A PATIENT GUIDE TO

Understanding Stress Urinary Incontinence
Q: What is SUI?
A: Stress urinary incontinence is defined as the involuntary leakage of urine. The problem affects approximately 18 million adults in the United States, 85% of them being women. You are not alone! It usually takes four to six years to see a healthcare professional for this condition.

Q: What type of SUI do I have?
A: One condition is called hypermobility, “hyper” means too much and “mobility” refers to movement, which can result from childbirth, previous pelvic surgery or hormonal changes. Hypermobility occurs when the normal pelvic floor muscles can no longer provide the necessary support to the urethra. This may lead to the urethra dropping when any downward pressure is applied, resulting in involuntary leakage.

Another condition is called intrinsic sphincter deficiency, also sometimes referred to as ISD. This refers to the weakening of the urethral sphincter muscles or closing mechanism. As a result, the sphincter does not function normally regardless of the position of the bladder neck or urethra.

Q: What are some of the symptoms and how is it caused?
A: Stress urinary incontinence is the involuntary loss of urine during physical activity, which may include but is not limited to: coughing, laughing or lifting. Incontinence occurs when the muscles that support the urethra (the tube that carries urine out of the body) are weakened or damaged. This can happen as a result of childbirth, trauma, hormone changes and many other reasons. You don’t have to live like this. This type of incontinence can be treated both surgically or nonsurgically.

For more information, visit the FDA’s Urogynecologic Surgical Mesh Implants website at http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/UroGynSurgicalMesh/default.htm
Q: What are some treatment options?

A: Stress urinary incontinence can be treated in several ways, depending on the exact nature of the incontinence and its severity. As disease state and anatomy differ for each patient, outcomes may vary. Consult your physician for all available treatment options.

You and your physician may discuss:
- Changes to your diet and fitness routine
- Physical therapy including pelvic floor muscle training
- Vaginal pessaries
- Surgical options including traditional mesh slings, single incision mini-slings, retropubic colposuspension and bulking

Q: How will my surgery be performed?

A: Your minimally invasive sling procedure is estimated to only take 30 - 45 minutes. Your doctor will determine the type of anesthesia you will have during the procedure. Once the anesthesia takes effect, your doctor will begin the procedure.

A small incision will be made in the vaginal area. Next, the synthetic mesh implant is placed to create a “sling” of support under the urethra.

When your doctor is satisfied with the position of the mesh, he or she will close and bandage the small incisions in the groin area (if applicable for your sling type) and the top of the vaginal canal.

Q: How can a mid-urethral sling system help my incontinence?

A: A mid-urethral sling system is designed to provide a ribbon of support under the urethra to prevent it from dropping during physical activity, which may include but is not limited to: coughing, laughing, or lifting.

Q: What are the types of sling options?

A: Many surgical options have been developed, the difference being how the mesh material is placed under the urethra. Your doctor will recommend which anchoring location is right for you. As disease state and anatomy differ for each patient, outcomes may vary. Consult your physician for all available treatment options.
Q: What are the potential risks and complications of surgery?
A: As with most surgical procedures, there are potential risks and complications associated with this SUI surgery. Your physician can further explain your specific risks based on your medical history and surgical approach used. Some potential adverse reactions related to surgical correction for stress urinary incontinence include:

- **Pain**
  - Ongoing pain (pelvic, vaginal, groin/thigh)
  - Dyspareunia (pain during intercourse)
- **Discomfort/Irritation**
- **Voiding dysfunction** (having difficulty with urination)
  - Retention (difficulty with urination)
  - Obstruction (inability to urinate)
  - Urinary urgency (uncontrolled urge to urinate)
  - Urinary frequency (taking multiple trips to the bathroom)
- **Infection, including abscess**
- **Erosion or the presence of mesh material within the organs surrounding the vagina**
- **Exposure or the presence of mesh material through the surrounding tissue**
- **Extrusion or the presence of mesh material within the vagina**
- **Vaginal discharge**
- **Bruising, bleeding**

Removal of mesh or correction of mesh related complications may involve multiple surgeries. For any questions on these potential complications, or additional information listed at the end of the brochure, please ask your doctor.

Q: What should I expect after surgery?
A: Before you are discharged from the hospital, you may be given a prescription for an antibiotic and/or pain medication to relieve any discomfort you may experience. You will be instructed on how to care for your incision area. At the discretion of your physician, most patients resume moderate activities within 2 to 4 weeks, with no strenuous activity for up to 6 weeks.

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Q: When will I stop leaking?
A: Most women see results right after the procedure. Talk with your physician about what you should expect. You are on your way!
Q: What is the Public Health Notification related to transvaginal mesh?

A: In 2011, the U.S. Food and Drug Administration issued a public health notification which reported higher than expected complication rates with synthetic mesh delivered through vaginal incisions for the treatment of pelvic organ prolapse.

Although complications from mid-urethral slings used for the treatment of stress urinary incontinence were NOT included in the FDA Public Health notification, FDA gathered an expert panel of physicians to debate the clinical evidence supporting the use of vaginal mesh for both pelvic organ prolapse and stress urinary incontinence.

In January 2012, an FDA panel recommended additional clinical studies to evaluate the safety and effectiveness of mesh used to treat POP. For traditional mid-urethral slings, “the panel consensus was that the safety and effectiveness of these devices is well established and post market studies for these devices are not necessary”. “The panel consensus was that the safety and effectiveness of mini-slings is not well understood and that premarket evaluation of new mini-slings should be supported by clinical studies”.

It is important to know that the FDA has **never** recalled these devices from the market. These devices are cleared for use in the United States.

The clinical studies requested by the FDA for mini-slings are currently underway. In addition to these studies, as an example, there are more than 35 clinical publications supporting the use of Boston Scientific mid-urethral sling products for the treatment of stress urinary incontinence. As a result, since 2002, over 750,000 patients have been treated worldwide with Boston Scientific mid-urethral slings.

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**Glossary**

- **Bulking**: Procedure in which a bulking agent is injected under the urethra and bladder neck to treat stress urinary incontinence.
- **Hypermobility**: A condition associated with stress urinary incontinence in which loss of urethral support and stability impacts ability of the urethra to close during a stress event.
- **Intrinsic Sphincter Deficiency (“ISD”)**: Refers to the weakening of the urethral sphincter muscles or closing mechanism.
- **Minimally Invasive Surgery**: A procedure that minimizes surgical incisions and reduces trauma to the body.
- **Pelvic Floor**:
  - **Pelvic Floor Reconstruction**: The surgical repair of prolapse and incontinence.
  - **Pelvic Organ Prolapse**: A medical condition that occurs when normal support of the vagina is lost resulting in the “sagging” or “dropping” of pelvic organs.
- **Pessary**: A removable plastic device that is inserted into the vagina to hold prolapsed organs back in place.
- **Retropubic Colposuspension**: Procedure used to treat stress incontinence by suspending a sagging bladder neck and urethra to the pubic bone.
- **Retropubic Sling Placement**: Refers to surgical delivery of a traditional mid-urethral sling which includes both transvaginal and abdominal incisions, leaving a graft material suspending the bladder neck and extending behind the pubic bone.
- **Single Incision (Mini) Sling Placement**: Refers to surgical delivery of a mini mid-urethral sling through a single vaginal incision.
- **Stress Urinary Incontinence**: The involuntary loss of urine during physical activity, which may include but is not limited to: coughing, laughing, or lifting.
- **Traditional Mesh Slings**: Refers to a full length sling that utilizes the ingrowth of surrounding tissue to remain in place and support the urethra to reduce stress urinary incontinence.
- **Transobturator Sling Placement**: Refers to surgical delivery of a traditional mid-urethral sling which includes transvaginal and groin incisions, leaving a graft material suspending the bladder neck and extending through the obturator regions.
- **Transvaginal Surgery**: Surgery that is approached through an incision in the vagina.
- **Urethra**: Tube that carries urine from the bladder outside of the body.
- **Sphincter Muscle**: Muscles in the urethra that squeeze together and prevent urine from escaping the body involuntarily.
### CONSIDERATIONS PRIOR TO SURGICAL REPAIR

If you are considering surgery for stress urinary incontinence your physician may ask you questions about your medical history, to ensure you are a candidate for this type of procedure. Some of these contraindications, warnings/ potential complications, and adverse events associated with stress urinary incontinence are listed below as a reference to you. You should consult your physician for a complete understanding of this information and to determine whether this procedure is right for you.

### INTENDED USE / INDICATIONS FOR USE

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

### CONTRAINDICATIONS

A mesh implant is contraindicated in the following patients:
- Pregnant patients, patients with the potential for future growth or patients who are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology that would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

### ADVERSE EVENTS:

- Local irritation at the wound site and/or a foreign body response may occur.
- Erosion/exposure/extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue Erosion (presence of mesh material within the organs surrounding the vagina) Extrusion (presence of mesh material within the vagina).
  - Scarring/scar contracture (tightening of tissue)
  - Device migration (implant moves from the original implantation site)
  - Fistula formation (a hole/passage that develops through the wall of organs)
  - Inflammation (redness, heat, pain or swelling resulting from surgery)

The occurrence of these events may require surgical intervention and possible removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
Allergic reaction has been reported.

Known risks of surgical procedures for the treatment of incontinence include:

- Pain, ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia (pain during intercourse)
- Infection, including abscess
- Detrusor instability (involuntary contraction of the bladder wall)

Complete failure of the procedure, voiding dysfunction (Difficulty with urination):

- Incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder
- Brusing, bleeding (vaginal, hematoma formation (pooling of blood beneath the skin)
- Abscess
- Vaginal discharge
- Dehiscence of vaginal incision (opening of the incision after surgery)
- Edema (fluid retention in the body) and erythema at the wound site (redness of the skin)
- Perforation or laceration of vessels, nerves, bladder or urethra may occur during placement. (damage to nerve, vessel, bladder, or urethra)

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

GENERAL WARNING

The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:

- Vaginal and urinary tract infection should be treated prior to a suburethral sling implantation procedure.
- Mesh is considered a permanent implant. Removal of mesh or correction of mesh related complication may involve multiple surgeries.
- Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

POST PROCEDURE WARNING

- If subsequent infection occurs, follow appropriate medical intervention practices.
- Patients should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

PRECAUTIONS

- The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, urter, and bowl. Treatment of the erosion may require surgical removal.
- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. These pathophysiologic processes should be understood and should not be ignored when considering if the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
- Patients should be counseled when to resume both normal and/or vigorous activities (heavy lifting, exercise), and intercourse following the procedure.
- Consult with your physician immediately if you experience painful urination, bleeding, or any other problems following surgery.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician trained in use of surgical mesh repair of stress urinary incontinence.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations.

Material not intended for use in France. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. Please check availability with your local sales representative or customer service.

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