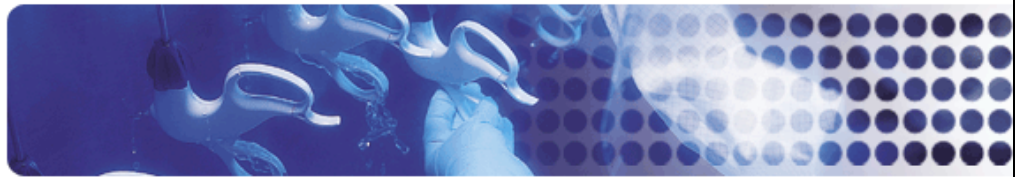




AMDR

Association of  
Medical Device  
Reprocessors



# STRAIGHT TALK

News from Association of Medical Device Reprocessors

## Misconceptions about the reprocessing of “single use” devices

**Myth:** Manufacturers label some medical devices for “single use” because these devices are unsafe for more than one use.

**Fact:** The “single use” label is not an FDA-requirement but chosen at the manufacturer’s discretion, often for economic reasons, not patient safety reasons. Original Equipment Manufacturers (OEMs) recognize that many of the devices that they have labeled for “single use” can appropriately be reprocessed and used again. For example, Millstone Medical, a Massachusetts based, third-party reprocessor works with OEMs to reprocess “single use” devices.<sup>i</sup> Synthes, a major orthopedic OEM, markets its own reprocessed “single use” external fixation devices.<sup>ii</sup> Over time, OEMs have changed the labels on some devices from “reusable” to “single use” without substantially changing the devices, further evidence that “single use” does not necessarily mean “single use.”<sup>iii</sup> The American Hospital Association (AHA)<sup>iv</sup>, the American Association of Orthopedic Surgeons<sup>v</sup>, and statements in the Government Accountability Office’s (GAO) report have all publicly criticized OEM misuse of the “single use” label.<sup>vi</sup>

**Myth:** Reprocessed medical devices fail more often than original devices, leading to more patient harm.

**Fact:** FDA’s adverse event database contains over 6,500 reports of patient deaths associated with original (unreprocessed) devices since 2004. According to the same FDA database, zero deaths have occurred as a result of the use of reprocessed devices.

FDA’s database of medical device adverse events is freely available via the Internet for anyone at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/search.CFM>. In a letter from FDA to Congressman Tom Davis and Harry Waxman dated January 23, 2006, FDA indicated that a total of 65,325 reports have been filed since October 2003 for the malfunction or injury associated with the first use of devices labeled for “single use.” The same search produced 176 cases of apparent malfunction or injury associated with reprocessed devices. Upon analysis of the latter reports, FDA determined that these adverse events were not related to the reprocessing of the “single use” device (SUD).<sup>vii</sup>

**Myth:** Reprocessing is inadequately regulated.

**Fact:** FDA rigorously regulates the reprocessing industry. In fact, reprocessing must meet the same regulations as OEMs and then some.

Here’s a brief history of legislation enacted to regulate the reprocessing of medical devices:

For Further Information:

Dan Vukelich    AMDR    202-518-6796    [dvukelich@amdr.org](mailto:dvukelich@amdr.org)  
Lory Olsson    AMDR    512-636-1489    [lolsson@amdr.org](mailto:lolsson@amdr.org)  
John Bartley    617-720-2060    [jbartley@tiac.net](mailto:jbartley@tiac.net)

**2000:** FDA required that reprocessors meet the same requirements as OEMs, including establishment registration and medical device listing, medical device reporting, reports of corrections and removals, quality system regulation (“QSR”), labeling, and premarket requirements.

**2002 (MDUFMA):** The Medical Device User Fee and Modernization Act of 2002 created additional premarket requirements for reprocessors. Pursuant to MDUFMA, reprocessors are subject to more stringent FDA regulation than original device manufacturers.

**2005 (MDUFSA):** The Medical Device User Fee Stabilization Act of 2005 amended MDUFMA to create even more requirements for reprocessors. All reprocessed SUDs must be clearly marked as reprocessed on the device itself as well as on the packaging. These requirements do not exist for OEM products.

**Myth: Cleaning detergents and other residue cannot be eliminated from certain devices that are reprocessed.**

**Fact: Reprocessors must prove that a device has been successfully cleaned, sterilized, and is functional, to the same, if not greater degree, as the original device before it is allowed to be commercially reprocessed.** Extensive data must be submitted to the FDA before the Agency clears a particular device for reprocessing. If a device cannot meet the same requirements as an original device, it does not receive FDA’s clearance for reprocessing.

**Myth: Tracheal tubes are currently reprocessed.**

**Fact: Tracheal tubes are not reprocessed by AMDR members and have not been reprocessed by hospitals since 2002.** In several news stories, including a recent article by the Associated Press, reporters failed to mention that tracheal tubes are no longer reprocessed even though the stories allude to dated examples of harm from their reuse. To clarify the confusion, AP printed a correction on 8/11/2006:

*“In addition, the story discussed the case of an infant who was permanently injured by a tracheal tube that was damaged when it was reprocessed by a hospital. The FDA did not regulate reprocessing at hospitals when the infant was injured in 2001, and hasn’t authorized reprocessing of tracheal tubes.”<sup>viii</sup>*

**Myth: “Reprocessed” and “reused” can be used interchangeably to describe medical devices that have been used more than once.**

**Fact: These two are distinctly different activities with different regulatory requirements.** In the case of devices which are reused, central sterile departments in hospitals clean and sterilize devices that are labeled as "reusable" by the original manufacturer (“reused”). In the case of reprocessed devices, third-party reprocessors clean and sterilize devices that have been labeled as "single use" devices, and bring them back to original specifications. Unlike hospitals’ central sterile activities, commercial reprocessing is performed under FDA's stringent oversight and pursuant to rigorously validated protocols. While both activities involve the re-use of medical devices, any safety problems associated with cleaning and sterilization activities by in-house central sterile departments have no bearing on the safety of commercial reprocessing of “single use” devices.

**Myth: Photos circulated by OEMs prove that reprocessed medical devices are dirty and not sterile.**

**Fact: Reprocessors meet stringent cleaning and sterilization requirements on all devices and have never come across a photo validating that this is not the case.** When presented with photos that indicate otherwise, we urge viewers to ask which health care facility or facilities did the

devices in these photos come from and when and how were they obtained? Where were they tested and by whom? Who allegedly reprocessed the device? How do you know? Can you give us the name, title and affiliation of the person who obtained the devices? Can you address the chain of custody for the devices between the time they left the possession of the health care facility and the time they were photographed? Did anyone, other than the photographer, open the packaging of the reprocessed devices? Under what conditions were the devices held between the time the devices left the health care facility until they were photographed? What has FDA said of this alleged “data? In one instance, AMDR requested that a reporter ask these questions of an OEM that presented such photos to the media outlet. According to that reporter, the OEM that supplied the photos had in fact “reprocessed” them at the OEM’s lab. So the devices in question were in no way reflective of devices reprocessed by third-party reprocessors.

**Myth: Items that come into contact with the central nervous system, including the brain and spine, are reprocessed and therefore may transmit Creutzfeldt-Jakob Disease (CJD).**

**Fact: FDA’s publicly available database, where all reprocessed devices must be listed, shows that no reprocessors reprocess any neurological devices, or any devices that potentially pose a risk of CJD transmission.** AMDR members have agreed to never reprocess these devices.

**Myth: Because reprocessed devices are riskier, patients should have to sign informed consent papers authorizing their use.**

**Fact: Reprocessed SUDs are not investigational or experimental devices and therefore is no legal, medical or ethical basis for imposing a requirement to seek informed consent for the use of reprocessed devices but not for the use of original devices.**

Comparing a reprocessed device to an original device is similar to comparing generic drugs to brand name drugs. Both are equivalent in the eyes of FDA and both must meet the same strict regulatory requirements. **Reprocessed devices are as safe and effective as original equipment, and there is no evidence that the use of reprocessed devices increases the risks associated with a medical procedure.** Obtaining informed consent from patients for the use of reprocessed "single use" devices does nothing to increase patient safety nor does it provide patients with any meaningful information about the actual risks and benefits of the medical procedures they are about to undergo. Reprocessed devices are legally marketable devices that are subject to stringent regulation by FDA. These regulations compel reprocessors to comply with all of the requirements applicable to original devices, including premarket clearance and approval requirements, along with some additional requirements applicable only to reprocessors.

**Myth: Reprocessing provides no benefits to patients.**

**Fact: Besides being just as safe as, if not safer than original devices, reprocessing keeps tons of medical waste from filling community landfills, and saves money for local hospitals that they can use to hire more patient care staff, improve technology, or provide care to the indigent.** The reprocessing industry has also helped with overall cost-containment in the medical device industry. Through the competition created by third-party reprocessors, OEMs have significantly lowered their prices on certain devices. For example, Microvvasive Endoscopy, a division of Boston Scientific, has entered into agreements with certain hospitals to discount biopsy forceps in exchange for the hospital agreeing to not reprocess those devices<sup>ix</sup>. In other instances, OEMs have discounted items so low that it made reprocessing less cost-effective for the hospital and no agreements were needed. **While medical costs continue to spiral out of**

control, reprocessing is one of the few things the medical community can do to save money without compromising patient safety.

**Myth: If a hospital uses reprocessed devices, it is probably providing inferior service.**

**Fact: AMDR members reprocess for 13 of the 14 “Honor Roll” hospitals as identified by U.S. News & World Report in summer 2006. Additionally, AMDR member reprocessors serve all ten of the top ten heart and heart surgery hospitals in the nation and nine of the top 10 orthopedic hospitals nationwide.<sup>x</sup>** Some of the most prestigious hospitals in the world use reprocessed devices, including Cleveland Clinic, Mayo Clinic, Johns Hopkins, and Massachusetts General. The nation’s best hospitals reprocess because it is safe for patients, good for the environment, and saves them valuable healthcare dollars that they can put back in to providing the best medical care by way of more nursing staff or better technology.

**Myth: OEMs are blamed for reprocessed device malfunctions because reprocessed devices are still marked with the original manufacturer’s name.**

**Fact: To our knowledge, no manufacturer has ever been found liable, nor has any lawsuit ever been filed against an original equipment manufacturer for the failure of a reprocessed device.** Pursuant to MDFMA and MDUFSA, all reprocessed medical devices are marked as such, therefore a doctor or nurse filing an adverse event report for any device would know whether or not it was reprocessed. Further, because all reprocessors have always traced their devices for internal tracing purposes, they’ve always including some sort of marking mechanisms to identify the device as reprocessed by their company.

*Information provided by the Association of Medical Device Reprocessors, 2007.*

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<sup>i</sup> Millstone Medical Outsourcing Launches Customized After-Market Services To Optimize Deployed Inventory, Three of the Top Five Orthopaedic Manufacturers Already Save Millions Yearly. March 8, 2005. Available at: <http://www.millstonemedical.com/March8.asp>

<sup>ii</sup> *Medical Design Technology*, “OEM Moves Into Reprocessing,” <http://tinyurl.com/r3opc>

<sup>iii</sup> Letter from USCI (Division of CR Bard) Product Manager Brian Dowling to doctors. July 24, 1980.

<sup>iv</sup> Testimony of the American Hospital Association before the Health, Education, Labor and Pensions Committee of the United States Senate on Reuse of Medical Devices, June 27, 2000, <http://www.aha.org/aha/advocacy-grassroots/advocacy/testimony/2000/reuse60027.html>

<sup>v</sup> American Academy of Orthopedic Surgeons, Academy Statement on Reprocessed Single-Use Devices, February 14, 2002, <http://www2.aaos.org/aaos/archives/acadnews/2002news/c14-4.htm>

<sup>vi</sup> U.S. General Accounting Office Report to Congressional Requesters, Single Use Medical Devices: Little Available Evidence of Harm From Re-Use, But Oversight Warranted, June 2000, <http://www.gao.gov/new.items/he00123.pdf#search=%22GAO%20single%20use%20devices%22>

<sup>vii</sup> Letter from The U.S. Food and Drug Administration to The Honorable Tom Davis and Henry Waxman, January 23, 2006

<sup>viii</sup> Associated Press, “Correction: Recycling-Medical-Devices,” August 11, 2006

<sup>ix</sup> Letter from Tim Krock, Microvase Endoscopy, September 23, 1999

<sup>x</sup> U.S. News & World Report, “Best Hospitals 2006.” <http://www.usnews.com/usnews/health/best-hospitals/tophosp.htm>