

AMDR Statement on Lack of Integrity in *Surgical Endoscopy* Article on Certain Reprocessed LigaSure Devices

(Washington, DC – 9 November 2020) A September 9, 2020 article published in *Surgical Endoscopy*, “Assessing Organic Material on Single-Use Vessel Sealing Devices: A Comparative Study of Reprocessed and New LigaSure Devices,” appears to contain significant conflict of interest, fails to address important chain of custody issues for the devices studied, fails to have misappropriated supportive research, and is being misused by the study funder to promote their economic agenda.

AMDR has filed a complaint with the *Journal’s* editors and requests that those who have read the article or subsequent prejudicial marketing materials from Medtronic/Covidien be made aware of the following serious discrepancies with the article’s findings.

Conflict of Interest

Covidien, a subsidiary of Medtronic and the source of the funding for this study, has a financial interest in seeing that its single-use devices (SUDs) are NOT reprocessed so that it can sell more new devices. It would appear from the disclosure Covidien not only provided funding, but also provided data collection and “editorial support.” This would appear to be an inappropriate level of influence by a company that stands to gain financially from the outcome of the research.

Further, the paper reveals that precautions were not taken to ensure consistency with well-established scientific principles for study controls. Specifically, there is no discussion on the purity of the chain of custody of the study devices, a vital factor because Covidien may have provided the devices. We do not know what, if any, efforts were made to ensure purity of the chain of custody of devices from the time they allegedly left the reprocessor/hospital to the time they were studied.

If these devices were obtained directly from Covidien, the funding source for the study, there would be further conflict of interest concerns. Devices were not, to AMDR’s understanding, provided by Stryker Sustainability Solutions, the reprocessed device manufacturer. Significantly, Stryker raises further questions about the chain of custody, because they believe the devices studied are more than two years old, as the model has not been produced for at least that amount of time and are no longer marketed. The lack of controls combined with the financial motive of the study funders draws the integrity of the entire study into question.

Referenced Studies are Misleading

The citations offered in the article do not necessarily support the conclusions made in the text. The authors purport that reprocessed devices present elevated health risks and refer to other articles in the literature noted in citations 4, 8, 9, 10, 23, and 24.

Specifically, the authors purport that “despite lower purchase prices, the reprocessed SUDs may have quality issues that impact surgery” (citation 8), that “reprocessed SUDs may have quality issues that impact surgery, such as infection or inflammatory responses” (citation 4,9) and that “existing functional and safety evidence for reprocessed SUD devices have been reviewed” (citation 10). References 4 and 9 refer to hospital-reprocessed devices, outside the United States and outside FDA’s regulation. However, FDA regulates all SUD reprocessing. Approximately 20 years ago, FDA regulations essentially banned the practice of in-house hospital reprocessing. The data cited refers to hospital reprocessing as being unsafe, misleading readers to falsely believe the practice is unsafe today. Instances of inappropriate reprocessing by hospitals outside the US and outside of FDA jurisdiction are not relevant in assessing the safety and effectiveness of devices reprocessed in the US, by FDA regulated commercial firms.

Further, both the Mansur and Ponce de Leon-Rodriguez papers (both a study of devices outside the US) (citations 4, and 9) call for FDA-like regulation of SUD reprocessing that took effect in 2000. These papers should not credibly be used to claim that reprocessed SUDs raise safety concerns – in fact they are better suited to demonstrate confidence that FDA regulation ensures device safety, including for reprocessed SUDs. The Renton paper (citation 10) also refers to unregulated reprocessed SUDs (or those not meeting FDA’s requirements). Further, one of the papers cited also appears to have been funded by Covidien. No citations are given to support the claim that reprocessed SUDs in the US are unsafe and/or no sources independently published *without* sponsorship by Covidien. Manufacturer-sponsored studies should be considered suspect given the manufacturer that funded this and several of the papers referenced, has an economic incentive to see that their devices are NOT reprocessed.

Surgical Endoscopy is Being Used to Promote an Economic Agenda

Our members have evidence from hospitals, falsely scared by the article into thinking reprocessed LigaSure devices are unsafe, indicating they have stopped reprocessing similar devices, driving up costs by tens of millions of dollars since publication of the article. At a time when healthcare dollars are stretched and our supply chain has been strained to its limits, this seems a particularly inopportune time for Covidien, and *Surgical Endoscopy*, to promote an economic agenda based on poor and misleading information.

About AMDR

The Association of Medical Device Reprocessors is the global trade association for the regulated, professional single-use device reprocessing and remanufacturing industry. For 20 years, AMDR has promoted remanufacturing as an important healthcare strategy that helps hospitals and healthcare providers increase quality, reduce costs, and strengthen the supply chain. AMDR protects the interests of its members in regulation, legislation and standard-setting.

AMDR members include [Innovative Health](#), [Medline Renewal](#), [NEScientific](#), [ReNu Medical](#), [Stryker Sustainable Solution](#), [Sustainable Technologies](#) (a Cardinal Health Business), and [Vanguard AG](#).

Having played a key role in the establishment of the reprocessing industry, AMDR continues to push the global medical technology industry and lead the way for remanufacturing to play a defining role in the evolution and use of new device technologies.

###