For immediate release
March 4, 2008
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Reprocessing industry group applauds GAO report findings----

Reprocessed medical devices are safe, stringently regulated and an answer to the health care cost-crisis

(Washington, DC) - Daniel J. Vukelich, President of the Association of Medical Device Reprocessors (AMDR) today applauded the findings of the U.S. Government Accountability Office (GAO) January 2008 report entitled "*Reprocessed Single-Use Medical Devices ---FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk."* The report was made public on March 3.

"Medical device reprocessing, as the GAO again confirms, is stringently regulated by the Food and Drug Administration (FDA). Twice in eight years GAO has looked at the practice of reprocessing 'single use' devices (SUDs) and found no evidence of increased risk to patients," said Vukelich.

This is the second time that GAO has been asked to look at the reprocessing industry. In June 2000 GAO issued a report entitled, *"Single Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted,"* which found "the safety of reprocessing some types of devices has been established by well-developed clinical studies. Studies have shown both that reprocessing procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of reprocessed SUDs [single use devices]."

Since the 2000 GAO report, FDA has instituted a number of regulatory requirements for medical device reprocessors, as noted in the full 2008 report. In fact, the most recent GAO report noted that participants in FDA's Medical Product Safety Network (MedSun) were aware "that reprocessing establishments are more stringently regulated by FDA than are the manufacturers of the original devices, and this provided them a sense of confidence in the reprocessing process."

The GAO report noted that FDA "has found no causative link between a reprocessed SUD and reported patient injury or death." The report also concluded that while there is insufficient data for a rigorous comparison of the safety of reprocessed SUDs compared to similar original SUDs, the cost of conducting such testing would not be an efficient use of FDA's limited resources, especially given that the available data "does not indicate that reprocessed currently in use pose an increased safety threat."

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Indeed, the report indicated that between 2003 and 2006, there were 320,000 total adverse reports (associated with all medical devices) filed with FDA. Of that total, only 65 had any connection or possible connection to reprocessed devices. This accounts for .002 percent of reports filed. The report notes that "FDA's analysis of reported device-related adverse events does not show that reprocessed SUDs present an elevated health risk."

> *After reviewing the available evidence - including FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed SUDs, peer-reviewed studies published since 2000, and the results of our and FDA's consultations with hospital representatives -- we found no reason to question FDA's analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs.*
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> *GAO – page 21-22*

The nation's third-party reprocessors have safely reprocessed over 50 million devices all the while maintaining an excellent safety record. Unlike original equipment manufacturers which may test or inspect a sampling of the devices they produce, AMDR's members test or inspect 100 percent of the devices they reprocess. In fact, the GAO report noted that some MedSun participants stated "that there were actually fewer performance problems with reprocessed SUDs than with new SUDs."

"Once again, the GAO report confirms what existing data has demonstrated for some time – reprocessed SUDs pose no elevated health risk to patients. Only original equipment manufacturers (OEMs) continue to oppose reprocessing. Their 'safety' objections are clearly baseless and a smokescreen for their real concern – money. OEMs lose a sale every time a device is reprocessed. Instead of putting more precious health care dollars into the pockets of device manufacturers, reprocessing allows hospitals to purchase new equipment, retain or hire staff, and offset the costs of providing indigent care," said Vukelich.

"Health care providers in the U.S. have a responsibility to deliver safe and effective medical care, and at the same time attempt to control spiraling health care costs. Third-party reprocessors in the U.S. are the only segment of the device industry actually reducing the costs associated with medical devices, reducing medical waste, and still providing the highest quality of medical care possible. While reprocessing is not the single solution to solving all health care cost-containment problems, it is a critical tool to a majority of the nation's hospitals. We are pleased that the GAO's findings further validate this," he said.

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AMDR is a trade association representing third-party reprocessors of medical devices labeled for "single-use." AMDR member companies serve the majority of hospitals in the U.S. and provide services for the top hospitals in the country as listed by *U.S. News & World Report* including all of the top ten cardiac and all the top ten orthopedic hospitals in the country, as well as 17 of the18 facilities on *U.S. News'* "Best Hospitals" list." For more information, visit our website at www.amdr.org