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**NEWS TRENDS**

**Reprocessed SUDs Get Clean Bill of Health**

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A report by the U.S. Government Accountability Office (GAO) indicates that use of reprocessed single-use medical devices does not present an elevated health risk. This runs counter to an argument that some advocates for the medical device industry have been making.

The report, titled *Reprocessed Single-Use Medical Devices—FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk*, was made public in March. It notes that no causative link has been found between a reprocessed single-use device (SUD) and reported patient injury or death.

There are insufficient data to develop a thorough comparison of the safety of reprocessed SUDs versus similar original SUDs, but GAO found that the cost of doing so would not be an efficient use of FDA’s resources.

“Medical device reprocessing, as GAO again confirms, is stringently regulated by FDA,” says Association of Medical Device Reprocessors (AMDR) president Daniel Vukelich. “Twice in eight years, GAO has looked at reprocessing SUDs and found no evidence of increased risk to patients.”

Device Reprocessing by the Numbers
<b>320,000</b> Total adverse reports associated with all medical devices from 2003 to 2006
<b>65</b> Adverse reports from the same period with a possible connection to reprocessed devices
<b>50 million</b> Devices that have been reprocessed



**AMDR president Daniel Vukelich says reprocessed SUDs have not been proven to increase patient risk.**

GAO’s report marks the second time in the past decade that the reprocessing industry has been examined. In June 2000, the office issued a report with similar findings, but noted that oversight of SUDs was warranted. Since that report, FDA has implemented more regulatory requirements for medical device reprocessors. In fact, “reprocessing establishments are more stringently regulated by FDA than are the manufacturers of the original devices,” according to the most recent report.

Between 2003 and 2006, there were 320,000 total adverse reports associated with all medical devices. Only 65 of these reports had a possible connection to reprocessed devices.

For its report, GAO reviewed FDA’s data on reprocessors, reprocessed SUDs, and device-related adverse events. GAO also examined FDA documents and inspection reports, studies in peer-reviewed journals, and relevant statutes and regulations. In addition, GAO interviewed FDA officials as well as representatives from associations of manufacturers, reprocessors, and providers. “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,” the report says.

AMDR. Third-party reprocessors have safely reprocessed more than 50 million devices to date, according to

To find out more about GAO’s findings, or to read the entire report, go to [www.gao.gov/new.items/d08147.pdf](http://www.gao.gov/new.items/d08147.pdf).

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