Reprocessing of “Single-Use” Medical Devices: Regulations Coming to Europe

Topics To Be Covered

- Introduction to AMDR
- Introduction to “single-use” medical device reprocessing
- How regulated reprocessing works
- Safety, economics, and environmentalism
- Regulations coming to Europe

AMDR Member-Companies

- Medline ReNewal
  - Located in Redmond, Oregon
  - Part of Medline Industries, the largest privately held manufacturer and distributor of healthcare supplies in the U.S.
  - Works with thousands of physicians and healthcare facilities across the country
- Stryker Sustainability Solutions, Inc.
  - Locations in Phoenix, AZ and Lakeland, FL
  - Division of Stryker Corporation since December 2009
  - Serve approx 2,600 hospitals
- Vanguard
  - European Market Leader in the reprocessing of medical devices
  - Operates more than 37 treatment centers
  - Over 15 years experience in the special treatment of complex medical devices

What is SUD reprocessing?

- Reprocessing is manufacturing
- Consistent with internationally-accepted standards, devices are:
  - Disinfected
  - Cleaned
  - Function-tested
  - Repackaged
  - Sterilized
- Devices returned are “substantially equivalent” to the predicate OEM device
Emergence of Third-Party 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.
- Globally, in-hospital reuse of SUDs is common.

The “Single Use” Label

- Chosen by the manufacturer.
- Not a regulatory requirement (in 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.

Safety Principles

- All reprocessed devices meet cleaning, functionality and sterility specifications and requirements.
- AMDR safety principles:
  - 100% device testing and inspection.
  - Commitment to reprocess only those devices that can safely be reprocessed.

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.”

Reprocessing Procedure

- Initial receipt and sort.
- All orders are ticketed to assure order content integrity.
- Remove rejects, heavily soiled items, and unapproved products.

Cleaning

- Array of automated cleaning equipment augments manual processes.
- Customized/proprietary device disassembly and cleaning equipment used.
- All protocols are device-specific.
Reprocessing Procedure

Cleaning (continued)
- Ultrasonics
- Vacuum desiccation
- Hydraulic flushing
- Motorized scrubbing

Data entry and cycle marking
- Each device is identified and coded with a distinct mark
- Number of reprocessing cycles indicated

Inspection
- Confirms that devices:
  - Meet all cleaning requirements
  - Are free of defects
  - Conform to specifications
- Inspectors are trained and audited for each device
- OEMs test only a sampling of new devices

Function Testing
- Mechanical:
  - Sharpness
  - Spring actuation
  - Pressure test of seals
- Electrical:
  - Sensor fluctuation
  - Insulation
  - Image
  - Diagnostics

Packaging
- ISO 11607
- ASTM D4169
- ASTM F-1140-00 and F-1980-02
- Shock/drop test
- Vibration test
- Package strength

Sterilization
- Ethylene Oxide Gas (EtO)
- SAL of $10^{-6}$
- AAMI/ANSI/ISO 11135
- EO Residuals ISO 10993-7/TIR 19
Reprocessing Procedure

Final inspection and shipping
  • Repeated inspection

Commonly Reprocessed Devices

Commonly Reprocessed & Cost Savings

Ultrasound cardiac catheter:
  • Cost new $2500 (each)
  • Cost reprocessed $1250
  • Savings $1250

External fixation clamp:
  • Cost new $450 (each)
  • Cost reprocessed $250
  • Savings $200

Pneumatic tourniquet cuff:
  • Cost new $20-40 (per pair)
  • Cost reprocessed $10-18
  • Savings $10-22

Pulse oximetry sensor:
  • Cost new $10-20 (each)
  • Cost reprocessed $6-10
  • Savings $4-10

Harmonic scalpel:
  • Cost new $250-500 (each)
  • Cost reprocessed $125-250
  • Savings $125-250

U.S. Reprocessing Industry Since 2000

• Fully regulated as device manufacturers since 2000
• Nearly $500 million industry today
• Independent analysts put Year-over-Year growth at 9-19% through 2017
• 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)
Regulated Reprocessing is Safe

- In-house (hospital) reprocessing has effectively been stopped in the US
- Nearly all SUD reprocessing conducted by regulated, third-party firms
- 20+ years of clinical history
- Zero deaths attributed to reprocessed devices in FDA's Manufacturer and User Facility Device Experience (MAUDE) database
- Decades of peer-reviewed literature and clinical experience
- Very few adverse event reports


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
- 90% 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

"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."

Sustainable Hospitals Help Bend the Cost Curve

“The savings achievable through sustainable interventions could exceed $5.4 billion over five years and $15 billion over 10 years.”

- Hospitals’ cost savings by contracting with an FDA-regulated medical device reprocessor:
  - Over five years was about $57 per procedure. If adopted nationwide, cost savings would be $540 million annually, or $5.7 billion over five years. Does not require any up-front hospital capital investment to get started.
  - Same standard of care.
  - Extend the life and value of the medical devices already own.

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).

Healthier Hospitals Initiative Milestone Report

- Of 638 participating hospitals, about $45 million in savings resulting from single-use medical device reprocessing in 2013 alone.
- Single-use device reprocessing was one of 4 HHI Challenge areas with the highest participation levels and fastest financial rewards.

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.
- Third-party industry exists in Germany.

Other Member States’ Regulations

- UK, France, Spain, Italy: ban or strong governmental discouragement.
- 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.

Current German Regulation

- Reprocessing of SUDs is lawful.
- Regulated and accepted under quality standards and validated procedures based on device risk as set by the Robert Koch Institute (RKI).
- No differentiation between “single use” and “reusable” devices.
- Result: higher assurance for patient safety, limited number of controlled reprocessors, enormous cost-savings and waste reduction.
Current Situation is Unfair to Healthcare Professionals

• All devices, regardless of how labeled, should be safe and effective
• Arguably subjects patients to varying levels of safety
• Health professionals should not feel compelled into illicit reuse of “single-use” devices to save money
• Devices that can be reused should come with cleaning instructions from the manufacturer...
• OR hospitals should have the lawful ability to reuse medical devices by outsourcing to regulated third-parties that demonstrate safety/substantial equivalence with the manufacturer

European Regulations Coming

• Article 12a of the last Medical Device Directive recast, June 1997, the Parliament and Council explicitly instructed the Commission to develop a report by September 2010 on the "reprocessing of medical devices in the Community"
• Regulatory proposal for SUD reprocessing included in European Commission 26/09/12 draft report
• European Parliament amended that proposal in 09/10/13
• European Council now deliberating
• Proposed regulation then goes to "trialogue"
• Effect: there will be a single, uniform policy for SUD reprocessing (like all other medical device regulations) across Europe

Commission Proposal – Article 15 Overview

• Covers both third-parties and hospitals (15.1)
• Reprocessors must meet manufacturer requirements (15.1)
• Only reprocessing that is considered “safe” is acceptable (15.3)
• Critical devices must be listed by Commission in order to be reprocessed (15.4)
• Name/address of reprocessor must appear on label and instructions for use (IFU) (15.5)
• Member States may maintain or introduce prohibition against reprocessing (15.6)

AMDR Position on EU-Regulation of Reprocessed SUDs

AMDR encourages the Commission to recommend a policy whereby SUD reprocessors:
• Can be legitimized through EU-wide regulation;
• Can obtain a CE mark for their devices by demonstrating appropriate quality standards and validated procedures
• Can use existing process of accreditation through notified bodies
• No critical device exclusion
• Modified conformity assessment

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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