

Quality Deficiencies of Sterile Packaged Dental Implants; How Much Safety can FDA Clearance or the Newly Implemented MDR in Europe Guarantee?

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When dentists began using dental implants in the late 80s, no implant was launched on the market without comprehensive studies and pre-launch tests in renowned dental centers, normally linked to universities of high international prestige. With an increasing number of dental implant manufacturers and suppliers, dental professionals can choose from a variety of implant types with different geometries, surface treatments, and core materials. However, can dentists blindly trust the quality of these implants?

In 2019, the FDA released two decades of previously unpublished data containing millions of malfunctions by medical devices, including 2.1 million reports of failed dental implants. This amounts to more than 100,000 reports in 2018 alone - most of them related to a lack of osseointegration. This information has raised major concerns among dentists in the US and abroad. Comments made by manufacturers regarding these numbers, focus on patients with unfavorable clinical preconditions and even blame dentists for their lack of experience and training. Is this the whole truth?

How many times have we asked ourselves whether the implants we place are free of surface contaminants capable of causing severe problems in the osseointegration process, or even supporting factors in the development of peri-implantitis? Avoidable contaminants on sterile packaged implants can cause an uncontrolled foreign body reaction resulting in osteoclastogenesis, leaving rough areas of the implant surface exposed to bacterial colonization [1,2].

In a 2017-2019 study, conducted by the CleanImplant Foundation in collaboration with the Charité University Berlin, more than 100 different sterile-packaged implants from 80 implant brands were analyzed with SEM and Elemental Analysis (EDS) in an officially accredited testing laboratory according to DIN EN ISO/IEC 17025. One in three implants showed significant

contaminations i.e. unwanted particles originating from the manufacturing, handling, or packaging of the implant.

Additional analysis of contaminated implants, using time-of-flight secondary ion mass spectrometry (ToF-SIMS), revealed thermoplastic materials, synthetic polymers, polysiloxanes... and even Dodecylbenzene Sulfonic Acid (DBSA). DBSA is a washing detergent and hazardous surfactant, according to the United States Environmental Protection Agency (EPA).

As an example of numerous other implants, one implant revealed complex contamination as the sample was sprayed with hundreds of small metallic particles, from 5 to 20 microns in diameter, each containing significant amounts of iron, chromium, nickel, niobium, and molybdenum (Image 1 shows these particles and the correspondent differential EDS measurement). Traces of elemental aluminum (not to be mistaken with aluminum oxide blasting material) were detected in other areas of 30-60 microns. Numerous organic particles with a diameter of 5 to 10 microns were found mainly on the implant shoulder, as seen in (Image 2). It should be noted that this "all-on-one" implant - contaminated with organic particles and different metallic materials - carried the CE mark on its packaging.

The European Medical Device Regulation MDR was initiated after the breast implant scandal led to new standards for the quality of medical devices and the need for greater control. Although paperwork and the level of staff resources required for the CE certification will be doubled if not tripled by manufacturers in the framework of the MDR implementation, urgent necessary tests on sterile packaged implants, at least biannually, are still missing. Experts at the 4th EAAR Annual Conference on New Medical Device Regulations (RMD2019 in Brussels last October) admitted that the few remaining Notified bodies that carry out the approval process have a lack of trained personnel so that even the standard approval process for new products under the

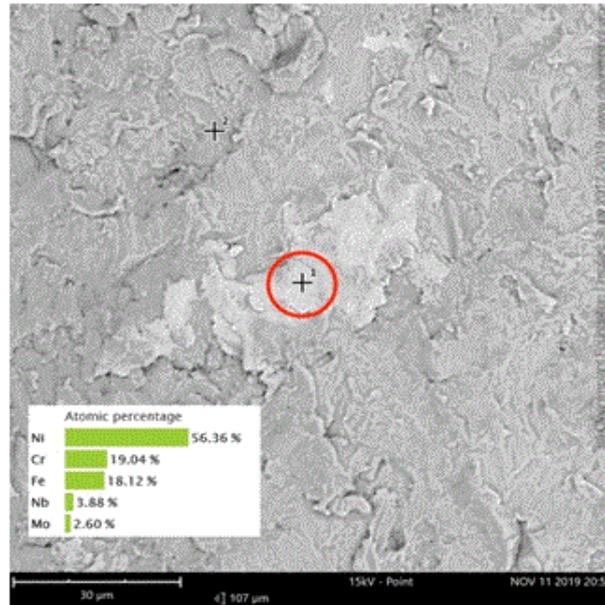


Image 1: Metal particles; differential EDS measurement of the bright spot; SEM 2,500x

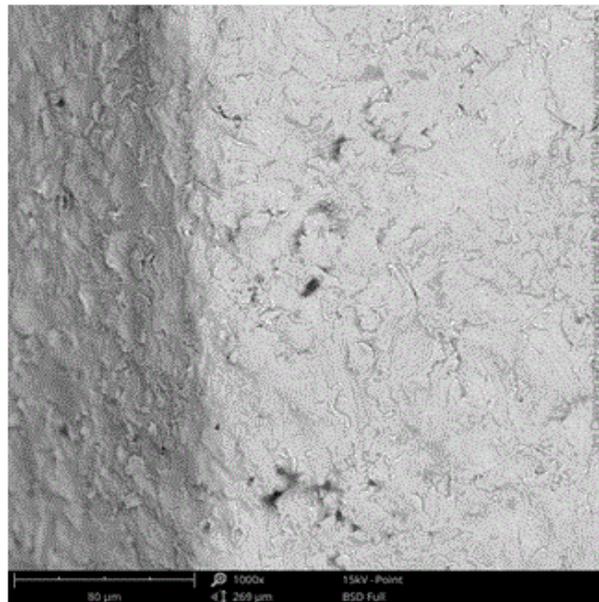


Image 2: Organic particles (dark spots) on the implant shoulder, SEM 1,000x

MDR will take more time than ever before. Notified Bodies may not be prepared to provide the necessary quality control on the level of periodic independent tests and quality assessments of the final sterile medical product. Thus, we should not expect a better quality of dental implants and significantly cleaner medical devices in the coming years.

The non-profit CleanImplant Foundation (www.cleanimplant.org) has presented a consensus statement on surface impurities[3]. CleanImplant, supported by renowned scientists such as Tomas Albrektsson, Ann Wennerberg, Hugo de Bruyn and many others, will stay laser-focused on the quality of sterile packaged implants and will closely monitor the outcome of the

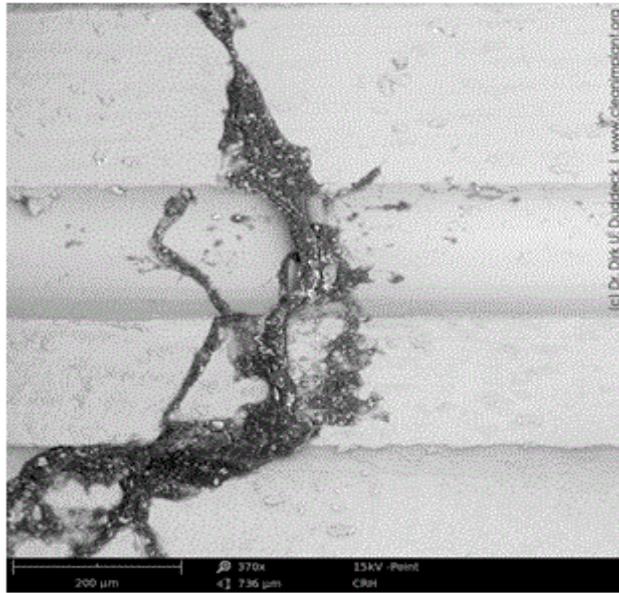


Image 3: Organic contamination on a sterile titanium implant, SEM 70x

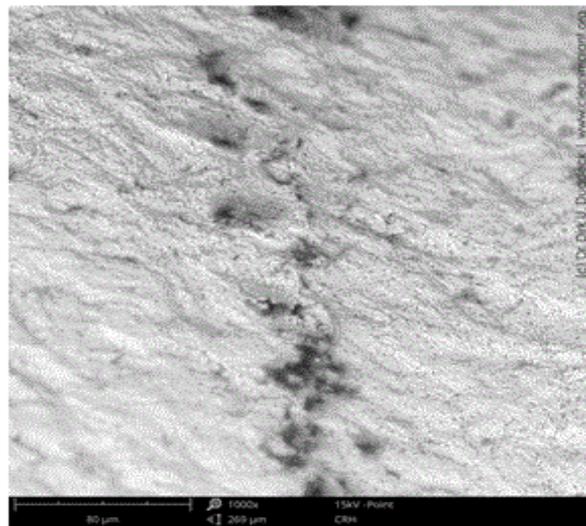


Image 4: Organic contamination on a sterile ceramic implant, SEM 1,000x.

MDR[4]. The current alarming situation of contaminated dental implants presents two different risks, for the patient and the practitioner. Contaminants can induce an uncontrolled foreign body reaction with peri-implantitis, bone loss or even the failure of an implant, thus compromising the clinical outcome and the expectation of our patients. On the other hand, practitioners unknowingly using dirty implants have to deal with the risk of patient lawsuits for dental malpractice. Both risks are avoidable.

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