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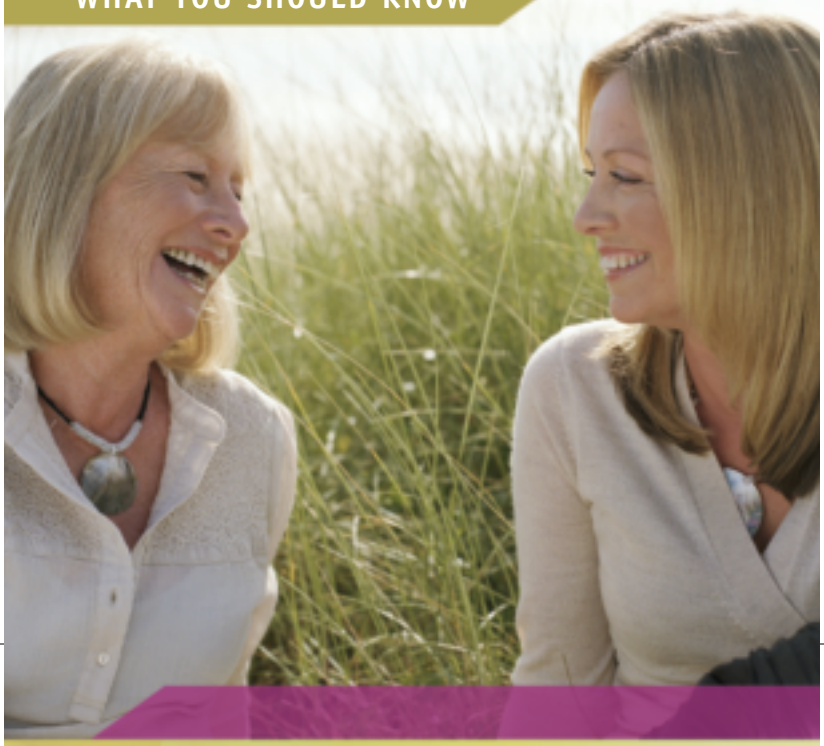
WHAT YOU SHOULD KNOW



ABOUT YOUR DIAGNOSIS OF STRESS URINARY INCONTINENCE

laughing. living life.
(worry free)

Boston Scientific

493495.q7:480499_P0 6/5/09 10:23 AM Page 2

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.

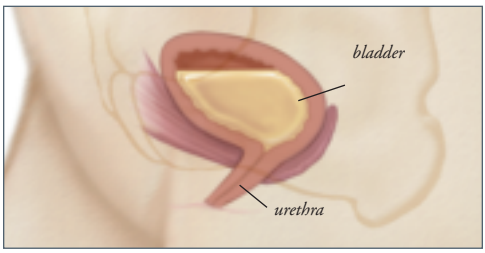


FIGURE 1: *Normal functioning anatomy*

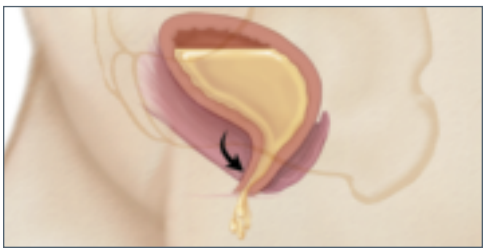


FIGURE 2: *A weakening of the muscles supporting the urethra causes the urethra to drop during physical activity, resulting in urine leaking.*

493495.q7:480499_P0 6/5/09 10:23 AM Page 3

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.

493495.q7:480499_P0 6/5/09 10:24 AM Page 4

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. Next, the synthetic mesh is placed to create a "sling" of support around the urethra.

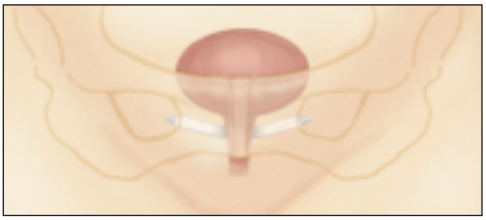
Your doctor will adjust the mesh tension so that the leakage of urine is reduced. When your doctor is satisfied with the position of the mesh, he or she will close and bandage the small incisions in the groin area and the top of the vaginal canal.

A minimally invasive approach to treating Stress Urinary Incontinence

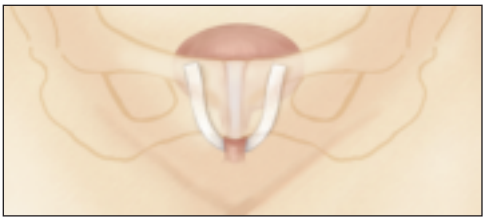
Many surgical options have been developed for the correction of SUI due to hypermobility and/or ISD. Boston Scientific offers many different minimally invasive procedures, the difference being in the placement of the “anchoring” location of the mesh material. Your doctor will recommend which anchoring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

493495.q7:480499_P0 6/5/09 10:24 AM Page 5

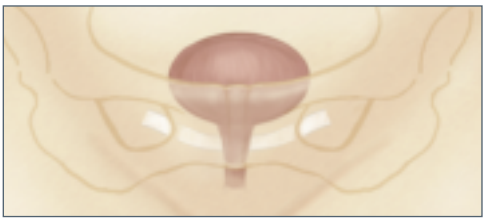
SLING PLACEMENT OPTIONS



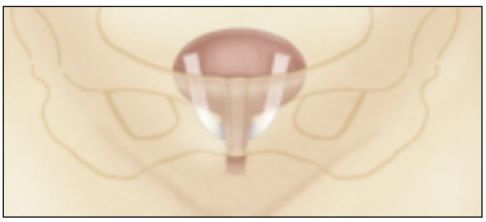
Single Incision Sling Placement



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.

493495.q7:480499_P0 6/5/09 10:25 AM Page 6

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.

493495.q7:480499_P0 6/5/09 10:25 AM Page 7

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 hypermobility and/or intrinsic sphincter deficiency.

Contraindications

A mesh implant is contraindicated in the following patients:

- Pregnant 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 which would compromise implant placement
- Patients with any pathology that would limit blood supply or infections that would compromise healing.

Warnings / Potential Complications

As this product is intended for use only by clinicians with adequate training and experience in the treatment of female stress urinary incontinence (SUI), the risks and benefits of a suburethral sling procedure in the following should be carefully considered:

- Patients with renal insufficiency and upper urinary tract obstructions
- If you should require a cystocele repair, it is recommended that your physician perform this prior to the sling procedure.
- Vaginal and urinary tract infection should be treated prior to a suburethral sling implantation procedure.

The following complications have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the would site and/or a foreign body may occur
- Tissue responses to the implant could include vaginal extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require 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
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pelvic and vaginal pain, dysparenia, vaginal bleeding, vaginal discharge, dehiscence of vaginal incision, edema and erythema at the wound site, have been reported due to suburethral sling procedure
- It has also been reported that groin pain, orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of hematoma in the obturator foramen*

Post Procedure

- Should dysuria, bleeding or other problems occur, contact your physician immediately
- In the event that infection presents post procedure, the entire mesh may have to be removed or revised
- Like all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis
- Tissue responses to the implant could include: local irritation at the wound site, vaginal erosion or exposure through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, foreign body reaction, and inflammation. The occurrence of these responses may require removal or revision of the mesh
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion/exposure, device migration, complete failure of the procedure resulting in incontinence due to inco-mplete support or overactive bladder

*For obtryx procedure only

491617.q7:480499_P0 6/16/09 4:47 PM Page 8

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

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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.