







Physicians

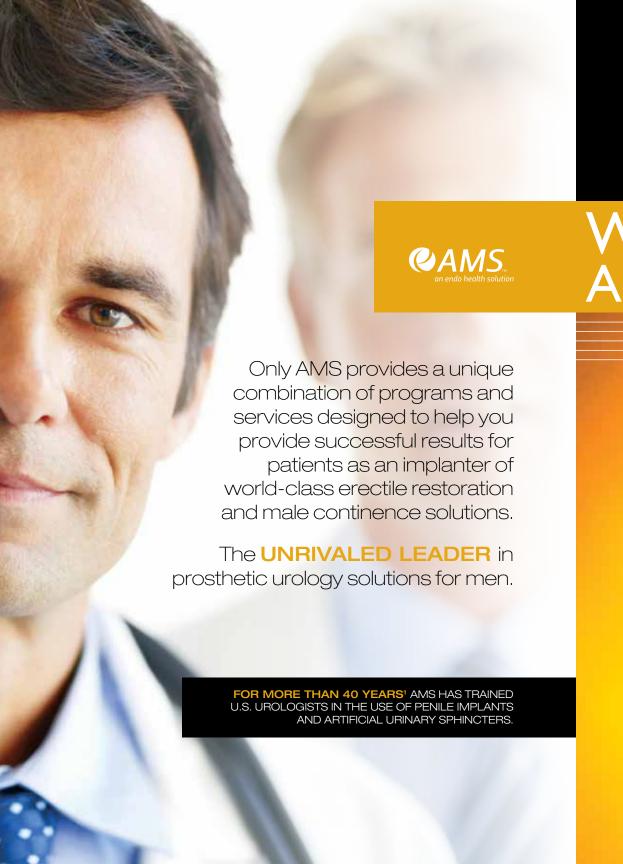
Patients

Innovation

Clinical Data

Societies

WE ARE COMMITTED TO YOU



## Physicians

• Training urologists in the use of penile implants and the artificial urinary sphincter for 40 years, over 500 U.S. physicians per year<sup>2</sup>

Providing prosthetic training for urology residents since

2002

- Expanding the field of prosthetic urology through the support of fellowship programs led by leading practitioners at top institutions
- Supporter of Society of Sexual Medicine ("SMS")/Society of Urologic Prosthetic Surgeons ("SUPS") Resident's Surgical Symposium since 2006
- Providing expert proctoring at Veterans Affairs Hospitals for staff and residents



# Patients

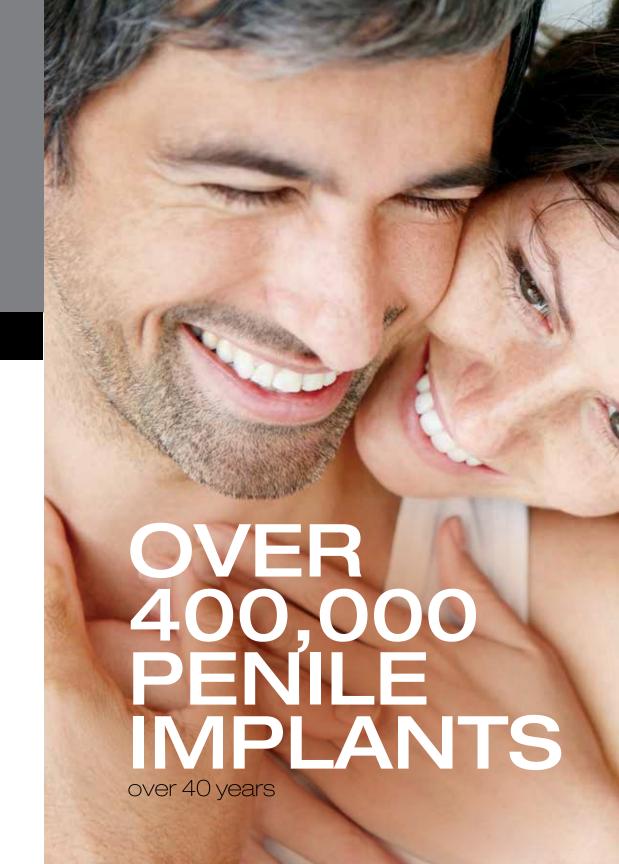
- Robust patient education materials that address both the emotional and technical aspects of surgical implants
- Direct to patient outreach
- Patient education websites with over 6,000 visitors per month<sup>2</sup>
- Over 40 years of clinical use for AMS penile implants and the artificial urinary sphincter<sup>2</sup>
- Over 400,000 patients treated with AMS penile implants<sup>2</sup>
- Over 150,000 patients treated with the AMS Artificial Urinary Sphincter<sup>2</sup>

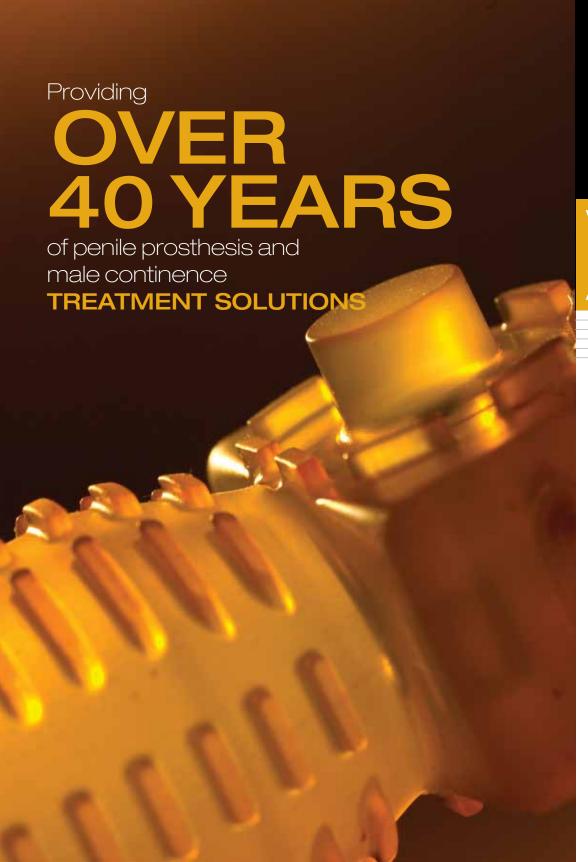
Dedicated field team conducting

HUNDREDS OF PATIENT EDUCATION

AND OUTREACH EVENTS – educating

more than 17,000<sup>2</sup> men each year





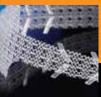


## Leadership

- Global Leader: Product available in over 50 countries
- AMS has been collaborating with physicians for more than 40 years<sup>1</sup> to provide new solutions for patient care
- AMS is the only company with a full range of penile prostheses –
  3-piece, 2-piece, and malleable providing an option for a broad
  range of patients the established market leader with 3 out of
  every 4 patients receiving an AMS inflatable penile prosthesis
  versus competitor<sup>2</sup>













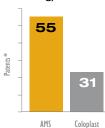


# Leadership (cont.)

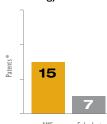
- AMS 700<sup>™</sup> Inflatable Penile Prosthesis with InhibiZone<sup>™</sup> Antibiotic Treatment only antibiotic-impregnated inflatable penile prosthesis with clinical evidence showing a significant reduction in the rate of revisions due to device related infection<sup>3</sup>
- AMS 700<sup>™</sup> with Momentary Squeeze (MS) Pump<sup>™</sup> first one touch deflation pump technology<sup>2</sup>
- AMS 700<sup>™</sup> Inflatable Penile Prosthesis (LGX) the only Length AND Girth Expanding Cylinder Technology with cylinders designed to optimize length and girth with cylinder expansion up to 20% elongation possible, depending on patients anatomy<sup>4</sup>
- Parylene Coating proprietary coating designed to increase cylinder durability<sup>2</sup>
- Conceal<sup>™</sup> Low Profile Reservoir for optimized fit and flexibility with fill volume from 65 ml or 100 ml
- Spectra<sup>™</sup> Concealable Penile Prosthesis offers simplified sizing, ease of placement, excellent concealment and rigidity<sup>2</sup>

- Locking snap-fit Rear Tip Extenders (RTE's)
- AdVance<sup>™</sup> Male Sling System first Transobturator Male Sling<sup>2</sup>
- The only FDA approved artificial urinary sphincter<sup>2</sup>
- Ambicor<sup>™</sup> Penile Prosthesis the only inflatable penile prosthesis available without a separate reservoir component requiring few squeezes for cylinder inflation<sup>5</sup> and provides high degree of patient satisfaction<sup>6</sup>
- AMS 800<sup>™</sup> Urinary Control System multiple sizes designed for optimal patient fit and has key components impregnated with Inhibizone<sup>™</sup> Antibiotic Treatment<sup>7</sup>

### Penile Prosthesis Technology







The MOST PATENTS OWNED for surgical treatment of male incontinence and erectile dysfunction<sup>2</sup>

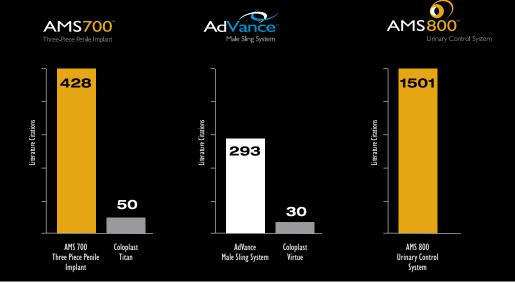
<sup>\*</sup>The patent numbers are an approximation of the respective companies as of December 3, 2013.



## Clinical Data

- AMS 700<sup>™</sup> Inflatable Penile Prosthesis 466 literature citations<sup>2</sup>
- AMS 800<sup>™</sup> Urinary Control System Over 1,500 literature citations<sup>2</sup>
- AdVance<sup>™</sup> Male Sling System 338 literature citations<sup>2</sup>
- AMS has received FDA approval of its post-market study on the AMS 700<sup>™</sup> Inflatable Penile Prosthesis with InhibiZone. This study was conducted for more than 6.5 years and is based on more than 40,000 patients implanted with AMS 700<sup>™</sup> devices. The results demonstrate the use of InhibiZone treated inflatable penile prosthesis provides a significant reduction in the rate of revisions due to device related infection in patients receiving both a first-time AMS 700<sup>™</sup> implant or an AMS 700<sup>™</sup> revision implant.³

Coloplast's Inflatable Penile Implants do not have any FDA approved claims concerning the reduction or prevention of infection.



- Sole sponsor of PROPPER (Prospective Registry of Outcomes with Penile Prosthesis for Erectile Restoration) study – the LARGEST Prospective, Multi-Year, Physician-Led Registry Designed to Study Real-World Penile Prosthetic Outcomes (www.ClinicalTrials.gov Identifier NCT01383018). AMS products were the most discussed products at medical conferences including the 2013 AUA.<sup>2</sup>
  - AMS had 14 abstracts related to penile prosthesis technology (Competitor had 4)
  - AMS had 25 abstracts for sling and artificial urinary sphincter technology (Competitor had 2)
- AMS is advancing the clinical literature in prosthetic urology through a robust Investigator Sponsored Research (ISR) Program



# WE ARE COMMITTED TO

# The Advancement of Urology

- Founding member of Society of Urologic Prosthetic Surgeons (SUPS)
- Founding member of the Coalition for the Advancement of Prosthetic Urology (CAPU)
- Supporter of the International Society for Sexual Medicine (ISSM) and the Sexual Medicine Society of North America (SMSNA)
- Supporter of the American Urological Association (AUA)
- Supporter of the Society of Genitourinary Reconstructive Surgery (GURS)
- Founding member of SMS/SUPS Resident's Surgical Symposiums



# Fully Supporting Urology

- Dedicated Health Care Affairs team coverage guidelines, coding guides, appeals assistance
- Dedicated patient assistance liaison (Phone: 952-930-6261) taking questions from patients concerning the use of their penile implant, artificial urinary sphincter or male sling as well as AMS Women's Health and Prostate Health products
- Comprehensive training and education programs for physicians and other health care professionals
- Patient education seminars and materials
- Clinical support library support, clinical data, field clinical team, trial implementation
- R & D meet with physicians to understand needs and requests for future product enhancements and innovations
- Experienced field team provides technical product support in the operating room





# The Leader in educating and treating Men's Pelvic Health conditions

We value the strong relationships we have with our customers and we are dedicated to providing products and services that enhance patients' lives. As the only company focused exclusively on pelvic health, AMS provides a robust, integrated offering of solutions designed to address the ever changing healthcare arena, while fully adhering to AdvaMed guidelines. The AMS 700<sup>™</sup> Series Inflatable Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery or (for the AMS 700<sup>™</sup> Series Inflatable Penile Prosthesis with Inhibizone<sup>™</sup> Antibiotic Treatment have a known sensitivity or allergy to rifampin, minocycline, or other tetracyclines). Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to, urogenital pain (usually associated with healing), urogenital edema, urogenital ecchymosis, urogenital erythema, reservoir encapsulation, patient dissatisfaction, auto-inflation, mechanical malfunction, impaired urination, and infection. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

The AMS Ambicor™ Inflatable Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery. Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries, or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to, urogenital pain (usually associated with healing), patient dissatisfaction, mechanical malfunction, auto-inflation, penile curvature or sensation change, urogenital hematoma, urogenital edema, and infection. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

The AMS Spectra<sup>™</sup> Concealable Penile Prosthesis is a sterile, non-pyrogenic, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in men who are determined to be suitable candidates for implantation surgery. These devices are contraindicated in patients who: have active urogenital infections or active skin infections in the region of surgery; patients whose proximal corporal length measurement is less than the proximal rigid section of the AMS Spectra<sup>™</sup> Concealable Penile Prosthesis cylinders, or whose total intracorporal length is not within the range of I 2cm to 27.5cm; patients who require repeated endoscopic procedures; or patients who have compromised tissue and as a result cannot withstand constant pressure. Implantation will make latent natural or

spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to: infection, erosion, migration, extrusion, mechanical malfunction, patient dissatisfaction, adverse tissue reaction, allergic reaction, pain, urinary obstruction, and silicone particle migration. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

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. 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.

The AMS 800™ Urinary Control System is intended to treat urinary incontinence due to reduced outlet resistance (Intrinsic Sphincter Deficiency). 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™ Urinary Control System with Inhibizone™ Antibiotic 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-skin 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.



- 1. Scott FB, Bradley WE, Timm GW. Management of erectile impotence: use of implantable inflatable prosthesis. Urology. 1973;2(1):80-82.
- 2. Data on File at AMS
- 3. AMS 700<sup>™</sup> Penile Prosthesis Product Line Instructions for Use. American Medical Systems. 2013.
- $4.\,Montorsi\,F,\,Rigatti\,P,\,Carmignani\,G,\,et\,al.\,AMS\,three-\,piece\,inflatable\,implants\,for\,erectile\,dysfunction:\,a\,long-term\,multi-institution\,study\,in\,200\,consecutive\,patients.\,Eur\,Urol.\,2000;37:50-55.$
- 5. AMS Ambicor™ Inflatable Penile Prosthesis Operating Room Manual. American Medical Systems, Inc. 2013.
  6. Levine L, Estrada C, Morgentaler A. Mechanical Reliability and Safety of, and Patient Satisfaction with the Ambicor Inflatable Penile Prosthesis: Results of a 2 Center Study. J Urol. 2001;166:932-937.
- 7. AMS 800™ Urinary Control System Operating Room Manual. American Medical Systems, Inc. 2011.



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