

Clinical study launched to compare efficacy of Bactiguard coated central venous catheters with non-coated

To gain additional clinical evidence of the efficacy of central venous catheters with Bactiguard's infection prevention coating technology (BIP CVC), Bactiguard today announces the launch of a clinical study to compare the BIP CVC with a non-coated standard catheter.

Healthcare-associated infections (HAI) affect patients being treated in hospitals or other healthcare facilities across the globe and lead to more frequent use of antibiotics. In turn, this escalates the risk of antimicrobial resistance which is an acute global health issue considered to be one of the most important sustainability challenges in modern medicine.

One in ten patients worldwide are affected by HAI and it is often the medical devices used that cause the infections. Infections caused by central venous catheters are an increasingly serious clinical problem, especially for patients in intensive care. To gain additional clinical evidence of the efficacy of central venous catheters with Bactiguard's infection prevention coating, Bactiguard today announces the launch of a clinical study to compare the BIP CVC with a non-coated standard catheter. The endpoints of the study will include, among others, catheter-associated blood stream infections and thrombosis rate. The study will be performed at multiple sites in India and is under the supervision of primary investigator Dr Yatin Metha, Medanta Hospital in New Dehli. The study has been approved by the local regulatory authorities DCGI (Drug Controller General of India).

It will be a randomized, controlled multi centre study that will be conducted over one year with the first patient enrolling in the first half of 2023. Important milestones and regular updates will be provided.

"We invest in studies as gaining more clinical evidence is a strategic advantage for Bactiguard. It is also an integral part of our development work, both with our own products, such as the BIP CVC, and with how we customize Bactiguard's infection prevention technology together with our license partners. Clinical evidence is crucial for patient safety and supports our ambition to bring our easy-to-use and biocompatible solutions to even more patients across the world. We look forward to following the progress of this study and we will present milestones along the way," says Dr Stefan Grass, Chief Medical Officer at Bactiguard.

Dr Yatin Metha continues "My expectation on the study is not only to define the actual differences between the two catheters, but also to find prevention solutions that give patients better outcome, which in this case means fewer and less severe infections. The study will be conducted in a rigorous, ethical, and scientifically sound manner with patients' safety as a main priority."



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The primary endpoint of the study will be the occurrence of central line associated blood stream infections following the definition by the CDC (US federal agency Centers for Disease Control and Prevention).

For more information, please contact:

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About Bactiguard

Bactiguard is a global medtech company with a purpose to prevent infections. We provide safe, cost-effective, and easy-to-use infection prevention technology and solutions across five therapeutic areas – orthopedics, urology, intravascular/critical care, dental, and wound care.

Bactiguard's unique technology is based on a thin noble metal coating that prevents bacterial adhesion and biofilm formation on medical devices. Bactiguard's solutions are biocompatible and make a positive impact by decreasing patient suffering, saving lives and healthcare resources. The solutions also fight antimicrobial resistance, one of the most serious threats to global health and modern medicine.

Bactiguard operates through license partnerships with leading global medtech companies, such as BD and Zimmer Biomet, differentiating their medical devices with our coating technology, and through the Bactiguard Infection Protection (BIP) product portfolio. BIP includes coated medical devices such as catheters and trauma implants, and wound care products and sutures.

Bactiguard is headquartered in Stockholm, has production in Sweden and Malaysia, and in total around 210 employees. Listed on Nasdaq Stockholm, the company reported revenues of 253.5 MSEK in 2022.

Read more on www.bactiguard.com

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