

1200 G Street NW, Suite 400
Washington, DC 20005-3814
Tel: 202 783 8700
Fax: 202 783 8750
www.AdvaMed.org

1466 5 JUN -6 A9:40



AdvaMed

Advanced Medical Technology Association

September 29, 2004

Daniel Schultz, M.D.
Director
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd., HFZ-01
Rockville, MD 20850

FDA/CDRH/DR/04/09/29
2004 SEP 29 AM 10:42

Re: Adverse Events Associated with Reprocessed Single Use Devices

Submitted to: ~~Docket No. 03N-0161~~: Medical Devices; Reprocessed Single-Use Devices; Termination of Exemptions from Premarket Notification; Requirement for Submission of Validation Data.

Docket No. 02N-0534: Medical Device User Fee and Modernization Act (MDUFMA)

Dear Dr. Schultz:

On behalf of AdvaMed¹, we are writing to bring to the attention of the Agency events involving actual serious injury associated with the use of reprocessed, single use devices. This is a follow-up to the letter from AdvaMed dated August 13 expressing concern about CDRH's recent decision to extend, by 90 days, the deadline for third-party reprocessors of single use devices (SUDs) to provide adequate Supplemental Validation Submissions as specified by Section 302 of MDUFMA.

Adverse Events Associated with Reprocessed Devices

An AdvaMed member company recently received a report that a reprocessed heart positioner failed during surgery. Heart positioners are used to manipulate the heart for access to vessels

¹ AdvaMed is the world's largest association representing manufacturers of medical devices, diagnostic products, and medical information systems, ranging from the largest to the smallest innovators and companies. AdvaMed's more than 1,100 members and subsidiaries manufacture nearly 90 percent of the \$75 billion in health care technology products purchased annually in the United States, and more than 50 percent of the \$175 billion purchased annually around the world. Nearly 70 percent of our members have fewer than \$30 million in sales annually.

2003 N-0161

C6

during beating heart bypass and other cardiac surgical procedures. In the specific case, the cardiovascular surgeon cut a patient's heart when the positioner failed to properly hold the heart during a CABG procedure. The surgeon was forced to repair the laceration, exposing the patient to excessive bleeding and a prolonged procedure that in itself has risks such as compromised hemodynamics of the heart (leading to patient instability) and infection. Based on a conversation with the surgeon, the company learned that the positioner had been reprocessed in such a manner that the foam gasket used on the suction cup to grasp the heart had decomposed due to reprocessing. Subsequent testing by the company confirmed this specific failure mode.

In another case, a reprocessed endoscopic vein harvesting system failed when a piece of shrink tubing broke free of the device and became lodged in a patient's leg. In this case, the physician was forced to 'fish' the dislodged part out of the patient's leg. As in the heart positioner case, the malfunction exposed the patient to excessive bleeding and a prolonged procedure. Failure analysis of the returned device by the original equipment manufacturer (OEM) found that the shrink tubing that broke free had deteriorated due to multiple sterilization cycles.

These unfortunate incidents raise two fundamental issues that require careful consideration by the Agency:

- 1) In both instances, the hospital contacted the OEM rather than the reprocessor, as required by MDUFMA. Based on these cases, it appears that user facilities do not understand that reprocessors are considered manufacturers and that OEMs are not responsible for any performance associated with reprocessed devices. We believe this speaks to the fact that additional education within user facilities is needed on this subject.
- 2) Since the OEM in these situation is not required to report the incident per MDUFMA, this can lead to under-reporting or non-reporting of the failures associated with reprocessed devices. Under-reporting can lead FDA, hospitals, reprocessors and the public to have inaccurate perceptions of the safety and efficacy of reprocessed devices.

Because of the public health implications associated with the failure of these reprocessed devices, the OEM plans to provide additional information to FDA regarding these cases.

Independent Testing of Reprocessed Heart Stabilizers

Two AdvaMed member companies have engaged in independent testing of reprocessed heart stabilizers and positioners. The first firm used an independent, academically affiliated imaging center to evaluate the cleanliness and visible physical aspects of

reprocessed heart stabilizers using a scientifically driven protocol. The evaluation is being conducted at the request of providers who questioned whether or not these types of single use

only devices could be effectively cleaned and sterilized without compromising functionality. The findings identified that 9 out of 10 reprocessed heart stabilizers contained material contamination and bio-contamination (identified by Syto 16 positive staining). In addition, 6 of 10 reprocessed devices had some level of physical defect, with 2 devices having partially or totally occluded openings in parts of the hypotube used to provide suction and which holds the anastomotic site stable during beating heart surgery. The 10 samples evaluated included two different product generations and samples from both reprocessors who re-sterilize these devices.

The second member company also used an independent test house for their evaluation on the effects of multiple reprocessing cycles on both heart stabilizers and positioners. Two out of 5 stabilizers were found to be contaminated after one cycle of reprocessing, posing a high potential risk for infection. Furthermore, these stabilizers exhibited physical defects after multiple cycles of reprocessing. As for positioners, all devices included in the testing exhibited the inability to properly maintain stabilization (suction) with the heart after 3 reprocessing cycles.

These data clearly demonstrate that the reprocessing of these single use only devices was not properly validated. As a result, the devices were not fully cleaned and exhibited material degradation and biological contamination. The condition of the reprocessed heart stabilizers and positioners brings into question the safety and functionality of these devices, potentially puts patients at risk and suggests that healthcare providers may be misinformed as to the cleanliness and equivalency of reprocessed heart stabilizers and positioners to new devices.

These data are being assembled for submission to FDA by the OEMs in conjunction with a request to remove the exemption for heart stabilizers and positioners.

Delays in Proper Classification of Heart Stabilizers and Positioners

Heart stabilizers and positioners continue to be categorized improperly as exempt devices. More than a year ago, on August 7, 2003, AdvaMed submitted a comment letter to the MDUFMA docket (#02N-0534) urging that the "exemption for this device be terminated and that the FDA immediately place the device on List I," the critical device list. As noted in our August 7th letter, FDA appropriately categorized the device as "critical" according to the Spaulding criteria but has failed to place the device on the critical device list. As a result, these devices have continued to be viewed by reprocessors as exempt from the requirement to submit validation data. Based on the case cited above, as well as the independent analysis, we believe these devices pose potential harm to patients and that FDA should immediately terminate the exemption from premarket notification.

In summary, AdvaMed remains concerned that adverse events involving reprocessed single use devices are being underreported either due to the general lack of knowledge of the proper pathway for reporting such events or the inability of users to appropriately identify the manufacturer (i.e., the reprocessor). AdvaMed believes that the reprocessing of devices

Docket No. 02N-0534 MDUFMA
September 29, 2004
Page 4 of 4

designed for single use is extremely difficult and we shall continue to closely monitor the review results of the remaining 80% of the Supplemental Validation Submissions for which FDA has extended the deadline. Further, in light of the high NSE (Not Substantially Equivalent) rate for the Supplemental Validation Submissions for which determinations have already been made, we are concerned about the real public health risks associated with reprocessed single use devices, such as those described above. As we have seen, serious injury events are real and have already begun to occur.

Again, as noted in our August 13th letter to FDA, reprocessed single use devices that remain on the market an additional 90 days, whose validation data may ultimately be deemed unacceptable, and particularly those where patient injuries have occurred, may create a significant risk to patients. For the reasons described herein, we believe this extension clearly does not represent the best interests of those patients on whom reprocessed single use devices may be used.

Respectfully,



Tara Federici
Associate Vice President
Technology and Regulatory Affairs

Cc: Dan Troy, Esq.
Donna-Bea Tillman, M.D.
Joanne Less, Ph.D.
Tim Ulatowski