Boston Scientific
Advancing science for life™

Designed for Protection:

Infection is still the most serious complication for a penile implant procedure. The innovative **AMS 700™ Inflatable Penile Prosthesis** is the only IPP line impregnated with InhibiZone™ Antibiotic Treatment, proven to reduce implant-related infections in even the most challenging patients.[1-4]

56% reduced risk of infection in **first-time implants (1.2% infection rate[1])**

32% reduced risk of infection in **revision procedures (2.5% infection rate[2])**

65% reduced risk of infection in **high-risk patients with diabetes (1.4% infection rate[3])**

Efficacious – proven protection that lasts

Contamination of the device during surgery is the most common mode of microorganism entry into the surgical field. Reducing the extra step of soaking the implant could contribute to lower infection rates.[4]

Bacterial colonization and attachment has been shown to take place 3 days post implantation.[5] The InhibiZone Treatment gives you peace of mind and the protection your patients need when you need it most.

Established – 20 years of clinical use

The AMS 700 Series has more than 20 years of clinical use and over 187+ publications showing that the InhibiZone Treatment consistently reduced IPP infections in the most challenging patients compared to non-InhibiZone-impregnated devices.[6]

Efficient – ready for the procedure

The AMS 700 Prosthesis comes ready for the procedure – no mixing, no dipping required – reducing extra steps for you and your staff. Instead, you can confidently start each procedure ready to go, eliminating unnecessary extra steps to ultimately enhance procedure efficiency.

Economically beneficial – for you and your patients

Costs are minimized for you and your patients with no additional procedure expenses for antibiotic "dips" and minimizes the costs associated with device infection.

Impregnated vs. Dipped Devices: Laboratory Testing Data[4]

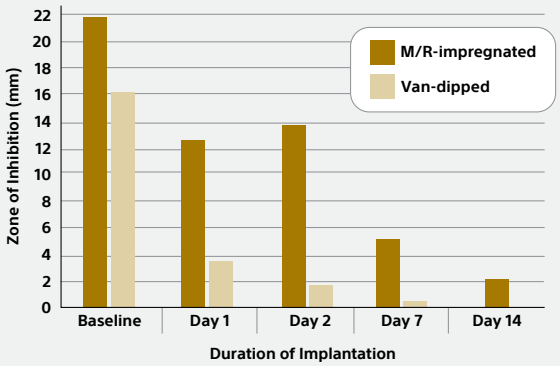
IMPREGNATED PROVIDES LARGEST ZONE OF INHIBITION

InhibiZone Treatment resulted in a significantly larger zone of inhibition, both in vitro and in vivo, up to 14 days after implantation.

Zones of inhibition against *Staphylococcus aureus* produced by devices explanted from rabbits. M/R = minocycline and rifampin (InhibiZone Treatment); Van = vancomycin.

Baseline zone of inhibition produced by I T 1-cm against *Staphylococcus aureus*, (a) control (b) minocycline and rifampin (M/R) - pre-impregnated segments 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 throughout the 14-day period of device implantation in rabbits ($p < 0.03$).



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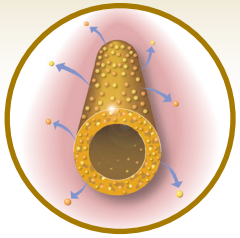
Mechanism of drug uptake and release



SLOW
elution over 14 days

BOSTON SCIENTIFIC AMS 700™ IPP

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

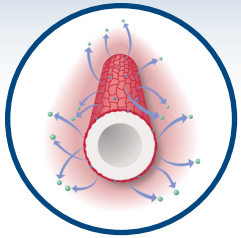
- InhibiZone Treatment is a proprietary combination of antibiotics, rifampin and minocycline that is impregnated deep into the silicone layers. Its gradual release over 14 days creates a zone of inhibition effective against the bacteria commonly associated with inflatable penile prosthesis infections[7,8]
- Consistent drug combination and dosage of rifampin and minocycline are clinically demonstrated in over 20 years of data to reduce infections in IPPs
- Rifampin and minocycline combination is used on other medical devices and has been shown to reduce infection risks by 70% to 100% in high-risk patients[12-14]
- Soaking and dipping are not required, which saves time, cost and potential contamination during the procedure

VS

COLOPLAST TITAN™ IPP

Designed to absorb aqueous solutions

- Coloplast Titan with hydrophilic coating rapidly releases antibiotics within minutes to hours[4]
- Antibiotics reside in the hydrophilic coating on the surface of the device vs. within the layers of the implant
- Soaking the implant in antibiotics adds variability to the procedure and may increase risk of device contamination
- Drug uptake and delivery vary on:
  1) Antibiotic combinations
  2) Antibiotic concentrations
  3) Soak/Dip time



RAPID
burst of diffusion

1. Carson CC III, Mulcahy JJ, Harsh MR. Long-term infection outcomes after original antibiotic impregnated inflatable penile prosthesis implants: up to 7.7 years of follow-up. *J Urol.* 2011 Feb;185(2):614-8. • 2. Nehra A, Carson CC III, Chapin AK, et al. Long-term infection outcomes of a 3-piece antibiotic impregnated penile prostheses used in replacement implant surgery. *J Urol.* 2012 Sep;188(3):899-903. • 3. Mulcahy JJ, Carson CC III. Long-term infection rates in diabetic patients implanted with antibiotic-impregnated versus nonimpregnated inflatable penile prostheses: 7-year outcomes. *Eur Urol.* 2011 Jul;60(1):167-72. • 4. Mansouri MD, Boone TB, Darouiche RO. Comparative assessment of antimicrobial activities of antibiotic-treated penile prostheses. *Eur Urol.* 2009 Dec;56(6):1039-45. 5. Hellstrom WJG, Hyun JS, Human L, et al. Antimicrobial activity of antibiotic-soaked, Resist-coated Bioflex. *Int J Impot Res.* 2003 Feb;15(1):18-21. • 6. Data on file with Boston Scientific. • 7. Dhabuwala C, Sheth S, Zamzow B. Infection rates of rifampin/gentamicin-coated Titan Coloplast penile implants. Comparison with InhibiZone-impregnated AMS penile implants. *J Sex Med.* 2011;8(1):315-20. • 8. AMS 700, Instructions for use, American Medical Systems, 2018. • 9. Bloom HL, Constantin L, Dan D, et al. Implantation success and infection in cardiovascular implantable electronic device procedures utilizing an antibacterial envelope. *Pacing Clin Electrophysiol.* 2011 Feb;34(2):133-42. • 10. Mittal S, Shaw RE, Michel K, et al. Cardiac implantable electronic device infections: incidence, risk factors, and the effect of the AigisRx antibacterial envelope. *Heart Rhythm.* 2014 Apr;11(4):595-601. • 11. Kolek MJ, Patel NJ, Clair WK, et al. Efficacy of a bio-absorbable antibacterial envelope to prevent cardiac implantable electronic device infections in high-risk subjects. *J Cardio Electrophysiol.* 2015 Oct;26(10):1111-6. • 12. Shariff N, Eby E, Adelstein E, et al. Health and economic outcomes associated with use of an antimicrobial envelope as a standard of care for cardiac implantable electronic device implantation. *J Cardio Electrophysiol.* 2015 Jul;26(10):783-9. • 13. Henrikson CA, Sohail MR, Acosta H, et al. Antibacterial envelope is associated with low infection rates after implantable cardioverter-defibrillator and cardiac resynchronization therapy device replacement: results of the Citadel and Centurion studies. *JACC Clin Electrophysiol.* 2017 Oct;3(10):1158-67. • 14. TYRX™ Absorbable Antibacterial Envelope. Medtronic. https://europe.medtronic.com/xd-en/healthcare-professionals/products/cardiac-rhythm/infection-control/tyrx-antibacterial-envelope.html. Accessed October 1, 2020.

Bench Test results may not necessarily be indicative of clinical performance. 14 AMS 700 IFU

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. 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™ 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 who 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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