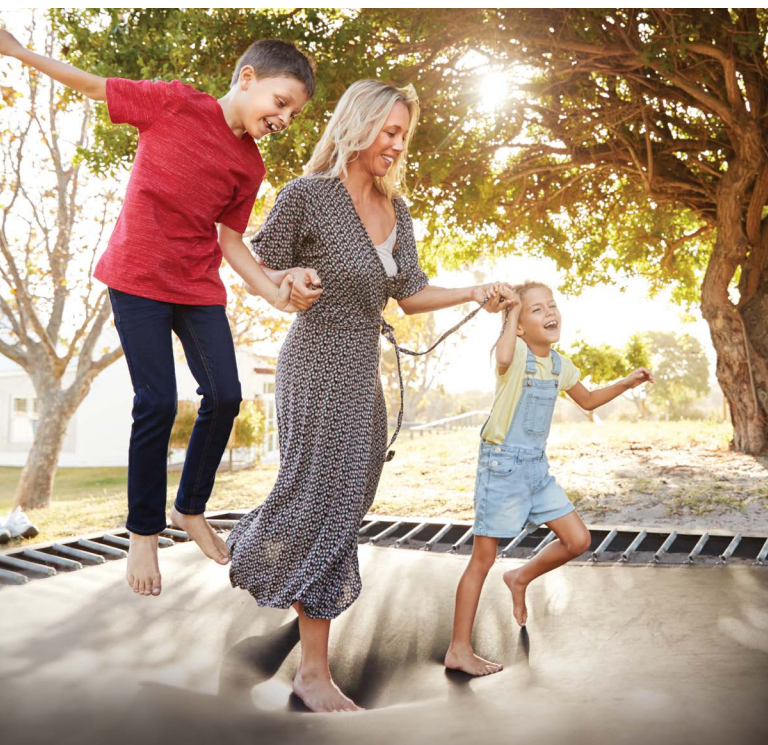


Relief from leaks is possible

Female Stress Urinary
Incontinence (SUI)

A Patient Guide



Coloplast

78 million

women in the U.S. have
Urinary Incontinence (UI)¹



68.8%

of women with UI suffer
from either Stress Urinary
Incontinence (SUI) or Mixed
Urinary Incontinence (MUI)*

*MUI is a combination of SUI and Overactive Bladder (OAB)
– definitions are on pages 8-9.



If you're experiencing urine leakage when you laugh, cough, exercise or sneeze – you might have **Stress Urinary Incontinence (SUI)**.

You're not alone

Keep reading to find out more about SUI, the causes, the treatment options, and how to find a specialist.

Relief from leaks is possible.



Find your path to incontinence relief

No two people walk the same path to a diagnosis or a solution. Every woman's experience with stress urinary incontinence (SUI) is different, and they may reach these steps at different paces and during different stages in their lives.

Do I have Stress Urinary Incontinence?

Page 6

- How does the bladder work?
- Types of urinary incontinence
- Symptoms and causes

What are my treatment options?

Page 12

- Non-surgical treatment options
- Surgical solutions - Altis®
- How Altis® works

What to expect

Page 16

- Talking to a doctor
- Questions to ask
- Insurance
- Before surgery
- During surgery
- Healing and recovery

Patient stories

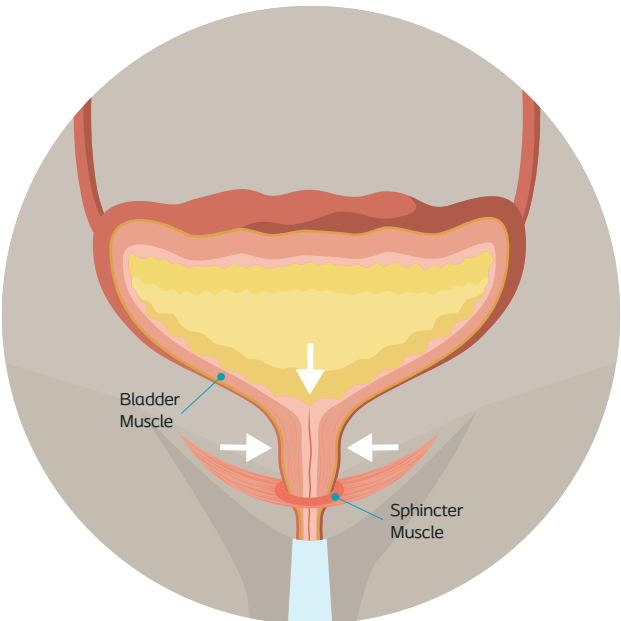
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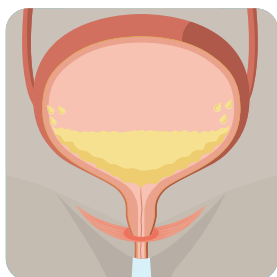
How does the bladder work?

Before we jump into how a bladder can begin to leak, let's discover how it functions properly.

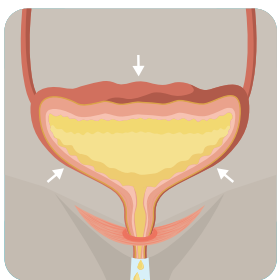
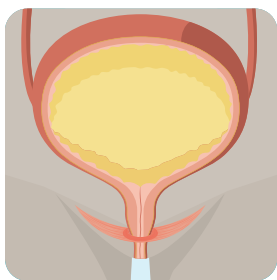
Urinary function starts with your brain and spinal cord, which work together to direct the urinary system.

When your urinary system is functioning normally, you can control when to hold and release urine. When your bladder becomes full, it sends a signal to your brain, which in turn sends a message to the bladder to release urine into the urethra. The urethral sphincter muscle, which surrounds the urethra, opens and closes the bladder neck – it will contract to temporarily hold urine, or release itself to allow urine to leave your body through the urethra.

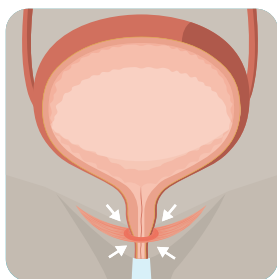




Bladder fills from the kidneys



Full bladder contracts/squeezes,
urinary sphincter opens, and
urine exits the body



Empty bladder relaxes, stops contracting
and urinary sphincter closes

Types of urinary incontinence

Women often show symptoms of more than one type of urine leakage, so it is important to seek a specialist to ensure you receive the correct diagnosis and find the treatment that is right for you.

Stress urinary incontinence² (SUI)

Stress urinary incontinence, also known as SUI, is a type of bladder leakage where urine leaks out of the bladder when stress or pressure is applied to the bladder when you run, jump, cough, sneeze, laugh, etc. The urine leaks out even if you do not feel the urge to go to the bathroom. It can be a small amount or a large amount depending on the severity of the incontinence.²

The word “stress” does not relate to the emotional toll associated with the condition. This word refers to the physical “stress” put on the bladder by activities like laughing or coughing.

SUI occurs more frequently among women, especially those who have given birth.

Overactive bladder² (OAB)

Overactive bladder, also known as urge incontinence or OAB, occurs when you feel a strong, urgent need to urinate even when your bladder isn’t full. OAB can result in urinating with excessive frequency. This condition occurs at similar rates in men and women.



What causes **stress urinary incontinence**?



Mixed incontinence² (MUI)

This condition is a combination of both SUI and OAB, where the individual experiences both stress and urge symptoms, which can be challenging to navigate in day-to-day life.

There are several solutions to help manage the symptoms associated with each type of urine leakage. But not all solutions are long-lasting. When it comes to SUI, there are surgical options that can provide a long-term solution and help you get back to regular activities.

Do I have stress urinary incontinence?

Symptoms of incontinence

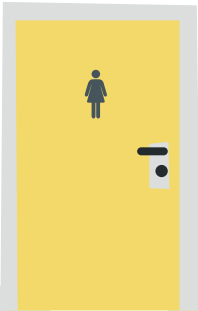
The muscles in your urethra work like a valve, opening and closing as needed to let urine out. But with stress urinary incontinence, also called SUI, the pelvic muscles that normally support the bladder and the urethra are weakened.

When this happens, urine leaks out of the bladder and can leave you feeling embarrassed, frustrated and unsure of what is happening to you.

Symptoms of stress urinary incontinence

Do you leak during any of the following activities?:

- Laughing
- Coughing
- Sneezing
- Heavy lifting
- Physical activity
- Sex



If you can say “yes” to one or more, you should talk to a doctor who is familiar with SUI and discuss a more permanent solution for treating urine leakage.



Find an
SUI specialist.

<https://www.femalepelvicsolutions.com/sui/find-a-sui-specialist/>

Causes of incontinence

Incontinence, also known as urine leakage or bladder leakage, can be caused by any number of factors. It can develop slowly or occur as the result of a specific life event.

Stress urinary incontinence (SUI) occurs when there is weakening of the muscles that support the urethra or control the release of urine. SUI does not have a connection to emotional stress.²

Some causes of SUI:

- Genetics
- Pregnancy and childbirth
- Menopause
- Pelvic floor disorders
- Previous pelvic surgeries
- Lifestyle



What are my treatment options?

Non-surgical treatment options

Maybe you've tried some of these non-surgical options.

- **Protective undergarments** - Pads/diapers
- **Lifestyle changes** (limiting physical activities, limiting caffeine, losing weight, drinking less fluids, quitting smoking)
- **Kegel exercises** or pelvic floor therapy
- **Biofeedback** therapy

Avoiding and covering up leaks only adds to the burden of having SUI in the first place. **A lasting solution, with minimal downtime, can help relieve the added burden of constantly hiding your SUI symptoms.**

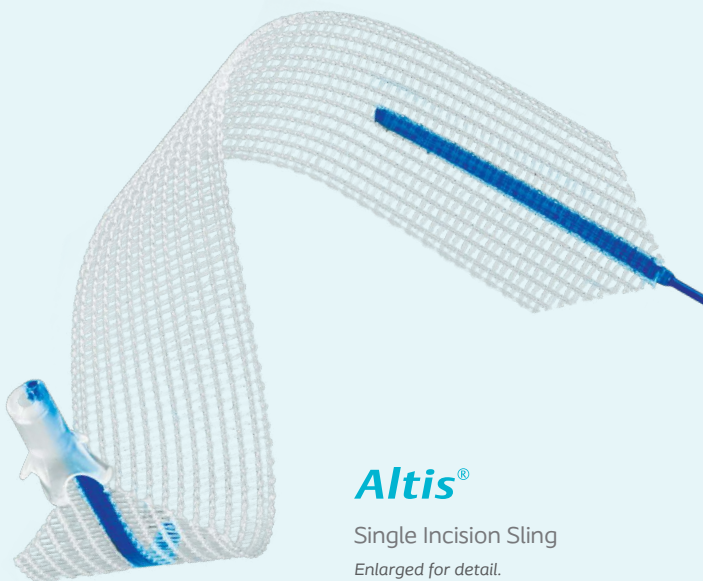
Surgical solutions for incontinence

You may have heard about sling procedures for addressing SUI.

There are transobturator, retropubic and single incision slings. Another option are injectable bulking agents.

Introducing Altis® Single Incision Sling

Altis is a single incision sling that treats stress urinary incontinence by supporting the urethra to keep it in its correct position.³ The procedure is a minimally invasive⁴ outpatient surgery.³



Altis®

Single Incision Sling

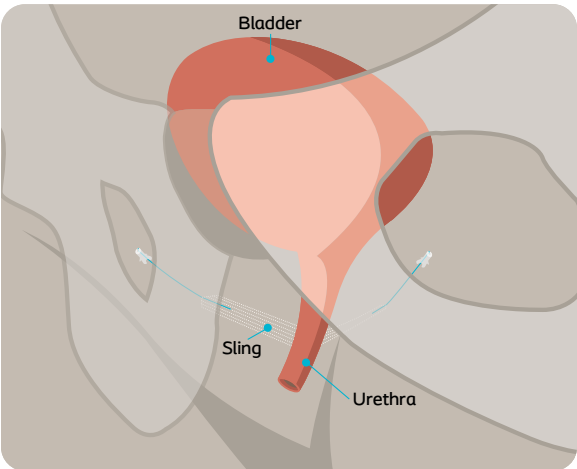
Enlarged for detail.

What are my treatment options?

How Altis[®] works

Altis is an implanted device used during a minimally invasive procedure that treats stress urinary incontinence at its source. In many cases, the surgery takes 30 minutes or less⁵ and is typically an outpatient procedure.

During the procedure, your doctor will make one small (typically 1-2 cm) incision to place an Altis sling beneath your urethra; this provides support to the urethra when there is stress on the bladder, such as when you cough, laugh or sneeze.

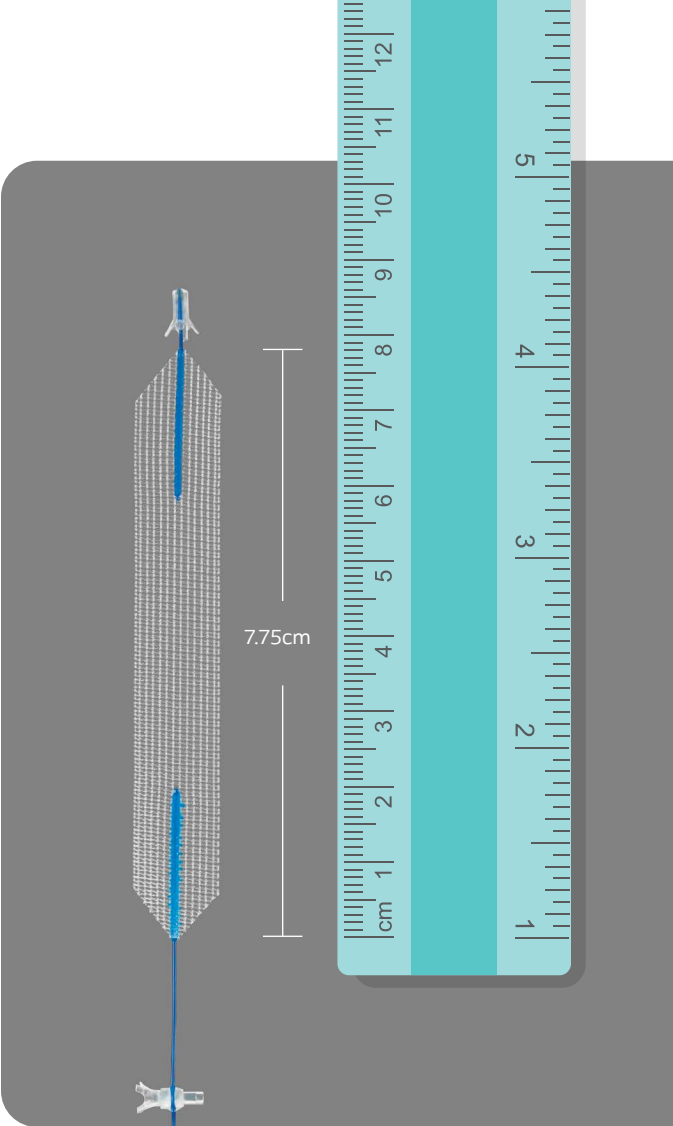


Altis[®] Single Incision Sling



Watch the animation
on **how Altis works.**

<https://www.femalepelvicsolutions.com/sui/how-altis-works/>



Altis® Single Incision Sling
actual size

Talking to a doctor

Congratulations on taking the first step. Reaching out to a doctor to discuss your urinary incontinence treatment options is an important step. On average, women wait 6.5 years from the first time they experience symptoms until they obtain a diagnosis for their bladder control problem(s).⁶



On average,

women wait

~6.5 years

before talking to a doctor
about their incontinence⁶



Find an
SUI specialist.

<https://www.femalepelvicsolutions.com/sui/find-a-sui-specialist/>

There are several types of doctors who treat urinary incontinence, but within each specialty there are those who focus on certain conditions and treatment options.

Urogynecologists

Urogynecologists are highly specialized – focusing on women’s reproductive system and urinary tract.

Most offer treatments for both stress urinary incontinence and pelvic organ prolapse. Since these conditions are often linked, seeing a urogynecologist may be a good option for you.

Urologists

Urologists provide care for both men and women and focus on the urinary tract and urogenital system – the kidneys, bladder and urethra.

If you have stress urinary incontinence, this may be the right specialist to seek. Some, but not all, urologists perform SUI surgeries, so be sure to do your homework and ask questions *like those on page 18* during your appointment.

Gynecologists

Gynecologists specialize in healthcare for women, especially the diagnosis and treatment of disorders affecting the female reproductive organs.

This is a broad specialty, so it is important to ask questions to understand what each gynecologist specializes in. If your gynecologist focuses more on obstetrics (childbirth) than pelvic floor surgeries, it may be best to find someone who has more experience with the care you need.

Questions to ask

If you are considering surgery with the use of a sling to repair your SUI, ask your surgeon these questions before you agree to the procedure:

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?

Insurance information

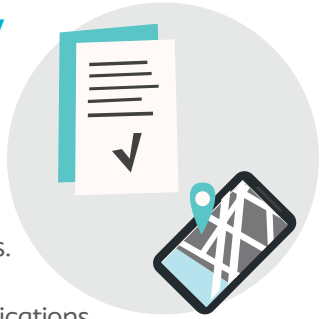
Most insurance plans, including Medicare, cover these procedures. Consult your insurance carrier to find out the specific criteria for coverage. The reimbursement specialist at your physician's office may also be able to help you with this.

Before surgery

Medical history

First, your doctor will collect and review your medical history and recent experiences.

You will be asked to provide a list of all medications and supplements you take, and information about your urinary habits and normal fluid consumption. It's important to accurately describe the leakage you are having, such as when and under what conditions leakage occurs.



Physical exam

Then, you'll likely have a physical exam, which can include:

- A **cough stress test** where you will be asked to cough and bear down with a full bladder to see if urine leaks
- An **"at home pad test"** to help estimate how much you are leaking throughout the day to determine the severity of your urinary incontinence⁷
- **Urinalysis** – testing of a urine sample
- **Post-void residual** – measures the amount of urine left in your bladder after urinating
- **Cystoscopy** – use of a scope to examine your bladder
- **Urodynamics** – testing that measures amount of urine in the bladder before urinating and the force of the urine as it leaves the body

Based on the results of your physical exam, you and your doctor will discuss and decide the right solution for your specific needs.

During surgery

A single incision sling procedure is the most common minimally invasive surgical option to correct stress urinary incontinence. It is usually performed as an outpatient procedure in less than 30 minutes.

Slings are placed through a small incision in the vagina and placed under the urethra. Once placed, the sling will provide support for the urethra and help prevent leaks during physical activity such as coughing, laughing, or exercise.



Healing and recovery

Your doctor will provide information about your recovery plan. In general, following sling placement, your doctor may suggest to resume some activities after two weeks, while avoiding others like physical strain, sexual intercourse and heavy lifting **for up to six weeks**.

Contact your physician if you experience any bleeding, pain, or any signs of infection.

Women receiving single incision slings reported **lower post-op pain**, **earlier return to normal activities**, and **earlier return to work** compared to those receiving transobturator or retropubic slings.⁸



What have others experienced?

Women experiencing SUI deserve a clinically proven, effective solution. Altis is a treatment backed by clinical studies with firsthand testimonials from women who've had the procedure with successful outcomes such as:

96.1%

saw a **median reduction** in pad weight⁹

90.4%

reported feeling **"very much better"** or "much better" improvements after their surgery at 24 months⁹

87.9%

reported no urine leakage related to SUI at 24 months post procedure⁹

“... the treatment is life-changing in such a positive way that you will never doubt getting it taken care of.”

JULIE

Actual patient not pictured.



How surgery helped Julie get back to her active lifestyle

Pregnancy and labor can damage muscles that support a woman’s pelvic organs, often resulting in stress urinary incontinence (urinary leakage). In Julie’s case, she began to notice leakage after the birth of her third child — especially while exercising. Discouraged about the need to use pads, she met with a urogynecologist. After a series of tests to determine if Julie was a candidate, her urogynecologist recommended surgery.

Her surgery lasted 45 minutes and she was home relaxing the same day. She was able to get up and walk around shortly after her surgery, and within four weeks she was able to resume her normal activities without limitations from urinary incontinence.



Learn from other women’s journeys though SUI.

<https://www.femalepelvicsolutions.com/sui/patient-story-sui-julies-story/>

Important safety information

Altis® Single Incision Sling System

Important Safety Information:

Stress urinary incontinence is a condition in which urine involuntarily leaks out of the urethra (the tube that brings urine from the bladder to the outside of the body) during times of high pressure such as coughing, sneezing or exercising. Stress urinary incontinence can be treated with a surgical procedure in which an incontinence sling is implanted to support the urethra. An incontinence sling is intended to provide support to the urethra to help stop urine from leaking and to help control when urine is emptied from the bladder.

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 the warnings, precautions and risks associated with the use of this mesh sling. 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.

Adverse events are known to occur with transvaginal synthetic mesh sling procedures and implants. Adverse events following mesh implantation may be new onset (de novo), persistent, worsening, transient, or permanent.

Additional potential complications include, but are not limited to: abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage 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.

Minneapolis, MN

PM-03328 02/2021

This image shows a full page of blank, lined paper. It features approximately 20 evenly spaced horizontal grey lines across its entire width, providing a template for writing or drawing. The background is a clean, solid white color.

[illegible]



Visit [FemalePelvicSolutions.com](https://www.femalepelvicsolutions.com)
or scan the QR code.

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