InhibiZone™
Antibiotic Treatment

InhibiZone is an impregnation of rifampin and minocycline
We help minimize the risk of infection with the proven protection of InhibiZone™. The AMS 700™ Inflatable Penile Prosthesis is the ONLY antibiotic-impregnated penile prosthesis on the market clinically proven to reduce the risk of infection.

**What is InhibiZone Treatment?**

InhibiZone Treatment is a proprietary combination of the antibiotics Rifampin and Minocycline that are impregnated into the surface of the prosthesis during the manufacturing process. The evolution of these antibiotics creates a zone of inhibition effective against the bacteria commonly associated with inflatable penile prosthesis infection. InhibiZone is intended and proven to act on those bacteria that attempt to colonize the prosthesis surfaces.

**InhibiZone offers peace of mind.**

**Efficient:**
- Standardizes the surgical approach and offers consistent results
- Eliminates extra steps required for device prep and soaking

**Efficacious:**
- Reduces the risk of device contamination at the time of surgery
- 17 years of clinical experience
- Broad spectrum of antibiotic coverage against bacteria commonly associated with implant infections, including MRSA, MRSE, VRE

**Economic:**
- No additional procedure costs for additional antibiotic “dips”

**Zone of Inhibition**

InhibiZone creates a zone of inhibition, effective against the bacteria commonly associated with IPP infections. In one clinical study, 16 clinical isolates, including MRSA, MRSE, VRE and E. coli were tested and compared to Vancomycin-soaked Coloplast implants. The InhibiZone-treated devices produced a larger zone of inhibition for MRSA, E. coli and VRE compared to the vancomycin-soaked implants.

**I believe the single most important and effective innovation in prosthetic urology that I have seen, is the InhibiZone infection retardant process.”**

Gerard Henry, MD

**Important Safety Information**

About InhibiZone

Use of InhibiZone Treatment should carefully be considered in patients:
- With hepatic or renal disease
- Taking methoxyflurane and warfarin.
  Carefully monitor for signs of renal toxicity.
- Using thioamides, isoniazid and halothane

Use of InhibiZone Treatment should be excluded in patients:
- With known allergy or sensitivity to tetracyclines
- With systemic lupus erythematosus

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Staphylococcus epidermidis

InhibiZone impregnated sample

Zone of Inhibition

Penile prosthesis impregnated with InhibiZone.

InhibiZone is impregnated into the three components of the prosthesis.

Following implantation, InhibiZone elutes from the penile prosthesis over a 14-day period.
The AMS 700™ Inflatable Penile Prosthesis with InhibiZone™ is the only antibiotic-impregnated inflatable penile prosthesis. The clinical evidence shows a significant reduction in the rate of revisions due to infection in both original and revision implants. InhibiZone is supported by post-market data provided in the product’s Instructions for Use, based on robust data with more than 40,000 patients reported over a 6.5-year period. The study concluded that use of InhibiZone resulted in a significant reduction in the rate of revision due to infection:

- In patients with penile prosthesis
- Among penile prosthesis implants in diabetic patients
- Among original and revision penile prosthesis implants
- In patients receiving a first-time AMS 700 implant
- In patients receiving an AMS 700 revision implant
- In diabetic patients receiving a first-time AMS 700 implant

No significant differences were found between treated and untreated AMS 700 Penile Prostheses for overall rates of revision due to mechanical malfunction, fluid loss, erosion, patient dissatisfaction or all other reasons.

### Post-market study data: AMS 700™ Inflatable Penile Prosthesis with InhibiZone™

<table>
<thead>
<tr>
<th></th>
<th>InhibiZone</th>
<th>Non-InhibiZone</th>
</tr>
</thead>
<tbody>
<tr>
<td>Original</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Penile prosthesis</td>
<td>1.2%</td>
<td>2.5%</td>
</tr>
<tr>
<td>with InhibiZone for</td>
<td></td>
<td></td>
</tr>
<tr>
<td>first-time AMS 700</td>
<td></td>
<td></td>
</tr>
<tr>
<td>implants revision</td>
<td></td>
<td></td>
</tr>
<tr>
<td>rate due to infection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>(p=0.0001)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

|                      |            |                |
| Diabetic             |            |                |
| Penile prosthesis    | 1.4%       | 4.0%           |
| with InhibiZone      |            |                |
| for first-time AMS 700 implants in patients with diabetes | |
| revision rate due to infection | (p=0.0001).  |

|                      |            |                |
| Revision             |            |                |
| Penile prosthesis    | 2.5%       | 3.7%           |
| with InhibiZone      |            |                |
| for AMS 700 revision |            |                |
| implants revision    |            |                |
| rate due to infection|            |                |
| (p=0.025).           |            |                |

"I personally think that the development of InhibiZone is probably the most important thing that’s happened with penile prosthesis implantation in the last decade."

Culley C. Carson, MD

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Protection supported by clinical data: Post-market study findings

"The most important thing we can do is reduce the infection rate. If you can dramatically reduce the number of patients where devices are being removed for infection, you’re going to get better outcomes."

LeRoy A. Jones, MD
InhibiZone is the only antibiotic coating on IPPs in the marketplace. In our four center study with over 300 patients being cultured at the time of Revision / Replacement / Removal surgery, none of the bacteria isolates showed resistance to the combination of minocycline and rifampin on the culture data reports.

Brian Christine, MD

### Infection rates for penile prostheses with InhibiZone

<table>
<thead>
<tr>
<th>Type of implant operation/patient</th>
<th>Patients</th>
<th>Observed infection rate; 3-year follow-up</th>
<th>Historical infection rate</th>
<th>P value (observed vs. historical)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Virgin implant, non-diabetics</td>
<td>223</td>
<td>0.0%</td>
<td>3%</td>
<td>0.0024</td>
</tr>
<tr>
<td>Virgin implant, diabetics</td>
<td>83</td>
<td>1.2%</td>
<td>8%</td>
<td>0.0141</td>
</tr>
<tr>
<td>Revision implants with washout</td>
<td>122</td>
<td>3.3%</td>
<td>10%</td>
<td>0.0095</td>
</tr>
</tbody>
</table>

Since the launch of InhibiZone in 2001, there have been 13 clinically stringent, peer-reviewed, published research studies confirming the efficacy of InhibiZone in reducing the rate of revision due to infection.11

### Freedom from revision due to infection

**Carson 2011**
A long-term retrospective study of 39,005 patients with first-time implants showed significantly fewer patients with antibiotic-impregnated implants had a revision due to infection. The authors concluded that this long-term outcome analysis provides substantial clinical evidence of a decrease in costly infection-related revision using an antibiotic-impregnated IPP.

**Infection-related revisions throughout 7.7 years:**
- 1.1% of 35,737 antibiotic-impregnated
- 2.5% of 3,268 non-impregnated

### Freedom from revision due to infection in diabetics

**Mulcahy 2011**
A sub-group study of 6,695 diabetic first-time implants showed significantly fewer patients with antibiotic-impregnated implants had a first revision due to infection. The authors concluded that this long-term evidence establishes antibiotic-impregnated IPPs as standard preferred choice in helping to reduce complication in the high-risk diabetic population.

**Infection-related revisions throughout 7.7 years:**
- 1.6% of 6,071 antibiotic-impregnated
- 4.2% of 624 non-impregnated

### Freedom from secondary revision due to infection

**Nehra 2012**
A separate long-term study of 11,396 implants showed secondary revisions due to infection were significantly less frequent in patients with antibiotic-impregnated replacement implants compared to non-impregnated replacement IPPs. Secondary revision was defined as the first recorded device revision operation for any reason after replacement implant surgery.

**Infection-related secondary revisions throughout 6.6 years:**
- 2.5% antibiotic-impregnated
- 3.7% non-impregnated

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**Wilson 2007**
This prospective study of 467 patients with implants impregnated with InhibiZone showed very low clinical infection rates throughout the 3-year observation:
- No infections developed among 223 non-diabetic patients (0.0%)
- One infection developed among 83 diabetic patients (1.2%)

"InhibiZone is the only antibiotic coating on IPPs in the marketplace. In our four center study with over 300 patients being cultured at the time of Revision / Replacement / Removal surgery, none of the bacteria isolates showed resistance to the combination of minocycline and rifampin on the culture data reports."

Brian Christine, MD

Caution: U.S. Federal Law restricts this device to sale by or on the order of a physician.

Caution: The law restricts these devices to sale by or on the order of a physician.

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 700™ Series Inflatable Penile Prosthesis product line is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence).

Contraindications: The AMS 700 Series Inflatable Penile Prostheses are contraindicated in the patients that have active urogenital infections or active skin infections in the region of surgery or (for the AMS 700 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: Implantation of the device 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 associated with the implantation of a prosthesis. Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition leading to infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical. If a hypersensitivity reaction develops to a device coated with InhibiZone, the penile prosthesis should be removed and the patient treated appropriately.

Precautions: Migration of the device components can occur if the cylinders are improperly sized, if the pump or the reservoir is not positioned properly, or if the tubing lengths are incorrect.

Potential Adverse Events: May include device malfunction/failure leading to additional surgery, device migration potentially leading to exposure through the tissue, device/tissue erosion, infection, unintended-inflation of the device and pain/soreness. MH-545408-AA

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