AMDR Response to ArthroCare's
"Questions Surrounding the Use of Reprocessed Coblation® Wands"

The Association of Medical Device Reprocessors (AMDR) is a trade association representing the FDA-regulated, third-party medical device reprocessing industry. AMDR members reprocess for a majority of U.S. hospitals including 14 out of 17 of the nation's "Honor Roll" hospitals as listed by *U.S. News & World Report*[1] and 95 percent of German University medical centers. AMDR members reprocess and remanufacturer, or clean, disinfect, test/inspect, repair, sterilize and return certain "single-use" medical devices, in order to help hospitals cut costs and waste, while maintaining patient safety. On behalf of its members, AMDR is providing this response to a sales brochure distributed by ArthroCare, Inc. AMDR believes that it is imperative for clinicians and other healthcare stakeholders to have complete, accurate, and unbiased information when making healthcare decisions. This belief requires AMDR to respond to attacks made by competitors, which rely on baseless, inaccurate, and/or out-of-context information with regard to the safety of reprocessed and remanufactured "single-use" devices (SUDs).

In its sales brochure entitled "Questions Surrounding the Use of Reprocessed Coblation® Wands," ArthroCare purports to "explain some of the issues a healthcare facility should consider before using a reprocessed Wand." It is AMDR's position that ArthroCare's brochure mischaracterizes the evidence supporting the safety of single-use device reprocessing, particularly as it disregards the regulatory requirements of the Food and Drug Administration (FDA), the objective and accepted standard for device safety by which all others in this country rely. The Agency's substantial equivalence requirements (510(k) process) as applied to medical device manufacturers—including reprocessors—is used to substantiate the supporting evidence demonstrating that a given device is "at least as safe and as effective as the legally marketed [predicate] device." [2]

As background to our rebuttal, it should be noted that ArthroCare fails to acknowledge that choosing to label a device "single use" is entirely in the hands of the original equipment manufacturer (OEM) and that a "single use" label does not necessarily indicate that a device cannot be reprocessed.[3] In fact, OEMs are not even required to validate their "single use" designation with FDA, leading many

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[1] *See*, AMDR blog, *Reprocessing Industry Overwhelmingly Supported by U.S. News & World Report's 2014-2015 "Honor Roll" Hospitals* (Aug. 29, 2014).

[2] 21 C.F.R. 807.100(b)(2)(ii)(B) ("The data submitted establishes that the device is substantially equivalent to predicate device and contains information, including clinical data if deemed necessary by the Commissioner, that demonstrates that the device is the as safe and as effective as a legally marketed device").

[3] 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*, 1 (Jan. 2008) (hereinafter "2008 GAO Report") ("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").

healthcare providers to perceive OEMs as having an *economic incentive* to market devices "single-use" when they are actually reusable.[4]

Since 2000, all SUD reprocessors have been fully-regulated by FDA as manufacturers.[5] FDA requires reprocessors to comply with all device manufacturing requirements that apply to OEMs, and there are some additional requirements that apply solely to reprocessors.[6] Reprocessors must demonstrate that their devices are "substantially equivalent to the predicate device" and "as safe and effective."[7] FDA and the U.S. Government Accountability Office (GAO) findings,[8] plus decades of clinical use, confirm the safety and efficacy of reprocessed devices that were labeled "single use" by OEMs. [9]

Despite FDA's clearance of reprocessed versions of the Coblation® Wands are "substantially equivalent" and "as safe and effective" as new versions, ArthroCare raises concerns about the reprocessing of Coblation® Wands and touts a debunked study as evidence that reprocessed devices are defective.[10]

ArthroCare states that reprocessed devices "may increase the risk of transmitting Creutzfeldt-Jakob disease (CJD), HIV, and Hepatitis A, B, and C," citing an article published by The Infectious Disease Clinic of North America (hereinafter "IDCNA article").[11] This statement is unsubstantiated by the IDCNA article, which fails to make any reference to CJD, and its references to HIV or Hepatitis only relate to the unsafe practice of reusing *syringes* for vaccinations in parts of Africa, as documented by the World Health Organization.[12] There is simply no relation between the reuse of syringes and FDA-regulated reprocessing performed in the U.S.

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[4] United States General Accounting Office, GAO-00-123, *Single-Use Medical Device Little Available Evidence of Harm From Reuse, but Oversight Warranted*, 11 (June 2000) (hereinafter "2000 GAO 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").

[5] FDA, CDRH, Guidance for Industry and for FDA Staff, *Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals*, 1 (Aug. 14, 2000).

[6] *See,* Testimony of Dr. Daniel Schultz, Director, CDRH, FDA (Sept. 26, 2006) (hereinafter, "Schultz testimony") ("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)).

[7] 21 C.F.R. 807.100(b)(2)(ii)(B).

[8] *See*, Schultz testimony at 2 ("FDA believes that reprocessed SUDs that meet FDA's regulatory requirements are as safe and effective as a new device"); *see also* 2008 GAO Report at 14-19 ("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. That is, the available information regarding safety, while not providing a rigorous safety comparison between reprocessed SUDs and other devices, does not indicate that reprocessed SUDs currently in use pose an increased safety threat" (emphasis added)); and 2000 GAO Report at 11 ("studies have shown both that reprocessed procedures can be safely accomplished and that patient outcomes are not adversely affected by the use of SUDs").

[9] *See,* AMDR, *Bibliography of Peer-Reviewed Articles and Other Scientific Literature on Reprocessing*.

[10] *See,* AMDR, Memorandum to Interested Parties (Oct. 2006); AMDR, Letter to study Author Dr. Jonathan S. King, Loma Linda University (May 2004); SterilMed Technical Addendum, *Response to "Assessment of Reprocessed Arthroscopic Shaver Blades" in the Journal of Arthroscopic & Related Surgery* (Oct. 2006).

[11] Shuman E.K., *Reuse of Medical Devices: Implications for Infection Control*, 26 Infectious Disease Clinic of North America 165-172 (Mar, 2011).

[12] *See Id*. (full quote includes: "In 2008, the World Health Organization (WHO) estimated that unsafe medical injections resulted in 340,000 human immunodeficiency virus (HIV) infections, 15 million hepatitis B infections, 1 million hepatitis C infections, and 850,000 injection site abscesses worldwide").

The cleaning requirements imposed upon regulated SUD reprocessors are stringent, and, as a result, the final product is a safe and effective alternative to costly new devices. In fact, the GAO issued a report in 2000 stating that FDA has "found no causal link between a reprocessed SUD and reported patient injury or death." This was later reaffirmed in 2008, when a subsequent GAO report stated:

> [N]one of the experts we interviewed cited the use of reprocessed single-use devices as a factor contributing to [Hospital Acquired Infections] in hospitals. Further, one of our recent reports found that available data, while limited, did not indicate that reprocessed single-use medical devices present elevated health risks to patients. *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk*, GAO-08-147 (Jan. 31, 2008)."[13]

ArthroCare states that the type of cleaning process that reprocessors use will "degrade the lumens and protective sheaths of the Wand, further degrading wand performance." However, ArthroCare offers no evidence to support this claim or its additional claims that this alleged degradation can cause "unpredictable wand performance when used in coblate or coag modes." ArthroCare further purports, without support, that the "use of inappropriate epoxies and/or the application of too much or too little epoxy by reprocessors can result in electrical failure and other patient safety concerns."

AMDR members are committed to providing clean, safe, and effective reprocessed medical devices, so these accusations are taken very seriously. As always, AMDR and its members urge anyone with credible evidence about potential risks posed to patients and users by reprocessed devices to report such information *to FDA*.

AMDR reaffirms its commitment to providing clinicians with the facts about reprocessed medical devices. As long as some OEMs continue to launch campaigns based on faulty studies, AMDR will act to provide complete and accurate information to providers and patients. The truth is that reprocessed medical devices allow hospitals to save money and reduce their impact on the environment while continuing to provide the same high quality care.

If you would like to learn more about the safe, high quality practice of third-party reprocessing, please visit AMDR's website at www.amdr.org or contact Daniel Vukelich of AMDR, at (202) 518-6796.

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[13] United States Government Accountability Office (GAO), GAO-08-1091R, *Health-Care-Associated Infections in Hospitals*, 6 (Sept. 26, 2008) ("Although the use of reprocessed single-use devices is on the list of potential causes included in the mandate, none of the experts we interviewed cited the use of reprocessed single-use devices as a factor contributing to HAIs in hospitals").