



September 24, 2009

Dear Valued Partner Customer,

It has come to our attention that a newsletter has been circulated, which attempts to cast doubt on the efficacy of our implant packaging with respect to the maintenance of sterility.

Nobel Biocare's standards for manufacturing and packaging are amongst the highest in the dental industry, which are part of our quality system, audited rigorously and regularly by independent external (e.g. USFDA) and internal authorities.

Similarly, Nobel Biocare's quality assurance processes and reviews ensure that Nobel Biocare products meet all required quality and safety standards. As part of these processes, product sterility is tested throughout the entire shelf life of our products. In particular, a recent independent external review of packaging and sterility records reported no quality issues with Nobel Biocare products.

Rumors being spread regarding potential packaging inadequacies seem to be the result of Nobel Biocare competitors wishing only to generate interest in their products. These claims lack substance, and Nobel Biocare has the necessary data to establish that its products are safe and maintain sterility.

Please feel free to contact us if you have any further questions, and thank you for your continued support.

Sincerely,

A handwritten signature in black ink that reads 'Kevin Mosher'.

Kevin Mosher  
President,  
Nobel Biocare, North America

## **Response to Nobel Biocare's September 24, 2009 Letter to its Customers regarding Implant Direct's Newsletter Revelations about Nobel's Packaging**

By Dr. Gerald Niznick, President of Implant Direct

### **Bausch Lomb [Example of typical Sterile Packaging Requirements]**

#### **510(k) Summary Statement**

**Typical Documentation submitted to FDA for sale of sterile medical devices.**

#### **Bausch & Lomb Irrigation and Aspiration Handpieces**

##### **6. Safety and Performance Testing:**

**Sterility:** Bausch & Lomb, Inc., Sterile Single-Use I/A Handpieces are provided sterile by gamma irradiation. Sterilization has been validated to a SAL of 10<sup>-6</sup> for all standard panel of ophthalmic organisms in accordance with ANSI/AAMI/ISO TR13409 Standards.

**Stability:** Seal Integrity Test with dye penetration of radiated product; and a Microbial Barrier Test after accelerated aging at one and five years, in accordance with adopted Standards.

**Biocompatibility:** The following tests were conducted on the devices: cytotoxicity, bioburden determination, LAL Endotoxin Test, and Particle Test. All tests were conducted on three separate lots of product manufactured at different times. The results indicated that all outcomes were within expected and acceptable limits of the tests. All stability and biocompatibility testing was conducted under adopted international standards as follows:

Dye Penetration: ANSI/AAMI/ISO 11607 (Annex C)

Microbial Barrier Test: DIN 58953-6, DIN EN 868-1; ANSI/AAMI/ISO 11607

Cytotoxicity: DIN EN ISO 10993-5-12, ISO 9363-1

Bioburden Determination: DIN EN 1174, ISO 11737-1, USP 25 [61]

LAL Endotoxin Test: DAB 1999 V.2, USP 25 [85], EP 2001, FDA Guideline

Particle Test: USP 25 [788]

### **Nobel Biocare**

**Kevin Mosher President North America, Customer Letter September 24, 2009**

**Letter Overview: Trust us – we are Nobel Biocare!**

1. *“Nobel Biocare's standards for manufacturing and packaging are amongst the highest in the dental industry.”*

[No evidence provided to support this claim.](#)

2. *.....our quality system is audited rigorously and regularly by independent external (e.g. USFDA) and internal authorities.*

[FDA may do inspections of medical device manufacturers every other year but they do not verify the validity of sterility and container integrity tests unless there is reason to doubt the manufacturer's documentation.](#) Implant Direct filed a Medwatch report with the FDA, revealing the results of Sterile Container Integrity Tests conducted by an independent FDA certified Laboratory, indicating [the failure of Nobel Biocare's implant packaging](#) to maintain a sterile seal and [the success of Implant Direct's implant packaging](#) to maintain a sterile seal.

3. ***“Nobel Biocare’s quality assurance processes and reviews ensure that Nobel Biocare products meet all required quality and safety standards.”***

No evidence provided to support this claim.

4. ***....product sterility is tested throughout the entire shelf life of our products.***

No evidence provided to support this claim plus it is neither realistic nor credible.

As shown above with Bauch and Lomb’s 510K submission, Biocompatibility tests, including Cytotoxicity, Bioburden, Endotoxin and Particle Tests, are conducted on several lots of products following sterilization. They do not need to be repeated “throughout the entire shelf life” if a “Microbial Barrier Test after accelerated aging,” is done to simulate 5 years of exposure. This test, in conjunction with a “Seal Integrity Test with dye penetration” is done to assure a 5 year shelf life. Testing the products throughout the entire 5 year period, as Mr. Mosher claims, in lieu of a Seal Integrity Test, is unrealistic because it would not allow Nobel to claim a 5 year shelf life until 5 years after the product was packaged. Mr. Mosher's letter neither refutes nor denies the validity of two failed dye leak tests of their implants, documented in Implant Direct's Medwatch Report posted on our website. Nor is it credible because if Nobel's implants fail the standard seal integrity test using dye, the validity of any tests used by Nobel to validate its claim that its implant vials remain sealed for 5 years only raises questions about the validity of those tests.

5. ***“....a recent independent external review of packaging and sterility records reported no quality issues with Nobel Biocare products.”*** What independent external review body conducted the audit? If it exists, why not post it on their website and provide a link to it in their letter? What did they evaluate – Sterility, Stability or Biocompatibility?

6. ***“Rumors being spread regarding potential packaging inadequacies seem to be the result of Nobel Biocare competitors wishing only to generate interest in their product.”***

The issue of Nobel’s “potential packaging inadequacies” was published online by Implant Direct in its September Newsletter and was not some unnamed “competitors” spreading rumors.

The narrative filed with the FDA and posted on Implant Direct’s website shows that our decision to go public with this information was based on concern for the public welfare and the credibility of the Implant Industry. It was also in response to Nobel’s efforts to “generate interest in their products” through false and misleading information being spread by a disgruntled, former Implant Direct employee, hired by Nobel Biocare, Canada for the expressed purpose of discrediting Implant Direct. If one is to speculate on motivations, then it is reasonable to assume that Nobel hired this person in the hopes that she would be able to slow the rate of their customer conversions to Implant Direct’s RePlant System, offering surgical and prosthetic compatibility as well as many cost and design advantages, compared to NobelReplace implants.

7. ***“These claims lack substance, and Nobel Biocare has the necessary data to establish that its products are safe and maintain sterility.”*** Nobel Biocare cannot credibly claim that an independent dye leak test performed by an FDA certified testing laboratory lacks substance by offering only marketing rhetoric by its North American President. If Nobel Biocare had the necessary data to refute this hard evidence, then one would think that it would have produced it to either Implant Direct to avoid the public controversy, to stock analysts to prevent the risk of a change from buy to sell of its stocks and to its customers to reassure them and their patients.

Mr. Mosher's letter attempts to satisfy Nobel's loyal customers, but their real concern is whether it will satisfy the global regulatory bodies like the FDA., Health Canada, Japanese Pharmaceutical Affairs and the Medical Device Directive that governs European sales.