

## 5. Describe Event, Problem or Product Use Error

I have experienced substantial and unexplainable failures with Nobel Biocare's ("Nobel") Replace™ Implants. Of 88 consecutively placed implants, 34 implants required removal due to pain or infection for a failure rate of 38.6% ([Attachment #1](#)). I doubt these failures are caused entirely by my case selection or surgical skill because I also recorded the clinical success of 51 consecutively placed Implant Direct RePlant™ Implants from 2008-2009 with only 2 requiring removal for a failure rate of 3.9% ([Attachment #2](#)).

While these results represent a retrospective, case series study, they offer a controlled comparison study because the Implant Direct RePlant and Nobel Replace Implants have the same body taper and dimensions and were all inserted by the same person using the same Nobel drills, recommended by both Nobel and Implant Direct for insertion of these similar implants. I brought this information to Nobel Biocare's attention, as shown in my letter of October 27, 2008 ([Attachment #3](#)) and submitted failure reports on their forms ([Attachment #4](#)). Nobel refused to take back my remaining implant inventory, contending that the problem lay with my surgical skills rather than with their implants. After Nobel's refusal, I continued to use some of my remaining inventory of Nobel Replace Implants while also incorporating Implant Direct's RePlant Implants into my practice. After experiencing a significantly higher failure rate with the Nobel Replace Implants compared to the Implant Direct's RePlant Implants, I stopped using the Nobel Implants altogether.

After learning of the MedWatch Report filed by Implant Direct, I contacted them to seek assistance on testing my remaining Nobel Implants for maintenance of a sterile seal. Seven Nobel Implants from my inventory were sent to Nelson Labs ([Attachment #5](#)) and eight were sent to an ISTA Certified Lab ([Attachment #6](#)) for dye immersion tests. As can be seen on these reports, all the implants tested failed to provide a seal required to assure the maintenance of sterility of the contents. Implant Direct has informed me that Nobel Biocare has not filed MDRs (medical device reports) on failed implants that it receives back under its implant guarantee policy. I am filing this MedWatch Report because I am concerned that the failures I experienced with Nobel's implants could be more widespread than is generally known and that this problem may be related to a lack of sterility due to its packaging failing to maintain the 5 year shelf life claimed on its implant vial label.