CleanMed Europe 2018
Creating Healing Environments

Disclosure

Potential conflict of interest	None/see below
Relationships with commercial companies	**Company names:**
I am employed by the Association of Medical Device Reprocessors (AMDR), the non-profit trade association representing companies in the business of commercial reprocessing	AMDR: • Cardinal Health • Innovative • Medline • Stryker • Vanguard

As a requirement of accreditation, The Royal Dutch Medical Association (KNMG) requires speakers to begin their presentations with a disclosure slide to make any financial relationships between speakers and commercial companies transparent.

CleanMed Europe 2018
Creating Healing Environments

Presentation: Lowering Your Hospital's Environmental Footprint with Remanufacturing of Single-Use Medical Devices

11 October 2018

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AMDR

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20TH
ANNIVERSARY
AMDR
ASSOCIATION OF MEDICAL
DEVICE REPROCESSORS

About AMDR

What is AMDR?

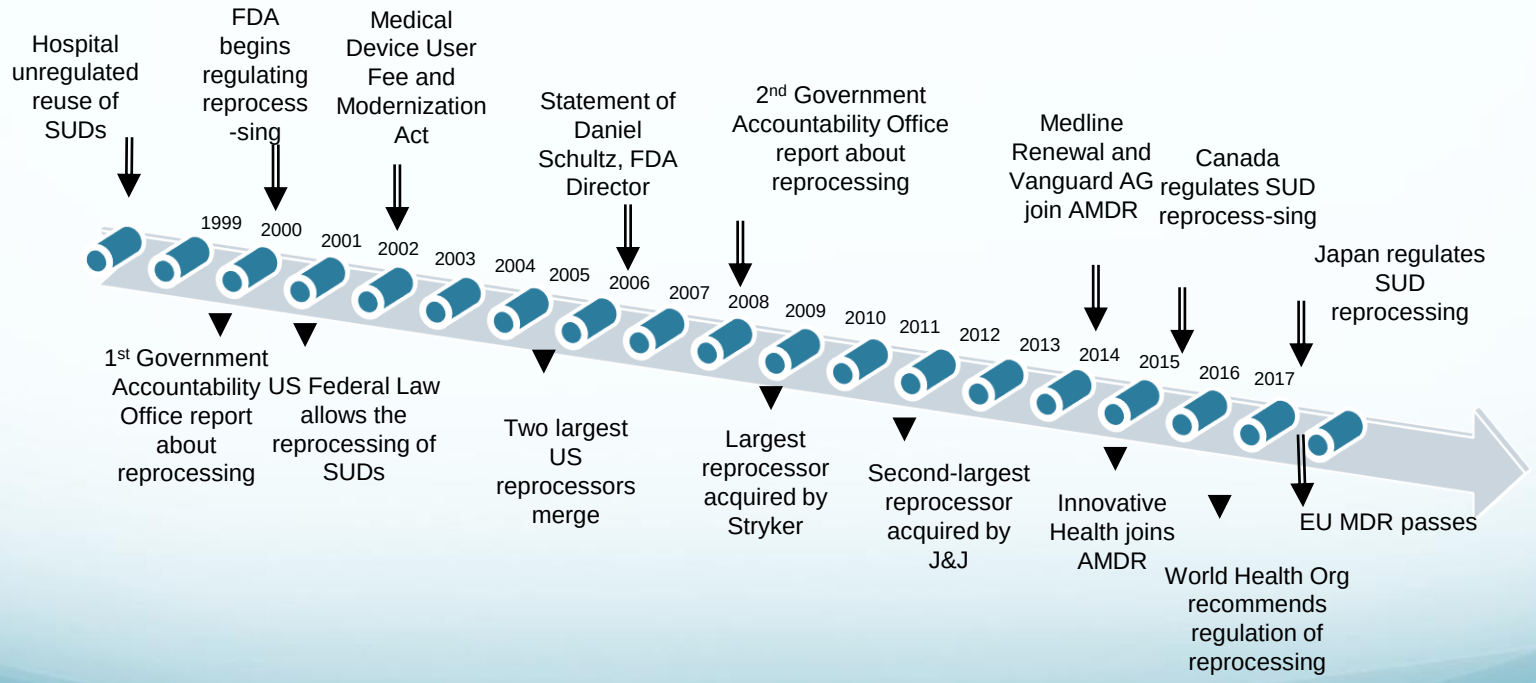
AMDR is the global trade association consisting of members of the commercial single-use device reprocessing and remanufacturing industry.

AMDR represents regulated, commercial remanufacturing, promotes remanufacturing as an important healthcare strategy that helps hospitals and healthcare providers increase quality, reduce costs and waste and improve patient care, and protects the interests of its members in regulation, legislation and standard-setting world-wide.

Mission

AMDR's mission is to *protect* the trade interests of the global commercial reprocessing/remanufacturing industry and *promote* reprocessing as a healthcare strategy that increases quality, reduces costs and waste and improves patient care.

Regulatory Milestones



AMDR Members

Cardinal Health
Riverview, Florida
Business under Medical Solutions Division

Hygia Health Services, *now part of Stryker*
Birmingham, Alabama
Focus on Non-Invasive Devices

Innovative Health
Scottsdale, Arizona
Targeted, high-impact cardiology focus

Medline ReNewal
Redmond, Oregon
Part of Medline Industries

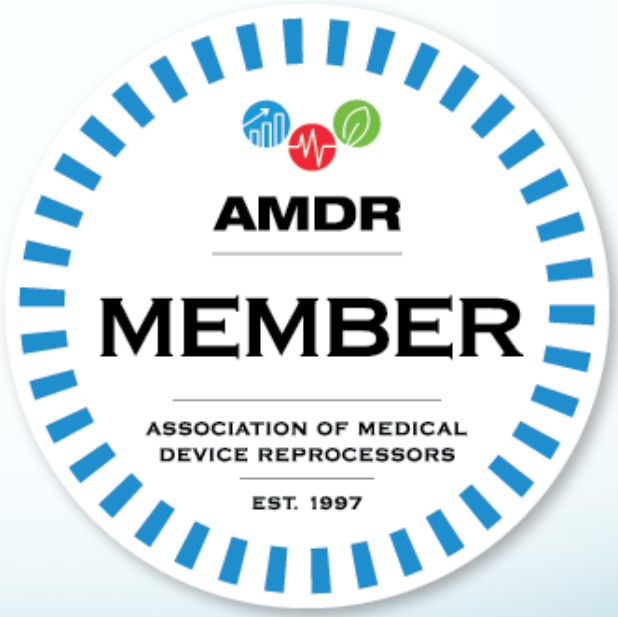
Stryker Sustainability Solutions
Tempe and Phoenix, AZ and Lakeland, FL
Division of Stryker Corporation since December 2009

Vanguard
Berlin-Germany
European market leader

Now a part of Stryker

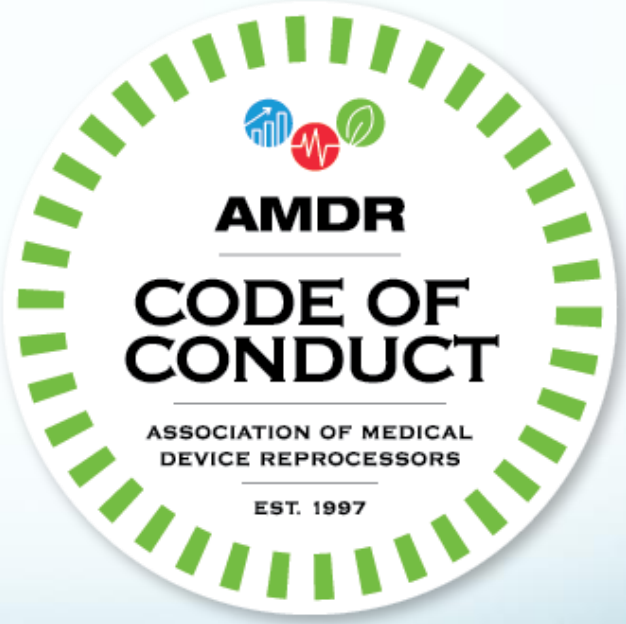
AMDR Credo

…We believe that the future of healthcare requires the medical device industry to enter into a new paradigm where the focus is on providing *value* to healthcare rather than pursuing one-sided profit goals. This means that remanufacturing should be an integrated element in medical device technology development and marketing.



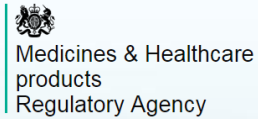
AMDR Code of Conduct

- …Better align the medical device industry with the fundamental interests of hospitals and healthcare providers;
- Prioritize single-use device reprocessing and remanufacturing as a key supply chain strategy for hospitals and healthcare providers;
- Promote an environment of transparency and fairness in interactions with hospital partners; and
- Maximize the value of remanufacturing in healthcare to increase quality, reduce costs and waste and improve patient care.



AMDR Representing Industry

- Governing and Standard-Setting Bodies
- Legislation/Regulation



AMDR Representing Industry

- AAMI TIR 30 approved to become a STANDARD
- AAMI STANDARD 98 (under development):

  Cleaning Validation of Health Care Products – Requirements for Development and Validation of a Cleaning Process for Medical Devices

- AMDR representative, voting member, liaison from commercial SUD reprocessing industry to work group.

About Remanufacturing

Benefits of Remanufacturing

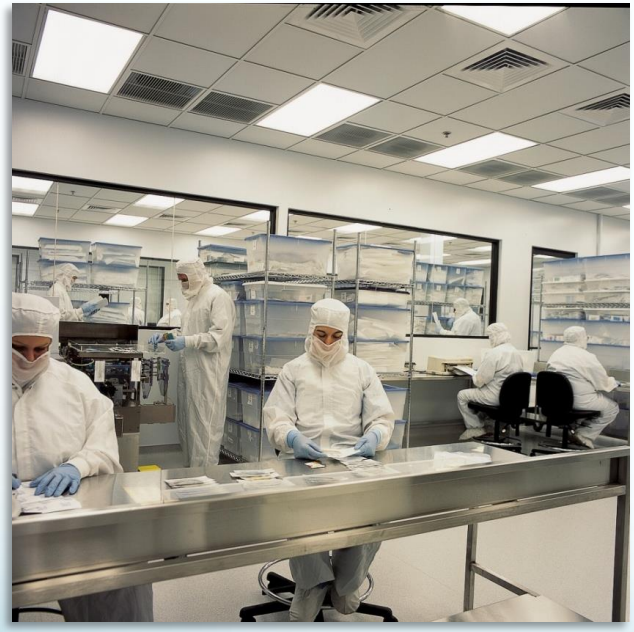


Photo courtesy of Stryker Sustainability Solutions

- By demanding more transparency in the supply chain, controlling manufacturer impact and remanufacturing single-use devices,
- Hospitals and healthcare providers optimize their device utilization,
- Medical device waste and waste disposal costs are reduced, and healthcare becomes more environmentally and financially sustainable,
- So that cost per use and overall supply costs go down,
- And with this more optimized use of devices, hospitals and healthcare providers free up resources allowing them to improve patient care.

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The Single Use Label

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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Commonly Remanufactured 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 and mapping 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

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Sample Remanufactured Device Savings

North America

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

Europe

Cardiac ablation catheter:
- Cost new 900-1500€ (each)
- Cost reprocessed 400-750€
- Savings 500-750€

EP diagnostic catheter:
- Cost new 300-500€ (each)
- Cost reprocessed 140-250€
- Savings 160-250€

Harmonic scalpel:
- Cost new 350-450€ (each)
- Cost reprocessed 180-220€
- Savings 170-230€

Sustainability and Circular Economy

- Single-use medical device remanufacturing is one of the most effective healthcare sustainability strategies available to hospitals and healthcare providers
- It is a strategy that simultaneously reduces the environmental impact from discarding used medical devices, enables hospitals to enhance their financial sustainability, and allows hospitals and healthcare providers to positively contribute to environmental sustainability

Sustainability and Circular Economy

- American Nursing Association, Association of periOperative Registered Nurses, Practice Greenhealth and Health Care Without Harm have all recognized or endorsed reprocessing (remanufacturing) 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)
- On average, hospitals can reduce annual medical waste by 50,000 pounds. This is the equivalent weight of more than 5 elephants.

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Remanufacturing in North America

Industry Acceptance

- FDA regulation in 2000
- 2 positive GAO reports
- OEMs buy remanufacturers
- Spurious “Patient safety” arguments no longer the mainstream battle cry
- Shifting market trends and the ACA

Market Adoption

- Since FDA's intervention in the practice of remanufacturing, tight regulation and the GAO reports, more and more hospitals have adopted remanufacturing as a key financial and environmental sustainability strategy
- Most reputable hospitals have extensive remanufacturing programs – they rely on remanufacturing to use the newest technologies and reach high patient care standards
- 94% the top *US News & World Report* "Honor Roll" hospitals use remanufacturing – some of them promoting their dedication to patient care by pointing to their reprocessing programs

MAYO CLINIC

Cleveland Clinic

BEST HOSPITALS U.S.News & WORLD REPORT RANKINGS

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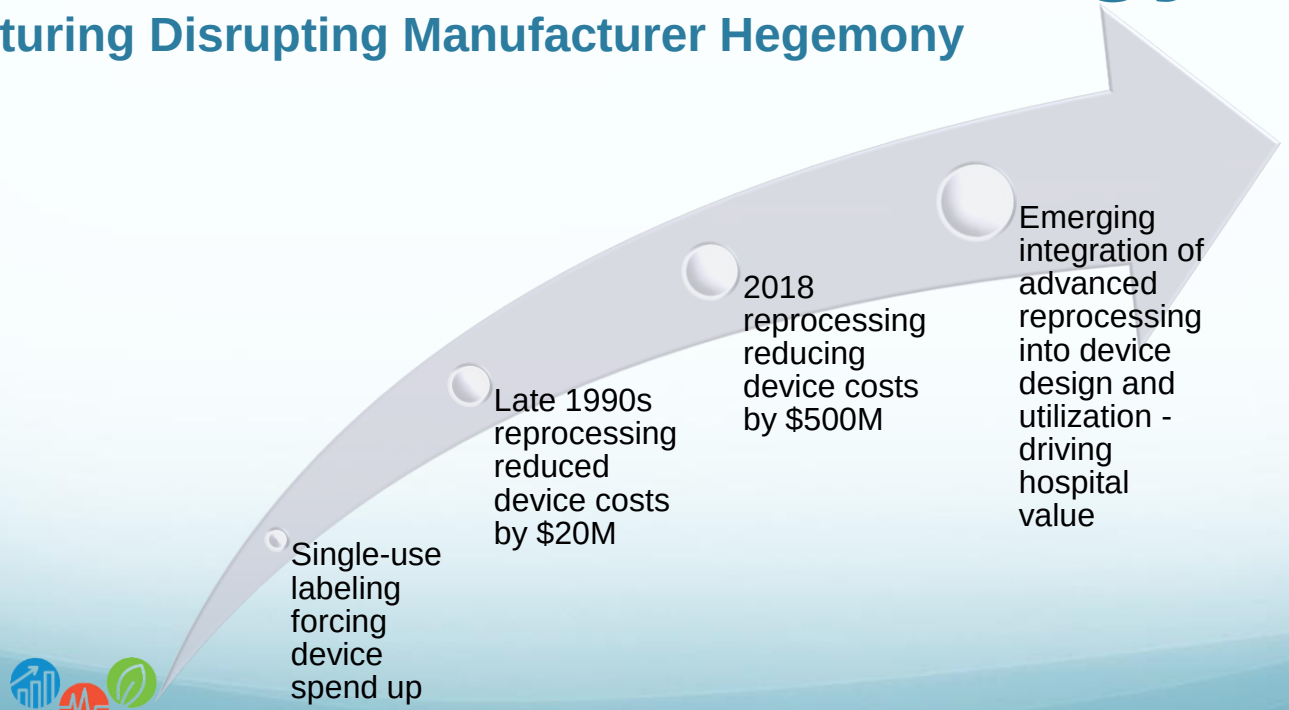
Towards a Paradigm of Value-Based Medical technology

Remanufacturing Disrupting Manufacturer Hegemony



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Scientific Literature

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Hospital and Clinical Support

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Safety

- Commercial remanufacturing is a highly regulated -- equivalent to or greater than other medical device manufacturing
- Remanufactured single-use devices are as safe and effective as new devices. FDA's and EU's review processes ensure that remanufactured devices are as clean, sterile and functional as the original device
- OEMs continue to spread fear and confusion among clinicians regarding the safety of remanufactured single-use medical devices
- Some clinicians continue to believe that patient care is better when using OEM devices – better safe than sorry

Photo courtesy of Medline Renewal

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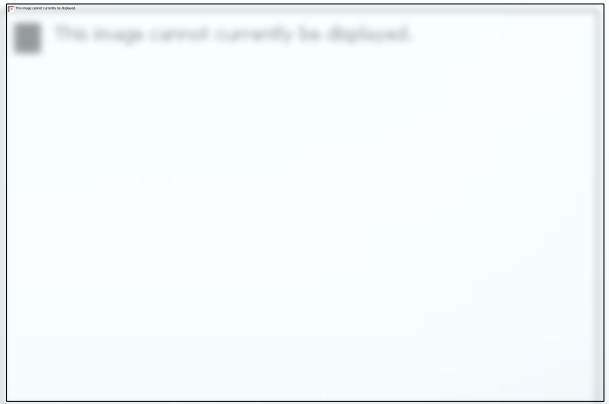
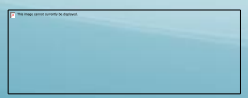
Safety

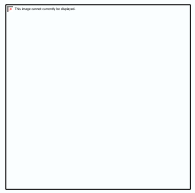
- Meanwhile, cleaning, validation and testing requirements render remanufactured devices arguably safer than original devices
- Current data about failure rates and safety are published by FDA and show that remanufactured devices do not fail more frequently than new devices
- In fact, a recent independent Banner Health study about remanufacturing safety (published in the *Journal of Medical Devices*) showed that original devices have a defect rate that is 4.9 times *greater* than reprocessed devices*





Safety

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

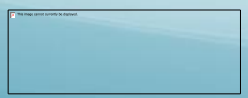


2008 US GAO Report

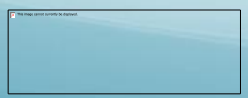
"we found no reason to question FDA's analysis indicating that *no causative link has been established between reported injuries or deaths and reprocessed SUDs."*

March 19, 2008 "Hospitals Reuse Medical Devices to Lower Costs

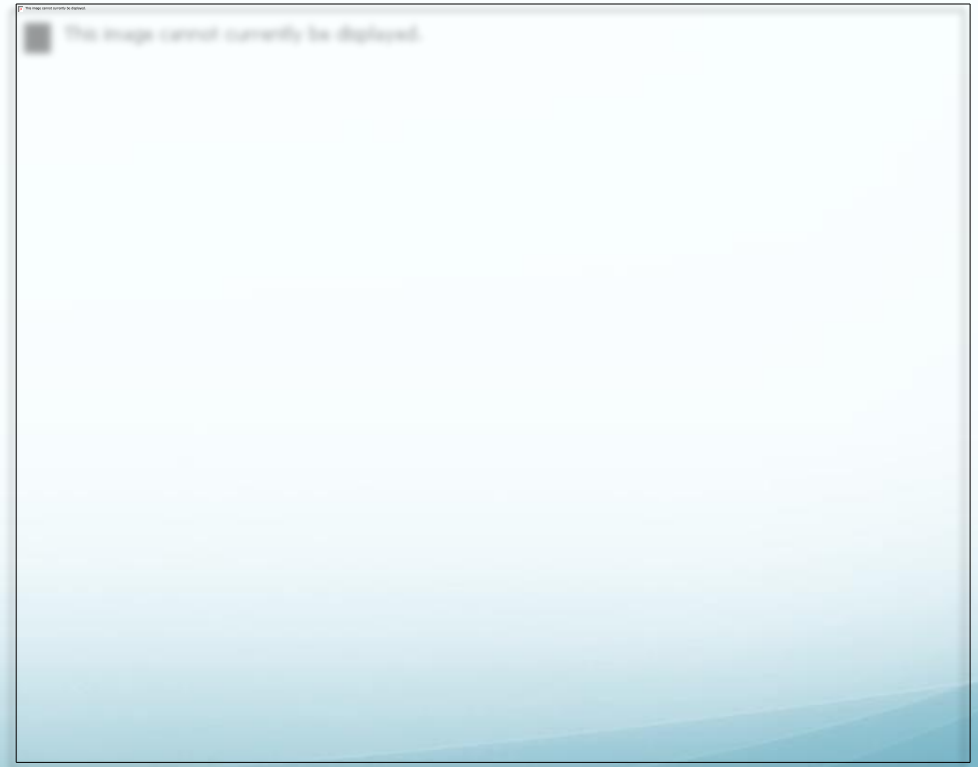
"In January, after reviewing eight years of FDA data, the Government Accountability Office weighed in with a report concluding there is no evidence that reprocessed single-use devices create an elevated health risk for patients." –

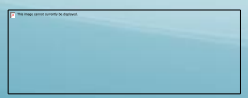


International Regulation



Global Harmonized Approach Emerging

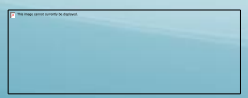




Global Harmonized Approach Emerging

Manufacturer standard for SUD reprocessing (re-manufacturing)

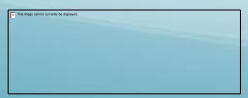
- US FDA – 2000
- Germany - 2002
- Australia – 2011
- Canada – 2015
- United Kingdom - 2016
- World Health Organization – 2016
- European Union – 2017
- Japan - 2017



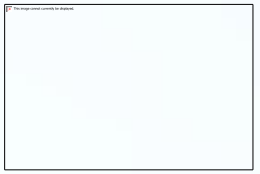
United Kingdom

Medicines & Healthcare Products Regulatory Agency, *Single-Use Medical Devices: UK Guidance on Re-Manufacturing (October 2016)*

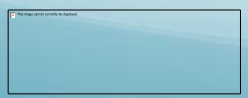
- Prohibits SUD reprocessing
- 2016 Guidance allows SUD remanufacturing
- Remanufactured SUDs must obtain CE mark
- Consistent with EU MDR - so “opting in”



European Regulations



- Historically, no SUD reprocessing policy has existed 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



NEW European Regulations

- 17.1 - Where permitted by national law
- 17.2 - **SUD reprocessing is manufacturing**
- 17.3 - MS may decide NOT to apply certain rules to reprocessing (for hospital and closed loop reprocessing) and outlines lengthy requirements
- 17.4 - Reprocessing by service provider allowed
- 17.5 - **Common specifications** to be developed
- 17.6 - Only devices put on EU market
- 17.7 - Only safe reprocessing
- 17.8 - Reprocessor must label with their name

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European Regulations

- Common Specifications – under development now
- Member States and AMDR believes likely opt in:
  - UK
  - Germany
  - Portugal
  - Netherlands
  - Belgium
  - Others to follow

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NEW European Regulations

- Ensures doctors and nurses have consistent, safe and effective reprocessed or remanufactured SUDs
- Stops inappropriate hospital reuse
- Legitimizes commercial industry through EU-wide regulation
- Uses existing process of accreditation through notified bodies
- Levels the regulatory playing field
- Encourages adoption of green medical device usage
- Promotes competition – lower pricing

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European Regulations

- Unfortunately, not the harmonized approach AMDR had sought
- “Opt in” undermines the “single market”
- Stricter requirements for SUD reprocessors = higher regulatory burden than OEM devices
- MS “service” model:
  - Likely similar to existing German requirements
  - MDR requirements still exceed what hospitals can likely meet: Notified Body certification, reverse engineering, quality system, plus forthcoming common specifications, etc.
  - AMDR discourages MS from allowing in-hospital, lesser regulated reprocessing

European Regulations

Next Steps:

- Ministries need to act to allow remanufactured SUDs (CE marked)
- Common specifications likely NOT a common approach to allowing reprocesing
- Hospitals and healthcare professionals need to urge Ministries to act – soon
- Pressure medical device sales reps for reprocessed/remanufactured options

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Thank you

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