INTRODUCTION

The CleanImplant Foundation, an independent non-profit organization, was founded by dentists for dentists. The organization initiates objective periodical quality assessments of numerous sterile-packaged dental implant types to identify unwanted (factory-related) contaminants. These wide-ranging inspections, carried out every two to three years, are completely free of any influence from manufacturers. The testing laboratories are all officially accredited in accordance to DIN EN ISO/IEC 17025:2018. It is the aim of the Foundation to provide objective, reliable, un-biased and substantive data about implant surface quality in terms of cleanliness or avoidable contaminations.

The CleanImplant Foundation, monitored by a renown Scientific Advisory Board – including Tomas Albrektsson and Ann Wennerberg (Sahlgrenska Academy Gothenborg, Sweden), Michael Norton (UK), Scott Ganz (USA), Florian Beuer (Charité Universit Berlin, Germany) and others – considers the cleanliness of implants to be another quality criterion that is still underestimated. Therefore, the initiative strives to shine a light on this aspect with its educational campaigns for clinicians and implant manufacturers working in the field.

In the current study, a total of 100 sterile-packaged implants were examined again under a scanning electron microscope. The first results show a high number of implant samples with contaminants of metallic origin and, particularly frequently, carbonaceous impurities – with consequences for patients and practitioners.

- **How many implant systems have been examined by the CleanImplant Foundation so far?**
  In the past few years, a total of well over 300 different implants have been analyzed in the scanning electron microscope. The set-up of our research studies allows us to track the quality progression of specific systems over a significant period of time. Unfortunately, we have found out that the development of quality is possible in both directions. The most recent quality assessment study involved 86 implant systems made of titanium or titanium alloys and 14 ceramic implants.

- **How high is the number of factory-contaminated implants?**
  Much too high. Lamentably, almost one in three implant samples showed residues originating from the manufacturing process or contaminations due to the packaging procedure or the packaging itself.

- **What kind of contaminants did the CleanImplant Foundation detect on sterile-packaged dental implants in the current study?**
  SEM imaging identified particulate contaminants of metallic origin, which included significant levels of chromium, iron, tungsten, nickel, or copper-tin compounds. We very frequently found organic carbonaceous foreign materials identified as polysiloxanes, i.e., synthetic polymers, thermoplastics, but also distinct residues of dodecyl benzenesulfonic acid (DBSA) or erucamide. The aggressive and surface-active chemical DBSA absolutely does not belong on sterile-packaged implants, even in residual quantities. After all, it is classified as a "hazardous substance." The CleanImplant Foundation asks: Why do affected manufacturers and users accept such foreign particles on sterile medical devices? Even if it sounds cynical: according to our knowledge, none of the substances mentioned has proven to be beneficial for any healing process.

- **Do the identified foreign particles have any influence on the healing process or even the development of peri-implant inflammations?**
  In literature, organic, i.e., carbon-containing contaminants are specifically associated with initial bone loss or even peri-implantitis. In particular, foreign particles with a size of 0.2 to 7.2 µm are classified as pro-inflammatory. If these detach from the surface during the implant insertion process, 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, secretion of TNF-α, IL-1b, IL-6, and PGE2 stimulates the differentiation of osteoclast precursors into mature osteoclasts. This would explain clinically abnormal bone loss after the insertion of contaminated implants, for example. In any case, there is a disturbance of the patient-individual foreign body equilibrium, which Albrektsson describes as one of the main causes of peri-implant bone loss.

- **Speaking of these foreign particles, what does the CleanImplant Foundation mean by a "significant quantity" of particles?**
  In some cases, we see implants under the SEM that are contaminated on all outer thread flanks. Other samples show only a few particles. Our Scientific Advisory Board worked with us to develop a quality guideline on this issue by consensus in 2017. The guideline defines the thresholds for the implant surface, measured from the shoulder to the apex at a viewing angle of 120 degrees, of less than ten particles with a maximum size of 50µm. In the meantime, some manufacturers have adopted this value as a standard in their quality management. This CleanImplant guideline was also published in the Journal of Clinical Medicine and is available to download on the CleanImplant project website.

- **Are such contaminants avoidable?**
  All the impurities we have identified can be reduced to a minimum with some technical effort or even avoided completely by optimizing the manufacturing and QM processes, the wet-chemical cleaning, the transport- and packaging methods or the quality of the packaging itself. The excellent results of those implant systems awarded the "Trusted Quality" seal by the CleanImplant Foundation are confirmation of surface quality meeting the above-mentioned consensus criteria.

- **Do we also find implants polluted with impurities on the European or US market?**
  Unfortunately, yes. As users of approved medical devices, we should be safe in assuming that all systems have demonstrated decent quality - at least once at the time of their European market approval or FDA clearance.
  However, the results of our scientific studies reveal far too many contaminated implants. The CleanImplant Foundation's conclusion: it seems that those manufacturers are unable to maintain a consistent level of quality in subsequent years after market clearance. After identifying significant impurities on their implants, the CleanImplant Foundation provide this information to the implant manufacturers. But we do not have any influence or insights from the manufacturers regarding recalls of the contaminated batches or elimination of the cause of the contamination.

- **What about ceramic implants? Are implants made of zirconia in general 'cleaner' than those made of titanium or titanium alloys?**
  We investigated this question in a specially designed study that we conducted in collaboration with the Charité University Clinic in Berlin, the Sahlgrenska Academy in Gothenburg and the University of Malmö. In this study, we analyzed 25 sterile-packaged ceramic implants from 5 manufacturers always using the same protocol. The results will be published in the International Journal of Oral & Maxillofacial Implants (JOMI). On two of these five tested systems, we revealed significant contaminations on all samples; one system showed partially clean samples and partially contaminated samples. Only two systems could prove consistently clean surfaces. This regrettably shows that ceramic implants are not cleaner per se simply because zirconia is white.

- **How are the studies of the CleanImplant Foundation designed?**
  Unlike conventional approaches in university research, CleanImplant analyses are carried out exclusively in specialized testing laboratories officially accredited according to DIN EN ISO/IEC 17025:2018. This is highly time-consuming and cost-intensive but an indispensable precondition for the liability, independence and validity of the analysis results. Even the unpacking of the samples and the SEM analyses itself are conducted in a Class 5 cleanroom according to DIN EN ISO 14644-1. This prevents any sample contamination caused by the laboratory environment.

- **The CleanImplant Foundation awards the "Trusted Quality Mark" to clean implant systems. What criteria are required for this certification?**
  The severe testing procedure requires the analysis of a total of five samples of the same system. At least two samples of these five are to be procured anonymously, that means with 'blind shopping' directly from practitioners. The five analyses are documented in a comprehensive test report and compared with the consensus guideline established by the Scientific Advisory Board. In a peer-review, two members of this advisory board independently review the technical analysis report. In addition, the clinical documentation of the implant system has to show a survival rate of at least 95 percent for more than two years. Only after all these criteria have been met, can the quality seal be awarded. The CleanImplant Trusted Quality award is valid for two years and the complete process has to be conducted again for its renewal.

- **Which implant systems have been awarded the "Trusted Quality Mark"?**
  The best way to find out is to check the project website at www.cleanimplant.org. There, we provide a constantly updated database showing those implant systems awarded the 'Trusted Quality' seal for the current period. New systems are constantly being added, while, as the seal is only valid for two years, others may also lose the quality mark again.

- **My implant system does not appear on the list on the CleanImplant Foundation website. Does that mean the implant system is contaminated?**
  No, it does not necessarily imply that. It is possible that the CleanImplant Foundation has not yet tested the implant system. Or it is still in the process of achieving the quality mark. It is even possible that we only have data on file from a previous study. Dentists who are committed to the uncompromised quality of their medical devices and support the CleanImplant mission as active members can get all the reliable information they need, even have their implant system tested as well as benefit from all the support CleanImplant offers to practitioners who really care.

- **As a dentist, how can I be sure that "my" implant systems are residue-free and how can I effectively communicate this to my patients or referrers?**
  As a member and supporter of the CleanImplant Mission, you will get answers and meaningful information about the quality of your practice's implant systems. However, you receive much more than just the comfort of knowing that you are using a medical device that is proven to be clean. As a "Certified CleanImplant Dentist," you benefit from a whole range of benefits like a certificate for your patients and referring colleagues, high-quality acrylic displays for your practice counters, patient brochures for the waiting area, stickers on your medical cost estimates and a CleanImplant logo for your correspondence etc. to effectively showcase your ethical commitment to the high quality of your medical practice for the well-being of all patients. If needed, we even provide a court-proof analysis of the implant system used in the event of a dental malpractice lawsuit.

- **Why is the information on the quality of implants and test results of individual systems not free of charge?**
  The CleanImplant Foundation is a non-profit organization. We receive no public funding and both our website and our regular newsletter for members are ad-free. The Foundation's effort into the independent analyses, continuous studies, awareness and education campaigns is tremendous. For our extensive comparative studies, we anonymously purchase countless implant samples. There are occasions when we must defend ourselves against threats of legal action from individual manufacturers, who seem to care less about the trust of their customers and the welfare of patients. Therefore, the entire project depends on every support. In return, we do all we can to support those practices that are committed to clean implants by providing convincing information material to promote referrers' confidence and patients' trust. For the latter, CleanImplant has created an informative but not intimidating website including a list of CleanImplant Certified Dentists with a link to their website.

- **What are the long-term goals of the CleanImplant Foundation?**
  Our common goals can be summarized very simply: every single colleague and member of the CleanImplant initiative helps to build a stronger voice on the quest for independently tested, reliable first-class medical devices. It is our responsibility to protect every practitioner and, in the end, every patient worldwide from suspect medical devices and help to benefit from the undoubtedly positive quality-of-life treatment with dental implants. A simple concern became a movement for better quality.

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science matters.

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