AMS 800™ Urinary Control System
The gold standard for male stress urinary incontinence

Help your patients find happiness.

96% of patients would recommend the AMS 800 procedure to a friend

Consider the AMS 800™ Urinary Control System to restore normalcy and renew confidence.

Urologist benefits

- Designed to treat all degrees of stress urinary incontinence (SUI)
- Established outcomes
  - More than 40 years of artificial urinary sphincter (AUS) clinical use, with over 180,000 systems implanted worldwide
  - 90% continence rate in a study of 435 patients with mean average follow-up of 68 months
  - InhibiZone™ Antibiotic Surface Treatment designed to reduce device infection

Patient benefits

- Restores normal sphincter function by opening and closing the urethra at the patient's control
- Components tailored to fit the patient's anatomy and based on their physical condition
- Can be used in combination with the AMS 700™ Inflatable Penile Prosthesis
The AMS 800™ Urinary Control System simulates normal sphincter function by opening and closing the urethra, under patient control. When the cuff is closed, urine stays in the bladder.4

**Mechanism of action**

The AMS 800™ Urinary Control System simulates normal sphincter function by opening and closing the urethra, under patient control. When the cuff is closed, urine stays in the bladder.4

**AMS 800 System ordering information**

<table>
<thead>
<tr>
<th>Accessory kit</th>
<th>Occlusive cuff</th>
<th>With InhibiZone</th>
<th>Non-InhibiZone</th>
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</thead>
<tbody>
<tr>
<td>720066-01</td>
<td>720157-01</td>
<td>720133-01</td>
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<tr>
<td><strong>Control Pump</strong></td>
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<td><strong>Pressure regulation balloon</strong></td>
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<tr>
<td>InhibiZone – 72404127</td>
<td>51-60 cm H2O</td>
<td>72400023</td>
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<tr>
<td>Non-InhibiZone – 72400098</td>
<td>61-70 cm H2O</td>
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<td></td>
<td>71-80 cm H2O</td>
<td>72400025</td>
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<tr>
<td><strong>Deactivation package</strong></td>
<td>Insertion package</td>
<td>AMS Quick Connect Assembly Tool</td>
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<td>72400095</td>
<td>72100005</td>
<td>72400271</td>
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Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

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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™ Urinary Control System 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 irreversible detrusor hyperreflexia or bladder instability, or (for the AMS 800 prosthesis with InhibiZone™ Antibiotic Surface Treatment) 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 those 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/irritation. MH-545609-AA