

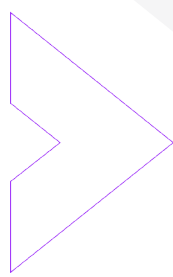
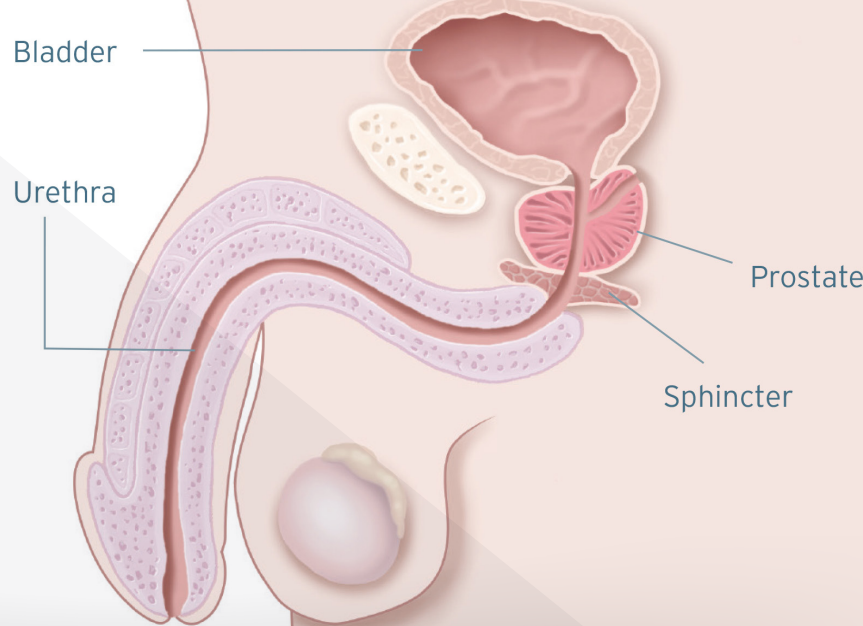


Male Stress Urinary Incontinence Media Fact Sheet

What is male stress urinary incontinence?

Male stress urinary incontinence (SUI) is leakage during actions – such as sneezing, coughing, laughing and lifting – that put abdominal pressure on the bladder.

Unrelated to psychological stress, SUI is caused by the weakening of the sphincter, the muscle that controls the release of urine.¹



Approximately **1 in 10 men** in the U.S. suffer from urinary incontinence, with rates rising for those over age 60.²

SUI after prostate cancer treatment



A common cause of SUI is prostate cancer treatment. Surgery, radiation or a combination of therapies can affect the external sphincter muscle and its functionality.^{1,3}



Approximately 1 in 10 men have persistent leakage one year after a prostatectomy.⁴



Approximately half of patients seek some form of treatment for incontinence following prostatectomy, with up to 5% of men electing surgical approaches.⁵

Some treatment options for SUI

Temporary Treatment Options⁶

Lifestyle Modifications – Limiting fluid intake, avoiding caffeine and alcohol, exercising pelvic floor muscles.

Long-Term Treatment Options⁷

Artificial Urinary Sphincter (AUS) – Placed inside the body to keep the urethra closed, a pump is used to allow urination on demand.

Male Sling – Implanted inside the body to reposition the urethra and provide support to surrounding muscles.

Coping options^{7,8}

Absorbent Products – Pads, diapers or undergarments.

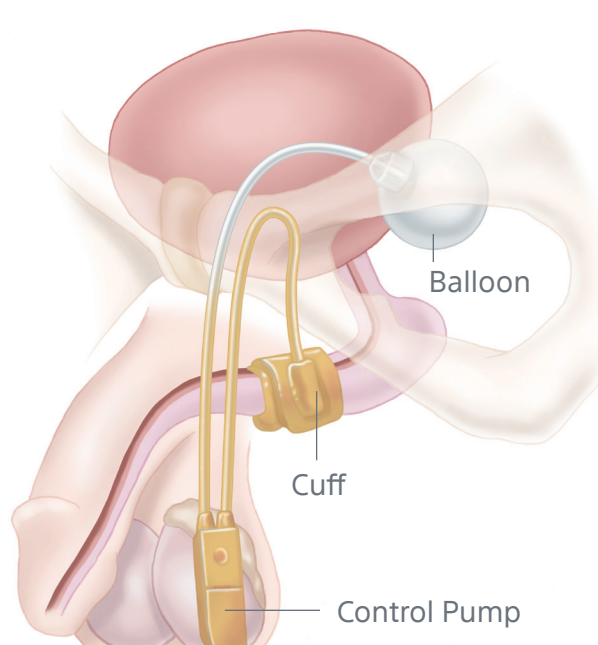
Penile Clamp – Uses a hinged, rigid frame that supports two pads and a locking mechanism. Controls leakage by applying constant pressure upon the penis.

External Collection Devices – A condom catheter or penis pouch gets placed on the penis so urine can flow into a drainage bag. Urine collection bags are strapped to the body underneath clothing during the day and may rest bedside at night.

About the AMS 800™ Artificial Urinary Sphincter (AUS)

The AMS 800 AUS is made up of three parts:

- 1 A control pump, implanted in the scrotum
- 2 An inflatable cuff placed around the urethra
- 3 A fluid-filled balloon implanted in a natural open space next to the bladder



How it works

When patients need to urinate, they squeeze and release the pump in the scrotum several times, which removes fluid from the cuff and pushes it to the balloon.

When the cuff is empty, urine can flow out of the bladder. After a few minutes, the cuff automatically refills, squeezing the urethra closed to restore bladder control.⁹

What is the procedure and where is it performed?

The procedure is performed under anesthesia on an outpatient basis or may require a short hospital stay. Small incisions are made near the scrotum and below the abdomen to insert the cuff, pump and balloon. The system is activated by a doctor four to six weeks after surgery.⁹

Is the device noticeable to others?

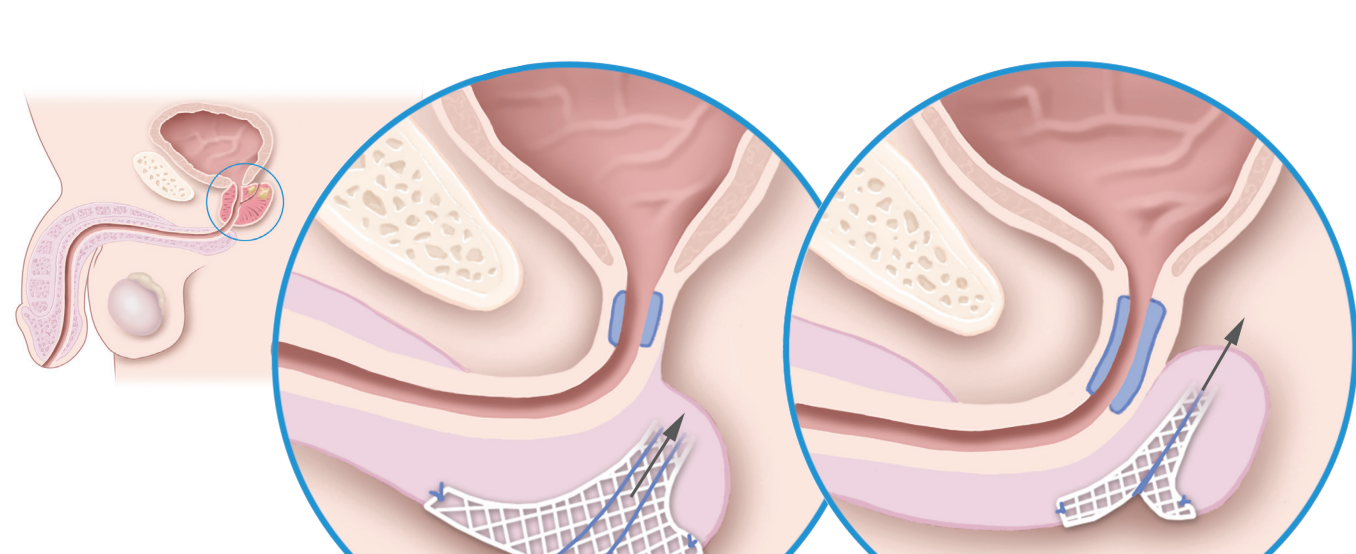
Since the AMS 800 AUS is inserted entirely into the body, it is undetectable to others.⁹

What are the potential risks?⁹

As with any medical procedure, complications can occur. The AMS 800 AUS requires manual dexterity to work the pump. Some risks include but are not limited to: device malfunction or failure which may require revision surgery, erosion of the urethra in the cuff area, urinary retention, post-operative pain and infection.

About the AdVance™ XP Male Sling System

The AdVance XP Sling is made of pliable mesh placed inside the body which repositions the urethra and provides support to a patient's surrounding muscles. This can help to keep the urethra closed, especially when coughing, sneezing or lifting.^{9,11}



How it works

The AdVance XP Sling acts as a "hammock," repositioning and supporting the urethra to help restore normal bladder control. Once in the body, the AdVance XP Sling requires no action by the patient to function.^{9,11}

How soon can patients resume activities after the procedure?

Patients may be continent immediately following the procedure. Most should be able to resume normal, daily activities within 1 to 2 weeks, per their doctor's discretion.⁹

Where is the procedure performed?

The procedure is usually done on an outpatient basis and is performed under anesthesia.⁹

What are the potential risks?

As with any medical procedure, complications may occur. Some risks include, but are not limited to: post-operative pain, inflammation, urethral or tissue damage, bleeding and irritation at the wound site, inability to urinate (typically resolved within a few days), device failure and foreign body response.⁹

Caution: Federal (U.S.) law restricts these devices 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 and the AdVance XP Male Sling System. Talk to your doctor for a complete listing of risks, warnings and important safety information.

AMS 800™ Artificial Urinary Sphincter

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

AdVance™ XP Male Sling System

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 dysfunction, 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, renal insufficiency, and upper urinary tract relative obstruction. MH-557011-AB

For more information about the AMS 800 AUS or the AdVance XP Sling, visit www.fixincontinence.com.

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