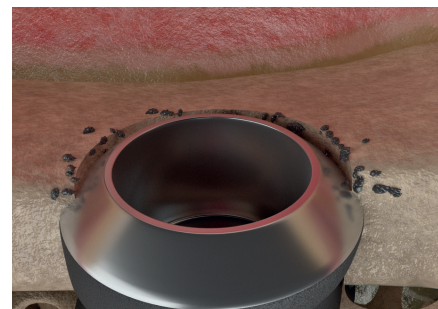
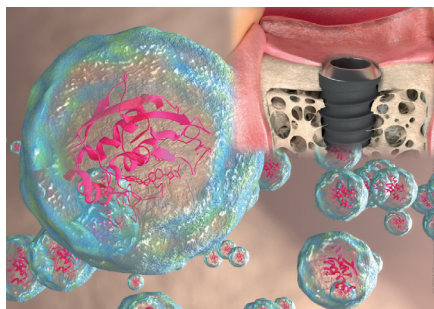


The CleanImplant Foundation: Championing purity in implant dentistry

In a time where dental implant success rates are scrutinised more closely than ever, a revolutionary non-profit organisation has emerged to challenge the fundamental assumptions about implant safety. The CleanImplant Foundation, spearheaded by Dr Dirk Duddeck, is transforming how the dental profession views implant purity through rigorous scientific analysis and an unwavering commitment to patient safety.



THE GENESIS OF A CRITICAL MISSION

Dr Duddeck's journey into implant contamination research began 15 years ago with a shocking discovery that would reshape his understanding of dental implant safety. "I started to analyse dental implants with a scanning electron microscope, and what I found in this early research actually led my blood to run cold because I found tiny particles all over some implants. We could identify these impurities as plastic particles," he recalled.

This revelation challenged a widespread assumption within the dental community. As Dr Duddeck explained: "If you ask dentists around the world, I assume the majority will assume that a sterile product is a clean product. But I had to learn that you can very well sterilise particulate contaminants. And while they are sterile, they are still there."

The distinction between sterile and clean represents a paradigm shift in understanding implant safety. Whilst sterilisation eliminates microbial threats, it does not address particulate contamination that can trigger devastating biological responses.

THE HIDDEN THREAT: CONTAMINATION BEYOND VISIBILITY

The insidious nature of implant contamination lies in its invisibility to conventional examination methods. "You cannot see these particles or thin film contaminants on the



dental implants. Not even with magnification glasses you have in your practice," Dr Duddeck emphasised. This invisibility means that contaminated implants can appear pristine to the naked eye whilst harbouring materials that could compromise long-term success.

The biological implications are profound. When macrophages encounter these foreign particles, they respond with "an expression of pro-inflammatory cytokines like Tumor Necrosis Factor-alpha (TNF- α) and Interleukin-1 beta (IL-1 β). That can lead to a substantial amount of bone loss and soft tissue degradation," Dr Duddeck explained. Crucially, "TNF- α is a potent accelerator in the

osteoclast development pathway resulting in bone resorption around the implant."

Whilst contamination does not guarantee implant failure, Dr Duddeck characterised it as "the beginning of a bad ending" — a factor that can predispose implants to complications and reduce their long-term prognosis.

REVOLUTIONARY TESTING METHODOLOGY

The CleanImplant Foundation's approach to contamination analysis represents a gold standard in scientific rigour. The organisation commissions accredited testing laboratories

to conduct analyses under stringent conditions. "We actually ask the laboratory to unpack the implant sample in an ISO Class 5 cleanroom environment. This is at least 100 times cleaner than the packaging of the implant itself is usually performed," Dr Duddeck detailed.

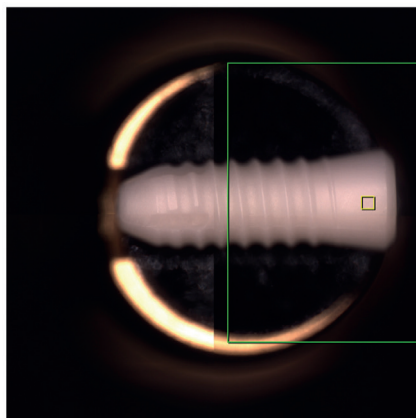
The analytical process involves sophisticated imaging techniques that capture comprehensive data. "We collect up to 400 single SEM frames from one implant, and then, electronically compiled, we receive a SEM mapping image of the complete sample in super-high resolution and we can actually count any material that is not intended to be there."

This meticulous approach allows researchers to identify and quantify various contaminants, from plastic particles and fluorocarbons to foreign metals including "iron-chromium compounds or remnants from the machining process such as tungsten, not known to be favourable for any osseointegration."

ESTABLISHING INDUSTRY STANDARDS

Perhaps most significantly, the CleanImplant Foundation has addressed a critical gap in regulatory standards. "Until today there is no reference, no ISO norm defining acceptable quantities of particular contaminants on any medical device, specifically on dental implants," Dr Duddeck shared.

To remedy this, the foundation developed a comprehensive guideline through collaboration with renowned experts. In 2017, working with a group of eight renowned scientists and practitioners they established contamination

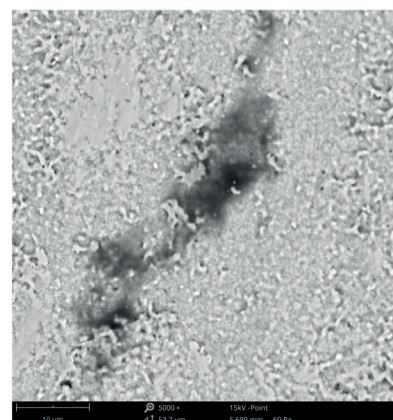


thresholds based on what macrophages encounter at the cellular level.

The resulting consensus paper and de-facto standard accepts "less than 10 particles smaller than 50 micron in a viewing angle of 120°" as reasonable, whilst also addressing chemical contamination. Using advanced analytical techniques, the foundation has identified concerning substances on numerous sterile-packaged implants such as residues of DBSA (Dodecyl benzene sulphonic acid) — "a very aggressive surfactant that actually kills the cells" — and even DDAC, "a quaternary ammonium compound and pesticide that is disrupting intermolecular interactions and the lipid bilayer integrity."

THE TRUSTED QUALITY SEAL

The foundation's certification process extends far beyond single-sample testing. To earn the Trusted Quality seal, manufacturers must undergo comprehensive evaluation combining technical cleanliness with clinical evidence. "We always have to analyse five implants, minimum two from the drawers of colleagues worldwide and maximum three of these samples from the factory itself", ensuring authentic random sampling that prevents manipulation.



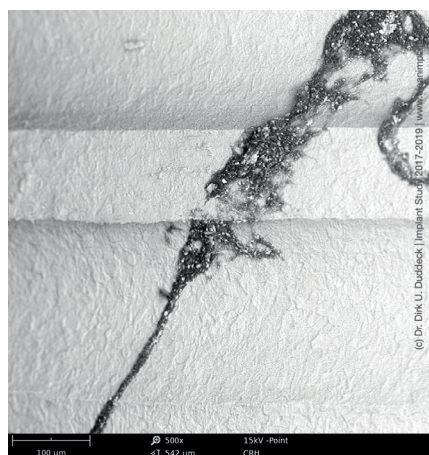
This dual approach requires both technical cleanliness and "substantial information from clinical research publications showing or proving a survival rate of more than 95% over a period of two years or longer". The certification requires renewal every two years, maintaining ongoing quality assurance.

Currently, the foundation has 21 systems awarded from 18 companies, with four systems under peer review, demonstrating the programme's growing acceptance within the industry.

CLINICAL IMPLICATIONS AND PROFESSIONAL RESPONSIBILITY

Research continues to illuminate the relationship between surface purity and implant success. The foundation has invested in collaborative research with the University of Zurich, investigating how contaminants affect cell viability and inflammatory responses in vitro. Preliminary results confirm that "cells don't like plastic".

Of course, biological responses vary based on individual patient factors. "For some patients, the presence of only a few foreign body particles might be too much, while a 20-year-old athlete, for example, might be able



CleanImplant Trusted Quality Seal | Five-step Approach

STEP 1	Neutral sampling of five implants	Batch-spanning random sampling: Three implants are ordered ex factory, and two implants of the same type are purchased via mystery shopping from practices.
STEP 2	Unpacking and scanning under clean room conditions	All five collected samples are carefully unboxed, mounted, and scanned in a clean room environment according to Class 100 FED-STD-209E and Class 5 DIN EN ISO 14644-1.
STEP 3	Externally audited process of analysis	Scanning electron microscope (SEM) imaging and elemental analysis (energy-dispersive X-ray spectroscopy) are performed according to DIN EN ISO/IEC 17025 accreditation process (competence of testing and calibration laboratories). The independent test laboratories are regularly monitored by an accreditation body.
STEP 4	Full-size and high-resolution SEM images	A special full-size, high-resolution SEM image – digitally composed of more than 360 single SEM images at 500x magnification – always shows the implant surface from shoulder to apex.
STEP 5	Peer-review process	Two members of the scientific advisory board independently review the comprehensive analysis report and sufficient clinical documentation or multi-annual Post-Marketing Clinical Follow-Up studies of the analysed implant system showing survival rates of > 95% for the device or device family.

to cope with it thanks to his stronger immune system,” Dr Duddeck observed. This variability underscores the importance of minimising technically avoidable contamination wherever possible.

The foundation’s transparency empowers clinicians to make informed decisions. Their website publishes comprehensive data on certified systems, allowing practitioners to verify product quality independently. When concerning patterns emerge, the foundation provides consultation to help clinicians address quality issues with manufacturers.

A CALL TO PROFESSIONAL ETHICS

Dr Duddeck frames implant selection as

fundamentally an ethical issue for every patient and every dentist. “Any medical and dental treatment is always a promise to the patients that to the best of our knowledge, we are using the best techniques, having the best training on it and using the best material.”

The statistics are sobering: “In the last study, the percentage of significantly contaminated implant systems, no matter what size, no matter what country of origin, is some 25%. Hence, one in four implants show significant avoidable contaminants.”

This reality demands that dentists “should know and not simply believe that an implant system is clean as promised by the industry”

and avoid making decisions based on prices and other cost benefits.

FUTURE DIRECTIONS AND REGULATORY RECOGNITION

The foundation’s influence continues to expand, with a recently published FDA guidance acknowledging the importance of particulate contamination analysis. “The FDA has finally recognised and is focusing now more than before on the cleanliness of dental implants,” Dr Duddeck noted with satisfaction.

This regulatory evolution, combined with growing industry engagement – including manufacturers seeking pre-market consultation – suggests a fundamental shift toward prioritising implant cleanliness. Dr Duddeck believes this focus could significantly impact peri-implantitis rates: “Given that significant manufacturing-related contamination was found on so many new dental implant samples, we believe that this simple fact is the most underestimated cause for peri-implantitis.”

CONCLUSION: A VISION FOR SAFER IMPLANTOLOGY

The CleanImplant Foundation represents more than a testing organisation – it embodies a movement toward transparency, accountability, and patient-centred care in implantology. By establishing scientific standards where none existed and providing practitioners with reliable quality data, the foundation empowers the dental community to make evidence-based decisions that truly serve patients’ best interests.

As Dr Duddeck concludes, “If we see more dental implants in the future that provide a certain batch-spanning cleanliness, I would be happy that a lasting impact of our project. We invite manufacturers to apply for the Trusted Quality seal, showing their customers, that they go the extra mile for highest production quality. On the other side, Dental professionals can participate in this initiative and become a CleanImplant Certified Clinic.” For implant companies and practitioners worldwide, the foundation’s work offers both a valuable resource and a reminder that our patients deserve nothing less than the cleanest, safest implants technology can provide. **DA**

The screenshot shows the CleanImplant website. At the top is a navigation bar with links: HOME, ORGANIZATION, CLEAN IMPLANTS, CERTIFIED & APPROVED, RESEARCH, MEET US, and CONTACT. Below the navigation bar is a hero section with the text "CLEAN IMPLANTS" and "Systems awarded the TRUSTED QUALITY Seal". There are two buttons: "IMPLANT BRANDS" and "CONTACT US". Below the hero section is a list of implant brands: Astra Tech, Bredent, Dentsply Sirona, Fuchs, Hologic, J. & S. Straumann, Komet, Komet Dental, Komet Dental AG, Komet Dental GmbH, Komet Dental Inc., Komet Dental Ltd, Komet Dental Pty Ltd, Komet Dental S.p.A, Komet Dental UK, Komet Dental USA, Komet Dental Vietnam, Komet Dental Thailand, Komet Dental Singapore, Komet Dental Malaysia, Komet Dental Indonesia, Komet Dental Philippines, Komet Dental Australia, Komet Dental New Zealand, Komet Dental South Africa, Komet Dental India, Komet Dental China, Komet Dental Japan, Komet Dental Korea, Komet Dental Taiwan, Komet Dental Hong Kong, Komet Dental Macau, Komet Dental Singapore, Komet Dental Malaysia, Komet Dental Indonesia, Komet Dental Philippines, Komet Dental Australia, Komet Dental New Zealand, Komet Dental South Africa, Komet Dental India, Komet Dental China, Komet Dental Japan, Komet Dental Korea, Komet Dental Taiwan, Komet Dental Hong Kong, Komet Dental Macau.

Below the list of brands is a section titled "TRUSTED QUALITY SEAL" with a circular logo. The logo contains the text "TRUSTED QUALITY", "CLEAN IMPLANT", and "CERTIFIED • PEER-REVIEWED". To the right of the logo is a sidebar with links: CONTACT, DONATION, and NEWSLETTER.

At the bottom left is a sidebar with the text "WWW.CLEANIMPLANT.ORG" and a button "IMPLANT BRANDS".