Quality seal for dental implants

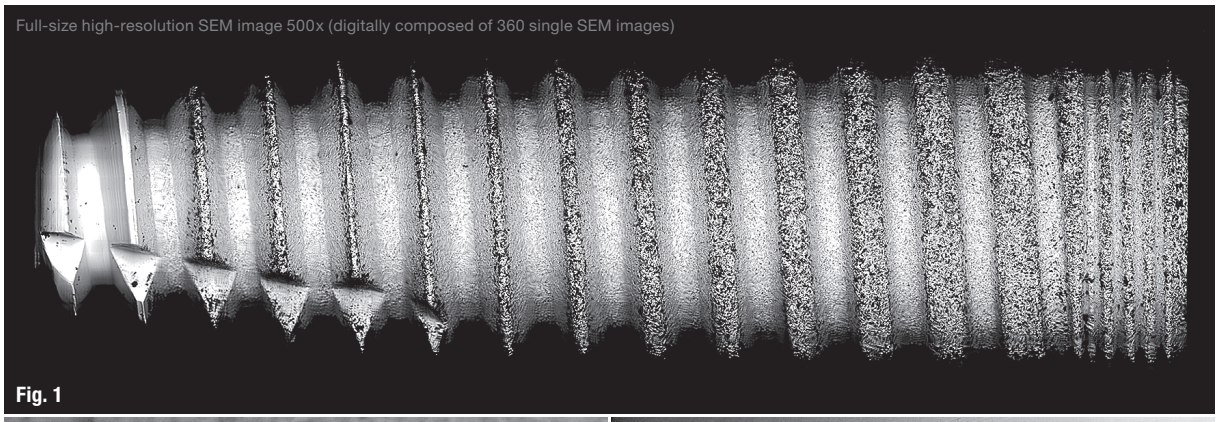
More safety for patients and practitioners

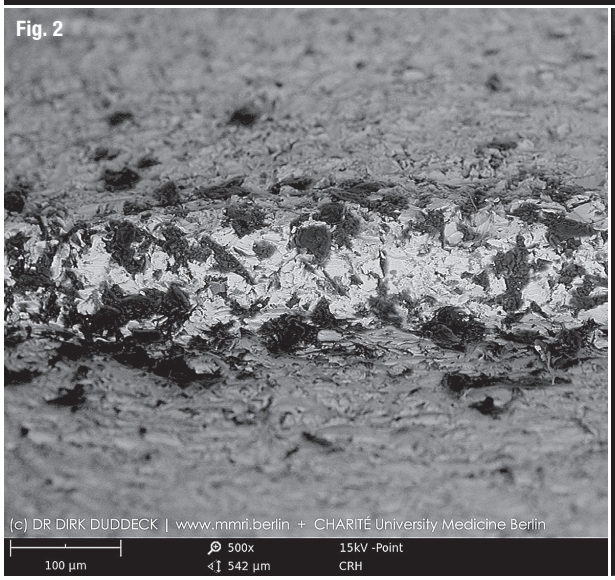
Dr Dirk U. Duddeck, Germany

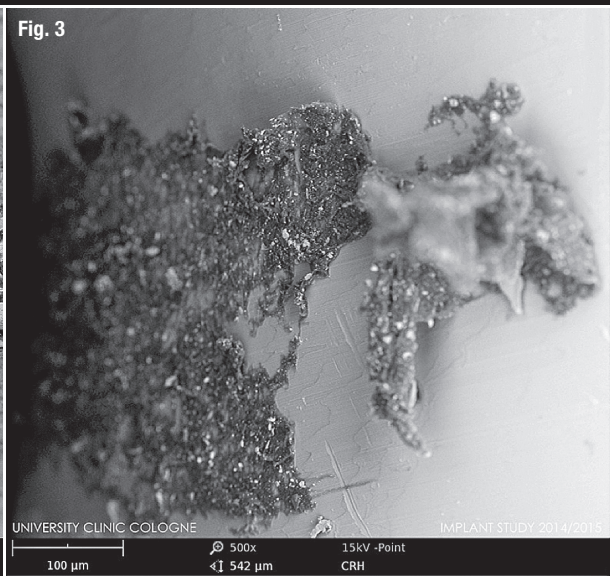
Dr Michael Norton, former president of the Academy of Osseointegration, summed up a problem of the implant market, stating “Dentists have to rely on the word of manufacturers and the FDA or CE marks to feel sure that the implants they are using are being manufactured to a standard one would expect of an implantable dental device. Sadly, this is often not the case.”

Impurities on sterile-packaged implants, in particular organic particles from the production or packaging process (Figs. 1–3), are highly suspected of being responsible for incomplete osseointegration of dental implants or even loss of bone in the early healing period.

Four consecutive studies over a period of more than ten years conducted in close cooperation with the University of Cologne and the Charité–University Medicine Berlin, both in Germany, have shown that neither CE (French: Conformité Européenne) marking nor U.S. Food and Drug Administration clearance can provide a reliable







Photos: © www.cleanimplant.com

Fig. 1: Massive organic pollution on sterile packaged implant (SEM mapping at 500x). **Fig. 2:** Organic particles on the implant thread (SEM image at 500x). **Fig. 3:** Organic particles with antimony on the implant shoulder (SEM image at 500x).

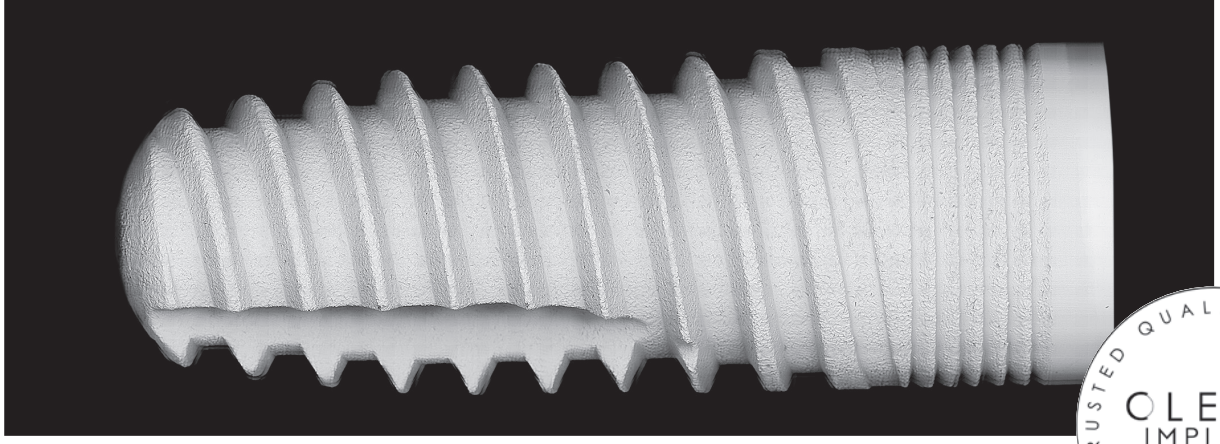


Fig. 4: blueSKY implant (bredent; SEM mapping at 500x).

indication of the cleanliness of dental implants. Scanning electron microscopy (SEM) imaging and elemental analysis (EDS) of more than 250 dental implants from over 200 brands were used to establish one of the largest, most comprehensive databases in implant dentistry. Recent analyses in 2018, revealed a continually growing number of implants with severe pollution, compared with previous reports. Areal pollution and particles containing iron, copper, chromium, nickel, tungsten and sulphur, and large quantities of stainless-steel particles, as well as remnants of polytetrafluoroethylene and other significant organic contaminations, give cause for concern.

The five-step approach

Step 1: Random sample collection

For the Trusted Quality Mark, five samples of each implant type will be collected for thorough analysis using a mixture of mystery shopping (two samples) and direct factory order (three samples) to ensure that samples are selected randomly.

Step 2: ISO Class 5 cleanroom environment

All implants have to be unpacked and analysed in the scanning electron microscope under cleanroom conditions according to ISO Class 5 (DIN EN ISO 14644-1).

Step 3: SEM analysis process accreditation

All collected samples are subjected to the same quality analysis protocol. Laboratories have to prove a quality management system according to DIN EN ISO/IEC 17025 and undergo regular audits and reassessments by external independent accreditation bodies.

Step 4: Full-size high-resolution SEM imaging

This technique produces approximately 400 single high-resolution SEM images of a single implant sample. Images are digitally composed to one large image with an extremely high resolution providing a perfect overview of the implant cleanliness.

Step 5: Peer review process

Two members of the scientific advisory board independently review the comprehensive report of analysis and correspondent clinical documentation.

How can the clinician know which implants are not affected by these impurities? With the variety of implant systems offered on the market it has become increasingly difficult for dentists to choose a safe system for their practice. The CleanImplant Foundation has set itself the goal of providing exactly this information worldwide. This independent non-profit organisation is supported and controlled by a scientific advisory board, which is chaired by renowned scientists and practitioners. In 2017 this board set the criteria for the CleanImplant Trusted Quality Mark. Implant companies and systems already carrying this seal are MIS V3, MegaGen AnyRidge, BTI UnicCa, bredent blueSKY (Fig. 4), NucleOSS T6 and NDI Replicate. Other implant systems are currently in the process of examination.

Objective analysis of dental implants

The CleanImplant Foundation established a thorough and accredited testing procedure that guarantees unbiased results for the new global quality seal (see information box “The five-step approach” on the left).

Practitioners interested in a personalised certificate for their practice and implant manufacturers who want to apply for the new quality mark will find more information and a corresponding newsletter at the project’s website www.cleanimplant.com.

contact

Dr Dirk U. Duddeck
Managing Director
CleanImplant Foundation
Pariser Platz 4a
10117 Berlin, Germany
Phone: +49 171 5477991
duddeck@cleanimplant.com
www.cleanimplant.com

Author details