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## **The Nation's Largest Medical Device Reprocessors Reaffirm Their Commitment to Patient Safety**

(Washington – March 31, 2005) The Association of Medical Device Reprocessors (AMDR), a trade association representing third-party reprocessors of medical devices, reaffirmed its “Commitment to Patient Safety and Hospital Customers” at their March Board meeting. The list sets out the steps that AMDR’s members take to protect patient safety and educate the public about medical device reprocessing. To date, over 25 million medical devices have been reprocessed by our members for hundreds of the nation’s hospitals, including 13 of the 14 “honor roll” hospitals, as identified by *US News & World Report*.

The Commitment to Patient Safety includes an initiative by the reprocessors to educate patients and the medical community that the reprocessing of medical devices, when conducted in accordance with FDA’s stringent requirements, is a safe practice that helps hospitals control their costs and significantly reduce their medical waste streams while allowing them to maintain the very highest standards of patient care. More information can be found at [www.amdr.org](http://www.amdr.org).

### **Commitment to Patient Safety and Hospital Customers**

- Provide hospitals and patients with reprocessed devices that meet or exceed all regulatory requirements. We are proud to have worked with FDA to develop regulatory requirements that are as stringent as (and, in some cases, more stringent than) those required of original devices.
- Inspect each and every reprocessed medical device to ensure patient safety and functional integrity, before releasing it to a hospital.
- Monitor every reprocessed device so that hospitals and patients can be certain that no device is reprocessed more times than the number that has been demonstrated through strict validation studies to be appropriate for the device model in question.
- Continue to conduct our manufacturing operations in conformance with FDA’s stringent manufacturing and quality assurance requirements, in order to maintain the outstanding safety record that third-party reprocessing has enjoyed since its inception.

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- Comply with all FDA adverse event reporting requirements, including forwarding to FDA reports of events that were mistakenly sent to the reprocessor concerning devices that were not in fact reprocessed.
- Continue to help our hospital customers protect the environment by reducing their medical waste.
- Continue to help our hospital customers achieve substantial cost savings, to assist them in meeting the growing patient care challenges of their communities including charitable care needs, women and infant programs, and otherwise unfunded community outreach programs.
- Work with our hospital customers to assure acceptance of reprocessing through an evidence-based educational campaign that communicates the benefits of reprocessing in terms of reducing hospital costs and medical waste. This includes informing our key audiences that the “single-use” label on medical devices is used at the discretion of the original equipment manufacturer. FDA does not require devices to be labeled for “single use.” Manufacturers frequently choose to label their products this way because they make more money if the hospital throws out each device after one use.

**About AMDR**

The Association of Medical Device Reprocessors (AMDR) is a trade association representing third-party reprocessors of medical devices labeled for “single-use.” AMDR members account for approximately 95 percent of the third-party reprocessing done in the United States. AMDR member companies reprocess for America’s best hospitals, as listed by *U.S. News & World Report* magazine. In the summer of 2004, *U.S. News* identified 14 Honor Roll hospitals as those outstanding medical centers that “merit acclaim for impressive quality and breadth of expertise.” AMDR members reprocess for 13 of those 14 hospitals.

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