

Answers for Men

Understanding your treatment options
for Stress Urinary Incontinence



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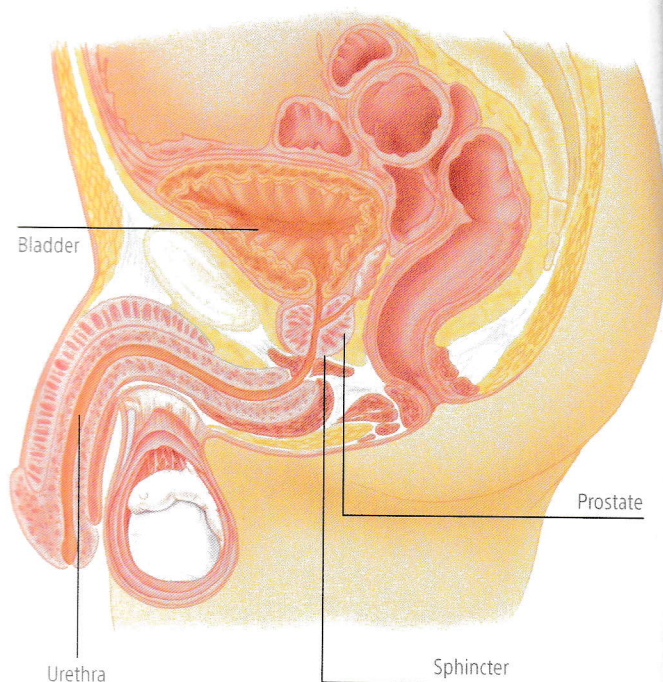
What is incontinence?

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.

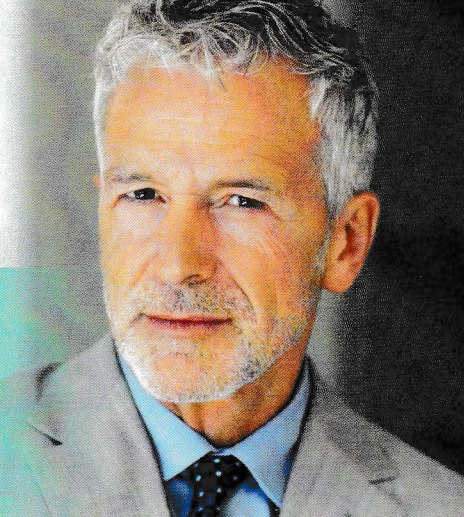
When damaged, this muscle cannot squeeze and close off the urethra, the tube that carries urine from the bladder to the outside of the body.

The result? Urine leakage.



Answers for Men

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



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

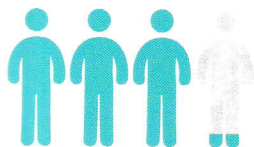
Leakage associated with both exertion and urgency.

Stress Urinary Incontinence

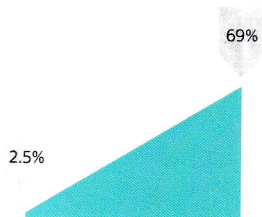
How common is SUI??



Worldwide, over 43 million men suffer from urinary incontinence (stress, mixed, and urge), approximately 10.4 million of whom are suffering from SUI⁵



4.8 million Australians are affected by incontinence⁶



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 Australia and New Zealand 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 in Australia and New Zealand include¹⁰:

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

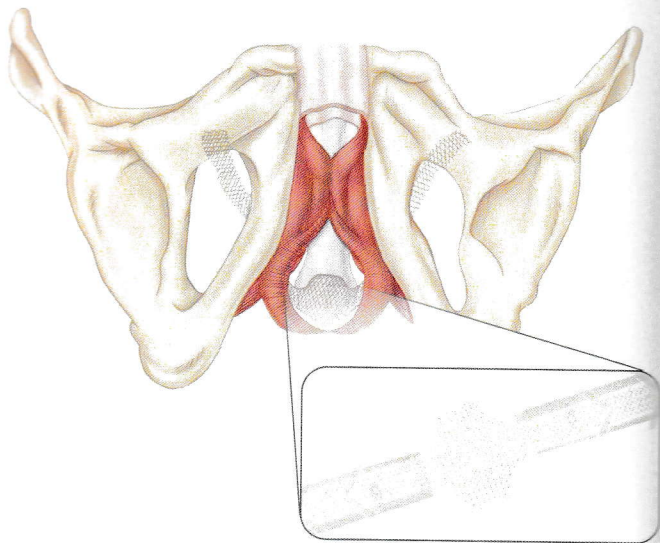
Boston Scientific offers 2 surgical treatment options for male SUI:

- AdVance™ XP Male Sling System
- AMS 800™ Urinary Control System



The AdVance™ XP – The latest version of the AdVance Male Sling Platform

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 physician's discretion, most patients can resume normal, daily activities 1 to 2 weeks later¹³

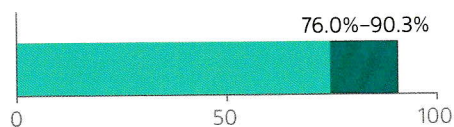
Benefits of the AdVance™ XP Male Sling Platform

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

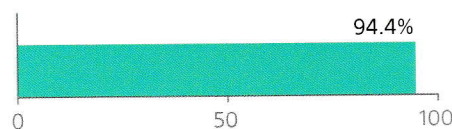
Side effects include, but are not limited to¹³:

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

AdVance™ XP Male Sling by the numbers



In peer reviewed clinical studies, the second generation AdVance XP Sling has demonstrated **success rates ranging from 76.0%–90.3%.**¹²



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



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

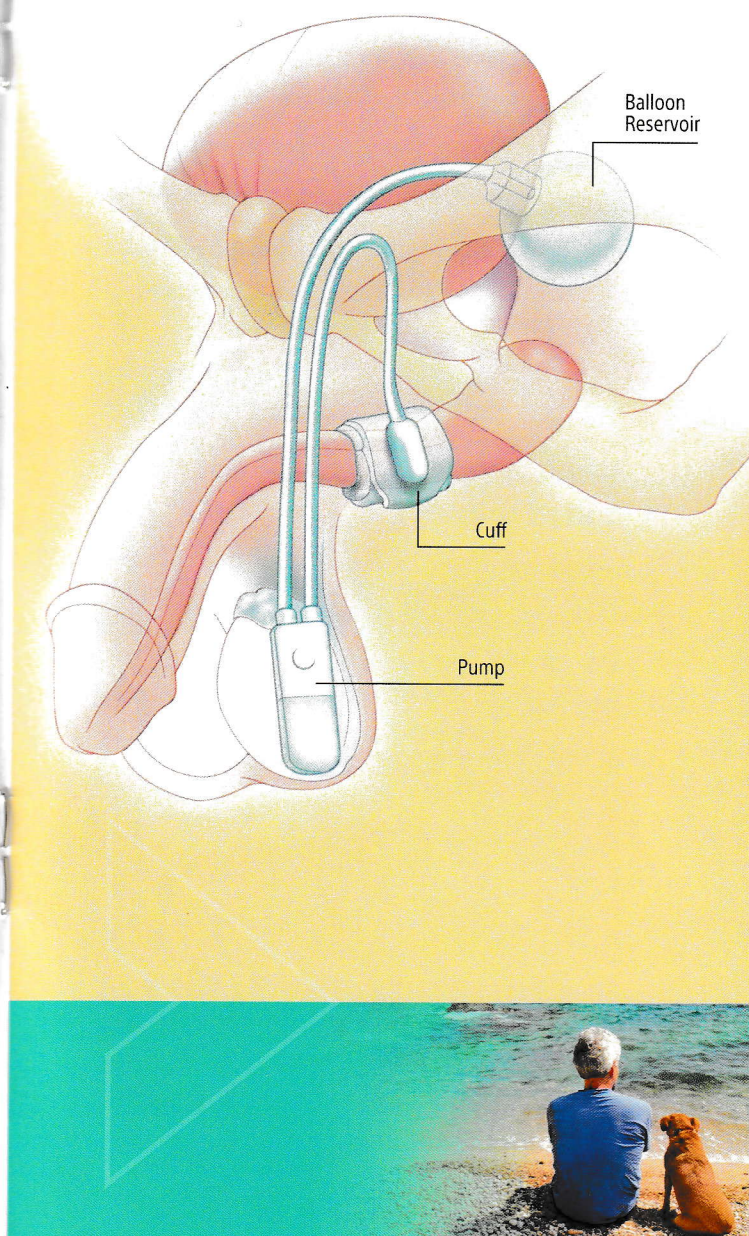
- The pump is implanted in the scrotum
- The inflatable cuff fits around the urethra
- A balloon reservoir is implanted in the abdomen

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
- Designed to mimic a healthy sphincter, allowing the patient to urinate when desired¹⁹
- Is patient-operated¹⁹
- Requires good cognitive ability and manual dexterity¹⁹



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 gives most men the ability to achieve continence²²
- In a study of 150 patients, 94.8% of men used 0-2 pads per day after the procedure.²²
- The AMS 800 can help restore quality of life²³

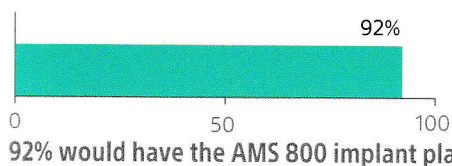
Side effects include, but are not limited to¹⁹:

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

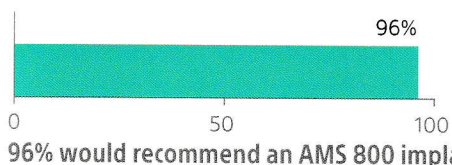
AMS 800™ Urinary Control System by the Numbers



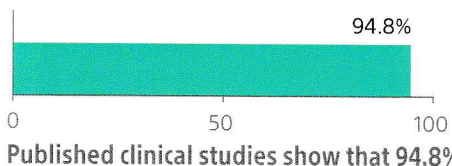
90% reported satisfaction.²⁴



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 94.8% of men used 0-2 pads per day after the procedure.²²



Advance™ XP Brief Summary

The AdVance™ XP 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. behaviour modification, bladder exercises, biofeedback, extra corporeal magnetic stimulation of the pelvic floor) 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, extrusion, or erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire sling. Incorrect sling tension may

cause temporary or permanent lower urinary tract obstruction and retention of urine which may require surgical intervention.

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™ Antibiotic Surface Treatment) 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.





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CAUTION: Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCL.com.

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Boston Scientific Pty Ltd
PO Box 332 Botany NSW 1455 Australia
Tel +61 2 8063 8100
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