

Understanding your condition

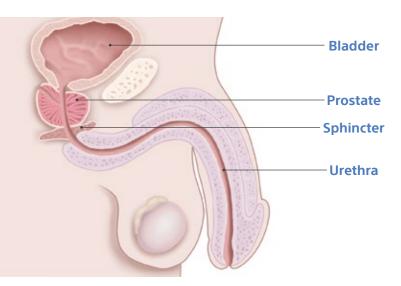
Incontinence is defined as any involuntary leakage of urine.¹ Male urinary incontinence is usually caused by a damaged sphincter or an improperly functioning bladder. The sphincter is the circular muscle that controls urine flow out of the bladder. When damaged, this muscle cannot squeeze and close off the urethra, the tube that carries urine from the bladder to the outside of the body. The result is urine leakage.

What are the types of incontinence?²

Stress urinary incontinence (SUI): Leakage during actions — such as sneezing, coughing, laughing, and lifting — that put abdominal pressure on the bladder

Urge incontinence (also known as overactive bladder [OAB]): An overwhelming need to urinate (gotta go, gotta go!) that may prevent reaching the toilet in time

Mixed incontinence: Symptoms of both urge and stress incontinence



Recognizing which type of incontinence you have will determine your treatment pathway to normalcy. Male SUI can be successfully treated.

"I was only dripping a very little bit and that in itself didn't bother me much. But when I exercised strenuously, that's when it bothered me. Because then there was zero control."

Richard

What causes male stress urinary incontinence (SUI)?

The most common cause of SUI in men is prostate cancer treatment. Surgery, radiation, or a combination of therapies can affect the external sphincter muscle and its functionality.^{2,3} Most men experience SUI after prostate cancer surgery.⁵ This is normal and for most patients usually resolves within the first 12 months of healing.^{4,5}

Other causes of male SUI:6

- Surgical treatment for enlarged prostate (BPH): TURP Transurethral resection of the prostate
- Conditions such as diabetes, multiple sclerosis, Parkinson's disease, spina bifida, or stroke
- Pelvic trauma or surgery

Most men experience SUI after prostate cancer surgery⁵

Changes in anatomy from prostate cancer surgery:



1. Cancerous prostate



2. Removal of prostate



3. Connect bladder and urethra

How common is male SUI?

254,000 men

in the United States have bothersome SUI⁶



Annually in the United States,

~17,000 new men

develop bothersome SUI⁶



Even with robotic prostate cancer surgery,

9-16% of patients

still experience SUI one year after surgery4



For patients who cannot heal completely following prostate cancer treatment and still experience SUI, there are treatment options to consider.



Living with SUI may cause emotional distress and can make daily life a hassle. You do not have to live with the burden of SUI.

What lifestyle modifications can I make or medications can I take to help my SUI?

Limiting fluid intake, avoiding caffeine and alcohol, and exercising pelvic floor muscles (called Kegel exercises) may provide SUI relief.8

Currently, no medications are approved in the United States for treatment of male SUI.⁹

Besides lifestyle modifications, are there other ways to treat my SUI?

Yes. Most other methods fall into two categories: coping and long-term treatment options.

Coping options include:10

- Absorbent products like pads or diapers
- Penile clamps
- Internal and external penile catheters

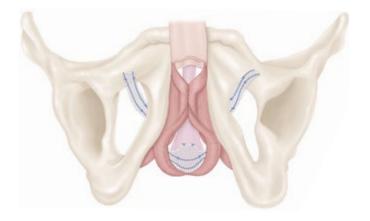
Long-term treatment options include:11-13

- Slings
- Artificial urinary sphincters (AUS)

AdVance[™] XP Male Sling System

A minimally invasive solution for male SUI

The sling acts as a "hammock," repositioning and supporting the urethra to help restore normal bladder control.⁶



Boston Scientific incontinence therapies can help remove the feeling of isolation in your relationships caused by your SUI.

"I think the emotional impact was probably the greatest change in my life. I suddenly did not want to be intimate with my wife. I felt unclean."

– Jerry

"When we were no longer intimate, it made me feel like he (Jerry) didn't love me, and I was no longer attractive to him. I also lost all my self-confidence."

Becky (Jerry's spouse)

Advance XP Male Sling System quick facts

- Intended for male stress urinary incontinence¹⁴
- Studies show high success and satisfaction with AdVance XP Sling in patients with mild to moderate SUI^{12,15,16}
- The sling, made of synthetic soft mesh, is placed entirely inside the body to reposition the urethra and provide support to surrounding muscles, making it undetectable to others. This can help to keep the urethra closed, especially when coughing, sneezing, and lifting.⁶
- Patients may be continent soon after their procedure¹⁷
- Minimally invasive procedure designed to allow most patients to resume normal, daily activities within 1 to 2 weeks after the procedure¹⁴

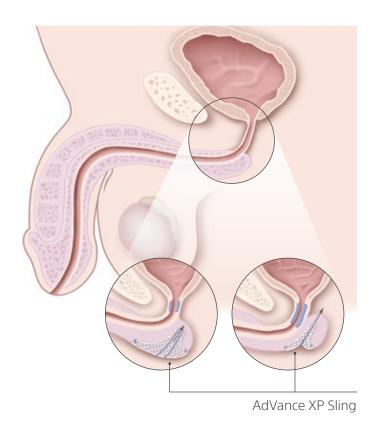


Intended benefits of the AdVance XP Sling:

- Minimally invasive procedure
- AdVance XP Sling works on its own to restore the continence¹⁷
- AdVance XP Sling can help restore your normalcy and renew your confidence

Possible side effects include, but are not limited to:6

- Post-operative pain
- Inflammation
- Urethral or tissue damage
- Bleeding and irritation at the wound site
- Urinary retention (typically resolved within a few days)
- Device failure
- Foreign body response
- Urge incontinence



AdVance XP Sling by the numbers

63.2-83.0%

cured and improved rates at 5 years in patients with mild to moderate incontinence^{12,15}

79.5%

would have the AdVance XP operation again¹⁸ 77.4%

who met ideal patient selection criteria reported satisfaction with the AdVance and AdVance XP Slings'⁸ 88%

of patients surveyed recommend the AdVance XP Sling procedure to a friend¹⁸

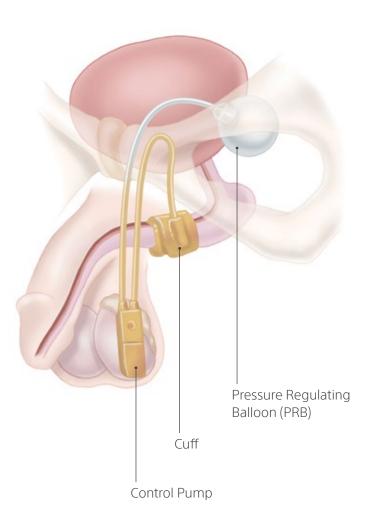
^{*}The index (ideal) population was defined as patients with mild to moderate postprostatectomy incontinence and naïve for pelvic irradiation or prior surgical treatment for urinary incontinence or urethral stricture.

AMS 800[™] Artificial Urinary Sphincter (AUS)

The gold standard treatment for male SUI¹⁹⁻²¹

The AMS 800 Artificial Urinary Sphincter (AUS) is a three-part urinary control system contained completely in the body⁶

- The control pump is implanted in the scrotum
- The inflatable cuff is placed around the urethra
- The saline-filled balloon (PRB) is usually implanted in a natural open space next to the bladder



How it works⁶

The AMS 800 AUS working mechanism: The AMS 800 AUS is filled with fluid and uses the fluid to open and close the cuff surrounding the urethra. To urinate, the patient needs to squeeze and release the pump in the scrotum several times to remove fluid from the cuff and send it to the balloon. When the cuff is empty, urine can flow out of the bladder. The cuff automatically refills with fluid after a few minutes. Once the cuff is filled, it gently squeezes the urethra closed to prevent leakage.

AMS 800 Artificial Urinary Sphincter quick facts

- Designed to treat male SUI following prostate surgery²²
- System can successfully treat all levels of male SUI^{19,20}
- Designed to discreetly restore the natural process of urinary control⁶
- The AMS 800 Artificial Urinary Sphincter mimics the function of a healthy urinary sphincter, closing off the urethra in order to stop the flow of urine, allowing patients to urinate when desired⁶
- Is operated by you⁶
- Usage requires good cognitive ability and manual dexterity²³⁻²⁵

AUS technology has been available to patients for 50 years, with over 250,000 Boston Scientific devices sold⁶

Benefits of the AMS 800 Artificial Urinary Sphincter (AUS):

- Designed to treat male SUI following prostate procedures²²
- Gives most men the ability to achieve continence²⁶
- The AMS 800 AUS can help restore your normalcy and renew your confidence

Possible side effects include, but are not limited to:6

- Device malfunction or failure, which may require revision surgery
- Erosion of the urethra in the cuff area
- Urinary retention
- Post-operative pain



Do not let your SUI stop you from doing the things you love in life. Find your happiness. Restore your normalcy. Renew your confidence.

"I got to the point where I didn't even want to golf anymore. I'd go golf with my buddies and I was afraid if I'd swing that club, I'd leak a little bit. I got to the point where I didn't do any activity that was strenuous."

Gary

AMS 800 Artificial Urinary Sphincter (AUS) by the numbers

~90%

of surveyed patients reported long term satisfaction¹³

+90%

of patients would get the AMS 800 AUS again²⁷

94%

would recommend the AMS 800 AUS to friends or family²⁸

Published long-term studies show that most patients are using one pad or no pads per day after receiving the AMS 800 AUS:

85%

of 155 patients at nearly 4 years²⁹ 96%

of 105 patients at 6 years³⁰

90%

of 435 primary AUS patients at 5 years³¹

AdVance™ XP Male Sling System

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Your doctor is your best source for information on the risks and benefits of the AdVance™ XP Male Sling System. Talk to your doctor for a complete listing of risks, warnings and important safety information.

The AdVance™ XP Male Sling System is intended for the treatment of male stress urinary incontinence (SUI). Potential risks may include inability to urinate (urinary retention), return to incontinence, infection, erosion, device migration, pelvic organ disfunction, bleeding, and pain. These devices are contraindicated for patients with urinary tract infections, blood coagulation disorders, a compromised immune system or any other condition that would compromise healing, with renal insufficiency, and upper urinary tract relative obstruction. MH-557011-AB

AMS 800™ Artificial Urinary Sphincter

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Your doctor is your best source for information on the risks and benefits of the AMS 800™ Artificial Urinary Sphincter. Talk to your doctor for a complete listing of risks, warnings and important safety information.

The AMS 800™ Artificial Urinary Sphincter is intended for use in the treatment of male stress urinary incontinence (intrinsic sphincter deficiency) following prostate surgery.

Men with diabetes, spinal cord injuries or skin infections may have an increased risk of infection. Some AMS 800 devices contain an antibiotic (InhibiZone™ Antibiotic Surface Treatment). The device may not be suited for patients who are allergic to the antibiotics contained within the device (rifampin, minocycline or other tetracyclines) or have systemic lupus.

Potential risks may include: device malfunction/failure leading to additional surgery, wearing away/loss of tissue (device/tissue erosion), inability to urinate (urinary retention), infection, and pain/soreness. MH-545611-AB

Patient testimonials

The stories throughout this brochure recount the experiences of people who are using Boston Scientific therapies related to stress urinary incontinence. Boston Scientific invited these people to share their stories candidly. As you review them, please bear in mind that the experiences are specific to these particular people. As with all medical treatment, not every response is the same. We recommend you talk to your doctor about what treatment is right for you.

The patients featured in this brochure may have been compensated for their travel and/or time.

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

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Visit **FixIncontinence.com** for more information on male SUI and to hear real patient stories.



Talk to someone who's been there:

Call us at 1-844-433-2873 or email MHPatientEducation@bsci.com and we'll connect you with a patient who found a successful treatment for their SUI.

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