CLEAN IMPLANT FOUNDATION

The CleanImplant® Trusted Quality Mark

Process Description and Performance Criteria

Quality is never an accident.
It is always the result of high intention,
sincere effort, intelligent direction and skillful execution.
It represents the wise choice of many alternatives.

William A. Foster

Content

Editorial Note:

The present revised edition of the CleanImplant Guideline has been prepared to ensure alignment with the most recent scientific evidence and the consensus of the Scientific Advisory Board. Compared to the initial version, this edition introduces updated recommendations, refined terminology, and editorial adjustments designed to improve consistency, clarity, and clinical applicability. The revisions underline our continued commitment to providing guidance that reflects both scientific rigor and the highest standards of patient care.

1 Introduction

Dentists and, of course, patients generally assume that dental implants delivered in sterile packaging and intended for medical treatment are free from contamination. However, multiple quality assessment studies have detected significant surface impurities, including plastic particles, foreign metals, and cell-toxic residues of chemical compounds, on many sterile-packaged implants.[1-3] These contaminants are suspected to cause unsuccessful or insufficient osseointegration and may contribute to implant failure. In particular, organic particles in the micrometer range can trigger an uncontrolled foreign body reaction, resulting in the release of pro-inflammatory cytokines such as TNF-α and IL-8.[4-6] The cellular response to small-sized particulate impurities might explain an unacceptable bone loss during the initial healing phase and the early onset of peri-implantitis.[7-13]

Following a defined protocol, the CleanImplant Foundation performs objective, periodic studies on the manufacturing quality of dental implants. The Foundation promotes and commissions research, in collaboration with leading universities, to investigate the clinical relevance and consequences of avoidable contamination and quality deficiencies in dental implants.

In March 2017, a quality assessment study revealed significant factory-related contaminants on numerous dental implants. Results were discussed with industry partners and the Scientific Advisory Board of the CleanImplant Foundation, as no applicable ISO standard existed that defined acceptable impurity levels for dental implants. The outcomes and recommendations of these discussions have been incorporated into this document. Further meetings with the Bundesanstalt für Materialforschung und -prüfung (BAM; German Federal Institute for Materials Research and Testing) resulted in the refinement of procedures for sample unpacking and subsequent scanning electron microscopy (SEM) analysis. In September 2017, the Scientific Advisory Board approved the first CleanImplant Guideline with thresholds and criteria for a new quality mark.

Years later, in October 2024, the U.S. Food and Drug Administration (FDA) published new guidance for the dental industry. The FDA's "*Performance Criteria for the Safety of Endosseous Dental Implants*" requires a "…*cleanliness analysis of the surface of the implant body, using scanning electron microscope (SEM) and energy dispersive X-ray spectroscopy (EDS)*…". https://www.fda.gov/media/182616/download

The comprehensive testing procedures and peer-reviewed processes developed by the CleanImplant Foundation in 2017 for the independent Trusted Quality Mark anticipated these FDA performance criteria for the safety of dental implants. The fact that there is still no ISO standard with acceptable contamination levels for sterile-packaged dental implants underlines the scope and importance of this project. Thresholds for impurities defined in this Guideline for the Trusted Quality Mark were published in the Journal of Clinical Medicine and have since been integrated into the quality management systems of implant manufacturers worldwide.[1]

Based on batch-spanning analyses performed exclusively in accredited laboratories and peer-reviewed by the most renowned scientists, the CleanImplant certification is a testament to the highest standards of cleanliness in the manufacture of dental implants. It serves to raise awareness of considerable quality differences in the market and, most importantly, it can guide clinicians to choose implant systems that are proven clean and clinically reliable.

2 Process Description

2.1 Sample Acquisition

For the intended quality assessment, five samples from each implant device or device family of every participating company are randomly selected – a minimum of two samples through mystery shopping and a maximum of three samples from direct factory orders.

2.2 ISO Class 5 Cleanroom Environment - DIN ISO 14644-1

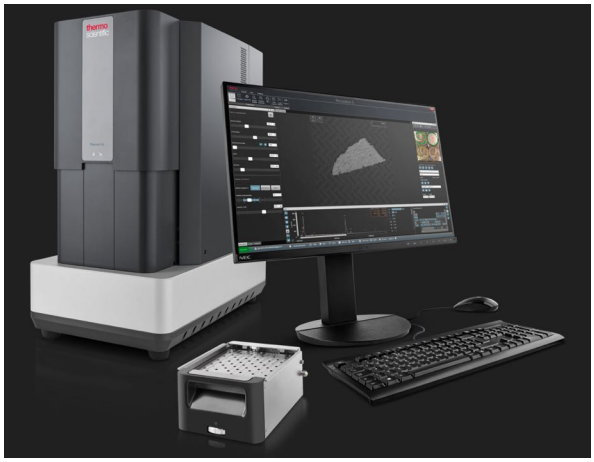
To avoid artifacts on the unpacked implant samples during transfer into the SEM, all implants must be unpacked and analyzed in the scanning electron microscope under cleanroom conditions, as specified in Class 100 FED-STD-209E and ISO Class 5 (DIN ISO 14644-1).

2.3 SEM/EDS Analysis: DIN EN ISO/IEC 17025:2018 and DIN ISO 22309

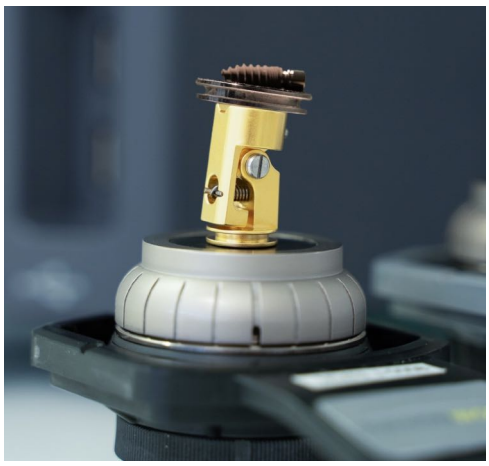
All collected samples are subjected to the same quality analysis protocol performed by independent laboratories that provide a Quality Management System according to ILAC MRA and DIN EN ISO/IEC 17025:2018 (general requirements for the competence of testing and calibration laboratories). These laboratories must implement a quality system designed to consistently produce accurate and reliable results. This includes the quality standard according to DIN EN ISO 9001:2015. The laboratories undergo regular audits and re-assessments by external, independent accreditation bodies (e.g., DAkkS). Elemental analysis of the implant samples is performed in accordance with DIN ISO 22039:2015.

2.4 Protocol of Analysis

The scientific workstation features a Phenom Scanning Electron Microscope, equipped with a high-sensitivity backscattered electron detector, which enables both compositional and topographical imaging modes. Energy Dispersive X-ray Spectroscopy (EDS) analysis is performed with a thermoelectrically cooled Silicon Drift Detector (SDD).

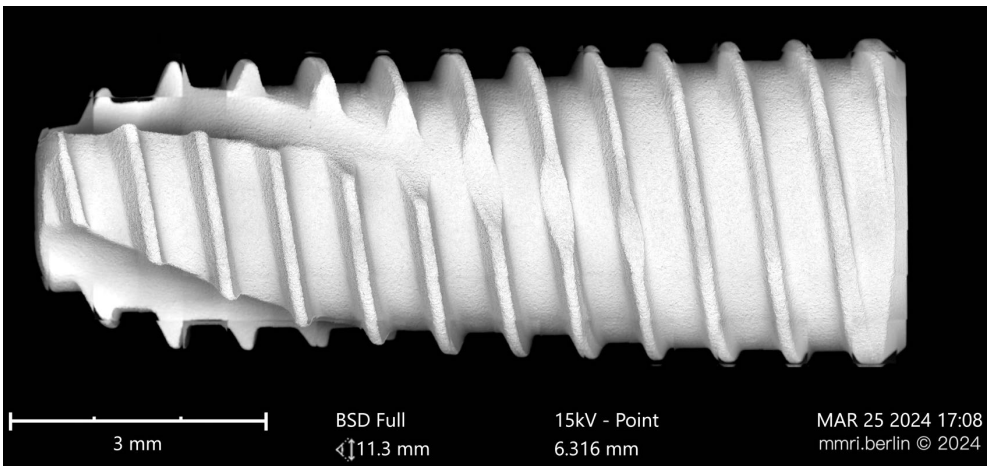


Workstation with Phenom Scanning Electron Microscope



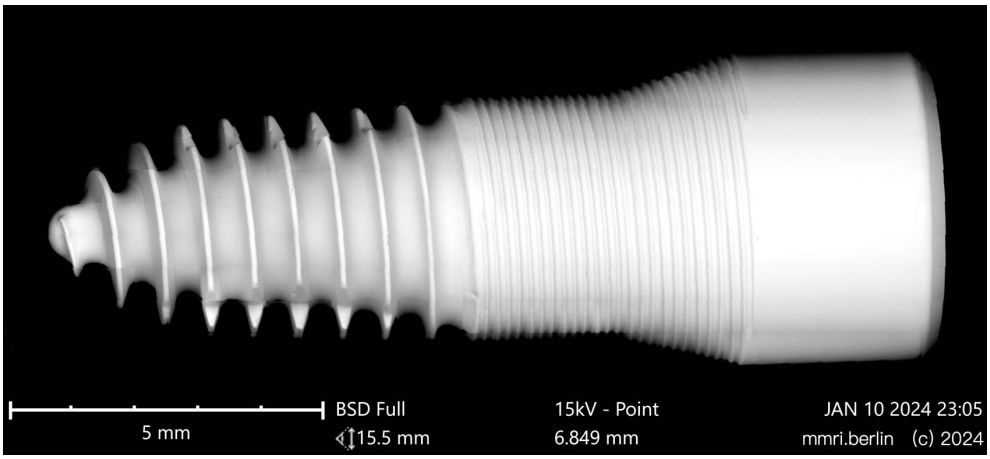
Horizontally aligned implant (example) on the special sample holder (developed by MMRI)

Unboxing and mounting of the implant on the SEM sample holder, as well as transfer to the SEM vacuum chamber, are performed within a laminar-flow environment under Cleanroom Class 5 conditions. During this procedure, the implant surface that is to be analyzed will not come into contact with any other material. After the vacuum is generated, SEM imaging and EDS analyses will be completed. Backscattered electron imaging (BSE) enables the determination of the chemical nature (density) and distribution of different contaminants and/or remnants on the sample material. Systematic scanning of the surface reaches approx. one third of the implant's surface in a viewing angle of 120 degrees.



Example of a clean, particle-free **titanium implant**; SEM image mapping from numerous tiles, 500x magnification

To achieve a comprehensive overview of the sample and high-resolution surface quality information, implants are scanned at a magnification of 500x in "Automated Image-Mapping" mode. This technique produces up to 400 single, high-resolution SEM images, which are digitally composed into a single, extremely high-resolution image (FSHR - Full-Size High-Resolution image). The composed image enables the counting of particles in the visible field and the identification of areas of interest for subsequent spot analyses.



Example of a clean, particle-free **zirconia implant**; SEM image mapping from numerous tiles, 500x magnification

3 Quality Mark Awarding Process

Possible project partners are invited to join a six-tier approach:

Tier 1: Single implant samples of recent production are the subject of continued quality assessment studies that follow the same protocol of analysis as described above (see 2.2 - 2.4). These research results are used to determine the entrance criteria to tier 2.

Tier 2: Based on tier 1, manufacturers will be invited to join the project if they can provide sufficient clinical data - proven by reports published in peer reviewed scientific literature or equivalent such as multi-annual post-market clinical follow-up (PMCF) studies or the “Summary of safety on clinical performance“ (as required in MDR 2017-745 Article 32) - showing survival rates of more than 95 %. Thus, future project partners are only selected if they place particular emphasis on quality and clinical evidence.

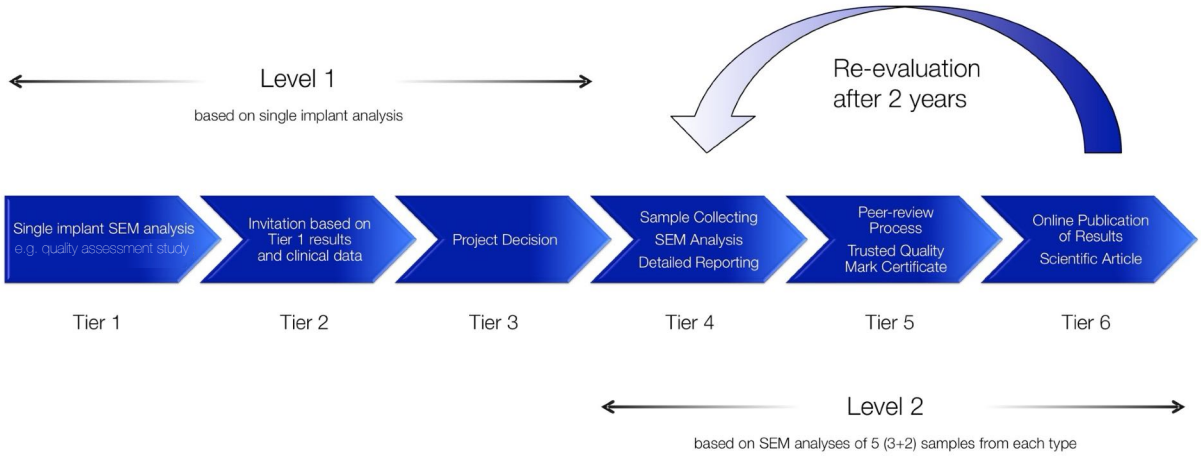
Tier 3: Project decision following a contractual agreement.

Tier 4: Sample collection and start of level 2: Five samples from each implant device/device family of every company will be selected through a combination of mystery shopping and direct factory orders. Independent laboratories will perform unpacking, sample mounting and transfer into the SEM under cleanroom conditions according to ISO class 5, DIN ISO 14644-1 and complete SEM-imaging and elemental analyses according to DIN EN ISO/IEC 17025:2018.

A comprehensive report will be generated and sent for evaluation to two members of the Scientific Advisory Board in order to guarantee a peer-reviewed process.

Tier 5: After successful completion of the peer-review process, the CleanImplant® certificate, the license to use the quality mark, and the comprehensive reports will be issued once the analyses have been passed successfully and the required clinical data is sufficient (->Tier 2).

Tier 6: Data and results will be published online and in scientific articles. Two years after receiving the quality award, a new set of samples will be collected and analyzed as part of a re-evaluation process for the renewal of the quality mark.

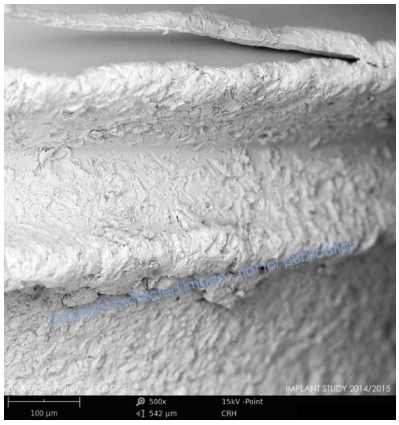


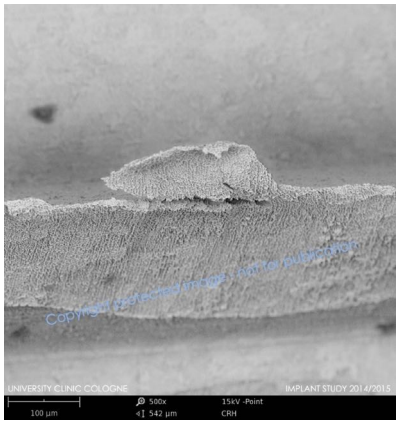
4 Database for the Quality Mark Criteria

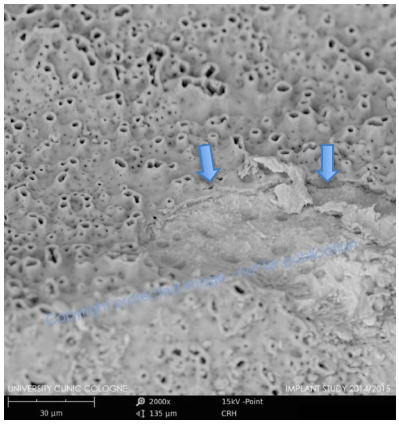
In a series of consecutive studies conducted since 2008, the cleanliness of dental implants has been systematically analyzed using scanning electron microscopy (SEM) and energy-dispersive X-ray spectroscopy (EDX), following a consistent study protocol. Across more than 350 implant samples examined, a wide range of manufacturing quality was observed. The majority of implants demonstrated a high standard of production, characterized by precise external geometry and surfaces free from inorganic or organic contaminants. Nevertheless, a notable proportion of implants exhibited significant surface contamination, likely introduced during various stages of manufacturing, handling, or packaging.

4.1 Surface Anomalies

Single implants showed cutting burrs (20-400 µm) that remained on the surface even after the blasting and/or etching process. Other implants showed anomalies in the oxide layer.

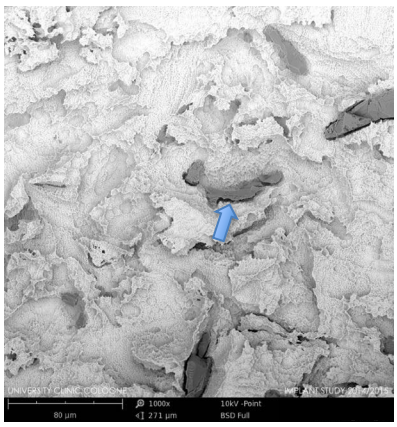




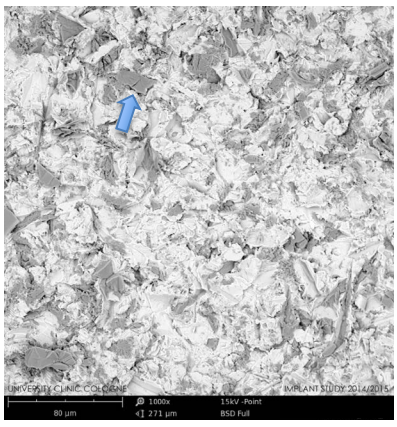


4.2 Remnants of Blasting Material

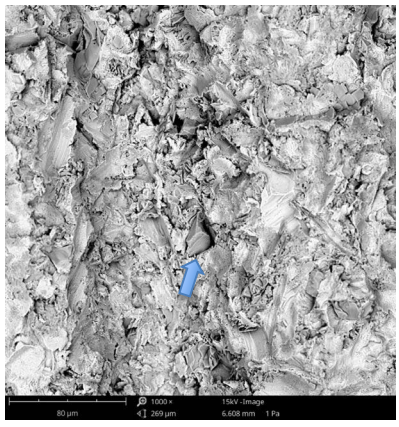
Many implants blasted with aluminum oxide showed remnants of the blasting material mechanically attached to the surface. TiO_2 particles can be seen in the right image.



Al_2O_3 particles, 1000x:



Al_2O_3 particles, 1000x:

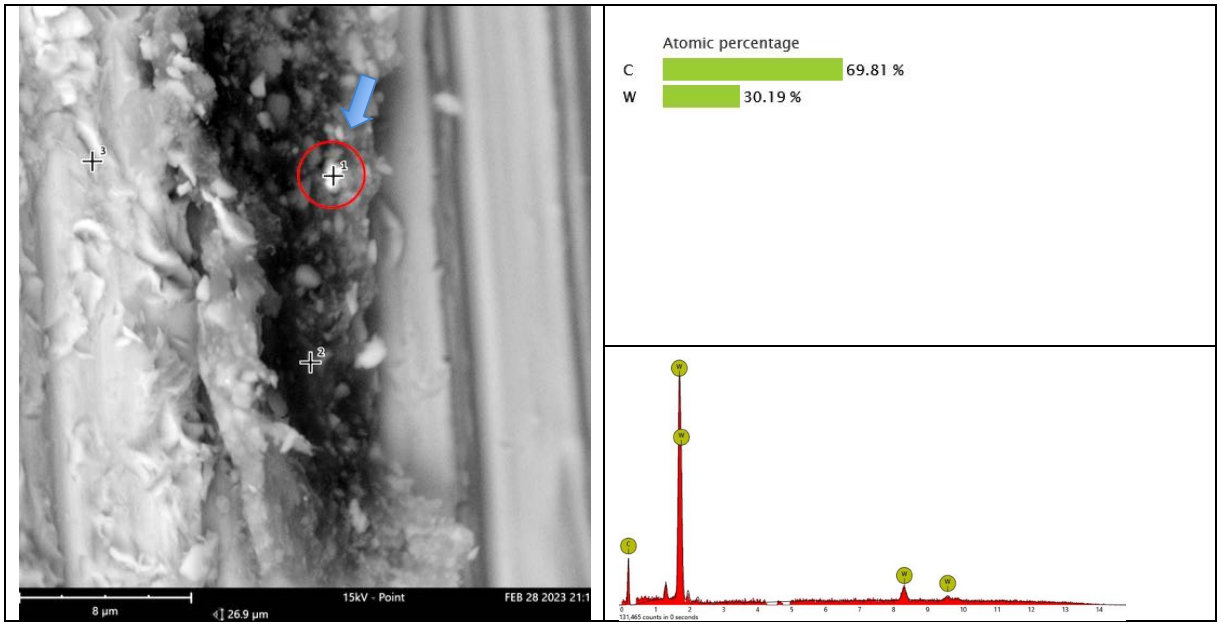


TiO_2particles, 1000x

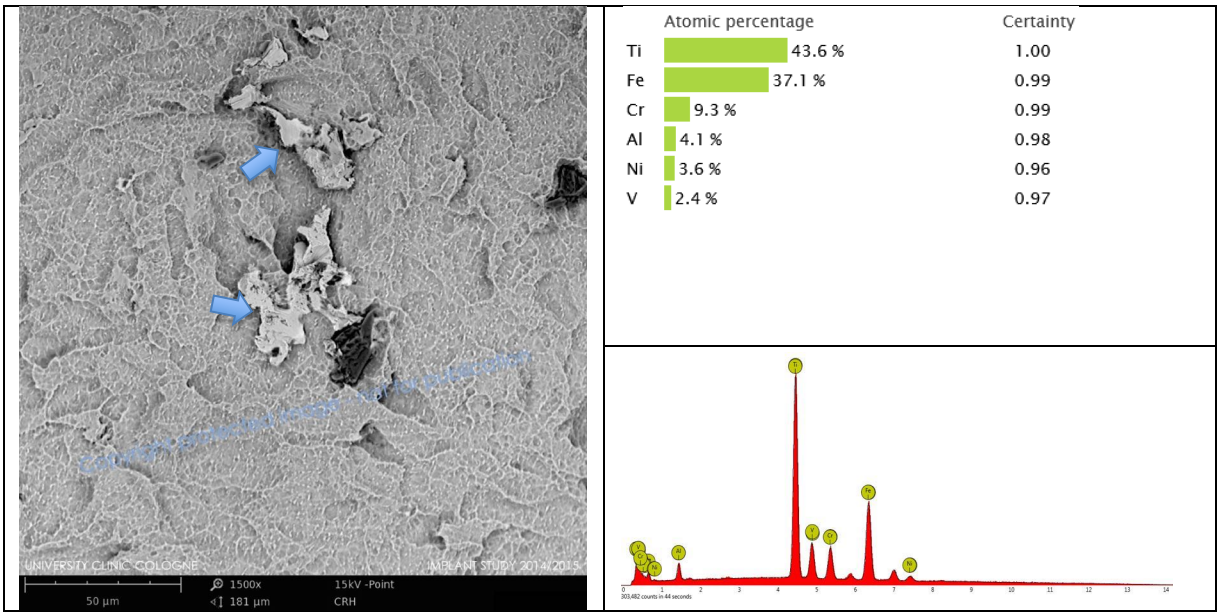
4.3 Metal particles

The spot analyses revealed a large variety of metallic remnants both as isolated particles or embedded in an organic matrix fixed on the implant surface.

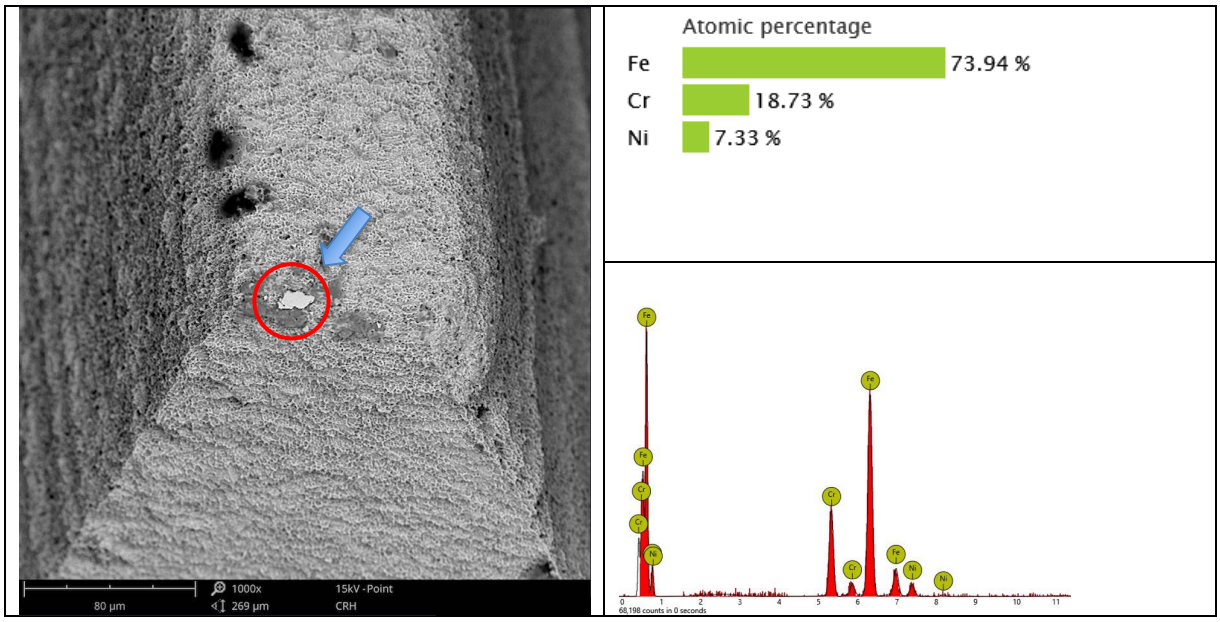
We found particles of tungsten (W) embedded in an organic matrix, as seen below.



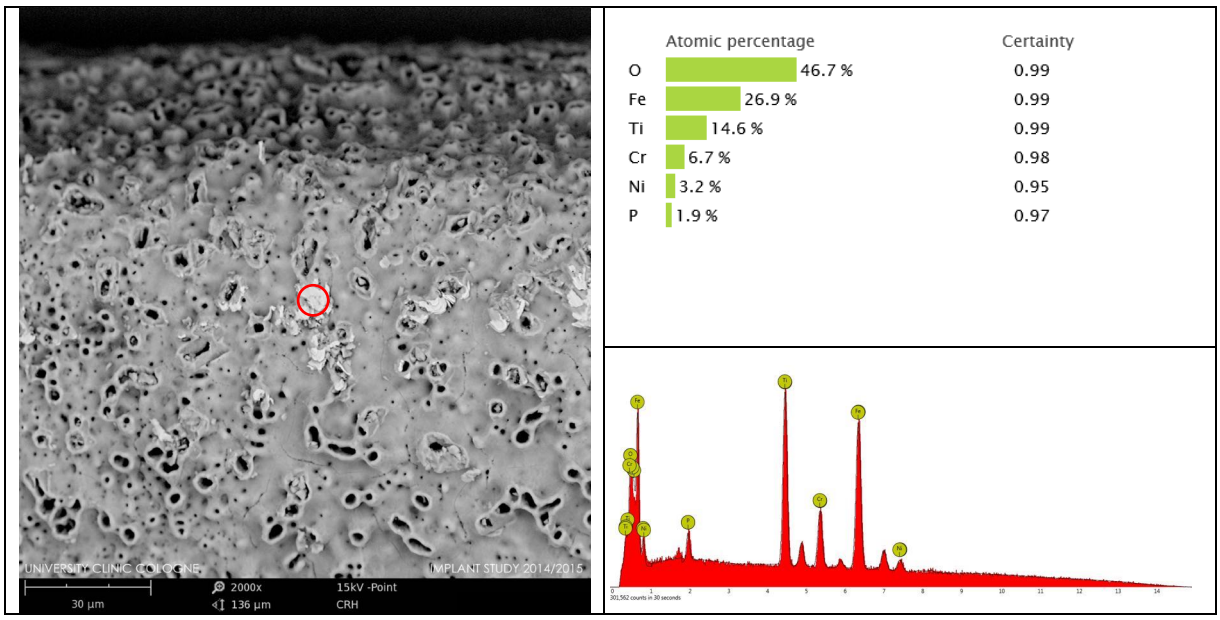
Significant signals of iron (Fe), chromium (Cr) and nickel (Ni) in the elemental spot analysis of particles (20-50 µm) on some implant samples may be a hint for recycled or polluted blasting material containing particles of stainless steel.



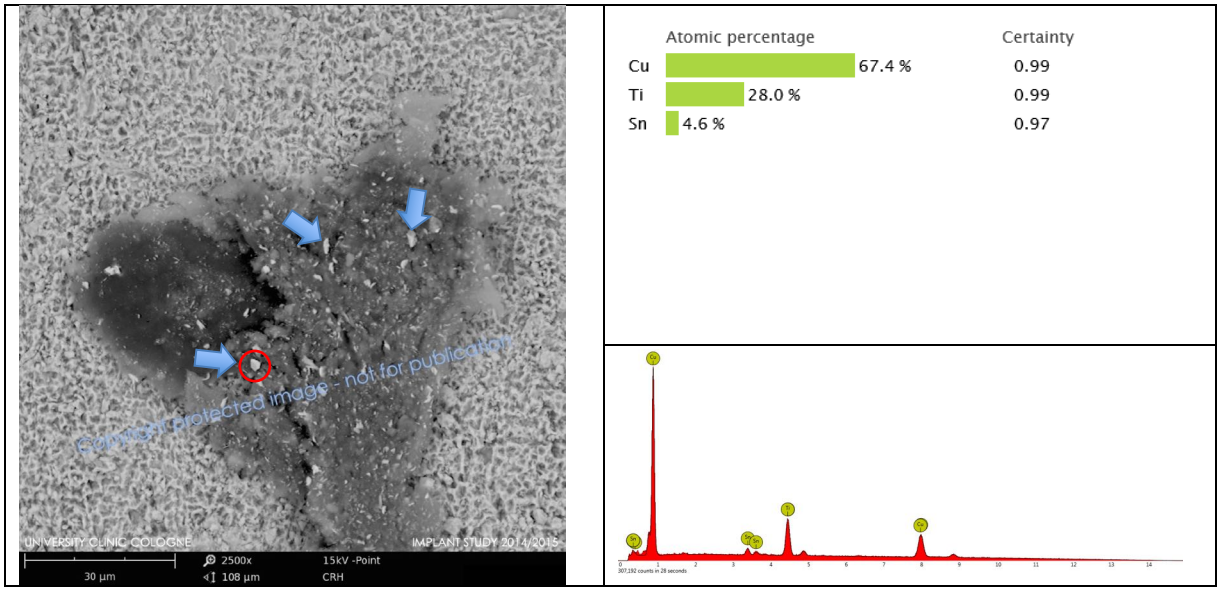
Some implants showed only single iron-chromium-nickel (stainless steel) particles with a diameter of up to 30µm. Since these particles are mainly attached to exposed implant sites, mechanical impact is a very likely cause.

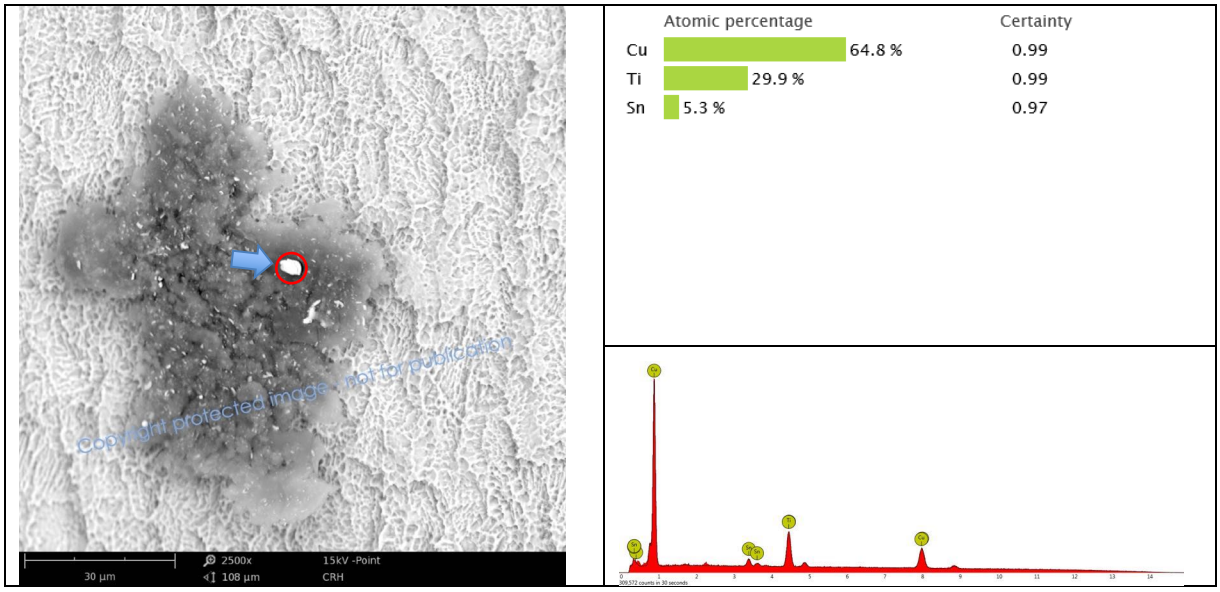


Other examined implant samples demonstrated a foreign metal contamination pattern characterized by numerous stainless-steel particles (2–10 µm) distributed in specific surface areas.

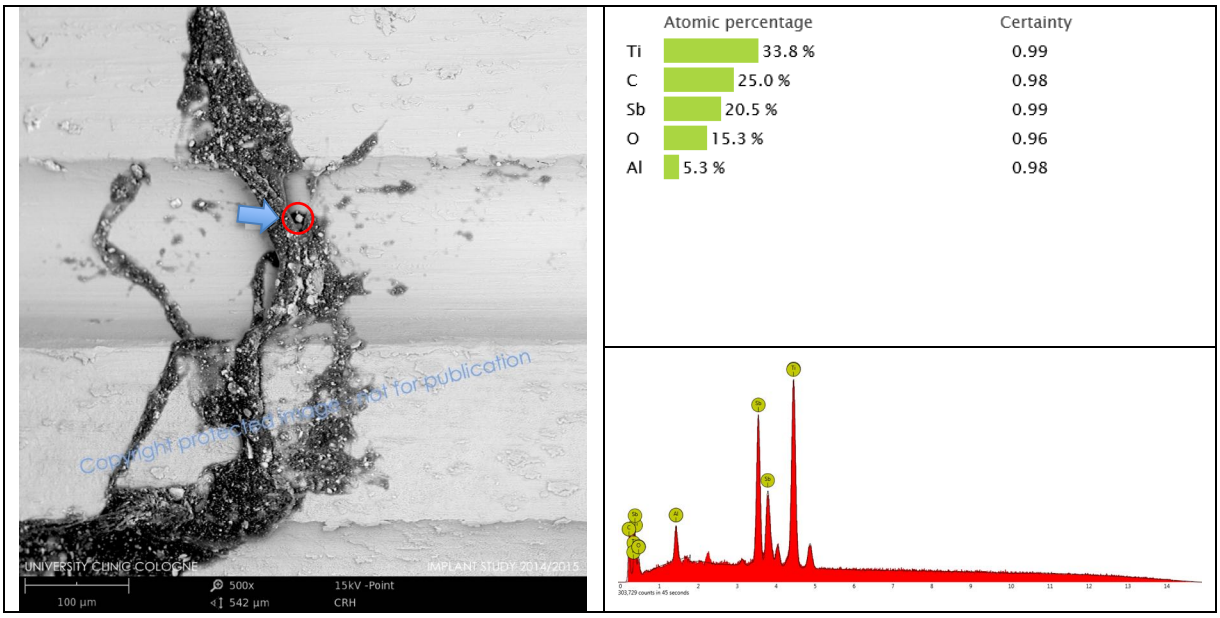


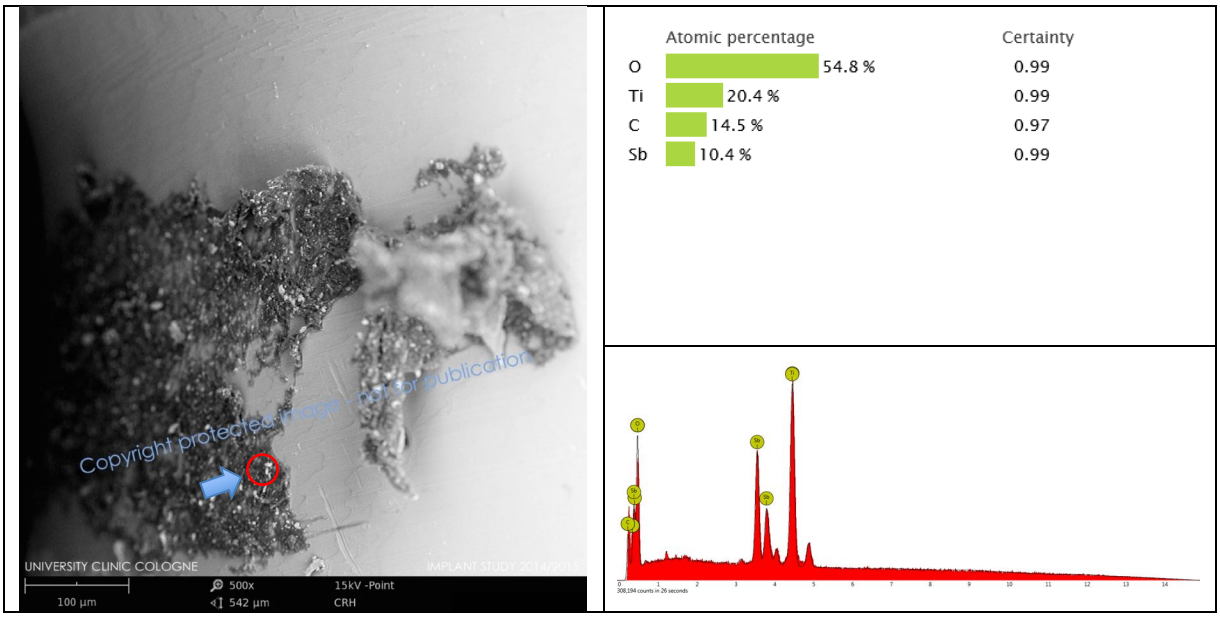
A few metal particles (1-5 µm) showed clear signals of copper and tin, i.e., bronze in the elemental analysis as seen in the images below. These foreign metal particles are each embedded in larger organic contaminants (30-100 µm). A possible source for this contamination is a sandblasting nozzle made of bronze.





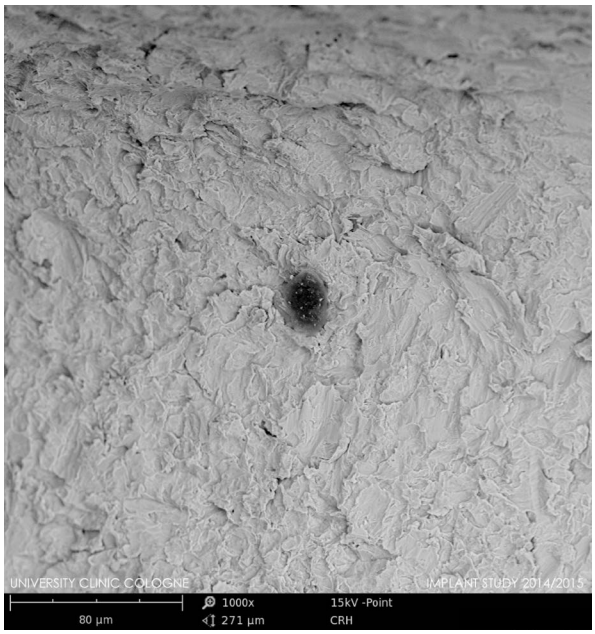
Surprisingly, even antimony (Sb) — as shown in the two images below — was detected in the EDS analysis of two implants.

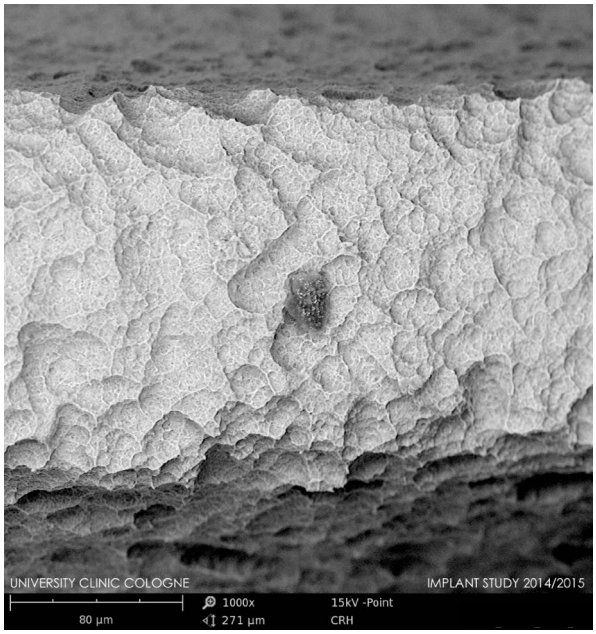


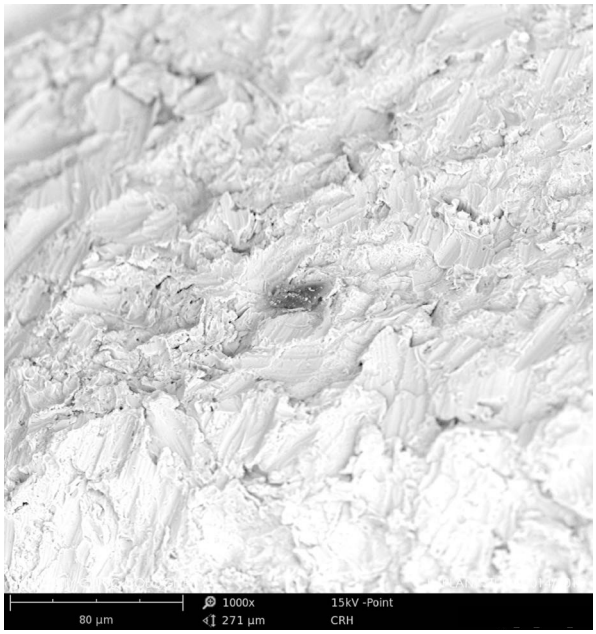


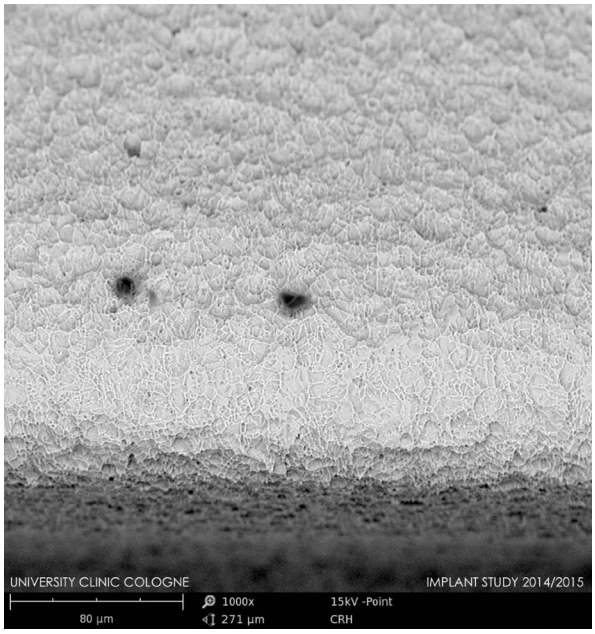
4.4 Single organic particles

Single organic particles (fewer than 10 particles on the implant surface in an angle of view of 120°) without a specific distribution pattern were found on many implants. The size ranges from 1 to 50 µm.



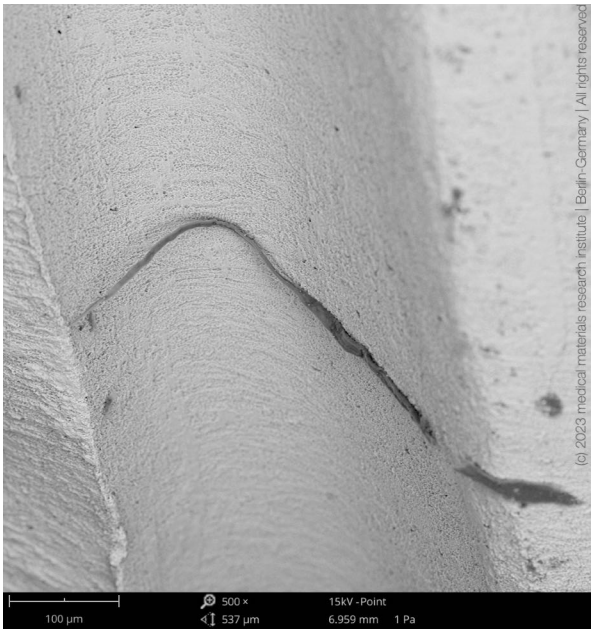


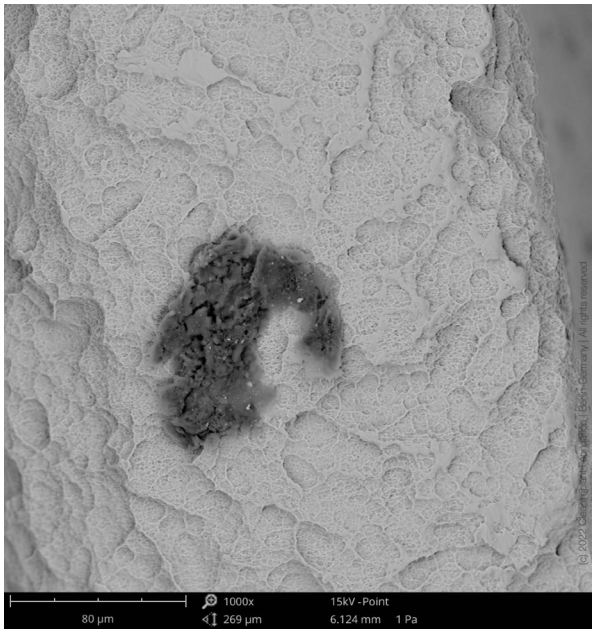




4.5 Significant organic (carbonaceous) impurities

Large contiguous organic particles (50-600 µm)

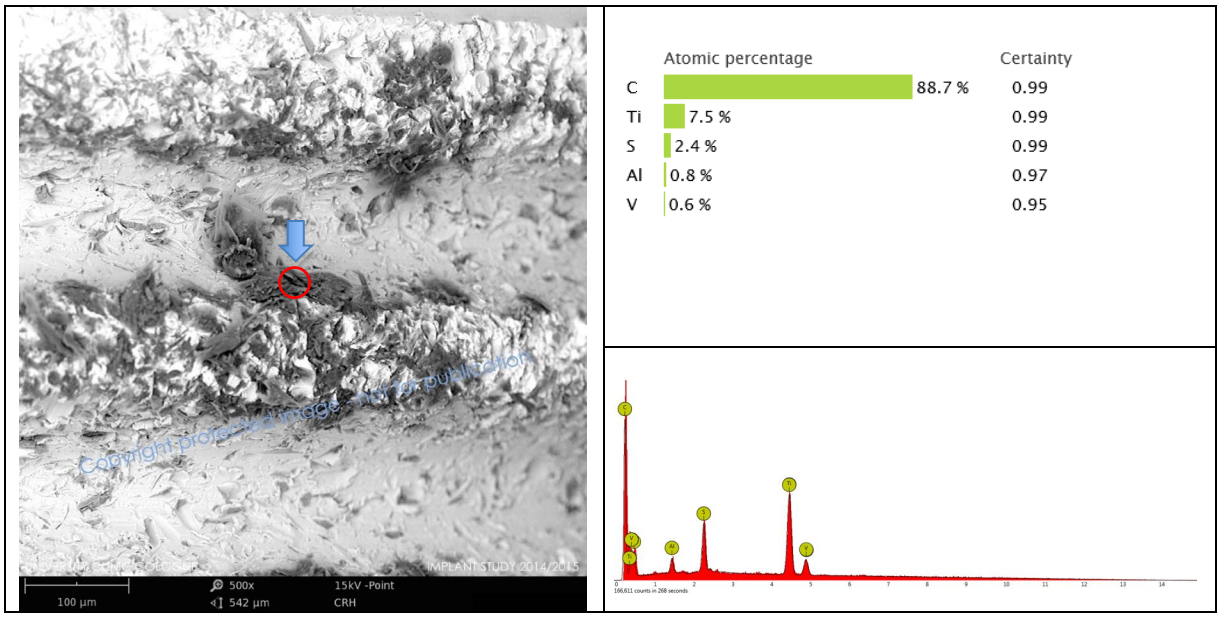


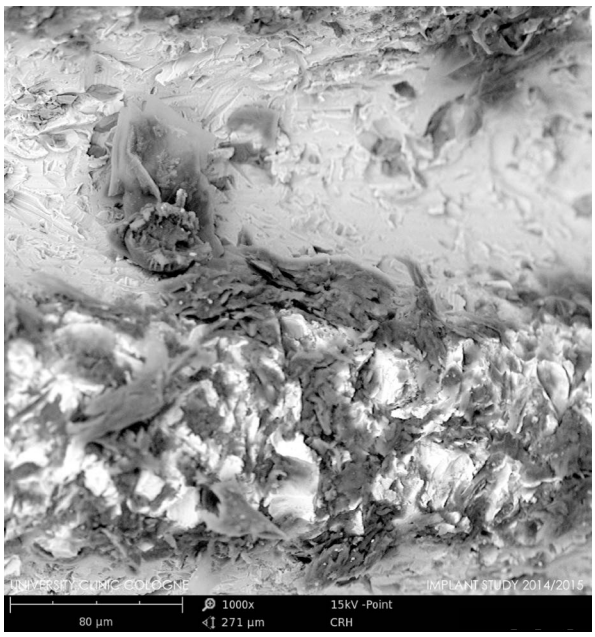


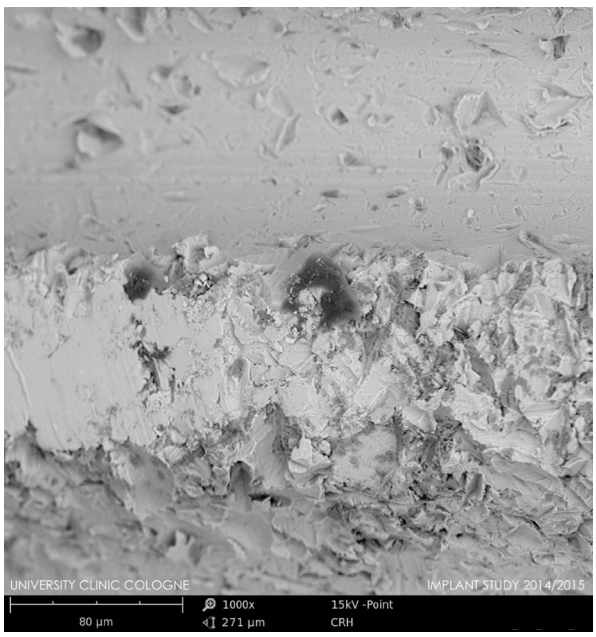
(Different implant systems)

A significant number of implants showed a **systematic distribution pattern of organic particles:** a) the outer exposed threads of an implant, b) the implant shoulder area, and c) the implant's apical region.

a) **Accumulation of carbonaceous impurities on the exposed outer implant threads**

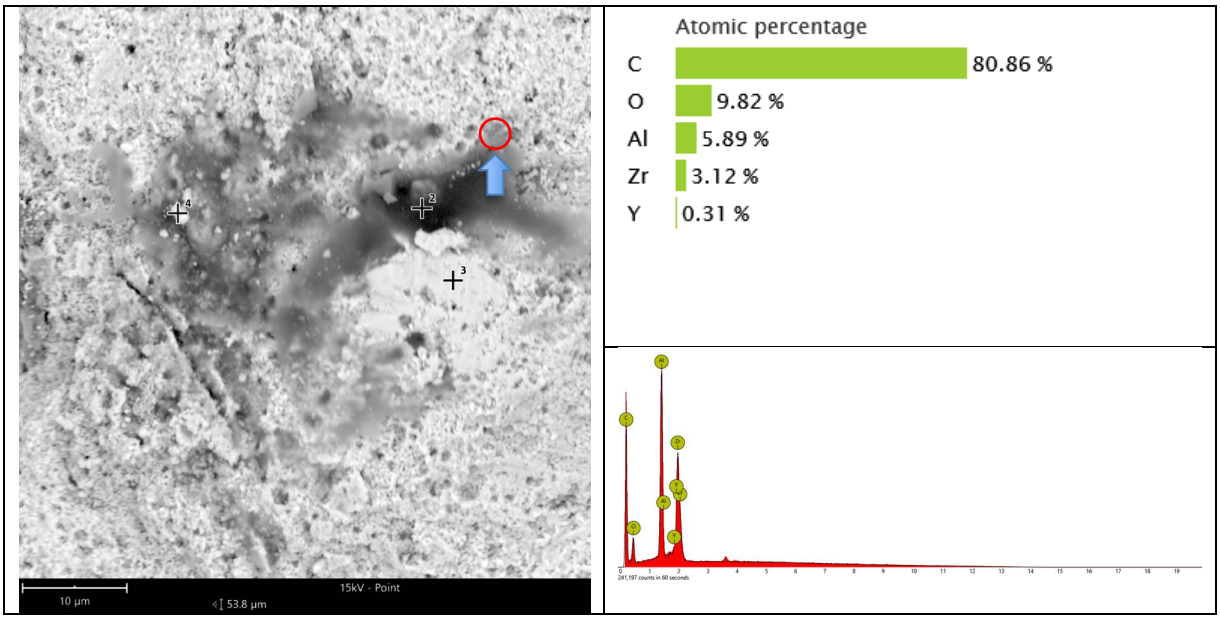


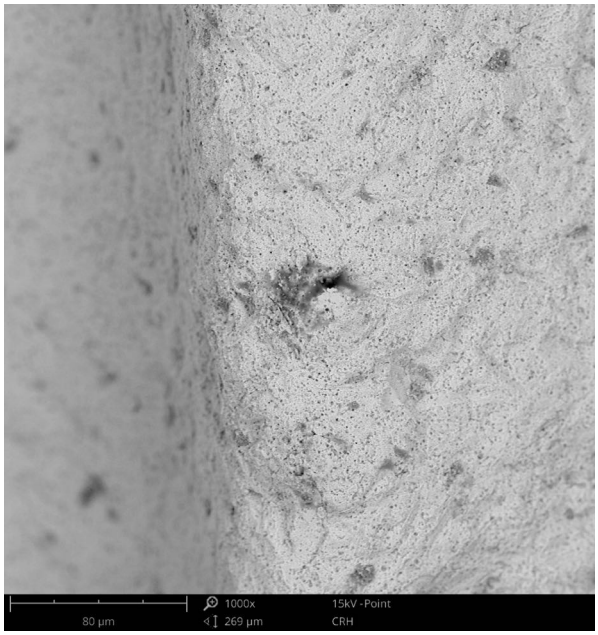


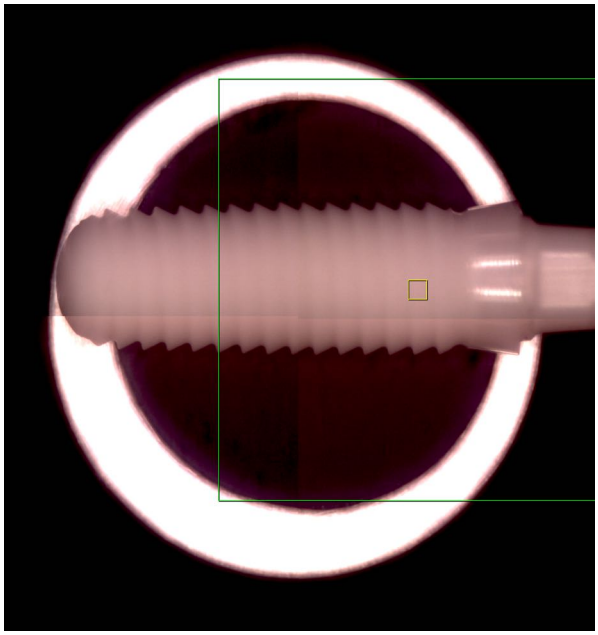


(All three images from the same implant made of titanium alloy (Ti-6Al-4V)

Accumulation of carbonaceous impurities on the exposed outer implant threads
(continued)

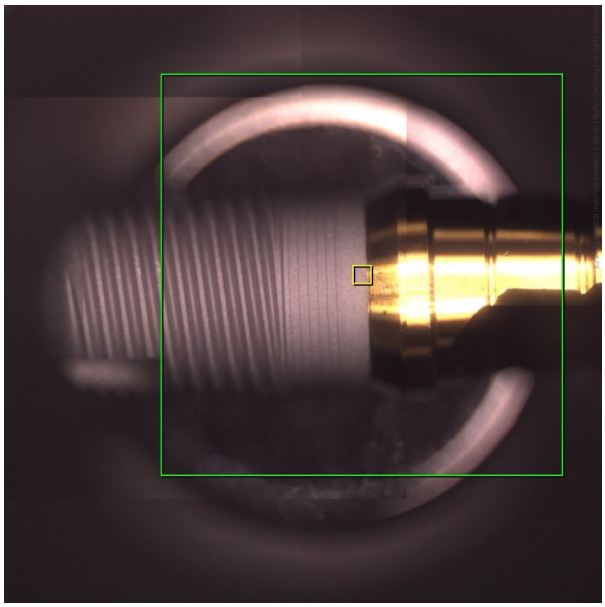


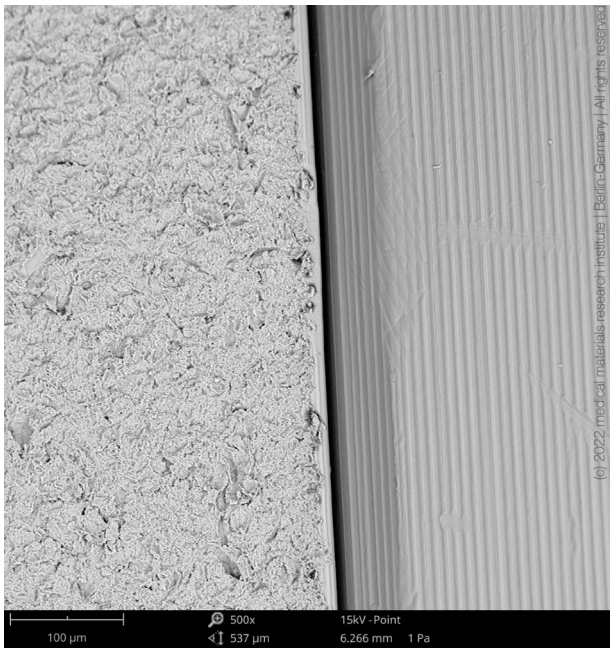


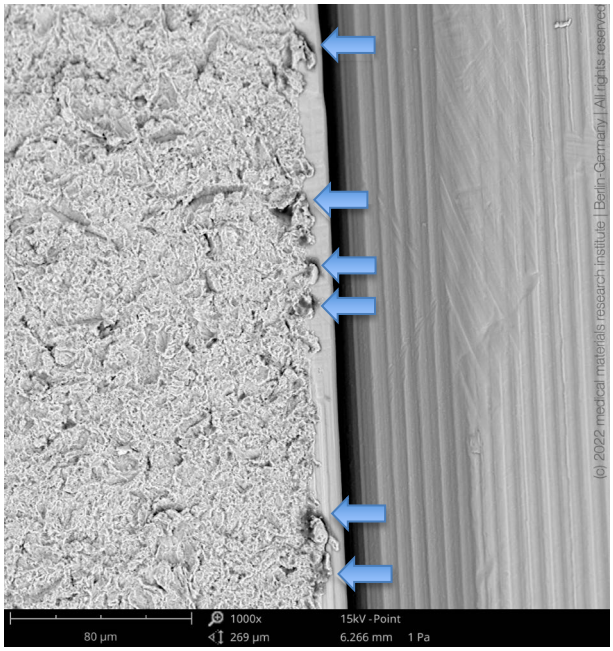


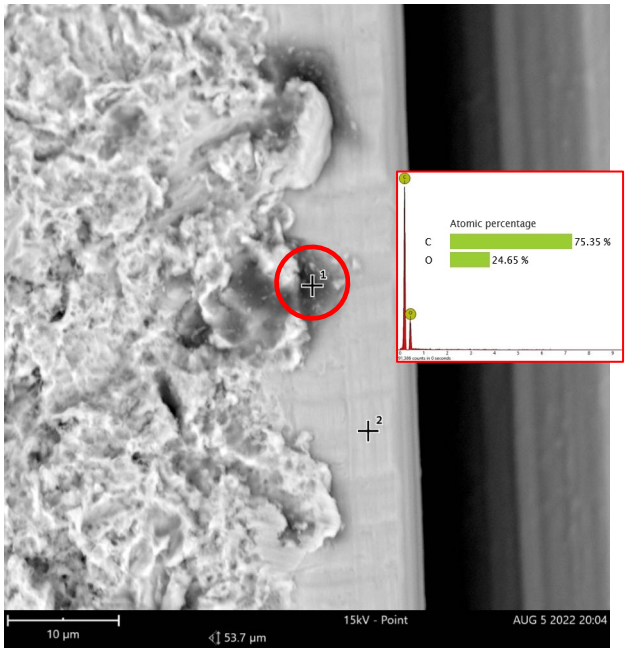
Zirconia implant with a carbonaceous contamination in close vicinity to an area with traces of a mechanical impact

b) **Accumulation of carbonaceous impurities on the implant shoulder**





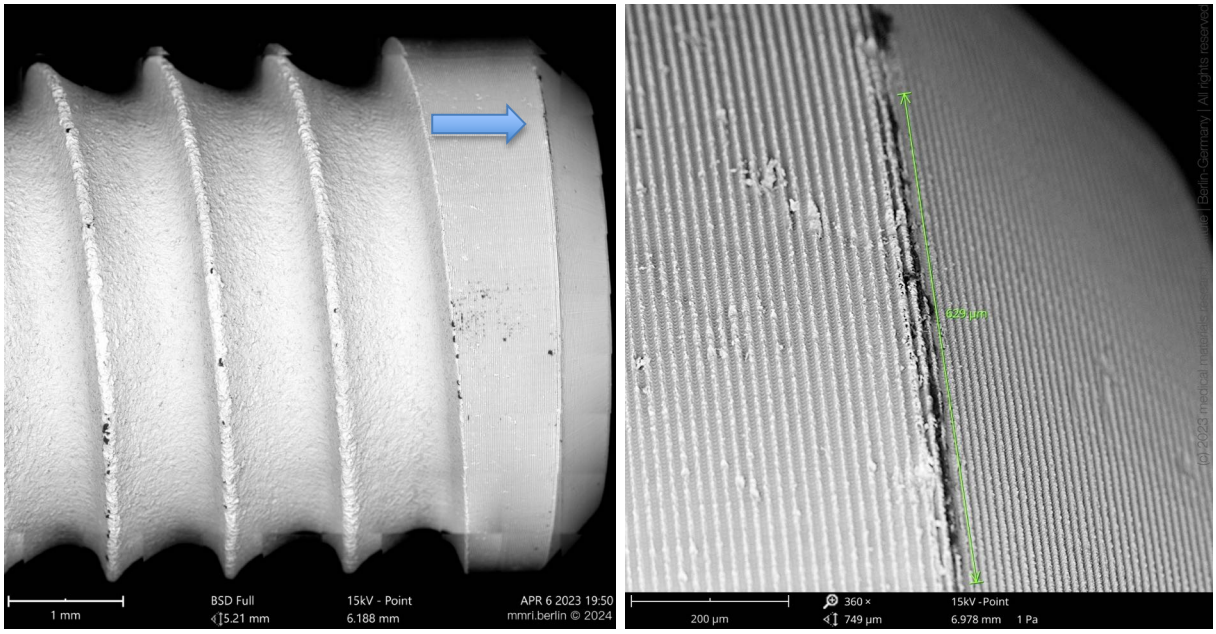


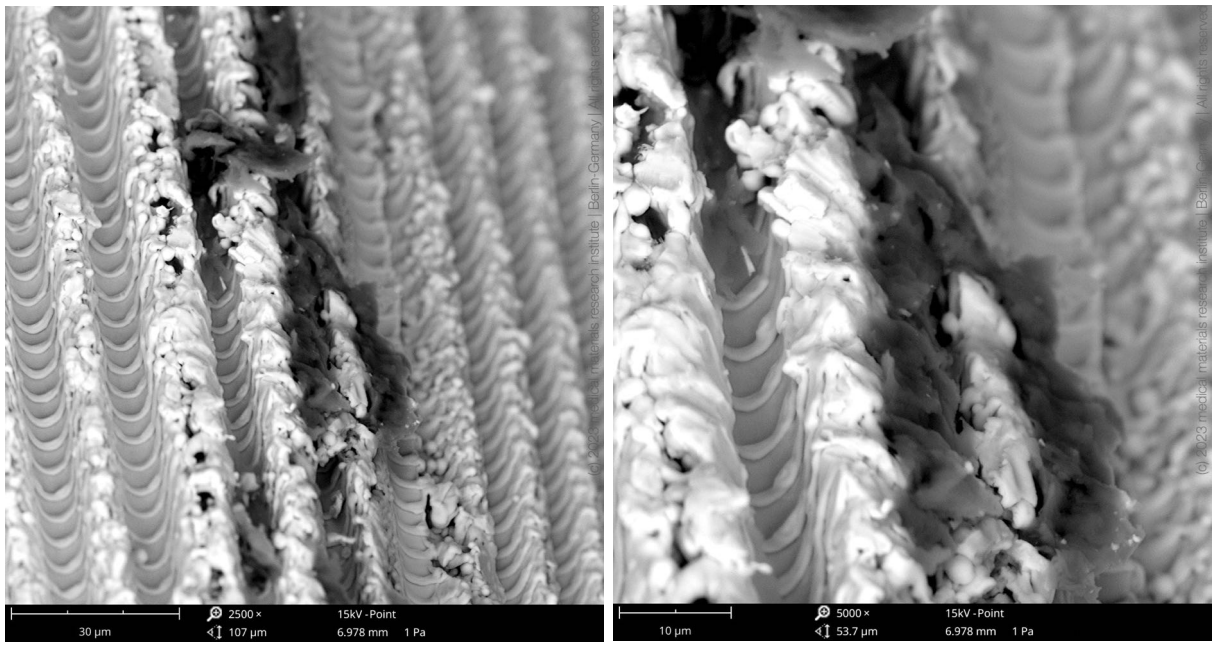


(Images from the same implant)

Accumulation of carbonaceous impurities on the implant shoulder
(continued)

Large (0,6 mm) organic, i.e., carbon-based contamination at the implant shoulder

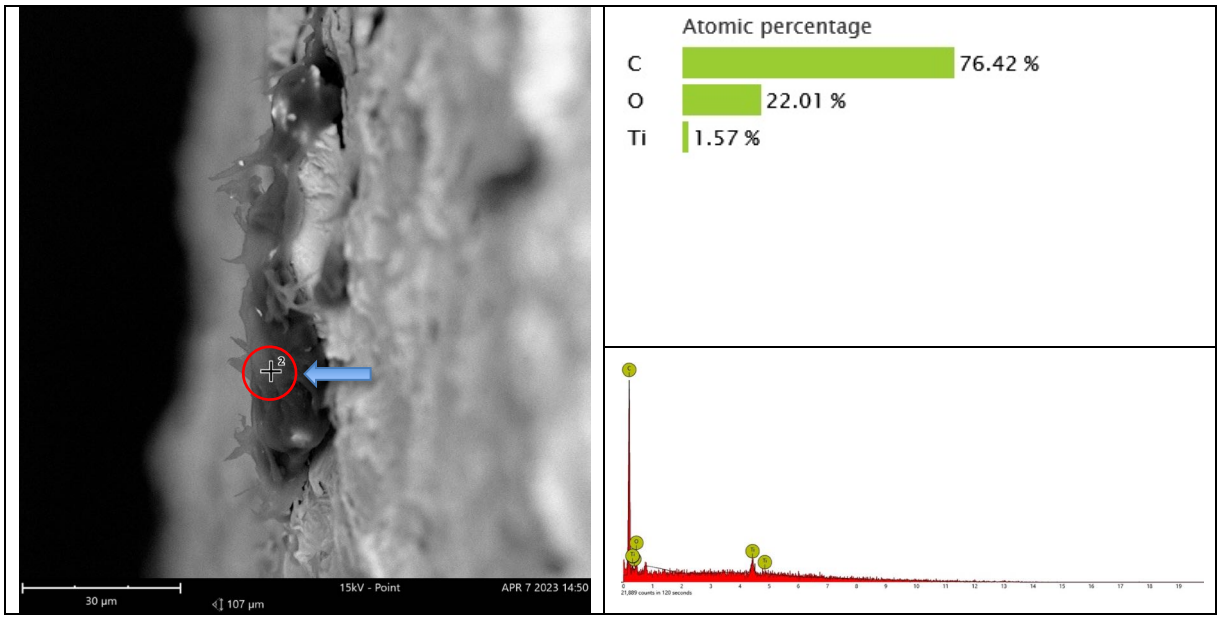


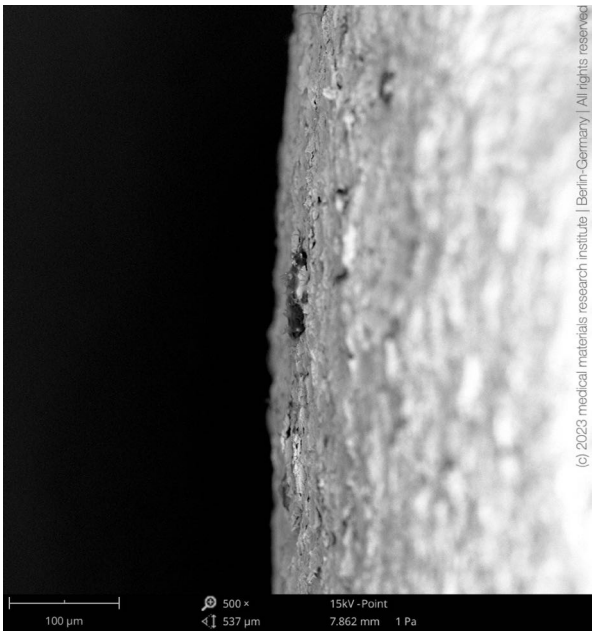


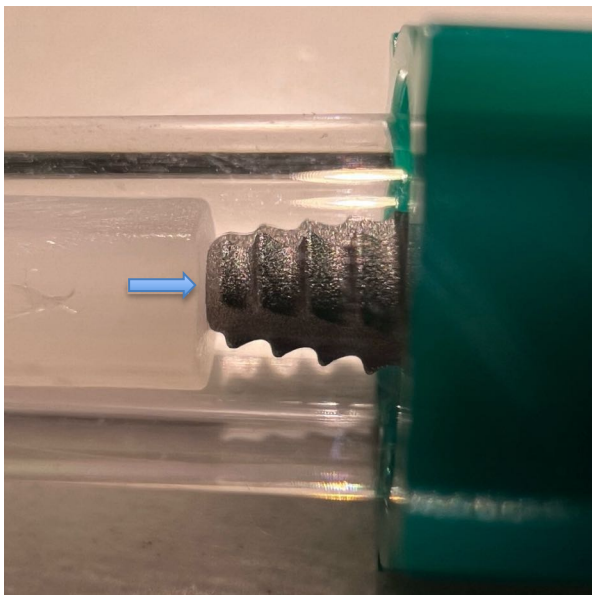
(Images from the same implant)

c) **Accumulation of carbonaceous impurities at the implant's apical region**

The example shows that plastic material from the packaging remains on the implant's apical region.

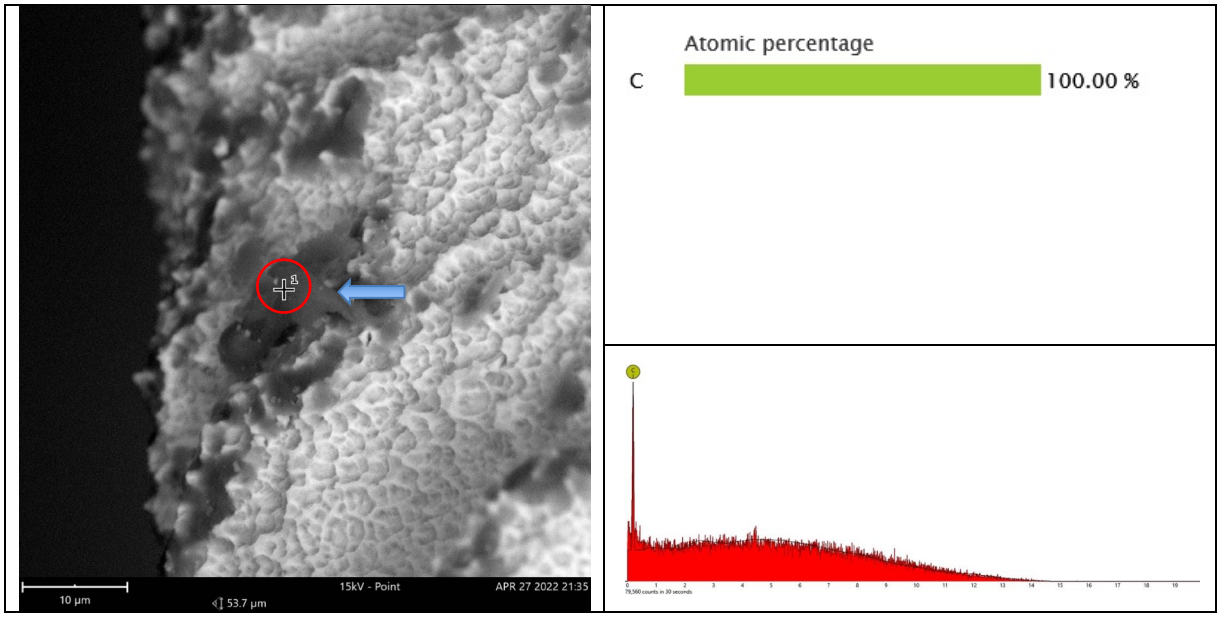


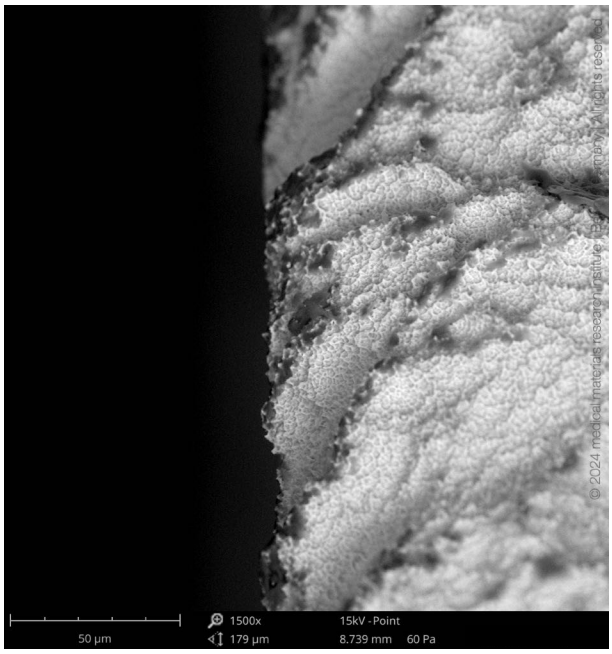


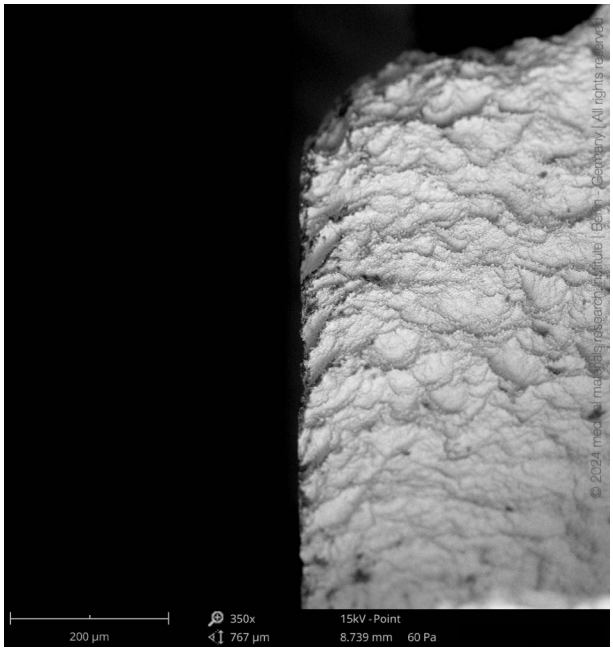


(Images from the same implant)

Example of another, mainly particle-free implant, except for the apical implant region showing significant carbonaceous impurities



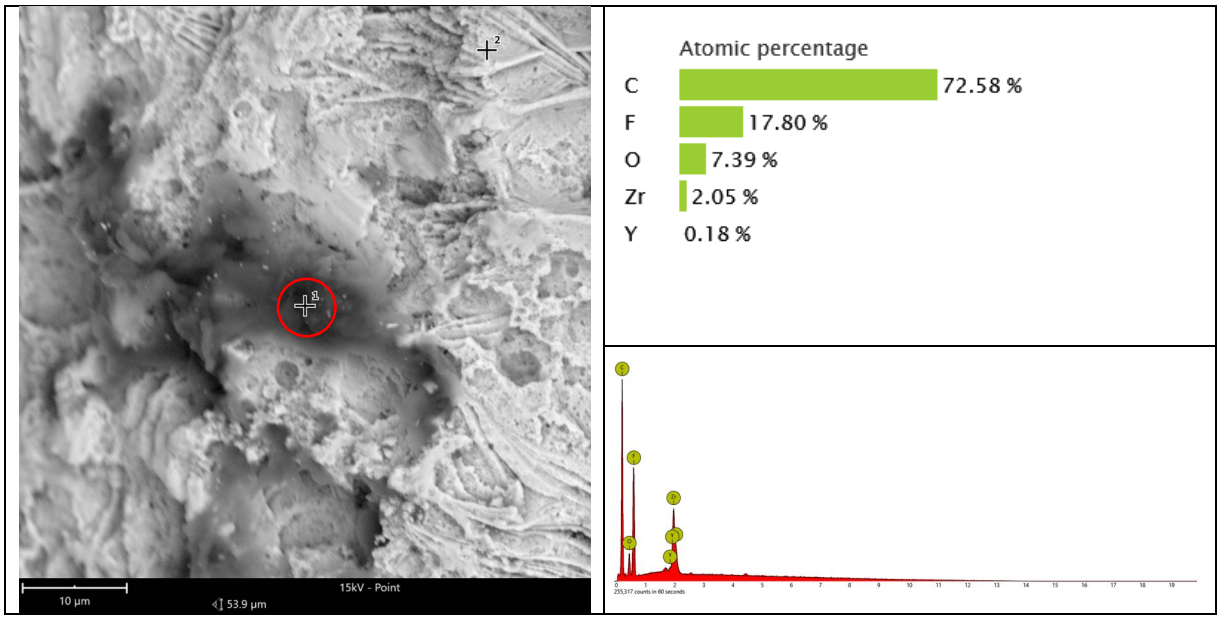


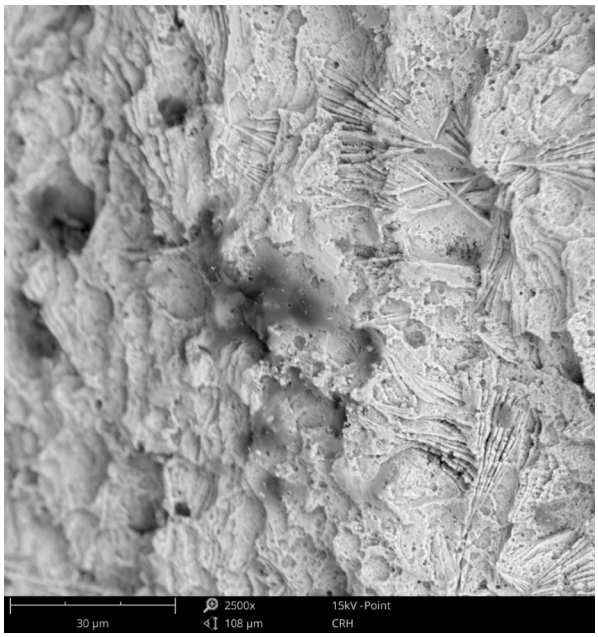


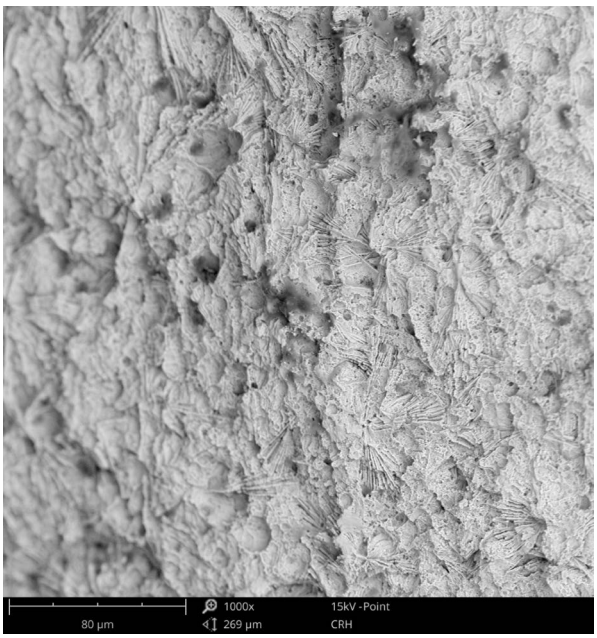
(Images from the same implant)

4.6 Remnants of fluorocarbon compounds

Example #1





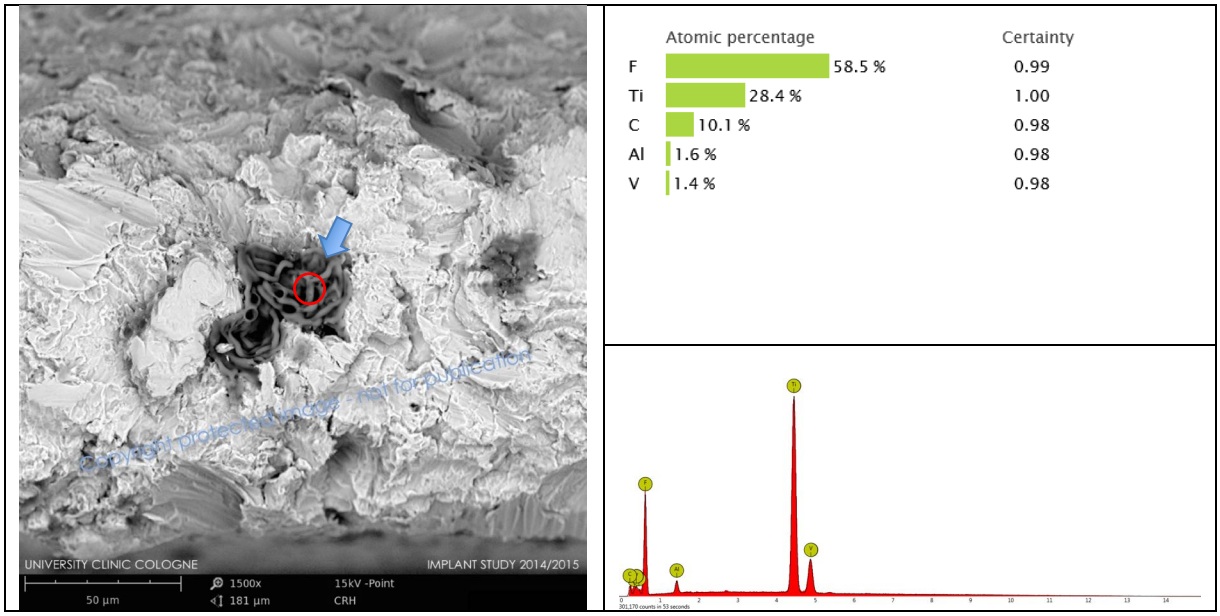


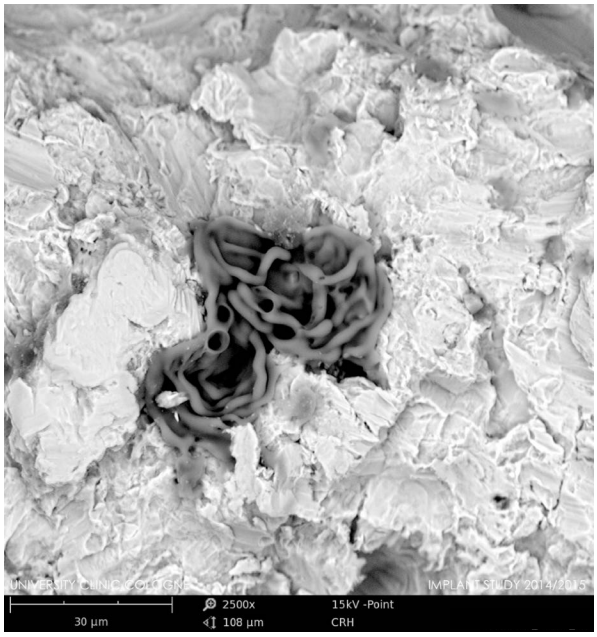
Significant contamination with fluorocarbon particles on the entire surface of a ceramic implant

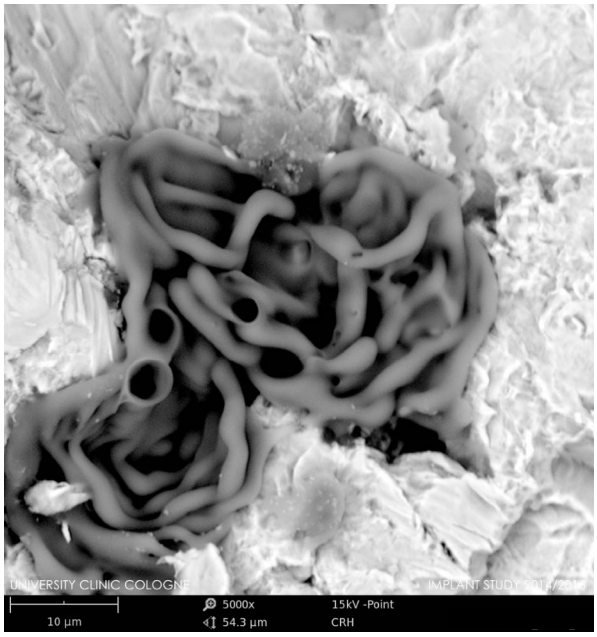
(Images from the same implant)

Remnants of fluorocarbon compounds (continued)

Example #2



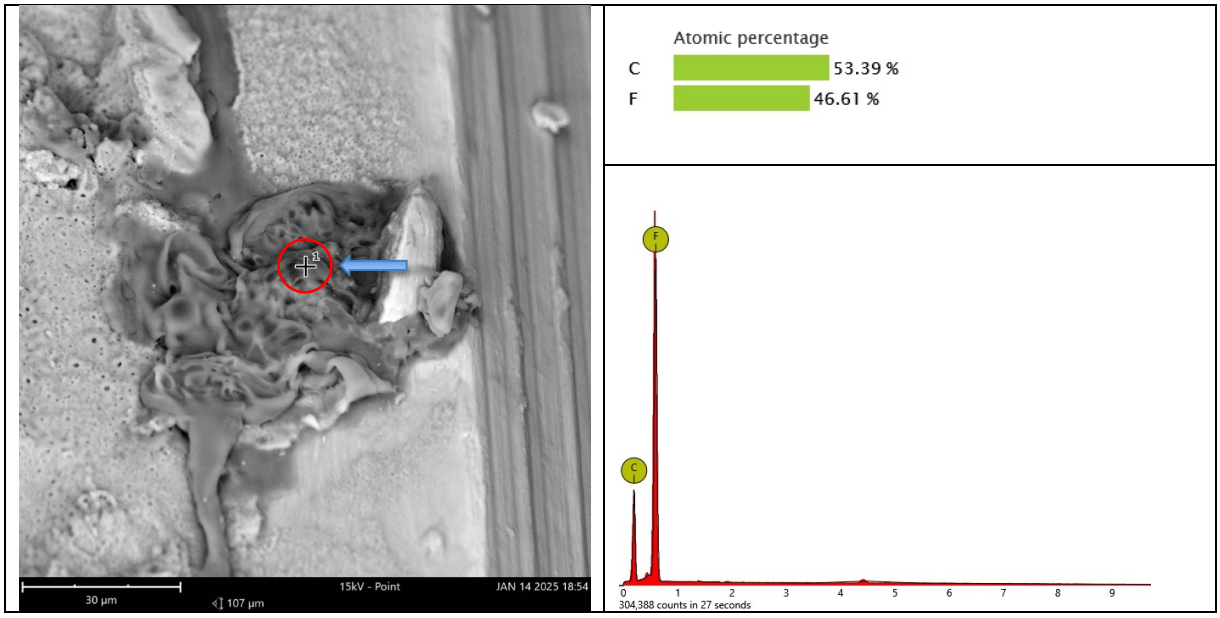


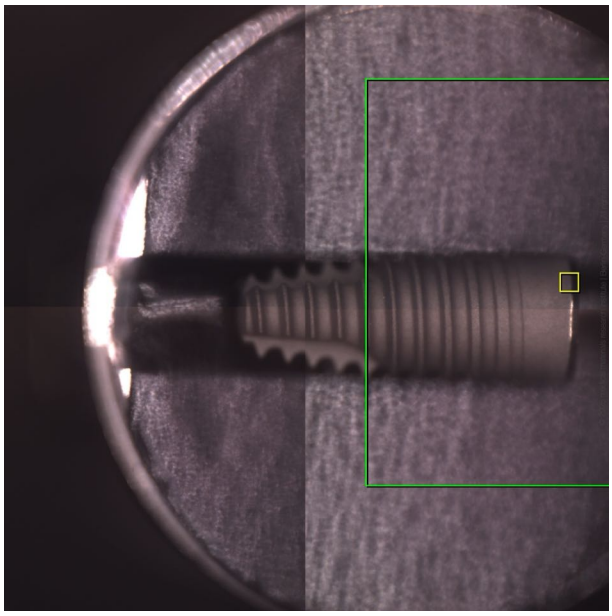


(Images from the same implant)

Remnants of fluorocarbon compounds (continued)

Example #3



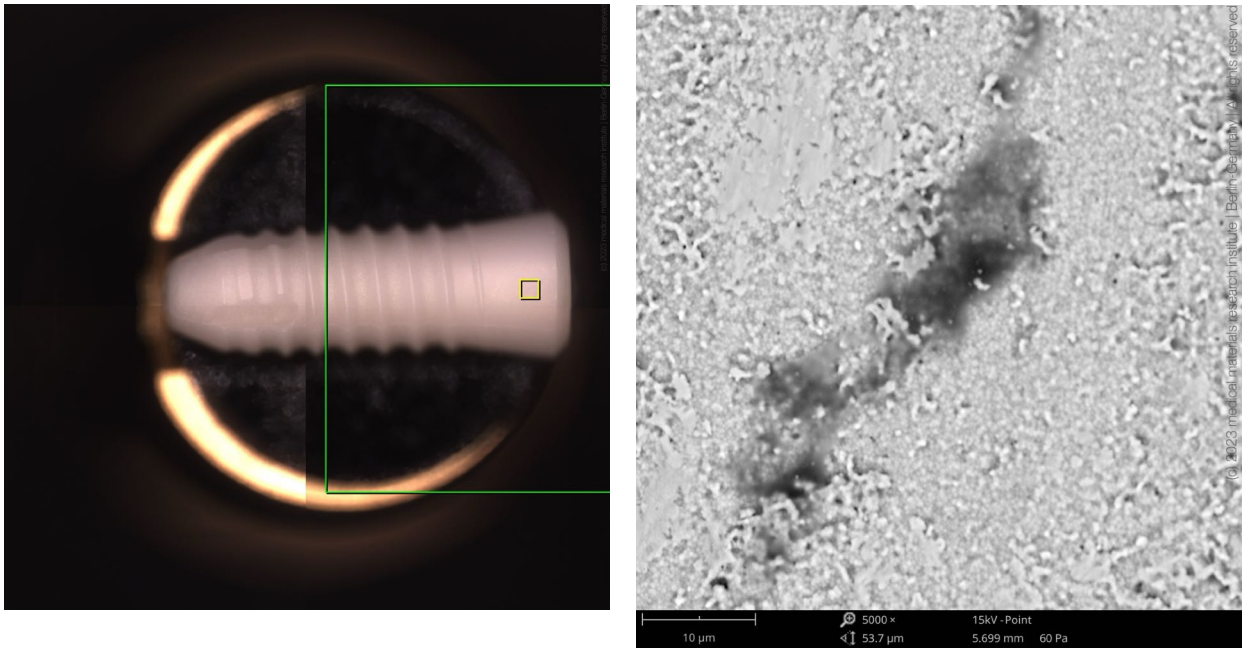


(Images from the same implant)

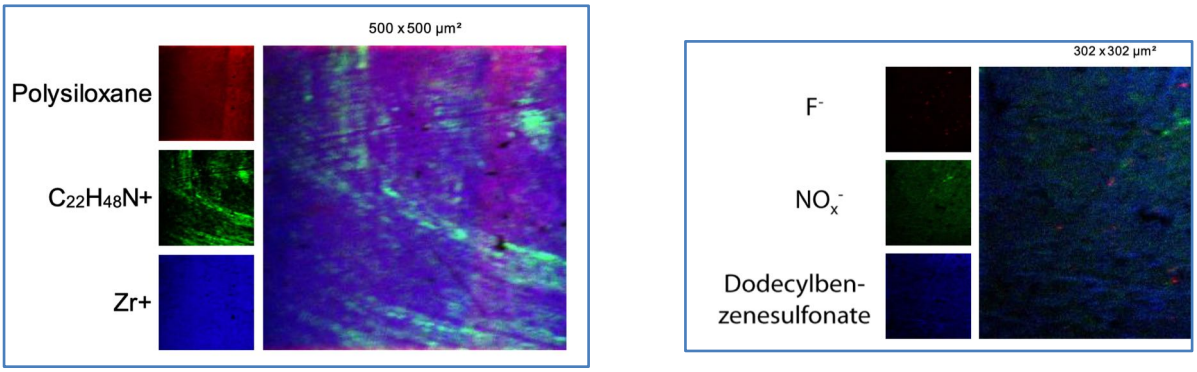
4.7 Thin-film contaminants

Due to the low atomic number (nuclear charge number) of carbon, carbonaceous (organic) thin-film contaminants appear as darker areas within the brighter titanium or ceramic material of higher atomic number in high-magnification material-contrast SEM images. Using Time-of-Flight Secondary Ion Mass Spectrometry (ToF-SIMS) allows a more detailed characterization of the organic material present.

For example, several surfactants—some with cytotoxic potential—were detected on the surface of dental implants, including dodecylbenzene sulfonate (DBSA) and didecyldimethyl-ammonium chloride (DDAC-10C), the latter a quaternary ammonium compound widely applied as a pesticide and biocide.



A ceramic implant showed areas with a thin gray layer of carbonaceous contaminants in the backscattered electron (BSE) imaging (left: camera view in the SEM; right: SEM 5,000x)



ToF-SIMS analysis of a sample from the same implant type revealed significant traces of two potentially cell-toxic chemical residues in the corresponding region of interest.

5 Criteria

Surface anomalies as shown in **4.1** do not have clinical relevance and should not be considered as criteria for the Quality Mark.

Remnants of blasting material like titanium dioxide, aluminum oxide etc. (see **4.2**) are not suspected to have a major impact on the level of BIC or removal torque as clinical data and documentation of the respective implants showed. Thus, remnants of blasting material should not be considered as criteria for the Quality Mark but will be mentioned in the corresponding documentation.

Foreign metal particles, in particular chemical compounds containing iron-chrome, iron-nickel, chromium, nickel, copper, tin, tungsten or antimony as shown in **4.3** are not part of the implant material. These particles pose a potential risk of inducing a significant foreign body reaction; some metals, like antimony, are even rated as cell-toxic. These particles are technically avoidable and should not be accepted to whatever extent on the surface of sterile packaged dental implants. Metals as part of the ceramic base material and, if applicable, metals from alloys of the implant material are excluded.

Titanium particles that may detach during implant insertion are not a criterion. Although these small particles may not necessarily hamper initial osseointegration, their release from the functioning implant over time may impact the reaction of cells responsible for the inflammatory process and bone remodeling.[14,15] In addition, Ti dissolution products may result in microbial dysbiosis and eventually lead to periimplantitis.[15] However, the role of titanium particles in the pathogenesis of peri-implantitis remains a matter of controversy. Some authors have reported that titanium microparticles are frequently present in tissues surrounding dental implants without being associated with the onset of peri-implantitis.[16] If titanium particles contribute less to disease development than previously assumed, future clinical research on peri-implantitis may shift its focus toward organic, carbon-based contaminants such as polyoxymethylene (POM) or polyethylene (PE), underscoring the relevance of the methodology presented in this guideline.

Organic particles are found on many implants. Here, single organic particles (**4.4**) should be distinguished from the systematic allocation of numerous organic particles (**4.5**). SEM analyses of over 400 dental implants revealed a consistent pattern of organic residues. Either the affected implants were covered by a significant number of single organic particles (> 50 particles in an angle of view of 120 degrees) or they showed none or only very few organic particles, i.e., less than 10/120°. As the reduction of organic residues is technically feasible, the recommendation of this guideline is to **set the threshold at 10 organic particles, each smaller than 50 µm**, visible in an angle of view of 120° to achieve the quality mark. Any higher amount or size of organic particles should be an exclusion criterion. In the years since the first release of this consensus document, the specified threshold values have proven to be effective. However, they remain a matter of constant evaluation for the following years to ensure further improvement of implant production.

Particles with traces of fluorine and carbon from **fluorocarbon compounds** are shown in **4.6**. These particles are technically avoidable and should not be accepted in the framework of the quality mark awarding process.

In cases where clinical reports indicate unusual failure rates or SEM imaging reveals conspicuous **thin-film impurities,** as shown in **4.7**, Time-of-Flight Secondary Ion Mass Spectrometry (ToF-SIMS) has proven to be a reliable complementary analytical method providing specific information about the chemical compound or substance class of a contaminant.[17] If impurities show significant traces of **cell-toxic residues of chemical compounds**, e.g., as dodecylbenzene sulfonic acid (DBSA), an aggressive detergent [18], which is classified as a "hazardous substance" according to the US Environmental Protection Agency (EPA), or didecyldimethylammonium chloride (DDAC-C10), which is a quaternary ammonium compound (QAC) disrupting intermolecular interactions and lipid bilayer integrity [19], these residues are rated as not acceptable.

Sufficient clinical data - proven by reports published in peer reviewed scientific literature or equivalent such as multi-annual post-market clinical follow-up (PMCF) studies or the “Summary of safety on clinical performance“ (SSCP) as required in MDR 2017-745 Article 32 - showing ≥ 95 % survival rates over a period of at least two years for the specific implant device or device family is an essential requirement to achieve the Quality Mark.

Before an implant system can be awarded the Trusted Quality Seal for the fifth time, updated clinical data must be resubmitted in full and thoroughly reviewed again in peer review.

Summary of Criteria

Criteria	Test method	Thresholds/Acceptance
Foreign metals (abrasion, transfer, metal shavings, particles)	Scanning electron microscopy (SEM) with backscattered electron (BSE) imaging and energy dispersive X-ray spectroscopy (EDS)	No particles acceptable at a viewing angle of 120° (relative to the horizontal sample). Metals as part of the ceramic base material and, if applicable, metals from alloys of the implant material are excluded.
Single organic particles < 50 µm	SEM/EDS	No more than 10 particles at a viewing angle of 120° (corresponding to 30 particles on the entire implant surface)
Clusters or single organic particles ≥ 50 µm	SEM/EDS	Any cluster formation from one or more particles ≥ 50 µm is not acceptable
Residues of cell-toxic chemical compounds	Time-of-Flight Secondary Ion Mass Spectrometry (ToF-SIMS)	Not acceptable
Clinical survival rate	Peer-reviewed scientific publications, PMCF report, SSCP	At least 95 percent survival rate over a period of at least two years

6 Decision

The signatories to this decision template for the CleanImplant Quality Mark certify that they have read this document in its entirety and agree to the recommendations as outlined in paragraph 5.

7 Signatures of the CleanImplant Scientific Advisory Board

Signatures of this revised version released 2025-10-15 (in alphabetic order)

Approver Name	Signature	Date Signed
Prof. Tomas Albrektsson		2025/09/12
Prof. Florian Beuer		2025/09/16
Dr. Luigi Canullo, PhD		2025/08/08
Prof. Hugo De Bruyn		2025/09/14
Dr. Dirk Duddeck		2025/10/06
Dr. Scott D. Ganz		2025/09/16
Dr. Birgit Hagenhoff		2025/10/05
Prof. Jaafar Mouhyi		2025/09/15
Dr. Michael Norton		2025/10/06
Prof. Ann Wennerberg		2025/08/06

8 Acknowledgements

The CleanImplant Foundation gratefully acknowledges the members of the Scientific Advisory Board who contributed to the revision of this Guideline. Their expertise, critical review, and consensus-building were essential in shaping the criteria and recommendations of this second edition. The Board's contributions, grounded in extensive academic, clinical, and research experience, have significantly enhanced the robustness and practical applicability of the document. Collectively, the Scientific Advisory Board has ensured that the recommendations presented here are scientifically rigorous, clinically relevant, and consistent with the highest international standards of patient safety.

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