Designed for protection

Infections associated with implanted inflatable penile prostheses (IPPs) are a disastrous complication of this common treatment for erectile dysfunction.[1] The innovative **AMS 700™ Inflatable Penile Prosthesis** is the only IPP line available impregnated with InhibiZone™ Antibiotic Surface Treatment, proven to reduce the risk of revision surgery due to infection even in challenging patients.[2-7]

56% reduction
(from 2.5%-1.1%)
in revisions due to infection in first-time implant patients[2]

32% reduction
(from 3.7% to 2.5%)
in secondary revision procedures due to infection[3]

65% reduction
(from 4.17% to 1.47%)
in initial revisions due to infection in high-risk patient with diabetes[4]

Efficacious – proven protection that lasts

Contamination of the device during surgery is a common mode of microorganism entry into the surgical field. Reducing the extra step of soaking the implant could reduce contamination.[8]

Bacterial colonization and attachment has been shown to take place in less than 3 days post implantation.[9] The InhibiZone Treatment is designed to give you peace of mind and is intended to provide infection prevention for patients.

Established – 18 years of clinical data

Consistent drug combination and dosage of rifampin and minocycline are clinically demonstrated in over 18 years of data to reduce infections in IPPs.[1]

Efficient – ready for the procedure

The AMS 700 prosthesis impregnated with InhibiZone Treatment comes ready for the procedure – no mixing, no dipping required – reducing extra steps for you and your staff. Instead, you can start each procedure ready to go, eliminating unnecessary extra steps.[10]

Economic considerations – for you and your patients

Costs are minimized for you and your patients with no additional procedure expenses for antibiotic "dips" and using an IPP impregnated with InhibiZone Treatment may minimize the costs associated with revision surgery due to device infection.[2]

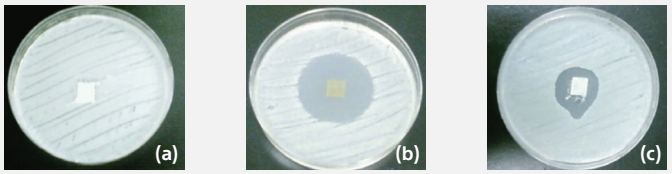
Boston Scientific
Advancing science for life™

Impregnated vs. dipped devices: Laboratory testing data[11]

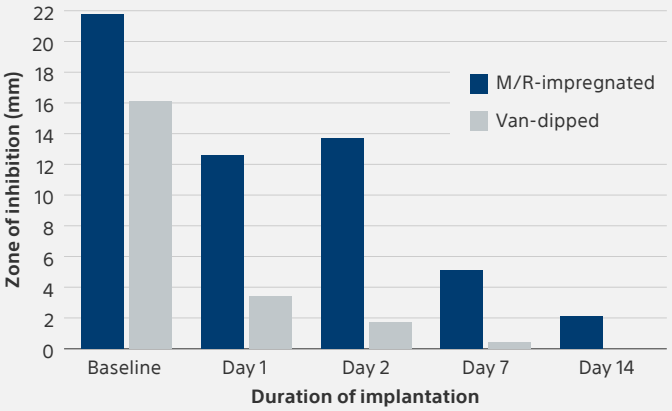
Impregnated device provides largest zone of inhibition

In an animal (rabbit) study, the M/R-impregnated (InhibiZone Treatment) device resulted in a significantly larger zone of inhibition up to 14 days after implantation.

Zones of inhibition produced by cylinder device segments explanted from rabbits.



Baseline zone of inhibition produced by 1x1 cm against ***Staphylococcus aureus***, (a) control, (b) minocycline and rifampin (M/R)-pre-impregnated segments (InhibiZone Treatment), and (c) vancomycin-dipped.



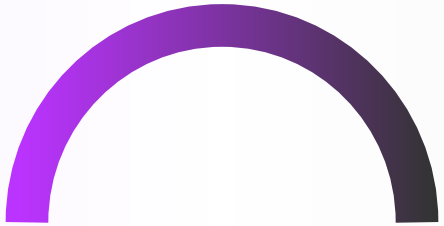
The M/R-impregnated devices also yielded significantly larger zones of inhibition against *Staphylococcus aureus* than vancomycin-dipped implants, both in vitro ($p < 0.003$) and in vivo at baseline, days 1, 2, 7, and 14 after device implantation in rabbits (day 14, $p < 0.03$).

Mechanism of drug uptake and release

Boston Scientific AMS 700™ IPP

Designed for slow elution to prevent microbial colonization on the surface of the device

- InhibiZone Treatment is a proprietary combination of antibiotics, rifampin, and minocycline, that is impregnated into the silicone layers.[10] Its gradual release over 14 days creates a zone of inhibition effective against the bacteria commonly associated with inflatable penile prosthesis infections.[10-12]
- Consistent drug combination and dosage of rifampin and minocycline are clinically demonstrated in over 18 years of data to reduce infections in IPPs[1]
- Rifampin and minocycline combination on cardiac implantable electronic devices has been shown to reduce infection risks by 70% to 100% in high-risk patients[13-18]
- Soaking and dipping are not required, which saves time, cost, and may reduce potential for device contamination during the procedure[8]



Slow
elution over 14 days

Rapid
burst of diffusion

Coloplast Titan™ IPP

Designed to absorb aqueous solutions

- Coloplast Titan with hydrophilic coating rapidly releases antibiotics within minutes to hours[10,11]
- Antibiotics reside in the hydrophilic coating on the surface of the device[8] vs. within the layers of the implant
- Soaking the implant in antibiotics adds variability to the procedure and may increase risk of device contamination[2-4,8,10]

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Bench Test results may not necessarily be indicative of clinical performance.

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. 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 700™ Inflatable Penile Prosthesis product line is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). **Contraindications:** The AMS 700 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 HCl or other tetracyclines, or patients with lupus erythematosus because minocycline HCl 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 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 treated 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-AD

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