

How **safe** is your implant?

Global initiative for clean dental implants

Author: Dr Dirk U. Duddack, Germany

Fig. 1: CleanImplant Kick-off meeting at IDS 2017 with renowned manufacturers and scientists: Prof. Tomas Albrektsson, Prof. Ann Wennerberg, Luigi Canullo, Prof. Jaafar Mouhyi (Scientific Advisory Board), Dr Dirk Duddack (Managing Director CleanImplant Foundation), Jonas Ehinger (Osstell), Shelly Akazany (MIS), Sergey Shulezhko, Vladlena Shulezhko (Trate), Marcellus große Holthaus (BEGO), Dr Christian Rähle, Dr Markus Kraft (CAMLOG), Salva Gregori (BTI), Dr Kwang Bum Park, Sian Matthews, Young Choi (MegaGen), Rüdger Rubbert (Natural Dental Implants), Prof. Sergio Bernades (Neodent), Armin Vollmer and Dr Michael Hotze (Straumann).

Residues on sterile packaged implants, in particular organic particles from the production or packaging process, are highly suspected of being responsible for an incomplete osseointegration of dental implants or even a loss of bone in the early healing period. Studies from recent years have shown that neither the CE mark nor the FDA clearance can provide a reliable indication of the cleanliness of dental implants. In March 2017, a new initiative was presented at the IDS in Cologne, which is focusing on this topic for the protection of both the users and the patients.

In three consecutive SEM studies, scientists of the University of Cologne and the Charité-University Berlin have analysed more than 200 sterile packaged implants since 2007. Results from the most recent study and comparisons with previous years showed an alarming increase in implants with conspicuous residues. The question we must ask is: How can the clinician know which implants are not affected by these impurities? Due to the variety of implant systems offered on the market, it has become quite difficult for the individual dentist to find a safe system for their practice.

The CleanImplant Foundation was established in 2016 and has set itself the goal of providing exactly this information worldwide. This independent non-profit organisation is supported by a Scientific Advisory Board, which is chaired by renowned scientists and practitioners such as Professor Tomas Albrektsson (University of Gothenburg, Sweden), Professor Ann Wennerberg (Malmö University, Sweden), Professor Florian Beuer (Charité-University Medicine Berlin, Germany), Professor Jaafar Mouhyi (University of Agadir, Morocco), Luigi Canullo (Rome, Italy) and Michael Norton (London, UK), the recently elected President of the US Academy of Osseointegration.

Technically it is possible to produce residue-free implants, as many of the implants have shown in the recent quality assessment studies. If, on the other hand, quality control steps are reduced for production and economic reasons, medical devices of inferior quality are the result despite the existence of a CE certification. However, implants with worrying impurities can only be found in the market if there are uninformed dentists who buy these implants.

If one follows the discussions on professional internet forums it is surprising to discover that apparently little attention is paid to clean medical products by some medical professionals and implantologists: "Do not make a big deal out of it... Can you convince me that super clean implants have significantly better outcome...? Dental implants have been dirty in the last 40 years and they still keep working." If it is the maxim of these colleagues to rely on the immune defense of the patients entrusted to them, then we can also take off our sterile gloves in the operating room again in order to ensure a better tactility during the implantation, commented Dr Dirk Duddack, head of the CleanImplant project. In order to offer no further room for this kind of misunderstanding, there is a need for a sustained information campaign, which will raise the importance for the awareness of clean dental implants.



Fig. 1

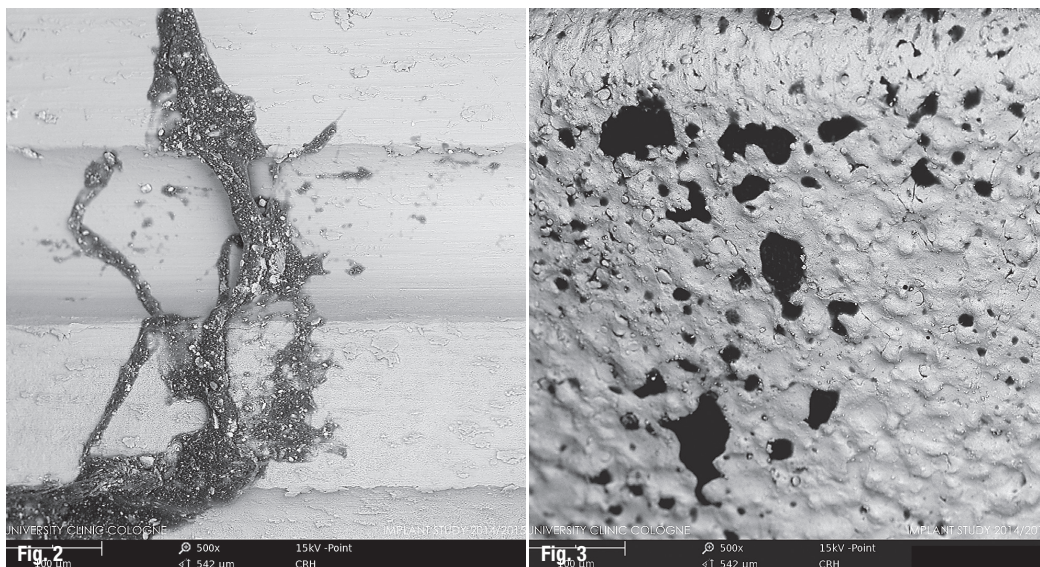


Fig. 2: Organic pollution on a titanium-made implant (SEM x500), left.

Fig. 3: Organic pollution on a zirconia-made implant (SEM x500), right.

At IDS 2017, members of the Scientific Advisory Board, supporting companies and interested implant manufacturers joined the first CleanImplant group meeting. The CleanImplant Foundation presented a new global quality mark, which is designed to enable clinicians to see at a glance whether the appropriate type of implant meets a minimum of cleanliness. The "CleanImplant Trusted Quality" award can be given to implants which have previously shown in a comprehensive neutral analysis that they are free of significant organic impurities (Figs. 2&3) and free of particles containing e.g. copper, chromium, nickel, iron, tin, zinc, bronze, stainless steel or antimony sticking on the implant surface.

To this end, five implants per type are examined, at least two of which are purchased through blind purchase from practices. The analytical reports are screened and released by the Scientific Advisory Board in a peer review process, that is, two board members have to come to the same conclusion independently of each other. "Through these procedures we want to make absolutely sure that there is no connection between the financial support of the project and the analysis result," says Dr Dirk Duddeck. "The biggest difference to all previous attempts to develop such a quality mark is that we not only reevaluate the results with new implants of the same type every two years, but also regularly tighten the criteria for this quality mark. To this end, the existing analytics will be substantially expanded in the coming years."

The results will be published on the project's website www.cleanimplant.com. This will allow interested implantologists a quick and easy way to find comprehensive information about the variety of possible implant pollution as well as numerous analysis results of contaminated and clean implants. The project is open to every dentist and manufacturer, which are

particularly concerned about the protection of patients from potentially inferior medical devices.

According to Albrektsson, we should abide to his fundamental guiding principle written in an article a decade ago that we should not only believe, but rather have to know that the implants we use do not harm our patients. To cut a long story short: Patients trust in our decision for the right dental implant system. Dentists should have an independent guide to find out which implant system meets the expectation of a high quality medical device. The CleanImplant Foundation will support future research on the clinical impact of impurities and extend the periodic analyses of dental implants all over the globe in order to provide dentists with independent research results and evaluate improvements in the manufacturing process of previous analysed implants. More information and a correspondent newsletter are available at the project's homepage: www.cleanimplant.com.



contact

Dr Dirk U. Duddeck

Managing Director
CleanImplant Foundation CIF GmbH
Pariser Platz 4a
10117 Berlin, Germany
Tel.: +49 171 5477991
duddeck@cleanimplant.com
www.cleanimplant.com