Contrary to EMDT’s recent editorial, many “single-use” medical devices are suitable for reprocessing:

The Association of Medical Device Reprocessors (AMDR), the trade association representing third-party reprocessors in the United States, takes strong issue with Norbert Sparrow’s recent editorial disparaging the reprocessing of “single-use” device (SUDs). Specifically, we find it quite troubling that the Editor of EMDT conveniently left out so many truths on the subject of SUD reprocessing.

Basing all of his conclusions on a white paper from EucoMed (the trade group representing the European medical device manufacturers), Mr. Sparrow neglected to check his facts:

Fact: Unlike Europe, in the United States, the Food and Drug Administration (FDA) regulates the reprocessing of so called “single-use” medical devices and has determined that “reprocessed SUDs that meet FDA’s regulatory requirements are as safe and effective as a new device.”

Fact: The “single-use” label is a designation chosen by the medical device manufacturer, not by FDA. In fact, some manufacturers simply shifted the labels on certain devices from “reusable” to “single-use,” or provided cleaning instructions to hospitals so they could reuse SUDs and some manufacturers have even marketed “remanufactured” or “recycled” “single-use” devices to hospitals -- all behavior that has eroded the credibility of the single-use label.

Fact: EucoMed, the trade association representing medical devices manufacturers in Europe, has a vested financial interest in making sure devices are not reprocessed, thereby forcing hospitals to buy more “single-use” devices. By failing to consider the science on both sides of reprocessing, EucoMed’s white paper on the subject blatantly furthers this economic agenda.

Fact: In the U.S. where SUD reprocessing is regulated (and contrary to EucoMed’s assertions), independent sources have noted the absence of any evidence, from any source, indicating an increased risk to patients from the reprocessing of SUDs. FDA and the Government Accountability Office (GAO), an independent arm of the U.S. Congress, have found “no causative link between reported injuries or deaths and reprocessed SUDs;” “[n]one of the experts… cited the use of reprocessed single-use devices as a factor contributing to [hospital acquired infections];” and “studies have shown both that reprocessed procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of SUDs.”

These facts are indeed inconvenient for those, such as EucoMed’s members, who stand to gain economically from preventing the adoption of third-party reprocessing. AMDR is confident that, after evaluating all the facts and evidence, the EU Scientific Committee working group studying the reprocessing of SUDs will conclude that the practice - when appropriately regulated - is safe, effective, lowers healthcare costs and reduces medical waste.
References:

**Association of Medical Device Reprocessors (AMDR)**, 2010. AMDR is a non-profit trade association representing the U.S. third-party medical device reprocessing industry. AMDR’s members perform approximately 95 percent of the third-party reprocessing conducted in the U.S. today. Its member-companies are in the business of providing FDA-regulated medical device reprocessing services (cleaning, remanufacturing, testing, and sterilizing, among other things) to a majority of the nation’s hospitals. AMDR’s members reprocess for 95 percent of the Honor Roll hospitals (“the best of the best – the 0.4 percent of all hospitals with high scores in 6 or more specialties”), as listed by *U.S. News & World Report* for 2009-2010. Additionally, AMDR's members reprocess for 95 percent of those hospitals listed as the top 25 for *Heart and Heart Surgery* and 92 percent of the nation's 25 Best Hospitals for Orthopedics.

Testimony of Dr. Daniel Schultz, Director, Center for Devices and Radiological Health, U.S. Food and Drug Administration (FDA), before the U.S. House Committee on Government Reform (September 26, 2006).


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.”

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

Medical Design Technology, “OEM Moves into Reprocessing,” (March 1, 2006). 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.”


The Journal of Bone and Joint Surgery, Inc., The Economic Impact of Reprocessing External Fixation Components, 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…”


For a more detailed discussion of FDA’s requirements for medical device reprocessors, the “single-use” label, and the safety record of reprocessed devices, see AMDR’s Best Clinical Practice Background paper.