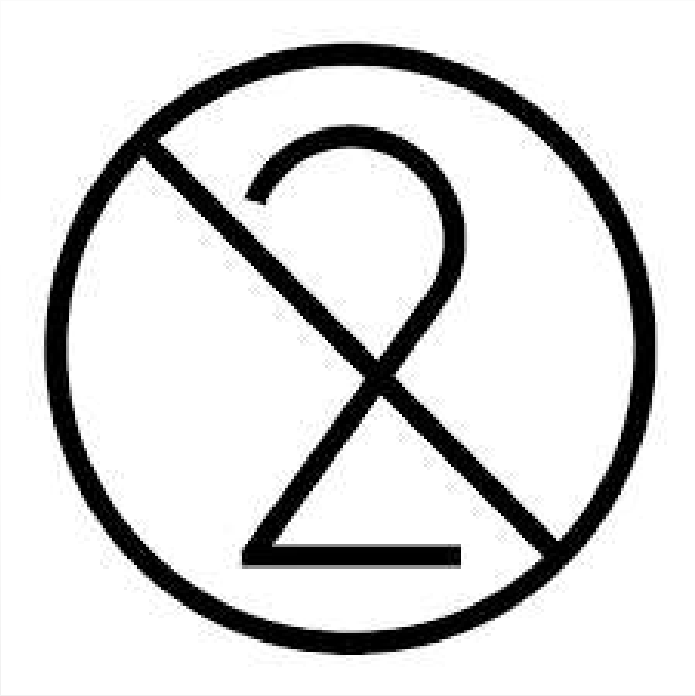
Reprocessing of Single Use Devices

Dr Vijay Samuel Richard

Hospital Infection Control Consultant
Narayana Health

Single use devices



Reasons to reprocess devices

- Cost
- Availability
- Technical / Quality issues with original products of certain companies
- To reduce medical waste

2000 - Guidance on re-use of single use medical devices

Goals of reprocessing

- As safe and effective as a new device
  - Safe from the risk of micro-organisms/endotoxins
  - Free from organic matter
  - Functional integrity – should be able to perform the intended function

In developed countries

- Very strict regulations and monitoring of reprocessing.
- Stringent evaluation and market clearance
- US FDA and US GAO (Government Accountability Office) – regulate and monitor
- Third party re-processing companies – streamlined process, state of the art equipment
- Quality Assurance

AMDR
ASSOCIATION OF MEDICAL DEVICE REPROCESSORS

Australian Government
Department of Health
Therapeutic Goods Administration

Health Canada

Automated washer

Large scale cleaning - high pressure water jets for devices with lumens

The Indian Scenario..

- Currently no strict national guiding/regulatory authority on reprocessing
- Lack of easily accessible and reliable third party re-processing companies
- Individual hospitals reprocess their own devices
  - Lack of sufficient automation – need to rely on manual reprocessing
  - No external regulation on the process
  - Quality Assurance: In-house

India...

- Hospitals do what is best considering the resources available
- Many correct ways to reprocess devices

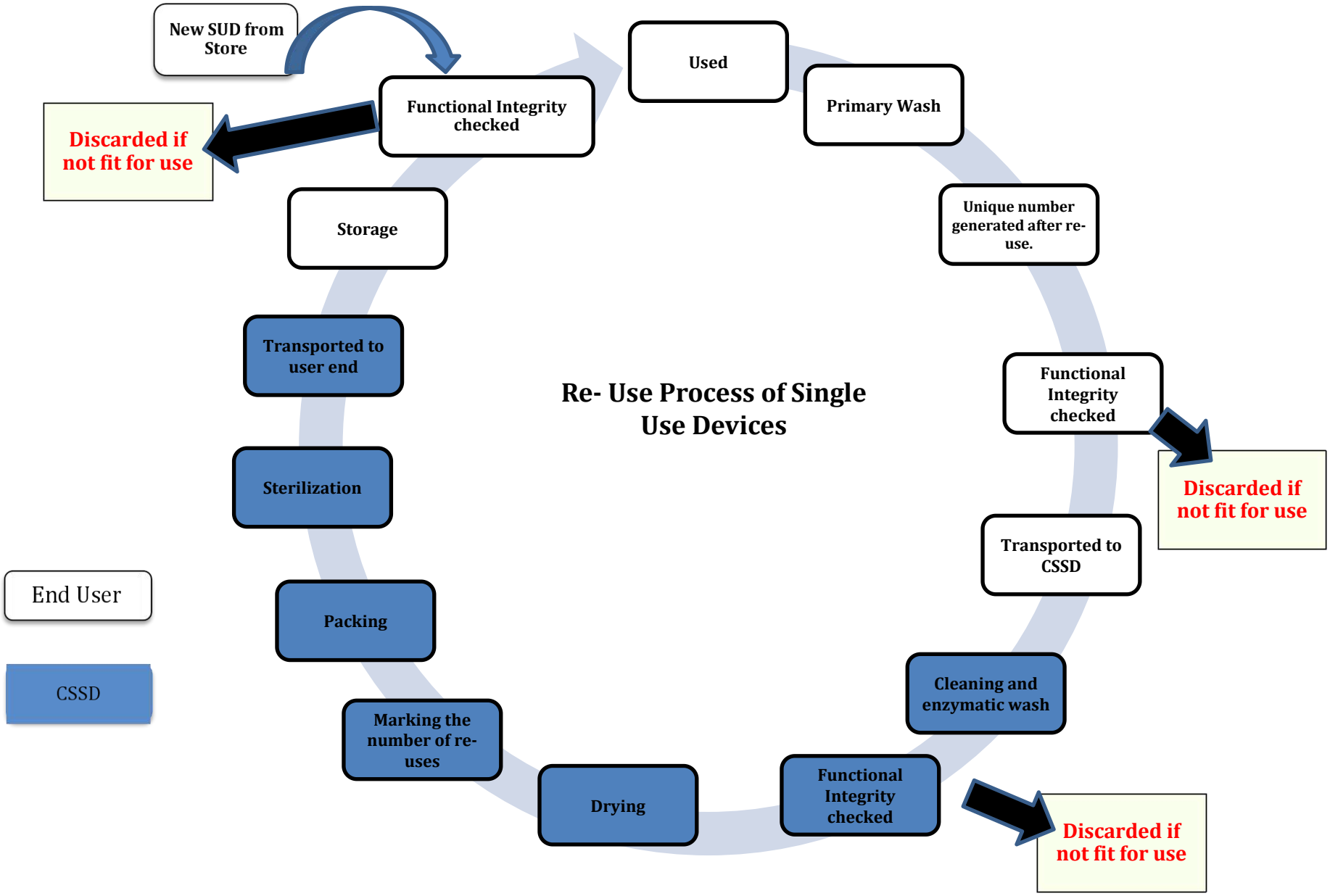
A practical approach

- Committee for re-using SUDs – end users, administration, HIC, CSSD.
- Written protocol – process flow/steps, items, number of re-uses to be defined.
- Training, training and training!
- Adequate space and resources
- Quality assurance including mock recall

Staff safety

- Appropriate protective gear
- Hepatitis B vaccination
- Fire training
- ETO safety

Process Flow – an example



Device used in a procedure or surgery

Preliminary wash

- As soon as possible
- Lumens flushed

An alternative to the automated lumen flushing system

Further cleaning

- Multi-enzyme solution
- Either manually or ultrasound assisted

- Follow recommended dilution and contact time
- **Discard solution after use**

- Rinse thoroughly
- Dry completely – compressed air (medical grade)

Functional integrity check

Packaging

Sterilization → Storage

HOW CAN I PROTECT MY PATIENT?

Ethical issues

- Hospital responsible for reprocessing
- To inform patient about re-used single use devices and obtain consent.
- Patient has a right to refuse re-used single use devices.

Quality Assurance

- Functional Integrity
  - Checked after use
  - Checked prior to packaging
  - Checked before re-use
  - Defective items – discarded
  - Maximum number of re-uses →for each item
  - Not to exceed the agreed number of re-uses.

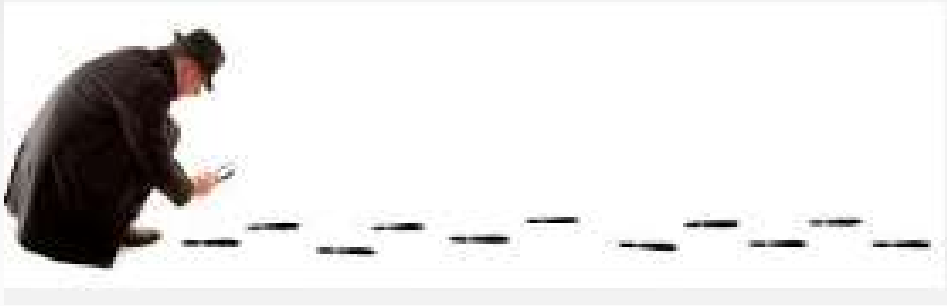
Quality Assurance

- Cleaning – free of organic matter
  - Monitoring of ultrasonic cleaning
  - Objectively check for residual protein – ATP (Adenosine Tri Phosphate) testing

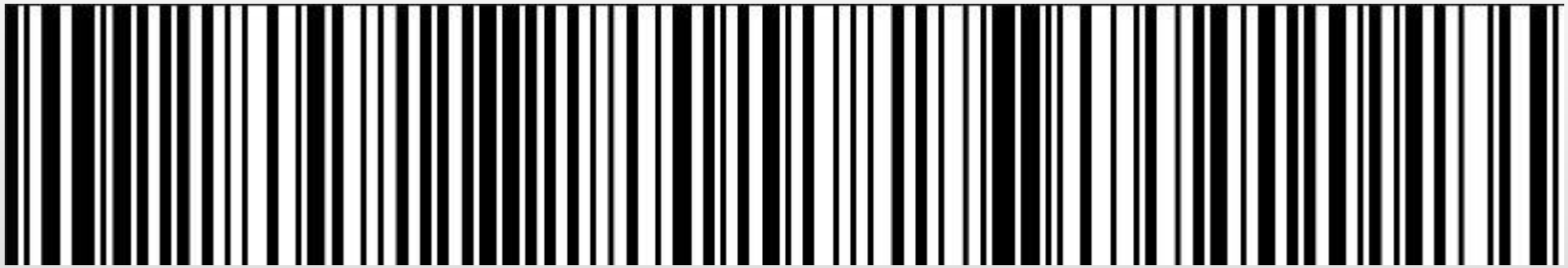
Quality Assurance

- Sterilization
  - Indicators
  - Cultures sent from reprocessed device after storing it for the shelf life.

Tracking reprocessed devices



- Should be able to identify patients in whom the device was used previously
- Manual records vs Barcodes
- Important from the medico legal perspective



Tracking the devices – practical examples

- Differentiate between identical devices
- Tracking the number of re-uses
- Tracking the patients on whom the device was used.

Possible ways forward....

- Government to regulate / legislate
- Hospitals to collaborate and centralize reprocessing
- Third party reprocessing – with accountability
- Input from various academic bodies/societies to frame practical guidelines and protocols

Summary

- Reprocessing single use devices
  - In the West
  - In India
- Practical difficulties faced in India
- Available modalities for quality assurance
- The way forward

References

1. Reprocessing and re-use of single use devices. US FDA, Centre for diseases and radiological health, 2000. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ReprocessingofSingle-UseDevices/ucm121544.htm
2. Monitoring and improving the effectiveness of cleaning medical and surgical devices. Michelle J. Alfa. American Journal of Infection Control 41 (2013) S56-S59.
3. Guidance on reuse of cardio-vascular catheters and devices in India: A consensus document. A.Kapoor et al,. Indian Heart Journal 69 (2017) 357–363.
4. Cardiac Catheters Reprocessing for Limited Resources Hospitals: An Experimental Study. S.S.Rashad et al,. Int.J.Curr.Microbiol.App.Sci (2015) 4(11): 640-649.
5. High-level disinfection, sterilization, and antisepsis: Current issues in reprocessing medical and surgical instruments. Rose Seavey. American Journal of Infection Control 41 (2013) S111-S117.
6. Reuse of single-use devices: Looking back, looking forward. M. Hussain et al., Natl Med J India 2012;25:151–5.

Thank you