



Press release

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Large clinical study starting in India

The planned multi-center clinical study in India has been initiated and the first patients recruited at two reputable hospitals. The purpose of the study is to further validate the efficiency and patient safety of Bactiguard's Foley catheters in the prevention of catheter-related urinary tract infections.

Healthcare associated infections are a huge problem worldwide. In India, with the largest consumption of antibiotics in the world and a high level of multi-resistant bacteria, healthcare associated infections lead to an even greater challenge.

- We have great challenges in healthcare associated infections. It is a growing problem that we seriously need to act against and overcome. We look forward to implementing the Bactiguard Infection Prevention solution, and to bring down the number of infections significantly, says Dr. Pankaj R. Shah, *Professor & Head, Department of Nephrology Institute of Kidney Diseases & Research Centre and Institute of Transplantation Sciences Civil Hospital, Ahmedabad.*

The clinical study includes 1 000 patients in total and will be conducted at six different sites in India, to reflect differences in the population between the regions. The study was initiated in December 2015 and the results are expected by the end of 2016. The target groups include patients affected by stroke, dementia, neuromuscular disease, bladder obstruction, urological surgery or other elective surgery, where the catheter is expected to be in use for more than two days.

- The study is an important element in implementing our products at some of the major hospitals in India. The results and experience from the study will further strengthen our clinical evidence and will also be a powerful marketing tool in India, says Cecilia Edström, Director of Sales and New Business.

Bactiguard has already received product approval in India. The aim of this post-approval study is to further validate the safety and infection prevention properties of Bactiguard's technology in the Indian population.

The study has started at two sites in Ahmedabad, one private and one public. Apollo hospital has a capacity of 350 patients and there, the Bactiguard catheters will be used throughout the hospital. At Civil Hospital, one of Asia's largest public hospitals with a capacity of some 4 000 patients, a specific unit named the Institute of Kidney



Diseases and Research Center will be responsible for the study. This Institute was founded by Dr H L Trivedi in 1981 and conducts between 10 and 12 transplantations every day. Some of the doctors at the Institute have been trained at the Karolinska University Hospital.

In addition to these two sites, trials will be initiated at PGI Chandigarh in the North of India before the end of the year. At the beginning of next year, three more sites will be added in the South and East of India.

- The Bactiguard Infection Protection solution has proven its superiority. This is the first such clinical study in the Indian population and we are excited to lead the future of infection control measures within the medical device industry of India, says Dr Bhaumik Mody, CEO of EthiTrials CRO (Contract Research Organization, Bactiguard's partner for clinical studies in India).

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About Bactiguard

Bactiguard is a Swedish medtech company with a mission of preventing healthcare associated 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 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 Europe, Middle East, Asia, Latin America and Southern Africa. The company has market presence in some 50 countries and has about 60 employees. Its headquarters are located in Stockholm and production facilities in Sweden and Malaysia. Bactiguard is listed on Nasdaq Stockholm. Read more about Bactiguard at www.bactiguard.com.