



Answers for Men

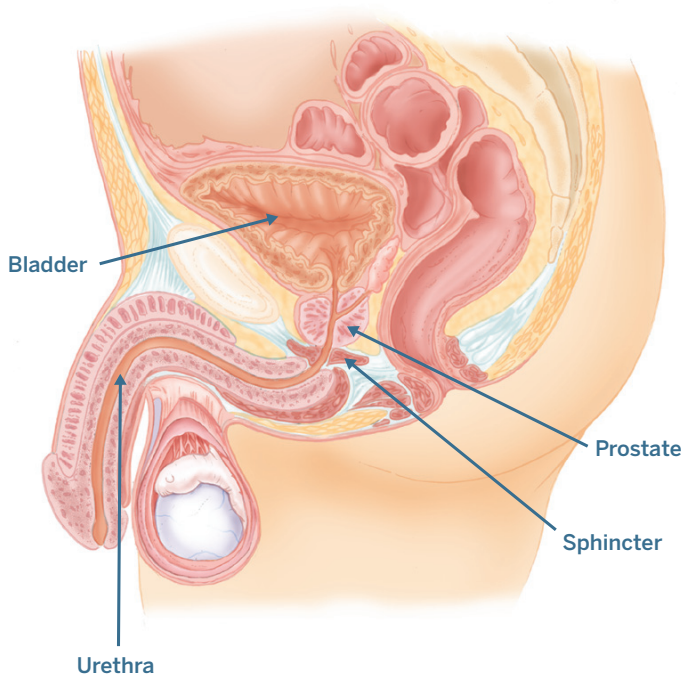
Understanding Your Treatment Options

Brought to you by American Medical Systems, Inc.



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? Urine leakage.



What are the common causes of incontinence?

There Are Several Reasons Incontinence Occurs in Men

- Prostate cancer treatments (radical prostatectomy or radiation therapy)²
- Conditions such as diabetes, multiple sclerosis, Parkinson's disease, or stroke²
- Pelvic trauma or surgery³

What are the types of incontinence?⁴

Stress Urinary Incontinence (SUI):

Involuntary leakage upon coughing, sneezing, or exertion

Urge Incontinence:

Leakage accompanied by an overwhelming need to urinate (overactive bladder)

Mixed Incontinence:

Leakage associated with both exertion and urgency

Recognizing which type of incontinence you have can help you decide among treatment options.



"It 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 and hear men talk about their SUI.



How common is SUI?

- Worldwide, over 43 million men suffer from urinary incontinence (stress, mixed, and urge), approximately 10.4 million of whom are suffering from SUI⁵
- 3.1 million men in the United States ages 60+ suffer from SUI⁶
- Rate of SUI ranges from 2.5% up to 69% after prostate surgery⁷

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.³

Currently, no medications are approved in the United States for treatment of male SUI.⁸

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

Yes. Most other methods fall into two categories: non-surgical or surgical treatment options.

Non-surgical treatment options include⁹:

- Absorbent products like pads or diapers
- External penile clamps
- Interior and exterior penile catheters

Surgical treatment options include¹⁰:

- Slings
- Artificial sphincters
- Compression balloons
- Bulking agents (e.g., collagen injections)

AMS[®] offers 2 surgical treatment options for male SUI:

- AdVance[™] Male Sling System
- AMS 800[™] Urinary Control System

Many men feel
frustrated with
their incontinence.



“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



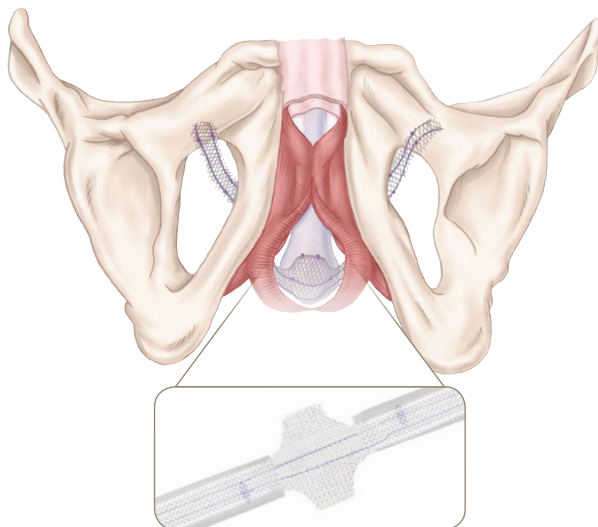
Watch the enclosed DVD and hear men talk about solutions that worked for them.



The AdVance™

Male Sling System

The sling acts as a “hammock,”¹¹ repositioning and supporting the urethra to help restore normal bladder control.¹²



Quick Facts

- Intended and designed to treat all levels of stress urinary incontinence¹³
- Several studies show higher success rates are achieved in patients with mild to moderate SUI^{11,12,14}
- The sling, made of synthetic mesh, is placed entirely inside the body, making it undetectable to others
- Most patients are continent immediately following the procedure¹⁵
- At their physicians discretion, most patients can resume normal, daily activities 1 to 2 weeks later¹³

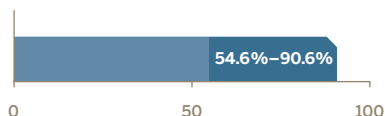
Benefits of the AdVance Male Sling

- Minimally invasive procedure¹⁶
- The patient doesn't need to do anything to operate the device; it operates automatically¹⁵
- The Advance Male Sling can help restore quality of life¹¹

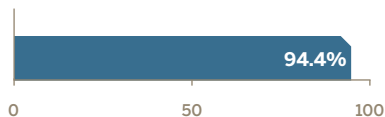
Side effects include, but are not limited to¹³:

- Pain and inflammation
- Bleeding and irritation at wound site
- Urethral or tissue damage
- Urinary retention¹²

AdVance Male Sling by the Numbers



Success rates of 54.6% to 90.6% have been reported in 6 clinical studies involving more than 500 patients.¹²



In a study of 42 patients, 94.4% would recommend the procedure to a friend.¹⁷

You're not alone in feeling isolated, even from the people you love most.



"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 (spouse)

Watch the enclosed DVD and hear more about the emotional toll SUI can have on men and their significant others.



The AMS 800™ Urinary Control System

The AMS 800 Urinary Control System is an artificial urinary sphincter placed completely inside your body.

A 3-part Urinary Control System¹⁸

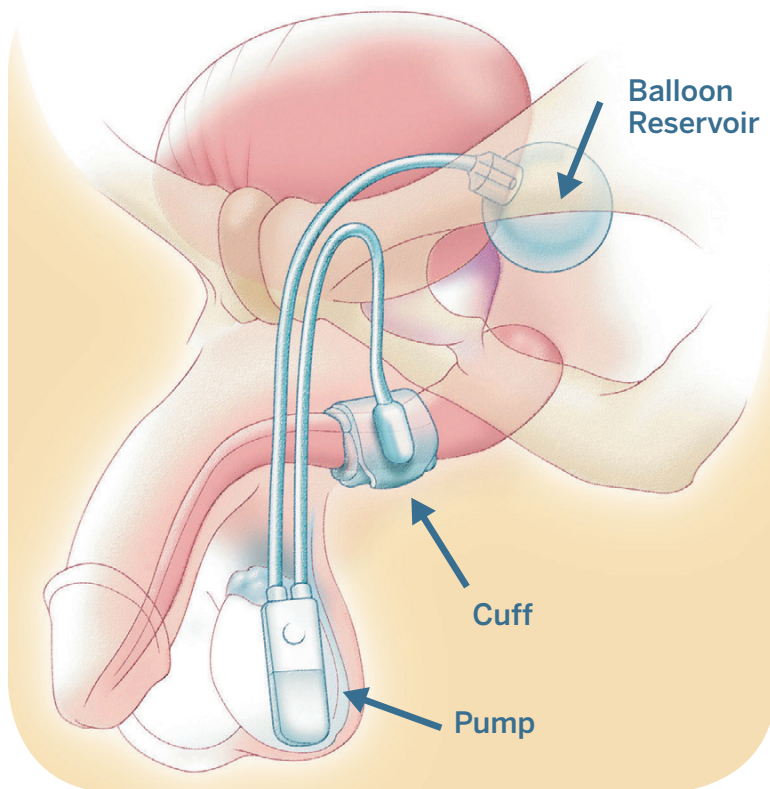
- The pump is implanted in the scrotum
- The inflatable cuff fits around the urethra
- A balloon reservoir is implanted in the abdomen

How It Works¹⁸

The cuff fits around the urethra, inflates and keeps it closed, thereby keeping urine in the bladder. To begin urinating, squeeze the scrotal pump several times. Doing so deflates the cuff, opens the urethra and allows urine to exit the body.

Quick Facts

- Designed to treat male SUI following prostate surgery¹⁹
- Most commonly used to treat moderate to severe male SUI²⁰
- Designed to restore the natural process of urinary control
- Provides discreet urinary control
- Mimics a healthy sphincter, allowing the patient to urinate when desired¹⁹
- Is patient-operated¹⁹
- Requires good cognitive ability and manual dexterity¹⁹



Sometimes SUI can keep you from doing the things you love.



"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 to hear more real-life stories of how SUI affected people's everyday lives.



The AMS 800™ Urinary Control System

*Many urologists call it
the “Gold Standard” for
treatment of male SUI²¹*

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 surgery¹⁹
- This system effectively gives most men the ability to achieve continence²²
- In a study of 68 patients with average patient follow up of 7.2 years, 80% of men used 0-1 pads/day²³
- The AMS 800 can help restore quality of life²³

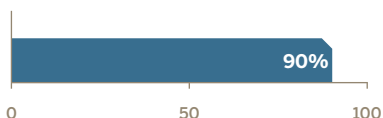
Side effects include, but are not limited to¹⁹:

- Pain/discomfort and inflammation
- Bleeding and irritation at the wound site
- Urethra and/or surrounding tissue damage
- Healing delays
- Recurrent urine leakage

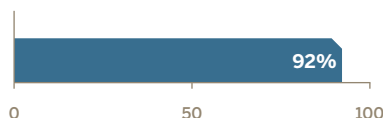
Finding a treatment option for your incontinence can be life changing.

AMS 800 Urinary Control System by the Numbers

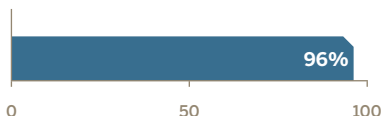
In one study of 50 patients,²⁴



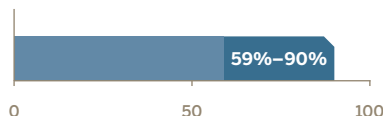
90% reported satisfaction.²⁴



92% would have the AMS 800 implant placed again.²⁴



96% would recommend an AMS 800 implant to a friend.²⁴



Published clinical studies show that 59%-90% used 0-1 pad per day after the procedure.²⁵



"I was, you know, expecting to walk out of there 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 to learn more about SUI.

AdVance™ Male Sling System

Brief Summary

The AMS AdVance™ Male Sling System is intended for the placement of a suburethral sling for the treatment of male stress urinary incontinence (SUI). 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. Proper patient evaluation, selection, and counseling of realistic expectations should occur. A 6-month period of non-invasive treatment (eg, behavior modification, bladder exercises, biofeedback, extra corporeal magnetic stimulation of the pelvic floor, or drug therapy) is recommended before a sling implant is considered for males with

stress urinary incontinence. The following warnings and precautions are advised:

- The possibility of urgency incontinence should be carefully considered before a sling implant is conducted.
- It is recommended that good bladder function (bladder capacity >250 mL and post void residual urine <50 mL) be demonstrated by candidates for a male sling.
- It is recommended that the presence of bladder neck or urethral strictures be ruled out for male sling candidates.
- It is recommended that a condition involving cystitis, urethritis, or prostatitis be ruled out for male sling candidates.
- It is recommended that detrusor instability of a neurological origin be ruled out for male sling candidates.

Possible adverse events include, but are not limited to, acute inflammatory tissue reaction and transitory local irritation, which has been reported with the use of the absorbable suture.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, and potential adverse events.

AMS 800™ Urinary Control System Brief Summary

The AMS 800™ Urinary Control System (or Artificial Urinary Sphincter) is intended to treat urinary incontinence due to reduced outlet resistance (Intrinsic Sphincter Deficiency) following prostate surgery. The device is contraindicated in patients who are determined to be poor surgical candidates, have an irreversibly blocked lower urinary tract, have irresolvable detrusor hyperreflexia or bladder instability, or (for the AMS 800 with InhibiZone™) have a known sensitivity or allergy to rifampin, minocycline, or other tetracyclines. Patients with urinary tract infections, diabetes, spinal cord injuries, open sores, or regional skin infections may have increased infection risk. Device-tissue erosion may occur. Proper patient evaluation, selection and counseling of realistic expectations should occur. Possible adverse

events include, but are not limited to, compromised device function, pain/discomfort, delayed wound healing, migration, and recurrent incontinence. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, and potential adverse events.

Patient Testimonials

The stories throughout this brochure recount the experiences of people who are using AMS therapies related to urinary incontinence. AMS 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—results vary.

*Watch this DVD and visit
www.malecontinence.com
for more information on SU1.*



Patient name _____

Set follow-up appointment in _____ *weeks.*

Doctor's name _____

Appointment date/time _____

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

1. Chapple C, Milsom I. Urinary incontinence and pelvic prolapse epidemiology and pathophysiology. In: McDougal WS, Wein JW, Kouvoussi AC, et al. *Campbell-Walsh Urology*. 10th ed. Philadelphia, PA: WB Saunders Elsevier; 2012:1871-1895. 2. Urinary incontinence in men. National Institute of Health (NIH) Web Site: <http://kidney.niddk.nih.gov/kudiseases/pubs/pdf/uimen.pdf>. Accessed July 9, 2012. 3. Sandhu, J. Treatment options for male stress urinary incontinence. *Nat Rev Urol*. 2010;7:223. 4. Abrams P, Andersson KE, Birdler 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. *Neurourology and Urodynamics*. 2010;29:213-240. 5. Irwin C, Kopp Z, Agatep B, Milsom I, Abrams P. Worldwide prevalence estimates of lower urinary tract symptoms, overactive bladder, urinary incontinence and bladder outlet obstruction. *BJU Int*. 2011;108:1134. 6. Anger JT, Saigal CS, Stothers L, Thom DH, Rodriguez LV, Litwin MS. The prevalence of urinary incontinence among community dwelling men: results from the National Health and Nutritional Examination Survey. *J Urol*. 2006;176:2103-2108. 7. Tewari AK, Bigelow K, Rao S, et al. Anatomical restoration technique of continence mechanism and preservation of puboprostatic collar: a novel modification to achieve early continence in men undergoing robotic prostatectomy. *Adult Urol*. 2007;69:726-731. 8. Bauer RM, Gozzi C, Hubner W, et al. Contemporary management of postprostatectomy incontinence. *Eur Urol*. 2011;59(6):985-96. 9. Moore K, Lucas M. Management of male urinary incontinence. *Indian J Urol*. 2010;26(2):8-9. 10. Elterman D, Chughtai B, Sandhu J. Treatment options for male stress urinary incontinence. *Eur Urol Rev*. 2012;7(2):127-131. 11. Rehder P, Haab F, Cornu JN, Gozzi C, Bauer RM. Treatment of post-prostatectomy male urinary incontinence with the transobturator retroluminal repositioning sling suspension: 3-year follow up. *Eur Urol*. 2012;62(1):140-145. 12. DeRidder D, Webster G. Clinical overview of the AdVance Male Sling in post-prostatectomy incontinence. *Eur Urol Supplements*. 2011;10:401-406. 13. AdVance™ Male Sling System Instructions for Use. American Medical Systems, Inc. 2010. 14. Rehder P, Webster G. The AdVance® male sling: patient selection and workup. *Eur Urol Supplements*. 2011;10:390-394. 15. Welk B, Herschorn, S. The Male Sling for post-prostatectomy urinary incontinence: a review of contemporary sling designs and outcomes. *BJU Int*. 2011;109:328-344. 16. 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;75:1494-1498. 17. Suskind AM, Bernstein B, Murphy-Setzko M. Patient-perceived outcomes of the AdVance sling up to 40 months post procedures. *Neurourol Urodyn*. 2011;30(7):1267-1270. 18. AMS 800™ Urinary Control System Operating Room Manual. American Medical Systems, Inc. 2011. 19. AMS 800™ Urinary Control System Instructions for Use. American Medical Systems, Inc. 2011. 20. Bauer R, Gratzke C. Urinary incontinence following radical prostatectomy. *Eur Urol Rev*. 2009;48:51. 21. Trost T, Elliott D. Male stress urinary incontinence: a review of surgical treatment options and outcomes. *Adv Urol*. 2012;2012:1-13. 22. Van der Aa F, Drake M, Kasyan G, Petrolekas A, Cornu J. The artificial urinary sphincter after a quarter of a century: a critical, systematic review of its use in male non-neurogenic incontinence. *Eur Urol*. 2012. <http://dx.doi.org/10.1016/j.jeururo.2012.11.034>. 23. Haab F, Trockman B, Zimmern P, Leach G. Quality of life and continence assessment of the artificial urinary sphincter in men with a minimum of 3.5 years of follow up. *J Urol*. 1997;158(2):435-443. 24. Montague, DK. Artificial urinary sphincter: long-term results and patient satisfaction. *Adv Urol*. 2012;835290. doi:10.1155/2012/835290. 25. Kahlon B, Baverstock RJ, Carlson K. Quality of life and patient satisfaction after artificial urinary sphincter. *Can Urol Assoc J*. 2011;5(4):268-272.

Rx Only

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