



**Press release**

Stockholm, 4 July 2014

## **Facts about the Bactiguard technology**

**Bactiguard's proven and patented technology is the company's most important asset. Following articles in the Swedish newspaper Svenska Dagbladet, Bactiguard wishes to clarify some important facts.**

An article was today published in Svenska Dagbladet newspaper featuring Bactiguard's technology. Since the article does not give a fair picture, the Company would like to present a summary of the facts and the available clinical evidence that Bactiguard's technology has a documented effect on healthcare associated infections.

Bactiguard has a patented technology in the form of a noble metal coating that prevents bacterial growth on medical devices, thus reducing the risk of healthcare associated infections. By reducing the risk of infection, Bactiguard's technology also reduces the need for antibiotics, which prevents the spread of multi-resistant bacteria.

This differentiates Bactiguard from its competitors on the market, which use e.g. antibiotic coating, which may contribute to antibiotic resistance, or coating which releases toxic substances to kill the bacteria. The great advantage of Bactiguard's technology is that the tissue-friendly surface reduces infections without negative side effects.

Some of the world's most respected institutions for the approval of medical devices, including the US Food and Drug Administration (FDA) and its Japanese counterpart, have approved Bactiguard's technology. These approvals include both patient safety and clinical efficacy. The US Centers for Disease Control and Prevention (CDC) also recommend the use of antimicrobial catheters of Bactiguard's type.

Since the mid-1980s, Bactiguard's coating has been tested in 37 clinical studies in eight countries and on more than 100,000 patients. The studies show that catheter-related infections and bacteriuria are reduced by using Bactiguard's coating. On average, the average reduction of catheter-related urinary tract infections (CAUTI) in these studies amounts to 39 percent, and up to 60 percent in several major studies. Based on these and other studies, the FDA and other authorities have verified that Bactiguard's technology is effective and reduces catheter-related infections, and have therefore approved it for use on patients.



One of the most recent studies<sup>1</sup> concludes that Bactiguard coated Foley catheters reduce the number of symptomatic catheter-related urinary tract infections by 47-58 percent, and antibiotic use by 60 percent.

"The Bactiguard technology (also referred to as the silver alloy coating) has been clinically proven to reduce catheter-related urinary tract infections and is by far the most well documented and effective technology that I know of," says Dr William R Jarvis<sup>2</sup>, one of the authors behind the most recently performed study and previously active at the CDC for many years.

So far, not a single case of adverse reaction has been reported from the 130 million catheters with Bactiguard coating used in patients since 1995.

"Approximately 130 million catheters with Bactiguard's coating have been used on patients since 1995. Nearly half of all indwelling urinary catheters sold in the US have Bactiguard's coating and have been on the market for nearly 20 years. This would not have been possible if the product did not have the intended effect. Especially in light of the fact that hospitals are paying five times more for Bactiguard's catheters compared with standard catheters," says CEO Johan Rugfelt.

There are two globally accepted criteria to be met in order for the infection to be considered as catheter-related: the patient should have had the catheter for more than two days; and the infection should occur during the time the patient uses the catheter or at the most two days after removal.

The study published in the Lancet, and which Svenska Dagbladet refers to, does not fulfil either of these globally accepted criteria. In the study, the product has only been in the patient for two days on average, which is too short a period. Moreover, the number of infections was measured up to six weeks after the removal of the catheter, which means

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<sup>1</sup> Lederer, Jarvis, Thomas, Ritter  
*Wound Ostomy Continence Nurses Society, 2014*  
Multicenter Cohort Study to Assess the Impact of a Silver-Alloy and Hydrogel-Coated Urinary Catheter on Symptomatic Catheter-Associated Urinary Tract Infections.

Link to the article in PubMed:  
<http://www.ncbi.nlm.nih.gov/pubmed/24922561>

<sup>2</sup>Dr William R Jarvis is one of the USA's foremost experts in infection control. He has his medical degree from the University of Texas, Houston, and has worked at the US Centers for Disease Control and Prevention for over 20 years. Dr Jarvis has been honoured by the Society of Healthcare Epidemiology of America (SHEA) through the founding of a special scholarship awarded each year, the "SHEA William Jarvis Award".

Link to William R Jarvis' biography:  
[William Jarvis, MD - Jason and Jarvis Associates](#)



that the infections could have been caused by other factors. Altogether, this means that this study is less relevant. The study has also been criticized by several renowned scientists, including Associate Professor Olof Akre.

"The overall clinical evidence from around 40 studies, and practical experience from the use of over 130 million catheters within healthcare, show that our technology effectively prevents infections. The market penetration we have achieved in two of the world's toughest markets, the US and Japan, is telling," says CEO Johan Rugfelt.

Learn more about the clinical evidence at: <http://www.bactiguard.se/about/the-solution-2/>

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**About Bactiguard**

Bactiguard is a Swedish medtech company with a business concept of preventing healthcare-related infections, reducing the use of antibiotics and saving lives by developing and supplying infection prevention solutions for the healthcare industry. The company's patented coating prevents healthcare-associated infections by reducing bacterial adhesion and growth on medical devices. Bactiguard®-coated urinary catheters are market leading in the US and Japan, and in recent years the company has developed its own product portfolio of coated catheters for the urinary and respiratory tract and the blood stream. Bactiguard is currently in a strong expansion phase, focused on new markets in the EU, Middle East, Asia and South America. The company reported sales of approximately SEK 130 million in 2013 and has 60 employees, headquarters in Stockholm and production facilities in Markaryd and Malaysia.