The X factor in implant dentistry

An interview with Dr Dirk U. Duddeck and Dr Ken S. Serota, Germany & USA

Research to determine the consequences and clinical relevance of avoidable contamination and quality deficiencies in dental implants, are promoted and commissioned in collaboration with renowned universities by the CleanImplant Foundation. The project was initiated in 2016 by Dr Dirk Duddeck, dentist, and biologist, who is working in this field of research for more than 15 years. In September 2022, they opened their new office in New York City with Dr Ken S. Serota, as a dedicated ambassador of the initiative. He will bring awareness of the problem of preventable, manufacture-created contamination of medical devices to the North American dental community. implants—**international magazine of** oral implantology spoke with the two scientists about their achievements, motivation and goals.

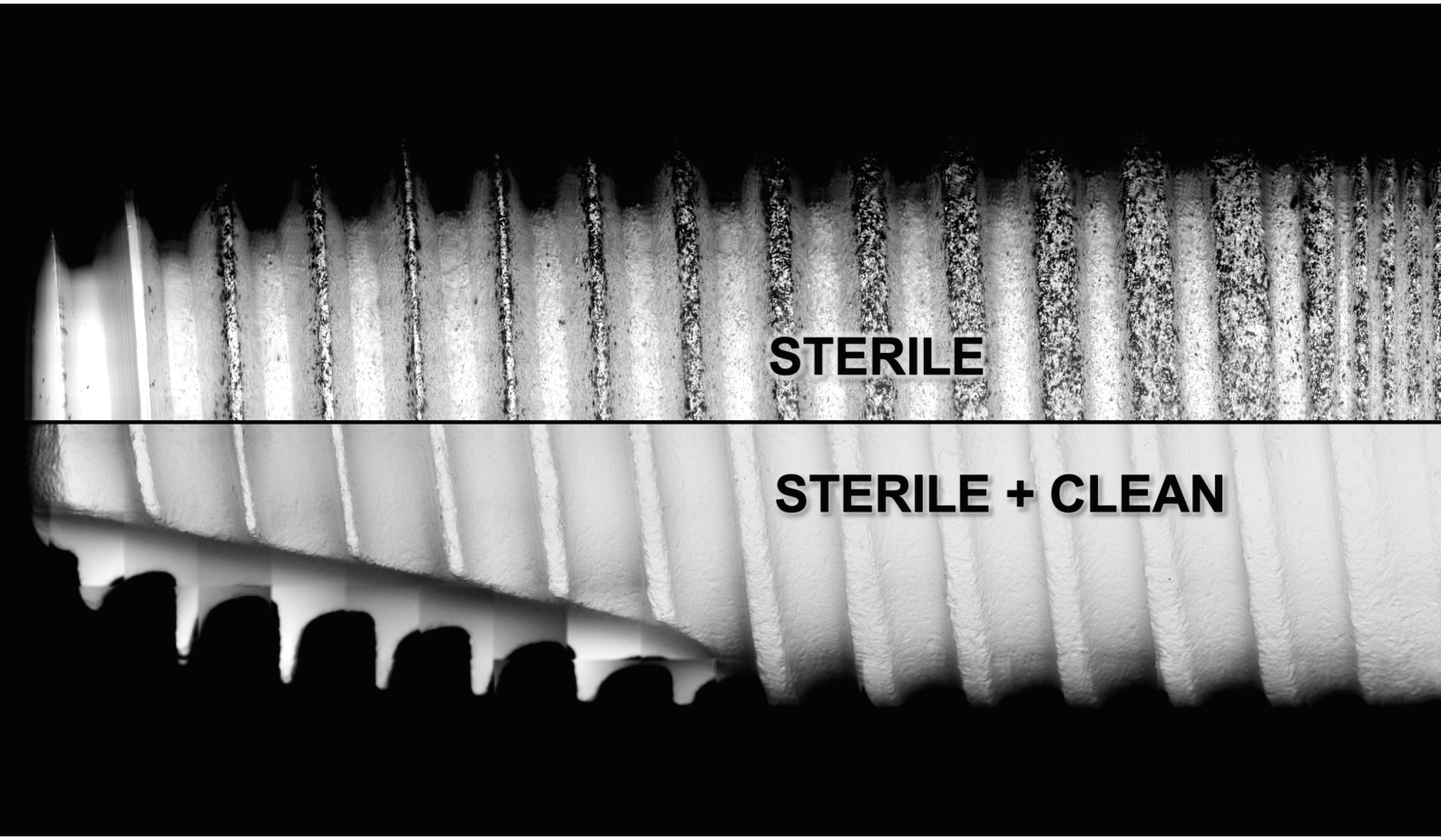
Dr Ken S. Serota (left) and Dr Dirk U. Duddeck.

Dr Duddeck, you founded the CleanImplant Foundation in 2016 as a non-profit organisation with the goal of raising awareness about factory-related contaminants on sterile packaged dental implants. Looking back over the years, what have you achieved?
Initially, at the start of the project on implant quality assessment, there was daunting resistance to our mission by manufacturers. Over time they have recognised that we are not adversaries. Rather, we are allies in ensuring the delivery of the highest levels of quality medical devices for patient care. It is an expected standard and our collective duty of care.

Irrefutably, it is within the capability of all companies worldwide to meet that standard. We welcome the opportunity to work with them for the good of our profession and the good of our patients. We are incredibly proud and thankful that, as of this date, more than 125,000 dentists acknowledge our advocacy for a cleanliness standard in implant dentistry.

You recently opened an office for CleanImplant North America in New York City. What is your intention?
We recognised that implant dentistry and patient care have no geographic boundaries, and we were not represented in North America. As such, we realised that it was time to redress the situation and include North American manufacturers in our growing family of quality-committed companies. With Dr Ken Serota as our representative, we found a comrade-in-arms to further amplify our mission and values.

Dr Serota, what is your motivation for joining the project?
Having been a practicing dentist for almost 50 years, I recognised that achieving 100 per cent is always difficult because there is invariably an X factor. The X factor is a combination of any number of things: The dentist is far too often accused of deficiencies in technical protocols, diagnosis, and treatment planning. As shown repeatedly in publications of the CleanImplant's Scientific Advisory Board, carbonaceous compounds abound as a consequence of inadequacies in manufacturing processes and packaging. If you seek 100 per cent success yet, the implant in question has deficits; you already have a condition where it's impossible to achieve that level of success before initiating the treatment.



The images show SEM mapping of two brand-new dental implants immediately after unboxing. Above: sterile implant (manufactured in the US and marketed with FDA clearance) covered with significant carbonaceous contaminants, most likely leading to uncontrolled foreign body reactions. Below: sterile and clean implant (Kontact S, Biotech Dental) awarded with the Trusted Quality Seal of the CleanImplant Foundation. SEM mapping images are compiled of up to 400 single SEM frames in 500x magnification.

Dentists have to trust in the quality standard of the products delivered by the manufacturer. Is this trust justified, in your opinion?
You can provide the patient with the means to improve their physical health prior to a surgical procedure. There are conditions you cannot control; however, you can control the use of the best-quality medical devices.

What we provide our patients with our knowledge, skills, and clinical expertise is within our control. The X factor that challenges 100 per cent success is determined by that provided by our corporate partners. If those devices exhibit flaws as a result of their manufacture, then we are delivering risk to our patients.

What is your perspective regarding the value of the Foundation for the dental community at large?
Our Foundation is dedicated to ensuring on behalf of our colleagues that medical devices from implant manufacturers worldwide are incontestably clean. We presume that they are sterile, but that does not imply that the manufacturing processes render them clean. Residual contaminants are an unacceptable by-product and wholly resolvable. THAT IS OUR MANDATE. We can evaluate, ascertain, and advise our corporate colleagues about what they leave behind and what they need to remove. It is well within their ethical mandate to eliminate any and all contaminants. That's the bottom line for the purpose and the vision of the CleanImplant Foundation. There is a responsibility to be ideal in all our clinical endeavours. It is the pursuit of excellence that defines professionalism.

Thank you Dr Duddeck and Dr Serota for the interview.

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