

Bactiguard® Infection Protection

BIP Foley Catheter

– For prevention of healthcare associated infections

Bactiguard® benefits

- Reduced healthcare costs
- Reduced use of antibiotics
- Save lives

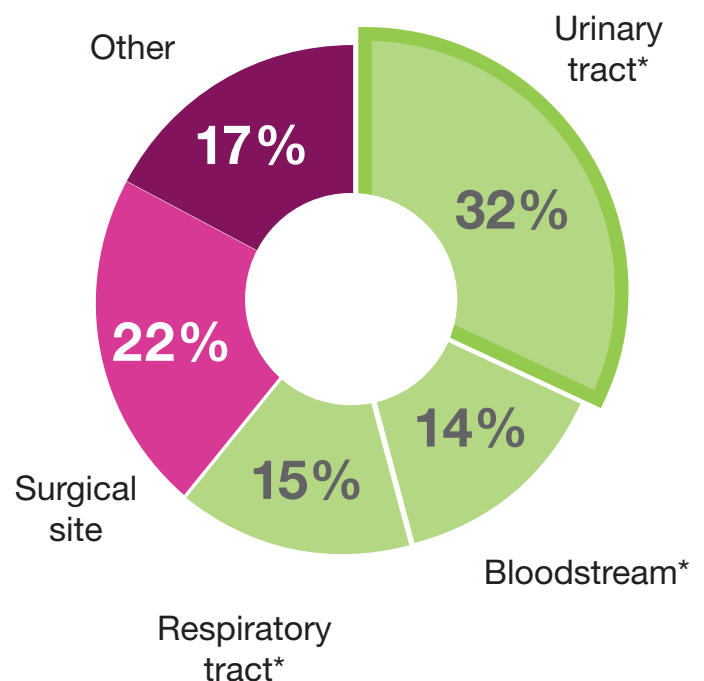
Catheter associated UTI (CAUTI)

Catheter associated urinary tract infections (CAUTI) account for a large proportion of healthcare associated infections (HAI)¹. These infections can result in serious complications such as urosepsis, which lead to patient suffering as well as increased mortality and healthcare costs².

The risk of CAUTI increases with the number of days of catheterization and if the patient's immune system is weak. Groups at risk include for example the critically ill and patients with urological malignancies and neurological diseases.

In addition, many of these infections are treated with antibiotics, which increase the risk of emergence and spread of multi-resistant microbes.

Healthcare Associated Infections¹



*Bactiguard products available

The solution – BIP Foley Catheter

The BIP Foley Catheter is an indwelling urinary catheter with Bactiguard coating which is proven to significantly reduce bacteriuria, symptomatic urinary tract infections and the use of antibiotics.

The Bactiguard Infection Protection (BIP) technology is based on applying a very thin noble metal coating, consisting of gold, palladium and silver, to medical devices. The Bactiguard coating is firmly bound to the surface of the device and reduces the adhesion and growth of microbes.

Material

The BIP Foley Catheters are available in both latex and silicone. For increased patient comfort, the Foley catheters also have a hydrophilic coating, to reduce friction when inserting the catheter.

Usage

The catheter can be used through the urethra or suprapubically, for up to 90 days.

Environment

The Bactiguard coating is environmentally friendly and requires no special procedures for handling, use or disposal.

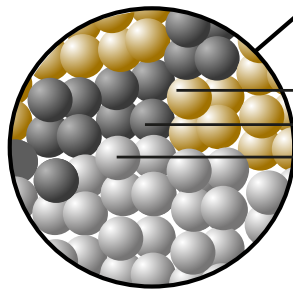
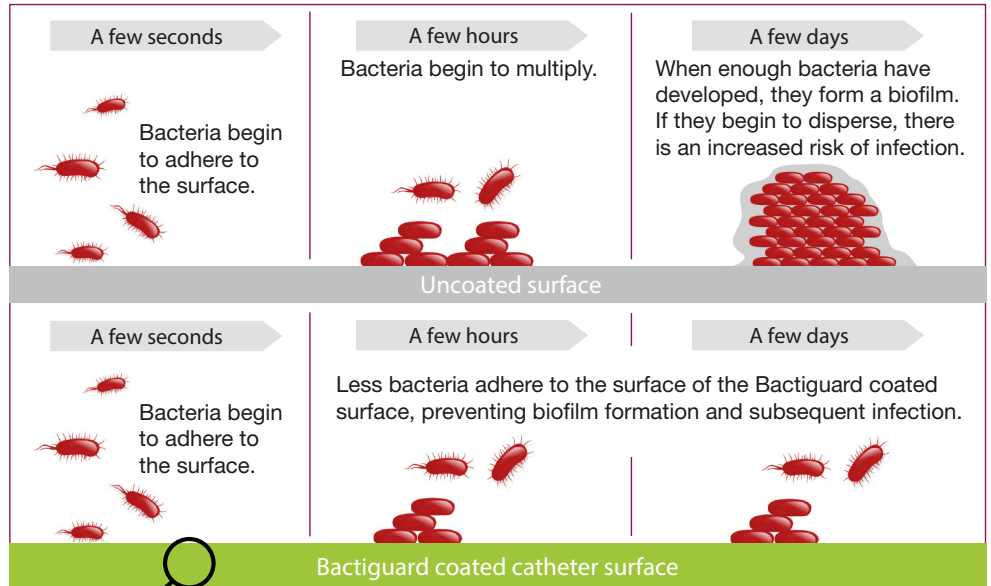
” More than 150 million Bactiguard coated urinary catheters have been sold for patient use, with no reported adverse events related to the coating.

The Bactiguard Infection Protection (BIP) technology

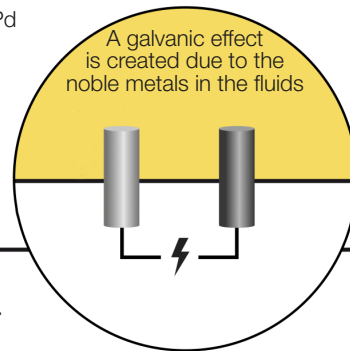
Preventing CAUTI

Medical device surfaces attract bacteria, which develop into a biofilm. Catheter associated urinary tract infections occur when there is an immune response to bacteria in the urethra or bladder.

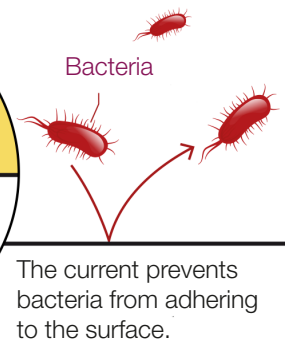
The noble metals in the Bactiguard coating cause a galvanic effect, which prevents bacteria from adhering to the surface. Coated products demonstrate a reduced bacterial adhesion, which in turn prevents biofilm formation and subsequent infection.



- Gold Au
- Palladium Pd
- Silver Ag



This creates a micro current.

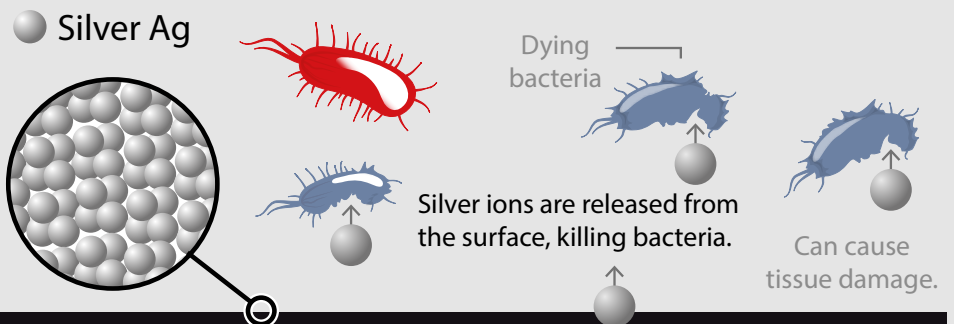


Galvanic effect

The three noble metals in the Bactiguard coating – gold, palladium and silver, cause a galvanic effect.

Bactiguard compared to traditional releasing technologies³

These technologies depend on release of toxic substances, such as silver ions, attacking the bacteria.



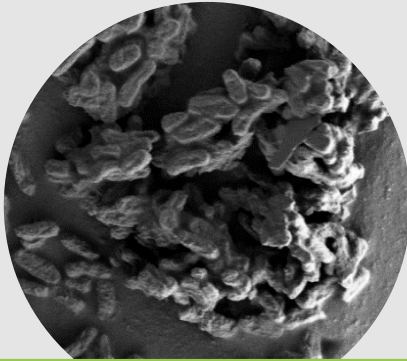
5 to 10 times thicker layer than a surface with Bactiguard coating. Becomes thinner over time due to release.

In Vitro/Ex Vivo Efficacy

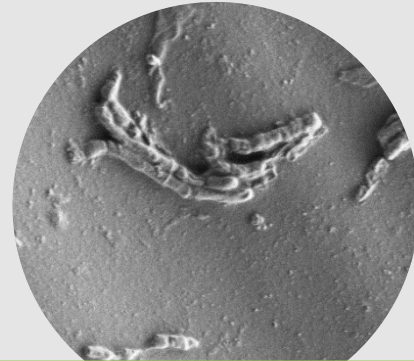
The reduction of microbial adhesion and colonization to device surfaces has been verified for clinically relevant microbial strains using an *in vitro* efficacy test. The *in vitro* test evaluates the adhesion of microorganisms to device surfaces. Example of results (*gram negative bacteria*) are presented in the figures below⁴. The reduction of microbial colonization has also

been verified clinically. Mazzoli et al. compared the presence and prevalence of microorganisms on Bactiguard coated Foley catheters to uncoated catheters after 30 days of clinical use. Using a Bactiguard coated Foley Catheter reduced the colonization of bacteria by approximately 60% compared to an uncoated catheter⁵.

Gram negative bacteria



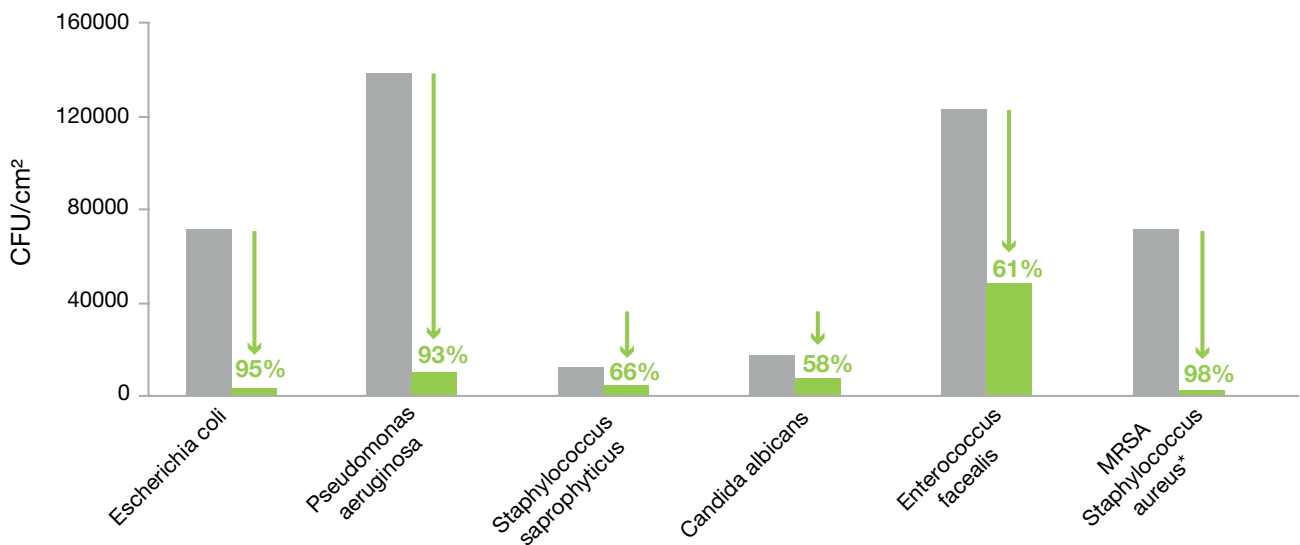
Microbe build-up without Bactiguard coating



Microbe build-up with Bactiguard coating

Less bacteria adhere to the Bactiguard coated surface

Reduction in microbial adhesion to BIP Foley Catheters ⁴



Average raw data from several batches of BIP Foley Catheter Latex and Silicone
Average raw data from several batches of both BIP Foley Catheter Latex and Silicone

* Only BIP Foley Catheter Silicone

Clinically proven against CAUTI

Bactiguard coated products have been used in a large number of clinical studies and evaluations (1986–2015) involving over 100,000 patients. In peer-reviewed studies (table below) looking specifically at the incidence of symptomatic CAUTIs in patients with >2 days of catheterization (in line with current standards), the weighted average reduction

was 35%^{6,7,8,9,10,11}. In certain studies a much larger reduction, over 70%, was observed⁹. In addition to this, a large study involving almost 28,000 patients proved a reduction in asymptomatic and symptomatic bacteriuria of 32% ($p=0.001$) and indicated a reduction in urosepsis of 44% ($p=0.42$)¹².

Author (year)	Study type	Size (#)	Settings	Catherter duration	Incidence reduction
Hidalgo F (2015) ⁶	RCT	116	Cardiology, Spain	Mean 4 days	38% ($p=0.037$)
Lederer (2014) ⁷	Before/after study	853	7 hospitals, hospital wide, US	Mean 9–15 days	53% ($p<0.0001$)
Pickard (2012) ⁸	RCT	1224	24 hospitals, surgical care, UK	3–10 days	19% ($p=0.16$)
Seymour (2006) ⁹	Before/after study	117	One acute general hospital, UK	>2 days	71%
Gentry (2005) ¹⁰	Before/after study	133	Medical and surgical wards, US	7–10 days	34%
Newton (2002) ¹¹	Before/after study	1 757	Burn unit (ICU), US	5–8 days	32% ($p=0.029$)

**Weighted
average
35%**

Tissue-friendly and safe technology

The Bactiguard solution is unique, tissue friendly and safe for patient use. As opposed to coating technologies which depend on the release of substances, which kill bacteria, e.g. large amounts of silver ions, chlorhexidine or antibiotics, the Bactiguard coating is neither toxic nor pharmacologic¹³. After 90 days in urine 99% of the coating is still bound to the surface of the BIP Foley Catheter¹⁴, meaning there is only a minimal release.

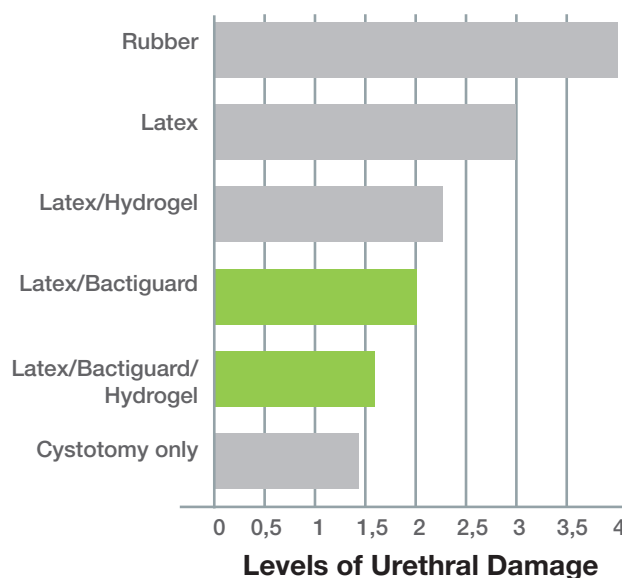
To date, more than 150 million Bactiguard coated urinary catheters have been sold for patient use, with no reported adverse events related to the coating.

**After 90 days in urine
99% of the coating is still
bound to the surface of
the BIP Foley Catheter¹⁴.**

Biocompatible

In a study comparing the biocompatibility of different materials¹⁵, the effects on urethral mucosa was measured after 72h. The catheter with Bactiguard and hydrophilic coating was as biocompatible as the control, which was a cystotomy only.

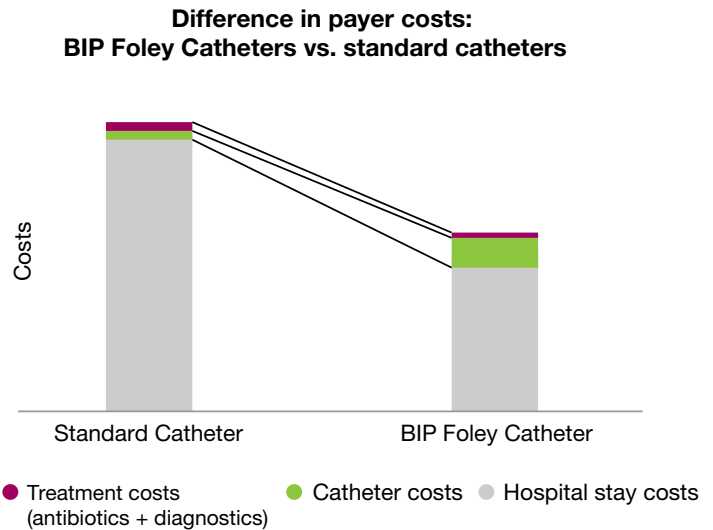
Results of implantation



Cost savings

BIP Foley Catheter has been shown to reduce CAUTI in a cost effective way. The costs savings are present in a wide variety of reimbursement systems^{12,16,17}. Several health economic evaluations have been conducted in Europe and USA^{12,16,17}. In one of these, a large, prospective, randomized study of almost 28 000 patients, Bactiguard coated catheters were shown to offer significant annual cost savings when considering the excess cost of CAUTI¹². In another 2-year prospective surveillance study of 10 patient care units, the introduction of a Bactiguard coated urinary catheter was associated with a significant decline in CAUTI and led to reduced costs¹⁶.

BIP Foley Catheters are associated with lower length of hospital stay costs, treatment costs and improved patient quality of life¹². The graph to the right is based on a Bactiguard health economy model using Saint et al. 2000¹⁷ (for local adaptations of costs, please contact your local Bactiguard representative).



References

1. Klevens RM et al, Public Health Rep. 2007 Mar-Apr;122(2):160-6
2. Kalra OP et al, J Glob Infect Dis. 2009 Jan;1(1):57-63
3. Data on file
4. Data on file
5. Mazzoli s. et al., Eurobiofilms 2009,Rom,Sept 02-05
6. Hidalgo Fabrellas et al. Enferm Intensiva. 2015; 26(2):54-62
7. Lederer JW et al, J WOCN 2014; 41(5):1-8
8. Pickard et al, The Lancet, Nov 5, 2012
9. Seymour C, British Journal of Nursing, 2006; 15(11): 598-603
10. Gentry H et al, Nursing Standard. 2005; 19, 50, 51-54
11. NewtonT et al, Infection Control and Hospital Epidemiology; 2002; 23(1): 217-8
12. Karchmer TB et al, Arch Intern Med. 2000 Nov 27;160(21):3294-8
13. Data on file
14. Data on file
15. H. Liedberg et al, 1989. The effect of different catheter material on the urethral mucosa. Data on file.
16. Rupp ME et al. AJIC. 2004; 32(8):445-450
17. Saint S. et al. Arch Intern Med. 2000; 160:2670-2675

Order information



Product range BIP Foley Catheter

Article number	Description	Size (Fr/Ch)	Balloon vol. (ml/cc)	Length (cm)
111080310	2-way Pediatric	8	5	30
111100310	2-way Pediatric	10	5	30
111120510	2-way Standard	12	10	40
111140510	2-way Standard	14	10	40
111160510	2-way Standard	16	10	40
111180510	2-way Standard	18	10	40
111200510	2-way Standard	20	10	40
111220510	2-way Standard	22	10	40
111240510	2-way Standard	24	10	40
111260510	2-way Standard	26	10	40
111280510	2-way Standard	28	10	40
111300510	2-way Standard	30	10	40
111123010	2-way Standard	12	30	40
111143010	2-way Standard	14	30	40
111163010	2-way Standard	16	30	40
111183010	2-way Standard	18	30	40
111203010	2-way Standard	20	30	40
111223010	2-way Standard	22	30	40
111243010	2-way Standard	24	30	40
111263010	2-way Standard	26	30	40
111283010	2-way Standard	28	30	40
111303010	2-way Standard	30	30	40
112163010	3-way Standard	16	30	40
112183010	3-way Standard	18	30	40
112203010	3-way Standard	20	30	40
112223010	3-way Standard	22	30	40
112243010	3-way Standard	24	30	40
112263010	3-way Standard	26	30	40

Product range BIP Foley Catheter – Silicone

Article number	Description	Size (Fr/Ch)	Balloon vol. (ml/cc)	Length (cm)
115060510	2-way Pediatric	6	3	31
115080510	2-way Pediatric	8	5	31
115100510	2-way Pediatric	10	5	31
115121010	2-way Standard	12	10	40
115141010	2-way Standard	14	10	40
115161010	2-way Standard	16	10	40
115181010	2-way Standard	18	10	40
115201010	2-way Standard	20	10	40
115221010	2-way Standard	22	10	40
115241010	2-way Standard	24	10	40
115261010	2-way Standard	26	10	40
115163010	2-way Standard	16	30	40
115183010	2-way Standard	18	30	40
115203010	2-way Standard	20	30	40
115223010	2-way Standard	22	30	40
115243010	2-way Standard	24	30	40
115263010	2-way Standard	26	30	40
116161010	3-way Standard	16	10	40
116181010	3-way Standard	18	10	40
116201010	3-way Standard	20	10	40
116221010	3-way Standard	22	10	40
116241010	3-way Standard	24	10	40
116261010	3-way Standard	26	10	40
116163010	3-way Standard	16	30	40
116183010	3-way Standard	18	30	40
116203010	3-way Standard	20	30	40
116223010	3-way Standard	22	30	40
116243010	3-way Standard	24	30	40
116263010	3-way Standard	26	30	40

Department pack = 10 pcs.
 Transport pack = 10x10 pcs.
 Size department pack WxHxD: 515x90x45 mm

The products are CE marked according
 to Medical Device Directive 93/42/EEC

CE 0344



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