



The Economic Impact of Reprocessing External Fixation Components¹

Response from AMDR

The Association of Medical Device Reprocessors (AMDR) applauds *The Journal of Bone and Joint Surgery (JBJS)* for publishing physician-initiated research concerning reprocessing of so-called “single use” devices. The *JBJS* article confirms existing data demonstrating the safety and efficacy of reprocessed external fixation (*ex fix*) components. For nearly ten years, AMDR’s members have been providing safe, effective, and Food and Drug Administration (FDA)-regulated reprocessed *ex fix* components to the nation’s best hospitals. *Ex fix* components, often made of titanium, steel and carbon fiber, are some of the most durable “single use” medical devices manufactured today. The reprocessing of these devices is not only safe, but also saves hospitals desperately needed financial resources, and reduces the amount of medical waste generated by our health care system.

As further evidenced by this article, reprocessing of these “single use” devices is practiced by the very companies that have also claimed that the reuse of these devices is unsafe.² In the interest of providing an accurate portrayal of regulated reprocessing, below AMDR provides a detailed analysis of some of the issues addressed in the article.

Above all else, *JBJS*’s article on reprocessed *ex fix* components confirms three basic facts:

1. “Single use” does not always mean single use:

The authors confirm yet another example of an original equipment manufacturer (OEM) reprocessing its own “single use” devices for subsequent use on other patients.³

2. Reprocessing of “single use” devices is fully regulated by FDA:

¹ “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 [*hereinafter*, *JBJS* article].

² See, e.g. “Self-Contradiction; The Reuse of Single-Use Devices; Is it Worth the Risk?” Stryker Instruments, 4100 East Milham Ave., Kalamazoo, MI 49001. Copyright 2005 Stryker. See also, “Important Message to Our Customers Regarding Refurbished Arthroscopic Blades,” letter from Carlos Gonzales, Vice President of Regulatory Affairs and Quality Assurance, Stryker Endoscopy, undated.

³ *JBJS* article, at 2133, *Materials and Methods*, “Stryker Orthopaedics applied for, and was granted, United States Food and Drug Administration (FDA) 510(k) approval of this recertification process.” AMDR responsive note: either the authors, and/or the OEM (Stryker) use the “recertification” nomenclature. Stryker does not define “recertification.” However, it appears, “reprocess” and “recertify” basically mean the reuse of a device labeled by the OEM as for “single use.” As another example of OEM reprocessing of *ex fix* components, 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.

As the authors indicate, FDA regulation means legitimization. The authors give tremendous deference to the manufacturer, Stryker, for its “FDA-approved program for recertification of external fixation components.”⁴ To be clear, all reproprocessors of “single use” medical devices are fully regulated by FDA as manufacturers.⁵ Reprocessors (OEM or third-party), like all manufacturers, are required to comply with FDA’s premarket notification procedures,^{6,7} the data of which demonstrates that reprocessed devices are “substantially equivalent to the predicate (OEM) device” and therefore “as safe and effective as a legally marketed device.”⁸ In some regards, reproprocessors are more stringently regulated than even the OEMs.⁹

3. Proper, regulated reprocessing is safe:

This peer-reviewed article demonstrates that *ex fix* components labeled by the OEM for “single use” can indeed be reused safely and effectively, if appropriate processes are put in place, subject to FDA’s regulatory requirements.¹⁰ Third-party reproprocessors have been

⁴ JBJS article, at 2134, *Discussion*, “We believe that we are the first to examine an FDA-approved program for recertification of external fixation components by the original manufacturer...”

⁵ 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].

⁶ 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.

⁷ AMDR has not been able to locate or confirm in FDA’s publicly accessible databases any clearances for any reprocessed devices by Stryker. Stryker does have multiple clearances for its own, original (non-reprocessed) devices. However, Stryker appears to lack the necessary agency clearance for lawful marketing of reprocessed *ex fix* devices (see further discussion below, *infra* page 5).

⁸ 21 CFR 807.100, FDA Action on a premarket notification (emphasis added). “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 as effective as a legally marketed device.” Also, *infra*, Schultz testimony, note 9, “FDA believes that reprocessed SUDs that meet FDA’s regulatory requirements are as safe and effective as a new device.”

⁹ *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 reproprocessors 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]. 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 reproprocessor’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, reproprocessors 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, reproprocessors 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).

¹⁰ JBJS article, at 2134, noting “during this study, there were no cases of mechanical failure of external fixation components after implementation of the reuse/recertification program.” The authors also note at 2134, two previous studies on the reuse of external fixators which resulted in “no increase in the complication rate,” and “no difference in complication rates between prospectively followed groups of patients who had been randomized to receive either a new or a reused nonimplantable external fixation system.” Further, the authors noted that “both studies showed that reuse of external fixation components was safe and efficacious even with limited evaluation and

safely reprocessing for a decade, and have been providing their manufacturing data to FDA since 2000 (if not earlier).¹¹ Many years of clinical use also confirm the safety and efficacy of reprocessing many other devices labeled by the OEM as for “single use” use.¹²

Further Discussion

The “Single use” label:

A very important issue the authors neglected to address was OEM use of the “single use” label. It is important for readers to know that device manufacturers, not FDA, choose the “single use” label.

Approximately two decades ago, 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.¹³ Rather, this is a designation chosen by the manufacturer. As OEM documentation from this time-period demonstrates, it

no mechanical testing of the components,” citing Dirschl DR, Smith IJ. Reuse of external skeletal fixators components: effects on costs and complications. *J Trauma*. 1998; 44:855-8; and Tornetta P III, Einhorn TA, Creevy WR, Levin R, Siegel J, Sung J. Reuse of external fixation components: a prospective randomized trial [abstract]. In: Proceedings of the 21st Annual Meeting of the Orthopaedic Trauma Association: 2005, October 20-22. Ottawa: Orthopaedic Trauma Association; 2005.

¹¹ FDA Guidance, *supra*, note 5.

¹² 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: Hygienic, 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 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).

¹³ 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., Center for Devices and Radiological Health (CDRH), Food and Drug Administration (FDA), *FDA Reviewer Guidance: Labeling Reusable Medical Devices for Reprocessors in Health Care Facilities* (April 1996).

appears that, in some cases, device labeling changed from “reusable” to “single use” without any significant design, performance or material changes to the devices that would preclude safe reuse:

- In a 1980 letter to a hospital-customer, USCI Cardiology & Radiology Products explained 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.”¹⁴
- In a 1987 letter, Boston Scientific Corporation’s Microvasive division informed a hospital that its “BICAP® Hemostatic Probes are recommended for single use only. However, this recommendation does not prohibit reuse under certain specific conditions. . . .”¹⁵

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. Hospital skepticism of the single use label was noted in a 2000 General Accounting Office (GAO) report entitled, “Single-Use Medical Devices: Little Available Evidence of Harm From Reuse, but Oversight Warranted.” According to the report, health care 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.”¹⁶

As with Stryker’s “recertified” *ex fix* components, the GAO report found, nearly eight years ago, that other manufacturers had also “contributed to the sense that compliance with the single-use label is not always necessary.”¹⁷ In 2000, 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 health care professionals that the single use label was not truly meaningful.¹⁸

FDA Regulation:

While the authors have given deference to the manufacturer, Stryker, for its “FDA-approved program for recertification of external fixation components,”¹⁹ the authors have overstated

¹⁴ See Letter from Brian Dowling, Product Manager, USCI Cardiology & Radiology Products (July 24, 1980).

¹⁵ See Letter from Geoffrey M. Allen, Boston Scientific Corp., Microvasive Division 2 (May 1, 1987).

¹⁶ 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).

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Supra*, notes 3 and 4.

FDA's regulatory role with regard to OEM-reprocessed devices,²⁰ and misstated the current regulatory status of third-party reprocessors.²¹

Overstatement of FDA's Role in Regulating OEM Reprocessed Devices

First, FDA does not "approve" the reprocessing of external fixation components. FDA has generally classified *ex fix* components as class II medical devices, subject to the agency's premarket control powers.²² FDA would "clear" a company, via the premarket notification system, to lawfully market a device, pursuant to these procedures.²³ It is also important to note that FDA does not, as a part of its premarket controls, approve or clear any "process," but instead clears a "device."²⁴ FDA, as part of the Quality System Regulation (QSR), generally evaluates processes, and all reprocessors are required to comply with FDA's QSR requirements (both OEM and third-party).²⁵

Therefore, Stryker does not have "FDA approval" for its recertified devices or the recertification program, contrary to the authors' assertion. Further, according to FDA's regulations, "any representation that creates an impression of official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding."²⁶ AMDR recommends *JBJS* investigate whether the authors, or Stryker, originally made claims of Stryker having an "FDA-approved recertification process"²⁷ for these *ex fix* components. If Stryker representatives made claims to having an "FDA-approved recertification process," AMDR urges that this be brought to FDA's attention for appropriate adjudication.

Second, as noted above,²⁸ it does not even appear that Stryker has obtained the necessary clearance to market reprocessed or recertified *ex fix* devices, in violation of FDA's regulations. AMDR has not been able to locate or confirm in FDA's publicly accessible databases any clearances for any reprocessed devices by Stryker.²⁹ Without actual clearance from FDA for recertified *ex fix* devices, Stryker's reprocessed devices may be misbranded under FDA's regulations.³⁰ The introduction into interstate commerce of misbranded devices is prohibited by

²⁰ *JBJS* article, at 2133, *Materials and Methods*, and 2134 *Discussion*, referencing Stryker's "FDA-approved process" (emphasis added) and "a third advantage to a manufacturer-based reuse program is its FDA-approved status. The benefit of FDA involvement in reuse programs is the added patient protection..."

²¹ *JBJS* article, at 2134 *Discussion*; See also 2135, *Discussion*, suggesting FDA has only "proposed a regulatory strategy that will subject reprocessors of single-use devices to the same requirements as imposed on manufacturing companies." (emphasis added). Indeed, this has been the case since 2000. Further, since 2002, FDA's regulatory requirements for reprocessors **exceed** even the regulatory requirements of the OEMs, *supra*, note 9. See, *infra*, notes 32-36.

²² Commonly referred to as a "510(k)." 21 C.F.R. Part 807, Subpart E. Premarket Notification Procedures, When a Premarket Notification Submission is Required.

²³ *Id.*

²⁴ *Id.*

²⁵ 21 C.F.R. Part 820.

²⁶ 21 C.F.R. § 807.97, Misbranding by reference to premarket notification [*hereinafter*, FDA Misbranding regulations].

²⁷ *Supra* note 4.

²⁸ *Supra* note 7.

²⁹ *Id.*

³⁰ FDA Misbranding regulations, *supra* note 26.

U.S. law and may be subject to injunction, civil and/or criminal penalties, and seizure.³¹ AMDR intends to bring to FDA's attention this possible violation(s) of the regulations.

Misstatement of FDA's Role in Regulating Third-Party Reprocessors

Contrary to statements made in the article, all third-party medical device reprocessors are fully regulated by FDA as manufacturers, and have been since at least 2002.³² Medical device reprocessors must, like all device manufacturers, comply with all of the applicable requirements of the Food, Drug, and Cosmetic Act (FDCA).³³ Reprocessors, like all manufacturers, are required to comply with FDA's premarket notification procedures,³⁴ the data of which demonstrates that reprocessed devices are "as safe and effective as a legally marketed device."³⁵ In some regards, reprocessors are more stringently regulated than even the OEMs.³⁶

Third-party Reprocessor Access to OEM Data:

The authors state that third-party reprocessing companies "do not have access to the original inspection and testing parameters used by the manufacturer."³⁷ At the least, this further insinuates that a lack of third-party access to OEM technical specifications makes third-party reprocessed devices less than equivalent products, as compared to OEM-reprocessed equipment.

It would be important for readers to know a number of facts the authors omitted, so that they can make an informed decision about third-party reprocessing. Specifically, the authors failed to note the available and respected sources by which third-party reprocessors do indeed obtain such data (through reverse-engineering and from publicly available data), and demonstrate to FDA that third-party reprocessed *ex fix* components are as safe and as effective as original equipment (by conforming to existing, internationally recognized standards).

As part of the reverse-engineering of a product that takes place to validate reprocessing methods, prior to obtaining FDA clearance to market such product, external fixators are sent through a battery of tests to ascertain specifications and set parameters as to functionality. Third-party reprocessors rely on guidance provided by FDA, entitled, "Reviewer's Guidance Checklist for

³¹ 21 U.S.C. §301, et. seq.

³² FDA Guidance, *supra* note 5.

³³ 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.

³⁴ *See, supra* note 6.

³⁵ *See, supra* note 8.

³⁶ *See, Schultz* testimony, *supra* note 9.

³⁷ JBJS article, at 2132, citing Sikka RS, footnote 4 of the article. *See also* 2134, *Discussion*, "An independent company offering recertification has no access to the original equipment manufacturing specifications for mechanical integrity of the recertified components."

Orthopedic External Fixation Devices.”³⁸ To establish testing methods, endpoints, and specifications for *ex fix* components, third-party reproducers rely on standards published by the American Society for Testing and Materials (ASTM), including historical standard F1541-01 (ASTM F1541-01), “Standard Specification and Test Methods for External Skeletal Fixation Devices.”³⁹ ASTM International “is one of the largest voluntary standards development organizations in the world—a trusted source for technical standards for materials, products, systems, and services.”⁴⁰

Reprocessors also perform patent searches on the devices for which the reprocessor is seeking clearance, further providing data to engineers as to the device, how it is used, how it functions – specifications provided to the patent office by the original equipment manufacturer.

Ex fix components must endure a rigid, validated, quality control system before they can be released after cleaning. All *ex fix* components are sent through a battery of tests to ensure conformance to specifications and functionality, including mechanical testing in accordance with ASTM F1541-01. These tests also include visual inspections, function testing,⁴¹ inspection under magnification,⁴² static testing,⁴³ and dynamic testing.⁴⁴ The reader should know that all of these tests not only conform to accepted standards, but must also be reviewed and cleared by FDA, prior to the lawful marketing of any third-party reprocessed *ex fix* component.

³⁸ U.S. Food and Drug Administration, “Reviewers Guidance Checklist for Orthopedic External Fixation Devices,” <http://www.fda.gov/cdrh/ode/829.pdf>.

³⁹ ASTM International, F1541-01 “Standard Specification and Test Methods for External Skeletal Fixation Devices.”

⁴⁰ ASTM International, <http://www.astm.org/cgi-bin/SoftCart.exe/ABOUT/aboutASTM.html?L+mystore+mbqj3322+1197068199> (December 07, 2007).

⁴¹ Reprocessors employ a battery of proprietary methods to clean, test, inspect and sterilize their equipment. All quality inspection processes include a test for appropriate function. All springs, threaded parts, inter-locking knurls, washers and spacers, swivels, ball and socket joints, clamps, rings, rods and tubes are inspected according to predetermined methods. Any component is rejected if it does not meet functional acceptance criteria. Again, all processes are verified in accordance with the ASTM F1541-01 standard. Additionally, MR-safe components are exposed to a powerful magnet to ensure that the product does not contain any ferrous materials that would respond to the magnetic field of the MRI machine. Any/all “MR-safe” *ex-fix* components that respond to the magnetic field are rejected and not returned to the hospital customer.

⁴² Using a microscope, each component is thoroughly inspected for wear, mangled threads, corrosion, rusting, and debris. If devices fail to meet preset performance and visual specifications, they are rejected and not sent back to the hospital customer.

⁴³ Static testing is completed during the validation stages of reprocessing development, in which failure loads are determined under different force loadings, such as axial, shear, torsion and bending. The static results are then used to determine an ultimate loading profile appropriate for dynamic testing. All devices are reprocessed through their respective max cycles prior to testing. See ASTM F1541-01.

⁴⁴ Dynamic testing is completed with regard to external fixation connectors, rods and pin attachments. These attachments on the fixator need to be evaluated after reprocessing to effectively ensure continued structural rigidity, so that these devices do not loosen during clinical reuse. Dynamic axial or cyclic loading is conducted to evaluate if any of the interconnections loosen over time and to determine the strength and stiffness of external fixation subassemblies after reprocessing. The test consists of a fully reversed-tension and compression loading profile, where the samples are subjected to both tensile and compression forces for a predetermined number of cycles or until a failure is achieved. ASTM F1541, Annex A4 “*Test Method for External Skeletal Fixator Subassemblies*” specifies a runout cycle limit of 50,000 cycles, though third-party reproducers exceed these cycle limits.

Correction; Current Regulatory Status of Reprocessed Carbon-Fiber Components:

The authors inaccurately stated that, “to date, no companies have considered recertification of carbon-fiber components.”⁴⁵

In fact, as of December 2007, the following companies have FDA clearances for reprocessed external fixation devices, including carbon-fiber components, in the FDA database: Alliance K012623 (June 02), K032058 (July 03), K012648 (June 02); SterilMed K051957 (Feb 05); Vanguard K051180 (Feb 05) and K031687 (April 04); and Synthes K043039 (Jan 05).⁴⁶

Conclusion:

AMDR applauds the authors of this study for further debunking the myth that all medical devices labeled by the manufacturer for “single use” are truly for single use only. And, in the interest of providing accurate information about the third-party reprocessing industry, we have provided this detailed response to the article. We hope it has provided useful information as to the true regulatory status of all reprocessed “single use” devices in the U.S. today and as to the safety of the practice.

Health care providers in the U.S. have a responsibility to deliver safe and effective medical care, and at the same time attempt to control spiraling health care costs. Third-party reprocessors in the U.S. are the only segment of the device industry actually reducing the costs associated with medical devices, reducing medical waste, and still providing the highest quality of medical care possible. While reprocessing is not the single solution to solving all health care cost-containment problems, it is a critical tool to a majority of the nation’s hospitals.

For too long, OEMs have fought reprocessing as a threat to their bottom line. It is our hope that Stryker’s move to join the reprocessing industry is a signal that Stryker intends to become part of the overall health care solution, instead of remaining part of the problem.

⁴⁵ JBJS article, at 2133.

⁴⁶ FDA’s 510(k) database: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm>.