

ZNN Bactiguard trauma nails get regulatory approvals in Japan

Since entering the initial license partnership with Zimmer Biomet, the ZNN Bactiguard trauma implants have been successfully launched across Europe, the Middle East and Africa. Today, Bactiguard announces that regulatory approvals have been obtained on the coated trauma implants in Japan, facilitating an upcoming commercial launch into the Japanese trauma market (valued at approximately USD 540 million according to GlobalData).

Leading orthopedic company Zimmer Biomet and Bactiguard have been working together in partnership since 2019. The 2019 partnership gives Zimmer Biomet exclusivity to use Bactiguard's unique infection prevention coating technology on their orthopedic trauma implant product line. The technology is based on a thin noble metal coating that prevents bacterial adhesion and biofilm formation on medical devices. The coating, which is fully biocompatible and environmentally friendly, is attached to the surface of the Zimmer Biomet's trauma implants to reduce the risk of infection.

The regulatory approvals follow an extensive authorization process by the PMDA (Pharmaceutical and Medical Devices Agency) in Japan and manifest the value-add of Bactiguard's infection prevention coating technology.

Anders Göransson, CEO of Bactiguard, comments "This is an important event for us, we are taking a first step into a new market within orthopedics, one of our key strategic therapeutic areas. The path to offer healthcare providers and patients in Japan our safe and effective infection prevention solutions, together with Zimmer Biomet, have now formally taken off. Going through such extensive and thorough approval process also shows the power of our partnership with Zimmer Biomet, the collaboration between our development teams has been great."

Gaining product regulatory approvals in different markets is of strategic importance for Bactiguard. Regulatory approvals are the first step towards a full commercial launch of the ZNN Bactiguard trauma implants which is expected once the local healthcare authorities have committed to reimburse. These types of processes take time, and the Japanese regulatory approvals are anticipated to have limited impact on the Bactiguard Holding AB P&L for 2023.

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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®

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.

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