Europace Case Report Q&A

Introduction – A case report was recently published in the online version of the journal Europace. The case report included inaccurate information. The author has since voluntarily requested that the article be removed acknowledging that it contained erroneous statements. The editorial staff has responded by removing the article.

What is the timeline of events in this matter?

The patient experience occurred on May 12, 2010 in the Slovak Republic. The issue was initially reported to the FDA using form 3500A (a Medical Device Report or MDR form) on May 19, 2010. An updated MDR form with the results of our analysis was submitted on June 7, 2010.

How is the patient doing?

The device was explanted and the patient has recovered from this procedure.

Why was the case report withdrawn?

The author reported that after submitting the case report to Europace in June, further analysis was conducted but not included in the original report. As such, there are inaccuracies that need to be corrected. Specifically, the author stated that the term "explosion" was not accurate given that the device was distorted, but had not exploded as previously described. The author also observed that while this is the first such incident with a BIOTRONIK device, it is not in fact the first experience of a battery overheating in the industry.

When was the case report withdrawn from Europace online?

The case report was voluntarily withdrawn by the physician-author, Dr Martin Hudec, on October 5, 2010. On October 6, 2010, the case report was removed from the Europace website.

How does BIOTRONIK report product complaints?

All worldwide product complaints are subject to the same rigorous internal BIOTRONIK reporting requirements. It is standard BIOTRONIK operating procedure to collect and evaluate all relevant details of any suspected product performance issue as soon as we become aware. BIOTRONIK's Technical Services department uses an internal system, in compliance with established FDA requirements, to perform the evaluation and record the details. Certain predetermined criteria determine whether the event must be reported using an MDR. If MDR submission is required, the report must be filed within 30 days of the event.

Is BIOTRONIK's process for reporting complaints different than those used by other CRM manufacturers?

All manufacturers including BIOTRONIK are required to use validated systems for reporting product complaints. Our system for reporting has been reviewed by the FDA and is in compliance with their requirements.

Where do reports like this end up? Aren't they public?

Yes, they do become public. The FDA posts MDR's to their online Manufacturer and User Facility Device Experience (MAUDE) database at the following address:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm

Although the FDA has our MDR, it has yet to be posted to the database.

Is the battery design of the Lumax 340 VR-T safe?

Yes, our extensive investigation confirmed the battery design to be safe and comparable to all other ICD batteries. The safety concept using separator foils is also industry-standard. This event represents a singular observation and should be considered as such.

Will this singular event result in a recall of Lumax 340 devices?

No. This is a singular event. An extensive investigation has confirmed that there is no reason to believe that there are quality or safety concerns with any BIOTRONIK CRM device.

Will BIOTRONIK be issuing a dear doctor letter or a formal communication to physicians?

No. This represents a singular event of no systematic nature and therefore, does not fall under product advisory requirements.

How did BIOTRONIK analyze the device?

After BIOTRONIK was informed about this incident, a team of internal and external experts was selected to perform thorough and immediate analyses. The analyses included non destructive testing as well as subsequent destructive testing of the ICD and all of its internal components. As with all of our testing, the results were verified and provided to the regulatory authorities.

What did the analysis we performed reveal?

Analyses of the device indicated that the battery housing overheated from an electrical short circuit causing a lithium reaction. Due to increased pressure, the battery housing subsequently vented which caused the change in shape of the ICD.

Is this the first time an issue like this has occurred?

It is the first time it has happened in a device manufactured by BIOTRONIK. However, sudden discharges of battery energy, commonly referred to as “hot pocket” have previously (but rarely) been reported in the CRM industry.

Who should my customer contact if they have questions regarding this matter?

The appropriate contact is Dan Dahlke in our US Technical Services department who can be reached by phone at 503-675-2148 or by e-mail at dan.dahlke@BIOTRONIK.com