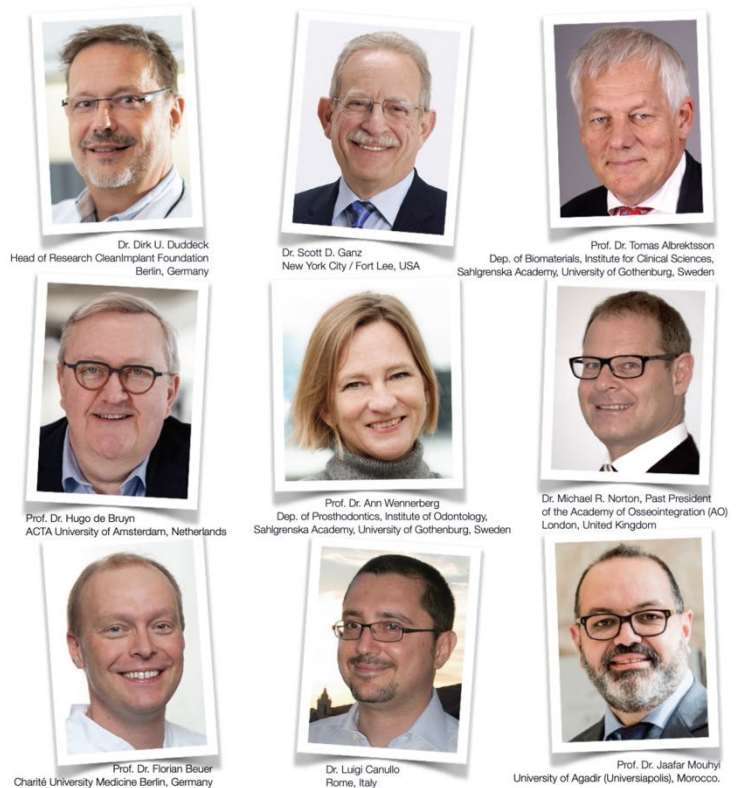


The CleanImplant Project · Questions & Answers

◆ Who is CleanImplant?

The CleanImplant Foundation, an independent non-profit organization, was founded by Dr. Dirk U. Duddeck, dentist and biologist. The organization conducts objective periodical quality assessments of numerous dental implant types. These wide-ranging inspections, carried out every two to three years, are entirely free of any influence from manufacturers. The commissioned 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 (Sweden), Hugo De Bruyn (Netherlands), Florian Beuer (Germany), Jaafar Mouhyi (Morocco), 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?

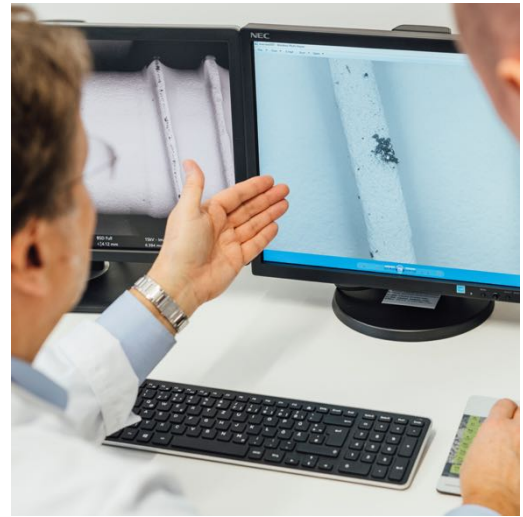
In the most recently concluded study, a total of 100 sterile-packaged implants were examined using Scanning Electron Microscope (SEM) imaging. The results indicated that at least one-third of the samples show high levels of particulate contaminants of metallic origin and, particularly frequently, organic 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.

◆ In which countries is CleanImplant currently active?

With headquarters in Berlin and new bases in New York and Seoul, the CleanImplant Foundation is now operating on three continents. The vital mission is currently supported by awareness campaigns and lectures of ambassadors from 20 countries, including the USA, Canada, Korea, India, UK, Germany, France, Spain, Portugal, Greece, Sweden, Belgium, Netherlands, Italy, Hungary, Romania, Turkey, Morocco, Egypt, and South Africa. Worldwide, more than 170,000 dentists have subscribed to information on dental implants. In just a few years, CleanImplant has become a grassroots movement of dental professionals on Social Media.

◆ Can we find 'sterile but dirty' implants 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 is that some manufacturers are not committed to maintaining a consistent level of quality in subsequent years after market approval or clearance. After identifying significant impurities on implants, the CleanImplant Foundation provides this information to the implant manufacturers concerned. However, in many cases, we receive no answer from these manufacturers regarding product recalls of contaminated batches or information about the elimination of the cause of the contamination.



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

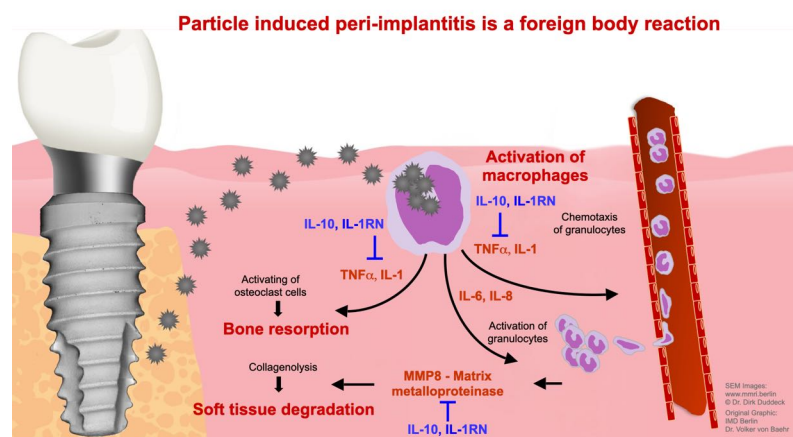
SEM imaging has identified particulate contaminants of metallic origin, including significant levels of chromium, iron, tungsten, nickel, or copper-tin compounds. Very frequently, organic carbonaceous foreign materials identified as polysiloxane, i.e., synthetic polymers, thermoplastics, but also distinct residues of didecyldimethylammonium chloride (DDAC-C10), dodecyl benzenesulfonic acid (DBSA) or erucamide have been found. Notably, DBSA is classified as a "hazardous substance" by the EPA. DDAC-C10 causes disruption of intermolecular interactions and dissociation of lipid bilayers. Neither the pesticide DDAC nor the cell-toxic and surface-active chemical DBSA should be found on sterile-packaged implants, not even in residual quantities. At the risk of sounding cynical: To the best of our knowledge, none of the substances mentioned has proven to be beneficial for the healing process in the human body or for the osseointegration of implants.

◆ 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 peri-implantitis.

In particular, foreign particles with a size of 0.2 to 7.2µm 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, while other samples only show a few particles. Our scientific advisory board developed a quality guideline on this issue by consensus in 2017. The guideline defines a threshold 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. Some manufacturers have since adopted this threshold 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 avoided entirely by optimizing the manufacturing and quality management processes, the wet-chemical cleaning, the transport and packaging methods, and the quality of the packaging itself. The excellent results of the implant systems, which have been awarded the "Trusted Quality Seal" by the CleanImplant Foundation, are confirmation of a 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 accredited and externally audited by the German authority DAkkS. Studies in this kind of setup are highly time-consuming and cost-intensive. However, official accreditation is an indispensable precondition for the reliability, independence, and validity of the analysis results. Even the unpacking of the samples and the SEM analyses are conducted in a Class 5 cleanroom according to DIN EN ISO 14644-1 to prevent any sample contamination caused by the laboratory environment.



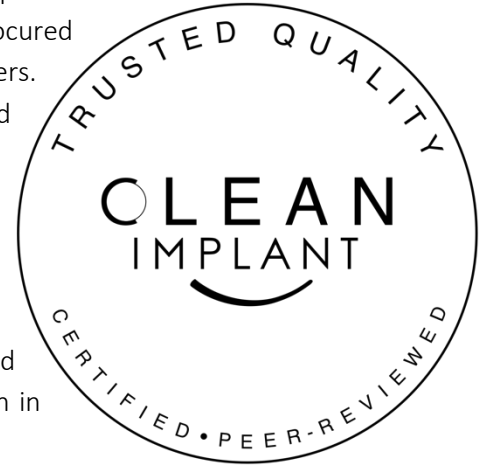
◆ **What about ceramic implants? Are implants made of zirconia 'cleaner' in general than those made of titanium or titanium alloys?**

We investigated this question in a study 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 contamination was revealed, while another system showed partially clean samples and partially contaminated samples. Thus, only two systems consistently showed clean surfaces. Regrettably, these results demonstrate 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, where at least two implant samples are procured anonymously, which means '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 (>95% survival rate for more than two years). The quality seal is awarded only after all these criteria have been met. The CleanImplant Trusted Quality Seal is valid for two years, and then 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 more about the project is to check the website at www.cleanimplant.org. This 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 some systems can lose their 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 application process for the quality mark. In some cases, we may have data from a previous study. Dentists can always send us a sterile implant sample for a quality assessment after they recognize inexplicable early implant failures or peri-implantitis shortly after implant placement.

◆ **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. As a "Certified CleanImplant Dentist", you will receive much more than just the comfort of knowing that you use a medical device that has been proven to be clean. 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 and practice website, etc. to effectively showcase your ethical commitment to the high quality of your dental practice and the well-being of all patients.



◆ **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. The results of our testing have not always been well received by the manufacturers if the product does not meet the cleanliness and thresholds specified in the

consensus-based CleanImplant Guideline. To some extent, the Foundation received threats of legal action if we shared our information on compromised dental implants in public. This is why dentists must register before we pass on analysis data.

We are supported by a wealth of colleagues who recognize and respect the mandate of our mission. In return, we do all we can to support practices committed to clean implants by providing well-founded informational material to promote referrer confidence and patient trust. For the latter, CleanImplant has created an informative 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 colleague and member of the CleanImplant initiative helps to build a stronger voice in the quest for independently tested, reliable, first-class dental implants. It is our responsibility to protect each practitioner and, ultimately, each patient worldwide from dubious medical devices and to facilitate the undoubtedly positive quality-of-life benefits of dental implant treatment.

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



science matters.