INFECTION PREVENTION AND CONTROL POLICY AND PROCEDURES
Sussex Partnership NHS Foundation Trust (The Trust)

IPC17
SINGLE USE AND SINGLE PATIENT USE MEDICAL DEVICES

INTRODUCTION

Single use medical devices are manufactured to be used on a single occasion and then discarded. They are not designed or manufactured for re-use even on the same service user. The re-use of single use devices is dangerous and has legal implications under the Medical Devices Regulations (2002).

The Medicines and Healthcare Products Regulatory Agency (MHRA) published guidance in 2013 Single-use Medical Devices: Implications and Consequences of Reuse.

The MHRA states that 'to reuse a single-use medical device without considering the consequences……could expose the patient and staff to risks which outweigh the perceived benefits of using the devices.'

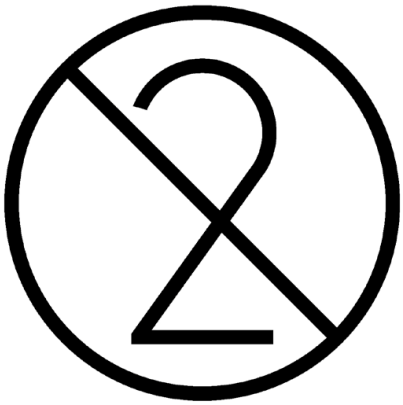
The MHRA advises against the reuse of any single-use medical device.

'MHRA Key points:

- A device designated for 'single-use' must not be reused. It should only be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used again, even on the same patient
- The reuse of a single-use device can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.
- The reuse of single-use devices has legal implications:
    - anyone who reprocesses or reuses a device intended by the manufacturer for use on a single occasion, bears full responsibility for its safety and effectiveness;
    - anyone who reprocesses a single-use device and passes it to a separate legal entity for use has the same legal obligations under the Medical Device Regulations 2002 as the original manufacturer of the device.'

Manufacturers are required to clearly identify single-use devices by displaying a “do not reprocess” symbol as shown below.

Figure 1: “Do not reprocess” symbol



See Appendix 1 MHRA Single-Use Medical Devices Leaflet.

See Appendix 2 MHRA Single-Use Medical Devices and Package Symbols.

TECHNICAL ISSUES

Reprocessing single-use devices may affect the capabilities and / or the materials from which the device is made.

Many single use devices are unable to withstand the decontamination and sterilization processes used in health care.

The manufacturer will provide a warranty for a medical device made for reuse if the recommended reprocessing is carried out. If a single use item is reprocessed, the manufacturer’s warranty will not apply and the re-processor will take on this responsibility

PROBLEMS ASSOCIATED WITH RE-PROCESSING

INADEQUATE CLEANING AND DECONTAMINATION

the cleaning process must be able to access all parts of the device to enable complete decontamination, the cleaning agents must be completely removed at the end of the process and this process must be validated by the processor. Many single-use devices have inaccessible angles and narrow lumens making cleaning and validation impossible

MATERIAL ALTERATION

Exposure to chemicals and other processes may cause corrosion or alteration of the device materials making it unsafe to use e.g. plastics may become brittle and break during subsequent use.

MECHANICAL FAILURE

Some devices if repeatedly processed may over time become stressed and fail or break in use e.g. single-use drills, burrs and blades, etc.

POTENTIAL FOR CROSS INFECTION

Cross infection is a major risk associated with the re-use of single-use items due to failure to clean, decontaminate, disinfect or sterilize adequately.

REACTIONS TO ENDOTOXINS

These are residues of bacteria which withstand exposure to heat and chemicals and may remain after re-processing and sterilization. The sterilization process may not inactivate the toxins even when cleaning and sterilization is effective in killing the bacteria.

RESIDUES FROM CHEMICAL DECONTAMINATION AGENTS

Some materials used in the device's manufacture may absorb the chemicals used in the decontamination process resulting in chemical burns or sensitization of the patient.

Reprocessing a medical device designed or designated as single use requires the device to undergo an extensive validation process to ensure that it is safe to reuse. The majority of organisations do not have the finances or the facilities to carry out this process as the re-use of these devices is likely to carry a significant risk.

PRION DISEASE (INCLUDING CJD)

The abnormal proteins associated with prion diseases are highly resistant to conventional methods of decontamination and sterilization. It is therefore an even greater risk to reprocess equipment that may have been exposed to patients known or suspected of being infected with this agent. See policy for Infections with Specific Alert Organisms for further information.

CONCLUSION

To re-use a single-use device without considering the consequences to the organisation, the professional and the patient could expose each or all of these individuals to significant levels of risk both personal and financial.

Single-use items will not have any reprocessing instructions. The user must therefore contact the manufacturer to determine the most appropriate method of decontaminating the device prior to it being returned to the manufacturer for investigation. It is not acceptable to re-process single use items – to re-use a single-use device without considering the consequences to the Trust, the professional or the patient could expose each or all of these individuals to significant levels of risk. This Trust will not condone the reprocessing of designated single use medical devices and would not support any member of staff who undertakes this procedure.

THE USE AND RE-PROCESSING OF SINGLE PATIENT USE DEVICES

There are a number of medical devices that are manufactured for limited re-use by the individual to whom they are initially supplied. The majority of these devices are non-invasive and do not require sophisticated reprocessing to ensure they are safe for re-use.

It is essential that when these devices are re-used there are written manufacturer's guidelines available for their use, cleaning, decontamination and disposal. **All staff should have access to manufacturer's guidelines which must be retained in a suitable folder/ location.**

Professional staff who use or supply these devices to patients must understand the requirements for safe use, decontamination between uses and disposal.

TYPES OF SINGLE PATIENT USE DEVICES

PATIENT SELF-ADMINISTERED INTERMITTENT URINARY CATHETERS

These are issued to an individual patient for their own use. They should be washed under running water after each use and stored clean and dry. Each catheter should be replaced according to the manufacturer's instructions or at least once a week, sooner if damaged. If used by a healthcare professional on behalf of the patient they must be treated as single use items and disposed of after a single use.

FACE MASKS FOR OXYGEN ADMINISTRATION

These items should be kept with the individual patient, particularly if the oxygen cylinder is shared. The facemask should be washed daily, and if soiled, with warm water and detergent, dried and stored dry. The mask should be replaced weekly. Tubing must also be single patient use, changed if wet and replaced weekly.

FEEDING SYRINGES FOR PATIENT WITH WELL-ESTABLISHED PEG FEEDING TUBES

Specific oral syringes are manufactured for use with PEG feeding tubes e.g Baxa syringes. They are supplied as a clean not sterile product. Some are classed as single use only and others for limited re-use on the same patient. Staff must ensure they are not re-using single use syringes when they display a single use symbol (as above). If appropriate for re-use, manufacturers' guidelines must be followed. Alternatively, they should be thoroughly cleaned after each use with warm water and detergent, rinsed in running water, shaken to remove water particles from the barrel of the syringe and dried externally with disposable paper towels prior to storing in a dry, covered container e.g. plastic food container with lid. These are for use by an individual patient, and must be replaced daily (or in accordance with manufacturers' instructions).

Single use disposable syringes are NOT appropriate for use with PEG feeding tubes. If used, they must be disposed of after a single use.

Newly inserted PEG feeding tubes are classed as surgical wounds and thus feeding syringes should be used once only and discarded after single use until such time as the stoma is healed.

NEBULISERS

These items should be kept with the individual patient. The nebuliser should be rinsed after each use with warm water ONLY (no detergent), shaken to remove water particles and drug residues and then dried with disposable paper towels and stored dry in a clean, dry, covered container. The nebuliser should be replaced weekly provided it maintains its efficacy or as per manufacturer's instructions. A label can be attached to the storage container indicating the date for change. Masks (if used) should be decontaminated as above.

PLACEBO INHALERS (FOR PRESCRIBED INHALED THERAPY)

Currently there is no evidence upon which to base local protocols for decontamination of these devices, when a mouthpiece cannot be used, therefore manufacturer's instructions must be followed. Ideally, devices that can be fitted with a disposable mouthpiece should be used.

Where these products are in use, guidance should be sought from the local respiratory nurse or clinician who prescribed the device. As a minimum, patients with a known or suspected respiratory infection should not use communal inhalers.

Appropriate methods of decontamination (in the absence of manufacturer's guidance) include: thorough washing with liquid detergent and warm water followed by shaking to remove water particles and drying with paper towels. In addition, disinfecting in a freshly prepared solution of sodium hypochlorite (1,000 ppm) followed by rinsing under running water, shaking to remove water particles and then drying with paper towels can be undertaken after initial washing in detergent.

OTHER ITEMS

There may be other items that can be designated single patient use. Each of these must have written guidelines for use, decontamination and frequency of replacement, preferably supplied by the manufacturer.