Salter Labs

Single Patient Use and Single Use Medical Devices – Risks of Reuse

Single Patient Use

A medical device that is intended for Single Patient Use means that the device may be used for more than one episode of use on one patient only. The packaging for Single Patient Use medical devices must be clearly labeled for "Single Patient Use". The device may be reprocessed between each use as per manufacturer's instructions, for example small volume jet nebulizer and oxygen nasal cannulas.

Single Use Medical Device

A Single Use device is a medical device that is intended to be used on an individual patient during a single procedure and then discarded. The packaging for Single Use medical devices must be clearly labelled with the words "do not reuse" or with the symbol of a '2' in a circle with a line through it. Examples of Single Use devices include disposable laryngoscope blades, CPAP Cannulaide, and Sticky Whiskers. Devices labelled as "Single Use" should not be reprocessed and used again, even on the same patient.

Limited Use Medical Device

A medical device that is intended only for a specified number of uses, the device can be re-processed in accordance with manufactures guidance; for example a reusable laryngeal mask airway (LMA). The number of times each individual item can be reprocessed is documented and appropriate records of reuse are maintained. Controls and monitoring arrangements are to be in place to ensure that the agreed number of reprocessing episodes is not exceeded.

Risks of Reusing a Single Use Device or Using Single-Patient Use Device on Multiple Patients

Medical devices designated for Single Use must not be reused. Medical devices designated for Single Patient Use must not be used on more than one patient. The reuse of Single Use devices or the use of Single Patient Use devices on multiple patients can affect the safety, performance and effectiveness of the device and expose patients and staff to unnecessary risks. Serious incidents related to reuse of Single Use medical devices have been reported. If you reuse a Single Use medical device or use a Single Patient Use device on multiple patients, you may be legally liable for the safe performance of the device.

Reuse of a Single Use medical devices and multiple patient use of a Single Patient Use medical device have been associated with the following risks.

- **Cross-infection**- The inability to clean and disinfect a device due the device design. The design of the device may make it difficult to remove micro-organisms completely or the material used may not be conducive to cleaning, disinfection or sterilization. Therefore, creating a potential risk of micro-organisms being transferred to the next patient.

Single Patient Use and Single Use Device (continued)

- **Endotoxin reaction**- Resulting from excessive bacterial breakdown of a product, which cannot be adequately removed by cleaning or disinfection.
- **Chemical burns or sensitization**- Skin irritation/burn caused from chemical decontamination residues on materials that can absorb/adsorb chemicals.
- **Patient Injury-** Injury caused by device failure from reprocessing or reuse because of fatigue or material alteration.

References

1. The safety of reprocessed medical devices marketed for single use. SCENIHR. 15 Apr 2010.
2. Reuse of single-use devices. Understanding risks and strategies for decision making for health care organizations. Joint Commission International. 2017
3. Single use medical devices: implications and consequences of reuse. MHRA Dec 2018 V2.2.
4. Consumer Protection Act 1987. http://www.legislation.gov.uk/ukpga/1987/43/contents

For most recent revisions of this technical bulletin and other product technical bulletins, visit Salter Labs website. www.salterlabs.com/resources