International Federation of Perioperative Nurses

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

Purpose:

There are many risks to the patient caused by the re-use of single use devices. Re-use can affect the safety of the device, it's performance and effectiveness exposing the patient and reprocessor to unnecessary risk. If critical and semi critical devices must be re-processed, it should be only undertaken by a licensed reprocessor. In this instance, the facility should have an accredited quality system covering cleanliness, sterility, safety and functionality of the reprocessed devices.

Manufacturers may define single use as: A device intended by the manufacturer to be used on one patient during one procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient.

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 labelled "limited use", does it indicate the number of times the item can be reprocessed.

- A cost comparison must be done between the reprocessing of a single use device and reusables with consideration given to the factors of decontamination, 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.
- Each facility using single use devices must have a policy regarding the use and re-processing of single use devices. Local legal situations will be part of the guidance which must be adhered to.
- A single-use label on any device means that the manufacturer only guarantees the product for one use. The recognised international symbol to identify single use devices is a circle with a two inside with a single line crossed through it.
- Policies and procedures to ensure that medical devices designated for single use are never reprocessed, must be in place.
- Staff must be trained, in decontamination and disinfection processes and display knowledge and skills in this field.

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Guidance on the reprocessing of Single use items

Health facilities reprocessing single-use devices need 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 is not informed on the reprocessing of items used, 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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References:

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World Health Organization 2016 **Decontamination and Reprocessing of Medical Devices for Healthcare Facilities**. Accessed at https://apps.who.int/iris/bitstream/handle/10665/250232/9789241549851-eng.pdf?sequence=&isAllowed=y

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