Questions and Answers on the European Commission Report*:*
The Issue of the Reprocessing of Medical Devices in the European Union (27.8.2010)

The Association of Medical Device Reprocessors (AMDR) supports clinical access to safe, effective, lower-cost and environmentally-responsible reprocessed devices. While U.S. hospitals have had access to FDA-cleared reprocessed devices for nearly a decade, most nations do not regulate the practice of reprocessing. AMDR urges international legal and regulatory bodies, including the European Union, to implement legislative and regulatory frameworks to ensure that all reprocessed devices are safe and effective for patients.

What is the European Commission report and what is its purpose?
At the direction of the European Parliament, on August 27, 2010, the European Commission released its report on the reprocessing of medical devices in the European Union. Like a prior report from the European Commission's *Scientific Committee on Emerging and Newly Identified Health Risks* (SCENIHR), this report is meant to help guide the European Parliament and the European Council as those bodies consider legislation or regulation on the subject of device reprocessing. On April 15, 2010, SCENIHR released its opinion.

What issues did the Commission address?
The first section of the document includes background information on reprocessing while the second and third parts of the report distinguish between the reprocessing of reusable and so-called "single use" devices (SUDs). The report also addresses in further detail the public health, ethical, liability, economic and environmental aspects of reprocessed SUDs in Europe. Like the SCENIHR opinion before, this report did not propose any potential legal or regulatory requirements for reprocessors in Europe nor did it address FDA's long history of regulating reprocessing in the U.S. Therefore, none of the opinion's conclusions should be construed to apply to reprocessing as it is conducted in the U.S.

Is the reprocessing of "single-use" devices regulated in the U.S.?
Yes. The reprocessing industry in the U.S. is the most stringently regulated in the world. In 2000 and the years thereafter, the U.S. FDA implemented a comprehensive regulatory scheme for reprocessed medical devices to ensure that reprocessed SUDs are as safe and effective as original devices. Medical device reprocessors in the U.S. are held to the same standards as all medical device manufacturers, and FDA implemented additional requirements for reprocessors regarding the cleaning, testing and sterilization of these devices. Ten years after implementation of FDA's regulatory scheme, there is ample data to demonstrate that FDA-regulated reprocessed devices from the U.S. are safe and effective.

Is reprocessing regulated in the European Community?
No. Unlike in the U.S., the reprocessing of SUDs in Europe is not currently regulated at the European Community level, and "different national legislations regulate this practice throughout

Europe." While a patchwork of different policies currently exists across Europe, the European Parliament may soon consider a European Community-wide standard.

Is the "single-use" label required in Europe?
No. Like in the U.S., the decision to market a reusable or a single-use medical device is the responsibility of the manufacturer. The "single use" label is a designation chosen by medical device manufacturers, not FDA or FDA's European counterparts. AMDR has long catalogued evidence that the "single-use" label is often used for marketing purposes, rather than for patient safety reasons, and that is why many hospitals, worldwide, reuse some SUDs

Did the Commission find evidence of increased harm to patients from reprocessing SUDs?
No. In addressing the potential risks of reprocessed SUDs, the Commission found that the number of documented incidents [of harm] is "very small." The SCENIHR opinion noted that "in the existing inventory in the US, no evidence of an increased risk was noted for patients from reprocessed devices." SCENIHR also determined that this apparent lack of an increased risk may be associated in part with the limitations the U.S. imposes on the reuse of reprocessed medical devices, noting FDA's strict requirements of medical device reprocessors in the U.S.

Didn't the Commission find "potential hazards" from the reuse of SUDs?
Yes. AMDR agrees and believes that not all SUDs are suited for reprocessing. Therefore, AMDR urges the European Parliament to adopt Community-wide regulatory requirements for reprocessed SUDs that will ensure that only a select segment of SUDs (those than can be adequately cleaned, sterilized and proven to be functional) are reprocessed – a regulatory system similar to the requirements already in place in the U.S. For AMDR's members, patient safety is of paramount concern, but so is ensuring clinical access to lower-cost, environmentally-friendly medical device products.

Did the Commission raise ethical and liability concerns with reprocessed SUDs?
Yes, but the Commission addressed those concerns in Europe, where reprocessing is not regulated, unlike in the U.S. The Commission raised ethical and liability concerns that have not yet been addressed by regulatory entities in Europe. In the U.S., on the other hand, these concerns were addressed when reprocessors became fully regulated by FDA as a manufacturers in 2000, and specific labeling, marking, quality system, and premarket requirements, to name a few, were put in place to ensure reprocessed devices are safe, effective and readily-identifiable. In the U.S., the FDA has determined that there is no increased risk to patients from reprocessed SUDs and has repeatedly emphasized the stringent regulatory requirements for reprocessors.

What did the Commission conclude?
In light of its findings thus far, the Commission will take further steps to assess the appropriate measures to be put forward in the context of the Recast of the European Medical Device Directive with regard to reprocessed SUDs in order to ensure a high level of protection for patients. AMDR supports a strong regulatory framework for Europe, akin to the U.S. model.

This information is provided by the Association of Medical Device Reprocessors (AMDR), September 2, 2010. For information on AMDR and reprocessing, please go to www.amdr.org.