Expert Report of Randolph Armstrong: Evaluation of Leland Braund ICD (1861 sn214977)

I have reviewed materials specific to this ICD, including Guidant-produced Memory Downloads and a printout from a 7 September 2005 interrogation. I have also performed a visual inspection of the ICD itself. The ICD was manufactured before the April 2002 manufacturing change. It was implanted 24 August 2001. On 7 September 2005 the ICD was explanted while the battery status was at mid-life (MOL1).

On 20 November 2006 I performed a visual inspection of the ICD (Figure 1) using a stereo microscope (magnification 8-50x) and digital camera.

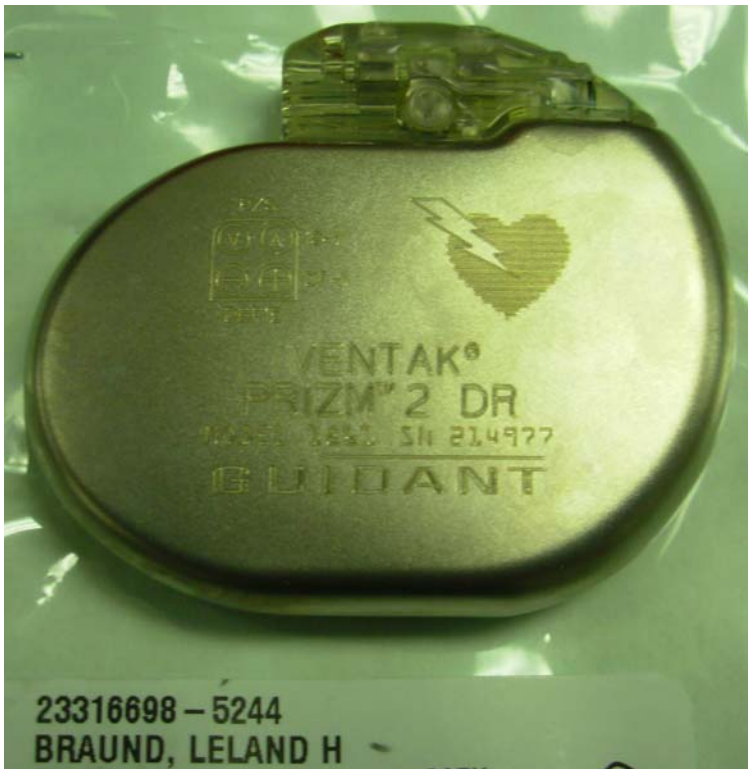

Figure 1

Even without the aid of the microscope it was evident that the DF- wire was routed directly over the backfill tube (Figure 2), which does not conform to the design specification. I have observed such defective routing (over the backfill tube) in 19 of the 20 ICDs I have visually inspected. It was also evident that moisture ingress into the header had occurred.

Figure 2

The routing of the DF- wire directly over the backfill tube was confirmed on microscopic inspection (Figure 3). Furthermore, severe kinking or buckling of the polyimide insulator (due to the tight bend radius of the DF- wire) was evident above and to the left of the backfill tube.

Figure 3

Unambiguous insulation breaching and arcing were not evident; however, based upon stereo microscopic evaluation, the tight radius of the DF- wire bend appears to violate the design specification (430394 N Header Requirement 4: “Inside bend radius of formed (tubed) wires of

Feedthru (Item 13) must be R0.025 minimum”). The minimum bend radius, approximately equal to the DF- wire thickness, is diagrammatically shown in Figure 4. Exceeding the minimum bend radius places stress on the polyimide insulator (as well the feedthrough wire conductor itself).

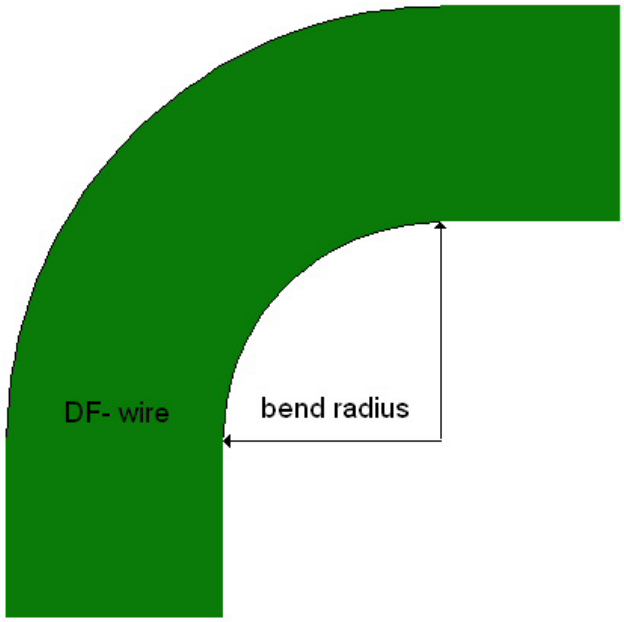

Figure 4

In my opinion, this ICD was not built per design specification and clearly demonstrates a lack of control in the placement and bending of the DF- wire during manufacturing. It is my opinion that Guidant was not reasonably prudent in controlling the placement or bending of the DF- wire, resulting in this manufacturing defect.

Dated this 25th day of May, 2007

RANDOLPH (RANDY) ARMSTRONG