Men’s Health

Signs, Symptoms and Treatment Options for Erectile Dysfunction and Stress Urinary Incontinence

Audio and video recording prohibited

To encourage open dialogue amongst participants and to safeguard their privacy expectations, the use of audio or video recording devices of any kind during this presentation is strictly prohibited.

Understanding erectile dysfunction and your treatment options

Erectile dysfunction

What is it?
Who has it?
What causes it?

Erectile dysfunction (ED)

What is it?

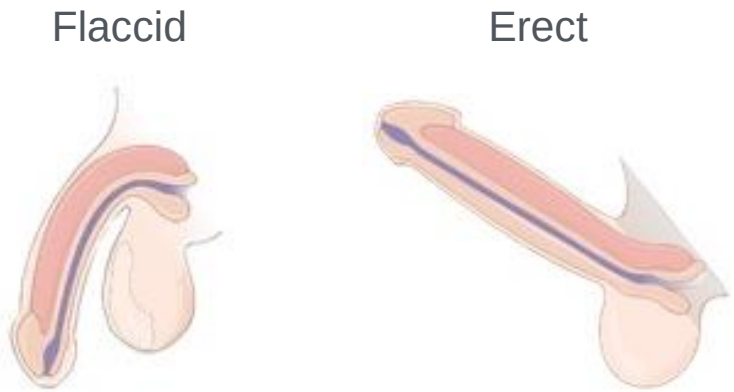
- The persistent inability to achieve or maintain an erection firm enough to have sexual intercourse

How prevalent is it?

- Approximately 1 in 5 American men ≥ 20 years old experience ED in their lifetime[1]
- More than half of men over 40 have some degree of ED[2]
- Affects approximately 39 million American men[3]

Erection process[4]

- When aroused, the nerves surrounding the penis become active
- Muscles around the arteries then relax and more blood flows into the penis
- The additional blood makes the penis stiff and hard, or erect
- This erection tightens the veins so the blood can’t leave the penis, enabling the penis to remain erect



Causes and comorbidities associated with ED[5]

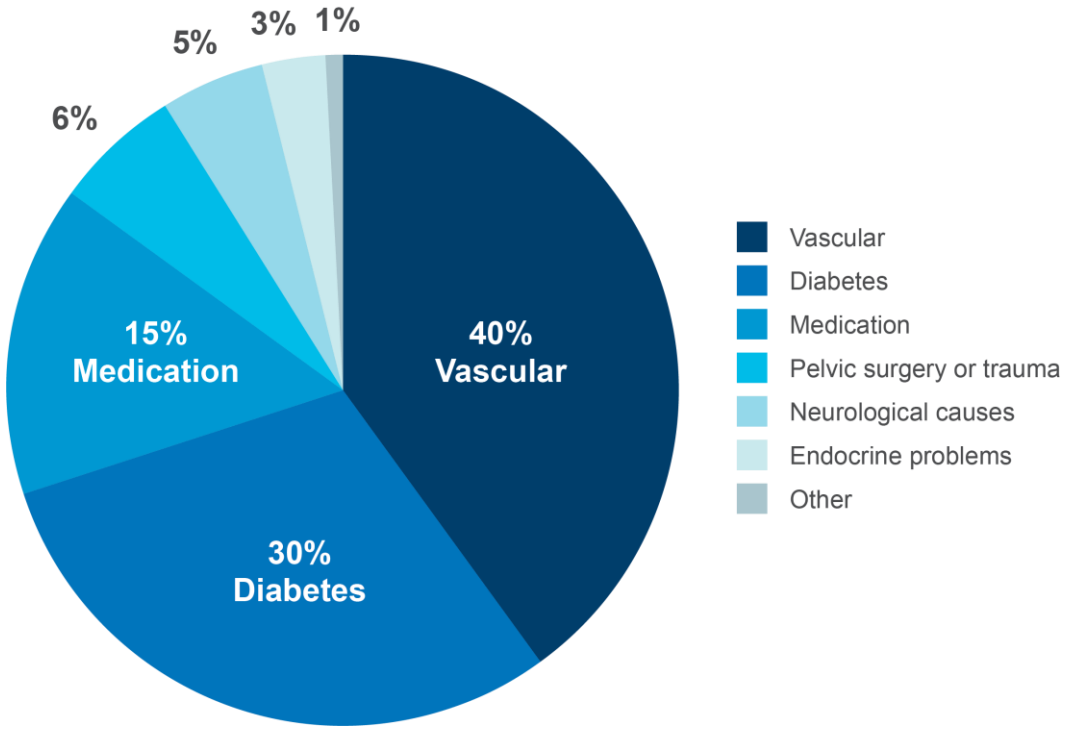
Correlates positively with overall poor health

Top three physical causes are:

- Vascular
- Diabetes
- Medication

Can be a result of or precursor to:

- Prostate Cancer Treatment
- Diabetes
- Heart Disease



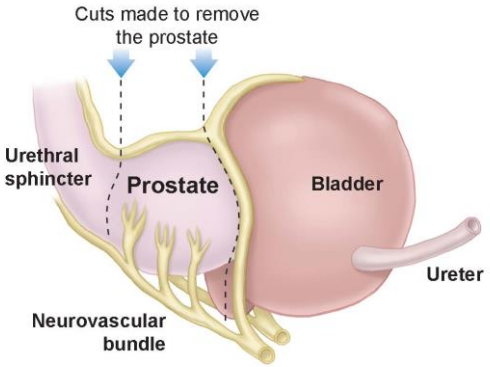
ED can affect quality of life[6-8]

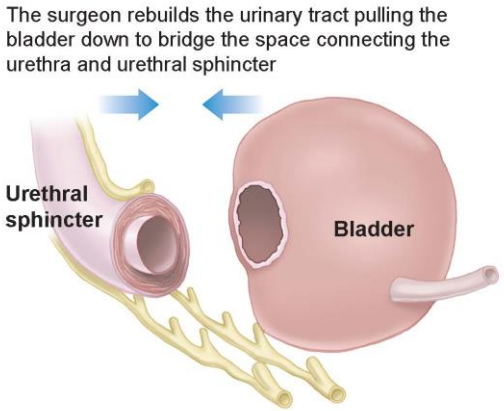
ED can have a broad negative impact on the health-related quality of life.

Erectile dysfunction and prostate cancer treatment

Erectile dysfunction as a result of prostate cancer treatment

- The nerves that provide stimulation for an erection lie very close to the prostate and may be injured during prostate cancer treatment[22]
- Prostate cancer treatments can affect a man's ability to get an erection on a temporary or permanent basis[22]





Sexual dysfunction after prostate cancer treatment

Overall erectile dysfunction affects 25–75% of men[23]

Erectile dysfunction as a result of prostate cancer surgery, robot-assisted radical prostatectomy (RARP), *10–46% of men 1 year after surgery had ED*[24]

Sexual dysfunction after radiation affects up to 50% of men[25]

Erectile restoration treatment options

Who can treat erectile dysfunction?

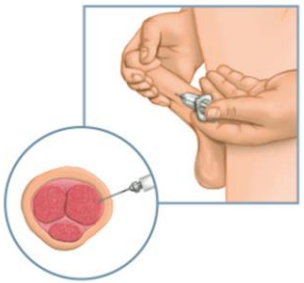
Family Physician/Primary Care Physician
A doctor with a general understanding of ED and is able to prescribe medical treatment options

Urologist
A specialist focused on diseases of the male and female urinary tract systems and the male reproductive organs

Prosthetic urologist (ED specialist)
Prosthetic urologists have additional training specific to men's health and erectile dysfunction, and specializes in the penile implant procedure

Treatment options

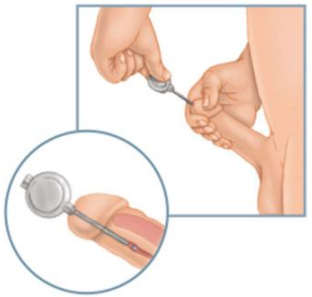
Oral Medications



Injections

Penile Implants

Vacuum Erection Devices



Urethral Suppositories

Oral medications (PDE-5 Inhibitors)

How do they work?[27-29]

- Increase blood flow to the penis, may improve ability to get erections and maintain them until sexual intercourse is successfully completed
- Requires sexual stimulation
- Usually taken within 1 hour before anticipated sexual activity
- Typically works for up to 4 hours (~36 hours with Cialis™)
- Not to be taken more than once a day
- Some oral medications' efficacy can be affected by food

How effective are they?

- Effective in approximately 60–80% of cases[27-29]
- Almost half of men with ED after prostate surgery give up or the pills stop working[23]
- Men with diabetes are 1.5 to 2 times more likely to move on to other treatments[14]

Oral medications[27-29]

Most common side effects:

- Headache, facial flushing, stuffy nose, upset stomach

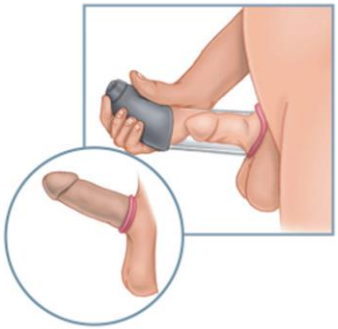
Some cautions:

- Talk to your doctor if sex is inadvisable because of cardiovascular status
- With alpha-blockers: generally, you should be stable on your alpha-blocker therapy before using an oral medication
- With nitrates: talk to your heart doctor about how to monitor your condition while on oral medications

Tell your doctor if you:

- Have ever had any heart problems, stroke or low or high blood pressure
- Have ever had liver or kidney problems

Vacuum erection device (VED)[30]



How does it work?

- A hollow plastic tube is placed over the penis
- The pump (hand/battery-powered) is used to create a vacuum that pulls blood into the penis
- Once an erection is achieved, an elastic tension ring is placed at the base of the penis to help maintain the erection

How effective is it?

- Patient satisfaction rates rage from 68–80%[31]
- Despite initial high success rates, in one study 86% of patients decide to move on to other sexual aids[23]

Encouragement for Weak Men.

No man can afford to be indifferent to a demonstrated fact calculated for his own good. We make the unreserved claim that our Improved Vacuum Developer will perform just what we advertise it to do, and any man will appreciate what it is who has long seen the sweets of life just beyond his reach.

It does the work. It cures when everything else fails. This is the reason why it is the best treatment offered to suffering men. Common sense will tell you that the Vacuum applied to the surface, draws the blood into circulation through the natural channels which before were dormant, thus setting up a wonderful vital action at once. Only one application of the instrument is sufficient to demonstrate its wonderful action and positive results.

It produces the same beneficial results upon the aged or middle aged as upon the young man.

The patient can apply the treatment himself without the service of a physician and can be followed without assistance of any kind. Its results are lasting, improvement commences from the first day of its use.

No Medicine to Destroy Your Stomach.

Write for our illustrated treatise, showing the parts of the male system involved, sent sealed free, explaining fully our improved method, or call upon us at our offices, where we shall be pleased to explain and further advise you, free of any charge.

HEALTH APPLIANCE COMPANY,
119½ South Spring Street, Los Angeles.

Office Hours, 10 a.m. to 4 p.m. Evenings, 6 to 8:30.
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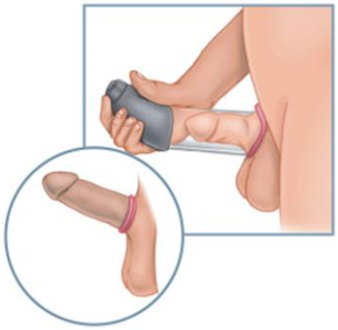
In use since the 1980s

Vacuum erection device (VED)



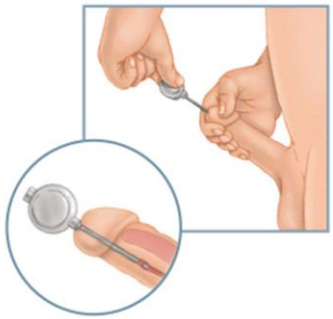
Most common side effects:[30,34]

- Blocked ejaculation
- Bruising of penile
- Penile discomfort
- Penile numbness or coldness

Most common reason for discontinuation:[10,35]

- Erections of insufficient rigidity or duration
- Difficult mechanics
- Penile bruising
- Lack of spontaneity

Urethral suppository



Alprostadil (MUSE™)

How does it work?[39]

- A urethral suppository, such as MUSE™, is administered by inserting the applicator stem into the urethra after urination
- Onset of erection is within 5 to 10 minutes
- The suppository must be refrigerated

How effective is it?

- In clinical literature, success rates are reported at 40–65%[32,33]
- 40–50% of men don't continue using this therapy after 6–8 months[23,41]

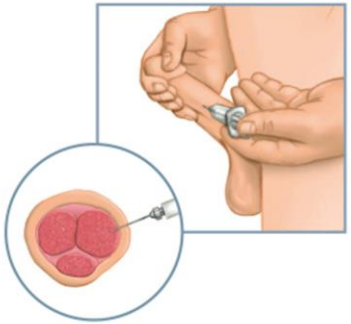
Most common side effects:[39,40]

- Pain in the penis, urethra or testes
- Urethral pain or burning
- Low blood pressure
- Dizziness

Most common reasons for discontinuation:[41]

- Insufficient erections suitable for intercourse
- Urethral pain and burning

Intracavernous injection therapy



Alprostadil
(CAVERJECT™)

How does it work?[42]

- Self-inject medication directly into corpora cavernosa
- Onset of erection within 5 to 20 minutes

How effective is it?

- Approximately 60% of patients were satisfied and continued use[36]
- Despite success rates, in a study of 254 men, only 20% continued the therapy[37]

Most common side effects:[37,42]

- Penile pain
- Penile fibrosis or scar tissue
- Priapism or prolonged erection
- Blood collection under the skin at injection site

Most common reasons for discontinuation:[37,43]

- Unsatisfactory erections
- Pain
- Dislike of injections

Penile implant

Entirely contained in body: no one can tell you have it

How does it work?[44]

- Pair of cylinders implanted in the penis, a pump placed inside the scrotum and a reservoir of saline placed in the lower abdomen
- Squeezing and releasing the pump moves fluid into the cylinders, creating an erection
- Deflate the device by pressing the deflate button on the pump. The penis then returns to a soft, flaccid and natural-looking state

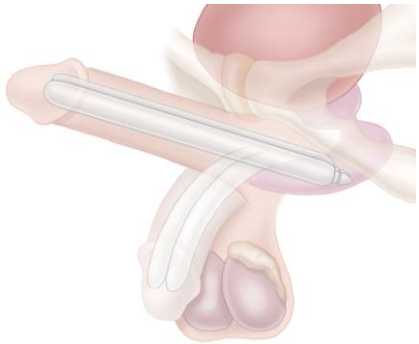
How effective is it?

- 98% of patients reported erections to be “excellent” or “satisfactory”[19]
- At 7 years, 94% are still in use and free of revision[38]

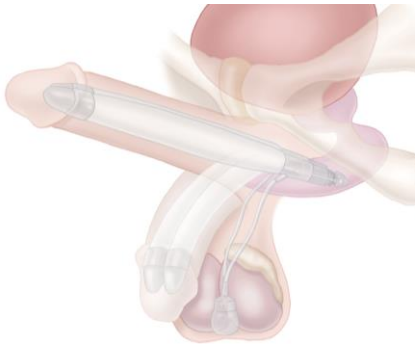
Most common side effects/complications or reasons for removal:[44]

- Post-operative genital pain
- Mechanical malfunction, including auto-inflation
- Infection
- Repeat surgery

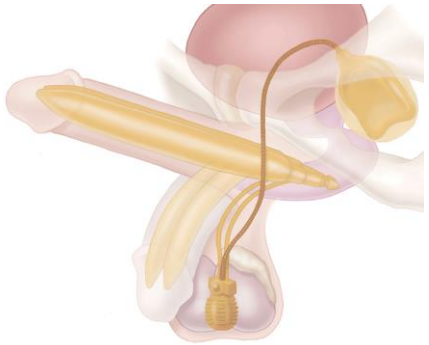
Types of Boston Scientific penile implants



Spectra™ Concealable Penile Implant



AMS Ambicor™ Inflatable Penile Implant



AMS 700™ Penile Implant with MS Pump™

- LGX
- CX
- CXR

Benefits of Boston Scientific penile implants

- Designed as a permanent solution to ED
- Spontaneous—have sex when the mood strikes
- Erection can last as long as you desire
- Entirely contained inside the body—no one knows you have one unless you tell them
- High patient and partner satisfaction[47,51]
- Typically does not interfere with ejaculation or orgasm[52]
- Implants have been in use for more than 40 years[49]
- Nearly 500,000 patients have been treated with a Boston Scientific penile implant[50]

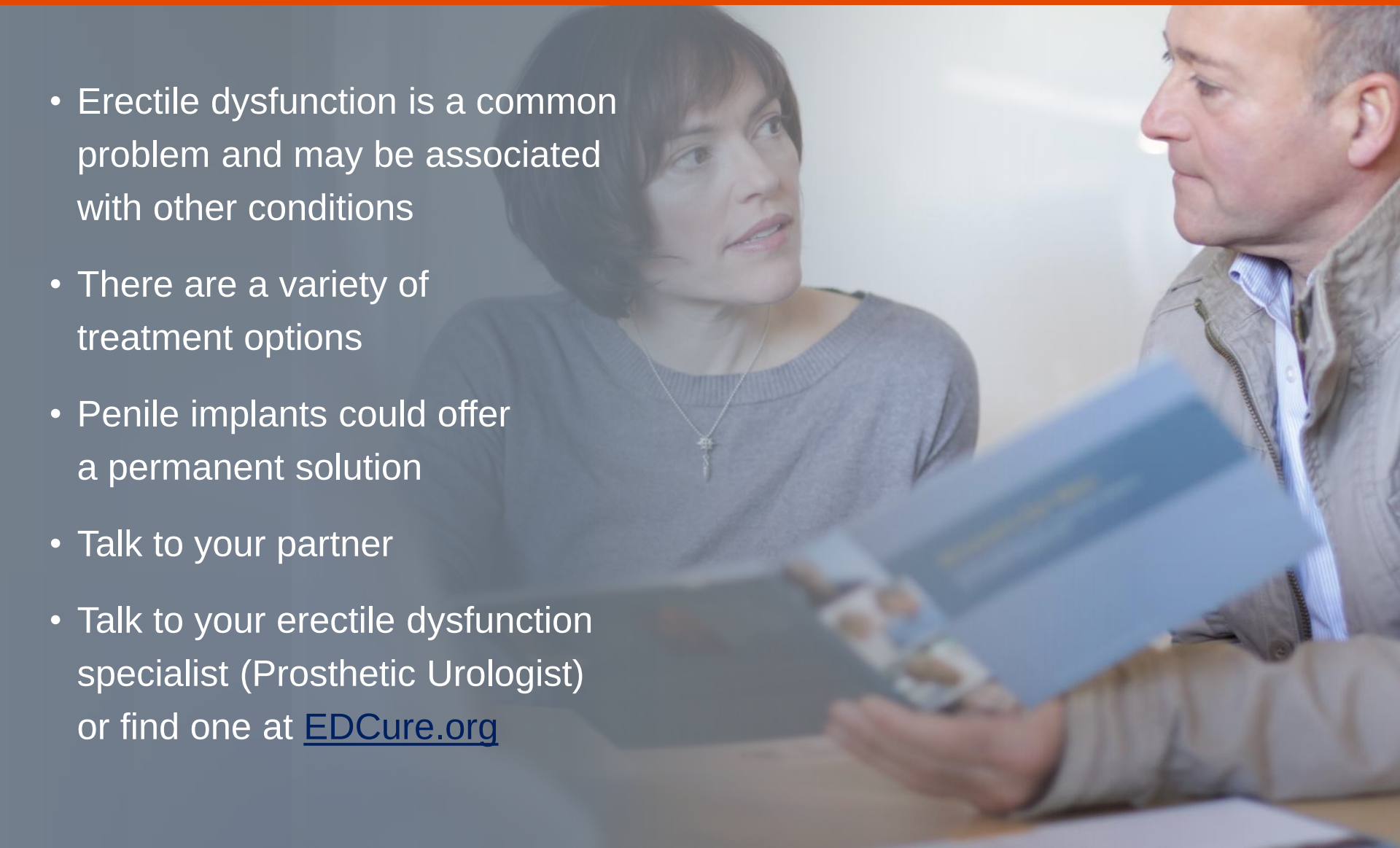
Penile implants are a surgical procedure—possible risks[44]

There are risks involved with any surgery. Not all patients are candidates for a penile implant. Discuss all the risks and benefits of this procedure in more detail with your doctor.

Some risks of a penile implant may include:

- Will make natural or spontaneous erections as well as other interventional treatment options impossible
- There may be mechanical failure of the implant, which may require revision surgery
- Pain (typically associated with the healing process)
- Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection
- There is a 1–2.5% risk of infection with the Boston Scientific inflatable penile implants.[44,45]

Summary



- Erectile dysfunction is a common problem and may be associated with other conditions
- There are a variety of treatment options
- Penile implants could offer a permanent solution
- Talk to your partner
- Talk to your erectile dysfunction specialist (Prosthetic Urologist) or find one at EDCure.org

Understanding male stress urinary incontinence and your treatment options

Male stress urinary incontinence

What is it?
Who has it?
What causes it?

Male stress urinary incontinence

What is it?

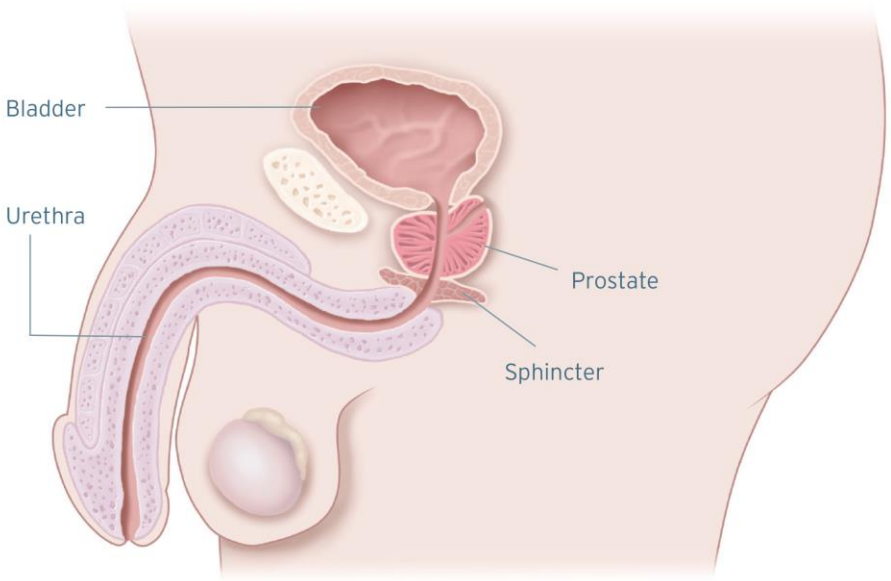
- Also known as bladder leakage, SUI is when the urinary sphincter muscle is damaged or weakened and it cannot squeeze and stop urine from flowing out of the body when you laugh, lift, walk, bend, push, pull and move

How prevalent is it?

- Studies suggest that as many as 50% of men report leakage immediately following surgery for prostate cancer but most heal within the first few weeks to few months[53]
  - Somewhere between 9% and 16% of men will have persistent SUI one year after surgery[54]
- Worldwide, approximately 500,000 men suffer from SUI[55]

Urinary process

- The bladder stores urine
- Urine exits the body via the urethra
- Part of the urethra is surrounded by muscles called sphincter muscles
- The sphincter muscles remain contracted in order to keep urine in the bladder
- When the sphincter muscles relax, urine is able to exit the body via the urethra



Causes and comorbidities associated with SUI

Strongly correlates with prostate cancer surgery

- Approximately 9–16% of men have persistent post-prostatectomy incontinence 1 year after treatment[54]

Can also be a result of:[56,57]

- Neurologic disorders
- Enlarged prostate surgery
  - Occurring in 0.5–3% of men after surgery
- External beam radiation (pelvic radiation)
  - Occurring in 1.6% of men after treatment
- Pelvic trauma

Urinary incontinence can affect quality of life[58]

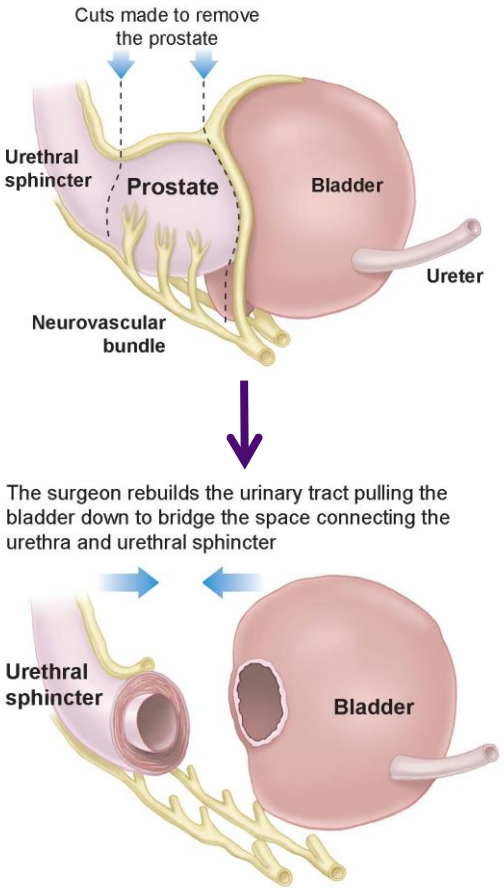
Urinary incontinence (UI) can have a significant negative impact on all aspects of quality of life (QOL)

Studies have shown that people suffering from UI are more depressed, psychologically distressed, emotionally disturbed and socially isolated

Male SUI and prostate cancer treatment

SUI and prostate cancer treatment connection

- 181,000 men are diagnosed with prostate cancer each year in the US[59]
- Approximately 70,000 radical prostatectomies are performed each year[60]
  - Radical prostatectomy is an operation to remove the prostate and some of the tissue around it[22]
- Approximately 9–16% of men have persistent post-prostatectomy incontinence 1 year after treatment[54]



A side effect of prostate cancer treatment

- Incontinence is normal immediately following radical prostatectomy
- Continence is often restored during the first year of recovery
- But not all patients are able to restore their continence[54,61]
- There are solutions for patients who want to restore their continence and normalcy

Male continence treatment options

Who can treat male SUI?

Urologist

A specialist focused on diseases of the male and female urinary tract systems and the male reproductive organs

Prosthetic urologist

Prosthetic urologists have additional training specific to men's health and urinary incontinence, and specialize in the male sling and artificial urinary sphincter procedures

Short-term treatment options

Behavioral modifications

- Reduced fluid intake
- Planned restroom breaks

Intervention

- Pelvic floor physical therapy
- Kegel exercises
- Biofeedback

Coping

- Pads
- Diapers
- Catheters
- Penile Clamps

Short-term treatment options

Short-term solutions can be expensive, a nuisance and can become problematic.

- Absorbent products are easy to use but can be bulky, likely to leak and smell
- Catheters may be discreet and may be uncomfortable, and long-term use may cause urinary tract infections
- A penile clamp can control leakage but has to be moved often and can be painful and uncomfortable[62]

Long-term treatment options

Male Sling

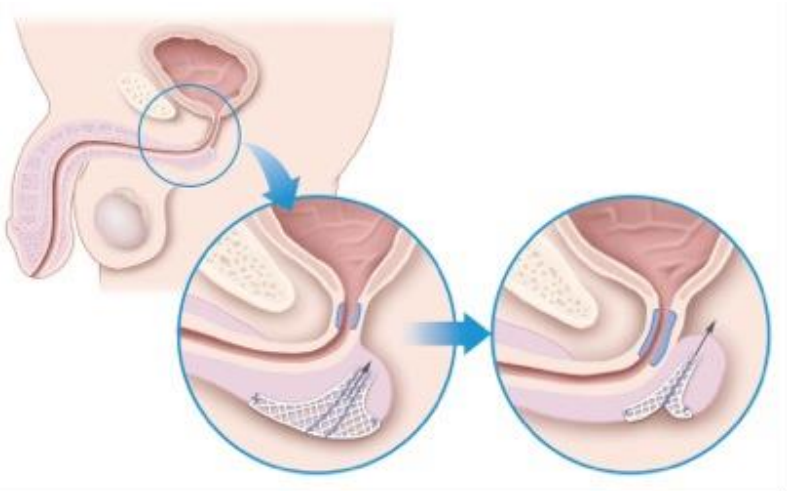
- Designed to *support* the urethra to better control urine[65]
- Studies have shown it may be most appropriate for mild to moderate SUI[64]
- Made of soft mesh material that is completely concealed inside the body[66]

Artificial Urinary Sphincter (AUS)

- Designed to *replicate* the function of the external sphincter muscle to control urine[67]
- Can treat all levels of SUI
- Made from three small connected components that are completely concealed inside the body[67]:
  - Cuff
  - Control Pump
  - Pressure Regulating Balloon

Long-term treatment options: AdVance™ Male Sling System

- **10 +** years of clinical use[50]
- Studies have shown it may be most appropriate for mild to moderate SUI (less than 4 pads per day)[64]
- Acts as a “hammock” to reposition and support the urethra, restoring normal bladder control[65]
- Most patients are continent immediately following the procedure[68]
- **92%** patient satisfaction[64]
- **94%** would recommend the procedure to a friend[69]

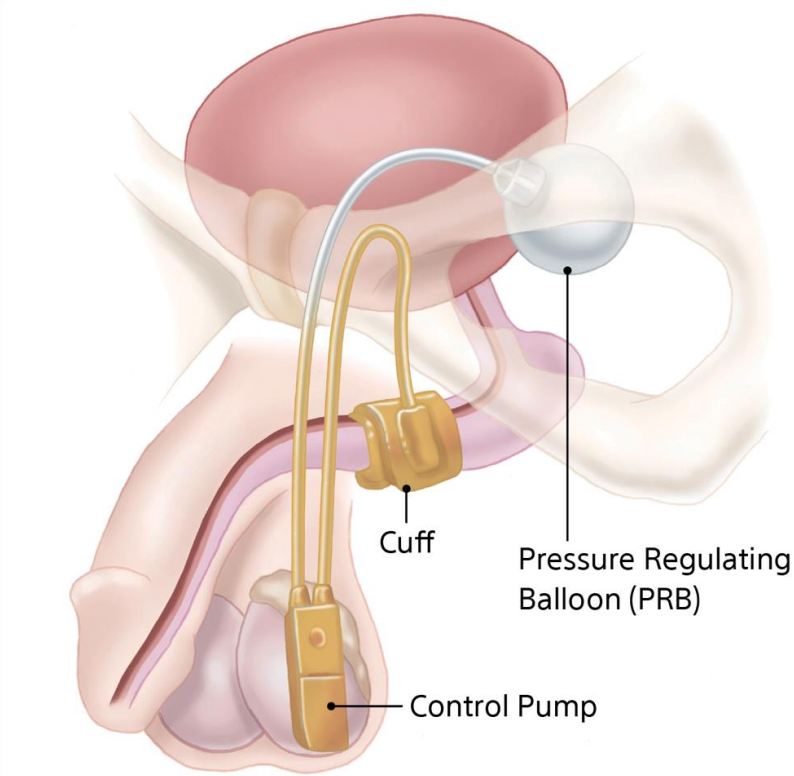


Benefits of the AdVance™ Male Sling System

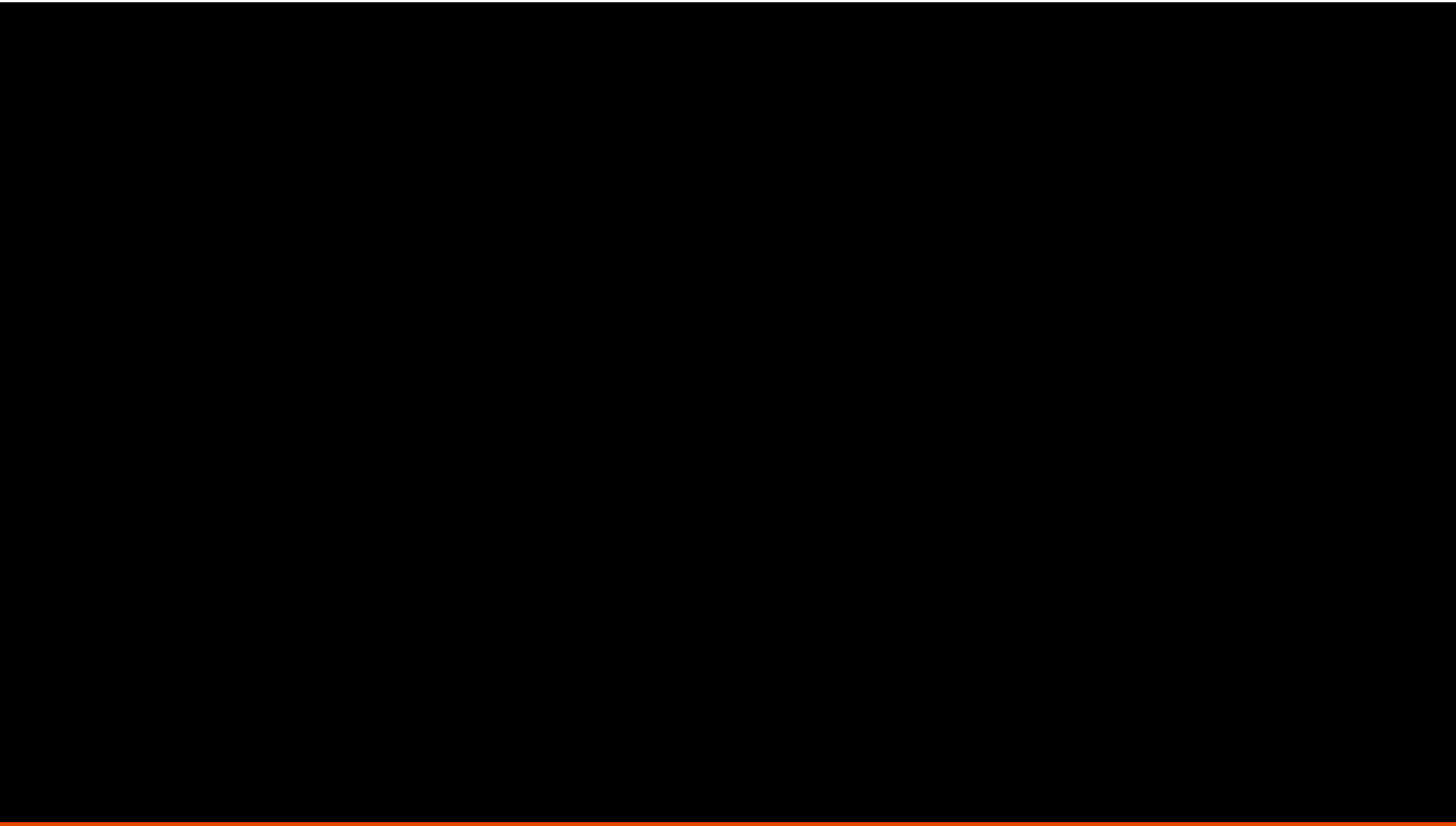
- Minimally invasive procedure[70]
  - Normal activities can be resumed 1 to 2 weeks after the procedure or at the discretion of your urologist[66]
- There is no interaction with the device, it works on its own to restore continence[68]
- Can help restore normalcy and renew confidence

Long-term treatment options: AMS 800™ Urinary Control System

- **40 +** years of AUS clinic use[50]
- Treats all levels of male SUI
- Recognized as the **"Gold Standard"** treatment for male SUI throughout medical literature[72]
- The cuff fits around the urethra, inflates and keeps it closed, thereby keeping urine in the bladder[65]
- To void, squeeze the scrotal pump several times. Doing so deflates the cuff, opens the urethra and allows urine to exit the body[71]
- After several minutes, the cuff re-inflates on its own, closes the urethra and keeps urine in the bladder[71]



AMS 800 Urinary Control System animation



Patient satisfaction with AMS 800™ Urinary Control System[73]

90% of patients report satisfaction with the AMS 800 System

92% or more would have the AMS 800 System placed again

96% or more would recommend the AMS 800 System to a friend

Benefits of the AMS 800 Urinary Control System

- Offers most men with a weakened sphincter muscle the ability to achieve continence[71]
- Mimics a healthy sphincter, allowing patients to urinate when desired[71]
- Placed entirely inside the body, it is undetectable to others
- High patient satisfaction[74]
- Can help restore normalcy and renew confidence

Take control and assess your condition

If you are bothered by your leakage, *take action* to restore your normalcy and renew your confidence:

- Speak with a urologist
- Share your daily pad usage
- Keep a weekly pad journal

For more information visit FixIncontinence.com

The male sling and artificial urinary sphincter are surgical procedures—possible risks

There are risks involved with any surgery. Not all patients are candidates for a male sling or AUS. Discuss all the risks and benefits of these procedures in more detail with your doctor.

Male Sling

Possible side effects include, but are not limited to:

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

Artificial Urinary Sphincter

Possible side effects 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
- Infection, pain and soreness

Insurance coverage

- Boston Scientific cannot guarantee insurance coverage
- Medicare and most private insurance companies cover male incontinence procedures; however, individual coverage may vary
- Work with your doctor’s office and insurance provider to check coverage levels prior to receiving treatment

Summary

- Male SUI is a known side effect of prostate cancer treatment and other conditions
- There are a variety of treatment options
- Coping short-term options can be expensive over time and uncomfortable
- A sling or artificial urinary sphincter could offer a permanent solution for male SUI
- Talk with your urologist to understand your options

Important safety information for AMS 700™ Penile Prosthesis with MS Pump

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 700™ with MS Pump™ Inflatable Penile Prosthesis. Talk to your doctor for a complete listing of risks, warnings and important safety information.

The AMS 700™ with MS Pump™ Inflatable Penile Prosthesis is intended for use in the treatment of male erectile dysfunction (impotence). Implanting a penile prosthesis will damage or destroy any remaining ability to have a natural erection, as well as make other treatment options impossible.

Men with diabetes, spinal cord injuries or skin infections may have an increased risk of infection. Implantation may result in penile shortening, curvature or scarring. Some AMS 700 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, device migration potentially leading to exposure through the tissue, wearing away/loss of tissue (device/tissue erosion) infection, unintended-inflation of the device and pain/soreness. MH-545411-AA

Important safety information for AMS Ambicor™ Inflatable Penile Prosthesis

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Potential risks may include: device malfunction/failure leading to additional surgery, device migration potentially leading to exposure through the tissue, wearing away/loss of tissue (device/tissue erosion) infection, unintended-inflation of the device and pain/soreness. MH-545613-AA

Important safety information for AMS Spectra™ Concealable Penile Prosthesis

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 Spectra™ Concealable Penile Prosthesis. Talk to your doctor for a complete listing of risks, warnings and important safety information.

The Spectra™ Concealable Penile Prosthesis is intended for use in the treatment of male erectile dysfunction (impotence). Implanting a penile prosthesis will damage or destroy any remaining natural ability to have a natural erection, as well as make other treatment options impossible.

Men with diabetes, spinal cord injuries or skin infections may have an increased risk of infection. Implantation may result in penile shortening, curvature or scarring.

Additional information is provided in the product Patient Manuals, available through your doctor.
MH-547820-AA

Important safety information for AMS AdVance™ Male Sling System

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

The AdVance™ 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 and pain. MH-547816-AA

Important safety information for AMS 800™ Urinary Control System

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-545611-AA

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