



The Gold Standard for Treating  
Male Stress Urinary Incontinence



AMS 800™

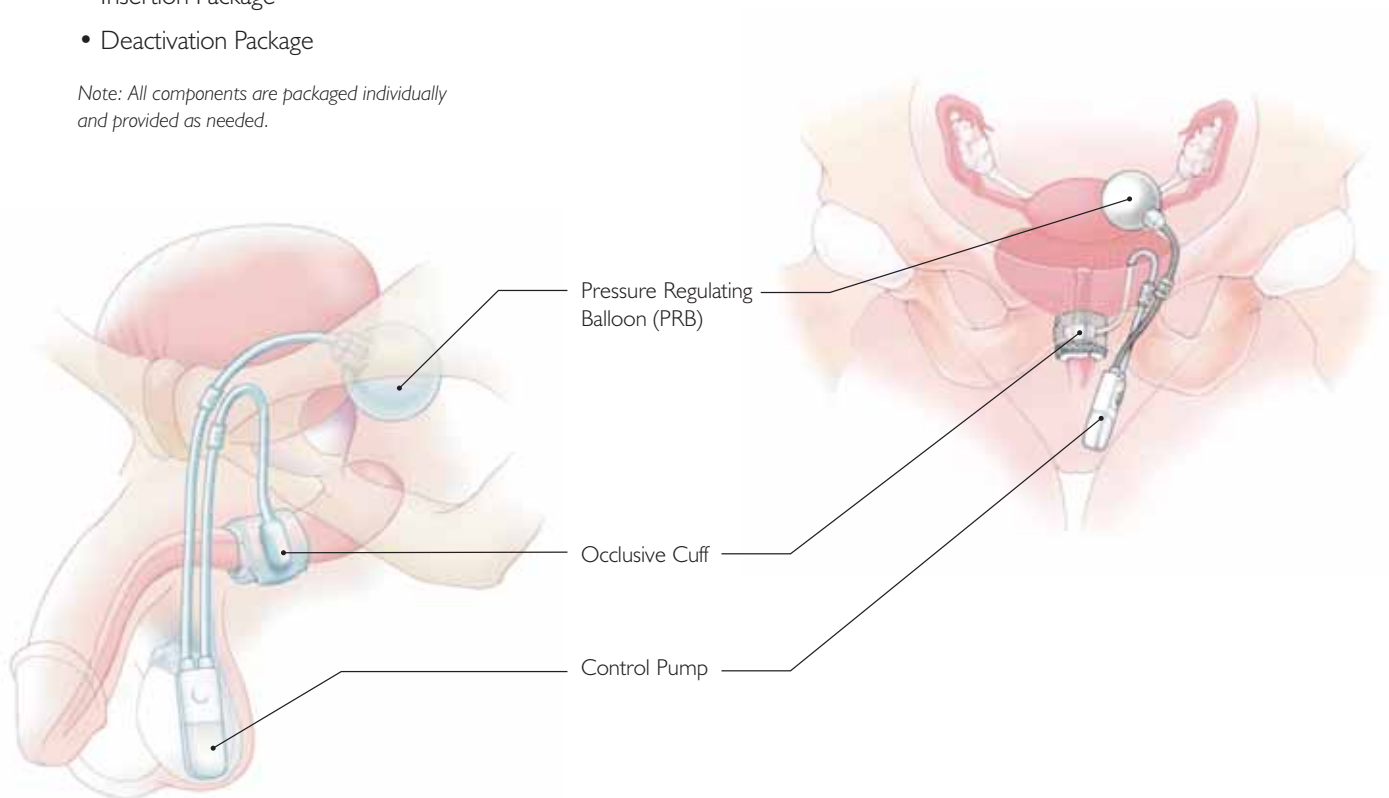
# Artificial Urinary Sphincter

The AMS 800 Urinary Control System is a completely concealed, implantable, fluid filled, solid silicone elastomer device used to treat male stress urinary incontinence (SUI). The AMS 800 treats urinary incontinence resulting from internal sphincter deficiency by artificially reconstructing the urinary sphincter's mechanism of action. The device simulates normal sphincter function by opening and closing the urethra at the control of the patient. The long-term safety and efficacy of the AMS 800 have made it the leading treatment for male SUI following prostate surgery.

## System Components and Accessories:

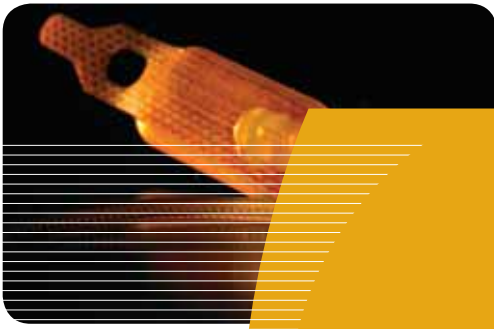
- Occlusive Cuff
- Pressure Regulating Balloon (PRB)
- Control Pump
- Accessory Kit
- Quick Connect Assembly Tool
- Insertion Package
- Deactivation Package

*Note: All components are packaged individually and provided as needed.*



## AMS 800 The Time-Tested, Gold Standard for Urinary Control:

- Over 40 Years of restoring continence control
- More than 150,000 patients treated
- Customizable treatment options based on the patients' physical conditions
- Components tailored to fit patient anatomy
- InhibiZone™ antimicrobial surface treatment



## Continually Improving the Gold Standard for Over 40 Years



(1972-1979)

**AS721** – Incorporated a fluid-filled reservoir, an occlusive cuff with pressure-regulating valve, and two pump bulbs for inflating and deflating the device.



(1976-1977)

**AS761** – A pressure-regulating balloon was incorporated into the AS721 design.



(1974-1979)

**AS742** – The first artificial urinary sphincter with a pressure-regulating balloon and a fluid resistor, which eliminated the need for an inflation bulb and made the device semi-automatic.



(1977-1979)

**AS791 & AS792** – Bladder-Neck Sphincter (AS792) and Bulbous-Urethral Sphincter (AS791) models were developed. These devices were identical except for the control mechanism, and included a smaller deflation pump.



(1981 to Today)

**AMS800** – Improvements over the years have included a narrow-backed cuff, kink-resistant tubing, quick connectors, Y-connectors, a deactivation button.



2007

**AMS800™** – InhibiZone™ antibiotic surface treatment introduced.



High Patient Satisfaction:  
 A 1996 study showed **90%** of the patients reported satisfaction with the AMS 800™ and **92%** would have the device placed again. Also **96%** would recommend or had recommended the device to a friend.<sup>1</sup>

## The AMS 800™ Urinary Control System

*“The AMS 800 has been my device of choice for nearly 30 years and 1,000 patients. With the unrivaled gold standard treatment for male SUI, patients no longer have to suffer the debilitating effects incontinence has on their quality of life.”*

– George D. Webster, M.D., Professor, Duke University, Durham, NC

### The AMS 800 Product Portfolio Includes:\*

Pressure Regulating Balloon: (Only available without InhibiZone™)		Occlusive Cuff:	With InhibiZone	Without InhibiZone	Accessory Kit:
41-50 cm H <sub>2</sub> O+	72400022	3.5 cm	720157-01	720133-01	US Version 720066-01
51-60 cm H <sub>2</sub> O	72400023	4.0 cm	72404130	72400160	International Version 72401685
61-70 cm H <sub>2</sub> O	72400024	4.5 cm	72404131	72400161	
71-80 cm H <sub>2</sub> O	72400025	5.0 cm	72404132	72400162	
81-90 cm H <sub>2</sub> O+	72400026	5.5 cm	72404133	72400163	<b>Additional Items:</b>
91-100 cm H <sub>2</sub> O+	72400027	6.0 cm	72404134	72400164	Deactivation Package 72400095
(+ Special Order Items)		6.5 cm	72404135	72400165	Insertion Package 72100005
		7.0 cm	72404136	72400166	AMS Quick Connect™ Assembly Tool 72400271
		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	

\* InhibiZone™ products not available in all markets.

### Brief Summary

The AMS Sphincter 800 Urinary Prosthesis device family is intended to treat urinary incontinence due to reduced outlet resistance (Intrinsic Sphincter Deficiency) following prostate surgery. 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 with InhibiZone™) 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. Montague DK. Artificial Urinary Sphincter: Long-Term Results and Patient Satisfaction. Advances in Urology 2012 V. 2012 P.3.



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