

Canadian and Global Update on Efforts to Regulate “Single-Use” Devices Reprocessing



AMDR
ASSOCIATION OF MEDICAL
DEVICE REPROCESSORS

2016 CADTH Symposium
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Disclosure

- I am employed by the Association of Medical Device Reprocessors (AMDR), the trade association representing the interests of commercial SUD repressing firms.

Topics To Be Covered

- Introduction to AMDR
- Overview of commercial SUD reprocessing (remanufacturing)
- SUD Reprocessing Regulation
 - U.S.
 - Germany
 - Canadian regulation
 - Emerging European and Japanese Regulations
- Safety, savings, and sustainability



Introduction to AMDR

- International, non-profit, vendor-neutral, Washington, DC-based trade association representing the legal, regulatory and other trade interests of commercial SUD reprocessors
- Reprocess for a majority of U.S. hospitals and a majority of German academic medical centers plus other international hospitals



AMDR Member-Companies

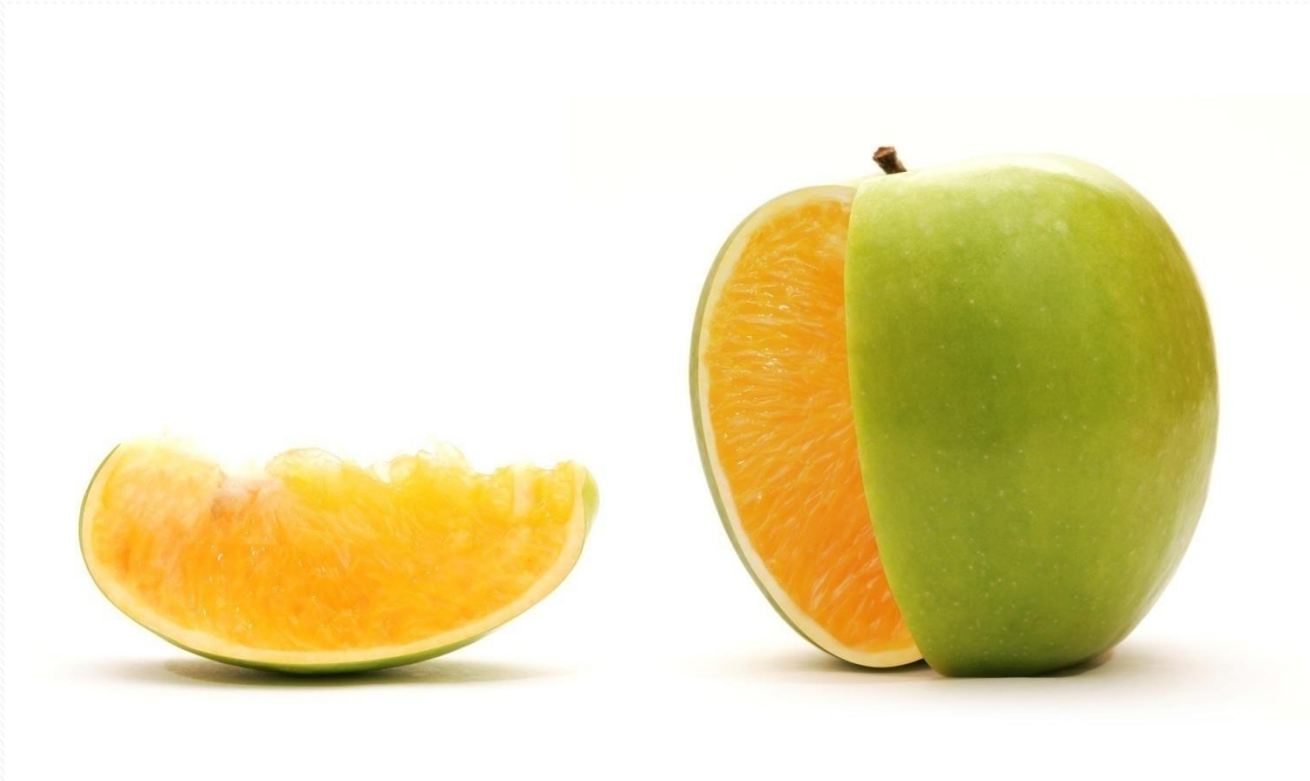
- **Hygia Health Services**
 - Birmingham, Alabama
 - Focus on Non-Invasive Devices
- **Innovative Health**
 - Scottsdale, Arizona
 - Targeted, high-impact cardiology focus
- **Medline ReNewal**
 - Redmond, Oregon
 - Part of Medline Industries, largest privately held manufacturer and distributor of healthcare supplies in U.S
- **Stryker Sustainability Solutions, Inc.**
 - Tempe and Phoenix, AZ and Lakeland, FL
 - Division of Stryker Corporation since December 2009
- **Vanguard**
 - Berlin-Germany
 - European market leader



Sustainability Solutions



What is commercial SUD reprocessing?



What Is Commercial SUD Reprocessing?

- Reprocessing is manufacturing
- Consistent with internationally-accepted standards, devices are:
 - Collections
 - Disassembly
 - Disinfection, Cleaning
 - Function-testing
 - Repackaging
 - Sterilization
 - 100% traceability
- Devices returned are “equivalent” to the predicate OEM device



The “Single Use” Label

- Chosen by the manufacturer
- Not a regulatory requirement (in Canada, Europe or U.S.)
- Labels switched from “reusable” to “single-use” approximately two decades ago without structural changes for many devices
- Some devices sold as “reusable” in one country and “single-use” in another
- Some OEMs included “cleaning instructions” with SUDs
- Some OEMs had/have reprocessing programs



The “Single Use” Label



“The decision to label a device as single-use or reusable rests with the manufacturer. ... Thus, a device may be labeled as single-use because ...the manufacturer chooses not to conduct the studies needed to demonstrate that the device can be labeled as reusable.”¹

- 1 GAO, Report to the Committee on Oversight and Government Reform, House of Representatives; *Reprocessed Single-Use Medical Devices: FDA Oversight Has Increased, and Available Information Does Not Indicate That Use Presents an Elevated Health Risk* (January 2008), at 1 (emphasis added).

Emergence of Commercial Reprocessing



- Historically, most reprocessing was conducted in-house at the hospital
- The third-party reprocessing industry emerged in the U.S. and Germany approximately two decades ago in response to the growing cost of healthcare, including “single-use” devices and because third-parties can reprocess more effectively
- Globally, in-hospital reuse of SUDs common

Safety Principles

- All reprocessed devices meet cleaning/biocompatibility, performance and sterility specifications and requirements,
- AMDR safety principles, include, among others:
 - 100% device testing and inspection
 - 100% device traceability
 - Commitment to reprocess only those devices that can safely be reprocessed



Commonly Reprocessed Devices



Commonly Reprocessed Devices

- Arthroscopic/Orthopedic
 - External fixation devices
 - Surgical saw blades, bits and burrs
- Cardiovascular
 - Sequential Compression Devices/Tourniquet cuffs
 - Pulse oximeter sensors
 - Femoral compression devices
 - Ultrasonic and electrophysiological diagnostic catheters
- Non-Invasive Devices
 - ECG leads
 - Air transfer mattresses
 - Blood pressure cuffs
 - Fall alarms
 - Pulse OX and cerebral and somatic sensors
- Laparoscopic Surgery
 - Trocars
 - Harmonic scalpels
 - Lap instruments: babcocks, dissectors, scissors/shears, graspers

Commonly Reprocessed Devices & Cost Savings



U.S. Dollars:

Ultrasound cardiac catheter:

- Cost new \$2500 (each)
- Cost reprocessed \$1250
- Savings \$1250

EP diagnostic catheter:

- Cost new \$400-600 (each)
- Cost reprocessed \$200-300
- Savings \$200-300

Harmonic scalpel:

- Cost new \$250-500 (each)
- Cost reprocessed \$125-250
- Savings \$125-250



U.S. Dollars:

Pulse oximetry sensor:

- Cost new \$10-20 (each)
- Cost reprocessed \$6-10
- Savings \$4-10

Pneumatic tourniquet cuff:

- Cost new 20-40 (per pair)
- Cost reprocessed \$10--18
- Savings \$10-22

External fixation clamp:

- Cost new \$450 (each)
- Cost reprocessed \$225
- Savings \$225

Commercial Reprocessing Industry Since 2000

- Regulated as device manufacturers since 2000 in U.S.
- Regulated and accepted under quality standards and validated procedures in Germany based on device risk as set by KRINKO
- Nearly \$500 million industry today
- Serve every major hospital system in the U.S. and 14/17 “top hospitals”
- Serve 95% of German University medical centers

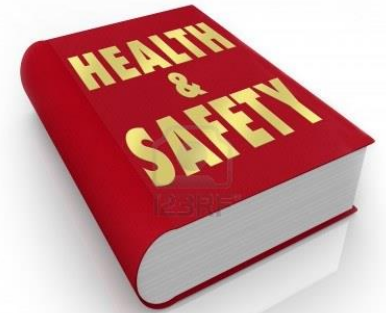




Legal: U.S. FDA Regulation

- In U.S., SUD reprocessing is legal and regulated
- All SUD reprocessing is regulated by the U.S. Food & Drug Administration (FDA)
- Reprocessors treated as manufacturers, and regulated and responsible as manufacturers
- Reprocessors must meet all manufacturer requirements, *plus* additional data and labeling requirements
- Reprocessors submit data to FDA that “exceed[s] the requirements for original manufacturers (OEMs)”
 - Dr. Daniel Schultz, Director, Center for Devices and Radiological Health, Food and Drug Administration, September 26, 2006, before Congress.

U.S. Regulatory Controls



- Premarket Approval and Clearance Requirements
- Facility Registration & Listing
- Medical Device Reporting of Adverse Events
- Medical Device Tracking
- Medical Device Corrections and Removals
- Labeling Requirements
- Quality System Regulation (similar to ISO 13485)



German Regulation

- Reprocessing of SUDs is lawful
- Regulated and accepted under quality standards and validated procedures based on device risk as set by the *Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO)*
- No differentiation between “single use” and “reusable” devices
- Result: higher assurance for patient safety, limited number of controlled reproprocessors, enormous cost-savings and waste reduction



Canadian Regulation

- Historically, NOT regulated by Health Canada, thus a Provincial matter
- As per CADTH
 - British Columbia, Ontario (PIDAC) & Saskatchewan: prohibit any in-house reuse and require outsourcing
 - Manitoba, New Brunswick and Quebec: prohibit hospital reuse of critical or semi-critical SUMDs unless done with licensed reprocessor
 - Alberta: prohibits SUMD reuse in hospitals of critical and semi-critical devices – exceptions may be granted
 - Nova Scotia: to issue SUMD policy (reported in 2015) to permit only licensed third-party reprocessing
 - PEI, Newfoundland and Labrador: prohibited entirely

CADTH Environmental Scan, Reprocessing of Single-Use Medical Devices: A 2015 Update (15 Feb 18)

Canadian Regulation

- Historical Health Canada Positions on SUD Reprocessing:
 - 2007: “Health Canada does not have the authority to regulate the reuse and reprocessing of SUMDs”
 - 2014: In-hospital reprocessing remains the purview of the provinces, but commercial SUMD reprocessors subject to same requirements as OEMs under Canadian Food and Drugs Act and Medical Devices Regulations
 - 2014: Health Canada approves first application for the sale of a reprocessed, non-invasive inflatable compression sleeve

CADTH Environmental Scan, Reprocessing of Single-Use Medical Devices: A 2015 Update (15 Feb 18)

Canadian Regulation

Feb. 5, 2015 Health Canada Notice following Bill C-17 (Patient Safety Legislation):

- Health Canada has authority under existing *Food and Drugs Act and Medical Devices Regulations* to regulate commercially reprocessed SUMDs
- Requirements, same as OEM, include licensing, quality system management, labelling, investigating and handling complaints, maintaining distribution records, conducting recalls, reporting incidents and informing Health Canada of any changes to license application
- By September 1, 2016 commercial reproducers must apply for licenses and phase out non-compliant devices

Canadian Regulations Going Forward

- Provincial and territorial health authorities still have the authority to develop their own policies and guidelines related to SUD reuse
- Commercial SUD reprocessors working on Canadian licensing now

Current European Landscape



- No policy currently exists at the European Union level
- Member States regulate on an individual basis
- SUD reprocessing likely occurring in hospitals across all Member States, regardless of national policy
- Regulated, third-party industry exists in Germany

Other Member States' Regulations

- Germany: Legal and regulated
- UK: in-house reprocessing discouraged, CE marked re-manufacturing allowed
- France: illegal
- Portugal: has strict guidelines which allow
- Most other Member States: no position
- Note: AMDR has evidence that the reuse of SUDs is common in Europe, even in countries where the practice is banned and/or discouraged

European Regulations Coming



- Article 12a of the last Medical Device Directive recast (2007), the Parliament and Council explicitly instructed the Commission to develop a report by September 2010 on the “reprocessing of medical devices in the Community”
- Proposal for SUD reprocessing included in European Commission 26/09/12 draft Regulation
- European Parliament amended that proposal in 09/10/13
- European Council adopted its position 09/21/15
- Proposed regulation now in final stages of “trialogue”
- Effect: there will be a single, uniform policy for SUD reprocessing (like all other medical device regulations) across Europe

Japan



- No current ban or regulation
- In-house reprocessing known to take place
- Ministry of Health, Labour and Welfare (MHLW) has formed study group. Have visited U.S. and German reprocessors and regulators
- Draft policy expected, possibly this year

Regulated Reprocessing is Safe

- In-house (hospital) reprocessing has effectively been stopped in the US and Germany
- Nearly all SUD reprocessing conducted by regulated, third-party firms
- 20+ years of clinical history
- Decades of peer-reviewed literature and clinical experience
- Very few adverse event reports

Regulated Reprocessing is Safe

“we found no reason to question FDA’s analysis indicating that no causative link has been established between reported injuries or deaths and reprocessed SUDs.”

2008 US GAO Report, at 21-22.



Regulated Reprocessing is Safe

In 2011 the German Federal Government answered to a **parliamentary inquiry** on the reprocessing of single-use medical devices and patient's safety. The **Government responded** to this inquiry by stating that in **their assessment the legal provisions regulating the reprocessing of both single-use and multiple-use medical devices in Germany is adequate**. The level of patient safety concerning reprocessed medical devices is high. The *quality problems reported on by the press concerned the in house reprocessing of multiple-use medical devices by hospitals.*



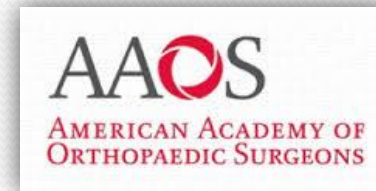
Bundesministerium
für Gesundheit

<http://dipbt.bundestag.de/dip21/btd/17/061/1706174.pdf>

Hospital Clinical Community Support



- American Hospital Association
- 95% of German university medical centers
- American College of Cardiology
- Heart Rhythm Society (formerly NASPE)
- American Academy of Orthopedic Surgeons (AAOS)
- American Nursing Association (ANA)
- Association of Operating Room Nurses (AORN)
- Mayo Clinic, Cleveland Clinic, Johns Hopkins University, Henry Ford Health System



THE WALL STREET JOURNAL.

“In January, after reviewing eight years of FDA data, the Government Accountability Office weighed in with a report concluding there is no evidence that reprocessed single-use devices create an elevated health risk for patients.”

- *The Wall Street Journal*, March 19, 2008, “Hospitals Reuse Medical Devices to Lower Costs.”

Scientific Literature



- Zeitschrift fur Kardiologie
- Journal of AOAC International
- Journal of Interventional Cardiac Electrophysiology
- The American Journal of Cardiology
- Gastrointestinal Endoscopy
- Journal of the American College of Cardiology
- The American Journal of Gastroenterology
- The Journal of Orthopaedic Trauma
- Academic Medicine

Economic Benefits

Reprocessing Provides a Multi-Fold Benefit to Hospitals:

- **Cost:** Immediate savings using the same brands physicians have always used
 - 50% cost savings, on average, for every reprocessed device utilized
 - Covers all third-party reprocessor costs: R&D, equipment and materials, staff, etc.
- **Waste:** Immediate reduction in red bag waste and associated disposal costs
- **Competition:** Hospitals that reprocess see reduced OEM pricing for new equipment and downward price pressure on other products
- **Moral high road:** Reprocessing allows hospitals to responsibly bend the cost curve, thereby extending their ability to do more with limited resources
 - Fiscally responsible
 - Environmentally sustainable

Environmental Benefits



- Reprocessed SUDs are the single most impactful sustainability initiative currently undertaken by US hospitals
- American Nursing Association, Association of periOperative Registered Nurses, and Practice Greenhealth have recognized or endorsed reprocessing as a way to reduce waste
- Titanium, gold, platinum, steel and valuable plastics recovered/recycled instead of disposed
- Identified as a Smarter Purchasing initiative of the Healthier Hospitals Initiative (HHI)

Benefits of Regulated Reprocessing

- Ensures patient safety
- Protects the public health
- Reduces healthcare costs
- Promotes competition
- Protects the environment
- Creates a level regulatory playing field for all participants

Thank You

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