Reprocessing of "Single-Use" Medical Devices: *Regulations Coming to Europe*

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

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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

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Introduction to AMDR

- Non-profit, vendor-neutral, Washington, DC-based trade association representing the global legal, legislative and regulatory interests of third-party reprocessors
- Reprocess for a majority of U.S. hospitals, and a majority of German Academic medical centers

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

AMDR Member-Companies

- Medline ReNewal
  - Located in Redmond, Oregon
  - Is 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.

ReNewal Full Circle Reprocessing

- Stryker Sustainability Solutions, Inc.
  - Locations in Phoenix, AZ and Lakeland, FL
  - Division of Stryker Corporation since December 2009
  - Serve approx 2,600 hospitals

stryker Sustainability Solutions

- Vanguard
  - European Market Leader in the reprocessing of medical devices
  - Operates more than 35 treatment centers.
  - Over 15 years experience in the special treatment of complex medical devices

VANGUARD

What is SUD reprocessing?

What Is SUD Reprocessing?

- Reprocessing is <u>manufacturing</u>
- Consistent with internationally-accepted standards, devices are:
  - Disinfected
  - Cleaned
  - Function-tested
  - Repackaged
  - Sterilized
- Devices returned are "substantially equivalent" to the predicate OEM device

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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 common

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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

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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).

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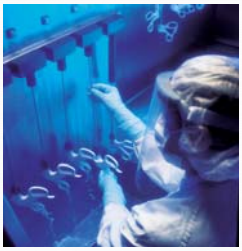
Safety Principles

- 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

Reprocessing Procedure

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

Reprocessing Procedure



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

Reprocessing Procedure

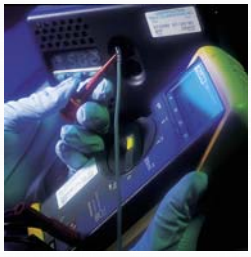
Data entry and cycle marking
- Each device is identified and coded with a distinct mark
- Number of reprocessing cycles indicated

Reprocessing Procedure

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

Reprocessing Procedure

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



Reprocessing Procedure

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

Reprocessing Procedure

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 Devices & Cost Savings

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

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

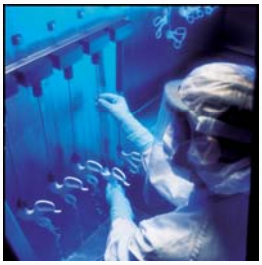
External fixation clamp:
- Cost new $450 (each)
- Cost reprocessed $225
- Savings $225

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. 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

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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.

Hospital Clinical Community Support

- American Hospital Association
- 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

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

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."

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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

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."

-- Research from Commonwealth Fund, with support from Health Care Without Harm and Robert Wood Johnson Foundation

- 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 $2.7 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)

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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

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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 1993, 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)

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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

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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

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Thank You

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