Bactiguard®

Bactiguard® Infection Protection

BIP Foley Catheter

Designed to:
Reduce CAUTI
Reduce use of antibiotics
Reduce healthcare costs



The challenge

The problem

Preventing healthcare associated infections (HAIs) has never been more important. Every infection prevented, is an antibiotic treatment avoided.[1] According to the World Health Organization (WHO), effective infection prevention and control can reduce HAIs by at least 30%.[2]

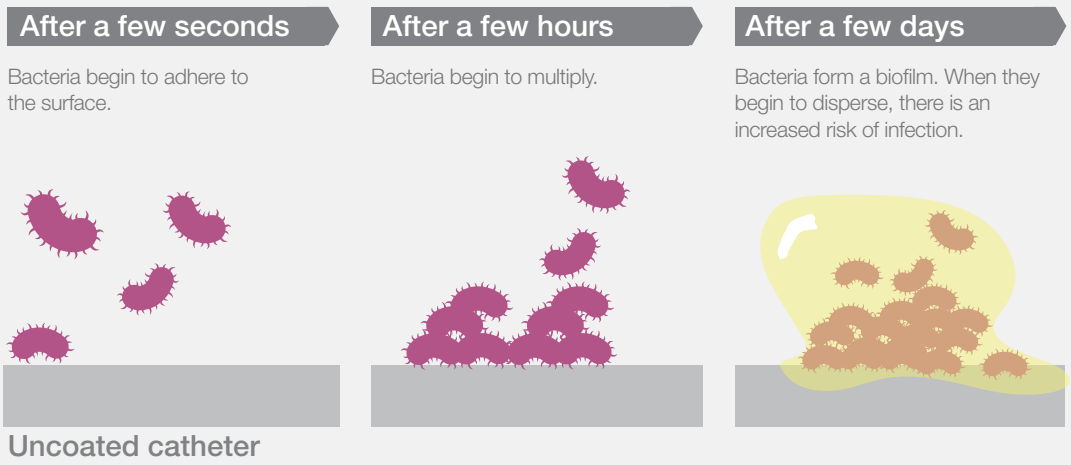
Every day, HAIs result in prolonged hospital stays, long-term disability, increased anti-microbial resistance, additional costs for healthcare systems, unnecessary suffering for patients and their families, and deaths.[3,4]

WHO: ”Infection prevention and control actions can save millions of lives, every year”[1]

Catheter associated urinary tract infection is the most frequent HAI, of which a large proportion is caused by indwelling urinary catheters.[5] The risk for invasion of microbes and subsequent infections increase with every day of catheterization.

Catheter associated urinary tract infection (CAUTI)

The surfaces of catheters attract microbes, which colonize it and may develop biofilm. CAUTI occurs when there is an immune response to microbes in the urethra or bladder. Microbes in biofilm are much more resistant to antibiotics and patient immune systems, than microbes not forming biofilm.



“Infections may either arise when we inadvertently insert bacteria into the patient’s urinary tract during catheterization. Or, infections can be caused by bacteria in the urinary tract forming a biofilm on a catheter, which results in an infection.”

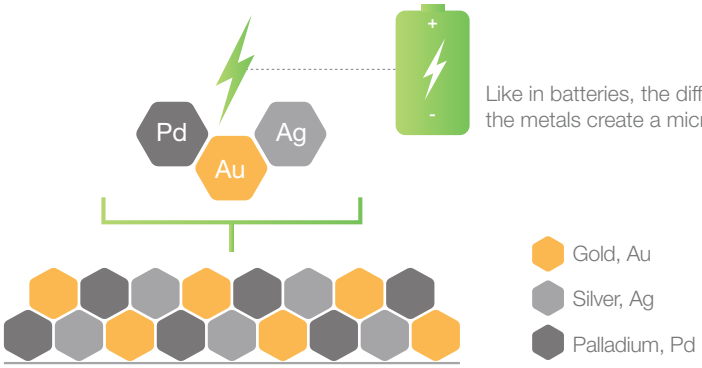
Urology nurse, Sweden

The solution

The technology

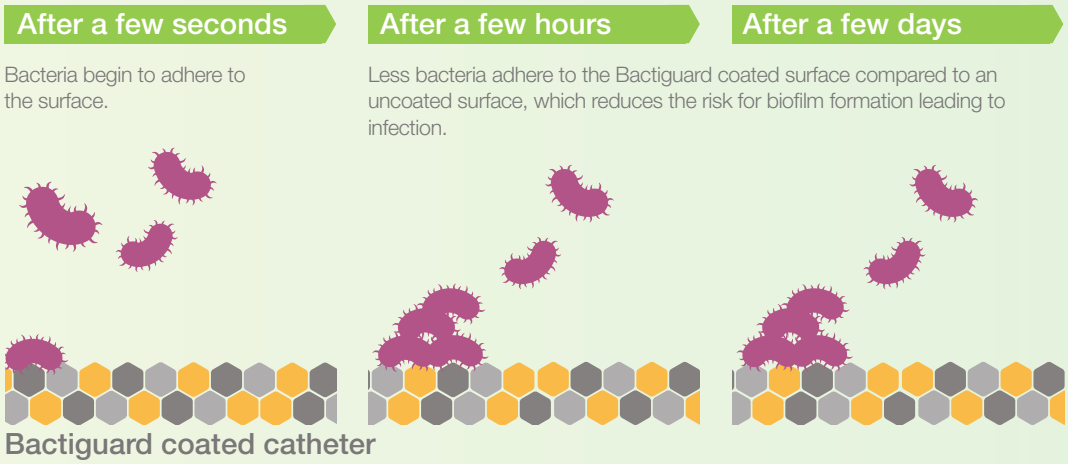
Galvanic effect

The Bactiguard Infection Protection (BIP) technology is based on a very thin noble metal alloy coating, consisting of gold, silver and palladium, firmly attached to medical devices. When in contact with fluids, the noble metals create a galvanic effect.



Reduction of microbial adhesion

The galvanic effect creates a micro current that reduces microbial adhesion to the catheter material, which decreases the risk for biofilm formation leading to infection.



The safety

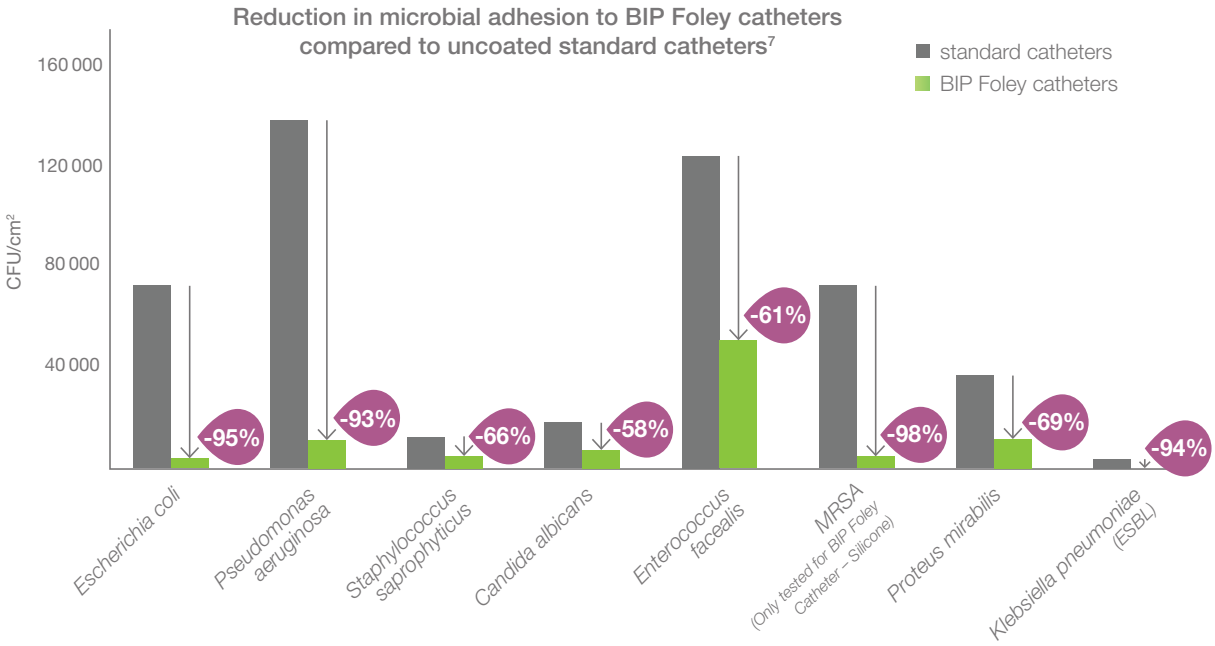
The amount of noble metals at the surface is very low and below all safety limits for each metal and there is no release of any toxic or pharmacological quantities. This makes the technology both tissue-friendly and safe as opposed to traditional coating technologies that often depend on the release of substances that kill bacteria, e.g. high concentrations of silver ions, chlorhexidine or antibiotics.[6]

The solution

The efficacy

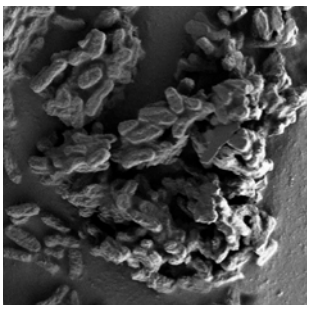
In vitro test

The reduction of microbial adhesion and colonization to device surfaces has been verified for clinically relevant microbial strains using an *in vitro* test. It evaluates the adhesion of gram-positive and gram-negative bacteria to device surfaces.[7]

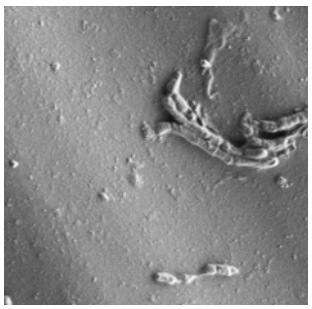


Scanning electron microscopy

The reduction of microbial colonization has been observed by scanning electron microscopy (SEM). The pictures show the microbe colonization of bacteria on an uncoated surface versus on a Bactiguard coated surface. Less bacteria colonize the Bactiguard coated surface.



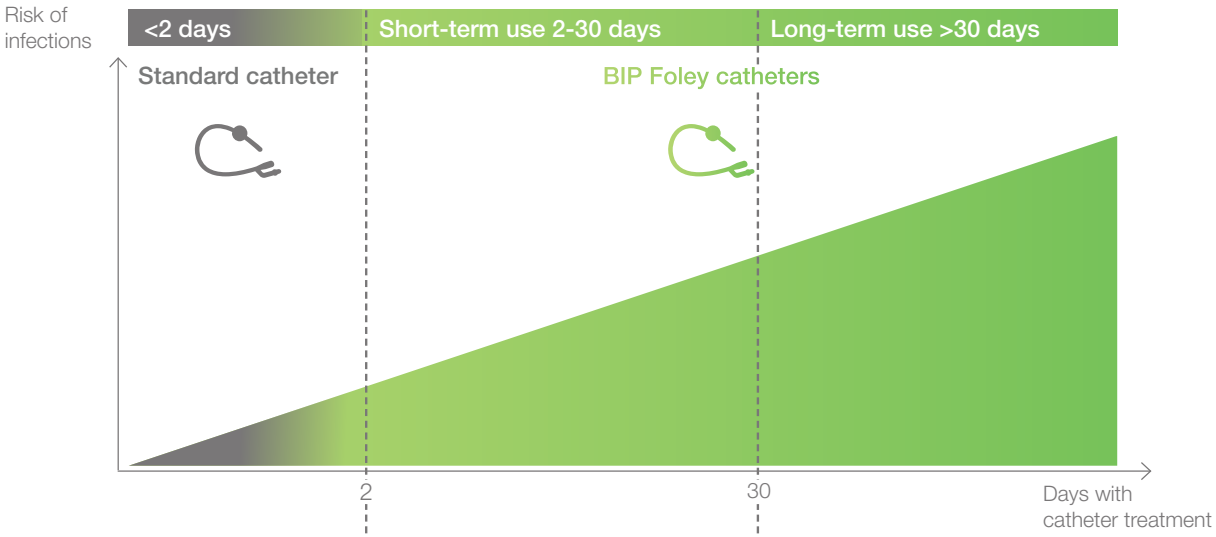
Microbe colonization on uncoated surface



Microbe colonization on Bactiguard coated surface

The patient

The BIP Foley catheters reduce the risk of CAUTI through reduction of microbial adhesion and biofilm formation and is intended for patients catheterized for longer than two days. Less than two days usage rarely leads to infection and a standard catheter can then be used.



Less than 2 days
Use a standard catheter.

Exception:
If the patient has an ongoing infection, consider a BIP Foley Catheter.

Short-term use (2-30 days)
Some patients catheterized for longer than two days will use a catheter only for a short term, but still with a high risk of developing infections.

E.g. the critically ill, geriatric patients, urology patients, surgical patients or patients with suppressed immune systems.

Long-term use (>30 days)
The long-term catheterized patients always have a high risk of developing infections and other problems related to bacterial colonization, such as smell or catheter blockage.

E.g. spinal cord injured patients or patients with neurological bladder dysfunctions.



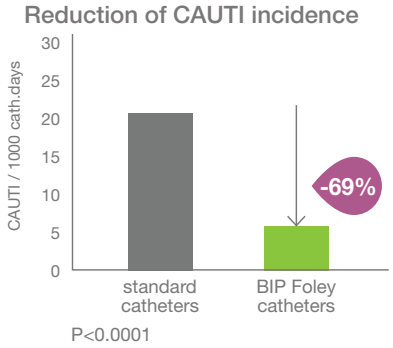
The evidence

Studies on short-term use (2-30 days)

The efficacy of Bactiguard coated catheters has been studied in more than 20 studies, published in peer reviewed journals. The studies below comply with the latest CAUTI definition, measuring only symptomatic infections for patients catheterized longer than 2 days.

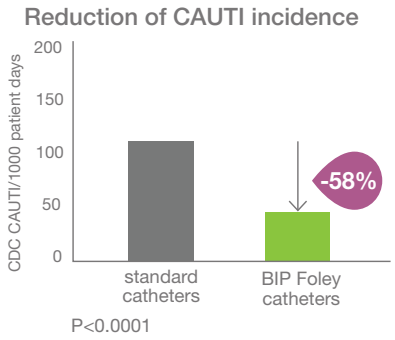
Randomized multicenter study, India

Kai-Larsen *et al* conducted a multicenter study with 1000 urology, general surgery and intensive care patients, catheterized for more than 2 days. The incidence of CAUTI decreased by 69% in the group with a BIP Foley catheter, compared with the standard catheter group. CAUTI / 1000 catheter days; 6.5 vs. 20.8.[8]



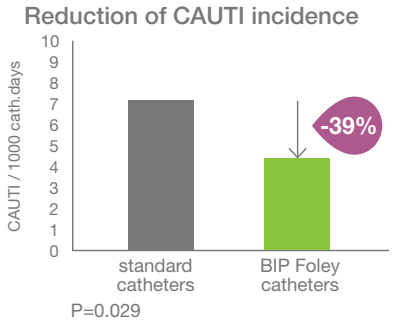
Multicenter study, USA

Lederer *et al* conducted a multicenter surveillance study in the USA, including 853 patients at 7 hospitals, catheterized for 8 days in average. The incidence of CAUTI infections was reduced by 58% after introduction of Bactiguard coated catheters.[9]



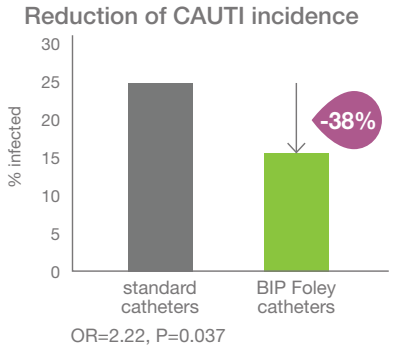
Burn unit patients, USA

Newton *et al* studied the effect of Bactiguard coated catheters on 1 757 patients with a 7–8 days mean catheter time in a burn unit in Georgia, USA. They found a 32% incidence reduction with Bactiguard coated catheters and a 39% reduction of CAUTI per 1 000 catheter days.[10]



Cardiac surgery patients, Spain

Hidalgo Fabrellas *et al* performed a randomized study on 116 post-op cardiology patients in Spain, with a 4 days mean catherization time, and found a 38% incidence reduction of CAUTI. The use of BIP Foley catheters was shown to be cost effective.[11]



Studies on long-term use (>30 days)

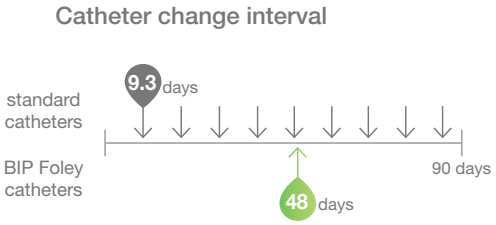
Long-term catheterized patients are highly exposed to infections since the risk for infection increases by approx. 5% per day. Also other problems related to bacterial colonization, such as smell, encrustation or catheter blockage are common and may be prevented with BIP Foley catheters.

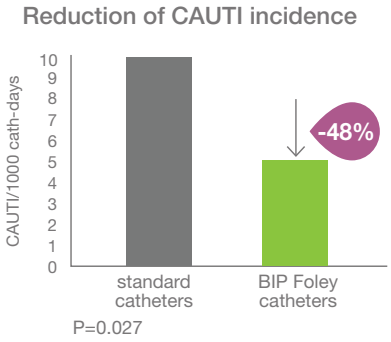
Medical rehabilitation patients, Hong Kong

Chung *et al* studied 306 medical rehabilitation patients. They observed a prolonged period of time with the BIP Foley Catheter until complications occurred and a change of catheter was needed: 48 days vs. 9.3 days for the patients treated with catheter for 80-90 days.

The average reduction of CAUTI for the sub group treated with catheter for as long as 80-90 days was 48% with BIP Foley catheters (p=0.027).

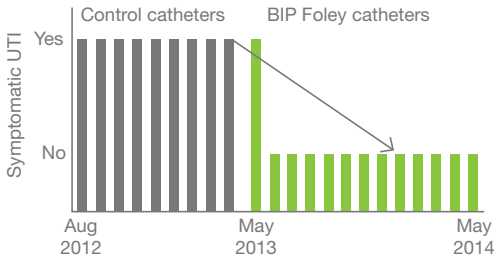
For the entire study population, the average reduction of CAUTI was 31% (p=0.095).[12]





Patient cases, USA and Sweden

Estores *et al* and Magnusson *et al* both describe cases of permanently catheterized patients with monthly recurring UTIs. After changing to Bactiguard coated catheters, the patients were free from symptomatic infections up to 2 years.[13,14]



Adapted from Magnusson *et al*

> “Things have never been as easy as they are now! I haven’t had any infections, I no longer need to take antibiotics and I have definitely regained my joy of life.”
>
> Elisabeth, BIP Foley user



The cost savings

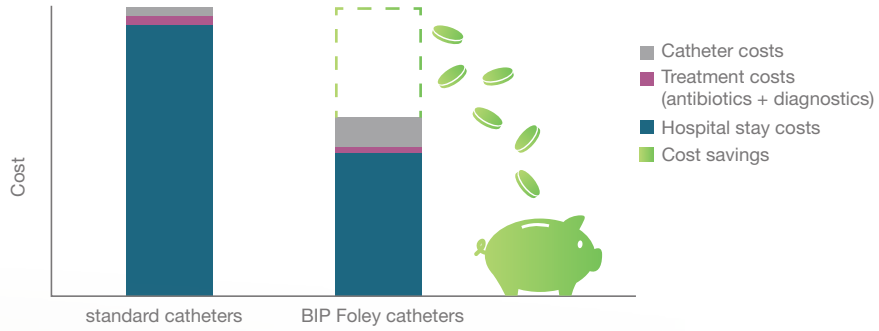
Health economy benefits

Investing in prevention with BIP Foley catheters has been shown to reduce CAUTI in a cost-effective way. The cost savings are present in a wide variety of reimbursement systems.[15,16] Several health economic evaluations have been conducted in Europe and USA.[11,15,16]

BIP Foley catheters are associated with lower costs related to length of hospital stays, lower treatment costs and improved patient quality of life.[15]

According to Saint *et al*[16], the estimated average cost for a CAUTI is $ 911 per patient. If it spreads to the blood stream, the estimated cost is $ 2 834 per patient.

Difference in payer costs: standard catheters vs. BIP Foley catheters[15]



Bactiguard health economic model based on Saint *et al* 2000.[16]
For local health economic calculations, please contact your Bactiguard representative.

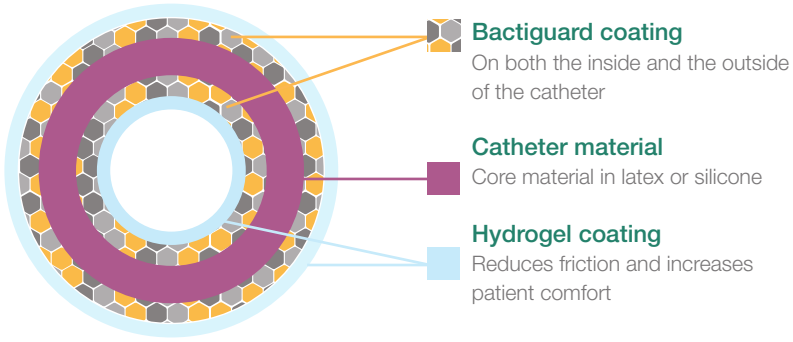


The product

BIP Foley catheters

The BIP Foley catheters are approved for transurethral and suprapubic use for up to 90 days, with the exception of the BIP Foley TempSensor, which is approved for transurethral use up to 30 days. The Bactiguard coating is environmentally friendly and requires no special procedures for handling, use or disposal.

The Bactiguard solution is unique, tissue-friendly and safe for patient use. To date, more than 200 million Bactiguard coated catheters have been sold for patient use, with no reported adverse events related to the coating.



The BIP Foley catheters are approved for use up to 90 days. After 90 days in urine, up to 99% of the Bactiguard coating is still bound to the surface of the catheters.[17]

Bactiguard Infection Protection Clinical Implementation Program

Better knowledge of the proper treatment of patients requiring catheters is one way of reducing catheter related urinary tract infections. With the aim of reducing these infections, Bactiguard has developed an educational material for healthcare professionals; Bactiguard Clinical Implementation Program, BIP CIP in collaboration with experts from Karolinska University Hospital, Sweden.

If you want to know more about BIP CIP in your country, please contact your Bactiguard representative.





Watch the BIP CIP instructional videos at www.bactiguard.com/media/films/

The order information





BIP Foley Catheter (Latex)

Article no.	Description	Size (FR/Ch)	Ballon vol. (ml/cc)	Length (cm)
111080310	2-way Pediatric	8	5	30
111100310	2-way Pediatric	10	5	30
111120510	2-way	12	10	40
111140510	2-way	14	10	40
111160510	2-way	16	10	40
111180510	2-way	18	10	40
111200510	2-way	20	10	40
111220510	2-way	22	10	40
111240510	2-way	24	10	40
111260510	2-way	26	10	40
111280510	2-way	28	10	40
111300510	2-way	30	10	40
111123010	2-way	12	30	40
111143010	2-way	14	30	40
111163010	2-way	16	30	40
111183010	2-way	18	30	40
111203010	2-way	20	30	40
111223010	2-way	22	30	40
111243010	2-way	24	30	40
111263010	2-way	26	30	40
111283010	2-way	28	30	40
111303010	2-way	30	30	40
112163010	3-way	16	30	40
112183010	3-way	18	30	40
112203010	3-way	20	30	40
112223010	3-way	22	30	40
112243010	3-way	24	30	40
112263010	3-way	26	30	40

BIP Foley Catheter – Silicone

Article no.	Description	Size (FR/Ch)	Ballon 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	12	10	40
115141010	2-way	14	10	40
115161010	2-way	16	10	40
115181010	2-way	18	10	40
115201010	2-way	20	10	40
115221010	2-way	22	10	40
115241010	2-way	24	10	40
115261010	2-way	26	10	40
115163010	2-way	16	30	40
115183010	2-way	18	30	40
115203010	2-way	20	30	40
115223010	2-way	22	30	40
115243010	2-way	24	30	40
115263010	2-way	26	30	40
116161010	3-way	16	10	40
116181010	3-way	18	10	40
116201010	3-way	20	10	40
116221010	3-way	22	10	40
116241010	3-way	24	10	40
116261010	3-way	26	10	40
116163010	3-way	16	30	40
116183010	3-way	18	30	40
116203010	3-way	20	30	40
116223010	3-way	22	30	40
116243010	3-way	24	30	40
116263010	3-way	26	30	40

Department pack = 10 pcs., TempSensor = 8 pcs.
Transport pack = 10×10 pcs., TempSensor = 10x 8 pcs.
Size department pack W×H×D: 515×90×45 mm

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



BIP Foley Catheter – Silicone (Female)

Article no.	Description	Size (FR/Ch)	Ballon vol. (ml/cc)	Length (cm)
115121020	2-way Female	12	10	26
115141020	2-way Female	14	10	26
115161020	2-way Female	16	10	26
115181020	2-way Female	18	10	26
115201020	2-way Female	20	10	26

More sizes available on request



BIP Foley Tiemann

Article no.	Description	Size (FR/Ch)	Ballon vol. (ml/cc)	Length (cm)
117121010	2-way Tiemann	12	10	41.5
117141010	2-way Tiemann	14	10	41.5
117161010	2-way Tiemann	16	10	41.5
117181010	2-way Tiemann	18	10	41.5
117201010	2-way Tiemann	20	10	41.5

More sizes available on request



BIP Foley TempSensor

Article no.	Description	Size (FR/Ch)	Ballon vol. (ml/cc)	Length (cm)
118080510	2-way Pediatric TempSensor	8	5	31
118100510	2-way Pediatric TempSensor	10	5	31
118121010	2-way TempSensor	12	10	44
118141010	2-way TempSensor	14	10	44
118161010	2-way TempSensor	16	10	44
118181010	2-way TempSensor	18	10	44

Department pack = 10 pcs., TempSensor = 8 pcs.
Transport pack = 10×10 pcs., TempSensor = 10x 8 pcs.
Size department pack W×H×D: 515×90×45 mm

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

Bactiguard®

Bactiguard – a Swedish history of innovation

Bactiguard was founded in 2005, but our technology is almost a hundred years old.

It stems from the Swedish Nobel Prize laureate, Gustav Dahlén, the man behind the famous AGA Lighthouse. Gustav Dahlén had an apprentice called Axel Bergström, who developed the technique of applying a thin layer of metals to non-conductive materials. Axel Bergström then passed this knowledge on to his apprentice, Billy Södervall.

Billy Södervall, the innovator behind the Bactiguard technology, refined the technique and in the 1970's, he started applying the noble metals to medical devices. Twenty years later, the technology was approved for use in patients, and the rest is a history of success.

Billy Södervall is very much an active part of the company, and he still works at the head-quarters, appropriately located at Alfred Nobels Allé in Stockholm, Sweden.

References

1. World Health Organization. (2016). The critical role of infection prevention and control. Retrieved 2017-11-13 from http://www.who.int/infection-prevention/publications/ipc-role **2.** World Health Organization. (2016). The critical role of infection prevention and control. WHO/HIS/SDS/2016.10 **3.** Burke JP. Infection control – a problem for patient safety. New England Journal of Medicine, 2003, 348:651–656. **4.** Allegranzi B *et al*. Burden of endemic health care-associated infection in developing countries: systematic review and meta-analysis. Lancet, 2011, 377:228–241. **5.** Klevens RM *et al*. Estimating healthcare associated infections and deaths in U.S. hospitals, 2002 Public Health Rep. 2007 Mar–Apr;122(2):160-6. **6.** Data on file. **7.** Data on file. **8.** Kai-Larsen, Y., Grass, S., Mody, B. et al. 2021 Foley catheter with noble metal alloy coating for preventing catheter-associated urinary tract infections: a large, multicenter clinical trial. Antimicrob Resist Infect Control 10, 40 (2021). **9.** Lederer JW et al, J WOCN 2014; 41(5):1–8. **10.** Newton T *et al*, Infection Control and Hospital Epidemiology; 2002; 23(1): 217–8. **11.** Hidalgo Fabrellas *et al*. Enferm Intensiva. 2015; 26(2):54–62. **12.** Chung PH *et al*. Hong Kong Medical Journal. 2017;23:Epub. **13.** Estores *et al*. Journal of Rehabilitation Res & Dev, 2008. **14.** Magnusson *et al*. Unpublished data. **15.** Karchmer TB *et al*, Arch Intern Med. 2000 Nov 27;160(21):3294-8 **16.** Saint S. *et al*. Arch Intern Med. 2000; 160:2670–2675. **17.** Data on file.

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RMH-14169-v.3.0