Peri-implantitis prevention starts with the choice of a clean implant

Two years ago, in *implants 4/2022*, we raised an important question: how clean must sterile-packaged implants be to meet the high expectations of dental professionals who entrust these medical devices to their patients? At that time, extensive quality assessments conducted by the CleanImplant Foundation revealed troubling impurities on the surfaces of new, sterile-packaged implants, identified through independent laboratory testing. It was reasonable to expect that the manufacturers involved would address these issues promptly and ensure that their medical devices meet the highest standards of cleanliness. Regrettably, even after two years, we cannot give the "all-clear". Here's an update to where things stand now.

Drs Dirk U. Duddeck and Dana Adyani-Fard, Germany

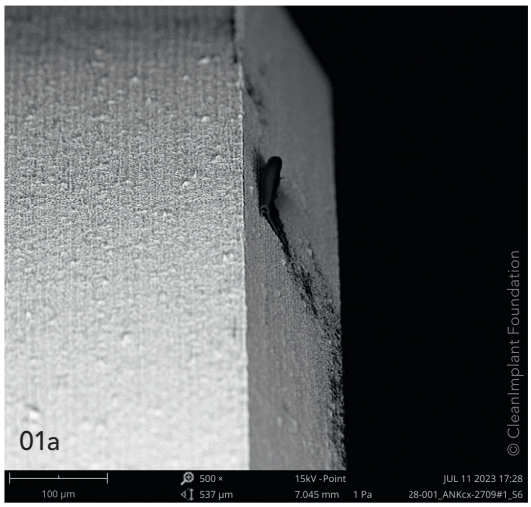
For decades, dental implants have been the gold standard for replacing missing teeth, whether it's a single tooth or an entire dental arch. However, alongside this success, experts have noted a rise in cases of peri-implantitis and the associated peri-implant bone loss.

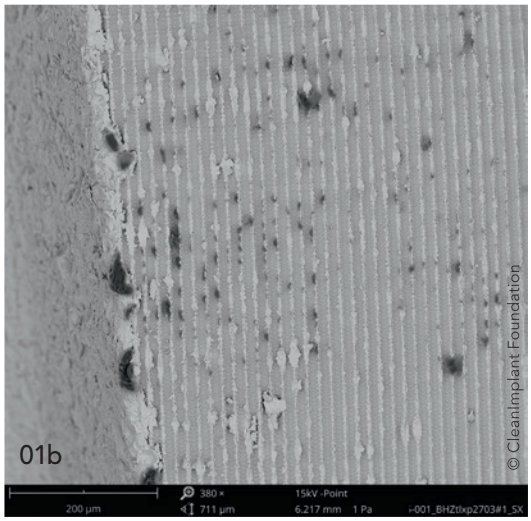
Peri-implantitis is a pathological condition affecting the bone surrounding dental implants, characterised by inflammation of the adjacent soft and hard tissues, leading to progressive bone loss.[1,2] If not diagnosed and treated promptly, this condition can result in the loss of the implant. Unfortunately, the clinical and histological factors that contribute to the progression from peri-implant mucositis to peri-implantitis are still not completely understood.[3] Clinically, sites affected by peri-implantitis often exhibit more extensive inflammatory lesions compared to periodontal sites around natural teeth.

Sterile yet contaminated implants

A vastly underestimated risk factor that needs to be better understood has recently gained attention: the manufacturing and packaging processes of dental implants. These largely overlooked factors can significantly impact the short- and long-term success of implants placed intraorally. The cleanliness of the implant surface is crucial, particularly because it directly affects the surrounding bone during placement and the early phases of osseointegration.[4]

It is imperative that every stage of the manufacturing process is meticulously controlled to ensure that the final





01a + b SEM 500x (a) and SEM 380x (b). Significant impurities located at the shoulders of two sterile packaged titanium implants.

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product is not only sterile but also free from any surface contaminants that could provoke an immunological response. While the implant may be sterile when it is removed from its packaging, there is a possibility of thin film contaminants, as well as plastic or metallic particles, remaining on the surface—residuals of the complex and intricate manufacturing process.[5]

Methods of analysis

Contaminants, whether in the form of particles or thin layers on the implant surface, can be accurately identified through a combination of advanced analysis techniques. In a particle-free clean room environment, the precise location of these impurities is determined using material contrast imaging in a scanning electron microscope (SEM). To further characterise the impurities, energy-dispersive X-ray spectroscopy (EDS) provides initial insights into their elemental composition. The exact chemical nature of these contaminants is then identified through time-of-flight secondary ion mass spectrometry (ToF-SIMS). The CleanImplant Foundation ensures that all these analyses are conducted exclusively in accredited testing laboratories, adhering to the stringent standards of DIN EN ISO/IEC 17025:2018, guaranteeing precision and objectivity in every analysis.

Results

In quality assessment studies conducted by the CleanImplant Foundation in collaboration with Charité–Universitätsmedizin Berlin and the Sahlgrenska Academy in Gothenburg, Sweden, significant impurities were discovered on new, sterile-packaged dental implants. These impurities affected both titanium and zirconia implants.[5,6] On average, one in three analysed implant systems exhibited notable factory-related contamination on the implant surface immediately after removal from the packaging. The contaminants identified included organic particles from the manufacturing process, metallic particles—such as iron-chromium compounds, nickel, or tungsten—resulting from milling or surface treatments, and plastic residues from handling and packaging. The areas most frequently contaminated were the shoulder region of the implant platform (Figs. 1a & b) and the implant threads (Figs. 2a & b). In some instances, analyses revealed not only isolated impurities but also larger areas of the implant surface that had either been inadequately cleaned during production or contaminated during packaging.

At high magnification, SEM images showed carbonaceous particles as black spots, alongside thermoplastic materials, synthetic polymers, and

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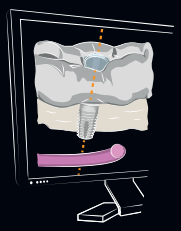

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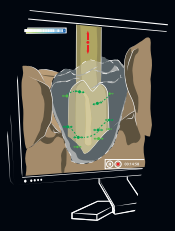

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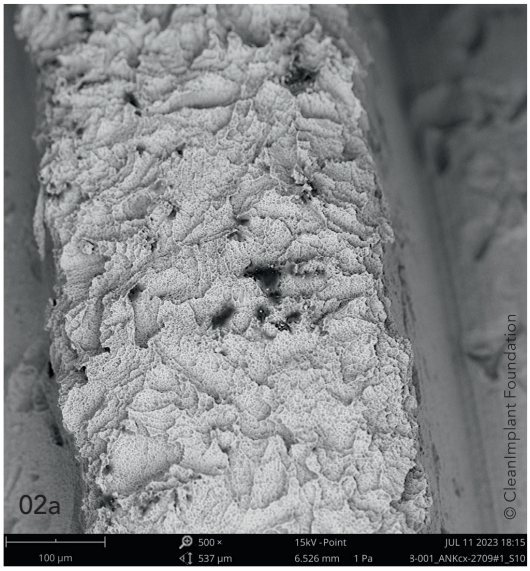

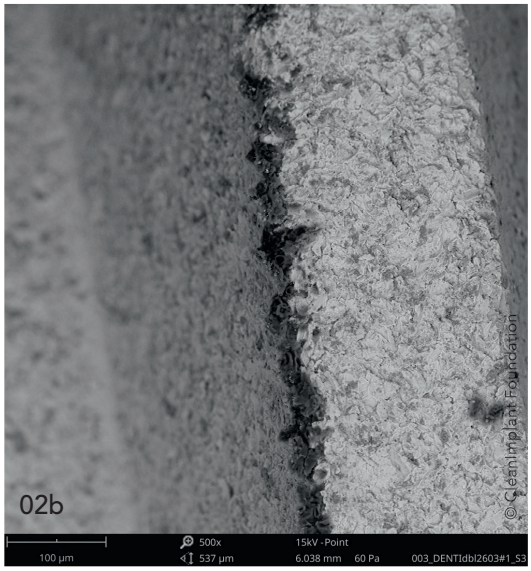

02a + b
Major carbon-based contamination of titanium implant threads straight after unpacking, shown at SEM 500x.

"As analyses by independent laboratories show, cell-toxic impurities can be found not only in some titanium implants but also in those made of ceramic. This makes choosing the right system even more important."

Dr Dirk U. Duddeck, Founder & CEO of CleanImplant Foundation

polysiloxanes on sterile implant surfaces. Both titanium implants (Figs. 1a–2b) and zirconia (ceramic) implants from various manufacturers were found to be affected by these contaminants.

Certain ceramic implants were found to have significant deposits of polysiloxane, which could be traced back to the packaging material (Fig. 3). Another potential threat to successful healing (osseointegration) after implantation comes from thin-layer residues of highly aggressive, cytotoxic cleaning agents, such as dodecylbenzene sulphonic acid (DBSA)[7] or the pesticide didecyldimethylammonium chloride (DDAC-C10)[8]. This quaternary ammonium compound was identified using ToF-SIMS on the surface of a sterile-packaged ceramic implant (Figs. 3 & 4).

Alarmingly, all implants analysed and found to contain contaminants carried the CE mark or had received clearance from the US Food and Drug Administration. This highlights a critical concern: even sterile-packaged medical devices can pose risks to patients if contaminated. Such contamination can lead to implant failure, often associated with peri-implantitis, as a result of inflammatory reactions triggered by these impurities.

However, it is important to note that many implants examined under SEM revealed flawless surfaces, completely free of inorganic, organic, and plastic particles (Fig. 5). This demonstrates that contamination is not only a significant concern but also one that is technically preventable.

Clinical effects

Even at low concentrations, thin-film contaminants—such as those containing DBSA or quaternary ammonium compounds—are cytotoxic to cells and impede rather than facilitate implant healing. DBSA, an aggressive surfactant, is categorised as a "hazardous substance" by the EPA. Similarly, the biocide/pesticide DDAC-C10 disrupts intermolecular interactions and destroys cell membranes.[9]

Carbon-containing organic particles that persist on the implant's surface during manufacturing or plastics from packaging can provoke an immune response in the form of a foreign body reaction (Fig. 6). During implant insertion, particles that detach from the surface are engulfed by macrophages through phagocytosis. This process triggers a cascade of proinflammatory cytokines, including TNF-α, interleukin(IL)-1β, and IL-6. These cytokines promote the differentiation of osteoclast precursors into mature osteoclasts, which can enhance osteoclastic activity and result in peri-implant bone resorption.[10]

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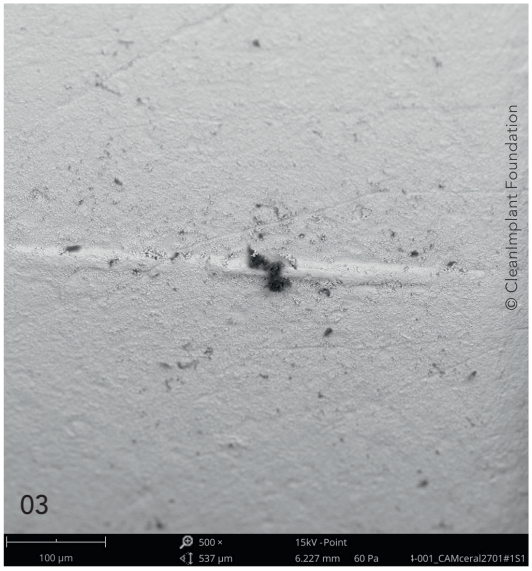

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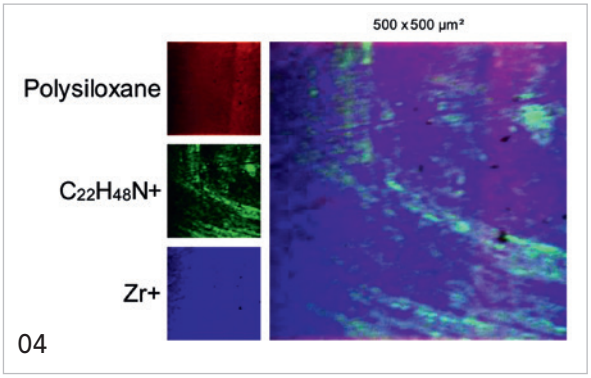
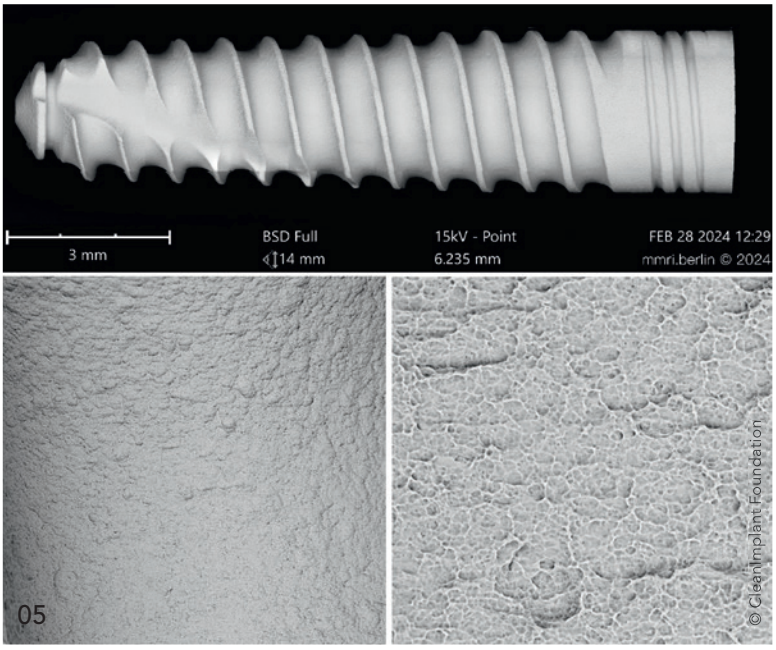
SEM image at 1,000× revealing significant plastic material and thin-film contamination on a sterile-packaged ceramic implant.



04
ToF-SIMS visualisation of polysiloxane (red) and the quaternary ammonium compound DDAC ($C_{22}H_{48}N+$; green) on the surface of the ceramic implant shown in Figure 3 (with permission of Tascon GmbH, Münster, Germany).



05
SEM mapping image of the whole implant after removal from the manufacturer's packaging (top); SEM magnification 500x (left) and 2,500x (right), demonstrating a clean surface free of any organic or metallic particles or other debris.

Particularly, foreign particles ranging from 0.2 to 7.2 µm in size are known to be highly proinflammatory.[11–13] The increased expression of Matrix Metalloproteinase-8 (MMP-8) exacerbates soft-tissue damage and inflammation, which can progressively affect the adjacent bone.[10] Consequently, the rough implant threads become exposed to the oral environment, leading to bacterial colonisation, often described as the "beginning of a bad ending" and accelerating peri-implant disease. This progression often culminates in further crestal bone loss and, potentially, implant failure.

Discussion

The immunological response to contaminants varies among patients. While some may exhibit minimal or no reactions, others may experience severe responses. The growing recognition of peri-implant disease, facilitated by advances in clinical understanding, indicates that contaminants can provoke immunological reactions in a significant number of patients.

Contaminants on an implant's surface signify a compromised implant. Addressing this issue is not complex: manufacturers have the capability to prevent such contamination, and it is their responsibility to do so. There is no justification for failing in this regard; the well-being of patients and the integrity of scientific standards demand the highest quality control. As dental implants become more widely used, it is imperative to monitor patients closely throughout the lifespan of their restorations. Early detection and intervention for peri-implant mucositis are crucial for preserving the surrounding bone, halting the progression of peri-implantitis, and enhancing long-term clinical outcomes.

However, preventing undesirable foreign body reactions and early-stage peri-implantitis begins with selecting an implant system that is rigorously proven to be clean. Sterility alone does not ensure safety, as contaminants—regardless of being labelled as "sterile dirt"—can still trigger immunological responses.

Conclusion

The quality of the implant surface and the cleanliness of the implant are crucial factors in peri-implant diseases, though they remain significantly underestimated. Whether the implants are made of titanium or ceramic, it is essential that the implant's surface is free from foreign particles after removal from sterile packaging. Particulate and thin-film contaminants are often invisible to the naked eye, even under magnification with magnifying glasses or microscopes.

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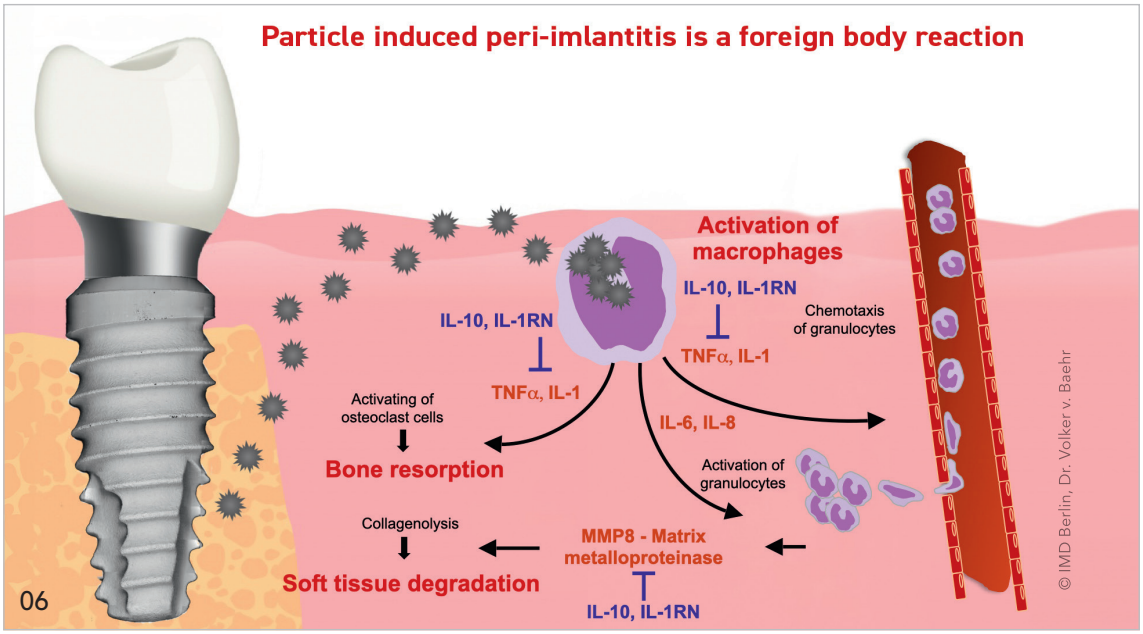

06
Impurities detach during implant insertion from the surface and induce a storm of pro-inflammatory cytokines leading to bone resorption and soft-tissue degradation.

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In most cases of peri-implantitis or implant failure, clinicians may attribute the issue solely to patient factors. However, the results from quality assessments of sterile-packaged implants suggest that the medical device itself should also be considered a potential source of inflammatory reactions and a possible trigger for peri-implantitis during the placement process.[5]

For the past eight years, the CleanImplant Foundation has collaborated with an expanding network of industry partners to ensure particle-free implant production. It has established the "Trusted Quality" seal as a mark of assurance for implants that have been rigorously tested and deemed clean.

The foundation acts as an intermediary, bridging the legitimate expectations of patients and providers with the quality assurance processes of medical device manufacturers. Through its initiatives, the foundation has frequently identified previously unrecognised deficiencies in manufacturing and packaging, leading to significant and lasting improvements in production protocols. The shared commitment to the fundamental medical ethics principle of *primum non nocere* (first do no harm) highlights the collaborative nature of the Foundation's work with its partners and manufacturers. Moreover, understanding the implications of residual biocides, such as DDAC, and cytotoxic, surface-active agents like DBSA on sterile-packaged implants intended for patient use is critical to ensuring product safety and efficacy.

Dentists interested in supporting the CleanImplant Foundation can become members through the website. This non-profit organisation provides details on the benefits of membership and showcases numerous implants that have received the prestigious seal of quality, the "Trusted Quality" mark, after thorough testing. The criteria for ensuring that implants are largely free of particles were established in a consensus paper published in 2017.[14]

The decision to award this quality mark is made by the renowned scientists on the Foundation's Scientific Advisory Board through a rigorous peer review process. To uphold the Trusted Quality seal, a random sample of five implants from each system undergoes comprehensive, independent analysis every two years.

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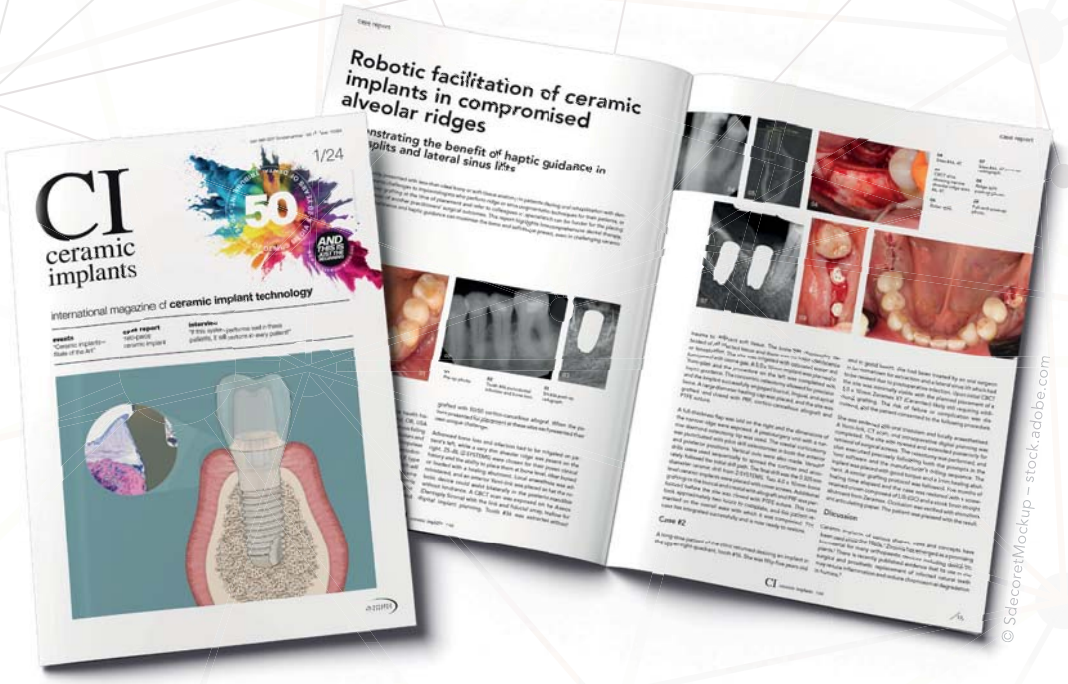

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