Bactiguard®

Bactiguard® Infection Protection

BIP Endotracheal Tube

– For prevention of healthcare associated infections

Ventilator associated pneumonia

Infections of the respiratory tract are serious and common healthcare associated infections (HAI) that affect patients using certain medical devices, such as endotracheal tubes (ET tube or ETT)[1].

Despite a limited and relatively short but necessary life-sustaining treatment with an ETT, many patients develop an infection in the respiratory tract – Ventilator Associated Pneumonia (VAP).

Microbial adhesion on the tube itself, resulting in biofilm formation is one major cause of infection. In long-term ventilated patients subglottic secretions can accumulate above the cuff of the ETT and hence, represent an ideal growth medium for bacteria. By microaspiration along the cuff, these contaminated secretions might pass into the lower respiratory tract and become a potential cause of lower airway infection, including VAP.

VAP is the second most common nosocomial infection in the ICU, and estimated to occur in 9% to 25% of patients.[2-4] It is associated with increasing the number of days the patients need to stay in the ICU by up to 22 days and hospital stays by up to 25 days.[5] Late-onset VAP is often associated with high-risk pathogens such as MRSA and is associated with a greater negative impact on patient outcomes and hospital cost.[6] Mortality that is directly attributable to VAP is estimated to be as high as 30-50 %.[7-8]

Antimicrobial resistance

In addition, many of these infections are treated with antibiotics, which increase the risk of emergence and spread of multi-resistant microbes. WHO estimates that antimicrobial resistance is so serious that it threatens the achievements of modern medicine[9].

IN PATIENTS VENTILATED >5 DAYS		
	WITHOUT VAP[10]	LATE-ONSET VAP[10]
Hospital stay (days)	29.1[10]	42.7[10]
Duration of mechanical ventilation (days)	12.6[10]	25[10]

The solution – A dual approach with BIP Endotracheal Tube Evac

The BIP Endotracheal tube Evac has been specifically designed to reduce ventilator associated pneumonia (VAP). It combines the known VAP reducing feature of subglottic secretion drainage with the clinically proven ability of the Bactiguard noble metal alloy coating to reduce microbial adhesion and prevention of biofilm formation.

Subglottic secretion drainage (SSD)

Several randomized, controlled studies have examined the efficacy of subglottic secretion drainage and it has been found to reduce VAP with approximately 50%.[11]

Clinical investigation by Bouza et al found a significant improvement in patient outcomes with the use of an endotracheal tube providing subglottic secretion drainage, including:

- Reduced antibiotic use in the overall patient population by 30%.
- Reduced ICU length of stay by 9.5 days.
- Shortened duration of mechanical ventilation by 4 days.[12]

Bactiguard coating preventing infections through less microbial adhesion

BIP Endotracheal Tube, BIP ETT (without subglottic suction) has been proven to reduce microbial adhesion by 76-98% in vitro.1[13]

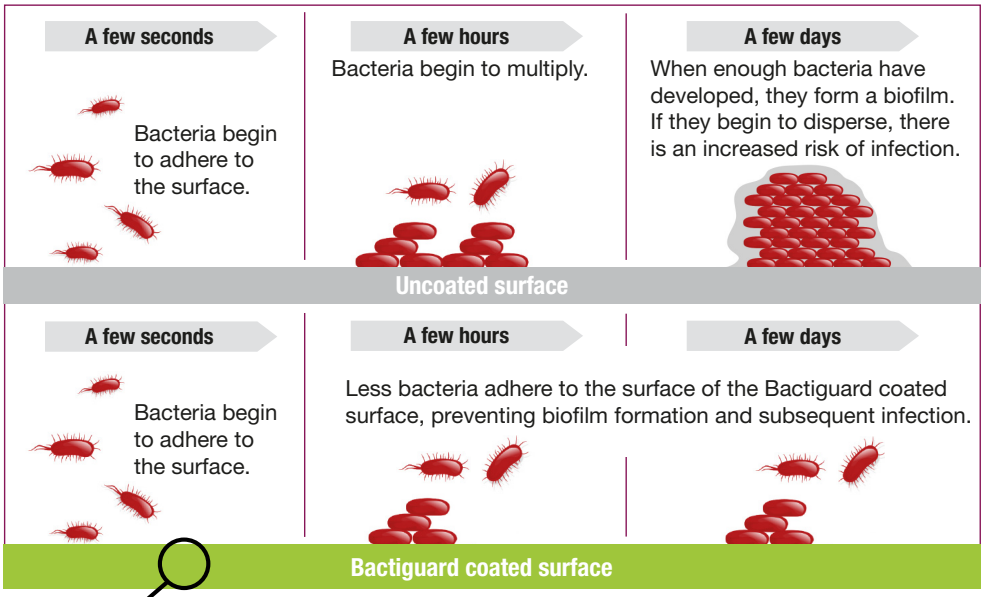
In a clinical study on 100 patients comparing a standard uncoated endotracheal tube with BIP ETT (without subglottic suction) it was concluded that the coating reduced the incidence of VAP by 67%. (OR 3.42; p=0.14)1[14]

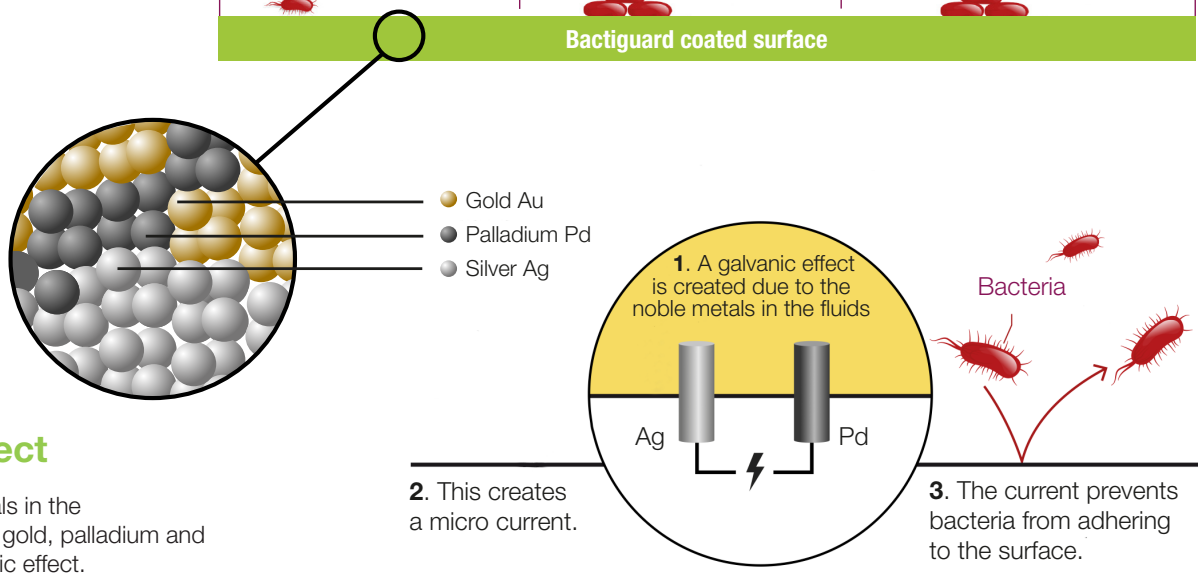
The Bactiguard Infection Protection (BIP) technology

Preventing VAP

Medical device surfaces attract bacteria, which develop into a biofilm. Ventilator Associated Pneumonia occurs when there is an immune response to bacteria in the respiratory tract.

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 infection.



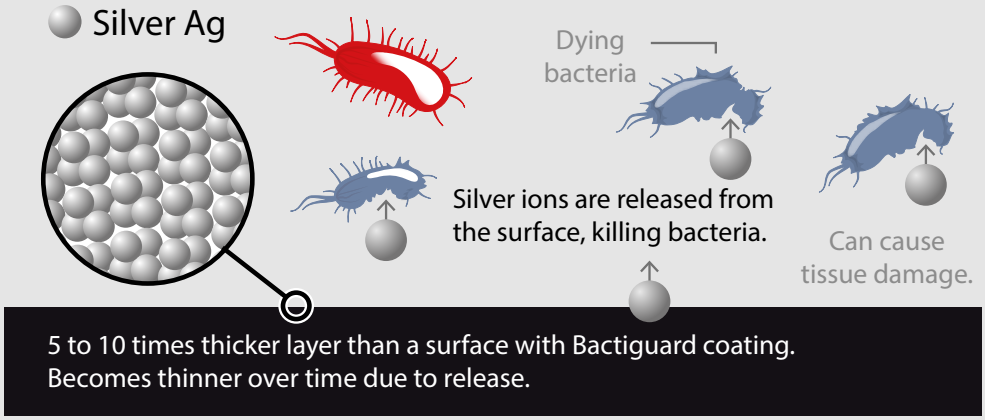


Galvanic effect

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

Bactiguard compared to traditional releasing technologies[5]

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

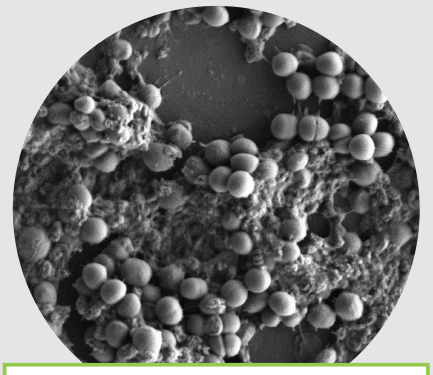


In Vitro/Ex Vivo Efficacy

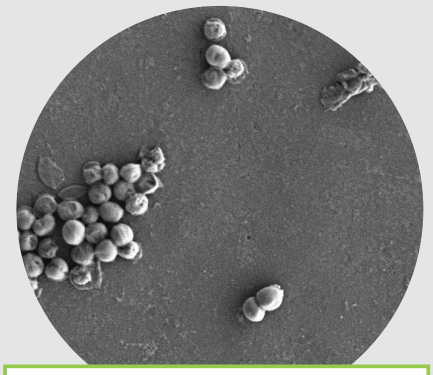
The reduction of microbial adhesion and colonization to device surfaces has been verified for clinically relevant microbial strains using an in vitro efficacy test. The in vitro test evaluates the adhesion of microorganisms to device surfaces. Example of results (Staphylococcus epidermidis) are presented in the figures below[15].

Less bacteria adhere to the Bactiguard coated surface and for those who adhere, further growth is expected to be suppressed, preventing biofilm formation and subsequent infection.

Staphylococcus epidermidis

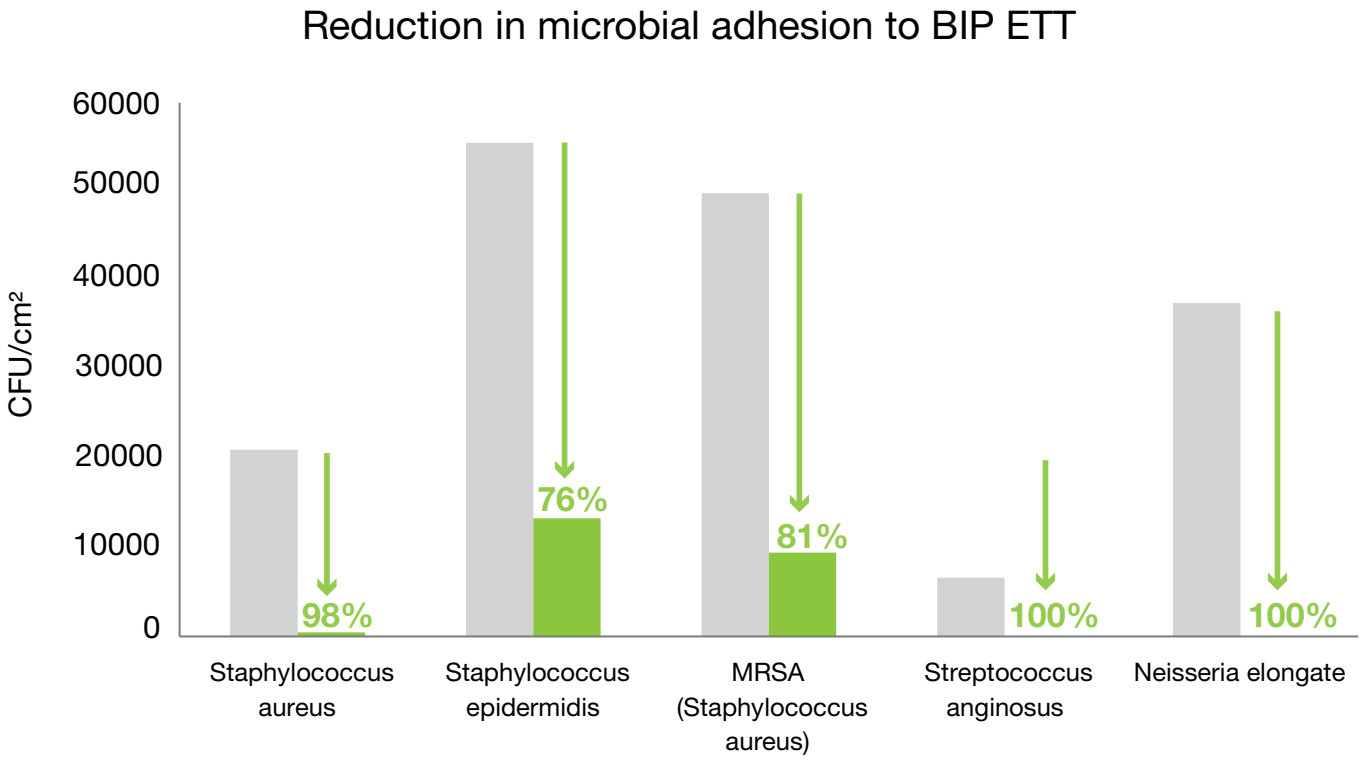


Microbe build-up without Bactiguard coating



Microbe build-up with Bactiguard coating

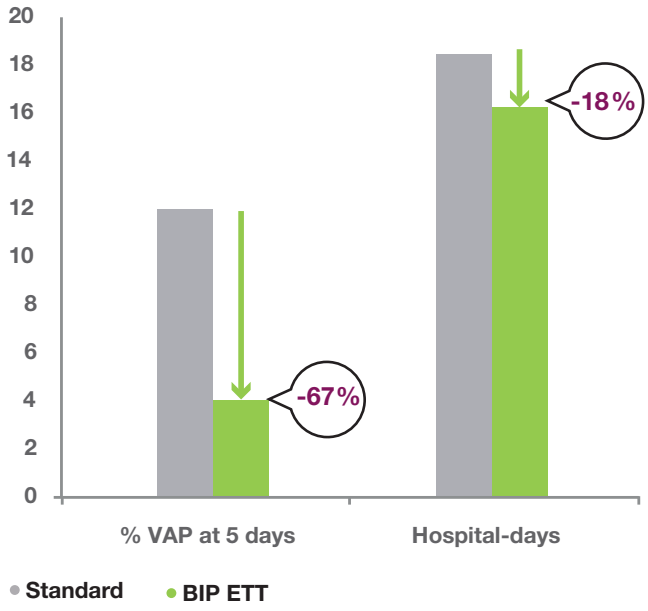
> **Less bacteria adhere to the Bactiguard coated surface**

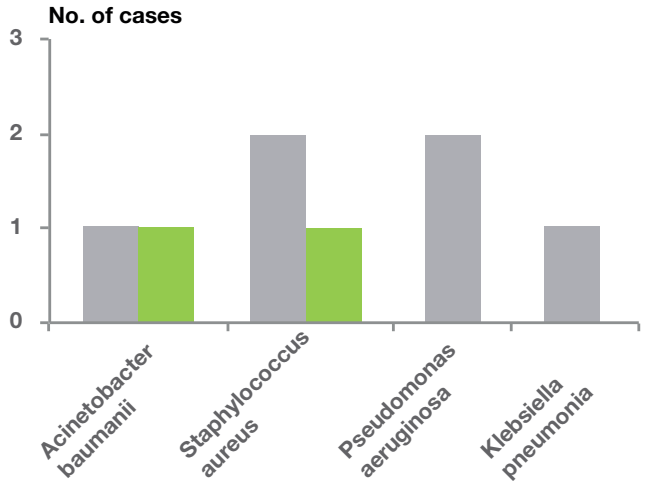


Average raw data from several batches of BIP ETT

Clinically proven effective against VAP

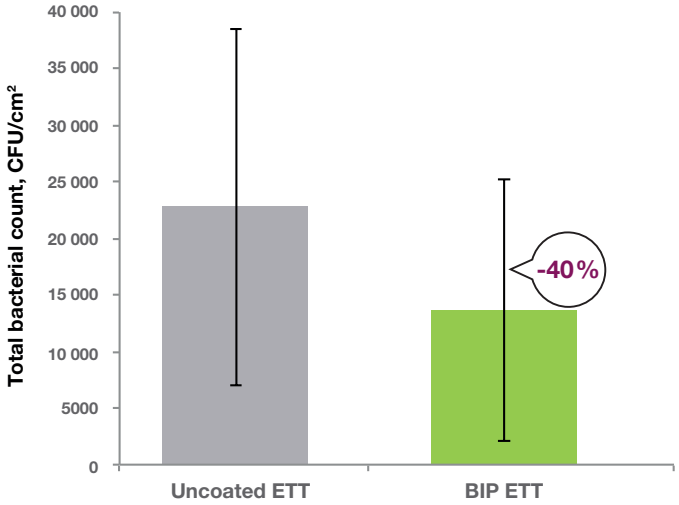
In a clinical study on 100 patients comparing a standard uncoated endotracheal tube with the BIP ETT, it was concluded that the coating reduced the incidence of ventilator associated pneumonia by 67% (OR 3.42; p=0.14)[16]. This prospective, randomized and independent investigation included patients suffering from drug poisoning. In addition to the infection rate, length of hospital stay as well as antibiotic use was also monitored. The BIP ETT group used significantly less antibiotics (OR 0.3, p=0.05) and stayed in hospital 2 days less in average (18 and 16 days, respectively).





Additionally in an oral in vivo study[17] on a total of 40 volunteers, an average reduction of 40% in microbial adhesion was seen after carrying a piece of uncoated ETT and a piece of BIP ETT in the mouth (p<0,001 in Wilcoxon Rank Sum test).

Reduction of microbial adhesion *in vivo* to BIP ETT after 2 hours in mouth



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 pharmacologic[18].

Biocompatible

The Bactiguard coated BIP ETTs have a strong biocompatibility profile. It has been shown non-toxic to cells, non-irritant to mucosa and not-sensitizing to allergic reactions[18]. It does not damage human mucosa and does not cause adverse events in patients[18-19].

Material

BIP ETT is made of PVC and coated with the Bactiguard coating on both the inside and outside of the tube. The beveled tip, Murphy Eye and high volume-low pressure cuff are designed to minimize the risk of damages to the patients trachea and ensure safe usage.

Environment

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

References

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17. Data on file
18. Data on file
19. Björling et al. BMC Anesthesiology (2015) 15:174

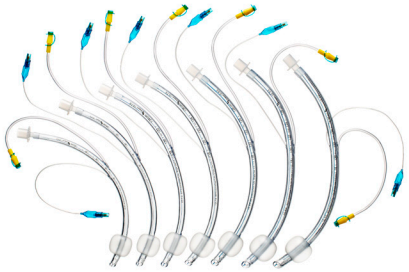
Order information

Bactiguard® benefits

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

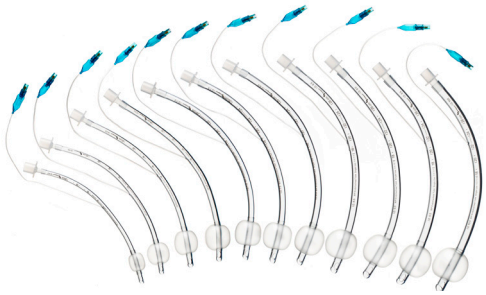
BIP Endotracheal Tube, Evac
With subglottic secretion drainage (SSD)

Article number	Article	Inner Ø (mm)	Outer Ø (mm)	Cuff Ø (mm)	Length (mm)
31VC06010	Oral with HVLP* cuff and SSD	6,0	9,0	25	280
31VC06510	Oral with HVLP* cuff and SSD	6,5	9,8	25	290
31VC07010	Oral with HVLP* cuff and SSD	7,0	10,4	26	300
31VC07510	Oral with HVLP* cuff and SSD	7,5	11,2	26	310
31VC08010	Oral with HVLP* cuff and SSD	8,0	11,8	28	320
31VC08510	Oral with HVLP* cuff and SSD	8,5	12,6	28	320
31VC09010	Oral with HVLP* cuff and SSD	9,0	13,1	28	320



BIP Endotracheal Tube

311005010	Oral/Nasal with HVLP* cuff	5,0	6,9	17	240
311005510	Oral/Nasal with HVLP* cuff	5,5	7,5	17	270
311006010	Oral/Nasal with HVLP* cuff	6,0	8,2	20	280
311006510	Oral/Nasal with HVLP* cuff	6,5	8,8	20	290
311007010	Oral/Nasal with HVLP* cuff	7,0	9,6	25	300
311007510	Oral/Nasal with HVLP* cuff	7,5	10,2	25	310
311008010	Oral/Nasal with HVLP* cuff	8,0	10,9	26	320
311008510	Oral/Nasal with HVLP* cuff	8,5	11,5	26	320
311009010	Oral/Nasal with HVLP* cuff	9,0	12,1	28	320
311009510	Oral/Nasal with HVLP* cuff	9,5	12,7	28	320
311010010	Oral/Nasal with HVLP* cuff	10,0	13,6	28	320



*HVLP - High Volume Low Pressure

Sterilization and storage; see packaging.
Department pack = 10 pcs. Transport pack = 10×10 pcs.
Size department pack W×H×D: 380×155×100 mm

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

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