



SAINT THOMAS  
HEALTH SERVICES

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Dockets and Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5603 Fishers Lane, Room 1061 (HFA-305)  
Rockville, MD 20852

RE: Docket Number (REDACTED) 99N-4491

Dear Sirs:

I have reviewed the FDA's Proposed Strategy on Reuse of Single-Use Devices, Docket Number 99N-4491. As an interested party and as a stakeholder, I have a burden to be heard. Although I cannot address all the devices which appear on the proposed list of "Frequently Reprocessed SUDs", I am very familiar with one in particular: Electrophysiology Catheters.

In my institution we have reused electrophysiology catheters since 1988. We have written policy governing our process ensuring integrity, function, and quality of each catheter. Our policy limits the number of uses for each catheter. A log is kept allowing for tracking of usage and performance. The charge for procedures utilizing these catheters is written to reflect the number of usages per catheter. Thereby, the patient and the payor also realize any cost saving that might be realized by the institution. There has not been a single incident related to the reuse of these catheters in the eleven years this practice has been in place.

I have completed a cost analysis examining the impact of reverting to "single use" of these catheters in my institution's Electrophysiology Lab. My lab performs, on an average, over 1,000 electrophysiology procedures annually, utilizing catheters that have been resterilized for reuse. Each of these procedures uses no less than two such catheters and many times up to five to six catheters. If we were hindered from reuse of catheters, in a one year time frame, the total expense associated with catheters would be increased by over \$500,000. Already with other pay practice changes with Medicare, hospitals are experiencing drastic revenue decreases that are threatening their very existence. With the prospective changes in payment for outpatient procedures expected in Spring-Summer of 2000 from Medicare, it will be impossible to survive such an increase in expense and decrease in payment.

My institution, like the FDA, has a reputation of serving its community with quality, efficiency, and positive outcome as its primary purpose. Never have we taken the easy road, but many times the "road less traveled" to insure our patients have the finest in health care. The choice to reuse electrophysiology catheters was made on sound judgment, strict policies, and the highest standards. I am concerned that manufacturers do not base their choice of labeling "single use" items for the same reasons. There is no denying that catheter manufacturers have much at stake financially if it becomes apparent that there is no valid reason these catheters should not be reused. I would reiterate that our charge to the patient has been built on the cost of the catheter divided by the number of times it is reused.

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With respect to the catheters having been used on one patient and then another, the same is certainly true of all surgical instruments. These instruments require inspection, cleaning, resterilizing and repackaging. This has been the practice for many, many years. We follow the same steps for resterilizing our electrophysiology catheters.

Finally, in closing, my fifteen-year-old daughter recently had ablation for supraventricular tachycardia. Without hesitation, I signed the informed consent for "resterilized equipment" to be used during her procedure. I stand firm that I believe our choice to resterilize is safe, efficient, and of the highest standard. So much so that I trusted my most valuable possession, my daughter, to be a part of such practice.

Respectfully submitted,



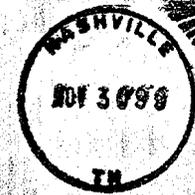
Deborah Monts, RN  
Patient Care Manager  
Electrophysiology Lab/Non-Invasive Cardiology

CC: Charisse Fizer



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