SAMED Position: Reuse of SUDs

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south african medical device industry association

advancing innovation responsibly

What We Will Cover

- SAMED - who we are and what we do
- Definition of single-use device
- Overview of single-use device reprocessing
- Overview of SA and other countries' regulatory frameworks
- Adverse events
- Product liability litigation
- Further considerations
- SAMED's position on SUDs

SAMED – Who we are and what we do

- Established 1985, grown significantly in recent years
- Represent interests of medical device and IVD industry
- 151 member companies, 4 associations, 14 associate members
- The majority of medical device companies in South Africa are small to medium in size
- Engage public and private stakeholders and work towards benchmarking professional conduct for its members
- SAMED members must comply with The Medical Device Code of Ethical Marketing and Business Practice

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Definition of Single-Use Device?

- Common definition: Single-use devices (SUDs) are designed and manufactured for single use and are intended by the original manufacturer to be disposed of permanently after use
- 9 Dec 2016 SA Med dev and IVD regs: "single use" in terms of a medical device means one use of a medical device on an individual …during a single procedure and then the medical device or IVD is disposed of and is not reprocessed and not used again;

What is Single-Use Device Reprocessing?

- Single-use device (SUD) reprocessing describes the operation of preparing a device, which was intended by the manufacturer for a single patient during a single medical procedure, for reuse
  - Steps include cleaning, decontamination, sterilization, functional testing, repackaging, and relabeling
- Practice is commonplace worldwide
  - Often occurs in an unregulated manner outside the U.S.
  - Has become the norm in Africa and Asia
- Practice is conducted by hospitals and third parties
- In the U.S., reprocessed SUDs are generally non-invasive or minimally invasive
  - Examples include compression sleeves, orthopedic blades, scissors, surgical gowns, and cardiac catheters

Breaking Down the "Single Use" Label

- Original manufacturers have discretion to label a device for "single use," or intended for a single patient during a single procedure
  - Often cite safety reasons
  - May also mean the original manufacturer has chosen not to conduct the additional studies necessary to demonstrate that the product can be reprocessed at the hospital level
  - Labeling does not mean that a device is incapable of being safely reused under certain circumstances
- The "single use" label may be motivated by economic reasons
  - Original manufacturers want to sell more devices

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Crux of the SUD Reprocessing Controversy

- Practice saves money and curbs medical waste – but does it jeopardize safety?
  - Reprocessed SUDs cost about half as much as new SUDs
  - They divert millions of pounds of waste from landfills each year
  - But what of the cost that comes with potential risks?
- Reprocessed SUDs pose many potential risks to patients
  - Cleaning and decontamination can be difficult
  - Residues from chemical decontamination agents can linger
  - Sterilization process can materially alter a device
  - Each cycle of reuse can increase risk of mechanical failure
  - Endotoxins can be released when bacteria break down
  - Cross contamination and hospital-acquired infections are more likely to occur

U.S. Regulatory Framework: Present Status

- Third parties and hospitals that reprocess SUDs must comply with all the regulatory requirements currently applicable to original manufacturers – and more
  - Registering reprocessing firms and listing all products
  - Submitting adverse event reports
  - Tracking devices whose failure could have serious outcomes
  - Correcting or removing from the market unsafe devices
  - Meeting manufacturing and labeling requirements
  - Submitting documents for premarket notification or approval
    - FDA regulation depends on traditional CFR device classification scheme (i.e., class I, class II, and class III)
    - For specific reprocessed SUDs, premarket review has additional requirements

EU Regulatory Framework: Patchwork Treatment

- EU does not currently regulate SUD reprocessing
  - In 1993, EU Parliament recognized practice as an issue needing additional clarification
  - In 2010, EU Commission issued a report highlighting the risks of unregulated device reprocessing
  - Proposal is under EU consideration
    - Would compel SUD reprocessors to adhere to the regulatory obligations incumbent on original manufacturers
- EU Member States treat SUD reprocessing differently
  - Germany regulates practice
  - France discourages practice
  - Spain prohibits practice
  - Most Member States do not have specific regulations

Other Countries: Different Stages of Regulation

- Reprocessed SUDs are known to be commonplace in Japan, South Korea, and India
- Canada has a new regulatory framework for reprocessed SUDs that will go into effect September 2016
- In Saudi Arabia and Israel, devices may be marketed and imported if approved in the U.S., including reprocessed SUDs
- Australia has an established regulatory framework for reprocessed SUDs that began in 2003
- African and Asian countries do not regulate reprocessed SUDs
- **South Africa:** MRA industry workshop 26 July 2016, Dr Gouws: indicated parliament has debated this and reprocessing of single use devices will not be allowed

What is an Adverse Event?

- An adverse event is any undesirable experience associated with the use of a medical product in a patient
- "Serious" adverse events include death, life-threatening injury, hospitalization, disability or permanent damage, birth defect, and necessary medical or surgical intervention
- SA med device regs clause 17: suppliers and users must report adverse events

Debate Regarding Adverse Events

- Opponents of SUD reprocessing argue that the practice increases the likelihood of adverse events, citing examples from FDA records
  - Electrode from a reused catheter broke off in a patient's heart
  - Resterilized tracheal tube rendered infant patient only capable of taking in food from a tube attached to the stomach
  - Reprocessed SUD impaled a patient's eyeball
- Proponents of SUD reprocessing argue that the practice does not increase the likelihood of adverse events, citing strict FDA regulation
  - Reprocessed SUDs are subject to the same regulatory requirements and meet the same standards as new SUDs
  - Long track records and clinical studies support the safety of reprocessed SUDs

Product Liability Implications: Who is Liable?

- Product liability refers to a manufacturer or distributor being held liable for placing a defective product into market
- Inevitably, some number of reprocessed SUDs will injure patients, just as new SUDs do
- In the U.S., FDA treats SUD reprocessors as manufacturers that must assume full liability and responsibility for SUD reprocessing

Why Original Manufacturers Should Remain Wary

- Original manufacturers may still be held liable for injuries caused by reprocessed SUDs
  - Millions of unmarked reprocessed SUDs that do not adhere to FDA labeling requirements are still in the market
  - Physicians and surgeons may not know or recall whether a SUD has been reprocessed
  - Plaintiffs' lawyers concentrate on "deep pockets"
  - Reprocessors' best defense is to blame the original manufacturers, citing SUDs as defective prior to reprocessing
- In US, only one state, Utah, has adopted legislation to give original manufacturers immunity from product liability claims involving reprocessed SUDs

Further considerations:

- How would you feel if a reprocessed SUD was used on you?
- Did you give informed consent?
- Did you know how it was reprocessed?
- Was the medical aid / patient charged for the re-use?
- Is it ethical or legal?

SAMED's position

- Supports the position of manufacturers that devices marked as single-use may not be reprocessed or re-used
- If a healthcare facility or third party re-processor makes a decision to reprocess a single-use medical device, liability resides with them
- **TAKE NOTE:** The re-use of a single use device may cause serious injury, illness or even death in a patient
- In terms of Med Dev and IVD regs, it is illegal

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Thank you

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