CLEAN IMPLANT
FOUNDATION

CleanImplant Trusted Quality Mark 2017 - 2018

Process Description
Quality Mark 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

1 Introduction

It should be a matter of course that all dental implants are clean, when delivered in a sterile packaging as surface pollution with organic particles or major inorganic residues originating from the production process are suspected to cause insufficient or missing osseointegration of dental implants. Unintended micrometre-scale particles may induce a foreign body reaction with a loss of bone in the early stages of osseointegration.

A new global quality label, the “CleanImplant Trusted Quality Mark” is the expression of highest quality level in the production of dental implants. It will raise the awareness for considerable differences in quality and, even more important, for clean implants not only practitioners but also patients may trust.

2 Process Descriptions

At the 1st CleanImplant Group Meeting on March 21st, 2017 criteria for the new quality mark were discussed with industrial partners and members of the Scientific Advisory Board. Results and recommendations are included in this document. In the following eight weeks meetings and discussions with the BAM, Bundesanstalt für Materialprüfung (German federal institute for material examination) led to new processes and environmental requirements of sample unpacking as well as to the subsequent SEM analysis. Thus, processes were redefined and complemented according to BAM recommendations.

2.1 Sample Acquisition

For the intended quality assessment five samples from each implant device / device family of every participating company will be selected through a mixture of mystery shopping (two samples) and direct factory order (three samples) to assure that the samples are selected randomly.

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

In order to avoid artifacts on the unpacked implant samples during the transfer into the SEM all implants have to be unpacked and analyzed in the scanning electron microscope under cleanroom conditions according Class 100 US Fed. 209 and ISO class 5 (DIN ISO 14644-1).

2.3 SEM Analysis Accreditation - DIN EN ISO/IEC 17025

All collected samples are subjected to the same quality analysis protocol performed by independent laboratories that are in the process for - or completed - a Quality Management System according to DIN EN ISO/IEC 17025 (general requirements for the competence of testing and calibration laboratories). These Laboratories have to implement a quality system aimed at improving their ability to consistently produce valid results. This includes the quality standard according to DIN EN ISO 9001:2015. The laboratories undergo regular audits and multiannual re-assessments by external, independent accreditation bodies (e.g. DAkkS).

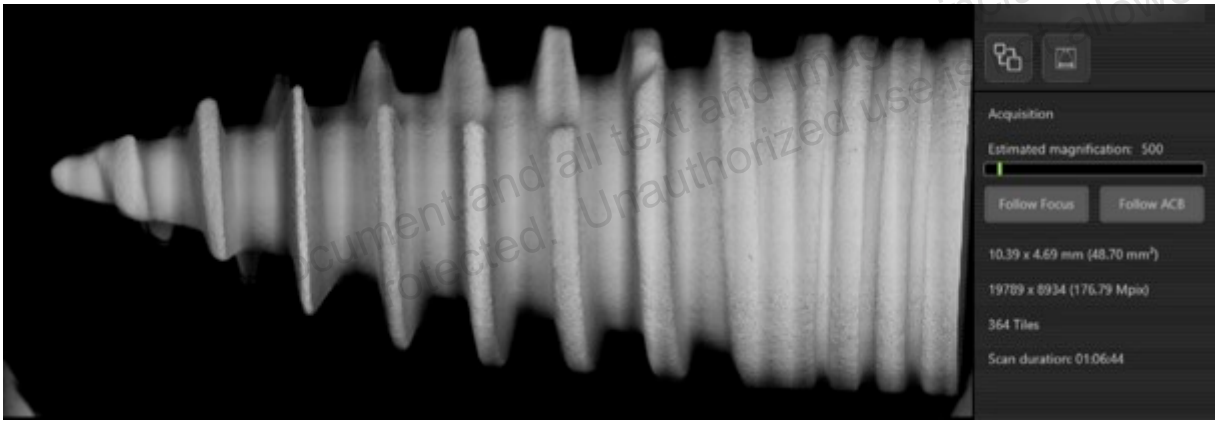
2.4 **Protocol of Analysis**

The scientific workstation is a Phenom proX Scanning Electron Microscope, equipped with a high-sensitivity backscattered electron detector that allow 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 proX Scanning Electron Microscope

Fixed implant (example) on the sample holder

Unboxing and mounting of the implant on the SEM charge-reduction sample holder and the transfer to the SEM vacuum chamber is performed inside a laminar-flow environment under Cleanroom Class 5 conditions. During this procedure the implant surface that is to be analyzed will not get in contact to any other material. After the vacuum is generated SEM-imaging and EDS-analyses will be completed. Backscattered electron imaging (BSE) allows drawing conclusions about the chemical nature (density) and allocation of the different contaminations and/or remnants on the sample material. Systematic scanning of the surface reaches approx. one third of the implants surface in a viewing angle of 120 degrees.



In order to achieve a complete overview of the sample and comprehensive surface quality information in high resolution, implants are scanned at a magnification of 500x in “Automated Image-Mapping” mode. This technique produces more than 360 single high-resolution SEM images that are digitally composed to one large image with an extreme high resolution (FSHR - Full-Size High-Resolution image). The composed image makes it possible to count the particles in the visible field and to identify areas of interest for the subsequent spot-analyses.

3 Quality Mark Awarding Process

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

Tier 1: Single implant samples of production year 2016 and 2017 are research subject of a new study that follows the same improved 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.

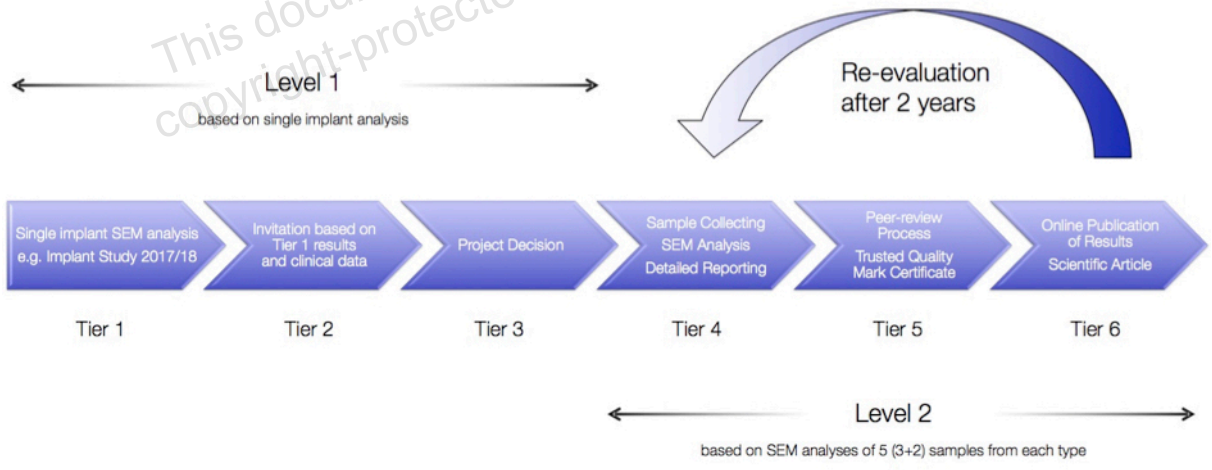
Tier 3: Project decision following a contractual agreement.

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 mixture of mystery shopping and direct factory order. Independent laboratories will perform unpacking, sample mounting and transfer into the SEM under cleanroom conditions according ISO class 5, DIN ISO 14644-1 and complete SEM-imaging and elemental analyses according to DIN EN ISO/IEC 17025.

A comprehensive report will be generated and send 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 the quality award a new set of samples will be collected and analyzed in a re-evaluation process for a renewal of the quality mark.

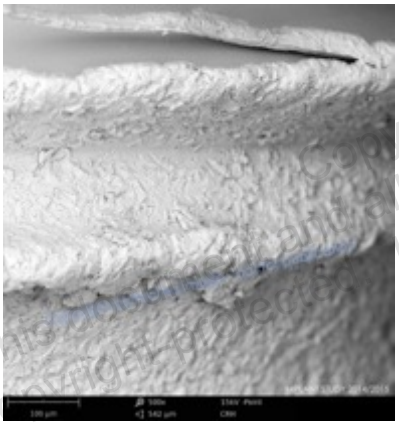


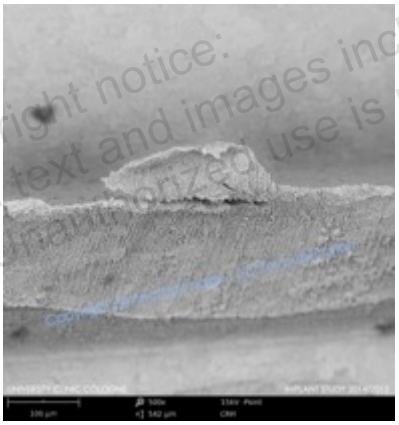
4 Database for the Quality Mark Criteria

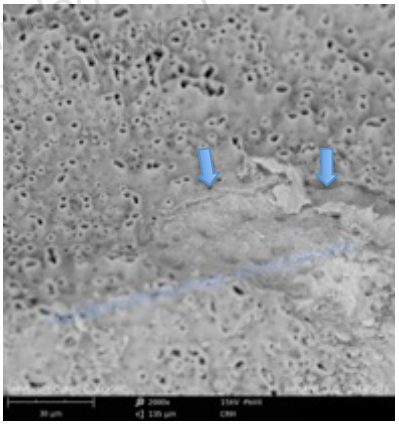
In three consecutive studies from 2008 until 2016 the purity of dental implants was analyzed by means of SEM/EDX using the same study protocol. In 2016 the large amount of 135 analyzed samples from 100 brands demonstrated a wide spread of production quality. The majority of all implants in this study presented a high standard of quality showing a precise outer geometry and no inorganic or organic particles. However, a fair number of implants surprised with major pollution on the implants surface that may have been caused by the various production-, handling- or packaging processes.

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.

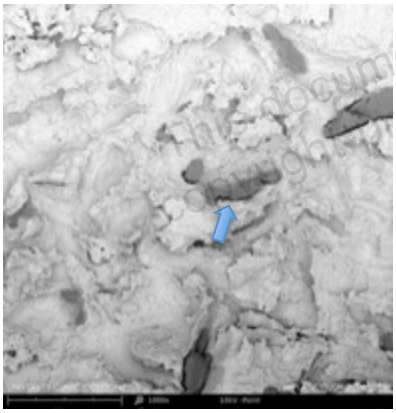




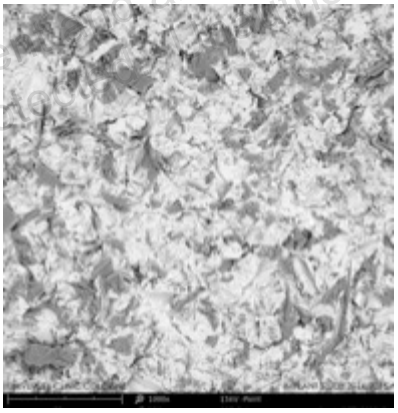


4.2 Remnants of Blasting Material

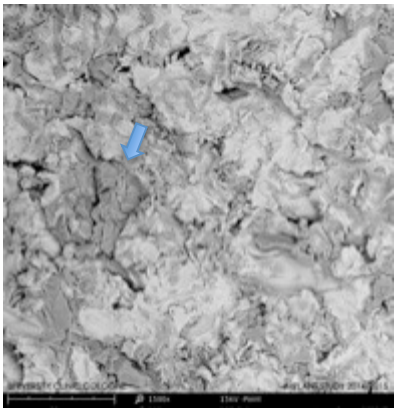
Many implants blasted with aluminum oxide showed remnants of the blasting material mechanically attached to the surface. TiO_2 particles can be seen on the right image.



Al_2O_3 particles, 1000x



Al_2O_3 particles, 1000x

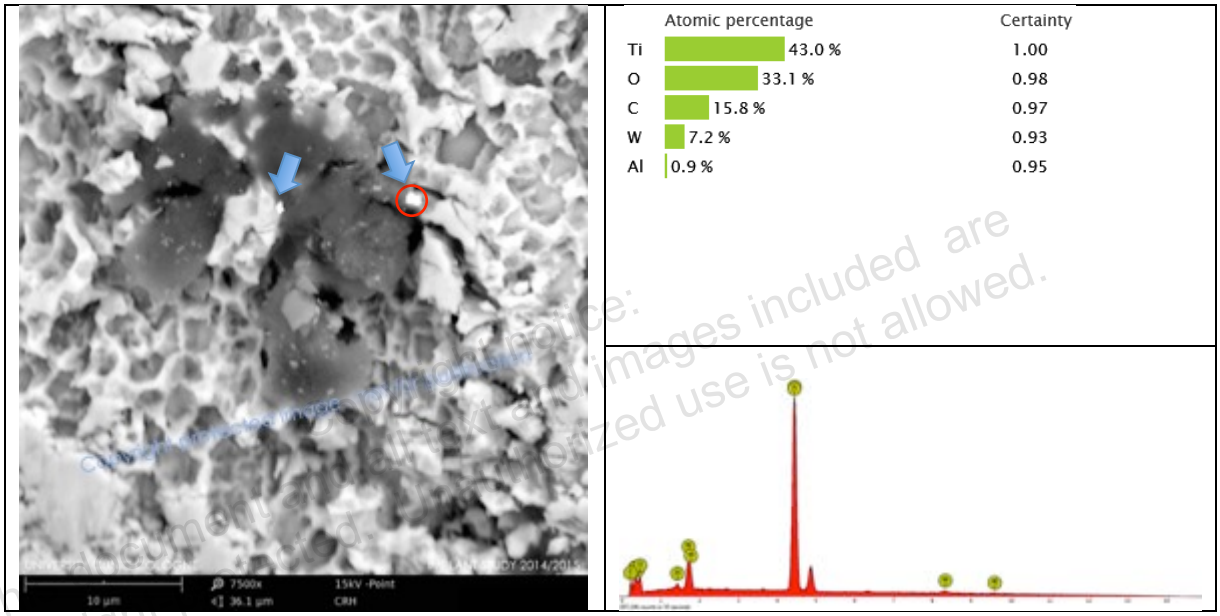


TiO_2particles, 1500x

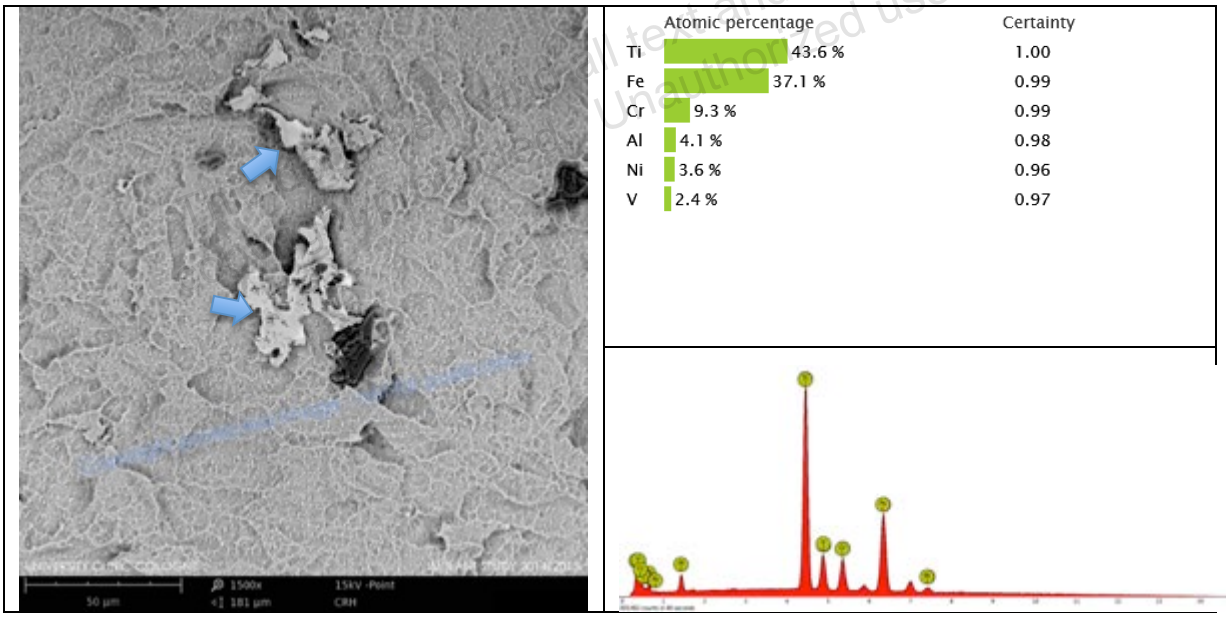
4.3 **Metal particles**

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.

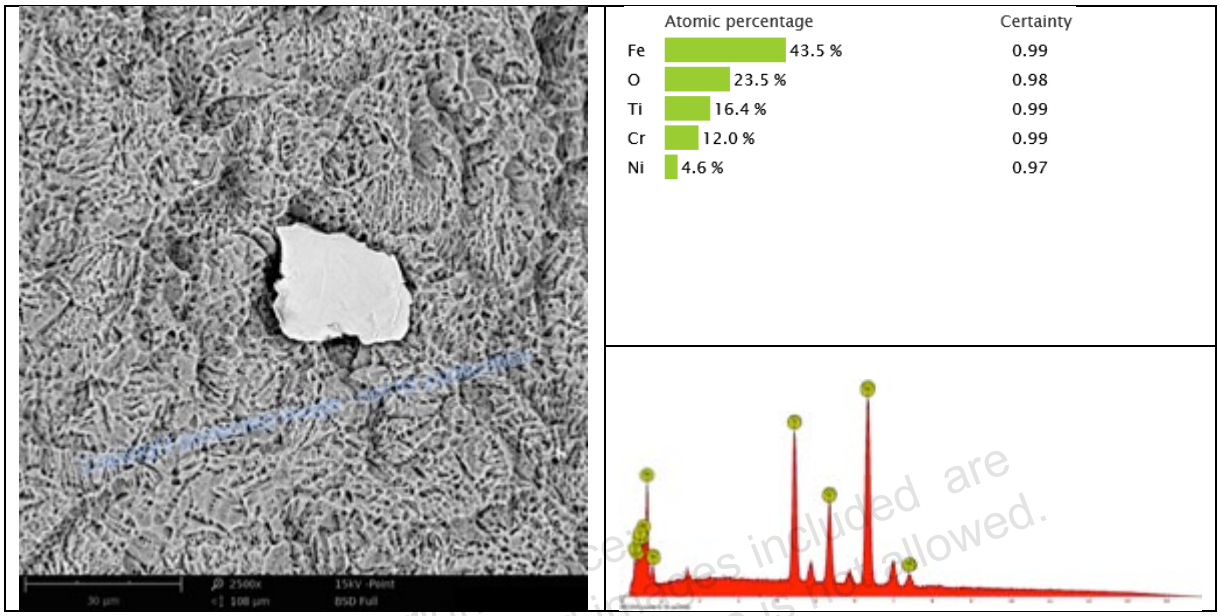
We found particles of **tungsten** (2µm) embedded in an organic matrix as seen below.



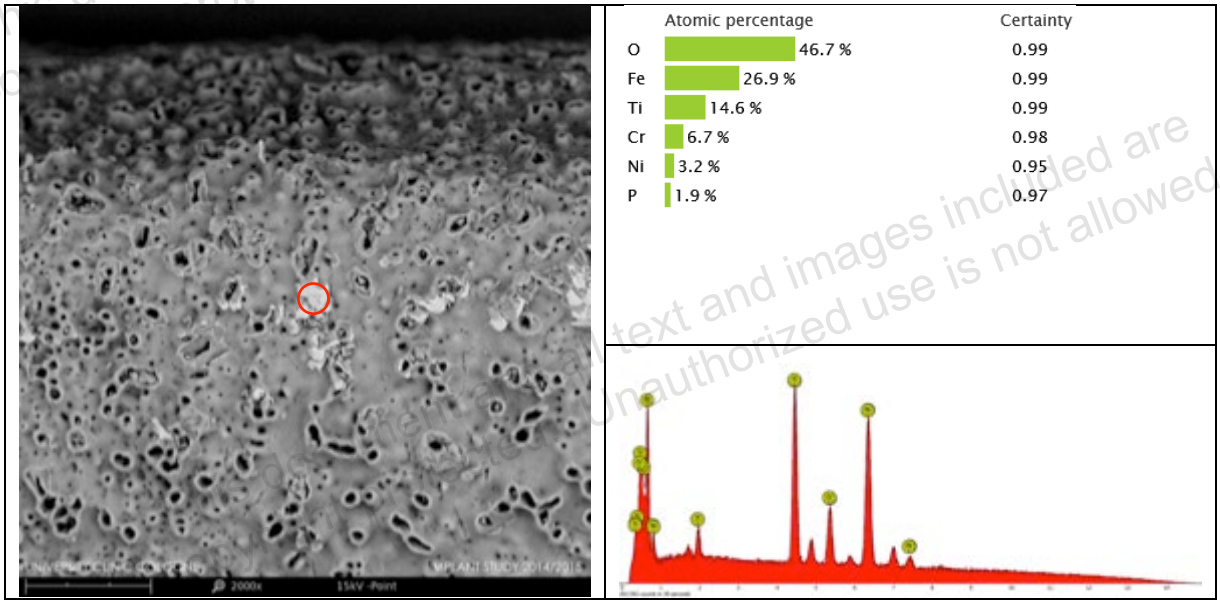
Significant amount of **iron, chromium** and **nickel** in the elemental spot analysis of particles (20-50 µm) on some implant samples may be a hint for recycled or polluted blasting material containing particles of stainless steel (next three images).



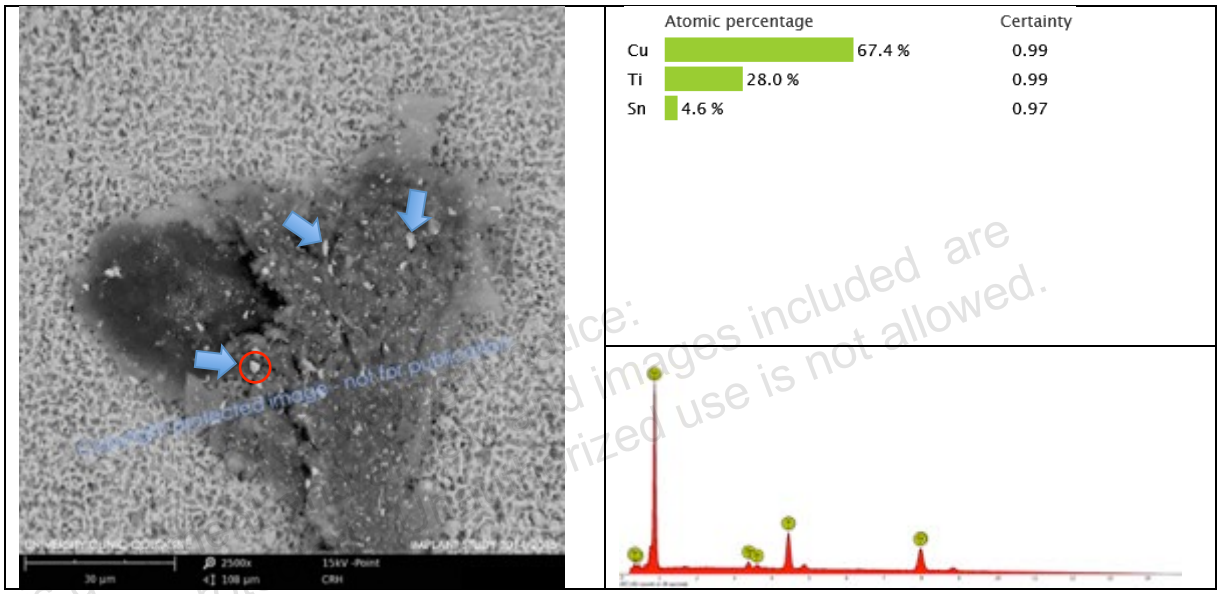
Some implants showed only single stainless steel particles with a diameter of up to 30µm...

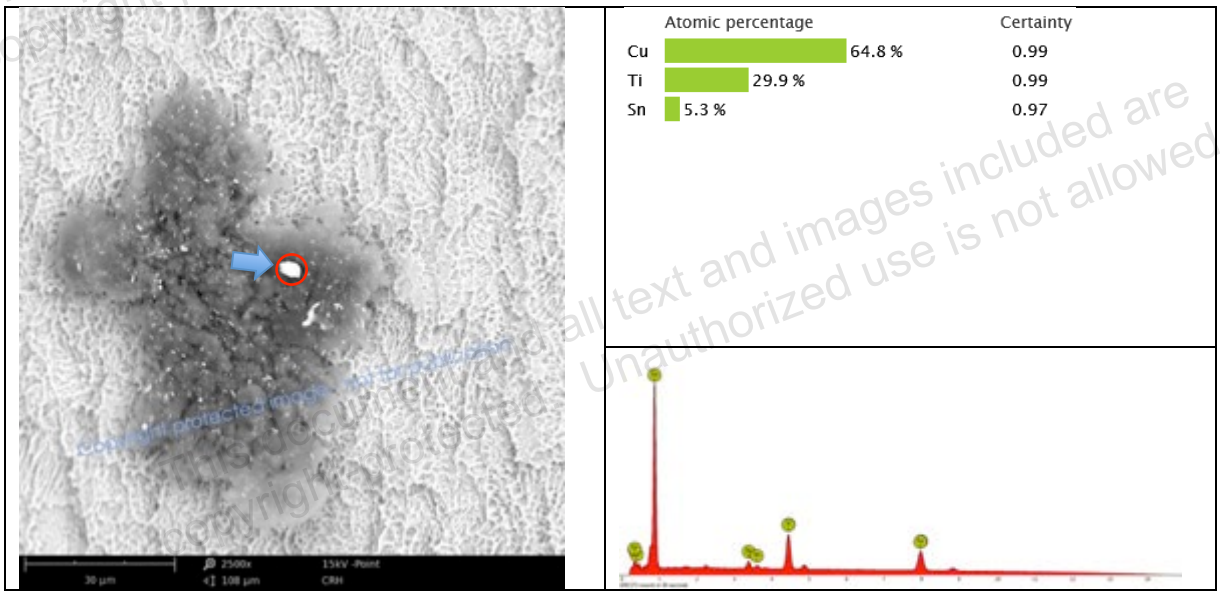


... others revealed a systematic distribution pattern of pollution with numerous stainless steel particles (2-10 µm).

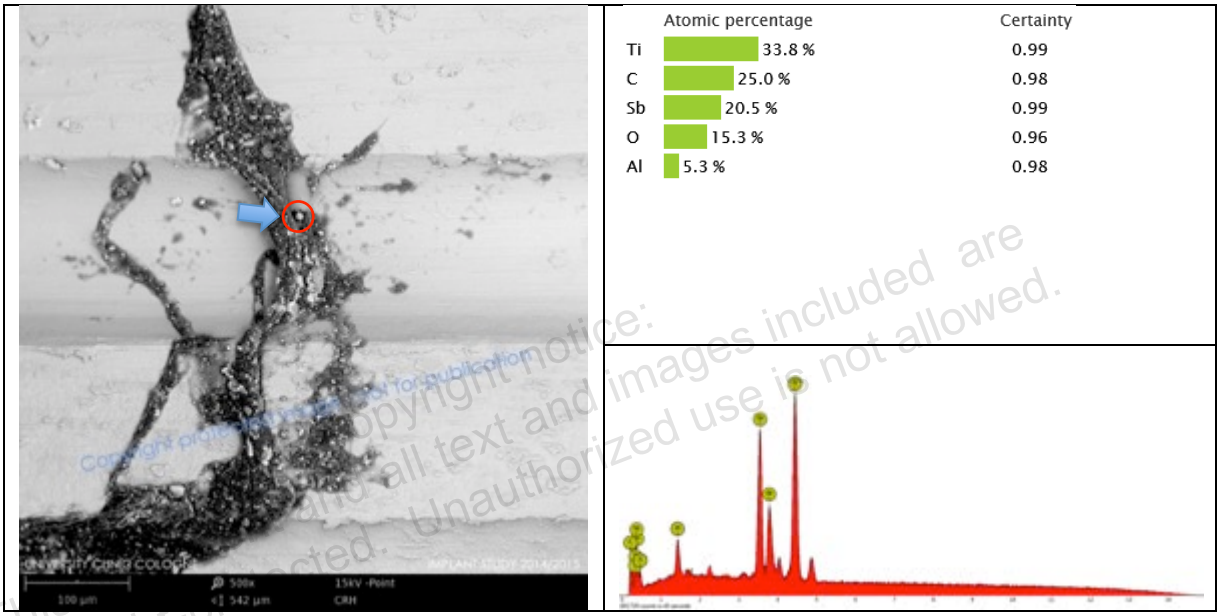


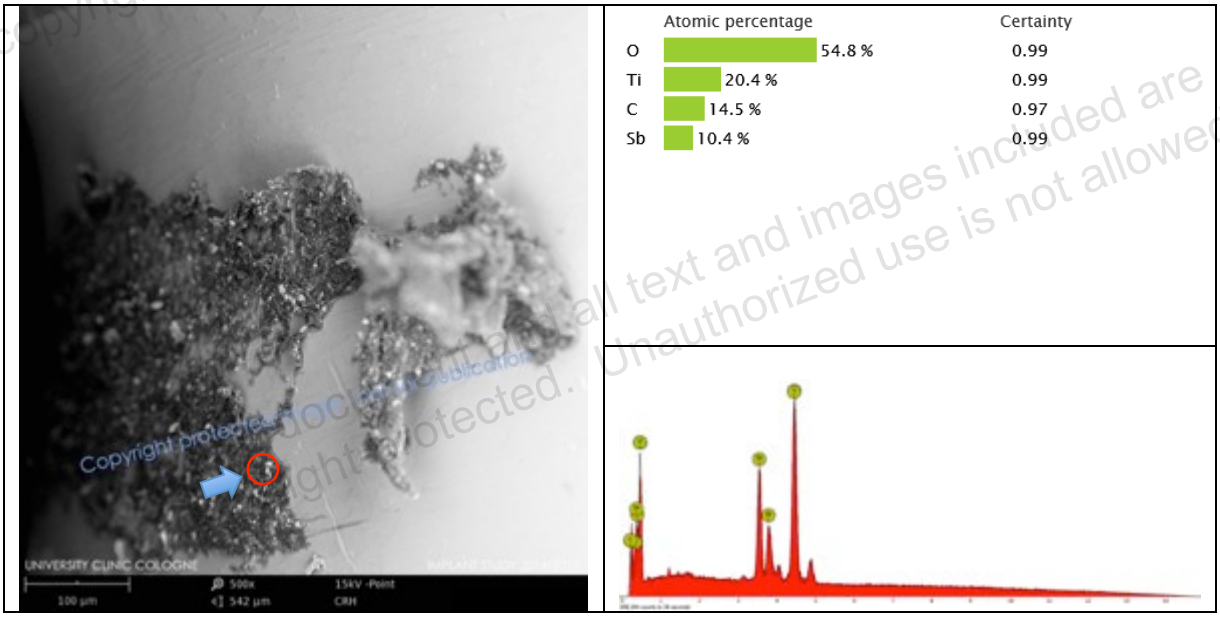
Some metal particles (1-5 µm) showed clear fingerprints of **copper** and **tin** in the elemental analysis as seen in the images below. These metal particles are each embedded in larger organic contaminants (30-100 µm).





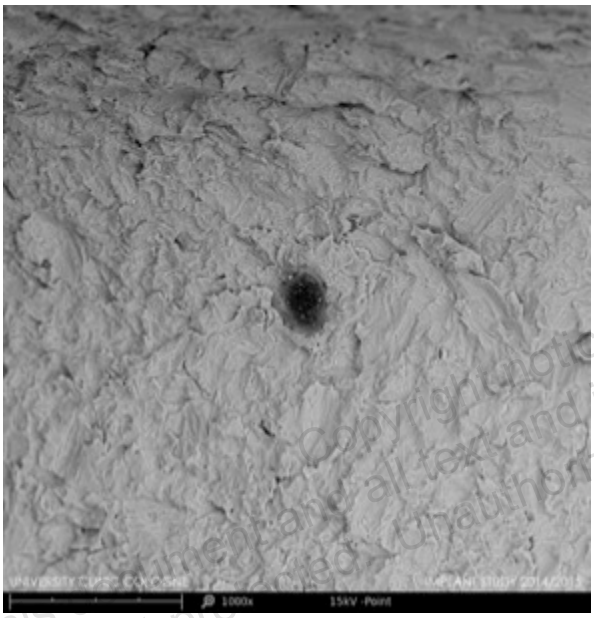
Surprisingly even **antimony** < Sb > (as seen in the two images below) was found in the EDX analysis of two implants.

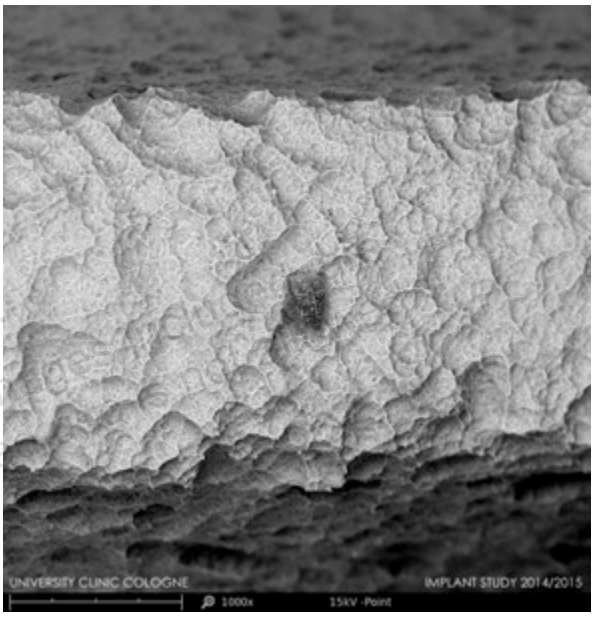


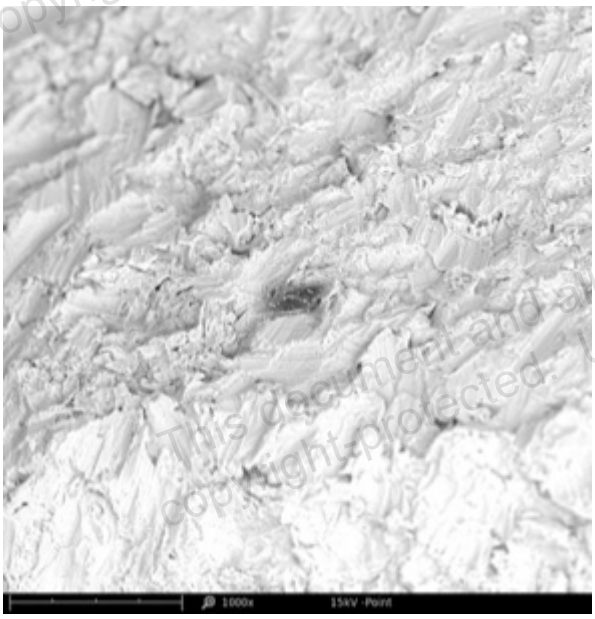


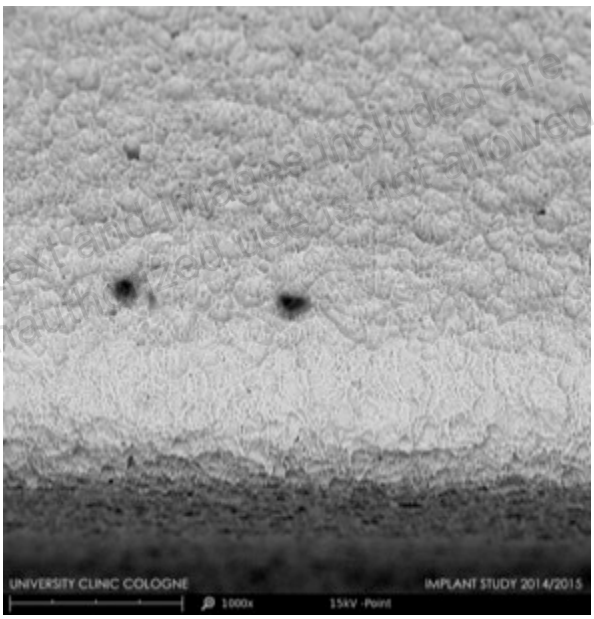
4.4 Single organic particles

Single organic particles (less 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 10 to 30 µm.



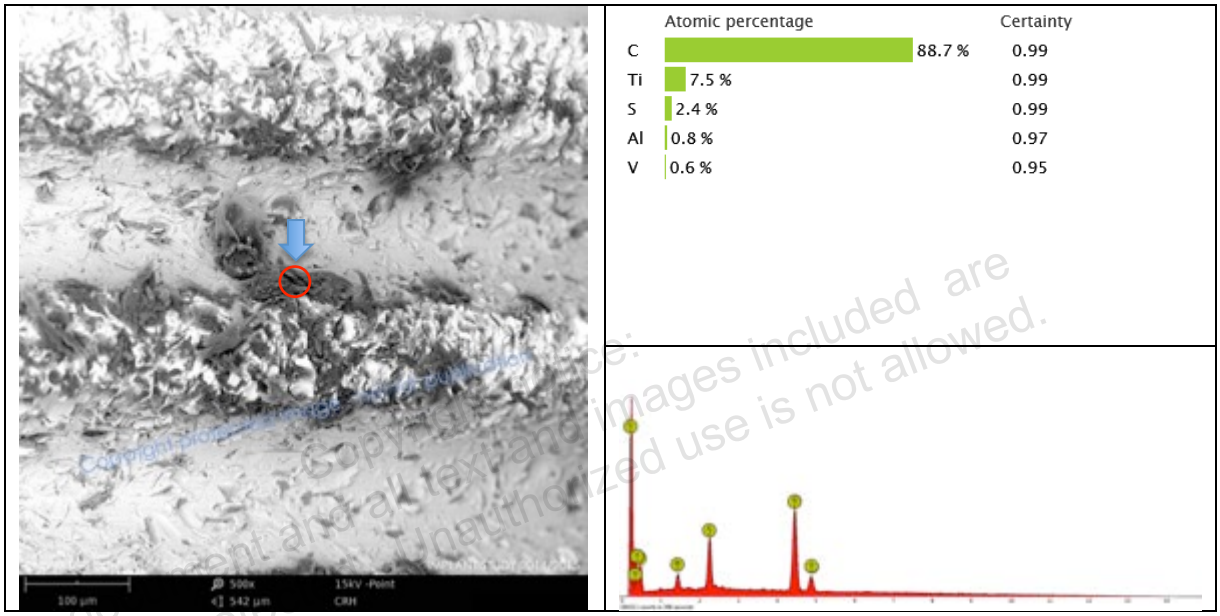


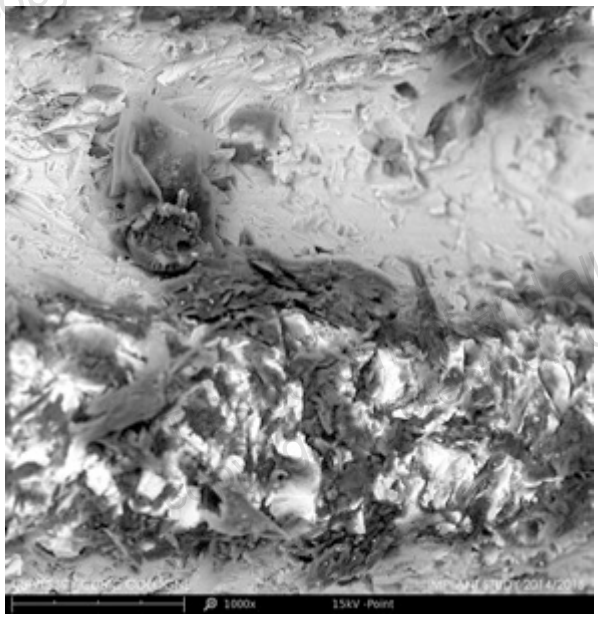


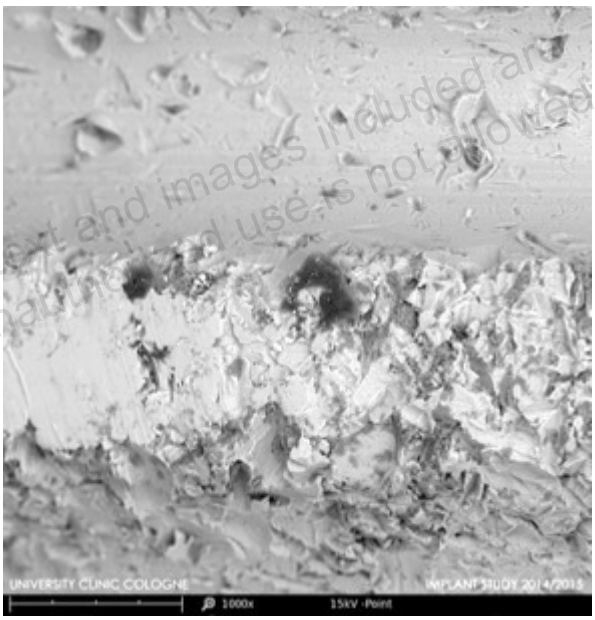


4.5 **Massive organic impurities**

However, a significant number of implants showed a **systematic distribution pattern of organic particles** i.e. mainly on the outer threads of the implant or on the shoulder area.

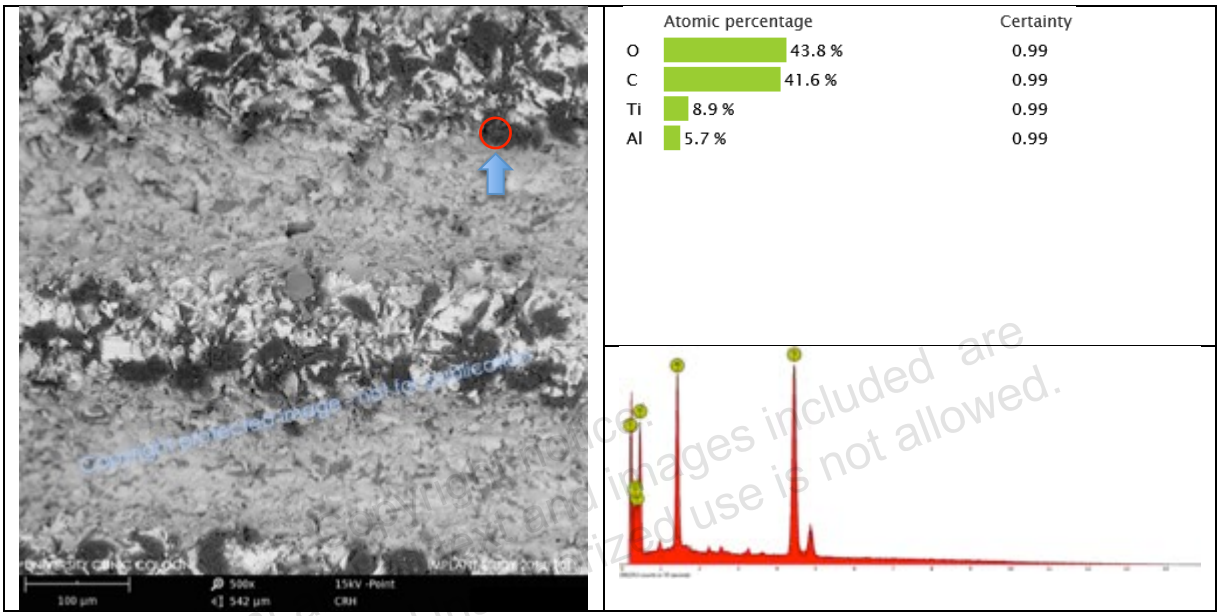


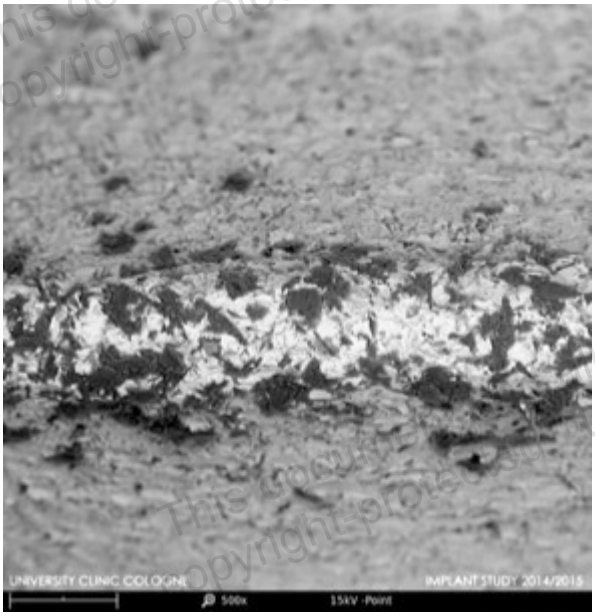


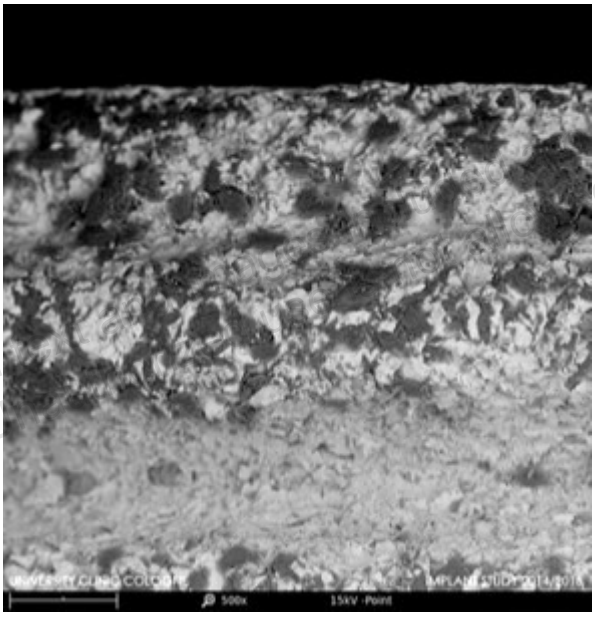


(All three images from the same implant)

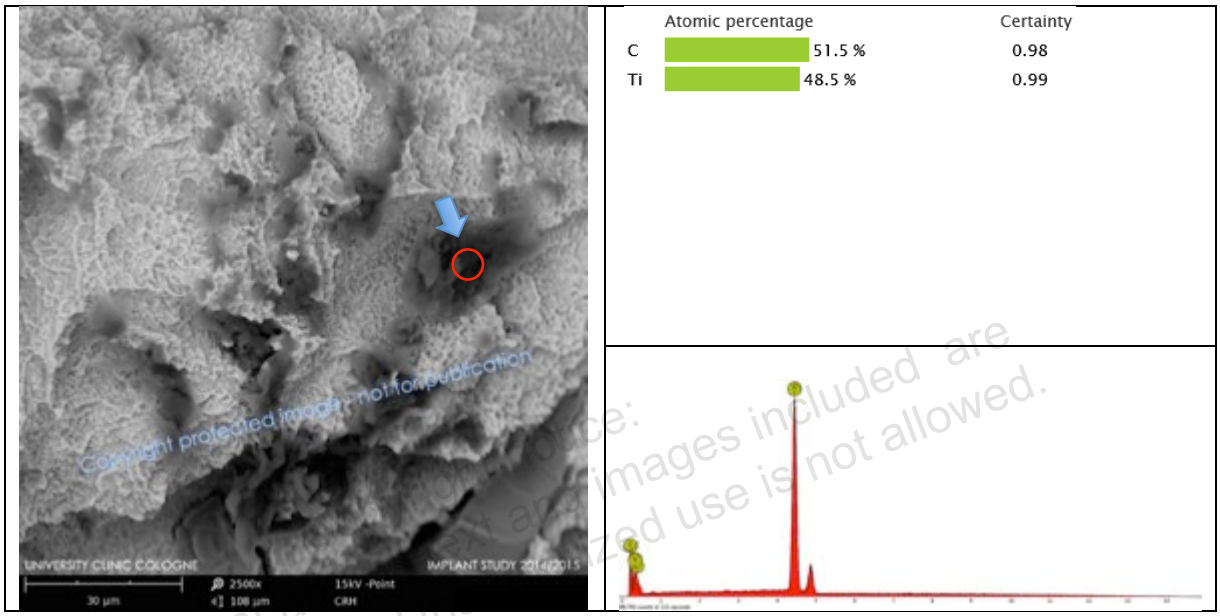
The difference in the distribution of these organic impurities compared to single organic particles is obvious as seen also on the following pages.

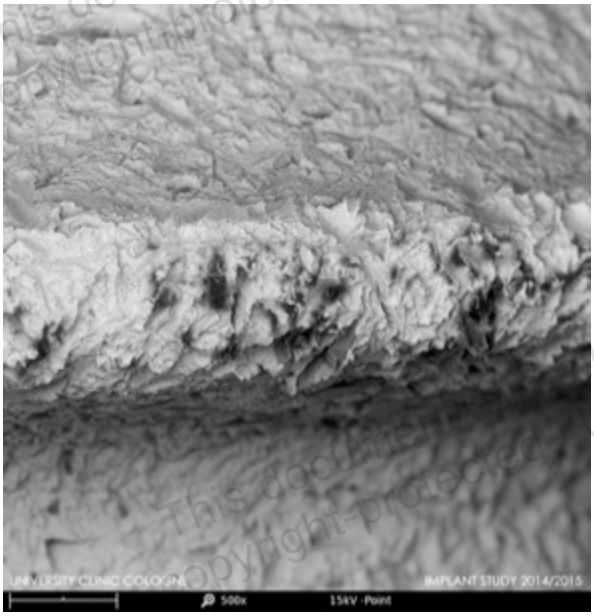


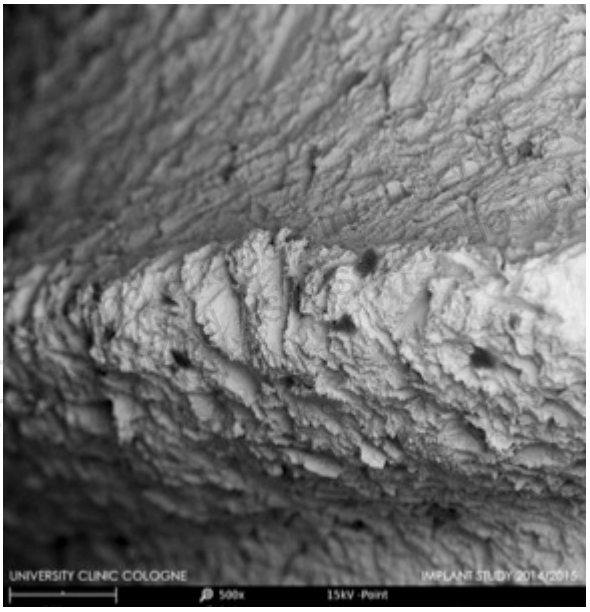




(All three images from the same implant)

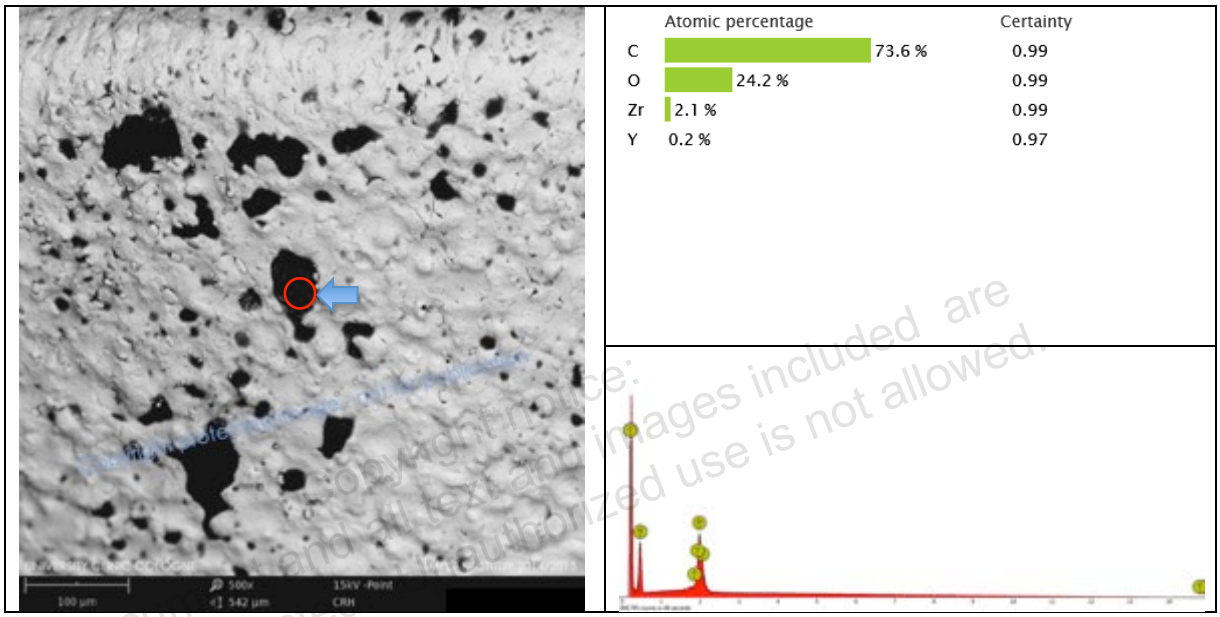


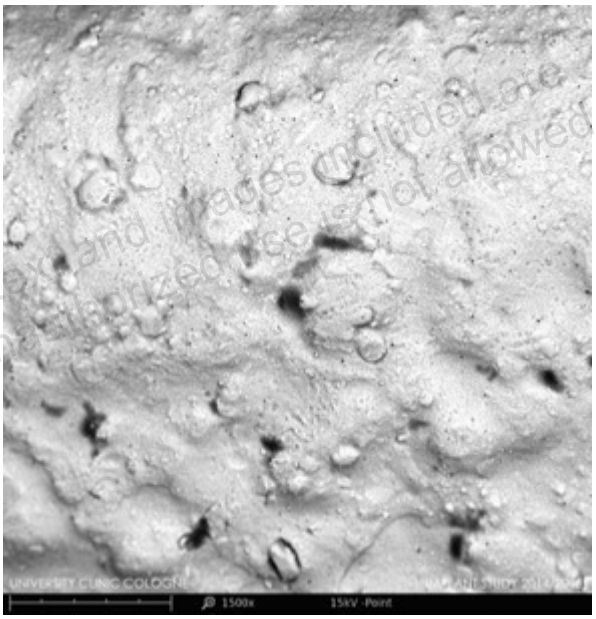




(All three images from the same implant)

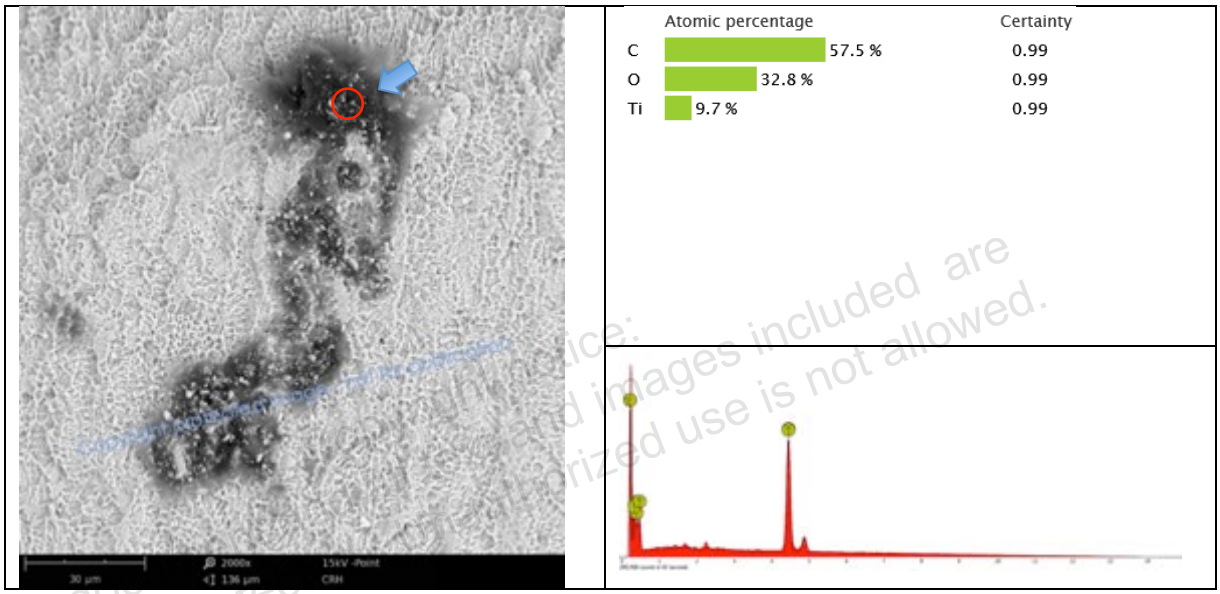
Numerous organic particles on a zirconium implant with a concentration at the implant shoulder.

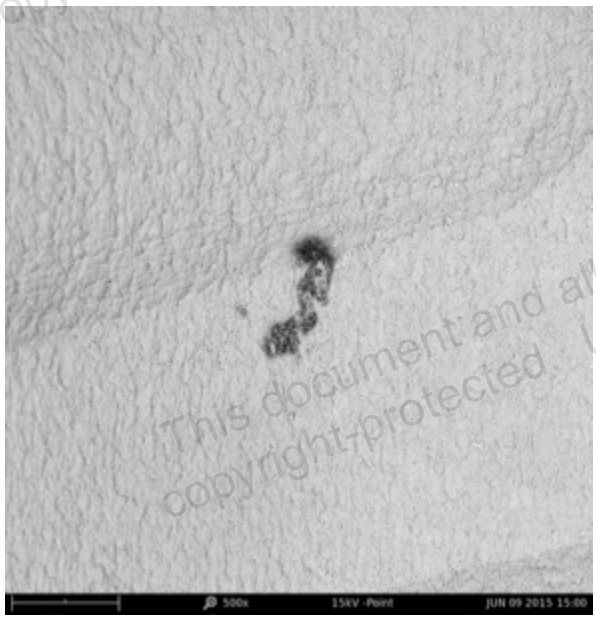


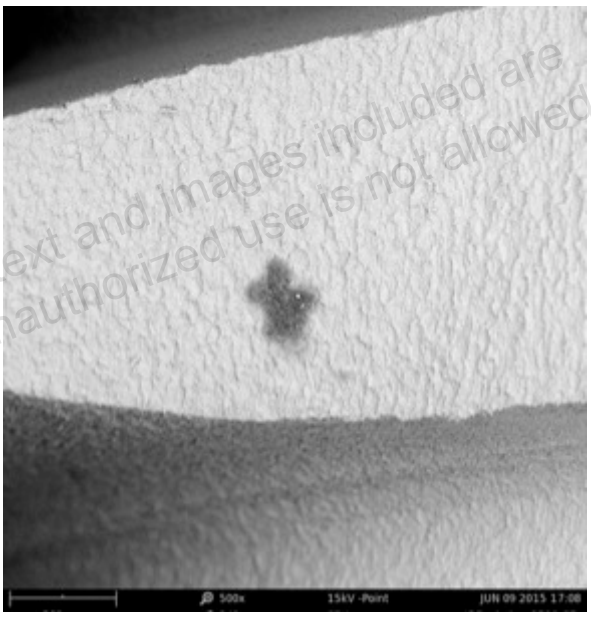


(All three images from the same implant)

Large contiguous organic particles (50-150 µm)



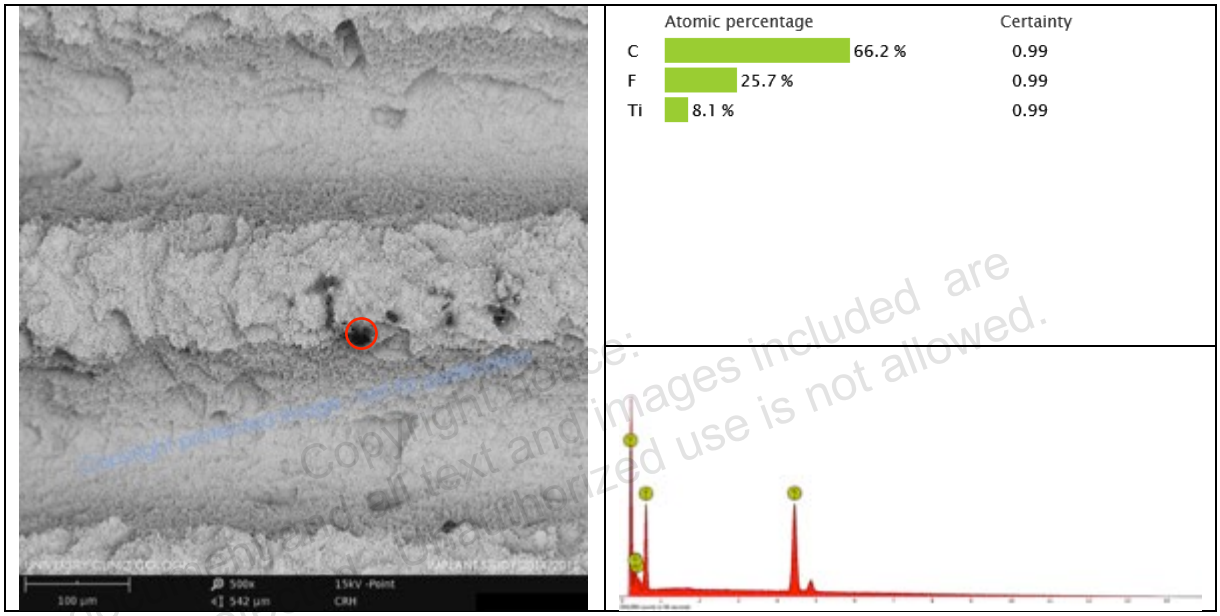


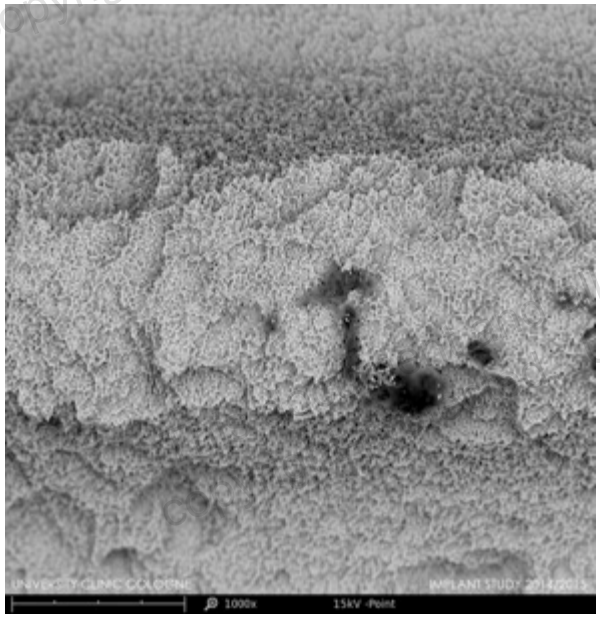


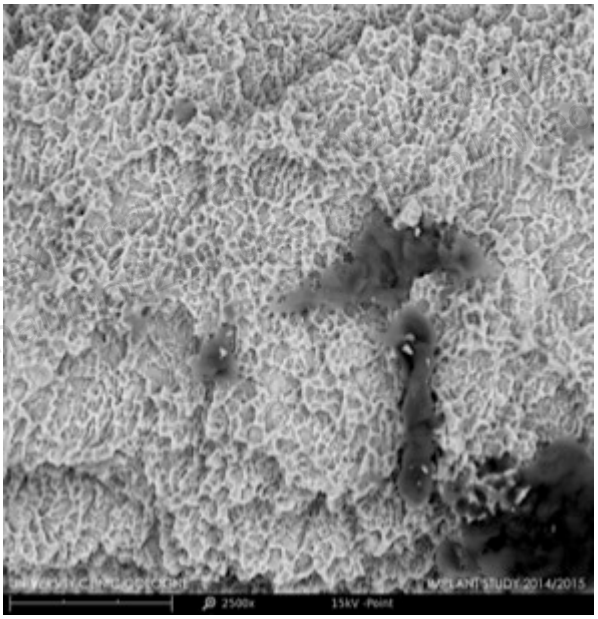
(All three images from the same implant)

4.6 **Remnants of Polytetrafluorethylene**

Two implants showed particle with a high amount of carbon and fluorine. Structure, elemental composition and size lead to the conclusion that these particles are most probably remnants of PTFE as seen in the Teflon-baskets where implants are carried e.g. during the acid etching process







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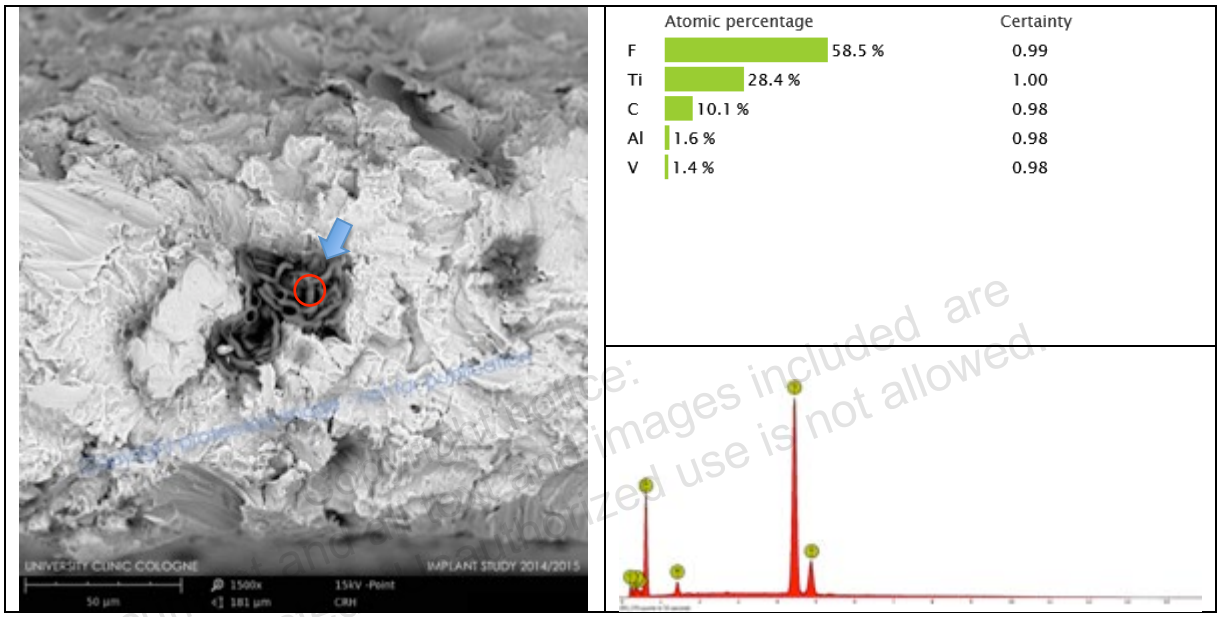

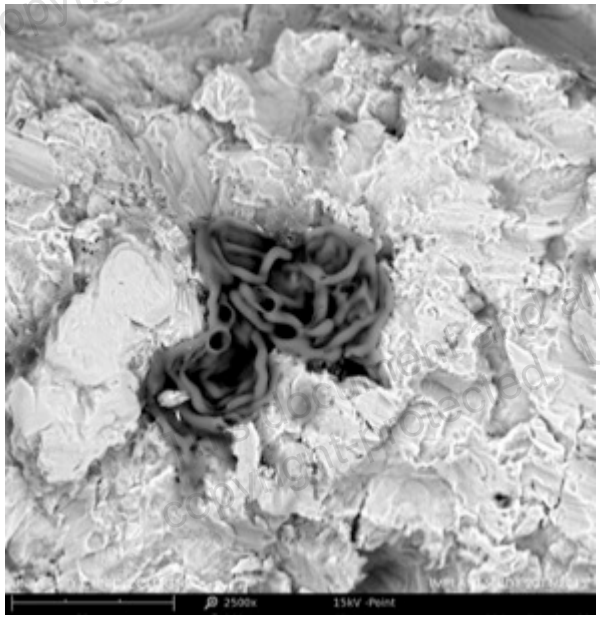

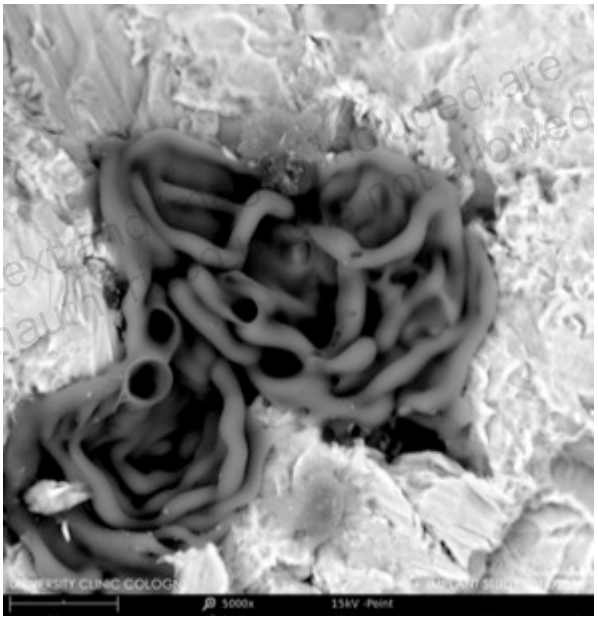

(All three images from the same implant)

5 Criteria

Surface anomalies as shown in **4.1** do not have any clinical relevance and should not be considered as criteria for the Quality Mark 2017/2018.

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 2017/2018 but will be mentioned in the analysis report and corresponding Quality Mark Certificate.

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 are a potential risk to induce a major foreign body reaction if they are not even toxic. These particles are technically avoidable and should not be accepted to which ever extend on the surface of sterile packed dental implants.

Organic particles are found on many implants. Here, single organic particles (**4.4**) should be distinguished from systematic allocation of numerous organic particles (**4.5**).

The threshold for the amount of single organic particles should be a matter of constant evaluation for the following years to ensure the improvement of implant production. Previous SEM analyses of 250 dental implants in the last 10 years showed a pattern of organic residues. Either the affected implants were covered by a massive number of single organic particles (> 50 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 obviously technically feasible the recommendation in 2017/2018 is to set the threshold at 10 organic particles, each smaller than 50 µm, seen in an angle of view of 120°. In regard to the complete circumference of the sample an implant should not reveal more than 30 single organic particles on the surface to achieve the quality mark 2017/2018 until 2019. Any higher amount or size of organic particles should be exclusion criteria. (This threshold value increases for the quality mark 2019 to 5 organic particles, each smaller than 50 µm, seen in an angle of view of 120°

Particles with traces of fluorine and carbon are shown in **4.6**. They appear like remnants of polytetrafluorethylene (PTFE) These particles as possible traces from damaged or old Teflon-coated baskets used during the implant production process are technically avoidable and should not be accepted in the framework of the quality mark awarding process.

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% for the specific implant device / device family is an essential requirement to achieve the Quality Mark 2017/2018.

Future criteria and thresholds for the Quality Mark 2019/2020 should be defined after re-evaluation of the protocol of analysis in cooperation with the Scientific Advisory Board. Additional or other sharper methods of elementary composition analysis than EDS e.g. XPS or Raman/LIBS spectroscopy after cleaning/washing the samples to identify the material of particles may complement the protocol of analysis and quality mark criteria in the near future.

6 Decision

The signatories to this decision template for the CleanImplant Quality Mark 2017/2018 certify that they have read this document completely and agree to the recommendation as given in paragraph 5.

7 Sign-Off

Approver Name	Signature	Date Signed
Prof. Tomas Albrektsson		2017/06/19
Prof. Ann Wennerberg		2017/06/20
Prof. Florian Beuer		2017/06/10
Luigi Canullo, PhD	luigi canullo	19 06 2017
Prof. Jaafar Mouhyi		25/06/2017
Dr. Michael Norton		2017 / 06 / 20
Dr. Dirk Duddeck	D. Duddeck	2017 / 06 / 18