



*AMDR Response to:*

***ClaimsRx; Clinical & Risk Management  
Perspectives, June 2007***

***Reprocessed Single-Use Devices; Let Patient Safety Be Your Guide<sup>1</sup>***

The Association of Medical Device Reprocessors (AMDR) applauds *ClaimsRx* for publishing an article aimed at enhancing physician and hospital executive knowledge of the reprocessing of “single use” devices (SUDs). However, the article contains a number of inaccuracies that mislead readers regarding the current regulatory status and safety record of SUD reprocessing.

AMDR urges *ClaimsRx* to remove this article from its website, from circulation and to cease issuing continuing medical education credits for the material. AMDR also asks that *ClaimsRx* publish corrected information as to the current regulatory status of SUD reprocessing in the U.S. and to provide accurate information as to the actual safety record of reprocessing in the last decade. AMDR asks that *ClaimsRx* make this information available on its website, to its subscribers, and to all those who sought or will seek ACCME credit for this material. Alternatively, AMDR suggests that *ClaimsRx* provide this response to readers.

**SUDs Reprocessed in Compliance with FDA’s Requirements are “Safe and Effective”**

The fact is that SUDs reprocessed in the U.S. must meet all of the same FDA requirements applicable to original SUDs, and are as “safe and effective”<sup>2</sup> as new equipment. The *ClaimsRx* article notes that opponents of reprocessing argue “SUD reprocessing probably decreases patient safety because safety cannot be proven”<sup>3</sup>—an argument lacking evidential support. Indeed, the only evidence *ClaimsRx* cites to support this argument is a 1997 online article questioning the safety of reprocessing.<sup>4</sup>

Since 2000, all SUD reprocessors (hospital and third-party) have been fully-regulated by FDA as manufacturers.<sup>5</sup> All reprocessors, like all device manufacturers, are required to comply with FDA’s premarket notification procedures;<sup>6</sup> the data of which must demonstrate that a reprocessed device is “substantially equivalent to the predicate device” and is “as safe and as effective as a legally marketed device.”<sup>7</sup> In some regards, reprocessors are more stringently regulated than even the OEMs.<sup>8</sup>

It is misleading for *ClaimsRx* to cite, as its sole source, a ten-year-old website as evidence that reprocessed SUDs may decrease patient safety. Quite simply, *ClaimsRx* was unable to cite actual, credible data showing an increased risk to patients from the use of FDA-regulated reprocessed SUDs because no such data exists. Even ECRI – the organization upon which *ClaimsRx* relied in its original citation - has since provided more up-to-date information on the subject of reprocessing.<sup>9</sup> Claiming that reprocessed SUDs may compromise patient safety without evidential support is misleading, and maligns the majority of U.S. hospitals that use reprocessed SUDs.

In fairness, the article does note that reprocessing proponents would argue that “reprocessed SUDs are as safe as new devices because studies have not shown that reprocessing SUDs increases the risk of injury to patients.”<sup>10</sup> However, *ClaimsRx* has seriously understated the evidence. It is not a mere set of “studies” that show an absence of harm to patients. Third-party reprocessors (TPR) have been providing their premarket manufacturing data to FDA since 2000, demonstrating substantial equivalence to original equipment since 2001.<sup>11</sup> And, indeed, decades of clinical use confirm the safety and efficacy of reprocessing many devices labeled by the OEMs for “single use” only.<sup>12</sup>

### ***ClaimsRx* Article’s Inaccurate Assumption that Hospitals Are Reprocessing SUDs In-House is Irrelevant and Misleading**

The reality is the nation’s hospitals have chosen to outsource reprocessing of SUDs to TPR with demonstrated expertise in reprocessing and compliance with FDA requirements. According to AMDR’s searches of FDA’s Registration and Listing databases, no hospitals in the U.S. have ever registered or listed to reprocess any SUDs.<sup>13</sup> Thus, AMDR is unaware of any hospital reprocessing SUDs in compliance with FDA’s requirements. Moreover, AMDR is unaware of any evidence of U.S. hospitals reprocessing SUDs outside of FDA’s requirements.

Despite all evidence to the contrary the article presumes hospitals themselves are reprocessing SUDs. AMDR believes this is an attempt to scare physicians and hospital executives into thinking unscrupulous reuse of SUDs is taking place and potentially putting patients at risk. The article is not only misleading but also maligns the integrity of hospitals that use reprocessed devices.

### ***ClaimsRx* Article’s “Policies and Procedures” Are Irrelevant and Misleading**

This article advocates that hospitals develop “policies and procedures to indicate whether a particular SUD will be reprocessed in-house and/or at a third-party reprocessor.”<sup>14</sup> The bulk of the policies and procedures outlined are based on inaccurate and/or dated information, and are irrelevant and misleading. There is no evidence that any U.S. hospitals are reprocessing SUDs in-house. *ClaimsRx* should provide corrected information to remove the misleading impression created by the article.

Additionally, the article cites outdated ECRI recommendations<sup>15</sup> when it suggests that hospitals should have informed consent policies in place for reprocessed SUDs. The fact is, FDA does not require informed consent for products that have been cleared or approved by the agency,<sup>16</sup> nor is it standard medical practice to obtain informed consent to use legally marketed, non-investigational, medical devices. Reprocessed devices are legally marketable devices subject to all of FDA’s device manufacturer requirements including premarket clearance requirements.<sup>17</sup> Reprocessed devices must comply with the same FDA requirements as original devices and are as safe and as effective. Therefore, there is no legal, medical or ethical basis for imposing a requirement to seek informed consent for reprocessed devices but not for original devices.

### **The *ClaimsRx* Article Provides Inaccurate Information in Its List of “Single-Use Medical Devices Known to Be Reprocessed”**

*ClaimsRx* misleads readers when it lists “examples from the Food & Drug Administration (FDA); ‘Single-Use Medical Devices Known to be Reprocessed.’”<sup>18</sup> At least half of the devices listed as

“commonly reprocessed” are not, indeed, reprocessed in the U.S. At the top of the very FDA website cited by the authors for this list is a clear disclaimer: “*Note: This list includes all devices that FDA historically believed either were being reprocessed or were being considered for reprocessing. It is not a current list of devices known to be reprocessed in the United States today. For a listing of devices currently being reprocessed, see FDA's web-page to search for "[Cleared Reprocessed Single-Use Devices](#)," or [search FDA's device "Listing" database](#).”<sup>19</sup> ClaimsRx should provide a current and accurate list of commonly reprocessed SUDs if it chooses to make such information available.*

### **The ClaimsRx Article’s Case Studies Are Irrelevant and Misleading**

The article cites two case studies, both of which refer to incidents which took place before FDA's full regulatory requirements went into effect.<sup>20</sup> Both case studies (nearly a decade old) are therefore irrelevant to readers. It is misleading to cite two unrelated examples to scare readers into thinking unscrupulous reuse of SUDs is currently taking place when no current evidence corroborates this.

### **“Single use” Does Not Always Mean Single Use**

The real issue the authors did not sufficiently address was OEM use of the “single use” label. Device manufacturers, not FDA, choose whether to label a device for “single use.” Approximately two decades ago, OEMs began to change labels on certain medical devices from “reusable” to “single use.” As OEM documentation from this time-period demonstrates, it appears that, in some cases, device labeling changed without any significant design, performance or material changes to the devices that would preclude safe reuse.<sup>21</sup> With this change in labeling, it became evident to many hospitals that the single-use label does not necessarily mean single use, and that certain devices designated by OEMs as “single use” can, in fact, be safely reprocessed.<sup>22</sup>

Manufacturers themselves have also “contributed to the sense that compliance with the “single-use” label is not always necessary.<sup>23</sup> In 2000, the Government Accountability Office (GAO) identified a manufacturer of pulse oximeter sensors that sold hospitals “remanufactured” sensors at a reduced price if the hospitals returned their used, “single use” sensors to the company. This “recycling” of devices by the manufacturer -- who itself had originally labeled the devices as “single use only” -- further contributed to the sense among healthcare professionals that the single-use label was not truly meaningful.<sup>24</sup> And today a number of “single use” device manufacturers offer their own reprocessing programs,<sup>25</sup> proof further that “single use” isn’t always just that.

### **Conclusion**

Reprocessed SUDs are safe and effective. America's finest medical facilities use reprocessed medical devices, including 17 of the 18 ranked by *U.S. News & World Report* in 2007 as the nation's "Honor Roll" hospitals. Reprocessing not only makes economic sense, but it is good for the environment, helping hospitals divert more than 10,000 tons of medical waste from landfills in the last decade. In short, reprocessing plays a critical role in our health care system. Hospitals that safely reduce costs and waste should be rewarded and recognized for their efforts, not misled or maligned by unsubstantiated allegations that they are putting patients at risk.

<sup>1</sup> [http://www.norcalmutual.com/publications/claimsrx/jun\\_07.pdf](http://www.norcalmutual.com/publications/claimsrx/jun_07.pdf) [hereinafter *ClaimsRx*].

<sup>2</sup> 21 CFR 807.100(b)(2)(ii)(B) “The data submitted establishes that the device is substantially equivalent to the predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is as safe and as effective as a legally marketed device” (emphasis added) [hereinafter, *Premarket notification requirements*]. See also, *Schultz testimony, infra* note 8, “FDA believes that reprocessed SUDs that meet FDA’s regulatory requirements are as safe and effective as a new device” (emphasis added).

<sup>3</sup> *ClaimsRx*, at 2, citing Solomon, R. ECRI expert reviews reuse of single-use medical devices. APSF website. Available at [http://www.apsf.org/resource\\_center/newsletter/1997/winter/](http://www.apsf.org/resource_center/newsletter/1997/winter/). Accessed Mar. 21, 2007 [hereinafter, *ECRI*].

<sup>4</sup> *Id.*

<sup>5</sup> Guidance for Industry and for FDA Staff, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals (August 14, 2000) at 1, <http://www.fda.gov/cdrh/comp/guidance/1168.pdf> [hereinafter *FDA Guidance*]. Specifically, reprocessors are subject to establishment registration and medical device listing, 21 U.S.C. § 360; 21 C.F.R. Part 807, subpart B; medical device reporting, 21 U.S.C. § 360i(a); 21 C.F.R. Part 803; medical device tracking, 21 U.S.C. § 360i(e); 21 C.F.R. Part 821; reports of corrections and removals, 21 U.S.C. § 360i(f); 21 C.F.R. Part 806; quality system regulation (“QSR”), 21 U.S.C. § 360j(f); 21 C.F.R. Part 820; and labeling requirements, 21 U.S.C. §352; 21 C.F.R. Part 801.

<sup>6</sup> Class I and Class II devices are required to have cleared premarket notification submissions (“510(K)s”), unless otherwise exempt. 21 U.S.C. § 360(k); 21 C.F.R. Part 807. See also, *Premarket notification requirements, supra* note 2.

<sup>7</sup> *Premarket notification requirements, supra* note 2 (emphasis added). Third-party reprocessors generally treat the OEM device as the predicate, legally marketed device.

<sup>8</sup> See Testimony of Dr. Daniel Schultz, Director, Center for Devices and Radiological Health, Food and Drug Administration, September 26, 2006. “Congress mandated a number of new requirements for SUD reprocessors including, for certain SUDs, the pre-market submission of data to the agency that exceeded the requirements for the original manufacturers (OEMs)” (emphasis added) [hereinafter, *Schultz testimony*]. Additionally, in 2002, Congress imposed additional requirements on reprocessed devices with Title III of the Medical Device User Fee and Modernization Act (MDUFMA), which amended the Food Drug and Cosmetics Act (FDCA) (Public Law 107-250). Among other things, MDUFMA requires that the labeling of reprocessed devices bear the reprocessor’s name and state that the device was reprocessed (21 U.S.C. § 352(v), effective January 25, 2004). The law also requires that, in many instances, reprocessors include validation data in their premarket submissions. In addition, the law requires FDA to identify “critical” and “semi-critical” 510(k)-exempt devices for which the exemptions should be terminated when the devices are reprocessed, “in order to provide a reasonable assurance of the safety and effectiveness of the devices” (21 U.S.C. § 360(o)). For devices that lost exemption from the premarket notification requirement, reprocessors had to submit a 510(k) within 15 months of FDA’s publication of a notice terminating the exemption, or the device in question could no longer be legally marketed (21 U.S.C. § 360(o)(2)(B)). See also 68 Fed. Reg. 38071 (June 26, 2003).

<sup>9</sup> See e.g., [http://www.ecri.org/Conferences/AudioConferences/Pages/Reuse\\_of\\_Single-use\\_Devices-Is\\_It\\_Right\\_for\\_Your\\_Hospital.aspx](http://www.ecri.org/Conferences/AudioConferences/Pages/Reuse_of_Single-use_Devices-Is_It_Right_for_Your_Hospital.aspx) (accessed December 2007).

<sup>10</sup> *ClaimsRX*, at 2.

<sup>11</sup> *FDA Guidance, supra*, note 5.

<sup>12</sup> Some peer-reviewed journal articles include, N. Ma, A. Petit, O. Huk, L. Yahia, and M.Tabrizian, “Safety Issue of Re-Sterilization of Polyurethane Electrophysiology Catheters: a Cytotoxicity Study,” 14 *Journal of Biomaterials Science, Polymer Edition* 213 (2003); T.A. Ischinger, G. Neubauer, R.Ujlaky, H.Schatzl, and M.Bock, “Reuse of ‘Single Use’ Medical Devices After Quality Assured Reprocessing: Hygenic, Legal and Economic Aspects. Potential for Cost Savings in Interventional Cardiology,” 92 *Z. Kardiol.* 889 (November, 2002); T.P. Kinney, R.A. Kozarek, S. Raltz, and F. Attia, “Contamination of Single-Use Biopsy Forceps: a Prospective in Vitro Analysis,” 56 *Gastrointestinal Endoscopy* 209 (August 2002); D. Dunn, RN, MBA, CNOR, “Reprocessing Single-Use Devices – Regulatory Roles,” 75 *AORN Journal* 98 (July 2002); T.P. Kinney, R.A. Kozarek, S. Raltz, and F. Attia, “Contamination of Single-Use Biopsy Forceps: a Prospective in Vitro Analysis,” 56 *Gastrointestinal Endoscopy* 209 (August 2002); D. Dunn, RN, MBA, CNOR, “Reprocessing Single-Use Devices – Regulatory Roles,” 75 *AORN Journal* 98 (July 2002); S. Mickelsen, BS, C. Mickelsen, BS, C.MacIndoe, BS, J. Jaramillo, S.Bass, MD, G. West, RN, and F. Kusumoto, MD, “Trends and Patterns in Electrophysiologic and Ablation Catheter Reuse in the United States,” 87 *The American Journal of Cardiology* 351 (February 1, 2001); C.M. Wilcox, “Methodology of Gastroenterology and Hepatology,” 10 *Gastrointestinal Endoscopy Clin N Am* 379 (April 2000); R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., T.J. Ball, M.D., D.J.Patterson, M.D., J.J. Brandabur, M.D, “Reuse of Disposable Sphincterotomes for Diagnostic and Therapeutic ERCP: A One-Year Prospective

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Study,” 49 *Gastrointestinal Endoscopy* 39 (January 1999); S.K. Roach, R.A. Kozarek, M.D., S.L. Raltz, R.N., M.S.N., and S.E. Sumida, Ph.D., “In Vitro Evaluation of Integrity and Sterilization of Single-Use Argon Beam Plasma Coagulation Probes,” 94 *The American Journal of Gastroenterology* 139 (January 1999); Blomstrom, Lundqvist, “The Safety of Reusing Ablation Catheters with Temperature Control and the Need for a Validation Protocol and Guidelines for Reprocessing,” 21 *Pacing Clinical Electrophysiology (PACE)* 2558 (December, 1998); M. Bathina, M.D., et. al., “Safety and Efficacy of Hydrogen Peroxide Plasma Sterilization for Repeated Use of Electrophysiology Catheters,” 32 *Journal of the American College of Cardiology* 1384 (November 1, 1998).

<sup>13</sup> See FDA’s Establishment Registration database at:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/registration.cfm>, and the agency’s Device Listing Database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/listing.cfm> (accessed December, 2007).

<sup>14</sup> *ClaimsRx*, at 6.

<sup>15</sup> *ECRI*, *supra* note 3.

<sup>16</sup> See FDA’s *Guide to Informed Consent*, <http://www.fda.gov/oc/ohrt/IRBS/informedconsent.html>.

<sup>17</sup> *FDA Guidance*, *supra* note 5.

<sup>18</sup> *ClaimsRx*, at 2.

<sup>19</sup> See, <http://www.fda.gov/cdrh/reprocessing/fr-attachment1.html> (emphasis added).

<sup>20</sup> Specifically, Case Study #1, at 3, discusses a well-known case in which a hospital resterilized a tracheostomy tube. To AMDR’s knowledge, no TPR in the U.S. reprocesses tracheotomy tubes. Case Study #2, at 4, discusses another well-known case of a cardiac catheter tip breaking and becoming dislodged in a patient’s heart. It may be possible that the hospital, not a third-party, reprocessed the catheter. Regardless, AMDR believes both of these instances took place before FDA put in place its full regulatory requirements in 2000 and before hospitals ceased reprocessing devices in-house.

<sup>21</sup> Letter from Brian Dowling, Product Manager, USCI Cardiology & Radiology Products (July 24, 1980). USCI representative explained to a hospital-customer that, although it was changing the label on its intracardiac electrodes from “reusable” to “single use,” “our manufacturing processes . . . have not changed. These electrodes are made with the same materials and in the same manner as they have been in the past.” See also, letter from Geoffrey M. Allen, Boston Scientific Corp., Microvasive Division 2 (May 1, 1987) which stated, “BICAP® Hemostatic Probes are recommended for single use only. However, this recommendation does not prohibit reuse under certain specific conditions. . . .”

<sup>22</sup> United States General Accounting Office, Report to Congressional Requestors, *Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted* 11 (June 2000). According to the report, healthcare personnel “distrust the single-use label for some devices because,” among other things, “FDA cannot require manufacturers to support the designation of a device as single-use,” and “they perceive that manufacturers have an economic incentive to market devices as single-use that could just as well be sold as reusable.”

<sup>23</sup> *Id.*

<sup>24</sup> *Id.*

<sup>25</sup> E.g, the orthopaedic device manufacturer Synthes offers hospitals the option to purchase previously used external fixation components as part of its own reprocessing program. “The U.S. division of this Swiss firm is reprocessing over a dozen of its fixation devices, including single use devices such as its ‘combination clamp’ and ‘tube to tube clamps,’” see “OEM Moves into Reprocessing,” *Medical Design Technology*, March 1, 2006. See also FDA 510(k) clearance K033158, “Synthes (USA) Reprocessed External Fixation Devices,” cleared by FDA on November 5, 2003. See also Synthes, External Fixation Reprocessing Program, Corporate Market Material, Synthes USA 2004. See also, “The Economic Impact of Reprocessing External Fixation Components,” *The Journal of Bone and Joint Surgery, Inc.*, Horwitz, Daniel S. MD, Schabel, Kathryn L.S. MD, Higgins, Thomas F. MD, Department of Orthopaedics, University of Utah, Salt Lake City, 2007; 89: 2132-2136, stating that “Stryker Orthopaedics applied for, and was granted, United States Food and Drug Administration (FDA) 510(k) approval of this recertification process...” and ...” “We believe that we are the first to examine an FDA-approved program for recertification of external fixation components by the original manufacturer...”