AMDR
Association of Medical Device Reprocessors

TO: Interested Parties

FROM: Dan Vukelich, Association of Medical Device Reprocessors
Christina Kales, Issues Management

DATE: October 24, 2006

RE: Reprocessed Medical Devices; Smith & Nephew "Study"

Original equipment manufacturers (OEMs) have recently launched yet another "dirty picture show" aimed at misleading the public about medical device reprocessing, this time under the guise of scientific research. The manufacturer, Smith & Nephew, issued a press release[1] from its Andover, Massachusetts headquarters announcing the publication of a "study" that it funded, which was published in the *Journal of Arthroscopic & Related Surgery*.[2]

Smith & Nephew is a major manufacturer of orthopedic medical devices including many devices labeled for "single use." The stated purpose of the study, was to evaluate the level of contaminants on, as well as the quality of, reprocessed shaver blades. Not surprisingly, given that the study was paid for by a company that gains financially when devices are *not* reprocessed, it purports to have discovered problems with reprocessed devices.

We have reason to believe that the Health Institute of New Jersey (HINJ) – the trade association representing OEMs in the state and/or the New Jersey Health Care Quality Institute (NJHCQI) may bring this study to your attention to support their claims that reprocessed medical devices present a risk to the public health.

You should be aware that this study has quite a bit of history. Smith & Nephew funded a similar "study" several years ago and sought to have it published in *Arthroscopy* in early 2004. On May 13, 2004, AMDR wrote a letter to the study's five authors, setting forth the concerns of the third-party reprocessing industry about the scientific integrity of the study and the

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1 *See* Joe Metzger, Smith & Nephew Endoscopy, press release, "Peer-Reviewed Study Shows Reprocessed Single-Use Only Medical Devices Used in Arthroscopic Surgery May Pose Health and Safety Risk to Patients," October 19, 2006, http://www.smith-nephew.com/news/item.jsp?id=331.

2 Jonathan S. King M.D., Marilyn M. Pink Ph.D, and Christopher M. Jobe M.D., Department of Orthopaedic Surgery, Loma Linda University, Loma Linda, California, "Assessment of Reprocessed Arthroscopic Shaver Blades," *Arthroscopy: The Journal of Arthroscopic & Related Surgery*, October, 2006, Vol. 22, pages 1046-1052.

conclusions drawn. Included in the letter were AMDR's specific concerns regarding the size of the sample studied, the origin of the devices used in the study and the chain of custody of the devices from the time they left the possession of the reprocessor to the time that the study authors examined them. Because of these concerns, AMDR asked the authors to withdraw the article from consideration for publication in *Arthroscopy*, and to refrain from publishing it elsewhere. Thereafter, AMDR was contacted by editors at *Arthroscopy* and had been informed that the authors had voluntarily withdrawn this study from consideration for publication in the journal.

Now, two years later, a remarkably similar study, with three of the five same authors has appeared. Like the old "study," this study also contains an inadequate sample size – this time of only 27 devices! Like the old study, this study also fails to document the chain of custody of the reprocessed blades; fails to document the hospital where the blades were allegedly used; and, **most importantly, fails to document any reports (adverse events) of patient injury, infection, or other harm related to arthroscopic shaver blades reprocessed in accordance with Food and Drug Administration (FDA) requirements.**

In conclusion, if this new study is brought to your attention by HINJ, NJHCQI or anyone else, we urge you to probe for the information necessary to evaluate the credibility of the study results. Who collected the blades? Who "reprocessed" the blades? Who can account for the chain of custody of the devices? Where are the adverse event reports? We believe the answers to these questions will make it clear that the new study, like the old one, is meaningless as an assessment of the degree to which reprocessed devices are clean and functional.

Please do not hesitate to call us with questions.