



STATEMENT TO MEDIA AND NOTICE OF MEDIA AVAILABILITY

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{Note to editors and reporters: experts from the nation's leading reprocessing companies are available for interviews and to answer questions about this safe practice that has been trusted by the nation's leading hospitals for years. Call contact to schedule interviews.}

Nation's Third-Party Medical Device Reprocessors:

Washington Post Investigation of Reprocessed Devices Unable to Find Link Between the Safe FDA-Regulated Practice of Reprocessing and an Increase in Risk to Patients

(Washington, D.C.) December 12, 2005 – A year-long Washington Post investigation into the widely-used practice of reprocessing medical devices found no evidence that patients are put at an increased risk from the practice. The article was irresponsible in avoiding a basic fact: that no surgery is without risk, and that hundreds of surgical incident reports are filed every year as a result of unprocessed or “original” devices. Any article that discusses failures of reprocessed devices and neglects to put that information in the context of the failure rate of their alternative – original devices– is deliberately misleading and unfairly disparages an industry that is doing good for patients, hospitals, and the environment.

A simple review of FDA's adverse event reporting database will uncover many times more examples of failures or problems involving original devices than failures or problems involving reprocessed devices. Over 30 million devices have been reprocessed, and the practice of reprocessing has been found to be every bit as safe, if not more safe than original devices.

Post Article Misinforms Readers About U.S. FDA Regulation

The article pointed to several anecdotal reports, mostly from years before stringent regulations were in place, or from overseas, where FDA's regulatory authority does not apply. The article does not demonstrate that the risk faced by a patient when a reprocessed device is used during surgery is any greater than the risk that would have been faced by that same patient had an original device been used.

The article also misleads readers by omitting the fact that FDA has in place stringent reprocessing-related regulations that protect the patient. Instead, The Post emphasizes graphic, tragic cases of two children who were injured by devices that were not reprocessed by commercial reproprocessors but rather by hospitals before hospitals were subject to these regulations, or by entities outside the USA. Furthermore, the article presents a "mishmash" of different types of problems, with no clear explanation whether a given problem was caused by original manufacturing of the device or by reprocessing.

For Vanguard Medical Concepts, SterilMed, and Alliance Medical – the three companies that comprise the Association of Medical Device Reprocessors (AMDR) – safety comes first. No device is ever reprocessed if the reproprocessor cannot establish and validate that the device can be cleaned, made sterile and made functional. AMDR adopted a strict “Commitment to Patient Safety,” which requires its members to meet or exceed all federal standards for safety. More information can be found at <http://www.amdr.org/news.html>.

The Post Fails to Identify That It Is the Original Manufacturers’ Concern for Profits, Not Concern for Patient Safety, That Fuels This Controversy

Is it any wonder that some of the nation’s largest original equipment manufacturers have tried to use the legislative and regulatory processes to drive the reprocessing industry out of existence? AMDR members pose a serious threat to the profits of the original equipment manufacturers. Because the original equipment manufacturers were unable to convince Congress or the FDA to eliminate the reprocessing industry, they’ve sought and found reporters willing to publicize their distorted views of the industry and misrepresentations of the facts.

The Post Ignores The Growing Numbers of Reports of Faulty Original Devices

From our first interview, we explained to The Post that no procedure that uses a medical device is without risk. Original equipment - new devices – fails on occasion. FDA has received thousands of reports of injuries and patient deaths resulting from the use of original equipment, and we need only look at last week's news to see the latest instance of an original device manufacturer recalling tens of thousands of original devices because of an unacceptable failure rate. So it should come as no surprise that reprocessed devices, on rare occasion, also may fail. But the ways in which reprocessed devices fail are similar to the ways in which original devices fail. For example, both original and reprocessed catheter tips sometimes break if a surgeon puts excessive pressure on a catheter tip, but such a failure cannot fairly be said to be due to reprocessing.

The Post was unable to find any evidence that reprocessing results in an increased risk to patient safety. This isn’t surprising, given that neither FDA nor the U.S. Government Accountability Office has identified an increased risk to patient safety from properly reprocessed devices.

The Post Does a Disservice to Patients By Instilling Panic Through Outdated or Irrelevant Examples

The problem with The Post article is that it seeks to alarm readers by exaggerating the risks associated with reprocessed devices. The fact is that there are far more problems reported for original devices than there are for reprocessed devices.

The article's use of two tragic incidents of children being injured by "reprocessed" devices is a blatant attempt to inflame the reader's passion. However, the fact is that both events occurred because the medical devices in question appear to have been reprocessed outside of the framework of FDA regulation. The Clowes case occurred in England where FDA has no jurisdiction. And the tracheal tubes used in the Van Duyn case were reprocessed by a hospital at a time when hospitals were not fully subject to FDA regulation. It is simply not appropriate for The Post to use either incident to cast doubt upon the safety of commercial reprocessing in the U.S. today. Indeed, The Post failed to point out that tracheal tubes like those used on Sean Van Duyn and air supply tubes like those used on Tony Clowes are apparently not reprocessed by third-party reprocessors in the United States.

The Nation's Third-Party Reprocessors Have a Stellar Safety Record

There is no evidence that third-party, FDA-regulated reprocessing increases the risk faced by patients. In fact, it may be that reprocessing makes medical procedures safer, because if an original device fails when it is first used, it is not reprocessed. And because every reprocessed device is inspected or tested prior to use, the strong likelihood is that the device will again work properly. The same cannot be said for original devices, which are subject only to sample-testing.

Single-Use Label, Not Required by FDA, But Serves to Sell More Original Devices

The Government Accountability Office report to which the article referred found that the "single-use" label is often little more than a marketing tool of the original equipment manufacturer, who has every incentive to use it in order to sell more devices and avoid the costly validation analysis our members must perform prior to reprocessing. Patients should understand that it is the manufacturer's choice to put the single-use label on a product, it is not an FDA requirement. We shared with The Post examples of original equipment manufacturers continuing to label certain devices as being "for single-use," even after these original equipment manufacturers entered into reprocessing agreements with our members. This is compelling evidence that even the original equipment manufacturers know that many "single use" devices can be safely reprocessed.

FDA Has Always Required Hospitals To Report and Identify Adverse Events Attributable to Reprocessed Devices

FDA has always required that hospitals notify the agency when a reprocessed device was involved in adverse events associated with death or serious injury. In April 2001, FDA issued a Guidance for hospitals that emphasized that hospitals should include in their adverse event reports information that specifies whether the device that is the subject of the report was reprocessed. More recently, the

Medwatch form was changed so that a box can be checked if a reprocessed device was used, but to say that this information was not tracked prior to last year is inaccurate. AMDR supplied this FDA guidance document to The Post.

FDA Regulation of Reprocessing Prior to 2000 Was Similar to FDA Regulation of Original Equipment

The Post is wrong to say that reprocessing “had little federal oversight” prior to 2000. Except for premarket submissions, FDA has always required reprocessors to meet the same regulatory requirements as the original equipment manufacturers, including registration and medical device listing for the single-use devices that were to be reprocessed; adverse event reporting; reports to FDA of voluntary corrections and removals; compliance with Quality System Regulation; and labeling controls.

Original Equipment Manufacturers Reverse Engineer Devices, Too

When an original equipment manufacturer wishes to introduce to the market an original device, the regulatory process requires, at a minimum, that the device be substantially equivalent to another device that is already legally marketed. To demonstrate this, the original equipment manufacturers often reverse engineer the marketed product to determine exactly how the competing product was made. Just as it does for original equipment, FDA requires that reprocessed devices be as safe and effective as legally marketed devices. Third-party reprocessors hire the same types of engineers to determine how to make their devices equivalent to the original equipment. If these biomedical, mechanical, electrical, and chemical engineers and microbiologists determine that, after reprocessing, a device may not be clean, sterile, and functional, AMDR’s members do not reprocess it. In fact, a very small percentage of the various types of “single use” devices on the market are actually reprocessed.

The Post’s investigation, which took nearly a year and purports to be based on an examination of “thousands of pages of documents, including FDA records, court filings and internal company reports,” confirms what has been known for quite some time -- that there is no evidence to suggest that the use of reprocessed devices increases patient risk.

We welcomed The Post’s investigation into the safe practice of reprocessing and cooperated completely. We are deeply disappointed that the investigation failed to compare the safety profile of reprocessed devices to that of the original equipment manufacturers. The Post missed its opportunity to provide a valuable public service, which we believe would have found that reprocessed devices are every bit as safe, if not safer than original devices.

Reprocessing saves valuable health care dollars, which hospitals can use to provide better access to care, more staff, and better technology. Reprocessing eliminates over 900 tons of medical waste per year. The nation’s third-party reprocessors are committed to providing safe products at a fraction of the cost.

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