

Decreasing dental implant failure with the Phenom Desktop SEM

Optimizing research and imaging processes while assuring cleanliness and safety

Dr. Dirk Duddeck, researcher on dental implants at the Charitè University Medicine, Berlin, managing director of the CleanImplant Foundation and the Medical Materials Research Institute (mmri.berlin).

Summary

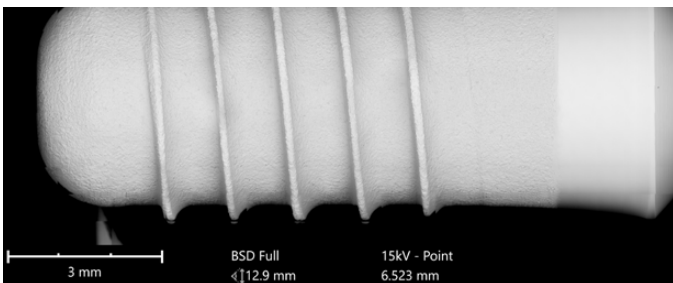
The non-profit CleanImplant Foundation and the MMRI, an accredited institute for scanning medical devices that is based in Berlin, perform processes of quality assessment in the medical-specific and the dental implant businesses. The foundation strives to gain full control of the cleanliness of medical devices and informs practitioners about the medical devices they use and the implications for their patients.

In doing so, the CleanImplant Foundation studies hundreds of dental implants on a periodical basis. Dr. Dirk Duddeck, an expert in the field of dental implant research, considers scanning electron microscopy (SEM) to be an essential tool in his quest to expose inferior implants, improve clinical outcomes, and protect patients. In this case study, Dr. Duddeck explains how SEM has revolutionized dental implant studies and how it can help manufacturers to significantly improve the cleanliness and safety of dental implants.

The challenge

In studying the cleanliness of dental implants, the main challenge is to identify contamination on implants that are no more than 5-15 millimeters long. To determine if a dental implant is either clean, contaminated, or contains only a few impurities, it is essential to get detailed information on a micron level. "We need to be able to find those particles that could effect the biology of the patients. If an implant has contamination between 5 and 10 microns, for example, these particles may lose contact with the implant during the insertion process." And that could have severe consequences for the patient, including a foreign body reaction, loss of bone, and even the loss of an implant. "We can reach a level of information that matches the visibility of a macrophage, only with a scanning electron microscope."

When contamination has been detected on a certain implant, Dr. Duddeck and his team need to find out if dental implants from the same batch cause similar problems and share the same root cause. This requires the analysis of multiple samples, which makes checking dental implants for contamination a timely process. "In former times, we had to wait half an hour just for the vacuum to be ready to image the next implant sample. Now with the fast changing of the samples, we were able to speed up our research process tremendously."



Automated Image Mapping (AIM) of implant with clean surface.
Image courtesy of Dr. Duddeck, CleanImplant Foundation, Germany.

The solution

By coincidence, a few years ago, Dr. Duddeck got the opportunity to work with a Thermo Scientific™ Phenom™ Desktop SEM. That turned out to be a breaking point in his research on dental implants. “The Phenom proved to be the perfect machine for this specific research topic, as material-contrast from the backscattered electron imaging delivered far more comprehensive information than the simple SEM imaging from the secondary electrons.”

The Phenom Desktop SEM enables Dr. Duddeck to learn more about his samples and analyze them in greater detail. It facilitates the analysis of samples on the micron level and provides insights into the biological consequences that patients have to deal with after implantation. Another valuable characteristic of the Phenom Desktop SEM is that it provides Dr. Duddeck and his team with material contrast images, which is of vital importance to their studies. “As we can now see the material contrast of an implant immediately, we can directly identify foreign material that is not titanium or zirconia, which are the core materials of dental implants. Black spots are signs of organic contaminants; bright spots originate from metal residues such as nickel, copper, tin or chromium—all of them certainly have no place on an implantable medical device. We can further analyze these particles with the EDX, which enables us to know what we are dealing with immediately.”

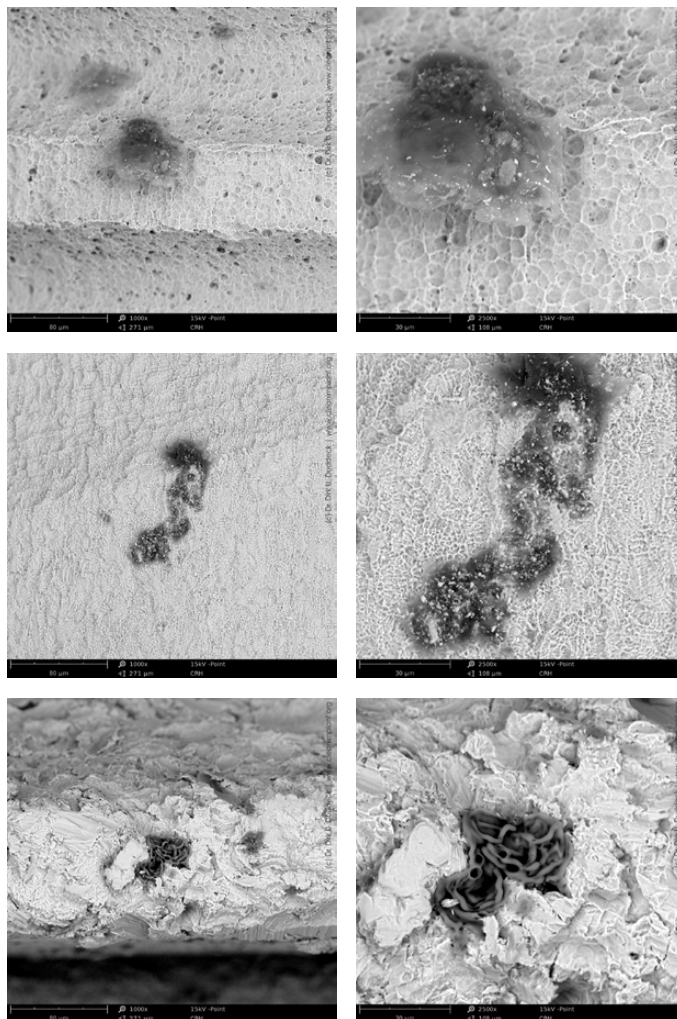
So, the Phenom Desktop SEMs have opened the eyes of the CleanImplant Foundation researchers. “Finding and counting particles of foreign material is one thing. Knowing the elemental composition of these contaminations, finding a solution on how to get rid of it from the manufacturing side, and finally knowing what kind of impact these technically avoidable particles have on the level of biology, is even more important.” The Phenom turned out to be the most suitable tool in providing a reliable answer to all of these questions.

The results

Labeling a dental implant as either clean or contaminated is a difficult and responsible task; and above all, a political decision, as the impact in a multi-billion Euro market of medical devices is huge. In order to make the right call, Dr. Duddeck and his team need reliable, detailed data on dental implant contamination levels. “We’re dealing with things that are more important than science itself. It’s about the trust of patients in their doctor’s decision for an implant system and the trust of dental professionals in the implants’ manufacturer and supplier. On the same level, our testing laboratory must have confidence in the data acquisition and the instruments we use.”

The Phenom desktop SEMs provides the CleanImplant Foundation and the medical materials institute with all the tools necessary for in-depth dental implant analyses from micron to the upper nano level.

In addition to improving the accuracy of their analyses, the Phenom Desktop SEM saves the CleanImplant Foundation valuable time. “Every day we have up to 10 samples that need to be analyzed three times. We can’t waste our time by simply waiting for the vacuum. The Phenom Desktop SEM helps us to change samples extremely fast.”



Phenom Desktop SEM images of organic pollution on a sterile implant with 1,000x (left column) and 2,500x (right column) magnification. *Images courtesy of Dr. Duddeck, CleanImplant Foundation, Germany.*

On behalf of the CleanImplant Foundation, Dr. Duddeck recently published a five-step approach for analyzing dental implants using scanning electron microscopy. All five steps must be completed for dental implants to receive the worldwide-established **Trusted Quality Mark** of the CleanImplant Foundation:

1. The random collection of implants

The first step is the random collection of implants, not only from the manufacturer but also from dentists' practices, in order to provide implants of the same type from different sources.

2. Unpacking implants in a clean room

The dental implants need to be unpacked in a clean room class 5 environment. This is of vital importance for the analysis, because only a clean room guarantees that the implant samples did not get contaminated during the unpacking process.

3. Image the complete implant

For a reliable analysis, you need to image the full implant. At this point, Phenom Desktop SEM's "Automated Image Mapping" application comes into play: A full-size high-resolution SEM image of the complete implant with a magnification of 500x is digitally composed of more than 400 single SEM images in less than 30 minutes. This special feature allows the researcher to locate and count particles of foreign material before subsequent elemental analysis of these contaminants.

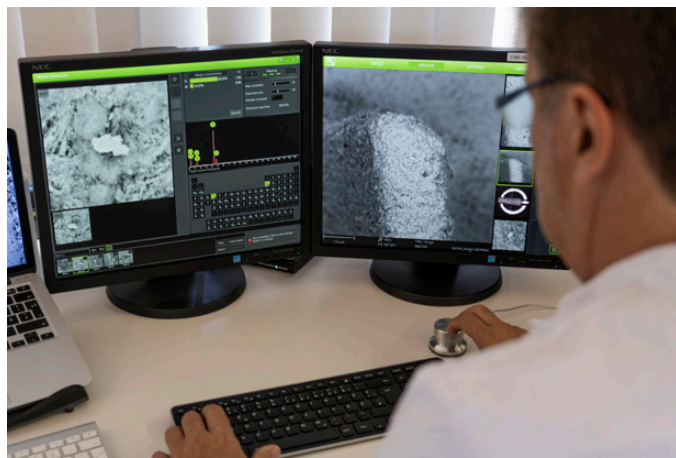
4. External audit

The complete process of elemental analysis by EDS has to be accredited according to ISO 22309. External audits by official institutions for accreditation, like the German DakkS, make sure all analyses are performed precisely, reliably, and correctly.

5. End report

The final reports of SEM/EDS analysis are judged by the scientific advisory board, where all members are renowned experts and professors in the field of dental implantology. Only with their signature in a peer-reviewed process will the CleanImplant Foundation label certain dental implants as technically clean.

Choosing the Phenom Desktop Scanning Electron Microscope as their primary tool for analyses turned out to be a rewarding choice for Dr. Duddeck and his team. "I cannot imagine reaching the level of information I have to date, if I hadn't been able to use all the features of the Phenom Desktop SEM. The microscope was the right choice as we got precisely the data we need, the brilliance we need, the timeframe we need."



Dr. Dirk Duddeck in the lab working on the Phenom Desktop SEM.



The CleanImplant Foundation

The CleanImplant Foundation is a non-profit organization focused on improving quality in implant dentistry. The foundation's goal is to continuously update the unbiased database of dental implants by separating implant systems with a high surface quality from those with avoidable impurities. The foundation strives to provide dental professionals with an orientation, improve clinical outcomes, and protect patients.

See cleanimplant.org

