



International Federation of Perioperative Nurses

IFPN Guideline for Reprocessing of Single-use Devices/Patient Single-use Devices

Introduction:

The ever-escalating cost of medical care, financial limitation and budget cuts have greatly impacted on surgical practices. More and more pressure is placed on practitioners to recycle single use devices to curb costs and decrease expenditure on these items.

However within every country across the globe an increase in litigation has been noted. The cost of which, we cannot ignore. It is therefore important that the perioperative practitioner understands the advantages and disadvantages of reprocessing single-use devices, the legal implications, actual reprocessing protocols and financial impact.

Definition:

Manufacturers may define single-use as:

- a. A device intended by the manufacturer to be used on one patient during one procedure.
- b. The device is not intended for reprocessing or use on another patient at another time, or, the same patient at another time (AORN, 2003).

Statement

Each healthcare facility using single-use devices should have a policy regarding the use and reprocessing of single use devices. Above policies should be developed in accordance with the countries' acts regarding Infection Control, Health and Safety, Sterilization and Disinfection all other relevant legal documents and the manufacturer's guidelines.

Recommendations:

A clear explanation of what "single use" means is very important. The input of the manufacturer when purchasing such an item must be clear and precise. Does it mean "one use only" or does it mean "single patient use"; if labeled "limited use", does it indicate the number of times the item can be reprocessed; and if reprocessing is done by the health facility, does the manufacturer accept liability.

- A cost comparison must be done between the reprocessing of a single use device and re-usables with consideration given to the factors of decontamination,

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disinfection supplies, packaging, labour, water, electricity, storage handling and transport if outsourced, validation and traceability processes.

- All involved in the reprocessing must be well informed on the legal implication as well as risks involved.
- A single-use label on any device means that the manufacturer only guarantees the product for one use.
- Policies and procedures to reprocess single use devices must be in place.
- Staff must be trained, in decontamination and disinfection processes and display knowledge and skills in this field.
- Appropriate equipment, supplies and enough time must be allowed for reprocessing.
- The manufacturer cannot guarantee the safety, functionality and sterility of an item if reprocessing takes place - Most manufacturers liability does not apply if an item is reprocessed.
- Reprocessing may impair performance of an item and increases the risk of infection.
- Health facility reprocessing single-use devices needs to have proof of validation of sterility and traceability process. The validation process has to include all efforts made to minimize risks as well as a validation of the integrity of the item.
- Single-use devices are designed for one use only; disassembling and cleaning of lumens, shafts and hinges cannot be validated.
- The reuse of a single-use device may place the patient at risk. Therefore, the legal and moral consequences of reusing a single-use device must be considered. If action is brought against a health facility the patient is placed in a very strong legal position, as the "duty of care" will have been breached.
- Health facilities can negotiate with manufacturers to reprocess single-use devices that were accidentally opened or where a procedure was cancelled or where an item has expired.
- Manufacturers will require possession of the original packaging, and an agreement that the facility will be able to validate and take liability for the reprocessing process.
- The consequences of taking responsibility for reprocessing may be very high, it is therefore important that health facilities and users consider the cost and implications "legal and personal" of implementing a policy to reprocess single-use devices.
- The cost of validating each step of the reprocessing process is difficult and carries high risks. A patient would not want their health and safety to be compromised by the use of reprocessed single-use devices.
- If the patient were not informed on the reprocessing of items used, the consent would be made invalid. Healthcare practitioners have a duty to ensure that the safety and risks to the patient in their care is never compromised.
- Reprocessing may lead to a chain reaction between chemical substances used in the process of the first and subsequent sterilization.

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- If a single-use device cannot be cleaned, is cleaned inappropriately, or is damaged during the cleaning process, it should not be used.

References:

- ACORN (2018) Australian College of Perioperative Nurses: **Standards for Perioperative Nursing in Australia.**

- AfPP (2016) Association for Perioperative Practice: Harrogate UK: **Standards and Recommendations for Safe Perioperative Practice.**

- AORN (2019) American Operating Room Nurses Association: Denver USA: **Guidelines for Perioperative Practice.**

- ORNAC (2017) Operating Room Nurses Association of Canada: **Standards for Perioperative Nursing Practice**

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