

GUIDANT

April 23, 2001

Summary of Investigations of Access Problems at St. Lukes:

Reference #'s 18613, 18009.

On January 30th 2001, St. Lukes Hospital experienced problems accessing a mid LAD vessel with 90% stenosis and a normal takeoff. Multiple force errors were seen on the first attempt to deliver treatment. The catheter was replaced and treatment proceeded normally.

A second problem occurred on February 23, 2001. After multiple force errors, a new catheter was inserted. In this case, the same errors occurred with the second catheter, and the procedure was abandoned.

No problems were found with the initial catheter used in the first case. The first catheter used in the second case had several bends and kinks, but it could not be determined if these occurred during the procedure, or in the process of returning the catheter to Guidant. The second catheter used in the second case has not been examined.

Given the success of the first case after catheter replacement, it is believed that the GALILEO™ system was functioning properly, and the force errors were due to a genuine restriction in the wire path. Subsequent examination of the cartridge used for both these cases indicated that its force sensing system was properly calibrated. The wires were also inspected and found to be within specifications.

In summary, the system components used in these procedures (SDU, wires, and catheters) all appear to have been within proper operating specifications and the system functioned as designed. The cause of the wire restrictions, which generated the force errors, cannot be determined with certainty. Possible explanations include an over tight Rotating Hemostatic Valve, positioning of the SDU relative to the patient, an undetected bend in the anatomy, or possible kinks in the catheter in the second case.


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