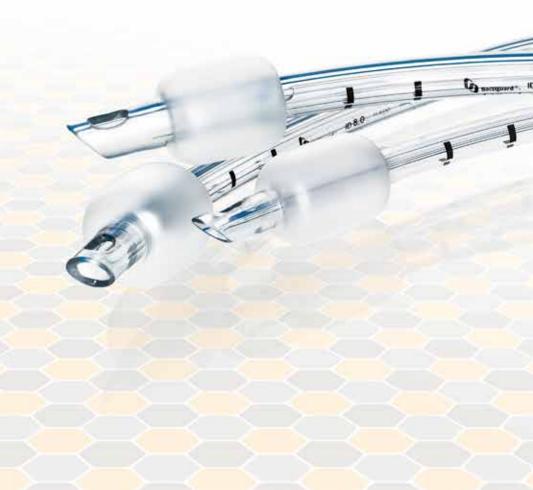
## Bactiguard®

Bactiguard<sup>®</sup> Infection Protection

### BIP Endotracheal Tube Reduce VAP

Reduce VAP 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.<sup>1</sup> According to the World Health Organization (WHO), effective infection prevention and control reduce HAIs by at least 30%.<sup>2</sup>

Every day, HAIs result in prolonged hospital stays, long-term disability, increased antimicrobial resistance, additional costs for health systems, unnecessary suffering for patients and their families, and unnecessary deaths.<sup>3,4</sup>

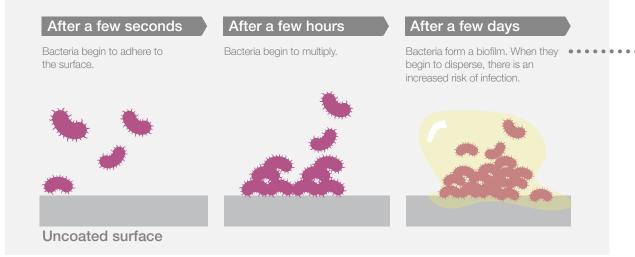
### WHO: "Infection prevention and control actions can save millions of lives, every year"1

Ventilator Associated Pneumonia is a common and very serious HAI of the respiratory tract that can affect intubated patients. It is the second most common nosocomial infection in the ICU and is estimated to occur in up to 25% of the patients.<sup>5-7</sup> Mortality directly attributable to VAP is estimated to be as high as 30-50%.<sup>8,9</sup>

### Ventilator Associated Pneumonia (VAP)

Even after a relatively short treatment with an ETT, many patients develop an infection in the upper or lower respiratory tract; Ventilator Associated Tracheobronchitis (VAT) or Ventilator Associated Pneumonia (VAP).

Microbial adhesion on the tube resulting in biofilm formation is a strongly contributing factor to infections. Biofilm can be formed from microbes coming either from inside the body or from external sources, such as personnel, other patients or medical devices.



#### Main causes of VAP

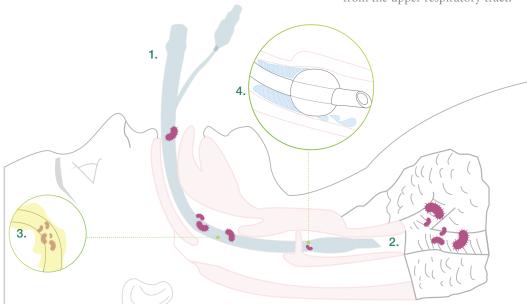
Intubation with an endotracheal tube is by far the most important risk factor to develop a VAP as it increases the risk that bacteria access the lower respiratory tract in many different ways.

#### 1. Intubation

During the intubation itself, the risk for microaspiration is high.

### 2. Impaired clearance of secretions

Intubation is a violation of natural defence mechanisms such as the cough reflex, which otherwise protects the lungs from secretions from the upper respiratory tract.



#### 3. Development of a biofilm

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Microbial adhesion on both the inside and the outside of the tube resulting in biofilm formation.

### 4. Subglottic secretions

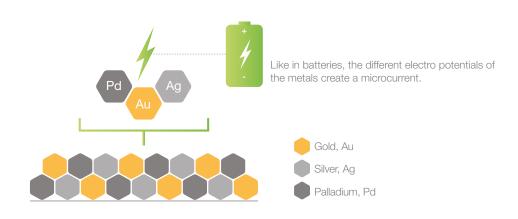
Secretions that accumulate above the cuff represent an ideal growth medium for microbes. The contaminated secretions might trickle down the sides of the cuff into the lower respiratory tract.<sup>10</sup>

# The solution

### The technology

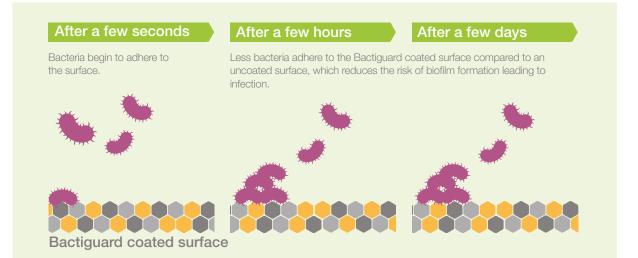
### Galvanic effect

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

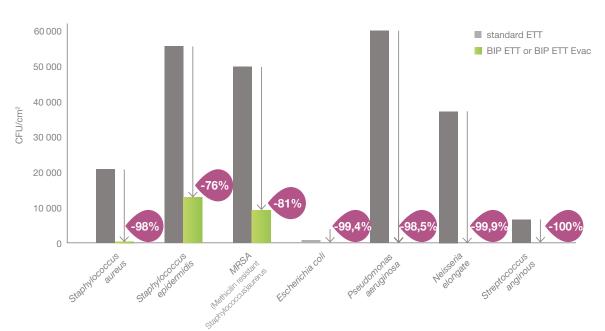
The galvanic effect creates a micro current that reduces microbial adhesion to the catheter material, which decreases the risk for biofilm formation leading to infection.



### The efficacy

### In vitro test

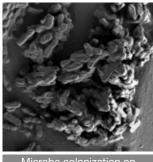
The reduction of microbial adhesion to and colonization on the device surfaces has been verified for different microbial strains, using an *in vitro* test. The test evaluates the adhesion of gram-positive and gram-negative bacteria to the device surfaces. These strains encounter for a large proportion of VAP infections.<sup>11</sup>



Reduction in microbial adhesion to BIP ETT and BIP ETT Evac<sup>11</sup>

### Scanning electron microscopy

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



Microbe colonization on <u>un</u>coated surface



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# The solution

### 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.<sup>12</sup>

The beveled tip, Murphy Eye and high volume-low pressure cuff is designed to minimize the risk of damages to the patient's trachea and ensure safe usage.

### The unique Bactiguard solution is safe to use while still efficient against infections.<sup>12</sup>

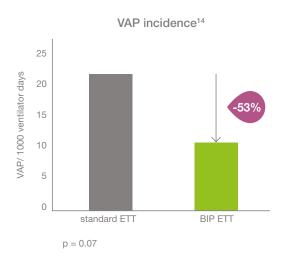
A safety study<sup>13</sup> has been performed at Karolinska University hospital, Sweden. It compared the tolerability and safety of a commonly used tube without coating, with BIP ETT. In total 30 surgery patients were assessed, of which 20 were in the study group and 10 in the control group. The study showed that the BIP ETT is well tolerated, safe to use and performs well.



## The evidence

#### Reduced risk of VAP in Belgian intensive care patients

A Belgian randomized, controlled, double-blinded study, Damas *et al*<sup>14</sup> including 323 patients, was performed to test the potential benefit of Bactiguards coating on endotracheal tubes (BIP ETT Evac) for VAP prevention. The patients were either intubated with a Bactiguard coated endotracheal tube or a conventional tube, both with subglottic secretion drainage. The study shows that the number of VAP cases were 22.4 per 1000 ventilator days in the control group compared with 10.5 in the Bactiguard group, which was just short of significance (p=0.07). The time to occurrence of VAP was significantly reduced in the Bactiguard group (p=0.02) as well as the antibiotics use (just above significance (p=0.06).



#### Reduced incidence of VAP

In a prospective, randomized and independent clinical study, Tincu *et al*<sup>15</sup> compared a standard uncoated endotracheal tube with the BIP ETT on 100 patients suffering from drug poisoning. The VAP rate was 24 cases / 1000 ventilation days (6 patients) in the standard group and 8 cases / 1000 ventilation days (2 patients) in BIP ETT group. The incidence of ventilator associated pneumonia was reduced by 67% (p=0.14).



*Staphylococcus aureus* and *Pseudomonas aeruginosa* were the most frequent causes of infections followed by *Acinetobacter baumanii* and *Klebsiella pneumonia*.<sup>15</sup>

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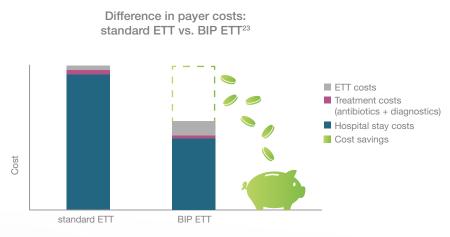
## The cost savings

### Health economy benefits

It is important to prevent VAP since it leads to increased morbidity, mortality and great human suffering for the patients.<sup>16-19</sup> It is also associated with a prolonged hospital stay and higher costs. On average a patient who has developed VAP stays 6.1 additional days in the ICU and 11.5 additional days in the hospital compared to a patient without VAP.<sup>20</sup>

All together, the attributable cost for a VAP infection is estimated to \$ 10 000 - 25 000 per case.<sup>21,22</sup>

There are great economical gains if you can reduce the risk of VAP. To evaluate your potential local savings when using BIP ETT instead of a standard product, please contact your Bactiguard representative.



Bactiguard health economic model based on Alpesh Amin, 2009.23



# The product

### **BIP Endotracheal tubes**

BIP ETT is made of phthalate-free 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 patient's trachea and ensure safe usage.

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

Bactiguard's endotracheal tube is available with or without an evacuation lumen; BIP ETT Evac and BIP ETT.

### Subglottic secretion drainage (SSD)

Meta-analysis of randomized, controlled studies have consequently shown reduction of VAP with approximately 50% when using tubes with subglottic secretion drainage.<sup>24</sup>

The BIP ETT Evac combines the known VAP reducing feature of subglottic secretion drainage with the ability of the Bactiguard noble metal alloy coating to reduce microbial adhesion and prevention of biofilm formation.<sup>15</sup>



# The order information

### BIP ETT Evac with subglottic secretion drainage (SSD)

| Article no. | Description                  | Inner Ø<br>(mm) | Outer Ø<br>(mm) | Cuff Ø<br>(mm) | Length<br>(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            |



| Article no. | Description                | Inner Ø<br>(mm) | Outer Ø<br>(mm) | Cuff Ø<br>(mm) | Length<br>(mm) |
|-------------|----------------------------|-----------------|-----------------|----------------|----------------|
| 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 x 10 pcs. Size department pack WxHxD: 380x155x100 mm



## 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.

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Phone +46 8 440 58 80 | Fax +46 8 440 58 90 | www.bactiguard.com | info@bactiguard.com