The Reprocessing of "Single-Use" Medical Devices; *Regulations Coming to Europe?*

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

CleanMed Europe
Malmo, Sweden
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Topics to be Covered

- Introduction to AMDR
- Introduction to “single-use” medical device reprocessing
- The safety record of reprocessing
- Economic and environmental benefits
- How regulated reprocessing works in the United States
- European regulations for reprocessing

Introduction to AMDR

- Non-profit, vendor-neutral, Washington, DC-based trade association representing the legal, legislative and regulatory interests of third-party reprocessors of “single use” devices (SUDs)
- Reprocess for a majority of U.S. hospitals
- 95% of the third-party reprocessing done in the U.S.
- Serve international base of hospitals
- Over 60 million devices reprocessed safely to date

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Introduction to AMDR

- Mission: *To promote and protect the legal, regulatory and other trade interests of the third-party medical device reprocessing industry.*
- Vision: A globally competitive market for reprocessed devices based on legislative frameworks that guarantee safe and effective devices

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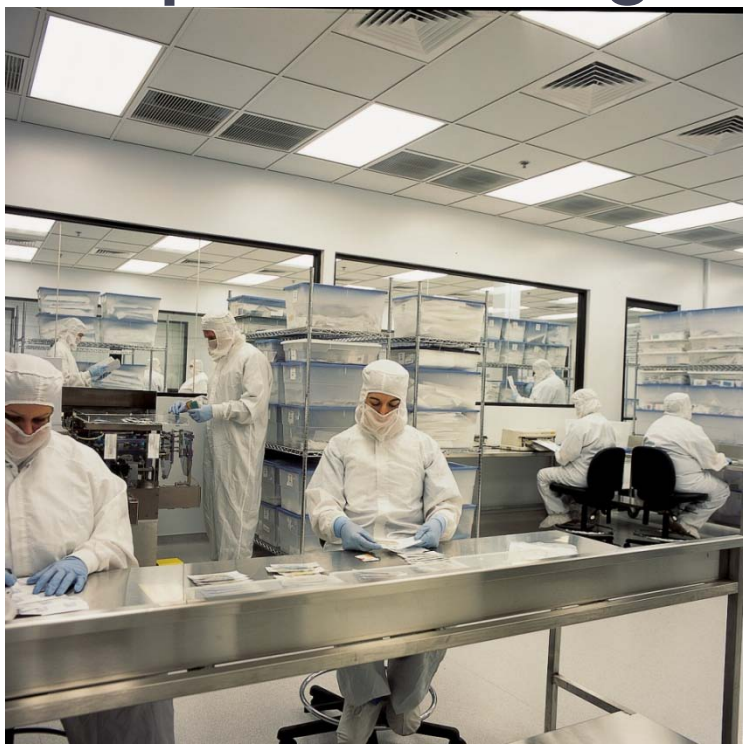
What Is Reprocessing?

- 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

Reprocessing Landscape

- $20 million industry in 2000
- Estimated $400 million now in hospital savings annually
- Independent analysts put Year-over-Year growth at 19% through 2017 (IBIS*World* Inc., Industry Report OD4955, May 2012)
- Agreements in place with every major U.S. Group Purchasing Organization
- Serve every major hospital system in the U.S.

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. approximately two decades ago in response to the growing cost of healthcare, including “single-use” devices

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

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).

Commonly Reprocessed Devices

- Arthroscopic/Orthopedic
  - External fixation devices
  - Surgical saw blades, bits and burrs
- Cardiovascular
  - Tourniquet cuffs
  - Pulse oximeter sensors
  - Femoral compression devices
  - Ultrasonic and electrophysiologic diagnostic catheters
- Laparoscopic Surgery
  - Trocars
  - Harmonic scalpels
  - Lap instruments: babcocks, dissectors, scissors/shears, graspers
- Opened-but-unused (repackaged/sterilized only)

Reprocessing Procedure

- All reprocessed devices must meet cleaning, functionality and sterility specifications and requirements, including:
  - ISO 13485 (same as OEMs) quality system requirements
  - All FDA manufacturer requirements

- AMDR safety principles:
  - 100% device testing and inspection
  - Commitment to reprocess only those devices that can safely be reprocessed

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

Hospital Savings from Reprocessing

- As international government budgets come under greater pressure, reprocessing becomes a necessity
- Annual savings now estimated at$400 million
- $2-3 billion potential market savings in the U.S. alone
- Typical electrophysiological (EP) lab savings: $400,000-500,000 a year
- Typical hospital savings: $500,000 - $2 million a year

Environmental Benefit

- Reprocessed SUDs are the single most impactful sustainability initiative currently undertaken by US hospitals
- Eliminated more than 13,000 TONS of medical waste in the US to date
- Over $65 million in saved waste disposal costs to date
- On average, hospitals can prevent 50,000 POUNDS of medical waste from being disposed
- Titanium, gold, platinum, steel and valuable plastics recovered/recycled instead of disposed

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
- 60+ million devices reprocessed in the US
- 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

Reprocessing Does Not Increase Risk to Patients

"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.

Clinical Support for Reprocessing

- AMDR member-companies serve 16 of 17 "Honor Roll" hospitals and most "Top 10" in the following specialties:
  - Cancer (9 of 10),
  - Cardiology & Heart Surgery (9 of 10),
  - Ear, Nose & Throat (9 of 10),
  - Diabetes & Endocrinology (***all*** 10),
  - Gastroenterology (***all*** 10),
  - Neurology & Neurosurgery (8 of 10), &
  - Orthopedics (8 of 10).

As listed in *U.S. News & Word Report*, 2012-2013.

Overwhelming Support from Hospital/Clinical Community in the US

- 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

U.S. Regulations

- SUD reprocessing is regulated by the Food & Drug Administration (FDA)
- Reprocessors treated as manufacturers, and regulated as manufacturers
- Reprocessors must meet all manufacturer requirements, *plus* additional data and labeling requirements
- "...**as safe and effective as a new device**...."
- 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)

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
- Small third-party industry exists in Germany

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

Other Member States' Regulations

- UK, France, Spain, Italy: ban or strong governmental discouragement
- Denmark and Sweden: allowed under controlled conditions
- 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

Emerging European Regulations

- European Parliament instructed European Commission to address SUD reprocessing (2007)
- Proposed regulation expected to be released on Sept. 26
- Concepts addressed by proposed Article 19:
  - Reprocessing will be addressed at the EU (federal) level, replacing the current system of 27 different Member State approaches
  - Reprocessing is *manufacturing* and should be subject to all medical device manufacturer requirements using existing regulatory pathways
  - There is concern about “critical” device reprocessing
- Next steps, legislative phase: to European Parliament and Council

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

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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