Boston Scientific
Advancing science for life™

InhibiZone™

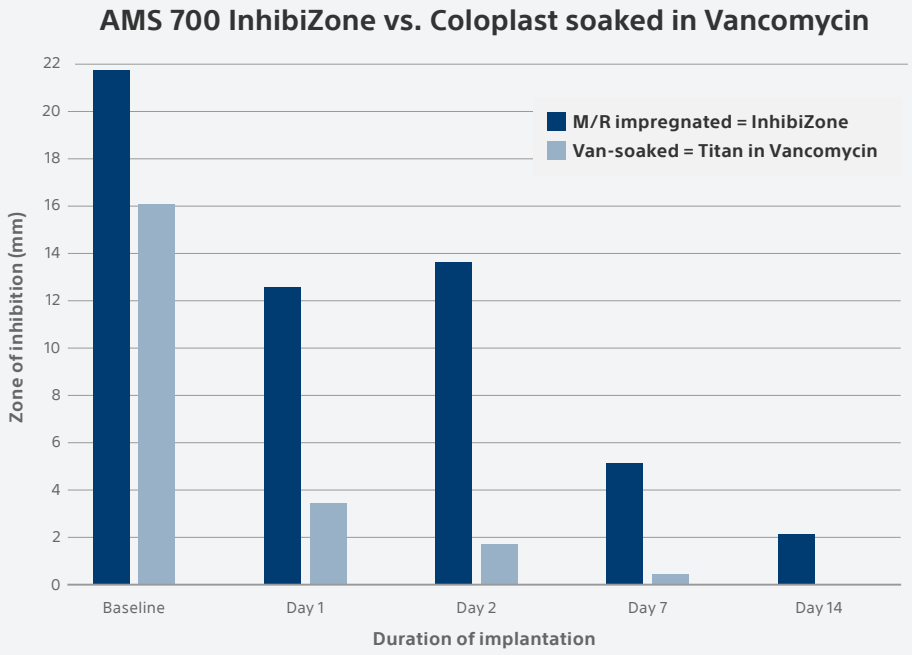
Antibiotic Surface Treatment

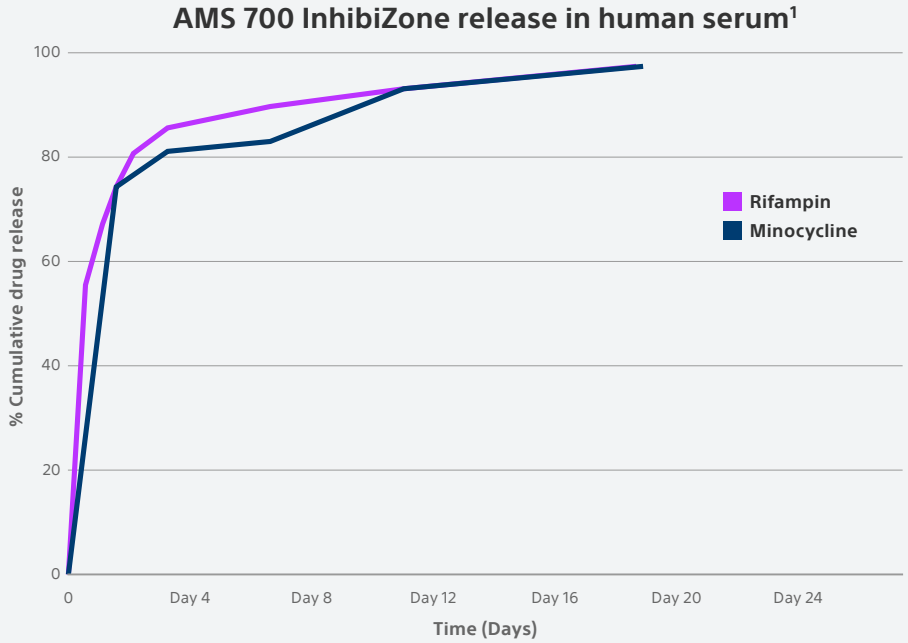
It's what's inside that counts

The AMS 700™ Inflatable Penile Prosthesis' porous, hydrophobic silicone makeup allows the minocycline/rifampin drug molecules of the InhibiZone Treatment to penetrate into the layer forming a barrier to drug diffusion.[1] The drug is gradually eluted over a 14-day period.*[1,2]
This has been clinically proven:

- **56% reduction** (from 2.5% to 1.1%) in revisions due to infection in first-time implant patients.[3]
- **65% reduction** (from 4.17% to 1.47%) in initial revisions due to infection in high-risk patients with diabetes.[4]
- **32% reduction** (from 3.7% to 2.5%) in secondary revision procedures due to infection.[5]

The InhibiZone Treatment is still present and releasing the drug past 14 days*[1]





This chart is created based on information published in Mansouri MD, Boone TB, Darouiche RO. Comparative assessment of antimicrobial activities of antibiotic-treated penile prostheses. *Eur Urol.* 2009; 56:1039 -1045.

Not all drug release mechanisms are equal

Hydrophilic coating mechanism of action:

Hydrophilic coatings absorb 25 times their weight when dipped in a aqueous solution creating a lubricious component surface to deter bacterial attachment.[6]

Hydrophilic coatings rapidly release 100% of the antibiotic drug within the first few minutes to hours once exposed to Phosphate-buffered saline (PBS) solution.[1]

Drug release testing with Coloplast Titan™ – Hydrophilic-coated IPP samples

Testing performed by or on behalf of Boston Scientific.

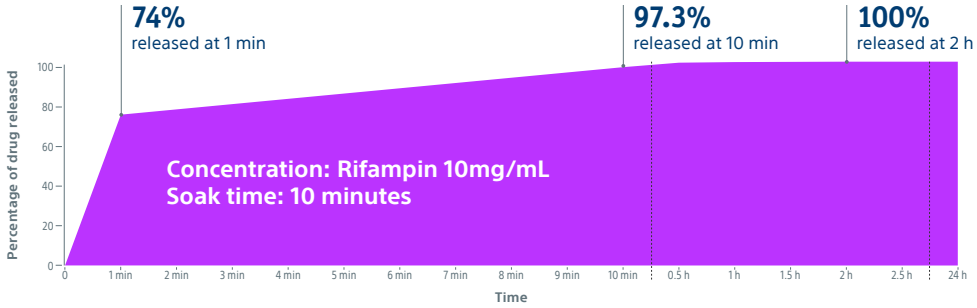
Results demonstrate the rapid “burst” or release of drug delivery via hydrophilic-coated IPP*[1]

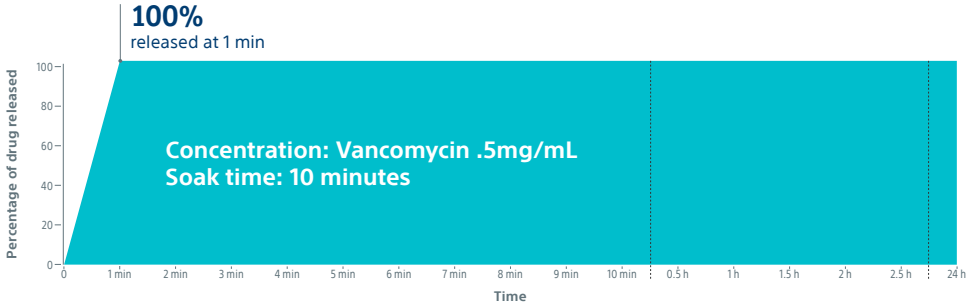
Bench test study design:

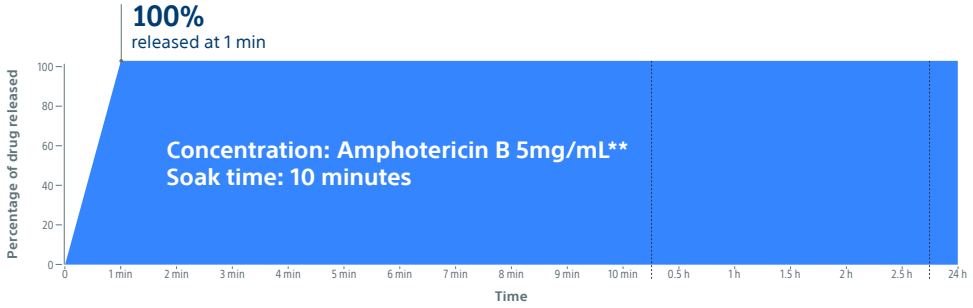
- 3” segments of Coloplast Titan IPP
- N=3 soaked in PBS solution for 10 min
- Ran KDR extraction in 10mL PBS at 37C on shaker
- T0 = ~10 seconds in PBS solution, then removed
- Put same sample into a new vial of 10mL PBS for 1, 10, 15, 30, 60, 120, 140 min timepoints

Bench test results*[1]

Testing performed by or on behalf of Boston Scientific.







Important risk information

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.

* Bench test results may not necessarily be indicative of clinical performance.

** 100 times higher than what is used clinically.

1. Testing performed by or on behalf of Boston Scientific. Data on file with Boston Scientific.
2. Mansouri MD, Boone TB, Darouiche RO. Comparative assessment of antimicrobial activities of antibiotic-treated penile prostheses. *Eur Urol*. 2009;56:1039–1045.
3. 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;185:614–618.
4. 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;60:167–172.
5. Nehra A, Carson CC III, Chapin AK, Ginkel AM. Long-term infection outcomes of a 3-piece antibiotic impregnated penile prostheses used in replacement implant surgery. *J Urol*. 2012;188:899–903.
6. Wilson SK, Salem EA, Costerton W. Anti-infection dip suggestions for the Coloplast Titan Inflatable Penile Prosthesis in the era of the infection retardant coated implant. *J Sex Med*. 2011;8:2647–2654.

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