

A photograph of an elderly man with glasses and a purple cardigan, laughing heartily while holding a young child in a blue plaid shirt. The child is also laughing and pointing upwards. They are outdoors, with a blue flag and greenery in the background.

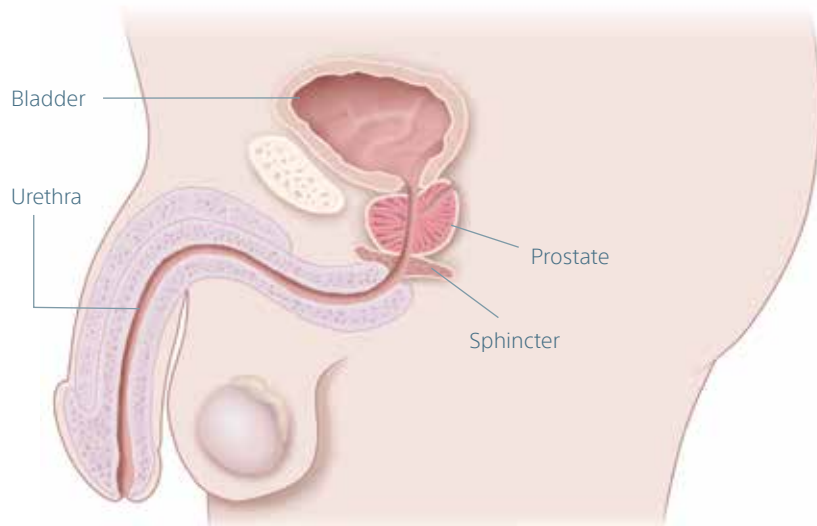
Fix your incontinence

Find your happiness.
Restore your normalcy.
Renew your confidence.

Male stress urinary incontinence

What is incontinence?

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

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. Almost all men experience SUI immediately after prostate cancer surgery. This is normal and for most patients usually resolves within the first six months of healing.³

Changes in anatomy from prostate cancer surgery:

1. Cancerous prostate



2. Removal of prostate



3. Connect bladder and urethra



Other causes of male SUI:

- Surgical treatment for enlarged prostate (BPH): (TURP – Transurethral resection of the prostate)⁴
- Conditions such as diabetes, multiple sclerosis, Parkinson's disease, or stroke⁴
- Pelvic trauma or surgery⁴

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



Watch the enclosed DVD or visit FixIncontinence.com to hear real patient stories.

How common is male SUI?

254,000 men in the United States have bothersome SUI⁴

Annually in the United States, about **17,000 new men** develop bothersome SUI⁴

Even with robotic prostate cancer surgery, **9 - 16%** of patients still experience SUI one year after surgery.³

Worldwide, approximately **500,000 men** suffer from SUI⁴

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 some temporary SUI relief.⁵

Currently, no medications are approved in the United States for treatment of male SUI.⁶

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:⁷

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

Long-term treatment options include:⁸⁻¹⁶

- Slings
- Artificial urinary sphincters (AUS)

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

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

"In the beginning of my incontinence, I was probably going through 4 or 5 pads a day. And as a man, naturally we feel we're not supposed to do things like this and this isn't supposed to happen to us."

— Herschel

To learn about all treatment options visit
FixIncontinence.com

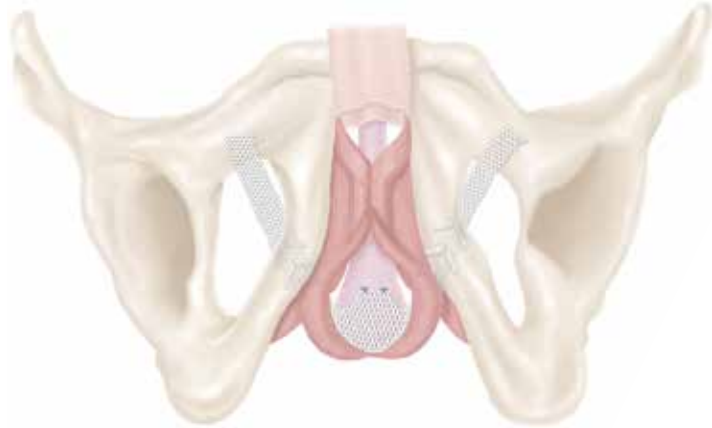


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AdVance™ XP Male Sling System

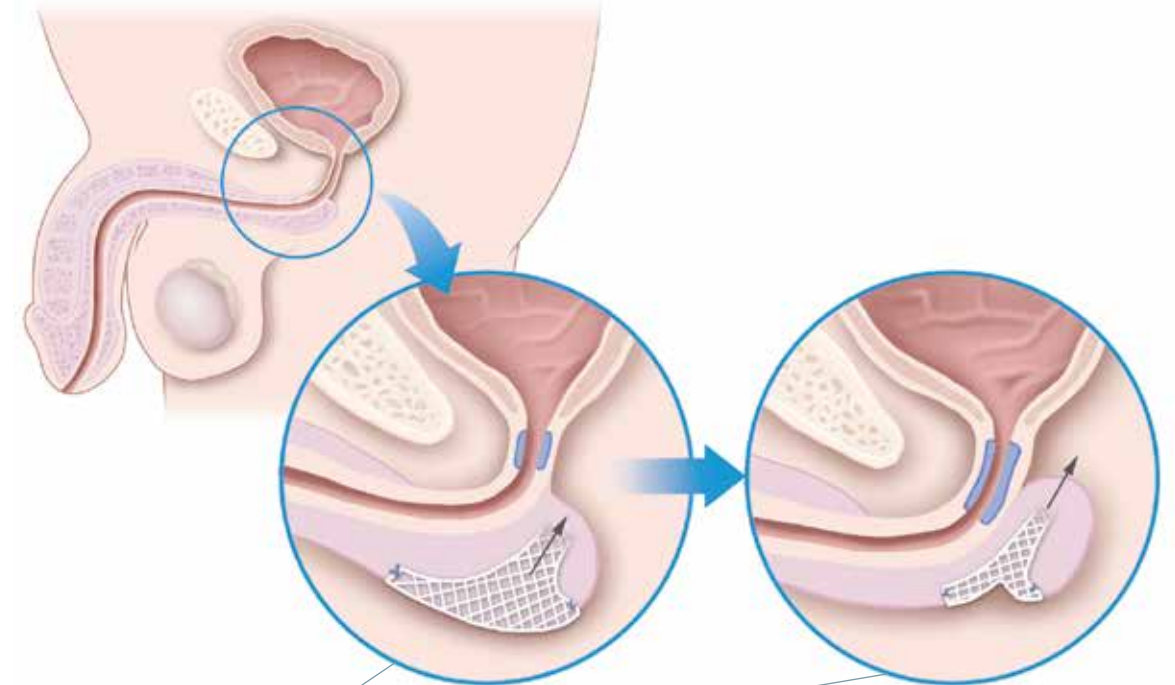
The minimally invasive solution for male SUI

The sling acts as a “hammock,”⁹ repositioning and supporting the urethra to help restore normal bladder control.¹⁷



Quick Facts

- Intended for adult male stress urinary incontinence
- Studies show high success and satisfaction with AdVance XP Sling in patients with mild to moderate SUI—less than 4 pads per day (PPD)^{9,10,17,18}
- The sling, made of synthetic mesh, is placed entirely inside the body, making it undetectable to others
- Most patients are continent immediately following the procedure¹⁹
- At your urologist’s discretion, you can resume normal daily activities within 1 to 2 weeks after your procedure²⁰



AdVance XP Sling



Watch the enclosed DVD or visit
FixIncontinence.com to hear real patient stories.

AdVance™ XP Male Sling System

Benefits of the AdVance XP Sling

- Minimally invasive procedure²¹
- AdVance XP Sling works on its own to restore your continence¹⁹
- AdVance XP Sling can help restore your normalcy and renew your confidence

Possible side effects include, but are not limited to:²⁰

- Device failure
- Urinary retention
- Post-operative pain
- Irritation at the wound site
- Foreign body response



Male SUI Sling treatment by the numbers*

Long-term success rates up to
89.4%²²
in patients with mild to severe SUI^{9,11}

92%
of patients who received an AdVance Sling would undergo the procedure again¹⁰

In a study of 399 patients,
83%
were cured
(0 post-operative pad use after surgery)¹²

94%
of patients would recommend the AdVance Sling procedure to a friend¹³

*Rates reflect research results with use of the AdVance Male Sling

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)



Watch the enclosed DVD or visit FixIncontinence.com to hear real patient stories.

AMS 800™ Urinary Control System

The gold standard treatment for male SUI²³

The AMS 800 System is a three-part urinary control system contained completely in the body²⁴

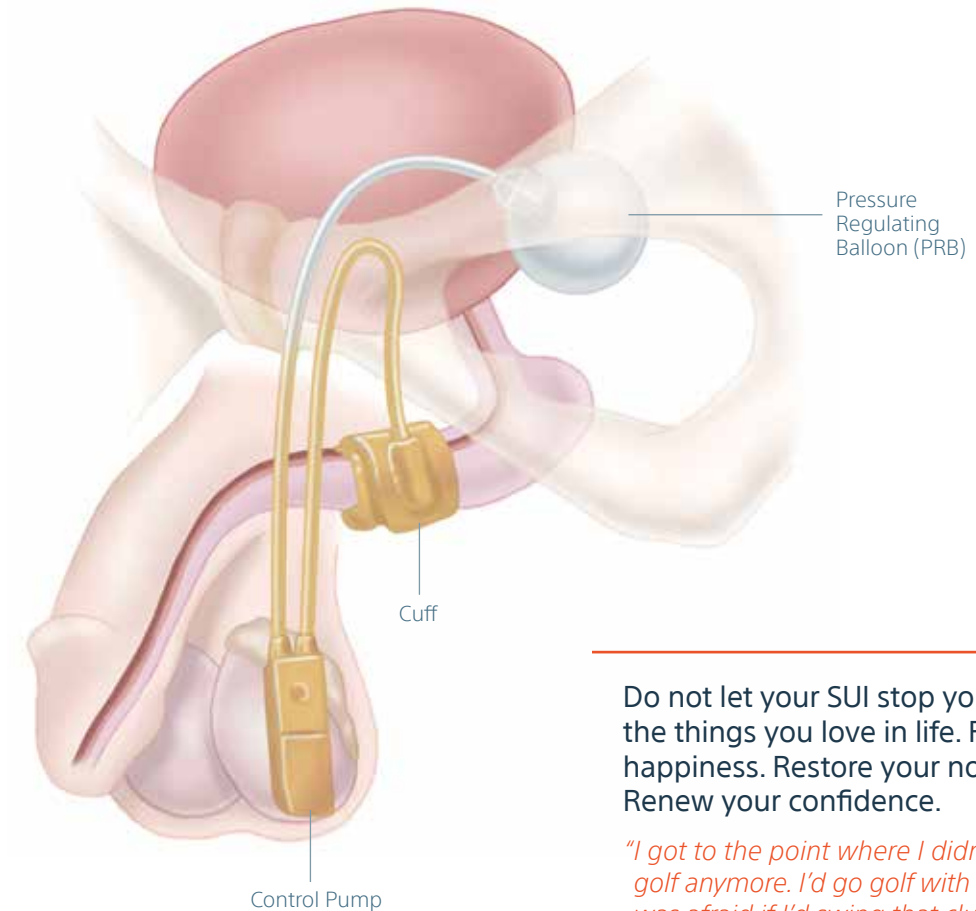
- The control pump is implanted in the scrotum
- The inflatable cuff is placed around the urethra
- The saline-filled balloon (PRB) is usually implanted in a natural open space next to the bladder

How it works²⁴

The AMS 800 System is filled with saline and uses the fluid to open and close the cuff surrounding the urethra. When you need to urinate, you squeeze and release the pump in the scrotum several times to remove fluid from the cuff. When the cuff is empty, urine can flow out of the bladder. The cuff automatically refills in a few minutes squeezing the urethra closed to restore bladder control.

Quick Facts

- Designed to treat male SUI following prostate surgery²⁵
- System can successfully treat all levels of male SUI
- Designed to discreetly restore the natural process of urinary control
- Mimics a healthy sphincter, allowing you to urinate when desired²⁵
- Is operated by you²⁵
- Requires good cognitive ability and manual dexterity²⁵



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



Watch the enclosed DVD or visit FixIncontinence.com to hear real patient stories.

AMS 800™ Urinary Control System

More than 40 years of AUS clinical use
and 200,000 implanted worldwide⁴

Benefits of the AMS 800 Urinary Control System

- Designed to treat male SUI due to a weakened sphincter muscle or the sphincter's inability to close and prevent urine leakage following prostate surgery²⁵
- Gives most men the ability to achieve continence²⁶
- The AMS 800 System can help restore your normalcy and renew your confidence

Possible side effects include, but are not limited to:²⁵

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

AMS 800 Urinary Control System by the numbers

Patient satisfaction study from the *Journal of Urology*²⁷

90%
reported
satisfaction

92%
would have the
AMS 800 System
placed again

96%
would recommend
an AMS 800 System
to a friend

Published long-term studies show 82 – 90% of patients use
0 – 1 pads per day (PPD) following their procedure¹⁴⁻¹⁶

82%
in *British
Journal of Urology*

83%
in
Urology

90%
in *Journal
of Urology*

Finding the right treatment option for your SUI and restoring your normalcy is life-changing.

"I was, you know, expecting to walk out of there [after device activation at the office] and not have to wear pads and some sense of normalcy with my life. And that's exactly what happened. I feel like a new man...and my friends and family can tell. They can tell I'm happy."

— Bill



Watch the enclosed DVD or visit FixIncontinence.com to hear real patient stories.

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™ Urinary Control System. Talk to your doctor for a complete listing of risks, warnings and important safety information.

The AMS 800™ Urinary Control System 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-545609-AA

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, and pain. MH-557011-AA

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.



FIX
INCONTINENCE

Watch this DVD and visit www.FixIncontinence.com for more information on male SUI.

Talk to your doctor about the next steps that are right for you.

Talk to someone who's been there:

Email us at MHPatientEducation@bsci.com or call 1-844-433-2873 and we can connect you with a patient who found a successful treatment for his SUI.

FixIncontinence.com is a website sponsored by Boston Scientific.

1. Chapple C, Milsom I. Urinary incontinence and pelvic prolapse epidemiology and pathophysiology. In: Wein AJ, Kavoussi LR, Novick AC, et al. (eds). *Campbell-Walsh Urology*. 10th ed. Philadelphia, PA: WB Saunders Elsevier; 2012:1871-95. 2. Abrams P, Andersson KE, Birder L, et al. Fourth International Consultation on Incontinence Recommendations of the International Scientific Committee: Evaluation and treatment of urinary incontinence, pelvic organ prolapse, and fecal incontinence. *NeuroUrol Urodyn and Urodynamics*. 2010;29:213-240. 3. Ficarra V, Novara G, Rosen RC, et al. Systematic review and meta-analysis of studies reporting urinary continence recovery after robot-assisted radical prostatectomy. *Eur Urol*. 2012 Sep;62(3):405-17. 4. Data on file with Boston Scientific and based on market research by Dymedex. 5. Sandhu J. Treatment options for male stress urinary incontinence. *Nat Rev Urol*. 2010 Apr;7(4):222-8. 6. Bauer RM, Gozzi C, Hubner W, et al. Contemporary management of postprostatectomy incontinence. *Eur Urol*. 2011 Jun;59(6):985-96. 7. Moore KC, Lucas MG. Management of male urinary incontinence. *Indian J Urol*. 2010 Apr-Jun;26(2):236-44. 8. Elterman D, Chughtai B, Sandhu J. Treatment options for male stress urinary incontinence. *Eur Urol Rev*. 2012;7(2):127-131. 9. Rehder P, Haab F, Cornu JN, et al. Treatment of post-prostatectomy male urinary incontinence with the transobturator retroluminal repositioning sling suspension: 3-year follow up. *Eur Urol*. 2012 Jul;62(1):140-5. 10. Sturm RM, Guralnick ML, Stone AR, et al. Comparison of clinical outcomes between "ideal" and "nonideal" transobturator male sling patients for treatment of postprostatectomy incontinence. *Urology*. 2014 May;83(5):1186-8. 11. Zuckerman JM, Edwards B, Henderson K, et al. Extended outcomes in the treatment of male stress urinary incontinence with a transobturator sling. *Urology*. 2014 Apr;83(4):939-45. 12. Christine B, Bella A. The AdVance Transobturator Male Sling: surgical tips that predict successful return of continence [abstract MP87-12]. *J Urol*. 2016 Apr;195(4):e1119. 13. Suskind AM, Bernstein B, Murphy-Setzko M. Patient-perceived outcomes of the AdVance sling up to 40 months post procedures. *NeuroUrol Urodyn*. 2011 Sep;30(7):1267-70. 14. Manunta A, Guillé F, Patard JJ, et al. Artificial sphincter insertion after radiotherapy: is it worthwhile? *BJU Int*. 2000 Mar;85(4):490-2. 15. O'Connor RC, Nanigian DK, Patel BN, et al. Artificial urinary sphincter placement in elderly men. *Urology*. 2007 Jan;69(1):126-8. 16. Raj GV, Peterson AC, Toh KL, et al. Outcomes following revisions and secondary implantation of the artificial urinary sphincter. *J Urol*. 2005 Apr;173(4):1242-5. 17. DeRidder D, Webster G. Clinical overview of the AdVance Male Sling in post-prostatectomy incontinence. *Eur Urol Supplements*. 2011 Jul;10(4):401-6. 18. Rehder P, Webster G. The AdVance® male sling: patient selection and workup. *Eur Urol Supplements*. 2011;10:390-4. 19. Welk B, Herschorn, S. The male sling for post-prostatectomy urinary incontinence: a review of contemporary sling designs and outcomes. *BJU Int*. 2012 Feb;109(3):328-44. 20. AdVance XP Male Sling System Instructions for Use. Boston Scientific. 2018. 21. Bauer R, Mayer M, May F, et al. Complications of the AdVance Transobturator Male Sling in the treatment of male stress urinary incontinence. *Urology*. 2010 Jun;75(6):1494-8. 22. Bauer RM, Grabbert MT, Klehr B, et al. 36-month data for the AdVance XP male sling: results of a prospective multicenter study. *BJU Int*. 2017 Apr;119(4):626-30. 23. Montague DK. Artificial urinary sphincter: long-term results and patient satisfaction. *Adv Urol*. 2012;2012:835290. 24. AMS 800™ Urinary Control System Operating Room Manual. American Medical Systems, Inc. 2014. 25. AMS 800™ Urinary Control System Instructions for Use. American Medical Systems, Inc. 2014. 26. Van der Aa F, Drake MJ, Kasyan GR, et al. The artificial urinary sphincter after a quarter of a century: a critical, systematic review of its use in male non-neurogenic incontinence. *Eur Urol*. 2013 Apr;63(4):681-9. 27. Litwiler SE, Kim KB, Fone PD, et al. Post-prostatectomy incontinence and the artificial urinary sphincter: a long-term study of patient satisfaction and criteria for success. *J Urol*. 1996 Dec;156(6):1975-80.

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