

a new treatment option for improving patient quality of life

Uro-Tainer® Polihexanide

CHALLENGES

WITH THE MAINTENANCE OF INDWELLING URINARY CATHETERS

CATHETER-ASSOCIATED COMPLICATIONS



HOW OFTEN DO YOUR PATIENTS EXPERIENCE?

- Decreased urine flow or catheter blockage
- Leakage along the catheter
- Mental and social distress from unpleasant urine odour
- The need for more frequent and unplanned care because of catheter-related problems
- Recurrent urinary tract infection (UTI)
- Increasing intolerance to side effects due to long-term treatment with systemic antibiotics

AS A HEALTHCARE PROFESSIONAL DO YOU EXPERIENCE?

- More frequent patient visits to change the catheter before it was planned
- Anxiety that disconnecting the system when the catheter is flushed will increases the risk of contamination of the catheter

If you recognise one or more of these challenges then Uro-Tainer[®] Polihexanide, the latest innovation in the field of catheter maintenance, may help to prevent and minimise these problems.

BIOFILM AND CATHETER-ASSOCIATED COMPLICATIONS

The rapid development of bacterial colonies (i.e. biofilm) is one of the key causes of catheter-associated complications such as blockage and UTI. $^{1, 2, 3}$

The catheterised urinary tract provides ideal conditions for the development of bacterial colonies, which adhere to the catheter surface and drainage bag.^{4, 5} Biofilm is critical to the persistence of UTIs as they function as microbe reservoirs.³ Biofilm may also cause crystallisation of calcium and magnesium phosphate within the urine resulting in encrustation of the catheter. All types of catheters are vulnerable to encrustation by biofilms.⁵

Clinical prevention strategies to prevent biofilm development are needed as:

- Bacteria growing in the biofilm mode are resistant to antibiotics⁵
- Long-term use of antibiotics in catheter-associated UTI can significantly increase the risk of multi drug resistance³
- Frequently changing an indwelling catheter due to blockage can result in an increased risk of infection and discomfort for the catheter wearer^{6,7}

Encouragingly there is evidence to suggest that physical removal, i.e. mechanical rinsing, is the best method of biofilm removal and regular cleansing is required to prevent regrowth.⁸

FIGURES

1 BACTERIAL BIOFILM ON A URINARY CATHETER

A New and Innovative Solution

Uro-Tainer[®] Polihexanide is a novel concept in catheter maintenance as it provides healthcare professionals and patients with a means of routine mechanical rinsing together with bacterial decolonisation of indwelling urinary catheters.^{10, 14}

2 URO-TAINER[®] POLIHEXANIDE

Polihexanide – Impact on biofilm

Polihexanide has been used as an antimicrobial for over 40 years and has demonstrated good clinical safety, with no evidence of resistance and minimal toxicity.⁹

Studies in wound management have shown that polihexanide solution significantly reduces bacterial biofilm load compared to a range of other irrigation solutions.^{11, 12} In a laboratory study using silicone tubing incubated with Pseudomonas Aeruginosa, a polihexanide solution (Prontosan[®]) significantly reduced biofilm load by 87 %.¹² Ringer's Solution and isotonic saline had no effect on the bacterial load.¹²

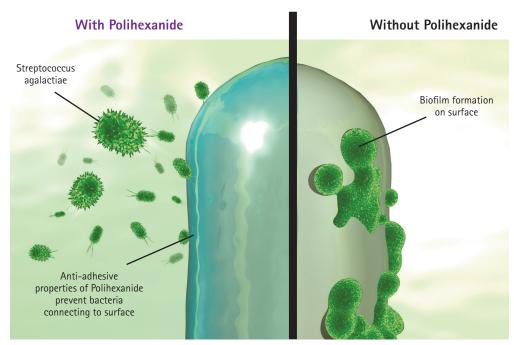
Sub-bactericidal concentrations of polihexanide have an antiadhesive effect, which prevents bacteria attaching to surfaces (such as catheters) and forming colonies.¹³ Thus maintaining safe and clean conditions.





3 ANTI-ADHESIVE EFFECT OF POLIHEXANIDE

To test the anti-adhesive properties of polyhexanide in isolation sub-bactericidal concentrations were used



Polihexanide led to a 95% reduction in the adhesive strength of the biofilm and

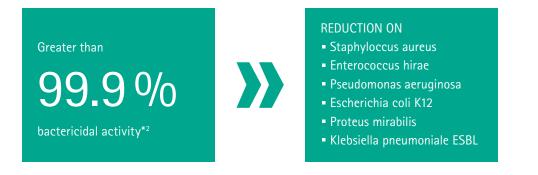
77 % reduction in mean number of adherent cells. ¹³

+ Streptococcus agalactiae

Uro-Tainer® Polihexanide

Bacterial decolonisation potential (in vitro results)

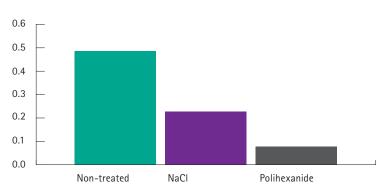
Laboratory tests have shown that Uro-Tainer[®] Polihexanide has bactericidal action against a wide range of bacteria (e.g. Proteus mirabilis) that are commonly associated with UTI in catheterised patients.¹⁴



Using a practice-like assay the decolonisation potential of Uro-Tainer[®] Polihexanide has been shown to be superior to both no treatment (standard practice) (p=0.02) and also irrigation with saline (p=0.034).¹⁰

4 BACTERIAL DECOLONISATION POTENTIAL OF URO-TAINER® POLIHEXANIDE VS. NO TREATMENT AND NACL¹⁰

Biofilm mass



Safety

The biological safety of Uro-Tainer[®] Polihexanide has been demonstrated in a clinically relevant animal model under physiological conditions.¹⁵

The Product

The Uro-Tainer[®] Polihexanide device has a simple and safe operating mode (gravity as sole input and output force) and like all the other Uro-Tainer[®] devices can be used by healthcare professionals as well as the patient. Uro-Tainer[®] Polihexanide is therefore an uncomplicated and non-systemic means of cleansing and decolonising urinary catheters, which avoids timeconsuming procedures for healthcare personnel and is comfortable for the patient.

Indications

- Routine mechanical rinsing of suprapubic and urethral catheters
- Bacterial decolonisation of the catheter

Contraindications

Uro-Tainer[®] Polihexanide 0.02 % should not be used:

- In case of hypersensitivity (allergy) to polihexanide, chlorhexidine, or excipient of the solution
- In cases of cystitis or other uro-genital condition that can produce haematuria (blood in the urine)
- For several days after surgery on the bladder or the urinary tract
- Avoid contact with open wounds, the inner and middle ear, the central nervous system, eyes, hyaline cartilage and meninges

Administration

- The regimen to be used will vary from user to user. Best results are obtained by adapting the dosage regimen to the individual patient
- Monitor response and adjust the frequency of application accordingly
- The tolerability of Uro-Tainer[®] Polihexanide is such that it can be used for up two irrigations per day if required
- Use only the quantity of solution that relates to the bladder capacity of the patient and do not use pressure on the bag to squeeze in all the remaining liquid

Composition

Per 100 ml: polyhexamethylene biguanide (polihexanide) 0.02 g, sorbitol in water for injections 5.0 g.

Uro-Tainer[®] Polihexanide solution does not contain the surfactant betaine (as used with Prontosan[®]).

CHOOSING THE CORRECT SOLUTION

Uro-Tainer[®] Polihexanide is the newest member of the Uro-Tainer[®] family and provides a novel approach to catheter maintenance. The illustration below outlines when to use each of the Uro-Tainer[®] solutions.

lssue	Risk of bacterial colonisation	Blockage	Debris formation
Treatment objective	Prevention or reduction of adhesive cells	Prevention or remove encrustation	Mechanical rinsing or flushing
Uro-Tainer [®] PHMB	\checkmark	_	\checkmark
Uro-Tainer [®] NaCl	_	_	\checkmark
Uro-Tainer® Suby G & Uro-Tainer® Solutio R	_	~	-

- Uro-Tainer[®] Polihexanide is a novel concept in catheter maintenance
- Uro-Tainer[®] Polihexanide provides healthcare professionals and patients with an effective means of routine mechanical rinsing and bacterial decolonisation of indwelling urinary catheters
- The Uro-Tainer[®] Polihexanide device has a simple and safe operating mode which is easy and quick to administer and is comfortable for the patient



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