Dental implant quality under scrutiny

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Fig. 1: SEM testing station at the International Dental Show.

On-site SEM analysis of implants at IDS 2021

"Sterile-packaged" does not mean an implant is necessarily free of contaminants. This disturbing realisation is slowly dawning on dentists not only in Europe but also in the US. Exceeding 100,000 subscriptions on CleanImplant's Facebook page, the number of dentists worldwide intrigued by this revelation increased tenfold over the past two years. For the International Dental Show (IDS) in Cologne in Germany coming up in September, the non-profit CleanImplant Foundation based in Berlin in Germany will once again showcase quality checking of dental implants under a scanning electron microscope (SEM). Installed exclusively for this event in Hall 10.2 in collaboration with Thermo Fisher Scientific and the Medical Materials Research Institute, the set-up will provide full transparency of the foundation's quality assessments (Fig. 1). Dentists and manufacturers alike will be able to witness the meticulous and independent quality check of dental implants in detail, from start to finish. The open and public demonstration will allow for spectators to learn about the extent of factory-related contamination of sterile-packaged implants and, most importantly, its direct consequences. The SEM unveils whether an implant meets the strict consensus-based CleanImplant quality guidelines, and dentists are encouraged to participate in finding out whether the implant system used in their practice is actually safe (Fig. 2).

Dentists and patients want clarity

Ever since the "Implant Files" became public in the media, dentists' concerns about substandard medical products worldwide have grown immensely—and rightly so. Current study data demonstrates that one out of three

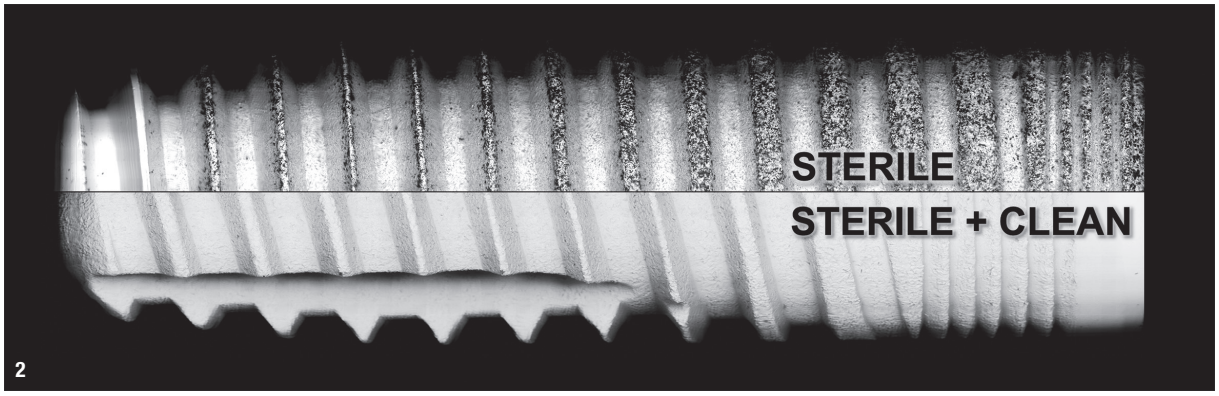

Fig. 2: Full-size high-resolution SEM image mapping of two implants, both samples of systems with U.S. Food and Drug Administration clearance.

implant systems analysed contains technically avoidable impurities. Contaminants include organic particles from the manufacturing process, plastic from packaging, and metallic particles of nickel, tungsten, iron, copper and chromium, just to name a few. Despite the shocking discovery, all of the implants with significant impurities carried the CE mark or had U.S. Food and Drug Administration clearance. When thoroughly analysed, an unexpectedly large number of implant systems fail to keep their promise of delivering clean medical devices. The sterile packaging does not change that either. This ultimately harms patients and endangers implantologists, as products with impurities produce poor clinical results and, upon failure, entail severe legal implications.

Clear the stage for manufacturers

The CleanImplant Foundation has been coordinating worldwide quality assessment studies of dental implants with renowned universities for many years. After a strict peer review process, the Trusted Quality Mark is awarded to particularly clean implant systems only. To date, recipients of the quality seal include selected implant systems by Biotech Dental, bredent medical, BTI Biotechnology Institute, CAMLOG, Global D, medentis medical, MegaGen, Nobel Biocare, NucleOSS, Straumann, Sweden & Martina and Zircon Medical. However, before the coveted Trusted Quality Mark is awarded, each implant system is tested based on five randomly selected samples from multiple batches. At least two of these samples are purchased from anonymous blind shopping or provided directly from dental practices as they would be used on patients, avoiding a possible preselection of testing samples by the manufacturer. Samples must comply with the strict thresholds set in a consensus process by renowned scientists of the scientific advisory board, such as Prof. Emeritus Tomas Albrektsson, Prof. Ann Wennerberg, Prof. Hugo de Bruyn, Dr Michael Norton and Prof. Florian Beuer. Technical cleanliness, however, does not suffice for the time-limited award. After additional proof of successful clinical documentation, the peer review process will determine whether an implant system meets the quality criteria and will thus receive the award. In order to remain relevant and up to date, this process must then be repeated every two years to refresh the quality seal's life cycle.

As of this year, dentists can showcase their commitment to dental excellence and clean implantology by applying to become a "CleanImplant Certified Dentist", ultimately rewarding their patients' trust with backed-up confidence in their chosen implant system. Dental trade show visitors and manufacturers can book appointments in advance for the live demonstration under the SEM. For more information, see www.cleanimplant.org.

Visit the CleanImplant Foundation at IDS 2021 in Cologne, Germany, in Hall 10.2, Booth P032.

about the author

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