

Report Narrative

September 17, 2009

Summary

Three Nobel Biocare implants (2 Nobel Active and 1 Nobel Replace) represented as sterile on the packaging, failed ASTM D4991-94: "Standard Test Method for Leakage Testing of Empty Rigid Containers" conducted by Nelson Laboratories, Salt Lake City Utah "in accordance with USFDA and USEPA Regulations." These test results indicate that Nobel Biocare's "sterile" implant packaging may not provide an effective sterility or microbial barrier and therefore could be considered as failing to perform as specified and potentially contributing to real or potential patient harm.

Time Line and Events

In January 2007, during the course of an evaluation of Implant Direct's packaging, Implant Direct LLC conducted Container and Closure System Integrity Testing on its dental implants. Using a calibrated pressure chamber, an internal dye penetration test was performed in accordance with *ASTM D4991-94: Standard Test Method For Leakage Testing Of Empty Rigid Containers By Vacuum Method*. Implant Direct included in these tests, two samples of Nobel Biocare implants, marked as "sterile." Implant Direct discovered that both samples of Nobel Biocare's implants failed the test as evident by the visual presence of dye within the vial. It is important to note that the samples were capped, unopened and the factory provided plastic wrapping around the entire cap-vial assembly was intact ([Attachment 1](#)). Implant Direct did not act on this information at that time but events ensued that resulted in revisiting this test.

In June 2009, Implant Direct Canada demoted its Director of Operations, Ms. Adele Fussi, to a sales position. She resigned and, while negotiating for a high paying position with Nobel Biocare, reported Implant Direct to Health Canada regarding a packaging issue that Implant Direct had experienced two years earlier. This resulted in an inquiry by Health Canada that has since been resolved. The packaging issue related to an August 2007 removal from inventory of a small number of implants with a cosmetic, micro-crack in the cap. Implant Direct, using [standard leak tests conducted in August 2007 and again in July 2009 confirmed that these micro-cracks did not result in a loss of the sterile seal](#). In August 2007, the white caps were replaced with clear caps of a different material eliminating the potential for micro-cracks following sterilization. Only seven (7) implants with micro-cracks, shipped prior to August 2007 to Canadian dentists were retrieved and exchanged for newer product. When Ms. Fussi and her sales managers at Nobel Biocare started to contact Implant Direct's customers with misinformation about Implant Direct's packaging and Health

Canada's response, Implant Direct initiated litigation that is now pending in Canada.

In August 2009, Dr. Gerald Niznick, Implant Direct's president, forwarded to Nobel Biocare the 2007 failed dye leak tests of their implants. When Nobel did not respond, Dr. Niznick arranged for a Nobel Biocare customer to order 2 NobelActive implants (newest design to assure recent packaging) and one NobelReplace implant. He sent these implants with their tamper-proof seals intact to a FDA approved Independent Lab for leak testing. The tests were conducted in accordance with GLP, US-FDA 21 CFR 58. The results of all three tested samples showed significant dye penetration into the vials ([Attachment 2](#)).

By comparison, Implant Direct performed dye penetration tests on six samples of its own sterile products using the same laboratory and test methodologies. None of the samples showed any signs of leakage ([Attachment 3](#)).

On September 12th, at an industry meeting in Boston, Dr. Niznick approached Mr. Kevin Mosher, VP and General Manager of Nobel Biocare, North America, and disclosed to him the outcome of the independent leak test. Mr. Mosher's response was that a dye leak test was not the appropriate sterility integrity test for Nobel Biocare's packaging. This prompted Dr. Niznick to send Mr. Mosher and Mr. Dominique Scala, President and CEO of Nobel Biocare, AG, an email on September 13th detailing the relevant regulatory requirements for sterility containment testing, including establishment of the validity of the test method. The email ([Attachment 4](#)) included a picture and chart from the independent test performed by Nelson Labs and pictures from the January 2007 leak tests performed on Nobel implants and previously provided to Nobel Biocare.

Mr. Mosher responded to the serious issues raised in Dr. Niznick's email the same day with the disingenuous comments below.

September 13, 2009

"Dear Dr. Niznick,

Thank you for bringing this to our attention. We have clearly defined standards of how to deal with such information and will act accordingly.

*Best regards,
Kevin Mosher"*

Based on this response and given the risk to public health Implant Direct felt it prudent to present this information to the FDA and to dental professionals to assure that Nobel Biocare's "clearly defined standards" comply with the FDA's clearly defined standards for the sale of sterile devices for human implantation.

Conclusion



Nobel Biocare products display this internationally recognized symbol for sterility obtained through radiation.



Nobel Biocare's implants also display this internationally recognized symbol for shelf-life, representing that the contents of the vial will maintain sterility after radiation for the 5 year period noted on their label. This is dependent on the integrity of the seal to isolate the contents from the outside environment.

Based on industry standard packaging and sterile container validation protocols there is a reasonable basis for questioning the validity of Nobel Biocare's claim that the contents of its implant vials maintained sterility after initial irradiation.

In the interest of the public good and to further promote the safe and effective practice of implant dentistry, we presented this information to the FDA and to dental professionals for their consideration.