



When Infection Rates Go Down

THE WHOLE HOSPITAL FEELS BETTER

Anti-Infection

ReleaseNF

Silicone Foley Catheter



RELEASENF[®] ANTI-INFECTION FOLEY

Advanced Technology

Catheter-associated urinary tract infections (CAUTI) are one of the most formidable infection prevention challenges in healthcare today. A relatively simple addition to your infection control protocol can dramatically reduce the incidence of CAUTI – and help your hospital deliver the best in care.

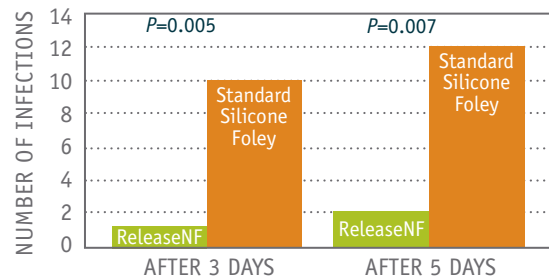
- Urinary tract infections account for 17% of all UK hospital acquired infections in acute hospitals and 28.1% in non-acute hospitals.¹
- Catheter associated urinary tract infections (CAUTI) cost the NHS £124 million every year.²

The ReleaseNF Anti-Infection Foley Catheter is proven to be safe and cost effective for reducing HAIs. A silicone catheter with a patented sustained-release of the urinary antiseptic nitrofurazone, ReleaseNF is advanced antimicrobial technology shown to be effective in reducing serious hospital infections.

ReleaseNF is the only Foley catheter with a FDA market clearance that includes an indication for CAUTI reduction

PROVEN REDUCTION OF BACTERIAL CAUTI³

The pre-market clinical trial involving 344 patients indicated a 90% reduction in bacterial CAUTI at 3 days and a 83% reduction at 5 days for ReleaseNF when compared to a standard all-silicone Foley catheter.



CATHETER: for Your Commitment to Prevention

- The only Foley catheter to elute an antibacterial drug into the urethra and bladder neck
- In vitro tests show ReleaseNF is more effective than silver-coated catheters against multidrug-resistant pathogens, including resistant strains of *E coli* and MRSA
- Shown to decrease the need for further antimicrobial treatment

1: : NHS Scotland National HAI Prevalence Survey, Final Report. July 2007. 2: Plowman R et al. The Socio-economic Burden of Hospital Acquired Infection. *Central Public Health Laboratory and London School of Hygiene and Tropical Medicine*. London 1999. 3: Maki DG, Holcomb RG. A report on the randomized, controlled clinical trial of the nitrofurazone-impregnated, antibacterial, indwelling urinary catheter. April 30, 1997. Data on file. Rochester Medical Corporation, Stewartville, MN.

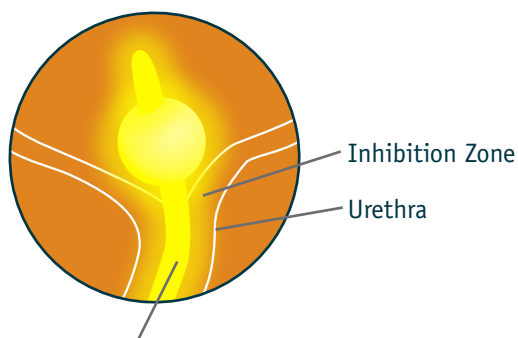
Uniquely Designed to Protect Against the

The ReleaseNF Anti-Infection Foley Catheter works by eluting a non-systemic antibacterial agent, nitrofurazone, into the urethral tract. Unlike some silver-coated catheters intended to prevent colonization of the catheter surface, the controlled release technology of ReleaseNF also provides site-specific bactericidal protection against common uropathogens.

Nitrofurazone's broad antimicrobial spectrum includes most Gram-positive bacteria and facultative Gram-negative bacilli, such as *E coli* and MRSA. Its antibacterial activity remains effective in the presence of blood, serum, or tissue.⁴

RELEASENF INHIBITION ZONE

ReleaseNF elutes controlled release nitrofurazone that protects the lower urinary tract



ReleaseNF features an all-silicone construction with nitrofurazone matrixed on the inside and outside surfaces of the catheter



TOUGHEST PATHOGENS

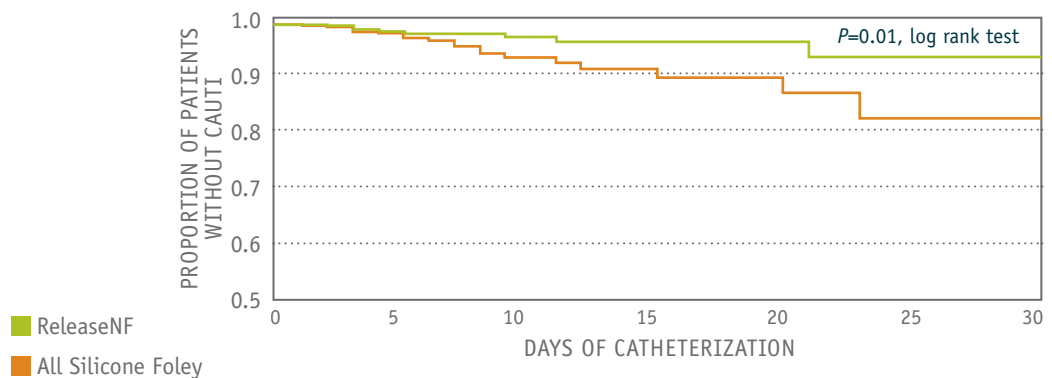


SUSTAINED RELEASE OF NITROFURAZONE

Testing by an independent laboratory found ReleaseNF elutes nitrofurazone at or above bactericidal levels for a minimum of 30 days.⁵

PROVEN PERFORMANCE

The unique design of ReleaseNF has been confirmed through clinical studies. In a recent randomized, controlled trial of trauma patients, the onset of CAUTI was significantly delayed through 30 days in the ReleaseNF catheter group.⁶



4: Chamberlain RE. Chemotherapeutic properties of prominent nitrofurans. *Journal of Antimicrobial Chemotherapy* (1976) 2, 325-336. 5: Data on file. Rochester Medical Corporation, Stewartville, MN. 6: Stensballe J, et al. Infection Risk with Nitrofurazone-Impregnated Urinary Catheters in Trauma Patients – A Randomized Trial. *Annals of Internal Medicine*, September 4, 2007; 290: Figure 2.

Data Proves NOT ALL

SUPERIOR PROTECTION AGAINST THE TOUGHEST PATHOGENS⁷

ReleaseNF Anti-Infection Foley Catheter showed excellent in vitro activity against multidrug-resistant CAUTI pathogens, including resistant strains of *E coli* and MRSA. In contrast, a silver hydrogel-coated catheter was only minimally active.

MORE AGGRESSIVE INHIBITORY ACTIVITY⁷

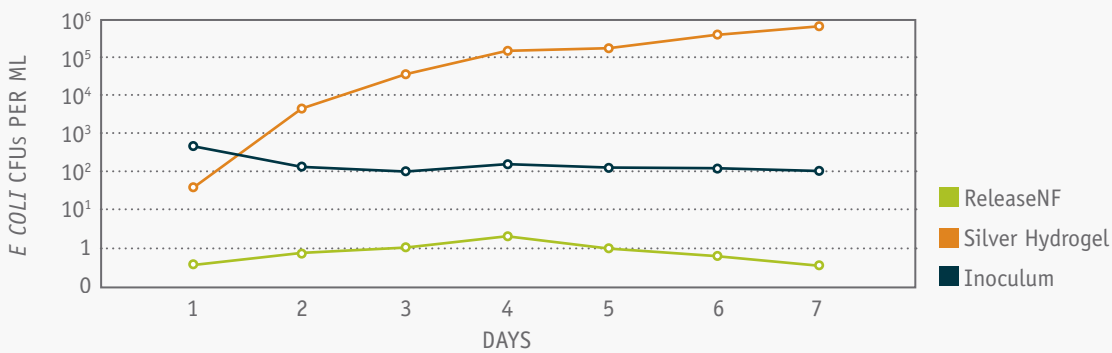
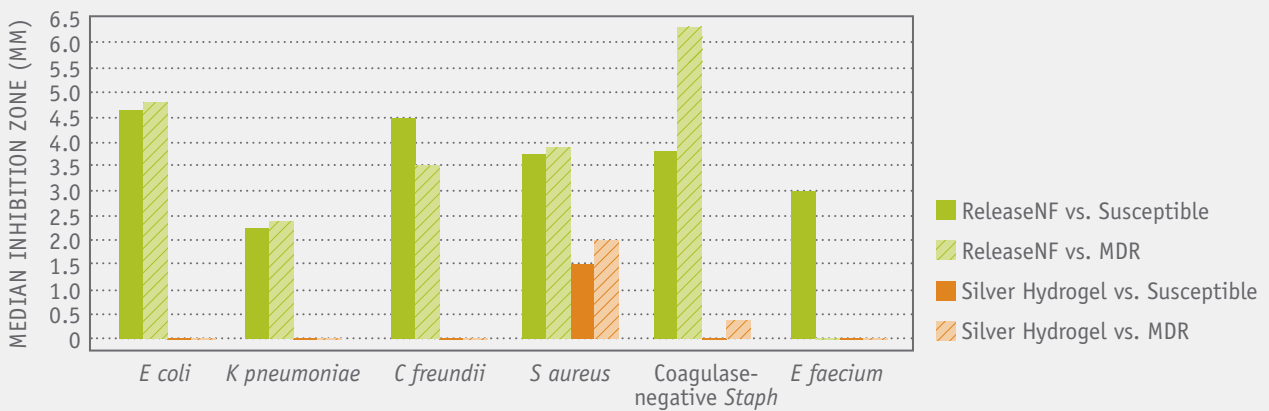
ReleaseNF also showed significantly larger inhibition zones than a silver hydrogel catheter for every pathogen tested.

MORE EFFECTIVE AT REDUCING BIOFILM⁸

Laboratory testing shows ReleaseNF exhibits greater *E coli* biofilm reduction than a silver hydrogel catheter, as indicated by the daily average Biofilm Colonization Plate Counts (CFUs).

CATHETERS ARE EQUAL

PATHOGENS	ReleaseNF		Silver Hydrogel	
	INHIBITION OF: Susceptible	MDR	INHIBITION OF: Susceptible	MDR
<i>Escherichia coli</i>	100%	100%	0%	0%
<i>Klebsiella pneumoniae</i>	100%	100%	0%	0%
<i>Citrobacter freundii</i>	100%	100%	0%	0%
<i>Staphylococcus aureus</i>	100%	100%	100%	100%
Coagulase-negative <i>Staphylococcus</i>	100%	100%	25%	75%
<i>Enterococcus faecium</i>	100%	0%	0%	0%



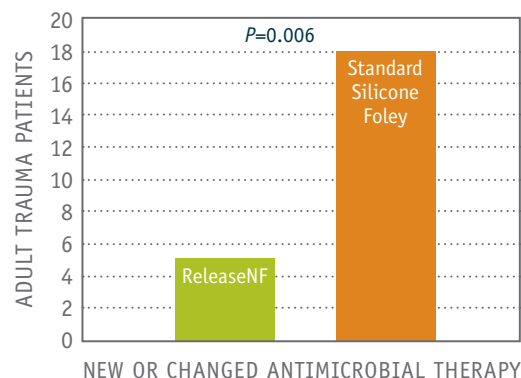
The inoculum counts confirmed all catheter segments were continuously challenged

By reducing the risk of developing infections, which can lead to serious complications and costly hospital stays, Rochester Medical's anti-infection catheter is safer for patients than a standard catheter.

Nitrofurazone is non-systemic and site-specific

SHOWN TO REDUCE THE NEED FOR SYSTEMIC ANTIBIOTICS⁹

In a randomized, controlled clinical trial of ReleaseNF, the reduction of catheter-associated bacteriuria and funguria resulted in a 72% decrease in the need to change or prescribe new antimicrobial therapy.



KEEPING PATIENTS SAFE

- Studies report there is no detectable systemic absorption of nitrofurazone from the urethra^{10,11}
- Nitrofurazone has been safely used worldwide for over 60 years
- The incidence of sensitisation and skin reaction to nitrofurazone is low – 1.2% overall; 0.3% in urological applications¹²
- All-silicone construction eliminates worries about latex allergies

⁹: Stensballe J, et al. Infection Risk with Nitrofurazone-Impregnated Urinary Catheters in Trauma Patients – A Randomized Trial. *Annals of Internal Medicine*, September 4, 2007; 285-293. ¹⁰: Rochester Medical Corporation. Data on file. ¹¹: Marion-Landais G, et al. Non-absorption of nitrofurazone from the urethra in men. *Curr Ther Res*. 1976;19:550-553. ¹²: Glascock HW, et al. Is Nitrofurazone a primary irritant or a potent sensitizer: a review of the literature, 1945-1965, and cases reported to medical director. *Review of Allergy*. 1969; 23:54-8. ¹³: Maki DG, Holcomb RG. A report on the randomized, controlled clinical trial of the Nitrofurazone-impregnated, antibacterial, indwelling urinary catheter. April 30, 1997. Data on file. Rochester Medical Corporation, Stewartville, MN. ¹⁴: Al-Habdan I, et al. Assessment of Nosocomial Urinary Tract Infections in Orthopaedic Patients: A Prospective and Comparative Study Using Two Different Catheters. *International Surgery*. 2003;88:152-154. ¹⁵: Lee SJ, et al. A Comparative Multicenter Study on the Incidence of Catheter-Associated Urinary Tract Infection Between Nitrofurazone-Coated and Silicone Catheters. *International Journal of Antimicrobial Agents*. 2004;24S:S65-S69.



is Your First Priority

In four controlled clinical trials involving 416 patients with the ReleaseNF catheter^{9,13-15}, there were:

- **No** reports of serious adverse reactions to the catheter
- **No** increases in the frequency of CAUTI due to non-susceptible bacteria
- **No** statistically significant differences in the incidence of yeast/fungal infections

A SMART PART of Your Infection

- ReleaseNF Anti-Infection Foley catheter has been reviewed to Recommendation Level 2 by the UK Health Protection Agency Rapid Review Panel (September 2007)
- The cost of treatment of CAUTI per patient is an additional £1,327¹
- Bed space is blocked for between 3.2 and 13.7 days²
- For every 1,000 patients catheterised 35 will contract a symptomatic CAUTI at an estimated cost to the NHS of £50,000^{1,16,17,18,19}

Prevent just one symptomatic CAUTI and recoup the cost difference between ReleaseNF and a standard silicone Foley

SUPERIOR TECHNOLOGY

The superior technology of ReleaseNF will help your hospital reduce costs, lower infection rates and improve patient care.

- The only Foley catheter indicated to reduce CAUTI
- Clinically proven to reduce CAUTI when compared to an all-silicone control catheter
- The only drug eluting catheter that kills bacteria
- Protects against the broadest spectrum of bacteria
- Non-systemic and proven safe for patients
- Shown to reduce the use of systemic antibiotics to treat CAUTI

1: Plowman R et al. The Socio-economic Burden of Hospital Acquired Infection. *Central Public Health Laboratory and London School of Hygiene and Tropical Medicine*. London 1999. **2:** NHS Scotland National HAI Prevalence Survey, Final Report. July 2007. **16:** Madeo D, et al. The impact of using silver alloy urinary catheters in reducing the incidence of urinary tract infection in the critical care setting. *British Journal of Infection Control*, 2004; 5; 21. **17:** Harstein AI et al. Nosocomial urinary tract infection: a prospective evaluation of 108 catheterised patients. *Infection Control*. 1981; 2:380-6. **18:** Garibaldi RA, et al. An evaluation of daily bacteriologic monitoring to identify preventable episodes of catheter-associated urinary tract infection. *Infection Control*. 1982; 3:466-70. **19:** Bryan CS, et al. Hospital acquired bacteraemic urinary tract infection: epidemiology and outcome. *Journal of Urology*. 1984; 132:494-8

Control Protocol



For More Information and Reprints of Published Studies,
Contact Us at 0800 0322 755

Site specific anti-infection technology for the lower urinary tract

Rochester Medical Corporation's proprietary technologies have made us a world leader in the fight against catheter-associated urinary tract infections. We developed the first antimicrobial intermittent catheter and the only silicone anti-infection Foley catheter clinically proven to reduce the incidence of CAUTI.

Today Rochester Medical holds over 20 U.S. patents and numerous foreign patents related to catheter designs and coating technologies.

ORDERING INFORMATION

Product	Size	Qty/Box	REF
2-way 10ml	12 - 26 Ch	12	952XX
2-way 30ml	16 - 26 Ch	12	932XX
3-way 10ml	16 - 26 Ch	12	953XX
3-way 30ml	16 - 26 Ch	12	933XX

ReleaseNF is available on Drug Tariff in 2-way 10ml sizes



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