Bactiguard®

Bactiguard® Infection Protection

BIP Central Venous Catheter

Designed to:
Reduce catheter-related infections
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 reduce HAIs by at least 30%.[2]

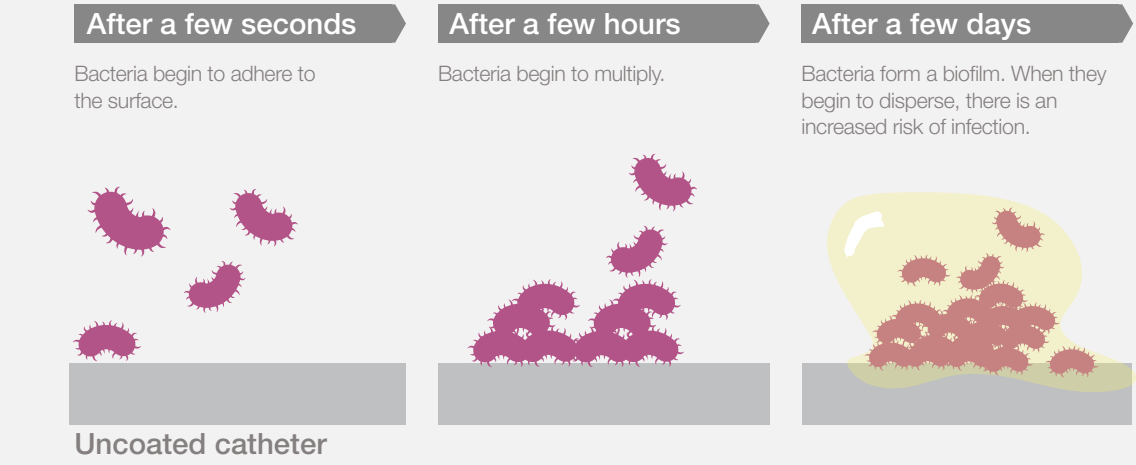
Every day, HAIs result in prolonged hospital stays, long-term disability, increased anti-microbial resistance, additional costs for health systems, unnecessary suffering for patients and their families, and unnecessary deaths.[3,4]

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

Catheter related bloodstream infection (CRBSI) is a common complication and one of the most frequent HAIs.[5] Also, thrombotic complications are common during treatment with central venous catheters (CVC).

Catheter related bloodstream infection

The surfaces of catheters attract microbes, which colonize it and may develop biofilm. CRBSI occur when there is an immune response to microbes in the blood. Microbes from either the host or from external sources such as personnel, other patients or medical devices can form biofilm. They are much more resistant to antibiotics and patient immune systems, than microbes not forming biofilm.



Thrombosis

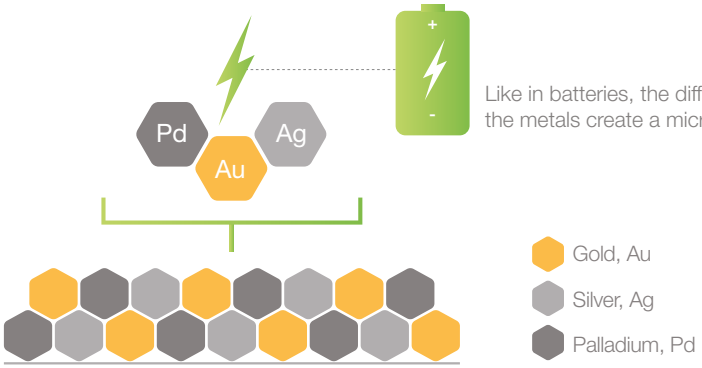
Thrombotic complications are common and lead to obstruction of blood flow and catheter dysfunction. The catheter may need to be exchanged and the risk of infection increases, leading to increased costs of care. Catheter-related thrombosis leads to increased morbidity and may increase mortality due to embolic events.[6]

The solution

The technology

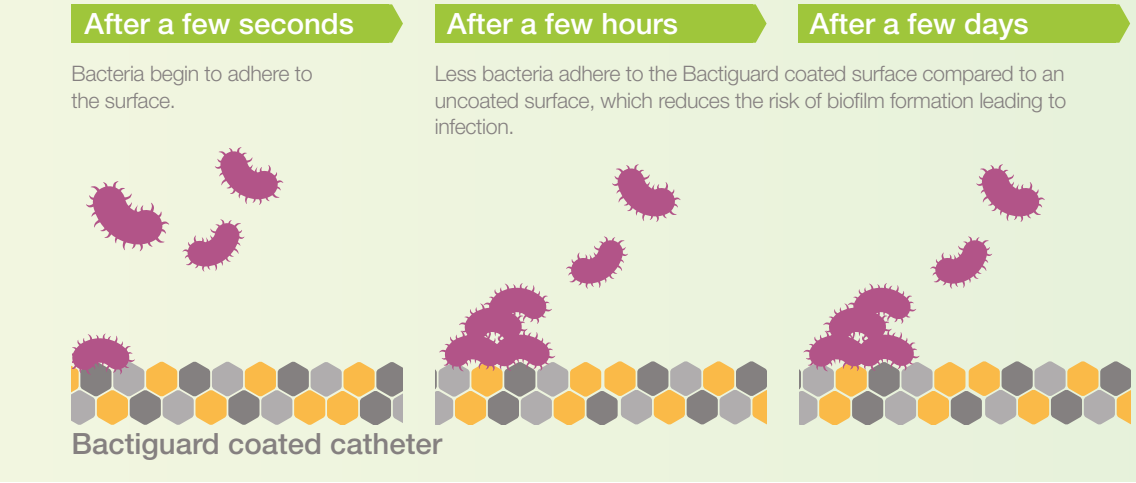
Galvanic effect

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.

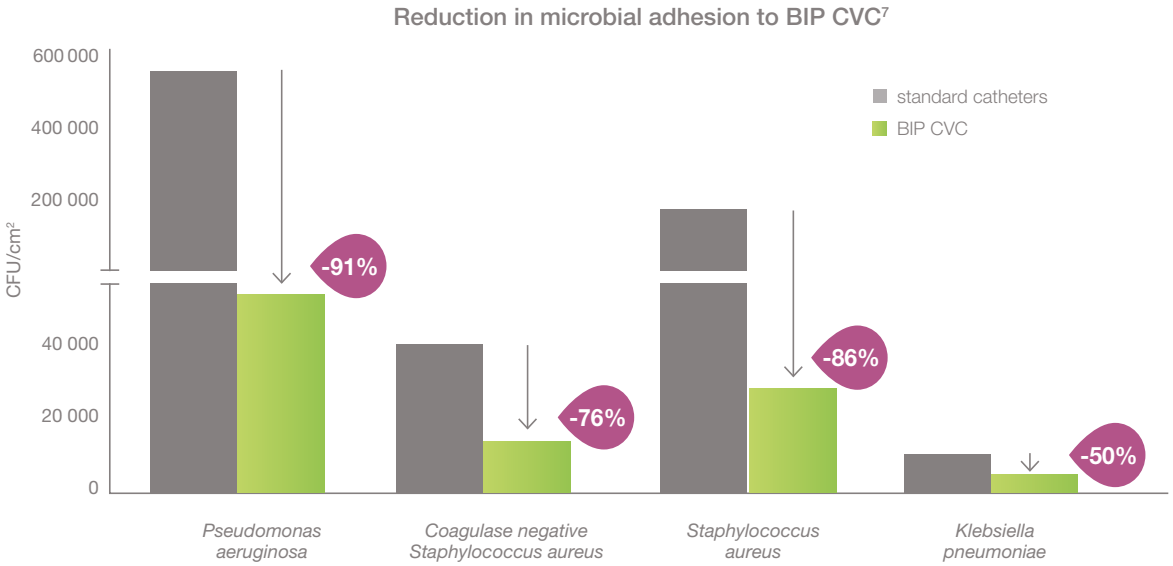


The solution

The efficacy

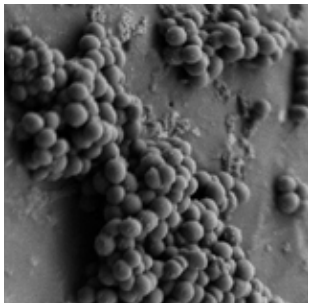
In vitro test

The reduction of microbial adhesion to and colonization on the device surfaces has been verified for clinically relevant microbial strains, using an *in vitro* test. The test evaluates the adhesion of gram-positive and gram-negative bacteria to the device surfaces. These strains account for a large proportion of CRBSI infections.[7]

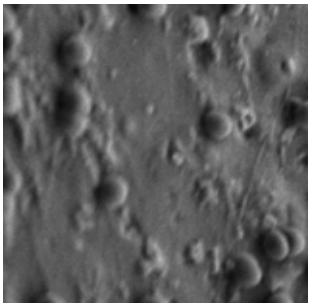


Scanning electron microscopy

The reduction of microbial colonization has been observed by scanning electron microscopy (SEM). The pictures show the microbe colonization of *Staphylococcus aureus* 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 safety

The technology is safe to use, the amount of noble metals at the surface is very low and below all safety limits for each metal. There is no release of any toxic or pharmacological quantities, 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.[8]

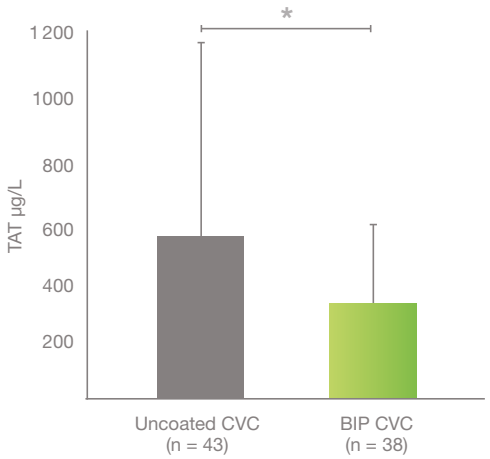
The unique Bactiguard solution is safe to use while still efficient against infections.[8]

Excellent blood compatibility shown in *ex vivo* study

The blood compatibility is excellent, with no increased risk of thrombosis compared to uncoated catheters. Thrombin-Anti-Thrombin (TAT) complex depends on activation of coagulation and was used as a marker for thrombotic risk in the study below.[9]

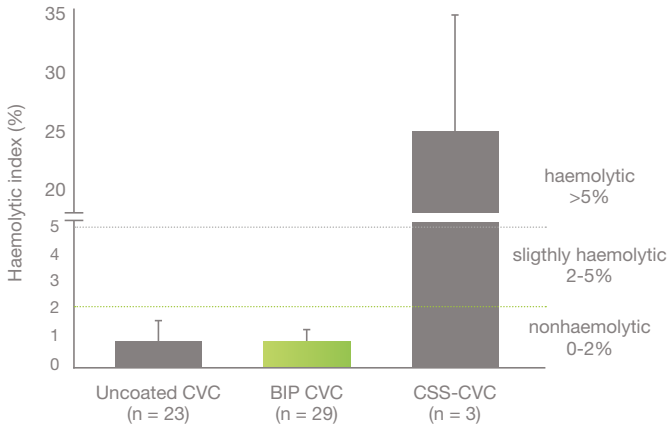
Also, a reduced risk of haemolysis compared to chlorhexidine coated CVCs was observed in this ex vivo study.[9] According to ASTM F756-00 standard, haemolytic index 0–2% is classified as "nonhaemolytic" 2–5% as "slightly haemolytic" and >5% as "haemolytic".

TAT levels relatively to blood control[9]



*p=0.02

Haemolytic grades[9]



p < 0.001 (CSS-CVC vs uncoated CVC and BIP CVC)

In the study the Chlorhexidine-Silver-Sulfadiazine coated CVC (CSS-CVC) was found to be haemolytic.[9]

The solution

Fewer cases of thrombosis

In the clinical study on 233 haematological oncology patients, published by Harter *et al*[10], it was concluded that the Bactiguard coated CVC group had no increased risk of thrombosis versus the uncoated standard CVC group: 1 case of thrombus in 120 patients versus 3 cases of thrombus in 113 patients (see Table below). These findings show similar trend as earlier mentioned *ex vivo* blood experiments.[10]

Table: Frequency of catheter-related thrombosis examined by ultrasound

Factor	standard CVC (n = 113)	Bactiguard coated CVC (n = 120)
Visualization of thrombus	3	1
Absence of spontaneous flow	2	0
Total no. of catheter-related thrombosis	**3**	**1**

Adapted from Table 2, Harter *et al* 2002.[10]

Less adverse events

In a controlled, randomized pilot study performed at Karolinska University Hospital in Sweden, 34 patients undergoing large abdominal surgery were included. 22 patients received a BIP CVC, and 12 patients received a uncoated standard CVC. The primary endpoint was safety, assessed by evaluation of adverse events. There were statistically less adverse events in the Bactiguard group compared to the standard group: 4 vs none (Table below).
The study has confirmed the safety and shown the coating durability in the bloodstream.[11]

Table: Evaluation of adverse events

Adverse events	standard CVC (n = 12)	BIP CVC (n = 22)	P-value
Sepsis (CLABSI)	1	0	0.35
Thrombo-embolism	2	0	0.12
All adverse events	**4**	**0**	**0.01**

Adapted from Björling *et al* 2017.[11]

The evidence

Effective against catheter-related infections

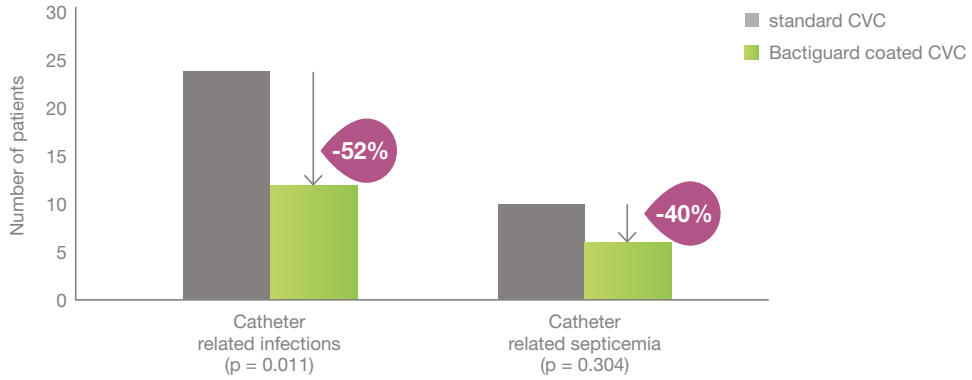
Randomized Clinical Trial, Germany

In the clinical study including 233 haematological oncology patients at the University of Heidelberg, Germany, published by Goldschmidt *et al*,[12] Bactiguard coated CVC has been shown effective against catheter-related infections.

The coating significantly reduced the incidence of infections by 52%. Catheter-related infections developed in 21% of patients with the uncoated standard catheter, but in only 10% of the patients with the Bactiguard coated catheter.

Catheter-related septicaemia was also reduced by 40% (p=0.304).

Frequency of catheter-related infections and septicemia[12]



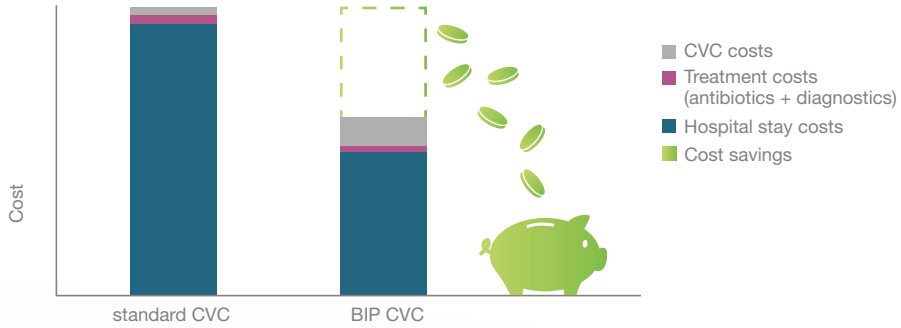
The cost savings

Health economy benefits

It is important to prevent CRBSI, since it leads to prolonged hospital stays, increased mortality, costs and use of antibiotics. According to the WHO, one case of CRBSI can cost up to 56 000 USD to treat.[13,14] The US Centre for Disease Control and Prevention estimates that between 12 and 25% of patients who acquire CRBSI die.[15]

The Bactiguard technology is associated with lower length of hospital stay costs, lower treatment costs and improved patient quality of life.[16] For local health economic calculations, please contact your Bactiguard representative.

Difference in payer costs standard CVC vs. BIP CVC[16]



Bactiguard health economic model based on Saint *et al* 2000.[16]

The product

BIP Central Venous Catheter

The BIP CVC is used for administration of drugs and intravenous solutions, sample blood and for blood pressure monitoring. It is made of polyurethane, coated with the Bactiguard coating and approved for use up to 30 days.

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

BIP Central Venous Catheter has the unique Bactiguard coating and is approved for use up to 30 days.

The order information

BIP CVC with straight or Y-valve needle

Article no.	Size (Fr/Ch)	Lumen Gauge (G)	Length (cm)	Introducer needle
1 Lumen				
EU-CVN-401-16-BIP	4	Gauge (G)	16	Straight
EU-CVN-401-20-BIP	4	18G	20	Straight
EU-CVN-501-16-BIP	5	16G	16	Straight
EU-CVN-501-20-BIP	5	16G	20	Straight
EU-CVN-701-16-BIP	7	14G	16	Straight
EU-CVN-701-20-BIP	7	14G	20	Straight
EU-CVN-501-16Y-BIP	5	16G	16	Y-valve
EU-CVN-501-20Y-BIP	5	16G	20	Y-valve
EU-CVN-701-16Y-BIP	7	14G	16	Y-valve
EU-CVN-701-20Y-BIP	7	14G	20	Y-valve
2 Lumen				
EU-CVN-402-06-BIP	4	22/22G	6	Straight
EU-CVN-402-10-BIP	4	22/22G	10	Straight
EU-CVN-402-16-BIP	4	22/22G	16	Straight
EU-CVN-502-10-BIP	5	18/18G	10	Straight
EU-CVN-502-16-BIP	5	18/18G	16	Straight
EU-CVN-502-20-BIP	5	18/18G	20	Straight
EU-CVN-702-16-BIP	7	16/16G	16	Straight
EU-CVN-702-20-BIP	7	16/16G	20	Straight
EU-CVN-702-30-BIP	7	16/16G	30	Straight
EU-CVN-802-16-BIP	8.5	13/13G	16	Straight
EU-CVN-802-20-BIP	8.5	13/13G	20	Straight
EU-CVN-802-30-BIP	8.5	13/13G	30	Straight
EU-CVN-502-10Y-BIP	5	18/18G	10	Y-valve
EU-CVN-502-16Y-BIP	5	18/18G	16	Y-valve
EU-CVN-502-20Y-BIP	5	18/18G	20	Y-valve
EU-CVN-702-16Y-BIP	7	16/16G	16	Y-valve
EU-CVN-702-20Y-BIP	7	16/16G	20	Y-valve
EU-CVN-702-30Y-BIP	7	16/16G	30	Y-valve
EU-CVN-802-16Y-BIP	8.5	13/13G	16	Y-valve
EU-CVN-802-20Y-BIP	8.5	13/13G	20	Y-valve
EU-CVN-802-30Y-BIP	8.5	13/13G	30	Y-valve

BIP CVC with straight or Y-valve needle

Article no.	Size (Fr/Ch)	Lumen Gauge (G)	Length (cm)	Introducer needle
3 Lumen				
EU-CVN-503-08-BIP	5.5	20/22/22G	8	Straight
EU-CVN-503-13-BIP	5.5	20/22/22G	13	Straight
EU-CVN-503-30-BIP	5.5	20/22/22G	30	Straight
EU-CVN-703-10-BIP	7	16/18/18G	10	Straight
EU-CVN-703-16-BIP	7	16/18/18G	16	Straight
EU-CVN-703-20-BIP	7	16/18/18G	20	Straight
EU-CVN-703-30-BIP	7	16/18/18G	30	Straight
EU-CVN-713-10-BIP	7	14/18/18G	10	Straight
EU-CVN-713-16-BIP	7	14/18/18G	16	Straight
EU-CVN-713-20-BIP	7	14/18/18G	20	Straight
EU-CVN-713-30-BIP	7	14/18/18G	30	Straight
EU-CVN-803-16-BIP	8.5	14/18/18G	16	Straight
EU-CVN-803-20-BIP	8.5	14/18/18G	20	Straight
EU-CVN-803-30-BIP	8.5	14/18/18G	30	Straight
EU-CVN-703-10Y-BIP	7	16/18/18G	10	Y-valve
EU-CVN-703-16Y-BIP	7	16/18/18G	16	Y-valve
EU-CVN-703-20Y-BIP	7	16/18/18G	20	Y-valve
EU-CVN-703-30Y-BIP	7	16/18/18G	30	Y-valve
EU-CVN-713-10Y-BIP	7	14/18/18G	10	Y-valve
EU-CVN-713-16Y-BIP	7	14/18/18G	16	Y-valve
EU-CVN-713-20Y-BIP	7	14/18/18G	20	Y-valve
EU-CVN-713-30Y-BIP	7	14/18/18G	30	Y-valve
EU-CVN-803-16Y-BIP	8.5	14/18/18G	16	Y-valve
EU-CVN-803-20Y-BIP	8.5	14/18/18G	20	Y-valve
EU-CVN-803-30Y-BIP	8.5	14/18/18G	30	Y-valve
4 Lumen				
EU-CVN-804-16-BIP	8.5	14/16/18/18G	16	Straight
EU-CVN-804-20-BIP	8.5	14/16/18/18G	20	Straight
EU-CVN-804-30-BIP	8.5	14/16/18/18G	30	Straight
EU-CVN-804-16Y-BIP	8.5	14/16/18/18G	16	Y-valve
EU-CVN-804-20Y-BIP	8.5	14/16/18/18G	20	Y-valve
EU-CVN-804-30Y-BIP	8.5	14/16/18/18G	30	Y-valve

Sterilization and storage; see packaging.
Department pack = 10 pcs. Transport pack = 10×8 pcs.
Size department pack W×H×D: 260×165×225 mm

BIP CVC with Raulerson syringe

Article no.	Size (Fr/Ch)	Lumen Gauge (G)	Length (cm)	Introducer needle
1 Lumen				
EU-CVN-501-16R-BIP	5	16G	16	Raulerson syringe
EU-CVN-501-20R-BIP	5	16G	20	Raulerson syringe
EU-CVN-701-16R-BIP	7	14G	16	Raulerson syringe
EU-CVN-701-20R-BIP	7	14G	20	Raulerson syringe
2 Lumen				
EU-CVN-702-16R-BIP	7	16/16G	16	Raulerson syringe
EU-CVN-702-20R-BIP	7	16/16G	20	Raulerson syringe
EU-CVN-702-30R-BIP	7	16/16G	30	Raulerson syringe
EU-CVN-802-16R-BIP	8.5	13/13G	16	Raulerson syringe
EU-CVN-802-20R-BIP	8.5	13/13G	20	Raulerson syringe
EU-CVN-802-30R-BIP	8.5	13/13G	30	Raulerson syringe
3 Lumen				
EU-CVN-703-10R-BIP	7	16/18/18G	10	Raulerson syringe
EU-CVN-703-16R-BIP	7	16/18/18G	16	Raulerson syringe
EU-CVN-703-20R-BIP	7	16/18/18G	20	Raulerson syringe
EU-CVN-703-30R-BIP	7	16/18/18G	30	Raulerson syringe
EU-CVN-713-10R-BIP	7	14/18/18G	10	Raulerson syringe
EU-CVN-713-16R-BIP	7	14/18/18G	16	Raulerson syringe
EU-CVN-713-20R-BIP	7	14/18/18G	20	Raulerson syringe
EU-CVN-713-30R-BIP	7	14/18/18G	30	Raulerson syringe
EU-CVN-803-16R-BIP	8.5	14/18/18G	16	Raulerson syringe
EU-CVN-803-20R-BIP	8.5	14/18/18G	20	Raulerson syringe
EU-CVN-803-30R-BIP	8.5	14/18/18G	30	Raulerson syringe
4 Lumen				
EU-CVN-804-16R-BIP	8.5	14/16/18/18G	16	Raulerson syringe
EU-CVN-804-20R-BIP	8.5	14/16/18/18G	20	Raulerson syringe
EU-CVN-804-30R-BIP	8.5	14/16/18/18G	30	Raulerson syringe

Straight needle

Y-valve needle

Raulerson syringe

Contents BIP CVC kit:

- Central venous catheter
- J-guidewire (Nitinol), sized to catheter
- Introducer needle (Y-Valve* or Straight)
- Dilator, size appropriate to catheter
- Scalpel with protective cover
- Luer slip syringe or Raulerson syringe 5 ml
- Guidewire advancer, for one hand use
- Suture wing and clamp fastener
- Clamp for extension tube
- Cannula holder

**Y-Valve needle allows for easy guidewire insertion while minimizing air embolism and backflow of blood*

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 headquarters, 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.** Wall *et al.* Catheter-related thrombosis: A practical approach, Journal of the Intensive Care Society 2016, Vol. 17(2) 160–167. **7.** Data on file. **8.** Data on file. **9**. Vafa Homann *et al*. 2015, J. Biomed. Mater. Res. Part B Appl. Biomater. **10.** Harter *et al,* Cancer. 94 (1):245-251 (2002). **11.** Björling G *et al.*, J Biomed Mater Res B Appl Biomater. 2017 Nov 6; (Epub ahead of print). **12.** Goldschmidt H. *et al*., Zbl. Bakt. 1995; 233: 215-223. **13.** Dimick JB *et al*. Increased resource use associated with catheter-related bloodstream infection in the surgical intensive care unit. Arch Surg 2001;136:229--34. **14.** Rello J, Ochagavia A, Sabanes E, *et al*. Evaluation of outcome of intravenous catheter-related infections in critically ill patients. Am J Respir Crit Care Med 2000;162:1027--30. **15.** Kluger DM, Maki DG. The relative risk of intravascular device related bloodstream infections in adults [Abstract]. In: Abstracts of the 39th Interscience Conference on Antimicrobial Agents and Chemotherapy. San Francisco, CA: American Society for Microbiology, 1999:514. **16.** Saint S. *et al.* Arch Intern Med. 2000; 160:2670-2675.

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