescribed by your physician. Discuss the treatment options with your physician to understand the risks and benefits of the various options to determine if a mesh sling is right for you.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.
Feel confident again. You have options and you can take back control.

References

2. Statistics from the National Association for Continence April 28, 2013.
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1-800-258-3476

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