The quest for safe and sterile implants

An interview with Dr Dirk Duddeck, Germany

Dental implants have revolutionised the way we treat missing or damaged teeth, giving patients a permanent and natural-looking solution. However, reports of sub-standard and contaminated implants have brought the quality of these devices under intense scrutiny. In this interview, we will be speaking with Dr Dirk Duddeck, the founder of the CleanImplant Foundation, a non-profit organisation dedicated to promoting high-quality, clean and safe dental implants for patients. Through its extensive research and advocacy efforts, the CleanImplant Foundation is leading the charge in ensuring that dental implants are not just safe but also effective in providing the desired results. Join implants—**international magazine of** oral implantology as we get a closer look at the work of the CleanImplant Foundation and learn about its efforts in ensuring the highest quality and safety for patients receiving dental implants.

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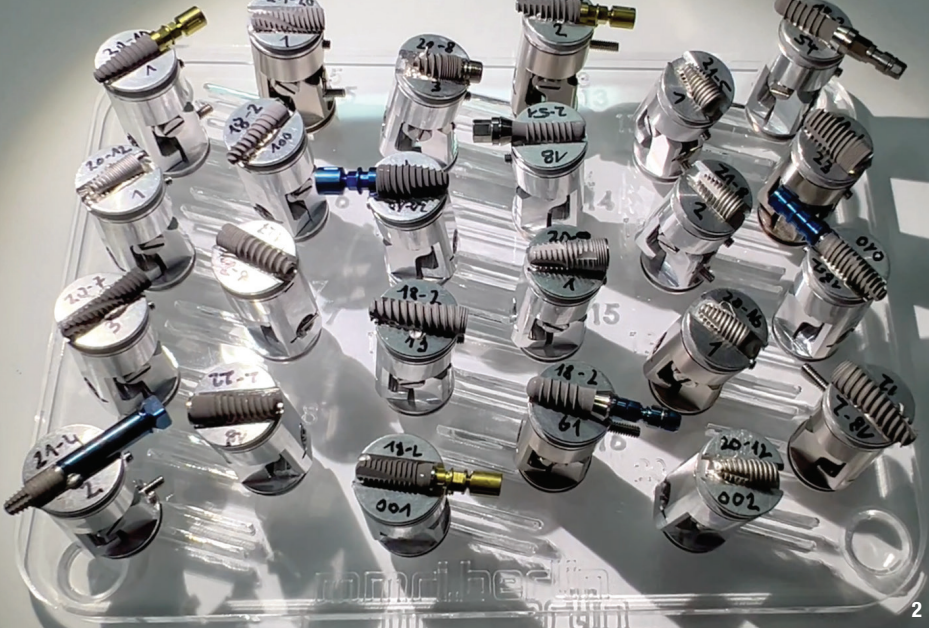
Dr Duddeck, as a non-profit organisation, the CleanImplant Foundation is dedicated to increasing the safety of medical devices and evaluating the factory cleanliness of dental implants. How many implant systems have you inspected or, to put it more precisely, analysed in the scanning electron microscope (SEM)?

From the inception of quality assessment tests on sterile-packaged implants, we have evaluated the surface cleanliness of over 300 implant systems from approximately 250 manufacturers. Every two to three years, we undertake a comprehensive study of the implants in the marketplace. Current batch samples are supplied by manufacturers on request, or if they choose not to participate in the study, the samples are blind purchased.

Fig. 1: Dr Dirk Duddeck, founder and head of research at the CleanImplant Foundation. (© CleanImplant Foundation)



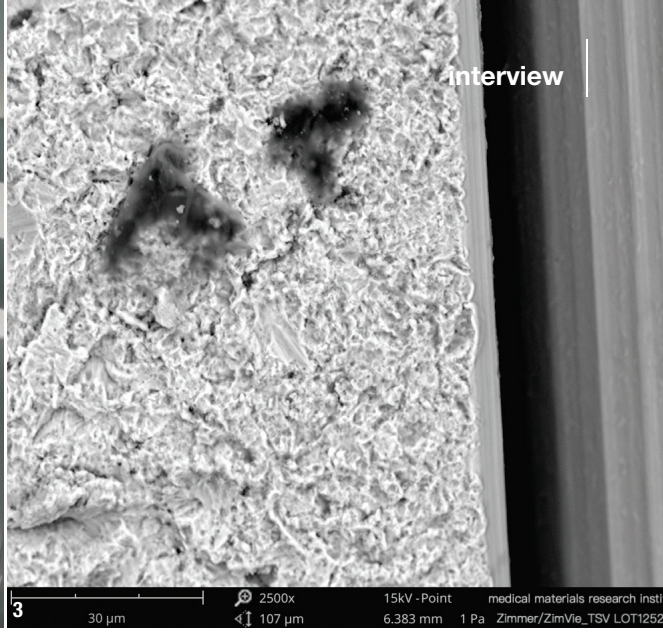


Fig. 2: Sterile implants mounted on a sample holder waiting for SEM analysis. (© CleanImplant Foundation)
Fig. 3: Organic contaminants on the entire implant shoulder–identified as silicone-containing plastic residues (polysiloxanes) by ToF-SIMS.

How can dentists and clinics with a focus on implantology benefit from the work of the CleanImplant Foundation?
On our website (www.cleanimplant.com) dentists can find implant systems that have proven their cleanliness every two years across various batches and have been awarded the Trusted Quality Seal. However, every practitioner can contact us directly. It becomes particularly interesting when colleagues report to us inexplicable early implant failures or peri-implantitis shortly after placement. In these cases, we have found implant samples from the same batch typically demonstrate clinically relevant amounts of plastic particles, residues from manufacturing or packaging, cell-toxic residues of aggressive cleaning substances such as dodecylbenzene sulphonic acid or lubricants such as perfluoropolyether.

How can you identify these contaminants so accurately? The SEM is not suitable for this, right?
Yes, you are correct. We combine two spectrometric methods to analyse unknown substances. In the SEM, we can see where high-carbon particles collect on the implant. With information about the localisation or accumulation of the foreign particles, subsequent time-of-flight secondary ion mass spectrometry can be used to determine the composition of the substances. In several cases, these essential findings enabled manufacturers to eliminate the cause of contamination and deliver residue-free implants after the corresponding quality management improvement.

Do these substances have any effect on healing after the placement of the implant?
It can be assumed that these substances significantly interfere with osseointegration or completely prevent it in contaminated areas. After phagocytosis by macrophages, those contaminants can trigger a storm of pro-inflammatory cytokines, resulting in bone resorption and soft tissue degradation. This year, the CleanImplant Foundation will conduct an elaborate study on this matter with the University of Zurich. Given the increasingly high reported levels of peri-implantitis, it is likely that the effect of particulate and thin-layered dirt particles on sterile-packaged implants is under-estimated as a contributing factor.

How have companies reacted to your analyses?
Our mandate is to encourage manufacturers and suppliers to engage in a constructive dialogue. Sadly, some companies have not yet cooperated with our efforts, as they have chosen not to believe that foreign particles are clinically relevant, despite evidence to the contrary.

The CleanImplant Foundation will once again be exhibiting at the International Dental Show in Cologne in Germany in March. What can users and manufacturers expect?
At this year's show, we will have an SEM at our booth in collaboration with Thermo Fisher Scientific. Those colleagues who bring sterile-packaged samples of their implant systems of choice for assessment will be able to view the level of surface cleanliness under the SEM. Manufacturers will be shown the nature and scope of our analyses as well as the results from a European-funded project that enables us to count and identify particles using artificial intelligence. On Thursday, 16 March, all manufacturers are invited to the fifth group and expert meeting. We look forward to sharing insights into the micrometre universe and unknown surface views of implants that colleagues will bring to our IDS booth (Hall 14.2, Booth O042).

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