



Combined SEM image of the surface of two implants, each removed shortly before from sterile packaging. Full-size resolution SEM image mapping, Backscattered electron imaging 500x.

# Your implant choice matters

In 2017, the CleanImplant Foundation, in conjunction with a cohort of world-renowned scientists, published the first consensus paper to establish a limit on the amount of particulate organic and metal residue from manufacturing and packaging to define a quality assurance standard of cleanliness for dental implants. Based in Berlin, Germany, this non-profit organisation is dedicated to ensuring implant surfaces are contaminant free, as medical devices in contact with sterile body tissues are considered critical items.

The CleanImplant Foundation now has more than 120,000 subscribers on its social media platforms. One thousand clinicians from around the world visit [www.cleanimplant.org](http://www.cleanimplant.org) monthly to review the quality assurance monitoring reported by the foundation's studies. On 1 September 2022, the CleanImplant Foundation opened an office in New York City. Its mandate: to bring best practices in implant manufacture to the profession and the industry in North America.

## Alarming study results and clinical consequences

In a recent quality assessment study performed in an accredited testing laboratory in collaboration with the Charité–University in Berlin, more than 100 different sterile-packaged ceramic and titanium implants from 80 implant manufacturers were analysed for surface contaminants caused by flaws in the manufacturing and packaging processes. Over one-third of the implant samples, removed from their package and examined by scanning electron microscopy in cleanroom conditions, showed unacceptable quantities of carbonaceous particles. These impurities, if detached from the implant's surface during surgical placement, lead to the release of pro-inflammatory cytokines after phagocytosis, followed by the expression of matrix metalloproteinase and the differentiation of osteoclast precursors into mature osteoclasts. The result is an expanding zone of soft tissue damage, inflammation, and peri-implant bone resorption leaving rough areas of the implant surface exposed to bacterial colonisation.

## CleanImplant's quality seal provides clinical and legal safety

The CleanImplant Foundation has introduced a globally recognised "Trusted Quality" seal to differentiate those manufacturers who have deficits in the quality control of their products from those who don't. Receiving this seal verifies that the recipient manufacturer has instituted production technologies to eliminate processing pollution of their implant systems. Five randomly selected implant samples of the same type from different batches are used to formulate the quality analysis data. Two members of CleanImplant's Scientific Advisory Board independently review the data from the analysis to ensure the results meet the consensus-based quality criteria for the "Trusted Quality" seal of approval. In addition, the implant system's clinical documentation must show a multi-annual survival rate of no less than 95 per cent. The Scientific Advisory Board responsible for the peer-reviewed process includes Prof. Dr Tomas Albrektsson, Prof. Dr Ann Wennerberg, Prof. Dr Florian Beuer, Prof. Jaafar Mouhyi, Prof. Hugo de Bruyn, Dr Luigi Cannulo, and Dr Michael Norton, past President of the Academy of Osseointegration. Their signatures on the CleanImplant "Trusted Quality" seal guarantee an unbiased quality assessment.

For the patient, surface contaminants causing an uncontrolled foreign body reaction resulting in peri-implantitis, bone loss, and potentially implant failure is a violation of trust. A compromised clinical outcome from a readily resolvable situation breaches the standard of care and duty of care for our patients. Clinicians who unknowingly use surface-contaminated implants run the risk of litigation. A readily identifiable x-factor that nullifies 100 per cent success is inconsistent with the mandate of excellence demanded of the profession and the industry.

More information



### Contact address

**Dr Dirk U. Duddeck**

Founder and Director of the  
CleanImplant Foundation  
[duddeck@cleanimplant.org](mailto:duddeck@cleanimplant.org)