



BEST CLINICAL PRACTICE



Background Information on Medical Device Reprocessing – Now a Best Clinical Practice in American Healthcare

Healthcare providers in the U.S. are under enormous pressure to provide high quality patient care, yet also control costs, and reduce their impact on the environment of the communities they serve. FDA regulated reprocessing, or remanufacturing of single use devices represents a singular opportunity to provide safe and effective patient care, while eliminating waste.

Increasingly, regulated reprocessing is a key component of most healthcare provider's sustainability programs: this form of remanufacturing allows for stabilization of variable device costs, while alleviating regulated medical waste. After over ten years of clinical history, and an outstanding patient safety record, many organizations are taking the additional step of designating regulated reprocessing as a best clinical practice. Reprocessing meets the basic criteria for such a designation: preserving quality patient care through safe and effective devices, while helping to decrease costs, and preserve the environment.

This document was developed to serve as background information on the practice of FDA regulated reprocessing, or remanufacturing of "single-use devices" ("SUDs"). It includes the applicable federal law and regulatory scheme, and the safety record of the practice for your evaluation of reuse of "single use" devices as a best clinical practice.

A. The Reprocessing of Devices Marketed by Manufacturers as "Single Use" is Lawful Under the Federal Food, Drug, and Cosmetic Act (FDCA) and Reprocessors are Considered to be Manufacturers

Since at least 1998, the U.S. Food and Drug Administration ("FDA") has considered third-party "reprocessors of devices labeled for single-use to be [medical device] manufacturers."¹ "A

¹ Letter from Melinda K. Plaisier, Associate Commissioner for Legislation, FDA, to The Honorable Thomas J. Bliley, Jr. (November 29, 2000), at 2 [hereinafter Plaisier letter]. See also Letter from D. Bruce Burlington, M.D., Director, Center for Devices and Radiological Health (CDRH), FDA, to Nancy Singer, Special Counsel, Health Industry Manufacturers Association (HIMA, now AdvaMed) (July 15, 1998), stating "reprocessors are inspected in accordance with the current Quality System regulation [QSR], Title 21, Code of Federal Regulations (CFR), Part 820, and they are subject to the labeling requirements of 21 CFR part 801. . . . In fact, FDA has considered such reprocessing firms to be manufacturers under the GMP regulations [which preceded the QSR] . . ." (emphasis

manufacturer can market a device for one more single use from a raw material that was a previously-used, SUD if that device meets the specifications of the device described in the market clearance.”² A device that complies with all of the applicable requirements of the FDCA is not misbranded or adulterated, and may be marketed legally in the United States. Therefore, a reprocessed device that complies with all of the applicable requirements of the federal Food, Drug, and Cosmetic Act (“FDCA”) is lawful and may be marketed legally in the United States.³

B. The “Single Use” Label is Chosen at the Discretion of Device Manufacturers; It Is Not an FDA Requirement

The “single use” label is a designation chosen by medical device manufacturers, not FDA. In a report made public March 3, 2008, the U.S. Government Accountability Office (“GAO”) wrote:

The decision to label a device as single-use or reusable rests with the manufacturer. If a manufacturer intends to label a device as reusable, it must provide data demonstrating to FDA’s satisfaction that the device can be cleaned and sterilized without impairing its function. Thus, a device may be labeled as single-use because the manufacturer believes that it cannot be safely and reliably used more than once, or because the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable.⁴

Approximately two decades ago, original equipment manufacturers (“OEMs”) began to change the labels on certain medical devices from “reusable” to “single use.” This shift in labeling was not required by FDA. Indeed, the agency does not require any device to carry a single use label.⁵ As OEM documentation from this time-period demonstrates, it appears that, in some cases, device labeling was changed from “reusable” to “single use” without any significant design, performance or material changes to the devices that would preclude safe reuse.⁶

This change in labeling was perceived by many hospitals for what it was – i.e., a marketing strategy aimed at increasing sales of new products. It was clear that certain devices designated

added). *See also*, CDRH, FDA, [Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions \(510\(k\)s\) for Reprocessed Medical Devices](#) (Sept. 25, 2006), at 15. *See also*, [Guidance for Industry and for FDA Staff, Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals](#) (August 14, 2000), at 1 [hereinafter FDA Guidance of 2000].

² Plaisier letter, *supra* note 1, at 2.

³ *See* 21 U.S.C. §§ 351, 352, 360, and 360c-360e.

⁴ U.S. Government Accountability Office, GAO-08-147, [Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk](#) (January 2008), at 1 (emphasis added) [hereinafter 2008 GAO Report].

⁵ In contrast, to market a device as “reusable,” a manufacturer must invest the resources necessary to demonstrate to FDA that the product in question can be safely reprocessed. *See, e.g.*, [FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessors in Health Care Facilities](#) (April 1996).

⁶ *See* Letter from Brian Dowling, Product Manager, USCI Cardiology & Radiology Products (July 24, 1980) (explaining that, although USCI 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., Microvase Division (May 1, 1987), at 2 (informing a hospital that its “BICAP® Hemostatic Probes are recommended for single use only. However, this recommendation does not prohibit reuse under certain specific conditions. . .”).

by OEMs as “single use” could be safely reprocessed. Hospital skepticism of the single use label was noted in a 2000 GAO Report. 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.”⁷

In 2000, the GAO report also found that other manufacturers had “contributed to the sense that compliance with the single-use label is not always necessary.”⁸ The GAO identified a manufacturer of pulse oximeter sensors that sold hospitals what it called “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 primarily for marketing purposes.⁹

Today a number of “single use” device manufacturers offer their own recycling, recertification, or reprocessing programs,¹⁰ further evidence that “single use” is not a meaningful designation.

C. The Reprocessing of SUDs is Stringently Regulated by FDA

Pursuant to the FDCA, FDA requires reprocessors to comply with all device manufacturing requirements that apply to OEMs,¹¹ as well as some additional requirements that apply only to reprocessors.

Like all devices, a reprocessed device is subject to premarket review by FDA, unless the agency has, by regulation, declared the device to be exempt from premarket requirements. Unless exempt, the lower risk “Class I” and “Class II” devices, whether “original” or reprocessed, are required to have cleared premarket notification submissions (“510(k)s”).¹² With regard to

⁷ U.S. Government Accountability Office, GAO/HEHS-00-123, [Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted](#) (June 2000), at 11 [hereinafter 2000 GAO Report].

⁸ *Id.*

⁹ *Id.*

¹⁰ For example, the orthopedic 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...”).

¹¹ FDA Guidance of 2000, *supra* note 1, at 1.

¹² 21 U.S.C. § 360(k).

premarket review, reprocessors are subject to *more stringent* regulation by FDA than are OEMs¹³ because, pursuant to provisions added to the FDCA in 2002 by the Medical Device User Fee and Modernization Act (“MDUFMA”), FDA has withdrawn the exemptions from the premarket notification requirement for a significant number of previously exempt reprocessed devices, although the “original” devices remain exempt from premarket review.¹⁴

Further, reprocessors must, in many cases, include in their premarket submissions a whole category of data that OEMs are not required to submit.¹⁵ Specifically, reprocessors are, in many cases, required to include “validation data . . . regarding cleaning and sterilization, and functional performance” to show that the reprocessed device “will remain substantially equivalent . . . after the maximum number of times the device is reprocessed as intended.”¹⁶ By contrast, OEMs, who also must validate their processes, are not required to submit such data on a premarket basis.

In addition, like OEMs, reprocessors are subject to establishment registration and medical device listing;¹⁷ medical device reporting;¹⁸ medical device tracking;¹⁹ reports of corrections and removals,²⁰ the quality system regulation (“QSR”);²¹ and labeling requirements.²²

The reprocessing of medical devices originally labeled for “single use” is subject to a stringent, comprehensive regulatory scheme. In short, “FDA believes that reprocessed SUDs that meet FDA’s regulatory requirements are as safe and effective as a new device.”²³ The 2008 GAO report concurs with FDA’s assessment and further elaborates on FDA’s requirements for medical device reprocessors.²⁴

¹³ See [Testimony of Dr. Daniel Schultz, Director, CDRH, FDA \(September 26, 2006\)](#) (“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].

¹⁴ Title III of MDUFMA amended the FDCA ([Public Law 107-250](#)). The law required 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, 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 \(June 26, 2003\)](#).

¹⁵ 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. 21 U.S.C. § 360(o)(2)(B); see also [68 Fed. Reg. 38071 \(June 26, 2003\)](#).

¹⁶ [68 Fed. Reg. 23139 \(April 30, 2003\)](#), citing 21 U.S.C. § 360(o) (emphasis added). For a full description of the validation data reprocessors must submit on a premarket basis, including more particular guidance on cleaning, functional testing, and sterilization data requirements, see [Guidance for Industry and FDA Staff: Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions \(510\(k\)s\) for Reprocessed Medical Devices](#) (Sept. 25, 2006), at 15.

¹⁷ 21 U.S.C. § 360 and 21 C.F.R. Part 807, subpart B.

¹⁸ 21 U.S.C. § 360i(a) and 21 C.F.R. Part 803.

¹⁹ 21 U.S.C. § 360i(e) and 21 C.F.R. Part 821.

²⁰ 21 U.S.C. § 360i(f) and 21 C.F.R. Part 806.

²¹ 21 U.S.C. § 360j(f) and 21 C.F.R. Part 820.

²² 21 U.S.C. § 352 and 21 C.F.R. Part 801.

²³ [Schultz testimony](#), *supra* note 13 (“FDA believes that reprocessed SUDs that meet FDA’s regulatory requirements are as safe and effective as a new device”).

²⁴ [2008 GAO Report](#), *supra* note 4, 14-19.

D. All Evidence Indicates That SUDs Reprocessed in Accordance with FDA's Requirements Are Safe and Effective

The safety record for reprocessed SUDs is outstanding. To date, more than 50 million devices have been reprocessed in this country²⁵ without any evidence of increased risk to patients.²⁶

The 2008 GAO report concluded:

After reviewing the available evidence – including FDA's process for identifying and investigating device-related adverse events reported to involve reprocessed SUDs, peer-reviewed studies published since 2000, and the results of our and FDA's consultations with hospital representatives – 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.²⁷

i. FDA's Analysis of the Agency's Adverse Events Database Finds "No Causative Link Between a Reprocessed SUD and Reported Patient Injury or Death"²⁸

The 2008 GAO report found that of the over 320,000 adverse events filed with FDA between 2000 and 2006,²⁹ only 65 adverse events "actually involved or were suspected to involve a reprocessed SUD and that the reprocessed SUD was one of several possible causal factors in the adverse event. In reviewing these 65 reports, FDA found that the types of adverse events reported to be associated with the use of reprocessed SUDs were the same types of events that were reported for new devices."³⁰

ii. FDA's Medical Product Safety Network Program Illustrates Hospital Support for the Safety of Reprocessing

Another source of information about the safety and efficacy of reprocessed SUDs is the opinions of clinicians who have used reprocessed SUDs. Specifically, the 2008 GAO report noted the findings of FDA's Medical Product Safety Network (MedSun) Program and confirmed that "none of the representatives of MedSun hospitals who participated in the FDA focus groups reported being aware of any infections related to the use of reprocessed SUDs."³¹ Of particular importance, "none of the hospital representatives expressed significant concerns about potential malfunctions with reprocessed SUDs..."³² GAO found that "participating hospital representatives generally expressed confidence in reprocessed SUDs, with some participants

²⁵ AMDR (2008).

²⁶ [2008 GAO Report](#), *supra* note 4.

²⁷ *Id.*, at 21-22 (emphasis added).

²⁸ *Id.*, at 20.

²⁹ *Id.* at 19.

³⁰ *Id.*, at 21.

³¹ *Id.* (emphasis added).

³² *Id.*

stating that there were actually fewer performance problems with reprocessed SUDs than with new SUDs.”³³

“According to FDA, all participants believed that reprocessing establishments are more stringently regulated by FDA than are the manufacturers of original devices, and this provided them a sense of confidence in the reprocessing process.”³⁴

iii. The Independent, Peer-Reviewed Literature Supports the Safety of Reprocessing

A significant body of medical literature from peer-reviewed journals supports the conclusion that some SUDs can be safely reprocessed.³⁵ As the GAO observed in 2000, when it evaluated the

³³ *Id.*

³⁴ *Id.*

³⁵ An exhaustive bibliography may be found on AMDR’s website at <http://www.amdr.org/bib.html>. Journal articles include the following: Von Eiff, Wilfried, M.D., [Report Confirms: Reprocessing Single-Use Devices Decreases Costs](#), [Medical Data Institute](#), March 2011; Metcalf, Carole L. BS, RN, CNOR, CRNFA, [Medical Device Reprocessing: A New Way to Go Green](#), [OR Nurse](#), March 2011, Vol. 5, Issue 2, pp. 43-46; Kwakye, Gifty; Brat, Gabriel A.; Makary, Martin A., [Green Surgical Practices for Health Care](#), [Archives of Surgery](#), February 2011, Vol 146, pp.131-6; Tessarolo, Francesco; Caola, Iole; Nollo, Giandomenico, [Critical Issues in Reprocessing Single-Use Medical Devices for Interventional Cardiology](#), [Biomedical Engineering, Trends, Research and Technologies](#), January 2011, pp. 619-644; Kwakye, G. MPH, Pronovost, P J. MD, PhD and Makary, M. A. MD, MPH, Johns Hopkins University, [A Call to Go Green in Health Care by Reprocessing Medical Equipment](#), [Academic Medicine](#); The Journal of the Association of American Medical Colleges, March 2010, Vol. 85, No. 3, 398-400; Sloan, T., [First, Do No Harm? A Framework for Evaluating New Versus Reprocessed Medical Devices](#), [Journal of the Operational Research Society](#), 2010, Vol. 61, 191-201; Lester, Bruce R., Boser, Nicole P., Miller, Keith, Schnapf, Mark, Jacques, Beth A., Sullivan, Brian F., and Marchin, George L., [Reprocessing and Sterilization of Single-Use Electrophysiological Catheters: Removal of Organic Carbon and Protein Surface Residues](#), [Journal of AOAC International](#); A Peer-Reviewed Journal Publishing Basic and Applied Research in the Analytical Sciences Related to Foods, Drugs, Agriculture, and the Environment, 2009, Vol. 92, No. 4, pp. 1165-73; Bank, Alan J., Berry, James M., Wilson, Robert F., and Lester, Bruce R., [Acceptance Criteria for Reprocessed Acunav Catheters: Comparison Between Functionality Testing and Clinical Image Assessment](#), [Ultrasound in Medicine and Biology](#), Official Journal of the World Federation for Ultrasound in Medicine and Biology, March 2009, Vol. 35, No. 3, pp. 507-514; Kramer, Axel, Assadian, Ojan, Jaekel, Christian and Kraft, Marc, [The Safe Processing of Medical Devices in the Interests of Patient Protection](#), [GMS Krankenhaushygiene Interdisziplinaer](#); [Deutsche Gesellschaft fuer Krankenhaushygiene](#), September 3, 2008, Vol. 3(3), Doc 27; ISSN 186-5245; Kramer, Axel and Assadian, Ojan, [Ethical and Hygiene Aspects of the Reprocessing of Medical Devices in Germany](#), [GMS Krankenhaushygiene Interdisziplinaer](#); [Deutsche Gesellschaft fuer Krankenhaushygiene](#), September 3, 2008, Vol. 3(3), Doc 25; ISSN 186-5245; Grosskopf, Volker and Jaekel, Christian, [Legal Framework Conditions for the Reprocessing of Medical Devices](#), [GMS Krankenhaushygiene Interdisziplinaer](#); [Deutsche Gesellschaft fuer Krankenhaushygiene](#), September 3, 2008, Vol. 3(3), Doc 24; ISSN 186-5245; Kraft, Marc, [Framework Conditions and Requirements to Ensure the Technical Functional Safety of Reprocessed Medical Devices](#), [GMS Krankenhaushygiene Interdisziplinaer](#); [Deutsche Gesellschaft fuer Krankenhaushygiene](#), September 3, 2008, Vol. 3(3), Doc 23; ISSN 186-5245; Klosz, Kerstin, [Quality Management for the Processing of Medical Devices](#), [GMS Krankenhaushygiene Interdisziplinaer](#); [Deutsche Gesellschaft fuer Krankenhaushygiene](#), September 3, 2008, Vol. 3(3), Doc 22; ISSN 186-5245; Krueger, Colin M., [Processing Single-Use Medical Devices for Use in Surgery – Importance, Status Quo and Potential](#), [GMS Krankenhaushygiene Interdisziplinaer](#); [Deutsche Gesellschaft fuer Krankenhaushygiene](#), September 3, 2008, Vol. 3(3), Doc 21; ISSN 186-5245; Gaertner, D., Muenz, K., Hueckelheim, E., and Hesse, U., [Ultrasound Scissors: New Single-Use Instruments vs. Resterilized Single-Use Instruments – A Prospective Randomised Study](#), [GMS Krankenhaushygiene Interdisziplinaer](#); [Deutsche Gesellschaft fuer Krankenhaushygiene](#), September 3, 2008, Vol. 3(3), Doc 20; ISSN 186-5245; Vom Woedtke, Thomas and Kramer, Axel, [The Limits of Sterility Assurance](#), [GMS Krankenhaushygiene](#)

safety of reprocessed SUDs, the safety of reprocessing some types of devices has been established by well-developed clinical studies. Studies have shown both that reprocessing procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of reprocessed [“single use” devices].³⁶

Interdisziplinär; *Deutsche Gesellschaft fuer Krankenhaushygiene*, September 3, 200, Vol. 3(3), Doc 19; ISSN 186-5245; Sung, Jinsil K., Levin, MD, Rafael, Siegel, MD, Jodi, Einhorn, MD, Thomas A., Creevy, MD, William R., and Tornetta, MD, Paul., [Reuse of External Fixation Components: A Randomized Trial](#), **Journal of Orthopedic Trauma**, February 2008, Vol. 22, No. 2, pp. 126-131; Horwitz, Daniel S. MD, Schabel, Kathryn L.S. MD, Higgins, Thomas F. 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Kusumoto, “Trends and Patterns in Electrophysiologic and Ablation Catheter Reuse in the United States,” 87 **The American Journal of Cardiology** 351 (February 1, 2001).

³⁶ [2000 GAO Report](#), *supra* note 7, at 13.

iv. **For Nearly a Decade, the Clinical Community Has Expressed Strong Support for the Safety and FDA Regulation of Reprocessed SUDs**

Because of reprocessing's exemplary record of safety, informed healthcare facilities and physicians support the practice of reprocessing. AMDR's members serve America's finest medical facilities, including 16 of the 17 ranked by *U.S. News & World Report* as the nation's "Honor Roll" hospitals.³⁷ Indeed, many of the most preeminent physicians in the country have publicly supported reprocessed devices as being safe and effective.³⁸

E. Reprocessed Devices Are Less Costly Than Original Devices and Have Substantial Environmental Benefits

i. **Cost-Savings**

Healthcare providers support the practice of reprocessing in large part because of the cost savings. Reprocessed devices are as safe and effective as original devices but much less costly - typically about half of the cost of an original device.³⁹ In 2000, the GAO found that facilities using reprocessed devices saved between \$200,000 to \$1 million annually, on average.⁴⁰ The savings enable hospitals to hire additional nurses, upgrade technology, take care of indigent persons, and make other patient care improvements.

³⁷ See <http://health.usnews.com/sections/health/best-hospitals>; AMDR (2012).

³⁸ See e.g., Dr. Stephen Hammill, Director of Electrocardiography and Electrophysiology Laboratories at the **Mayo Clinic** ("For more than 20 years, the catheters used in electrophysiology procedures have been reprocessed at Mayo and have continued to function normally without any evidence of infection. Reprocessing the catheters has allowed us to use each catheter five or six times, greatly decreasing the cost of the procedures . . . Reprocessing of the catheters has proven to be a safe and effective technique and has allowed us to gain the most use from the catheters, making them as cost efficient as possible."); Letter from Stephen C. Hammill, M.D., Professor of Medicine and Director of Electrocardiography and Electrophysiology Laboratories, Mayo Clinic, Rochester, Minnesota to Senator Paul Wellstone (June 23, 1999); See also, Testimony of Dr. John Clough, representing the **American Hospital Association (AHA)** before the Senate Committee on Health, Education, Labor and Pensions (June 27, 2000) ("[m]any medical products can be safely reused as evidenced through decades of hospital experience in reprocessing both reusable devices and those labeled 'for single use.' The AHA is unaware of any evidence to demonstrate a problem with reprocessing devices labeled 'for single use.'"); Testimony of John Clough, M.D., Chair of Health Affairs, **Cleveland Clinic Foundation**, Cleveland, Ohio, on behalf of the American Hospital Association before the Senate Committee on Health, Education, Labor and Pensions 3-4 (June 27, 2000); see also **Association for Professionals in Infection Control and Epidemiology (APIC)**, *Reprocessing of Single Use Medical Devices*, [Position Statement](#) (August 31, 2007); **Association for Healthcare Resource and Materials Management**, [Position Statement](#); **American College of Cardiology**, [Position Statement](#) (2000); **American Medical Association**, [Report 3 of the Council on Scientific Affairs: Reprocessing of Single Use Medical Devices](#) (2000); **American Nursing Association**, 2010 House of Delegates, [Resolution, Safety and Effectiveness of Reprocessed Single Use Devices in Healthcare](#) (2010); **Association of Peri-Operative Registered Nurses**, [Position Statement: Environmental Responsibility](#) (March 2006); **Hospitals for a Healthy Environment**, [Regulated Medical Waste](#); **North American Society for Pacing and Electrophysiology (NASPE)** (now Heart Rhythm), [Letter](#) to Senator Richard Durbin, (June 22, 1999); **American Association of Orthopaedic Surgeons (AAOS)**, (August 30, 2001).

For links to other statements of support, see AMDR's Web site at www.amdr.org.

³⁹ [2000 GAO Report](#), *supra* note 7, at 19.

⁴⁰ *Id.*

In addition, use of reprocessed devices reduces a facility's waste disposal costs (see subsection ii below) and creates price competition that has been shown to decrease the price of new devices. As the GAO explained, the "overall prices of some [SUDs] that are reprocessed appear to have decreased in recent years, even for healthcare institutions that do not reuse them."⁴¹

ii. Environmental Waste Reduction

Hospitals realize savings from reprocessing because their waste disposal costs are significantly reduced. In previous years, members of the Association of Medical Device Reprocessors (AMDR) diverted more than 2,000 tons of waste from landfills.⁴² One third party reprocessor claims to have eliminated more than 10,000 tons of medical waste from local landfills in the last decade.⁴³

Reprocessing is a critical tool for the nation's hospitals seeking to achieve the objectives of the Hospitals for a Healthy Environment (H2E) national movement. Jointly formed by the American Hospital Association, the U.S. Environmental Protection Agency, Healthcare Without Harm, and the American Nurses Association, H2E has made a national goal of reducing the quantity and toxicity of healthcare waste -- from manufacturing, purchase and use of products and materials to improved end-of-life management.⁴⁴ Reprocessing is listed as a best practice for its environmental benefits by organizations such as AORN⁴⁵ and as a top green purchasing practice by GHSE, an evolution of H2E dedicated to encouraging reuse, recycling and green purchasing practices in healthcare facilities across the country.

Conclusion

Third-party medical device reprocessing is legal, stringently-regulated, and results in safe and effective devices at about half the cost of original equipment. Reprocessing helps reduce medical waste and stimulates price competition. The safety record of medical device reprocessing is excellent, as noted by FDA and GAO, and the practice has enjoyed wide clinical acceptance for over a decade.

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⁴¹

Id.

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AMDR (2008).

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See [Ascent Healthcare Solutions Inc.](#),

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See [Hospitals for a Healthy Environment](#).

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Association of Peri-Operative Registered Nurses (AORN), *supra* note 38, [Position Statement: Environmental Responsibility](#) (March 2006).