

A woman with blonde hair, wearing a white lab coat, stands in a laundry room with her arms crossed. She is looking directly at the camera with a slight smile. In the background, there is a wooden rack with several white towels hanging on it. The lighting is warm and soft.

# What you should know

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about your diagnosis  
of incontinence

**Boston  
Scientific**

# What is Stress Urinary Incontinence?

## WHAT IS NORMAL URINARY FUNCTION?

Urine is a normal waste product of the body that is manufactured by the kidneys and stored in the urinary bladder. From the bladder, the urine is eliminated through the urethra, an outlet tube which joins the bladder at the bladder neck. Elimination of urine is a normal voluntary process for adults. When the bladder becomes full, you experience the need to urinate. Urination is a fairly complex function of various muscles and nerves, and therefore it is not uncommon for a disruption in normal bladder control to occur. When this happens, incontinence – the involuntary loss of urine from the bladder – is the result.

## WHAT IS 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.

## WHAT IS STRESS URINARY INCONTINENCE?

Stress urinary incontinence is the involuntary loss of urine during physical activities such as coughing, sneezing, laughing and lifting. In describing this condition the word “stress” does not refer to emotional stress, but the stress of increased physical pressure on the bladder. It is important to note that there are two types of conditions that result in stress urinary incontinence. Your doctor will determine whether you have one or both of these conditions and your treatment will depend on this diagnosis.

## 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 urethra sphincter muscles or closing mechanism. As result of this weakening, the sphincter does not function normally regardless of the position of the bladder neck or urethra.

# How will the Advantage™ Sling System help to restore bladder control?

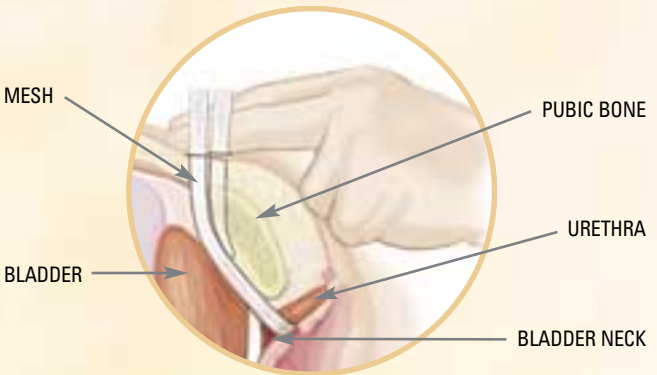
Many surgical options have been developed for the correction of SUI due to hypermobility and/or ISD. The procedure your physician has recommended for you is the Advantage Mid-Urethral Sling System. This is a less invasive procedure that requires only a few small incisions in the lower abdomen and the top of the vaginal canal.

The Advantage Sling System will add support to the urethra and stabilize it as well. It is through these two functions that the Advantage System treatment goal is to restore normal urination.

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.



YOUR DOCTOR WILL PASS TWO SIDES OF A THIN POLYPROPYLENE MESH ON EACH SIDE OF YOUR URETHRA.



YOUR DOCTOR WILL ADJUST THE MESH TENSION SO THAT THE LEAKAGE OF URINE IS MINIMIZED. WHEN YOUR DOCTOR IS SATISFIED WITH THE POSITION OF THE MESH, HE OR SHE WILL CLOSE AND BANDAGE THE SMALL INCISIONS.

# What will I do after the procedure?

Before your discharge from the hospital, you, your doctor and a nurse will review all information that you will need when you return home. This is a good time to get answers to your questions.

- 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 can recommend an over-the-counter drug that should relieve any discomfort you may have.
- Your physician or nurse will also instruct you on how to take care of the catheter during the short time it will be in place.
- You may also be instructed on how to care for your incision area. Depending on the type of treatment, the care will vary.
- 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.

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.

# FAQ's

## WHAT IS STRESS URINARY INCONTINENCE?

In this context the word stress refers to increased pressure on the bladder from activity rather than emotional stress. This increase in pressure can result from a variety of common tasks such as lifting a bag of groceries, sneezing, coughing or rising from a sitting position. There are two forms: hypermobility and ISD.

## WHAT IS HYPERMOBILITY?

Many women with stress urinary incontinence have weakened pelvic floor muscles. These muscles are the ones that support the bladder, bladder neck and urethra. When there is an increase of pressure the bladder neck and urethra can shift out of their normal position and momentarily drop. This downward movement can cause the bladder neck to open briefly resulting in the loss of urine.

## WHAT IS ISD?

There is a ring of muscle at the level of the bladder neck that seals off the flow of urine from the bladder. This ring of muscle is called the sphincter. If the sphincter is defective then it will fail to maintain its seal. Without the proper seal urine will leak regardless of the bladder and bladder necks position. This is especially true during physical exertion.

## HOW DOES THE ADVANTAGE TENSION FREE SLING WORK?

The Advantage™ Sling System will provide your physician a means to place a strip of a thin polypropylene synthetic mesh under the urethra. This strip is called a sling. The Advantage Sling creates hammock-like support of the urethra to correct both your hypermobility and ISD problems.

## IS AN ADVANTAGE SLING RIGHT FOR ME?

Consult with your doctor to see if the Advantage Sling is right for you. The Advantage Sling System is not appropriate for all women. It is not appropriate for women who are pregnant or women who have plans for future pregnancy.

**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 (U.S.) law restricts this device to sale by or on the order of a physician.

# Boston Scientific

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