Who we are. The CleanImplant Foundation, an independent non-profit organization, was founded in Germany by Dr. Dirk U. Duddeck, dentist and biologist. The organization conducts objective periodical quality assessments of numerous dental implant types to reveal the existence of unwanted (factory-related) contaminants on sterile-packed dental implants. These wide-ranging inspections, carried out every two to three years, are entirely free of any influence from manufacturers.

The testing institutes are all officially accredited in accordance with DIN EN ISO/IEC 17025:2018. The Foundation aims to provide objective, reliable, unbiased, and substantive data on implant surface quality in terms of cleanliness or foreign particle contaminations.

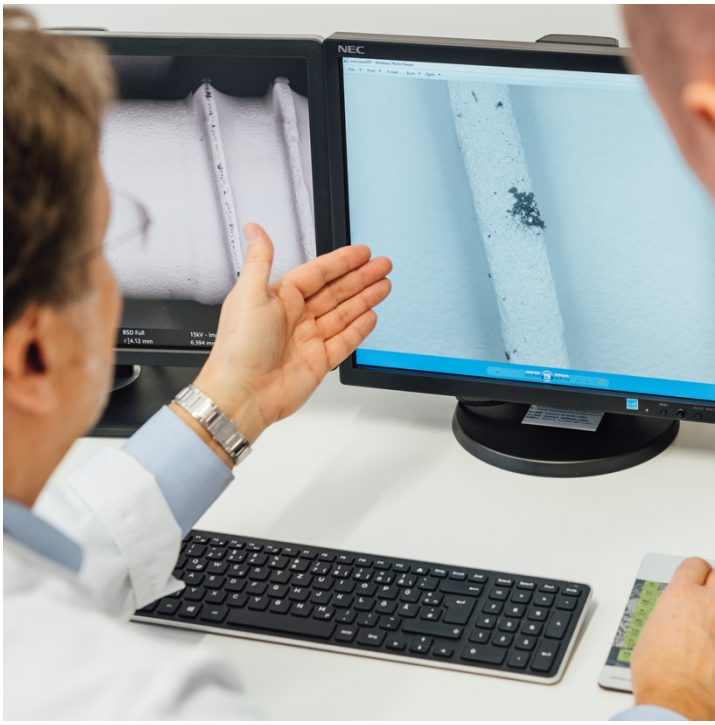
The CleanImplant Foundation, monitored by a renowned Scientific Advisory Board – including Professors Tomas Albrektsson and Ann Wennerberg (Gothenburg), Hugo De Bruyn (Nijmegen/Ghent), Florian Beuer (Charité Berlin), Jaafar Mouhyi (Casablanca), and practitioners such as Scott D. Ganz (USA), Luigi Canullo (Italy) and Michael Norton (UK) – 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.

What's at stake: In the most recently concluded study, a total of 100 sterile-packaged implants were examined with a Scanning Electron Microscope. Results have indicated that at least one-third of the samples show a significant number of particulate contaminants of metallic origin and, particularly frequently, organic carbon-containing pollutants. Significant impurities on sterile and ready-to-use packaged medical devices have consequences for every patient that should not be understated – neither by practitioners nor by manufacturers.

- **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 using the Scanning Electron Microscope. The setup of our research studies allows us, for example, to track the quality progression of specific systems over a significant period and on a repeated basis. Unfortunately, it has been determined that quality can develop both ways. 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. Regretfully, almost one in three implant samples have shown residues originating from the manufacturing process or contaminations due to the packaging procedure or the packaging itself.

- **What kind of contaminants has the CleanImplant Foundation detected on sterile-packaged dental implants in the current study?**



SEM imaging has identified particulate contaminants of metallic origin, including significant levels of chromium, iron, tungsten, nickel, or copper-tin compounds. Very frequently, organic carbonaceous foreign materials identified as polysiloxane, i.e., synthetic polymers, thermoplastics, but also distinct residues of dodecyl benzenesulfonic acid (DBSA) or erucamide were found. The aggressive and surface-active chemical DBSA definitely does not belong on sterile-packaged implants, even in residual quantities. Notably, it has been classified as a "hazardous substance." The CleanImplant Foundation poses the question: Why do the manufacturers concerned and their implant users accept such foreign particles on sterile medical devices?

Even if it sounds cynical, according to our knowledge none of the substances mentioned have proven to be beneficial to the healing process in the human body.

- **Can foreign material particles influence 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. When these contaminants 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. 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, implants contaminated on all outer thread flanks have been observed. Other samples have shown only a few particles. Our scientific advisory board includes renowned scientists such as Tomas Albrektsson and Ann Wennerberg from the Sahlgrenska Academy in Sweden and practitioners such as Michael Norton (UK) and Scott Ganz (USA). They developed 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 50 µm. In the meantime, some manufacturers have adopted this value as a standard in their quality management. This CleanImplant guideline has also been published in the Journal of Clinical Medicine and is available as a PDF download on the CleanImplant project website.

- **Are such contaminants avoidable?**

  All the impurities identified can be reduced to a minimum with some technical effort or can even be avoided entirely 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 these implant systems which have been awarded the "Trusted Quality Seal" by the CleanImplant Foundation are confirmation of surface quality meeting the above-mentioned criteria.

- **How are the studies of the CleanImplant Foundation designed?**

  Unlike conventional approaches in university research, CleanImplant analyses are conducted exclusively in specialized testing laboratories officially accredited according to DIN EN ISO/IEC 17025:2018. Studies in this kind of setup are highly time-consuming and cost-intensive. However, they are an indispensable precondition for the reliability, independence, and validity of the analysis results. Even the unpacking of the samples and the SEM analyses themselves are conducted in a Class 5 cleanroom according to DIN EN ISO 14644-1 in order to prevent any sample contamination caused by the laboratory environment.

- **Do we also find implants contaminated 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. The results of our scientific studies, however, reveal far too many contaminated implants.

  The CleanImplant Foundation's conclusion is that it seems that those manufacturers are unable to maintain a consistent level of quality in subsequent years after marketing clearance. After identifying significant impurities on implants, the CleanImplant Foundation provides this information to the implant manufacturers. However, we do not have any influence or insights from the manufacturers regarding product recalls of the contaminated batches or the elimination of the cause of the contamination.

- **What about ceramic implants? Are implants made of zirconia 'cleaner' in general than those made of titanium or titanium alloys?**

  We investigated this question in a study specially designed and conducted in collaboration with the Charité University Clinic in Berlin, the Sahlgrenska Academy in Gothenburg, and the University of Malmö. This study analyzed 25 sterile-packaged ceramic implants from five manufacturers using the same protocol. On two of these five tested implant systems, significant contaminations were revealed on all five samples; one system showed partially clean samples and partially contaminated samples. Only two systems have been able to consistently prove that the surfaces have been clean. Regrettably, this result has demonstrated that ceramic implants are not cleaner per se simply because the core material appears white.

- **The CleanImplant Foundation awards the "Trusted Quality Seal" to particularly clean implant systems. What criteria are required for this certification?**
  This strict testing procedure requires the analysis of a total of five samples from the same system. At least two implant samples of these five must 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 as well as the clinical documentation of the implant system (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 Seal is valid for two years, and the entire process must be conducted again in order to be renewed.

- **Which implant systems have been awarded the Trusted Quality Seal?**
  The best way to find out is to check the project website at www.cleanimplant.org. The site provides a continuously updated database listing those implant systems awarded the Trusted Quality Seal for the current period. New implant systems are continually being added, while others may also lose the certification as the seal is only valid for two years.

- **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 may be the case that the Foundation has not yet tested the implant system in question. Or it is still in the process of qualifying for the quality mark. It is possible that we only have data on file from a previous study. Dentists that are committed to an uncompromised quality of their medical devices and support the CleanImplant mission as active members can get all the reliable information they need, even after their implant system has been tested, and can 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 contaminant-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. Please note, you will receive much more than just the comfort of knowing that you use a medical device that has proven to be clean. As a "Certified CleanImplant Dentist", you can enjoy a whole range of benefits, such as 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 and the well-being of all patients.
  If needed, we even provide a court-proof certified SEM analysis of the implant system used in the event of a dental malpractice lawsuit.

- **Why do I have to register before receiving information on the quality of implants in general and test results of specific implant systems that I use in my clinic?**

  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 to provide independent analyses, continuous studies, awareness, and educational 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 by individual manufacturers, who seem to care less about the trust of their customers and the welfare of patients. Because of this, the entire project depends on a lot of support. In return, we do all we can to support practices committed to clean implants by providing well-founded informational material to promote referrers' confidence and patients' trust. For the latter, CleanImplant has created an informative though non-intimidating website, including a list of CleanImplant Certified Dentists with a link to their websites.

- **What are the long-term goals of the CleanImplant Foundation?**

  Our shared goals can be summarized very simply: Each and every colleague and member of the CleanImplant initiative helps to build a stronger voice in the quest for independently tested, reliable first-class medical devices. It is our responsibility to protect each practitioner and, in the end, each patient worldwide from dubious medical devices and to help them benefit from the undoubtedly positive quality-of-life treatment with dental implants.

A single concern became a movement for better quality in implant dentistry!

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MORE INFO: WWW.CLEANIMPLANT.ORG