“We fight dirty”

How a simple quality assessment on dental implants became a grassroots movement

The CleanImplant Foundation performs tests on the quality of randomly selected, sterile-packaged dental implants in cooperation with accredited testing laboratories. We interviewed Dr Dirk U. Duddeck, Managing Director and Head of Research of the foundation.

Dr Duddeck, you founded the foundation in 2016. How well recognised is it today?
The foundation is proud to acknowledge the 150,000 Facebook followers who look to us for guidance. There are 40 ambassadors and key opinion leaders who present our findings at congresses and continuing education courses around the world. Through their efforts, the negative impact of factory-related contaminants on implant surfaces is now understood to be a key risk factor in implant failure.

Last year, the CleanImplant Foundation expanded its footprint by establishing an office for North America in New York City. This year, we will open a third office in Seoul, South Korea. As a result of our activities on three continents, the CleanImplant initiative has seen dramatic growth in its membership, well beyond our expectations. Our grassroots movement, carried forward by “CleanImplant Certified Dentists”, is delivering the strongest possible message to the implant manufacturers; they must do better.

What is the feedback from manufacturers?
To date, we have analysed well over 300 implant systems from all leading brands. Our mandate is to encourage manufacturers and suppliers to engage in a constructive dialogue. Implant manufacturers react very differently when we draw their attention to unexpected analysis results. Some companies are eager to listen to our suggestions and work with us to find solutions to optimise their quality management. In the past, this has often led to substantial and sustainable improvements in production. However, some companies have not yet cooperated with our efforts, as they have chosen not to believe that cell-toxic impurities on a sterile packaged implant are clinically relevant, despite evidence to the contrary.

What are these contaminants on implant surfaces?
SEM imaging has identified particulate contaminants of metallic origin, containing chromium, iron, nickel, or copper-tin compounds. Frequently, significant organic, i.e. carbonaceous impurities are found. Time-of-Flight Secondary Ion Mass Spectrometry (ToF-SIMS) demonstrates plastic particles made of polysiloxane, synthetic polymers, and thermoplastics. We have also discovered thin-film residues of dodecyl benzenesulfonic acid (DBSA), an aggressive and surface-active chemical cleaning agent, classified as a hazardous substance, or the quaternary ammonium compound didecyl-dimethylammonium chlo-

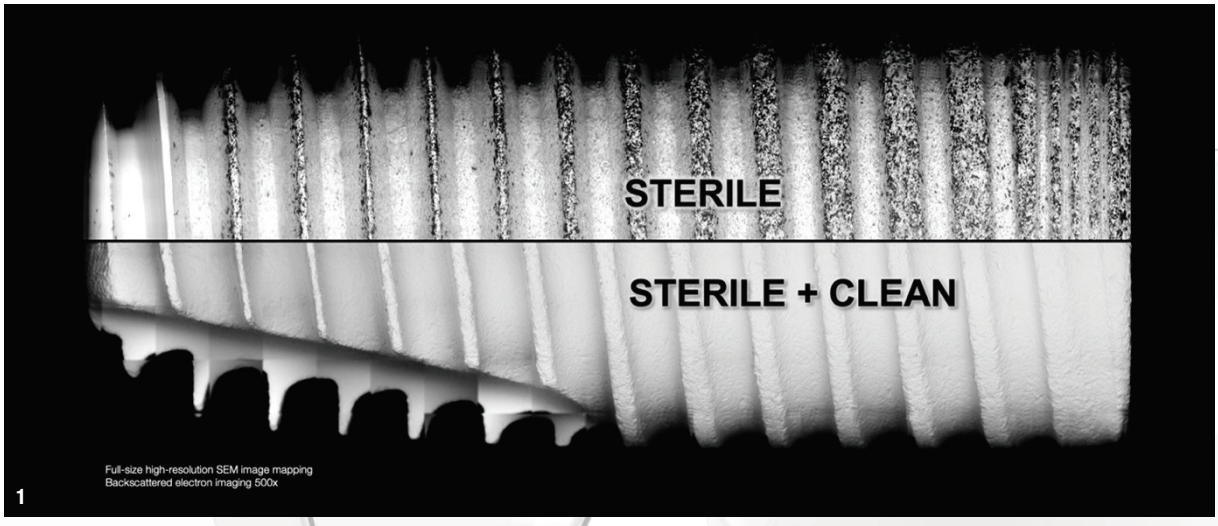

Fig. 1: SEM image mapping of two new, ready for use sterile-packaged implants after unboxing. Both implants carry the CE label and have FDA clearance.

Fig. 2: Dr Dirk U. Duddeck inspecting an implant mounted for SEM analysis in a particle-free cleanroom.

ride (DDAC), which is commonly used as a biocide or green algae remover. If appropriate manufacturing controls and packaging techniques are followed, none of these chemicals should be identifiable on sterile-packaged implants, not even in residual quantities.

What effects do these impurities possibly have on implant healing and long-term success?
Carbon-containing contaminants, mainly plastic particles with a size of 0.2 to 7.2 µm, are classified as pro-inflammatory. When these impurities detach from the surface during implant insertion, macrophages take up the particles by phagocytosis and release pro-inflammatory cytokines. The result is an expanding zone of soft-tissue damage and inflammation. In addition, TNF-α, IL-1β, and IL-6 secretion modulate osteoclast differentiation that can lead to early bone loss at the implant site. In summary, factory-related impurities are the most underrated risk factor for peri-implantitis, cortical bone loss, and implant failure. That's the reason for our catch phrase "We fight dirty".

Can you tell us more about implants that showed no significant impurities after unboxing and that have been awarded the Trusted Quality seal?
The seal of quality, which underlines the first-class surface purity of dental implants, is awarded by the CleanImplant Foundation's scientific advisory board only after a rigorous peer-reviewed analysis and testing process. The certification is valid for two years and then must be renewed. To date, the following implant systems carry the coveted "Trusted Quality" seal: Kontact S (Biotech Dental), whiteSKY (bredent group), UnicCa (BTI Biotechnology Institute), (R)evolution and Patent/BioWin! (Champions-Implants), SuperLine (Dentium), Astra Tech EV (Dentsply Sirona Implants), In-Kone (Global D), ICX-Premium (medentis medical), AnyRidge and BLUEDIAMOND (MegaGen), T6 (NucleOSS), Prama (Sweden & Martina), Inverta (Southern Implants) and SDS 1.2 and SDS 2.2 (Swiss Dental Solutions). Test results on other systems are pending. In addition, we tested the products of two contract manufacturers of ceramic implants, the CeramTec Group and Komet Custom Made. Both received CleanImplant's "Certified Production Quality" awards after thorough analyses.

CleanImplant will be an exhibitor at the joint EAO-DGI congress in Berlin in September. What is the foundation's focus at this event?
We will install a high-resolution scanning electron microscope (SEM) in the exhibition area at the CleanImplant booth C06, thanks to cooperation with Thermo Fisher Scientific, a world-leading supplier of analytical instruments. Dentists bringing sterile-packaged samples of their implant system can have them assessed on-site to determine the level of surface contaminants present. Visitors get information about all implant systems that have been previously tested to be free of impurities. As an example of transparency, implant providers will receive detailed information on the comprehensive testing procedure and the equipment used.

What is the take-home message you hope to deliver at the congress in Berlin?
We look forward to sharing our history, research, and passion for ethical standards of care with those who visit us at our booth. Many have joined us on this mission; many more are coming forward as they embrace the new normal of quality standards for the devices we use to care for our patients. Our calling is to ensure that all those involved in implant-centric dentistry are partners in excellence.

Many thanks for the interview and a successful time in Berlin.

More information:
www.cleanimplant.org
www.facebook.com/cleanimplant
www.instagram.com/cleanimplant
www.linkedin.com/cleanimplant
EAO booth C06

contact

CleanImplant Foundation
Berlin, Germany
+49 30 200030190
info@cleanimplant.org
www.cleanimplant.org

CleanImplant