CleanImplant Foundation

Advancing implant safety and quality: The role of CleanImplant in a changing regulatory landscape

Dental implantology has seen remarkable advancements over the past decades, improving patient outcomes and expanding treatment possibilities. However, with innovation comes the critical responsibility of ensuring implant safety, biocompatibility, and quality. Regulatory frameworks such as the US Food and Drug Administration (FDA) and the European Medical Device Regulation (MDR) establish stringent requirements for implant manufacturers, influencing how implants are designed, tested, and marketed. In this landscape, CleanImplant has emerged as a vital mediator, bridging the gap between patient care, scientific research, and industry collaboration.

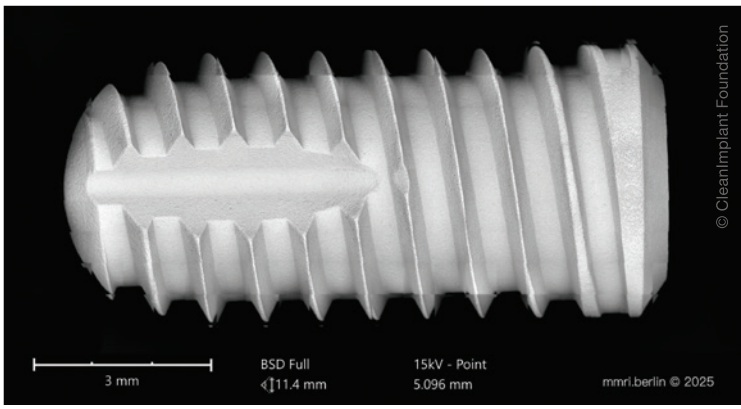

Fig. 1: Example of a particle-free dental implant in the scanning electron microscope (high-resolution SEM mapping image electronically compiled of up to 400 single SEM frames).

The regulatory landscape for dental implants

The FDA's regulatory process for medical devices, including dental implants, involves various submission pathways, with the 510(k) premarket notification being one of the most common. The recent updates to the FDA 510(k) guidance now recommend advanced analytical techniques such as scanning electron microscopy (SEM) and energy-dispersive spectroscopy (EDS) to evaluate particulate contamination on implant surfaces. These measures aim to enhance patient safety by ensuring higher purity standards and reducing the risk of adverse immune responses or implant failure.

In parallel, the European MDR has imposed stricter controls on medical devices, including more comprehensive clinical evidence requirements, increased post-market surveillance, and higher accountability for manufacturers. As a result, manufacturers must now provide more extensive documentation and independent assessments to demonstrate compliance with safety and performance standards.

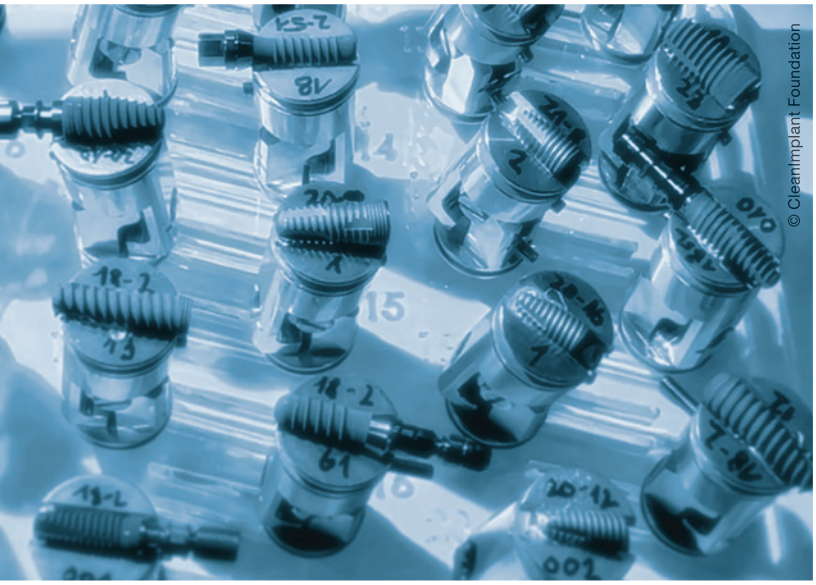

Fig. 2: Implant samples mounted for SEM inspection (medical materials research institute).

CleanImplant: a catalyst for transparency and quality assurance

Recognising the growing concerns about factory-related implant contamination and quality inconsistencies, the CleanImplant Foundation has taken a proactive role in independently assessing and verifying implant cleanliness. By conducting rigorous scientific evaluations using state-of-the-art methodologies, CleanImplant provides objective, transparent data to ensure that dental professionals and patients can make informed decisions about implant selection. Commissioned by the CleanImplant Foundation, quality assessment studies on hundreds of dental implant systems used exactly the analytical techniques that the FDA now recommends identifying impurities.

Particulate contaminants as found repeatedly on new, sterile packaged implants, can trigger immune responses leading to peri-implantitis, soft- and hard-tissue degradation and, ultimately, implant failure. Collaborative research with institutions such as the University of Zurich further highlights the impact of surface contamination on cell viability, reinforcing the need for stringent quality standards.

A collaborative approach for better patient care

Beyond its role as an independent institution for dental implant quality assurance, the non-profit organisation has evolved into a platform that unites stakeholders across the dental implant industry. The initiative fosters collaboration between manufacturers, researchers, and clinicians, ensuring that advancements in implant technology align with patient safety and regulatory expectations. With the introduction of the new platform CleanImplant 4 Me, the Directory for patients serves as a bridge, connecting certified clinics with individuals seeking reliable, certified implant solutions. By creating a network of trusted providers, CleanImplant enhances the accessibility of superior implant treatments while encouraging manufacturers to meet elevated quality benchmarks.

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Furthermore, industry support for CleanImplant has grown significantly over the past years, reflecting a shared commitment to transparency and patient well-being. As regulatory requirements become increasingly stringent, manufacturers partnering with CleanImplant can proactively reinforce their credibility and commitment to excellence.
The dental implant industry is undergoing a significant transformation, driven by regulatory changes, scientific advancements,

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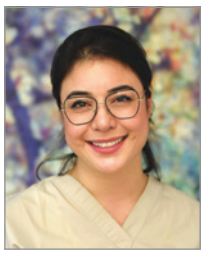
and growing patient awareness. At the same time, we are navigating an era of global uncertainty, where socioeconomic shifts and evolving political landscapes demand greater transparency and accountability. In such times, credibility and collaboration become essential fundaments for progress. CleanImplant plays a crucial role in fostering this trust by providing independent assessments, facilitating industry dialogue, and advocating for higher standards in patient care by reinforcing transparency and scientific integrity—verified & peer-reviewed.
More information is available on the project’s website www.cleanimplant.org or meet the experts during the IDS 2025 in Cologne (Hall 4.1, Booth C080/D081).

References

Dr Dana Adyani-Fard

contact



Dr Dana Adyani-Fard
Berlin, Germany
info@cleanimplant.org
www.cleanimplant.org

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