Boston Scientific
Advancing science for life™

AMS 800™

Artificial Urinary Sphincter

The gold standard for male stress urinary incontinence[1]

Help your patients find happiness. Consider the AMS 800™ Artificial Urinary Sphincter to restore normalcy and renew confidence.

94% of patients would recommend the AMS 800 to a friend or family member[2]

Urologist benefits

- Designed to treat all degrees of stress urinary incontinence (SUI)[3,4,5]
- Established outcomes
  - More than 40 years of artificial urinary sphincter (AUS) clinical use, with over 235,000 implants worldwide[6]
  - Dry or improved rates were 79%, ranging from 61% - 100%[7]
  - InhibiZone™ Antibiotic Treatment designed to reduce device infection[6]
  - Overall device survival was 72% at 5 years, 56% at 10 years, 41% at 15 years and 33% at 20 years[8]

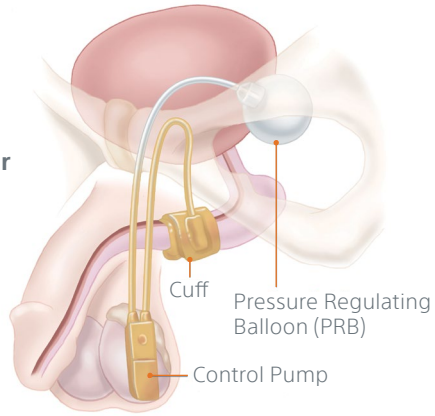
Patient benefits

- Restores normal sphincter function by opening and closing the urethra at the patient's control[6]
- Components tailored to fit the patient's anatomy and based on their physical condition[6]
- Can be used in combination with the AMS 700™ Inflatable Penile Prosthesis[9]

Mechanism of action

AMS 800™
Artificial Urinary Sphincter

All degrees of SUI



The AMS 800™ Artificial Urinary Sphincter simulates normal sphincter function by opening and closing the urethra, under patient control. When the cuff is closed, urine stays in the bladder.[6]

Ordering information

Accessory kit
720066-01

Control pump	Pressure regulation balloon
InhibiZone: 72404127	51-60 cm H_2O: 72400023
non-InhibiZone: 72400098	61-70 cm H_2O: 72400024
	71-80 cm H_2O: 72400025

Deactivation package	Insertion package
72400095	72100005

AMS Quick Connect Assembly Tool
72400271

Occlusive cuff	with InhibiZone	Non-InhibiZone
3.5 cm	720157-01	720133-01
4.0 cm	72404130	72400160
4.5 cm	72404131	72400161
5.0 cm	72404132	72400162
5.5 cm	72404133	72400163
6.0 cm	72404134	72400164
6.5 cm	72404135	72400165
7.0 cm	72404136	72400166
7.5 cm	72404137	72400167
8.0 cm	72404138	72400168
9.0 cm	72404140	72400170
10.0 cm	72404142	72400172
11.0 cm	72404144	72400174

1. Biardeau X, Aharony S; AUS Consensus Group, et al. Artificial Urinary Sphincter: Report of the 2015 Consensus Conference. *Neurourol Urodyn*. 2016 Apr;35 Suppl 2:S8-24.
2. Linder BJ, Rivera ME, Ziegelmann MJ, et al. Long-term Outcomes Following Artificial Urinary Sphincter Placement: An Analysis of 1082 Cases at Mayo Clinic. *Urology*. 2015 Sep;86(3):602-7.
3. Montague DK. Artificial urinary sphincter: long-term results and patient satisfaction. *Adv Urol*. 2012;2012:835290
4. AMS 800™ Artificial Urinary Sphincter for Male Patients Directions for Use. Boston Scientific. 2019.
5. James MH, McCammon KA. Artificial urinary sphincter for post-prostatectomy incontinence: a review. *Int J Urol*. 2014 Jun;21(6):536-43.
6. Data on file with Boston Scientific.
7. Van der Aa F, Drake MJ, Kasyan GR, Petrolekas A, Cornu JN; Young Academic Urologists Functional Urology Group. *Eur Urol*. 2013 Apr;63(4):681-9.
8. Boswell TC, Elliott DS, Rangel LJ, et al. Long-term device survival and quality of life outcomes following artificial urinary sphincter placement. *Transl Androl Urol*. 2020;9(1):56-61.
9. Segal RL, Cabrini MR, Harris ED, et al. Combined inflatable penile prosthesis-artificial urinary sphincter implantation: no increased risk of adverse events compared to single or staged device implantation. *J Urol*. 2013 Dec; 190(6):2183-8.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

Prior to use, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

INDICATIONS FOR USE The AMS 800™ Artificial Urinary Sphincter is used to treat urinary incontinence due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery.

CONTRAINDICATIONS Patients whom the physician determines to be poor surgical candidates, urinary incontinence due to or complicated by an irreversibly obstructed lower urinary tract, have irresolvable detrusor hyperreflexia or bladder instability, or for the AMS 800 with InhibiZone™ Antibiotic Surface Treatment, patients who have a known sensitivity or allergy to rifampin, minocycline or other tetracyclines, or patients with lupus erythematosus because minocycline has been reported to aggravate this condition.

WARNINGS Patients with urinary tract infections, diabetes, spinal cord injuries, open sores or regional skin infections may have increased risk of infection associated with a prosthesis. Erosion may be caused by infection, pressure on the tissue, improper cuff sizing, improper balloon selection, tissue damage, and component misplacement. Patients with urge incontinence, overflow incontinence, detrusor hyperreflexia or bladder instability should have these conditions treated and controlled (or resolved) prior to implantation of the device. Surgical, physical, psychological, or mechanical complications, if they occur, may necessitate revision or removal of the prosthesis.

POTENTIAL ADVERSE EVENTS May include device malfunction/failure leading to additional surgery, device/tissue erosion through urethra/bladder/scrotum, urinary retention, infection, and pain/soreness. MH-545609-AB

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