Artifex INC.
The art and science of dental reconstruction

January 4, 2016

Dear Doctor,

As of November 2015, the Food and Drug Administration (FDA) has put new regulation on dental laboratories for milling abutments which are class II medical devices. At Artifex Dental, we can assure you we are aware of these new regulations and are, and always have been, in total compliance with the FDA.

The FDA is now enforcing that CAD /CAM milled titanium and zirconium abutments have to be milled by a company that is 510(k) cleared and compliant. Currently, the only system that has 510(k) clearance for labs is Sirona. Since we do not have a Sirona system, all of our abutments are designed in house and the file is sent to the corresponding implant company for milling, as we have always done. Milling abutments with the original implant company is the only way to ensure you are getting parts that are FDA-compliant.

There are many after-market milling centers that are not FDA-compliant. In fact, the FDA is on record stating that Sirona is the only one that is FDA-compliant. All of our abutments will be clearly identified on the invoice and the actual packaging the abutment came in from the implant company, will be sent in the case to you upon delivery. This should allow you to easily track the parts should you ever be audited by the FDA. We do have our own milling unit for milling crowns and bridges but we have never, nor will we, use it to mill abutments. The reason for this is the FDA has announced that it is illegal to mill a titanium or zirconium blank unless you are a manufacturer (or have a Sirona system).

We have always been very proud of using the authentic part to their corresponding implant systems. We are allowed to mill a zirconium body for screw retained units and cement it to a Ti-Base, provided the manufacturer of the Ti-Base has a 510(k) clearance for that part, as it is considered to be a crown. The FDA is not only regulating the implant interface, they are also regulating the milling of the axial walls of the abutment. The regulation should help the dental industry keep track of, and ensure better quality of manufactured parts on implants.

Again, we assure you the process, nor the price has changed in the way Artifex Dental fabricates our implant restorations. Attached is the FDA alert and the response by the National Association of Dental Laboratories (NADL) to the FDA alert. I know this can be difficult to understand. If you have any questions, you may call me at 703-751-2656.

Sincerely,

Tony Prestipino, CDT
President
Artifex Dental Laboratory