AMDR Overview of January 2008
Government Accountability Office report:

Reprocessed Single-Use Medical Devices --
FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk

A. Background:

In a document made public on March 3, 2008, the United States Government Accountability Office (GAO), provided a report to the Committee on Oversight and Government Reform of the U.S. House of Representatives titled, *"Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk."*

The report came as a follow-up to a GAO report in June 2000 titled, *"Single Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted."* Since publication of the 2000 report, Congress has strengthened FDA oversight through The Medical Device User Fee and Modernization Act of 2002 (MDUFMA.)

B. Key Points of the 2008 GAO Report:

The report attempts to answer three questions:

- What is known about the reprocessing industry?
- What steps has FDA taken to strengthen its oversight of reprocessed devices?
- How does the safety of reprocessed devices compare to the safety of original "single use" devices (SUDs)?

1. What is known about the industry?

- FDA surveyed more than 5,000 hospitals in 2002 and found that nearly half with more than 250 beds reported using reprocessed devices
- GAO found that 11 companies are actively reprocessing more than 100 different types of SUDs in the US. Of these 11, GAO estimated that 3 companies account for approximately 90 percent of the total reprocessing business in the U.S.

- GAO found that reprocessed devices are being used across a wide spectrum of the nation's hospitals, including military hospitals

2. FDA oversight

- Since 2000, the Food and Drug Administration (FDA), the agency responsible for reviewing the safety and effectiveness of medical devices, has stepped up its regulation of reprocessed medical devices, both prior to going to market and through oversight after the product goes to market
- Additional tools were provided to FDA through the Medical Device User Fee and Modernization Act (MDUFMA)
- FDA has strengthened its oversight by requiring additional pre-market data submissions for 72 types of SUDs and by conducting additional post-market activities such as inspections and other surveillance
- Hospital participants in FDA focus groups (Medical Product Safety Network/MedSun) generally expressed confidence in reprocessed SUDs and believed that reprocessed establishments are more stringently regulated by FDA than are the original manufacturers and this provided them with a sense of confidence in the reprocessing process
- FDA has clarified that post-market inspections for reprocessing facilities are the same as for other device manufacturers

3. Safety comparison

- GAO found that available information does <u>not</u> indicate that use of reprocessed SUDs presents greater risk to patients than use of new devices
- Hospital participants in FDA focus groups (MedSun) said that there were actually fewer performance problems with reprocessed devices than with new devices
- FDA analysis of adverse events related to SUDs shows there is no "causative link between a reprocessed SUD and reported patient injury or death"
- FDA has concluded that the cost of conducting additional testing is not warranted, especially since the available data do not indicate that reprocessed SUDs present an elevated health risk

- GAO found that FDA's processes for monitoring and investigating data are sound, and sees no reason to question the FDA analysis of the safety issue

C. What This Means: the Reprocessing Industry Perspective

- The GAO report confirms AMDR's long-held position that there is no increased risk to patients with the use of reprocessed devices, there is no evidence linking SUD reuse with higher risks to patients, and there is no reason to question the FDA's analysis of these facts
- FDA-regulation of reprocessing is stringent. Third-party reprocessors are more stringently-regulated than original equipment manufacturers and have a history of more FDA-inspections than the overall medical device industry
- In this time of increased demand for FDA oversight on such issues as the safety of our food supply and the oversight of devices and drugs that ARE causing patient injury and deaths, AMDR agrees with FDA that it would be unreasonable to divert more time and resources toward the reprocessing segment of the device industry
- The safety of reprocessing some types of devices has been established by well-developed clinical studies
- Adverse event reporting, as documented in the GAO report, shows a tiny rate (65 reports in 4 years for reprocessed devices and 320,000 reports alone filed in 2006 for original devices) of all adverse events possibly involved a reprocessed device.
- Further, FDA found that the types of adverse events reported to be associated with the use of reprocessed devices were the same types of events that are reported for new, non-reprocessed devices
- Third party re-processors 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. We are pleased that the GAO report validates reprocessing as a critical tool for modern health care cost containment