Treatment Option for Male Stress Urinary Incontinence
Patient Benefits

- Minimally invasive procedure\(^1\) allowing most patients to resume normal, daily activities 1 to 2 weeks later\(^2\)
- Patients may be continent immediately following the procedure\(^4\)
- The implanted device contains no moving parts, operates automatically and therefore patient manual dexterity and mental acuity are not criteria for exclusion\(^14\)
- Can be used in combination with the AMS 700\(^6\) Inflatable Penile Prosthesis\(^10\)

Patient Risks

- Side effects include pain, inflammation, urethral or tissue damage, bleeding and irritation at the wound site, and urinary retention\(^2,5\)
- Contraindications include patients with urinary tract infections, blood coagulation disorders, compromised immune systems, renal insufficiency or upper urinary tract obstruction\(^2\)
- Patients should abstain from heavy lifting, strenuous exercise, and intercourse for a minimum of six weeks\(^2\)
- Acute inflammatory tissue reaction and transitory local irritation has been reported with the use of the absorbable suture\(^2\)
AdVance® Male Sling System

Durable Treatment for Male Stress Urinary Incontinence (SUI)¹

The AdVance® Male Sling System, intended for the placement of a suburethral sling for the treatment of male SUI. This retourethral sling is implanted utilizing a transobturator placement technique.²

The AdVance Male Sling has been extensively studied and shown to be a viable treatment option yielding high success rates and a low incidence of serious complications.¹,³,⁴ In 6 peer reviewed clinical studies encompassing over 500 patients, success rates ranged from 54.6% - 90.6%.³ In another study, success rates were shown to be durable throughout a 3-year follow up period (76.9% - 76.8%, at 1-year and 3-year follow-ups respectively).¹

The most commonly reported complication is transient urinary retention, occurring at a rate of 0-21.3%.⁶ The retention generally has been shown to resolve spontaneously after a few weeks.⁷

Mechanism of Action

The sling is placed on the bulbar urethra

The AdVance sling is tensioned thereby repositioning the bulbous urethra. The result? Increased functional urethral length and a backdrop of support to the distal membranous (sphincteric) urethra during stress events.¹⁷

In a study of 42 patients, 94.4% would recommend AdVance to a friend¹⁵
According to published clinical literature, the following patient selection criteria should be considered:

Optimal candidates may include:

- Sufficient residual sphincter function to remain continent while recumbent
- Ability to interrupt urine stream while voiding
- Mild-to-moderate SUI
- Stable bladder neck contractures prior to implantation
- No prior radiation

**1. Sling**

The sling acts as a “hammock” to reposition and support the urethra. 1

a. Heat sealed edge for sling fixation

b. Polypropylene liner reduces pull-through resistance during sling passage and enables desired sling placement prior to sling fixation

c. Resorbable tensioning suture increases sling tensile strength
2. Needle Passers
   a. Helical wireform is designed specifically for transobturator needle passage in the male anatomy.
   b. Arrows indicate on which side of the patient’s body to use.

3. Percutaneous Needle
   Assists in the identification of the correct obturator foramen needle passer entry point.

4. Disposable Retractor System
   Assists with surgical retraction and increases the physician’s field of view.
   Consists of:
   a. Retractor Ring
   b. Blunt Stay Hooks

Urodynamic Findings\textsuperscript{12,13}

AdVance significantly improved abdominal leak point pressure and Valsalva leak-point pressure\textsuperscript{12,13}
No changes were noted in other uroflowmetry parameters:\textsuperscript{12}

- No change in detrusor voiding pressure
- Post-void residual
- Maximum and average uroflow
- No de novo reduced bladder compliance
- No de novo overactivity
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 (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.


2. AdVance® Male Sling System Instructions for Use.