

Press release

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Bactiguard's central venous catheters approved in India

The product approval for Bactiguard's central venous catheters has been announced by the Indian Ministry of Health & Family Welfare. This provides new opportunities for Bactiguard in providing effective infection prevention in one of the largest and fastest growing markets in the world.

The Central Drugs Standard Control Organisation (CDSCO), under the Ministry of Health & Family Welfare, has announced the regulatory approval of Bactiguard's central venous catheters for infection prevention (BIP CVC).

"We are very pleased with this relatively rapid product approval, which means that we expand our product portfolio in India and can offer effective infection prevention for the most vulnerable patients. The problem of healthcare associated infections is huge and India is the largest consumer of antibiotics in the world, which has led to a high level of multi-resistant bacteria. This means that there is an urgent need for preventive solutions", says Cecilia Edström, SVP Sales & New Business.

Bactiguard has earlier received product approval for its infection preventive urinary catheters (BIP Foley) and sales in India started in 2015. In parallel, a clinical study, involving 1 000 patients in total, at six prestigious hospitals in different regions of the country is being conducted. The regulatory approval for BIP CVC, a class III product with higher safety requirements than for BIP Foley, which is a class IIb product, is unconditional and there are no requirements for post approval clinical trials.

Central venous catheters with antimicrobial coatings have gained increasing importance, given the escalating costs associated with hospital acquired infections, particularly in ICUs where patients are critically ill and CVCs are frequently used in their treatment.

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About Bactiguard

Bactiguard is a Swedish medical device company with a mission to save lives. To achieve this mission we develop and supply infection protection solutions which reduce the risk of healthcare associated infections and the use of antibiotics. This way, we save significant costs for healthcare and the society at large.

The Bactiguard technology prevents bacterial adhesion and biofilm formation on medical devices. Bactiguard offers the technology through licence agreements and our BIP (Bactiguard Infection Protection) portfolio of products. Through our licence partner CR Bard, urinary catheters with Bactiguard's coating are market leading in the USA and Japan. Bactiguard's own product portfolio of urinary catheters, endotracheal tubes and central venous catheters prevent some of the most common infections, which appear in the urinary tract, the blood stream and the respiratory tract.

Bactiguard is in a strong expansion phase in the European markets, China, India and the Middle East as well by establishing license agreements in new therapeutic areas. The company has about 60 employees around the world. Its headquarters and one of two production facilities are located in Stockholm, the other one in Malaysia. Bactiguard is listed on Nasdaq Stockholm.

Read more about how Bactiguard saves lives on www.bactiguard.com