

# IMPLANT STUDY 2024-2025

Global Quality Assessment of Dental Implants by SEM+EDS

According to new FDA guidance & recommendations  
on performance criteria for the safety of dental implants\*



## STUDY PROTOCOL

and Details for Study Participants

### Scientific Advisory Board:

Prof. Tomas Albrektsson (Gothenburg University, Sweden)  
Prof. Florian Beuer (Charité University, Berlin, Germany)  
Prof. Hugo de Bruyn (ACTA University of Amsterdam, Netherlands)  
Dr. Luigi Canullo (Rome, Italy)  
Dr. Dirk U. Duddeck (Charité University, Berlin, Germany)  
Dr. Scott Ganz (Fort Lee, New Jersey USA)  
Prof. Jaafar Mouhyi (University of Agadir, Morocco)  
Dr Michael R. Norton (London, United Kingdom)  
Prof. Ann Wennerberg (Gothenburg University, Sweden)

### Principal Investigator

Dr. med. dent. Dirk U. Duddeck  
Guest Researcher at Charité  
University Medicine Berlin

### Contact + Study Coordination

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### Technical Implementation

medical materials research institute berlin  
Max-Planck-Str. 3, 12489 Berlin-Adlershof  
(DIN EN ISO/IEC 17025:2018 accredited)

CLEAN IMPLANT FOUNDATION

Berlin New York Seoul



**RESEARCH  
MADE IN  
GERMANY**

## background and aim

Over the past decade, more than 400 implants have been analyzed on behalf of the CleanImplant Foundation using the same protocol of SEM analysis. Conclusive evidence derived from extensive clinical studies corroborates the suspicion that residues on sterile-packaged implants, in particular organic particles originating in the production or packaging processes, play a significant role in incomplete osseointegration or early bone loss. These studies have shown that neither the CE mark nor the US FDA clearance is a reliable indicator for the cleanliness of sterile dental implant surfaces.

However, suppliers of high-quality implants may find it increasingly difficult to assert themselves in the highly competitive market environment. The CleanImplant Project aims to promote these quality-oriented companies. With this Implant Study 2024-2025, CleanImplant conducts a new global quality assessment of dental implants, providing an overview of the production quality of all major players in this market.

Considering your market presence and your unwavering commitment to achieving the best clinical results, the CleanImplant Scientific Advisory Board has selected your implant system for the current sample group.

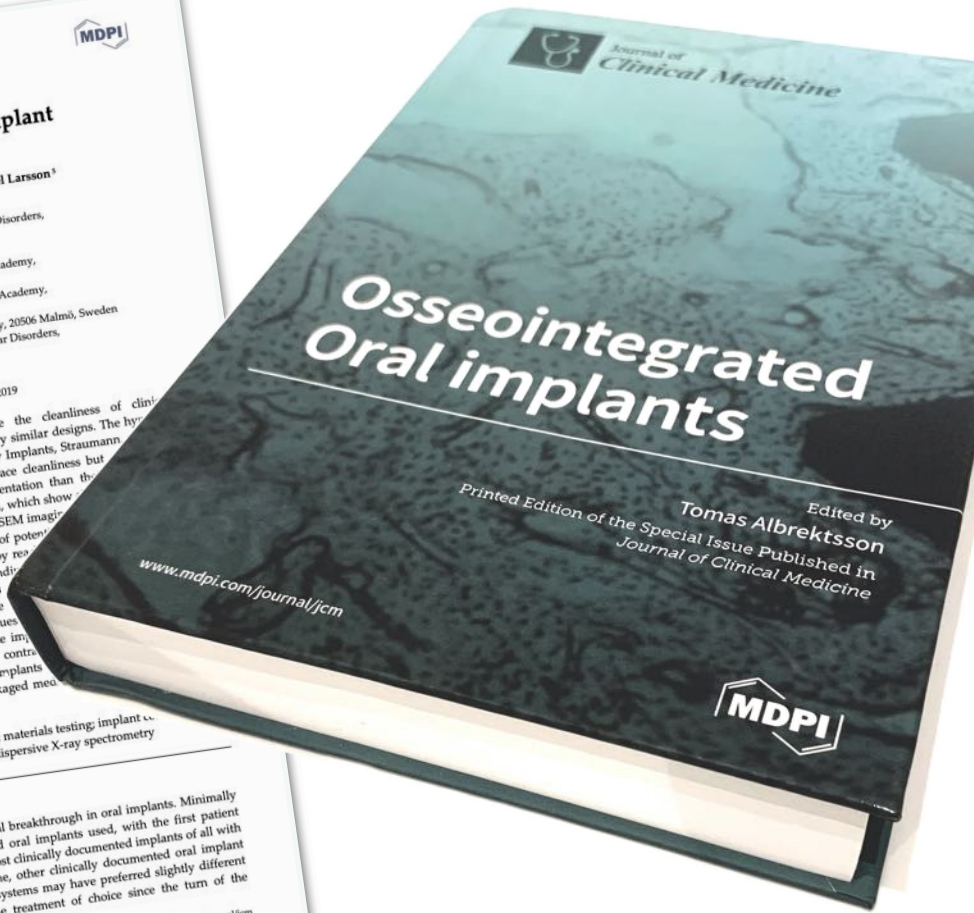
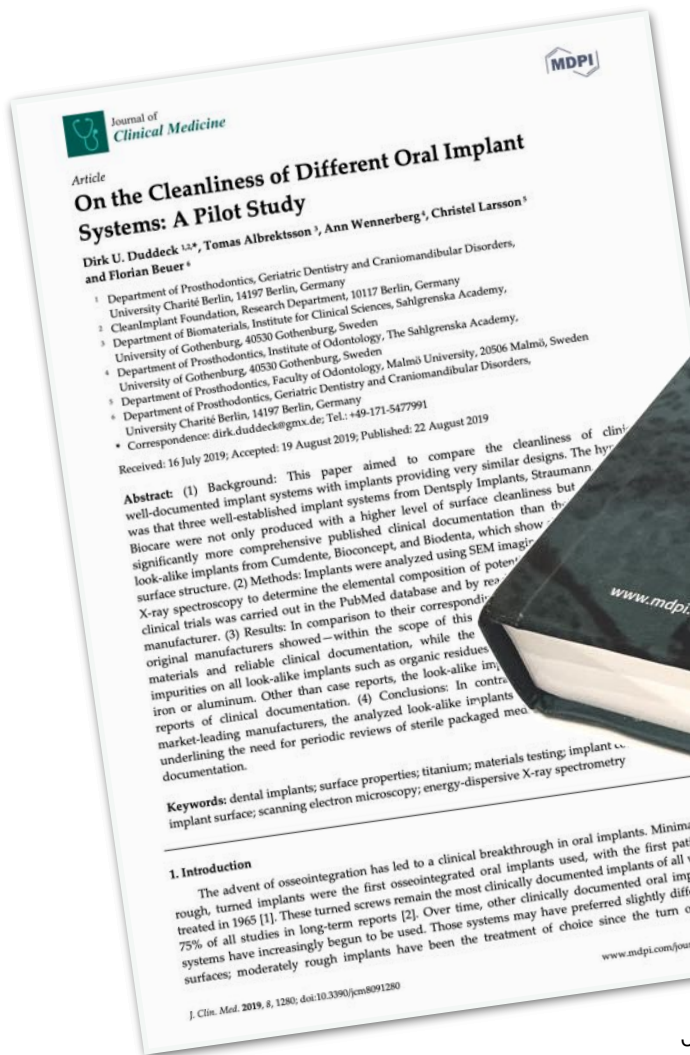
The authors of this study publish results in high-ranked peer-reviewed journals. Additionally, excerpts will be available in high-circulation scientific journals, presented at various congresses worldwide and through social media, supporting dentists on a previously unreached global scale in orientation when deciding on a clean implant system. After all, the excellent results of this independent comparative study may serve as a powerful message for worldwide advertising purposes.

## who is conducting this study?

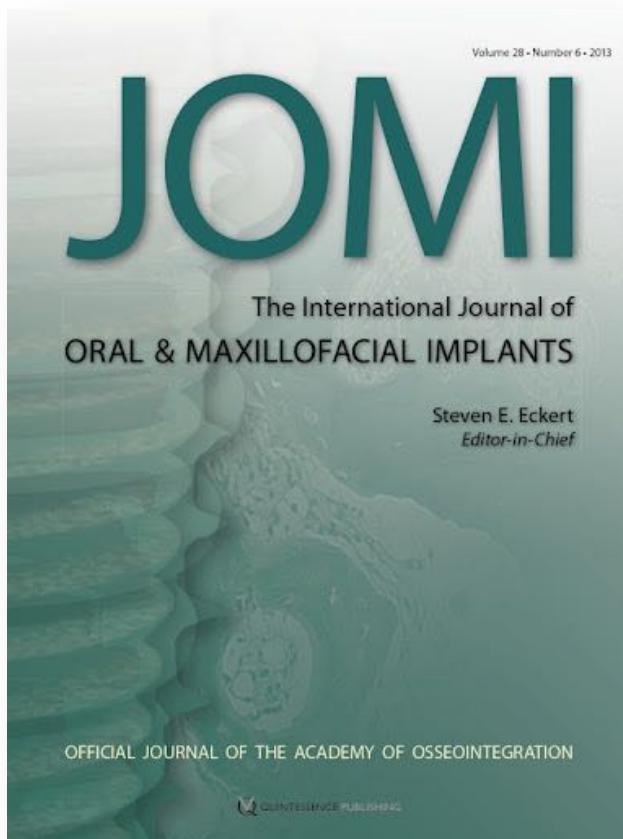
This worldwide quality assessment study on dental implants is being conducted by the CleanImplant Foundation in cooperation with Charité University Medicine, Berlin. The CleanImplant Foundation was established as a non-profit organization in 2016 with the aim of providing unbiased information and guidance for dental practitioners on endosseous packaged dental implants sold worldwide.

An international Scientific Advisory Board of renowned experts supports this study and all scientific work of the CleanImplant Foundation:

- Professor Tomas Albrektsson  
Department of Biomaterials; University of Gothenburg, Sweden
- Professor Hugo de Bruyn; ACTA University, Amsterdam, Netherlands
- Professor Florian Beuer; Charité University Medicine, Berlin, Germany
- Dr. Luigi Canullo; Rome, Italy
- Dr. Scott Ganz; Fort Lee, New Jersey, USA
- Professor Jaafar Mouhyi; International University of Agadir, Morocco
- Dr. Michael R. Norton, President of the Academy of Osseointegration 2017-2018; London, UK
- Professor Ann Wennerberg  
(Sahlgrenska Academy, Faculty of Medicine at the University of Gothenburg, Sweden).



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## how to benefit from participating

The CleanImplant Foundation's vision has been to raise awareness about the different levels of surface cleanliness of implants available in the market. By positioning companies adhering to a standard of duty and care, they are acknowledged as pursuing a path to excellence for end-users and patients.

Those manufacturers with implant systems selected in this phase of CleanImplant's worldwide quality assessment study have several options for cooperation and support to choose from.

The extent of any collaboration will not affect the results of the technical analysis conducted by independent and accredited testing laboratories.

The Foundation appreciates participants actively supporting the research funding, thus expediting the completion of the study. All active participants receive a comprehensive technical report of SEM/EDS analysis according to ISO 22309 of their respective samples, including high-resolution images and detailed reports ahead of schedule and prior to publication. All high-resolution SEM images and data provided can be used for commercial purposes.

## performed along the lines of new FDA performance criteria

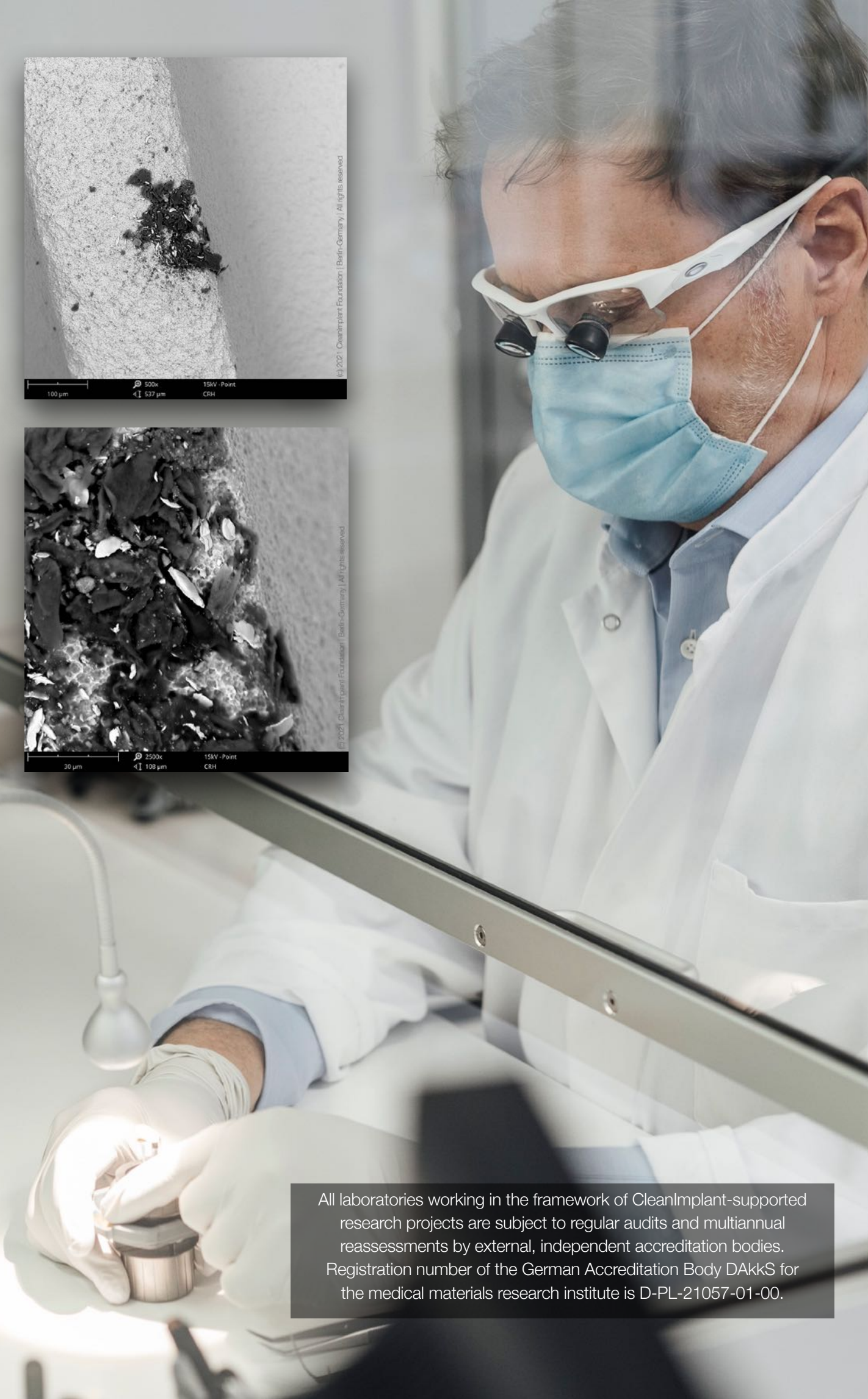
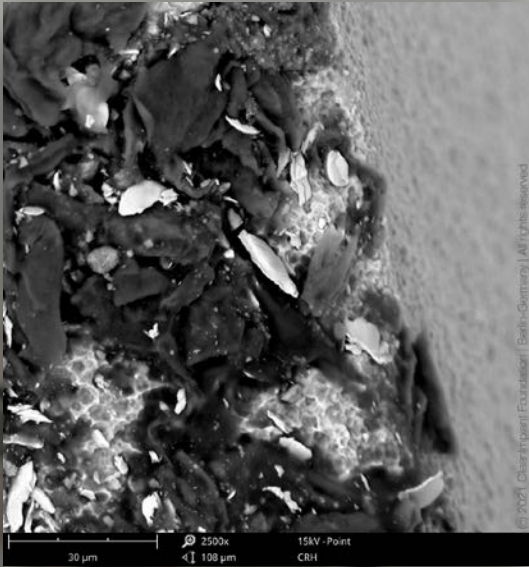
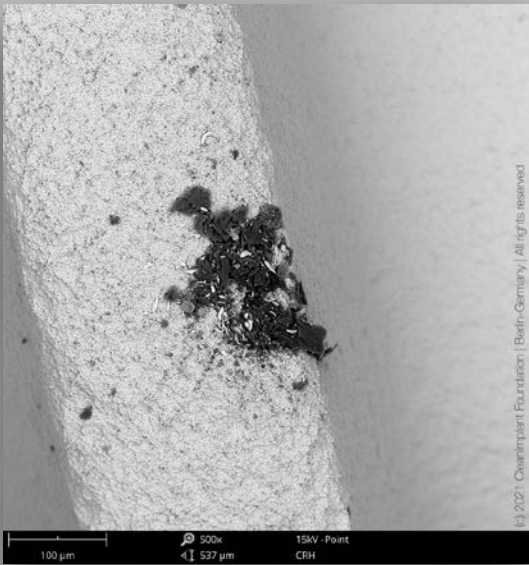
On October 15, 2024, the FDA released **new guidance for the dental industry\***. FDA's "Performance criteria for the safety of Endosseous Dental Implants", demand a "**Surface Cleanliness Analysis**" providing "analysis of the surface of the implant body, using scanning electron microscope (SEM) and energy dispersive X-ray spectroscopy (EDS), that allows for magnified images of the implant surface and determination of the surface elemental composition. The magnified images should be of sufficient magnification to show the entire representative surface of the implant." We are grateful that the **FDA acknowledges the comprehensive testing procedure** developed by our group already in 2016 for a long series of quality assessment studies.

\*) <https://www.fda.gov/media/182616/download>

Please feel free to contact us for more information on supporting the Foundation's work, covering the technical and organizational costs associated with conducting this large-scale study, and how to become an active collaborator in shaping safer implantology. Terms and conditions for active participation can be found on the feedback page at the end of this brochure. A sample study contract is available upon request.

## key advantages for active participants

- Complimentary **15-30 pages testing report according to FDA recommendations**, provided by an officially accredited testing laboratory with **detailed data** directly after performing the technical analysis and before publication of the test results
- Collection of **SEM images in extremely high resolution for marketing activities**
- **Validation of your internal quality management** with an unbiased, independent SEM/EDS analysis from an external source accredited according to DIN EN ISO/IEC 17025:2018
- Comprehensive **500+ pages final report of the Implant Study 2024–2025** with data on all dental implants examined after study completion (PDF)
- Optional 500+ pages final report of the Implant Study 2021–2023



All laboratories working in the framework of CleanImplant-supported research projects are subject to regular audits and multiannual reassessments by external, independent accreditation bodies. Registration number of the German Accreditation Body DAkkS for the medical materials research institute is D-PL-21057-01-00.

# study protocol

## Highest Standards for the Implant Analysis

All collected samples are subjected to the same quality analysis protocol performed by the medical materials research institute, Berlin-Adlershof, Germany. In order to provide a setup that complies with the highest standards of scientific research, this independent laboratory is officially accredited by the German accreditation body DAkkS according to

- DIN EN ISO/IEC 17025:2018 (general requirements for the competence of testing and calibration laboratories). This includes the quality standard according to
- DIN EN ISO 9001:2015 and the implementation of international standards for microbeam analysis scanning electron microscopy, such as
- ISO 16700:2016 (Guidelines for calibrating image magnification)
- ISO 14595:2014 (Guidelines for the specification of certified reference materials)
- ISO 22309:2015 (Quantitative analysis using energy-dispersive spectrometry EDS).

## ISO Class 5 Cleanroom Environment DIN EN ISO 14644-1

The unpacking of the implants themselves, the fixation of the samples on a specimen holder, and even the imaging process and elemental analysis by the scanning electron microscope take place in a particle-free environment that meets class 100 cleanroom requirements according to United States Federal Standard (US FS) 209 and ISO class 5 according to DIN EN ISO 14644-1.

## Scanning Electron Microscopes

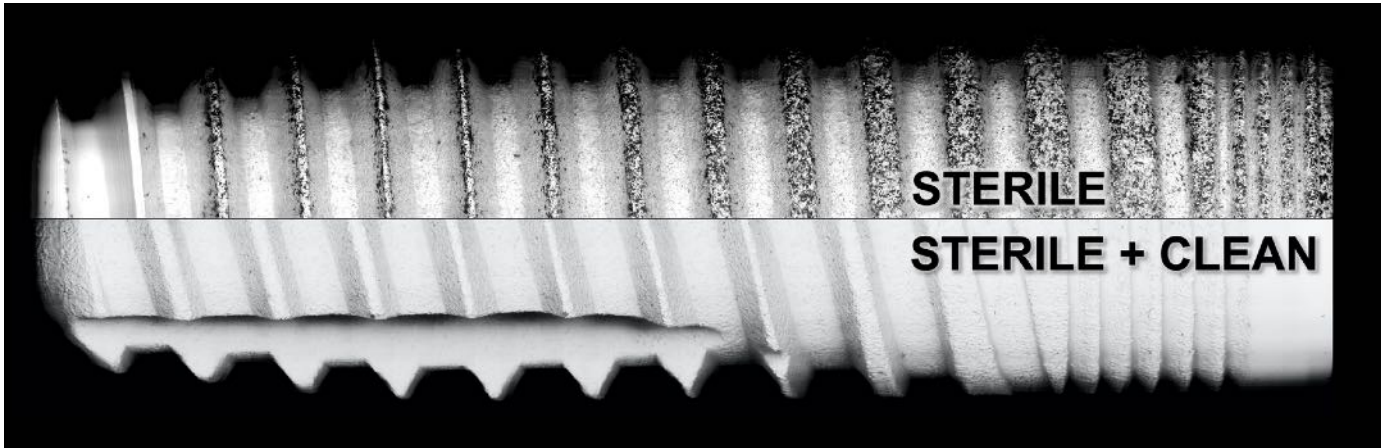
The scientific workstations in the testing laboratory are Phenom proX and Phenom XL Scanning Electron Microscopes provided by Thermo Fisher Scientific, equipped with a high-sensitivity backscattered electron detector that allows compositional and topographical imaging modes. Energy Dispersive X-ray Spectroscopy (EDS) analysis is performed with a thermoelectrically cooled Silicon Drift Detector (SDD). Active area: 25mm<sup>2</sup>; Energy resolution Mn K $\alpha$   $\leq$  140 eV; Processing capabilities: Multi-channel analyzer with 2048 channels at 10 eV/ch; Max. input count rate: 300,000 cps.

## High-resolution SEM Mapping Images

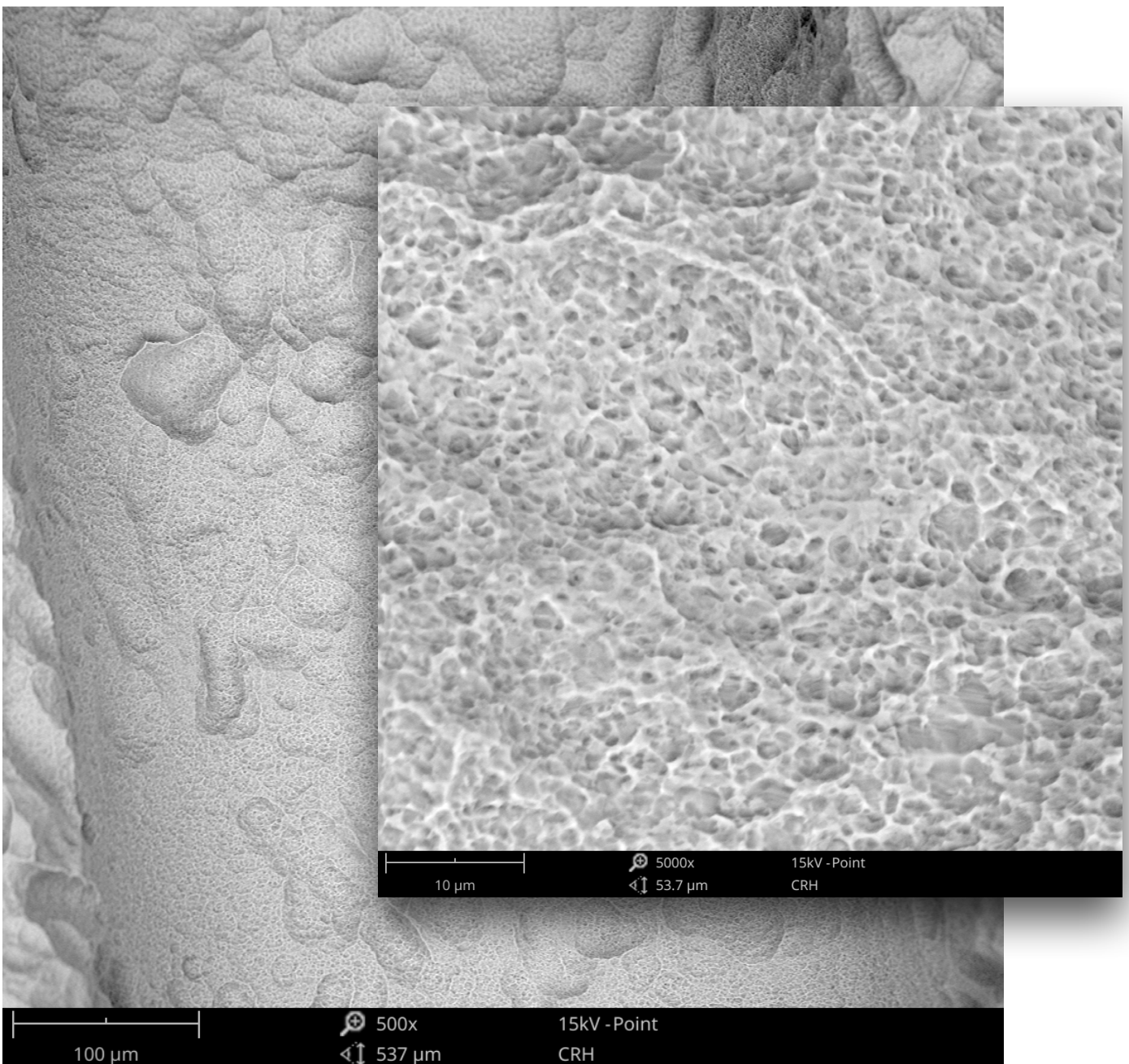
Implants are scanned at a magnification of 500x from shoulder to apex in the "Image-Mapping" mode. This technique produces up to 600 single high-resolution SEM images that are digitally composed to one large image with an extreme high resolution, the FSHR image (Full-Size High-Resolution). Mapping images of implant samples in this study show the complete surface at an angle of view of 120°. Thus, the detailed report of every implant provides information not only on single sections or small areas of the sample but always a complete and precise overview of the implant surface. The composed FSHR mapping image allows the laboratory to count particles in the visible field and identify areas of interest for subsequent spot analyses.

## Detailed SEM-Imaging and Analysis into the sub-micron Range

Scanning electron microscopy (SEM) enables the topical evaluation of the implant surface. The high-sensitivity backscattered electron (BSE) detector produces material-contrast images of implants made of titanium, titanium alloy, and zirconia up to a magnification of 5,000x, showing particles as small as 0,5  $\mu$ m in diameter. BSE imaging provides additional information about the implant sample, such as the chemical nature and allocation of different remnants or superficial contaminants.



Example: Two sterile dental implants with a different level of cleanliness (FSHR imaging)



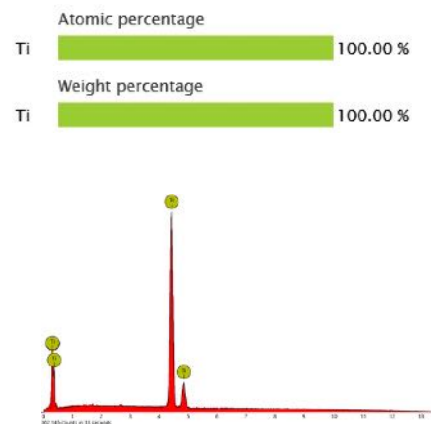
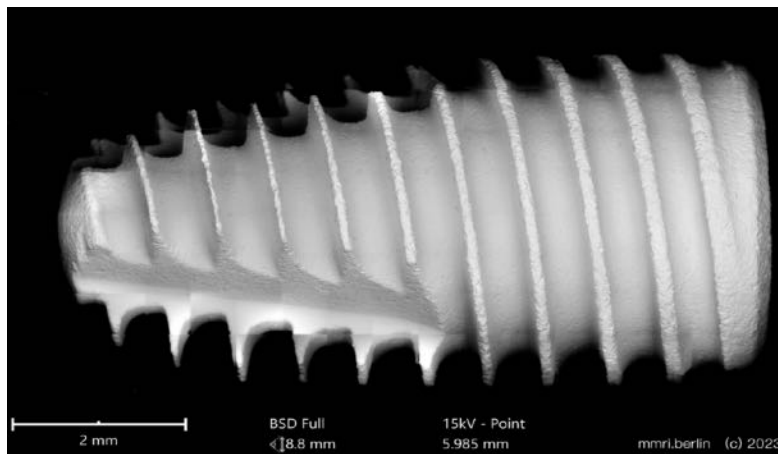
Example: Sterile and clean implant surface in SEM BSE-mode, 500x (left) and 5,000x (right)



### Elemental Analysis

Energy Dispersive X-ray Spectroscopy (EDS) analyzes X-rays generated by the electrons of the electron beam (CeB<sub>6</sub> electron source) while they are interacting with the sample. Each element emits specific X-ray peaks. The element identification software identifies even hidden elements within the sample via spot mode analysis. All results are verified using iterative peak stripping deconvolution.

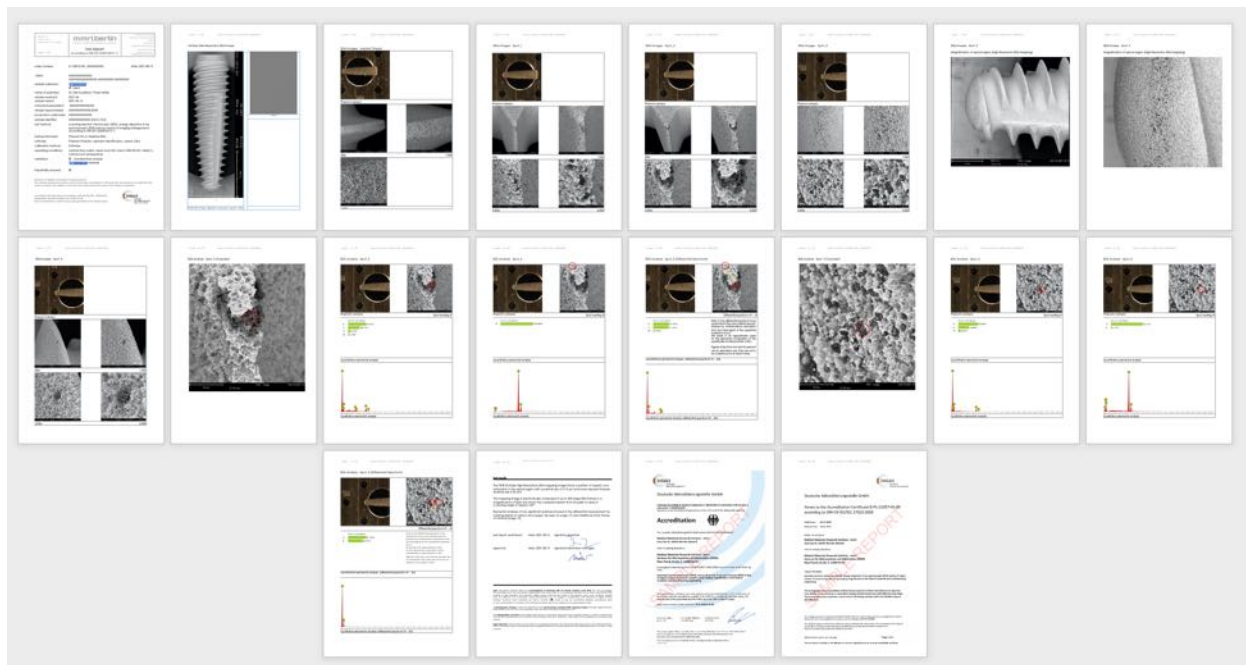
For each tested implant, area analysis and multiple spot analyses are performed (elemental analysis of spots and areas by EDS). The area analysis covers the entire implant area in the scanning electron microscope's focus. For a spot analysis, the electron beam is focused on a specific area to get information about selective accumulations on the implant surface.



Full-size high-resolution SEM mapping image of a clean implant.

EDS data of Ti Gr4 implant (left)

### Comprehensive testing report of an independent implant sample analysis



Example of a comprehensive testing report with SEM image magnifications up to 5,000x and elemental analysis by Energy Dispersive X-ray Spectroscopy - EDS - according to ISO 22309:2015. Tests performed at MMRI.BERLIN, (Medical Materials Research Institute, Berlin-Adlershof, Germany), The independent testing laboratory is officially accredited according to DIN EN ISO/IEC 17025:2018.

# implant sample specification shipping address

The study requires

- 2 original packaged sterile implant samples of every type
- year of production 2024 or later
- preferred length 10-13 mm
- preferred diameter 3-4 mm.

**Contact:** For further questions call +49 (0) 30 2000 301 90  
or send an email to [study@cleanimplant.org](mailto:study@cleanimplant.org).

**Shipping address** for all implant samples:

**MEDICAL MATERIALS RESEARCH INSTITUTE**  
c/o LFM Labor für Mikroanalytik  
Max-Planck-Str. 3  
14542 Werder (Havel)  
Germany

**Note:** To avoid customs if samples were sent from outside the EU,  
please add a **proforma invoice** with a value of 1 Euro/sample  
and add **“for testing only, not for medical purposes”**.



## response form



Please send a FAX to:

+49 30 221 872 37

or send a PDF scan to:

study@cleanimplant.org

Please select your type of study participation here and send us your feedback.

- Yes, **we will join this study as active participants**. Please send us the contractual agreement for this study. The fee for the first implant type is € 2,800 and € 1,800 for every additional implant type by the same manufacturer. We wish to receive a comprehensive testing report according to DIN ISO 22309 of corresponding implant type(s) and a complete set of high-resolution SEM images for commercial purposes prior to publication. The 500+ pages report of the Implant Study 2024-2025 will be provided as a PDF after completion of the study. On request, the report of the preceding Implant Study can be supplied as a bonus, free-of-charge.
- We can only support this study with **two samples of one of our implant types free-of-charge (so called "passive participation")**. We will receive brief information on the testing results via email and a PDF copy of any scientific publication containing the results of our implant samples.
- (Optional) As a passive participant in the current study, we hereby order the 500+ pages report of the Implant **Study 2021-2023** (PDF only) with data of 100 implants (€ 980). Please contact us.
- (Optional) As a passive participant, we hereby order a PDF copy of the **final report of the Implant Study 2024-2025** with data of approx. 100 implants on more than 500 pages, including published testing results of our samples provided (€ 1,980). Please contact us.
- We are interested in learning more about this quality assessment study.**  
Please contact us and send an email to our address below.
- Sorry, we cannot provide samples for this study.  
**Please order the requested implant samples from a local dealer.**



Contact details: (please fill out with company name, responsible manager, email, phone etc.)



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