

Our patients and ourselves need reassurance

Founded in Germany in 2016 by dentist and biologist Dr. Dirk Duddeck, the CleanImplant Foundation quickly developed a global standing and attracted supporters and ambassadors from all over the world. What made one of the world's most renowned implant surgeons from London join the initiative?

**Interview with Dr. Michael R. Norton BDS FDS RCS(Ed)
Past President, Academy of Osseointegration**



What made you get involved with the CleanImplant Foundation to begin with?

There is a massive need to drive assurance of quality in all medical device fields. The PIP breast implant scandal highlighted the importance and need for tighter regulatory control of medical devices, and the need for device registration so patients can easily be identified when sub-standard or faulty devices are identified. The CleanImplant Foundation is one big step towards this quality assurance program, providing both dentist and patient the reassurance that their implants meet a minimum standard for surface purity and minimal contamination. 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. The CleanImplant Foundation is an objective, independent non-profit foundation that has been established to fill this void and to help provide both dentist and patient the reassurance they need and must have when using dental implants.

We have GMP, we have CE, we have the MDR and many many more – why do you still see a need for further control?

Until the introduction of MDR we had weaker regulatory control in Europe with MDD and still today weak control in the USA with the FDA, whereby the so-called equivalence test allows any implant produced to replicate a device already approved and successfully sold on the market to gain approval. This has resulted in a vast array of clone implants to be manufactured and sold without any pre-market experimental or clinical documentation. The need to satisfy GMP comes nowhere near close enough to ensure that just because one implant looks and feels

like another that it delivers the same tissue response and clinical performance. This is why the FDA is now inundated with millions of complaints regarding failing and ailing implants which are sub-standard.

Is it that you can in general rely on the quality with global players and better check smaller and more 'exotic' manufacturers only?

I believe all manufacturers should be held to account and meet the quality assurance standards including all of the big players. That said the CleanImplant Foundation did originally publish data to show that the premium brand implants do demonstrate a high degree of integrity for their implant surfaces, so perhaps we can trust them a little more.

How important do you consider the 'trusted quality' mark also for dentists and their patients?

I think it is very important. Currently my own choice of implant does not have the QA mark but I am pushing very hard for them to do so because I believe eventually this will become a patient driven demand and rightly so.

Do you think that the work of the CleanImplant Foundation will improve the attentiveness of manufacturers?

One would hope so. I think in reference to your previous question it needs all the main players to be involved if we are to force all the minor players to take this seriously. If they do then it will surely improve industry attentiveness!

Thank you very much for your time and this interview. ●

The independent NPO CleanImplant Foundation conducts objective periodical quality assessments of numerous dental implant types to reveal the existence of unwanted (factory-related) contaminants on sterile-packed dental implants. These wide-ranging inspections, carried out every two to three years, are entirely free of any influence from manufacturers. The Foundation aims to provide objective, reliable, unbiased, and substantive data on implant surface quality regarding cleanliness or foreign particle contaminations.

More information: www.cleanimplant.org



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