What Others are Saying about Single Use Medical Device Reprocessing

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

<u>On reducing wasteful spending and strengthening the supply chain</u>

"When hospitals started throwing away SUDs, a whole new third-party reprocessing industry sprung up willing to assume that risk—essentially outsourcing the cleaning of these devices. The reprocessing industry is tightly regulated by the FDA, and hospitals can now safely and routinely outsource the sterilization of many single-use disposable medical supplies. Only a small fraction of medical devices is reprocessed by third-party vendors, however, approximately 2 to 3% overall, and so there is tremendous capacity to reduce supply chain vulnerability.

"…we need to expand the reprocessing industry and incentivize manufacture of things closer to where they are used. This will reduce supply chain vulnerability and provide employment opportunities for members of local communities."

> Dr. Jodi Sherman, Associate Professor of Anesthesiology at the Yale School of Medicine, and of Epidemiology (Environmental Health Sciences) at the Yale School of Public Health. She also serves as Director of the Program on Healthcare Sustainability, Yale Center for Climate Change and Health., Yale Sustainability, May 2020.

<u>On lowering costs for hospitals</u>

"Reprocessing medical devices originally labeled for single use saved hospitals and surgery centers nearly $500 million in 2018, according to survey findings released by an industry trade group Monday.

"For hospitals, reprocessing a device after patient use typically involves sending it to a third-party reprocessor, which cleans, sterilizes and repackages the device. Hospitals reprocess a range of single-use devices, ranging from non-invasive items like blood pressure cuffs to invasive surgical instruments."

> Modern Healthcare, July 2019

"The main result we have been able to achieve through reprocessing is to minimize hospital spending while at the same time maximizing hospital revenue through the addition of more case volume complimented by newly approved reprocessed devices. With new devices continuously being approved for reprocessing we are seeing a consistent decrease in spending in proportion to case volume….We have experienced minimal to no resistance from doctors in the EP lab regarding the quality of our reprocessed items. *The rate of faulty catheters and cables from reprocessing is far below the defective rate of the OEM companies that provide brand new straight out of the package catheters and cables*" (emphasis added).

> Evyatar Nitzany, EP Lab Coordinator, El Camino Hospital, Mountain View, CA. *Growing El Camino Hospital's Reprocessing Program*, **Innovative Health Case Study**, April 2019.

"The use of remanufactured circular mapping catheters is safe, efficient and reliable. Widespread use of remanufactured SUDs offers the possibility of significant economic benefit."

Lisa WM Leung, Banu Evranos, Alexander Grimster, Anthony Li, Mark Norman, Abhay Bajpai, Zia Zuberi, Manav Sohal and Mark. M. Gallagher, *Remanufactured Circulated Mapping Catheters: Safety, Effectiveness and Cost*, **Journal of Interventional Cardiac Electrophysiology**, December 2018.

"Reprocessing is a very effective method in reducing operating expenses, particularly for more expensive devices. Since the quality of the reprocessed device has been demonstrated and the physicians are supportive this is truly a win-win."

Rick Meier, VP Materials, ProHealth Care. *ProHealth Care/Waukesha Memorial Hospital Implements Reprocessing Program that Saves Cardiology More than $120,000 Per Year,* **Innovative Health Case Study**, 2018.

"Reprocessing by the original device manufacturers has yielded substantial savings at our institution and is an example of the cost savings that can be expected when implementing an EF reprocessing system."

Sorawut Thamyongkit, Malick Bachabi, John M. Thompson, Babar Shafig and Eric A. Hasenboeler, *Use of Reprocessed External Fixators in Orthopaedic Surgery: A Survey of 243 Orthopaedic Trauma Surgeons*, **Patient Safety in Surgery,** June 2018.

"Single-use medical devices are expensive resources that end up in the landfill after use. By using reprocessed medical devices, Virginia Mason has provided the highest quality of care, while reducing waste to the landfill and reducing supply costs by over $3M in three years. In 2014, Virginia Mason reprocessed or recycled over 18,850 pounds of devices, which may have otherwise have been discarded in a landfill."

Virginia Mason; Single Use Device Reprocessing, **Healthier Hospitals: A Practice GreenHealth Program, Case Study**, February 2016.

"Single-use device (SUD) reprocessing in the electrophysiology lab is a strategic initiative for many leading U.S. hospitals to help maximize limited healthcare resources. For good reason: hospitals that are highly engaged in a vascular reprocessing program can save $300,000 or more per year."

Helen Brann, CMRP, Materials Manager, Duke University Heart Center and Angela Capone, RN, BSN, Cardiovascuar Specialist, Wakemed, *A Tale of Two SUD Reprocessing Programs: How Two Similar Health Systems Can Achieve Very Different Savings Results in the EP Lab*, **EP Lab Digest,** September 2015.

On eliminated waste

"Reprocessing single-use devices (SUDs) allows Dignity Health to better utilize limited resources. In FY2013, Dignity Health saved over $8 million and eliminated more than 271,000 pounds of medical waste by reprocessing SUDs. Over the last four years, Dignity Health has saved more than $27 million and eliminated more than 872,000 pounds of medical waste from our nation's landfills."

Dignity Health: Reprocessing Single Use Devices, **Healthier Hospitals: A Practice GreenHealth Program, Case Study**, September 2013.

On defect rate of original equipment versus reprocessed devices

"Reprocessing has emerged as an attempt to control the cost of single-use bipolar and ultrasound diathermy devices despite limited data on defect rates. This study compares the defect rates, as reported by surgical teams, between original equipment manufacturer (OEM) single-use bipolar and ultrasound

diathermy devices and reprocessed (RP) devices. Data were retrospectively collected on 3112 devices over a 7-month period for two types of bipolar and ultrasound diathermy devices. There is a significant difference ($p < 0.001$) in reported bipolar and ultrasound diathermy device defects between OEM and RP. OEM single-use bipolar and ultrasound diathermy devices were reported to be defective more frequently than RP devices based on reports from the surgical team."

> Abstract, *A Comparison of the Defect Rate between Original Equipment Manufacturer and Reprocessed Single-Use Bipolar and Ultrasound Diathermy Devices*, *Terrence J. Loftus, MD,* **Journal of Medical Devices**, August 2015 (Summary at link; f*ull PDF coming).*

On competition

"Some OEMs were reluctant to lose the revenue represented by the decreased purchase of new devices. These OEMs engaged in informal lobbying of physicians and staff to prevent implementation of the program. The primary technique used was attacks on the safety of reprocessed devices. The resolution was two-fold, provide information from the selected reprocessing vendor on their steps to assure safety and provide the external reports by the GAO and others finding no issues with reprocessed devices. The 100% inspection rate for reprocessed devices, compared to the statistical sampling inspection for OEM devices was also pointed out to those expressing concerns."

> *Efficient Use of Resources: Reprocessing of Single Use Devices at Hospital Corporation of America*, **Healthier Hospitals: A Practice GreenHealth Program, Case Study**, March 2012.
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> *(July 2019)*