



# Answers for Men

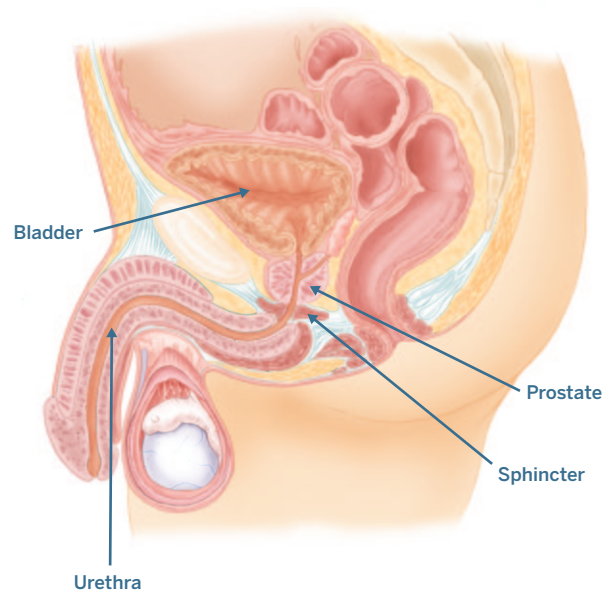
*Understanding Your Options  
for Male Urinary Incontinence*

LEARN MORE

*Brought to you by American Medical Systems, Inc.*



## What is incontinence?



Incontinence is defined as any involuntary leakage of urine.<sup>1</sup> 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, the muscle cannot squeeze and close off the urethra. 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)<sup>2</sup>
- Conditions such as diabetes, multiple sclerosis, Parkinson's disease, or stroke
- Pelvic trauma or surgery<sup>3</sup>

## What are the types of incontinence?

### 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

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 Chalk



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



## How common is incontinence?

- Worldwide, over 43 million men suffer from urinary incontinence (stress, mixed, and urge), approximately 10.4 million of whom are suffering from SUI<sup>4</sup>
- 3.4 million men (17%) in the United States ages 60+ suffer from SUI<sup>5</sup>
- Rate of SUI ranges from 2.5% up to 69% after prostate surgery<sup>6</sup>

## 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.<sup>3</sup>

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

## 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<sup>7</sup> include:

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

### Surgical treatment options include:

After consultation with their doctors, men with varying severity levels of incontinence often opt for surgery. During surgical procedures, doctors implant a device that works with your urinary system to help control leakage.

### AMS offers 2 surgical treatment options for male SUI:

- AdVance® Male Sling System
- AMS 800® Urinary Control System

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 Hollis

*"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."*

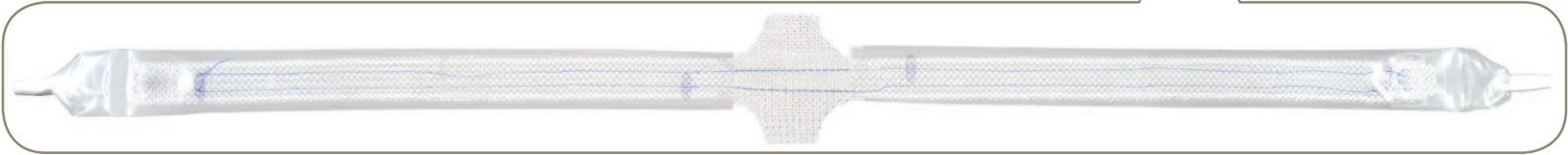
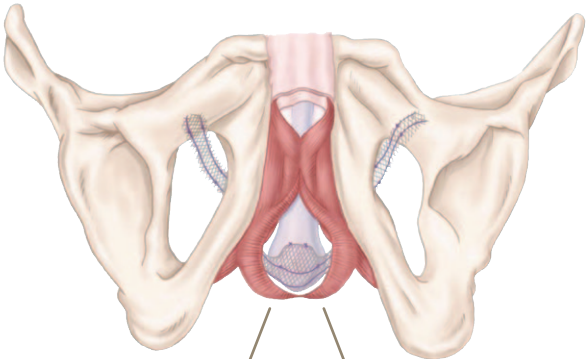
—Becky Hollis (spouse)

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



# The AdVance® Male Sling

The sling acts as a “hammock,”<sup>8</sup> supporting the urethra to help restore normal bladder control.<sup>9</sup>

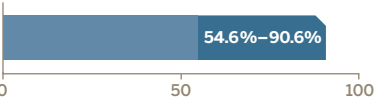


## Quick Facts

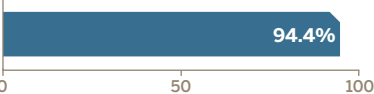
- Designed to treat male SUI
- Most commonly used to treat mild to moderate SUI<sup>10</sup>
- The sling, made of synthetic mesh, is placed inside the body through small incisions
- Most patients are continent immediately following the procedure
- At their physicians discretion, most patients can resume normal, daily activities 1 to 2 weeks later<sup>11</sup>

## 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.<sup>9</sup>



In a study of 42 patients, 94.4% would recommend the procedure to a friend.<sup>12</sup>



## Benefits of the AdVance Male Sling

- Minimally invasive procedure<sup>13</sup>
- The Advance Male Sling can help restore quality of life<sup>14</sup>

## Side effects include but are not limited to<sup>11</sup>:

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

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 Joseph



Watch the enclosed DVD to hear more real-life stories of how SUI affected people’s everyday lives.





# The AMS 800® Urinary Control System

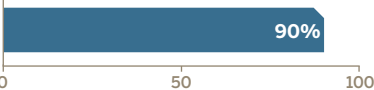
The AMS 800 Urinary Control System is an artificial urinary sphincter placed completely inside your body surgically.

### Quick Facts

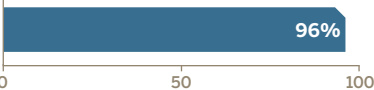
- Designed to treat male SUI following prostate surgery<sup>15</sup>
- Most commonly used to treat moderate to severe male SUI<sup>10</sup>
- The AMS 800 is designed to restore the natural process of urinary control<sup>16</sup>
- Provides discreet urinary control<sup>10</sup>
- It mimics a healthy sphincter, allowing the patient to urinate when desired
- Is patient-operated
- Requires good cognitive ability and manual dexterity

### AMS 800 Urinary Control System by the Numbers

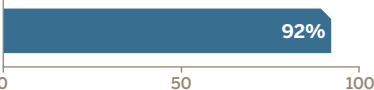
In one study of 50 patients,<sup>17</sup> 90% reported satisfaction.



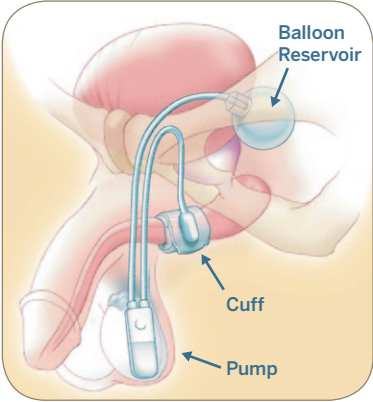
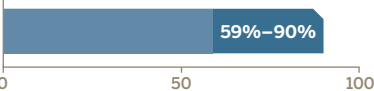
96% would recommend AMS 800 implantation to a friend.



92% would have the AMS 800 placed again.



Published clinical studies show that 59%-90% used 0-1 pad per day after the procedure.<sup>18</sup>



### A 3-part Urinary Control System<sup>16</sup>

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

### How It Works<sup>16</sup>

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.

### 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 surgery<sup>15</sup>
- In a study of 68 patients with average patient follow up of 7.2 years, 80% of men used 0-1 pads/day and over 80% were satisfied with the AMS 800<sup>18</sup>
- The AMS 800 can help restore quality of life<sup>19</sup>

### Side effects include, but are not limited to:

- Pain/discomfort and inflammation
- Bleeding and irritation at the wound site
- Urethra and/or surrounding tissue damage (implant performance problems and/or movement)
- Healing delays
- Recurrent urine leakage

Finding answers to your questions and an incontinence solution that works for you can be life-changing.



*"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 Anderson



Watch the enclosed DVD to learn more about SUI.

**Advance® Male Sling 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 (e.g., 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 >250ml 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.

Watch this DVD and visit [www.malecontinence.com](http://www.malecontinence.com) for more information on SUI.

Patient record #

Follow up appointment date

Doctor's name

AMSUS7MC-XXX

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

## References

1. Chapple C, Milso I. Urinary incontinence and Pelvic Prolapse Epidemiology and Pathophysiology. In: McDougal WS, Wein JW, Kavoussi AC, Novick AC, Partin AW, Peters CA, 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.** Irwin D, 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. **5.** 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 Nutrition Examination Survey. *J Urol*. 2006;176:2103-2108. **6.** Tewari AK, Bigelow K, Rao S, Takenaka A, El-Tabi N, Tea A, Vaughan ED. Anatomic restoration technique of continence mechanism and preservation of puboprostatic collar: a novel modification to achieve early urinary continence in men undergoing robotic prostatectomy. *Adult Urol*. 2007;69:726-731. **7.** Moore K, Lucas M. Management of male urinary incontinence. *Indian J Urol*. 2010;26(2):8-9. **8.** 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. **9.** DeRidder D, Webster, G. Clinical overview of the AdVance Male Sling in post-prostatectomy incontinence. *Eur Urol Supplements* 10. 2011:401-406. **10.** Trost T, Elliot D. Male stress urinary incontinence: a review of surgical treatment options and outcomes. *Adv Urol*. 2012;2012:1-13. **11.** AdVance Male Sling System Instructions for Use. American Medical Systems. **12.** Suskind AM, Bernstein B, Murphy-Setzko M. Patient-perceived outcomes of the AdVance sling up to 40 months post procedure. *NeuroUrol Urodyn*. 2011;30(7):1267-1270. **13.** Bauer R, Mayer M, May F, Gratzke C, Buchner A, Soljanik I, et. al. Complications of the AdVance Transobturator Male Sling in the treatment of male stress urinary incontinence. *Urology*. 2010;75:1494-1498. **14.** Rehder P, Haab F, Cornu JN, Gozzi C, Bauer RM. Treatment of postprostatectomy male urinary incontinence with the transobturator retroluminal repositioning sling suspension: 3-year follow-up. *Eur Urol*. 2012;62(1):140-145. **15.** AMS 800 Urinary Control System Instructions for Use. American Medical Systems. **16.** AMS 800 Urinary Control System Operating Room Manual. American Medical Systems. **17.** Montague DK. Artificial urinary sphincter: long-term results and patient satisfaction. *Adv Urol*. 2012;835290. doi: 10.1155/2012/835290. **18.** 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. **19.** Haab F, Trockman B, Zimmern P, Leach G. Quality of life and continence assessment of the artificial urinary sphincter in men with a minimum 3.5 years of follow up. *Jour Urol*. 1997;158-2:435-443.



[BrandName] is a registered trademark of American Medical Systems, Inc.

© 2013 American Medical Systems, Inc. All Rights Reserved. Minnetonka, MN 55343

XXXXXXXXXX/January 2013 [www.AmericanMedicalSystems.com](http://www.AmericanMedicalSystems.com) 1-800-328-3881

[Geographic region]