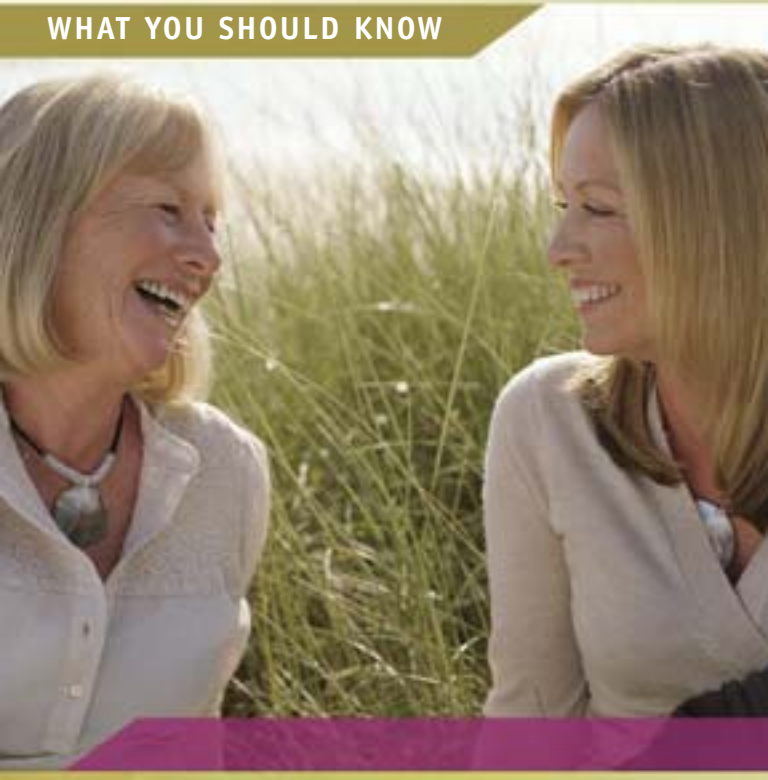
WHAT YOU SHOULD KNOW



ABOUT YOUR DIAGNOSIS OF STRESS URINARY INCONTINENCE

laughing. living life.
(worry free)

Boston Scientific

What is Stress Urinary Incontinence?

Urinary incontinence is defined as the involuntary leakage of urine. The problem afflicts approximately 13 million adults in the United States, 85% of them being women. There are many conditions that can cause loss of bladder control. Among women, the problem is most commonly associated with a specific condition called Stress Urinary Incontinence or SUI.

Stress urinary incontinence is the involuntary loss of urine during physical activity such as coughing, laughing, or lifting. The muscles that support the urethra (the small tube that carries urine out of the body) and bladder neck (the opening that connects the urethra to the bladder) have weakened, causing the urethra to drop during physical activity, resulting in urine leaking out of the body (see Figure 1 and Figure 2). This type of incontinence can be treated both surgically and nonsurgically. The next few pages will describe a minimally invasive surgical approach called a sling procedure.

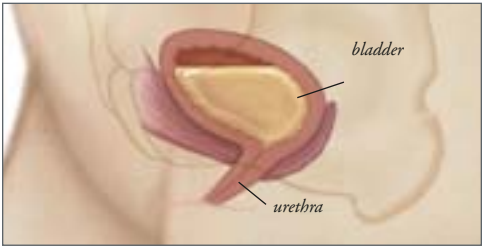


FIGURE 1: *Normal functioning anatomy*

FIGURE 2: *A weakening of the muscles supporting the urethra causes the urethra to drop during physical activity, resulting in urine leaking.*

Conditions that cause Stress Urinary Incontinence

The first condition is called hypermobility, ("hyper" means too much and "mobility" refers to movement) which is a common condition resulting 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 and bladder neck. As a result, the bladder neck is free to drop when any downward pressure is applied and thus, involuntary leakage occurs.

The second condition is called intrinsic sphincter deficiency, usually called ISD. This medical term refers to the weakening of the urethral sphincter muscles or closing mechanism. As a result of this weakening, the sphincter does not function normally regardless of the position of the bladder neck or urethra.

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

A minimally invasive sling procedure using a mid-urethral sling system is designed to provide a ribbon of support under the urethra to prevent it from dropping during physical activity. The dropping of your urethra out of the correct anatomical position may be what causes your incontinence. Providing support that mimics the normal anatomy should prevent urine from leaking or reduce the amount of leakage.

What can I expect during my sling procedure?

Your sling procedure with a mid-urethral sling system will take an estimated 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.

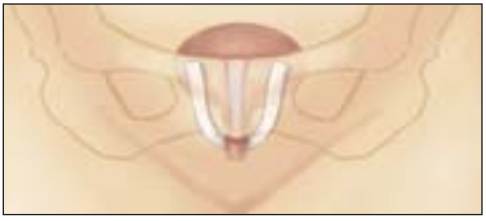
A small incision will be made in the vaginal area and two small incisions will be made through the skin in the groin area. Next, the synthetic mesh is placed. When it is placed, it will extend from one skin incision, in towards the vagina, around the urethra and back out though the second skin incision. This creates a “hammock” of support around the urethra.

Your doctor will adjust the mesh tension so that the leakage of urine is reduced. 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 and the top of the vaginal canal.

A minimally invasive approach to treating Stress Urinary Incontinence

Many surgical options have been developed for the correction of SUI due to hypermobility and/or ISD. Boston Scientific offers many different minimally invasive procedures, the difference being in the placement of the "anchoring" location of the mesh material. Your doctor will recommend which anchoring location is right for you.

SLING PLACEMENT OPTIONS



Pre-pubic Sling Placement

Transobturator Sling Placement

Retropubic Sling Placement

The sling system is designed to add support to the urethra and stabilize it as well. With the sling system in place, normal urinary function may be restored.

What to expect after the procedure

To help with the healing process, a catheter may be placed into your bladder. The catheter will be connected to a drainage bag, which will collect your urine. The catheter will be removed within a short period of time. After the procedure is complete, specialized nurses will monitor you. You will probably be discharged within 24 hours.

Before your discharge from the hospital, your doctor and nurse will provide you information on what to expect and how to care for yourself during your recovery time. Below are a few things included in these instructions:

- You may be given a prescription for an antibiotic. It is important to take the medication as prescribed.
- You may be given a prescription for pain medication. If not, your physician or nurse may recommend an over-the-counter drug that should relieve any discomfort you may experience.
- If you need to go home with a catheter, your physician or nurse will also instruct you on how to take care of it.
- You will be instructed on how to care for your incision area.
- Routine physical activity may be restricted for a short time after the procedure. Strenuous activity may be restricted for 6-12 weeks. Your doctor or nurse will provide you with specific guidelines.

Notes

A follow-up appointment will be made for you, however it is important to call your doctor if any question or issues arise before you are scheduled for a follow-up visit.

WARNING Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative. For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient. This product is intended for use only by clinicians with adequate training and experience in the surgical treatment of stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures. **DEVICE DESCRIPTION** The Advantage® System is a sterile, single use system, consisting of one Advantage Delivery Device and one Advantage Mesh Assembly. The Mesh Assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the Mesh Assembly are two dilators designed to be placed over the needle end of the Delivery Device. The disposable Delivery Device consists of a handle with a curved needle, a sliding metal cannula with a blunt distal end and a pusher component. The Delivery Device is designed to facilitate the passage of the Advantage Mesh Assembly through bodily tissues for transvaginal placement. **INDICATIONS FOR USE** The Advantage Mesh implant is intended as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency. **CONTRAINDICATIONS** The Advantage Mesh Assembly is contraindicated in pregnant patients. Additionally, this procedure should not be performed in patients with potential for future growth or patients with plans for future pregnancy. Use of the surgical mesh is contraindicated for use in any patient in whom soft tissue implants are contraindicated. These patients include those with: • Pathology of the soft tissue into which the implant is to be placed. • Any pathology which would compromise implant placement. • Any pathology such as blood supply limitation or infection that would compromise healing.

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to package insert provided with the product for complete Instructions for Use, Contraindications, Potential Adverse Effects, Warnings and Precautions prior to using this product.

Individuals depicted are models and included for illustrative purposes only.

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