Single-Use Medical Devices

Reuse and Reprocessing
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Presented by: Mario Castaneda
Prepared by: Antonio Hernandez

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“Medical Device” means any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article:

a) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing information for medical or diagnostic purposes by means of *in vitro* examination of specimens derived from the human body; and

b) which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its intended function by such means.

* Global Harmonization Task Force for Medical Device
**Note 1:** The definition of a device for *in vitro* examination includes, for example, reagents, calibrators, sample collection and storage devices, control materials, and related instruments or apparatus. The information provided by such an *in vitro* diagnostic device may be for diagnostic, monitoring or compatibility purposes. In some jurisdictions, some *in vitro* diagnostic devices, including reagents and the like, may be covered by separate regulations.

**Note 2:** Products which may be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:
- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- accessories for medical devices (see Note 3),
- disinfection substances,
- devices incorporating animal and human tissues which may meet the requirements of the above definition but are subject to different controls.

**Note 3:** Accessories intended specifically by manufacturers to be used together with a ‘parent’ medical device to enable that medical device to achieve its intended purpose should be subject to the same GHTF procedures as apply to the medical device itself. For example, an accessory will be classified as though it is a medical device in its own right. This may result in the accessory having a different classification than the ‘parent’ device.

**Note 4:** Components to medical devices are generally controlled through the manufacturer’s quality management system and the conformity assessment procedures for the device. In some jurisdictions, components are included in the definition of a ‘medical device’.
Outline

- Medical Device Definition
- Medical Device Characteristics & Classification
- Reuse of Single-Use Devices (SUD)
- Reprocessing & Risk
- Final Considerations
Medical Devices

- **Characteristics**
  - Efficacy
  - Safety
  - Quality

- **Classification**
  - Risk
  - Four Levels

- **Standards**
  - ISO
  - IEC
  - ITU
  - IEEE
  - IHE
  - AAMI
  - Country Specifics
Medical Devices

- **Single-Use Devices**

- **Multiple-Use Devices**
  - ✓ Life cycle
  - ✓ Reprocessing protocols
  - ✓ Performance evaluation
  - ✓ Maintenance routines
Reuse of Single-Use (SUD) Background

- It is a growing practice
- Due to limited resources
- Limited or no access to devices
- Economic benefit
- Public concern
- Legal and ethic issues
- Policies and standards
- Patient consent
- Minimal evidence of problems does not mean the current practice is safe and effective
Reprocessing of SUD

- Reprocessing is Manufacturing
- Reprocessing is a Regulated activity
- Conducted by third party or hospitals
- SUD are designed and validated for one use
  - Materials selected for one use
  - Biocompatibility ensured for intended environment
  - Validation and performance test limited for the initial failure

- Reprocessor should know materials and manufacturing
- Reprocessor is responsible for adverse events
Risk of Reuse SUD

Technical Issues

- Control of “Raw Materials”
- Design specifications of the device
- Identification of changes to original device
- Unknown effects of cleaning, disinfecting and sterilization
- Validation
- Variation on functionality
- Traceability of reprocessed devices
Risk of Reuse SUD

Operational Issues

- Risk classification of the device
- Reprocessing protocols
- Quality Systems
- Number of reprocessing per device
- Labeling
- Recall and retirements of products
- Risk for patients
- Risk-Benefit of this practice
Final Considerations

- Primary goal is to protect public health
- In most countries Reprocessing of SUD is a regulated activity (manufacturing)
- If there are Reprocessed SUDs, these devices should be as safe and effective as new SUDs
- FDA research shows reprocessing may be feasible, but “IS Difficult” and “Possibly Dangerous”
- Reuse of SUD should consider:
  - Effectiveness, safety and quality of the devices
  - El cost-benefice
  - Risk
- There is available information on Reuse of SUD
“Technology appropriately deployed and used is a contributive factor to equity in health”

A. Hernández - 2004
Thank You

Mahalo

Kiitos

Toda

Grazie

Obrigado

Takk

Gracias

Merci