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

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

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.

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.

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

AMS800® – InhibiZone® antibiotic surface treatment introduced.
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:*  

<table>
<thead>
<tr>
<th>Pressure Regulating Balloon:</th>
<th>Occlusive Cuff:</th>
<th>Accessory Kit:</th>
</tr>
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<tbody>
<tr>
<td>(Only available without InhibiZone)</td>
<td>With InhibiZone</td>
<td>Without InhibiZone</td>
</tr>
<tr>
<td>41-50 cm H2O+</td>
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<td>720157-01</td>
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<td>61-70 cm H2O+</td>
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<td>71-80 cm H2O+</td>
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<tr>
<td>81-90 cm H2O+</td>
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<tr>
<td>91-100 cm H2O+</td>
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<tr>
<td>(+ Special Order Items)</td>
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<tr>
<td></td>
<td>11.0 cm</td>
<td>72404144</td>
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Control Pump:  
With InhibiZone | Without InhibiZone
---|---
72404127 | 72400098

Additional Items:

- Deactivation Package: 72400095
- Insertion Package: 72100005
- AMS Quick Connect™ Assembly Tool: 72400271

* 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.