

POLICY FOR 'SINGLE-USE' MEDICAL DEVICES

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1. Introduction

A single-use Medical Device 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.

This symbol is used on medical device packaging indicating 'do not reuse' and may replace any wording.



2. Aim of the policy

The aim of this policy is to set out the implications of improper use of single-use medical devices. The policy defines a 'single-use Medical Device' and informs staff that a Medical Device designated for 'single-use' must not be reused.

The reuse of single-use devices can affect their safety, performance and effectiveness, exposing patients and staff to unnecessary risk.

The reuse of single-use medical 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 Devices Regulations 2002 as the original manufacturer of the device

3. Key objectives

It is the responsibility of managers and supervisors to ensure that all staff are aware of the correct use of single-use medical devices.

It is the responsibility of staff to ensure they follow the requirements detailed in this policy.

4. Policy scope

This policy applies to all NHS Lothian employees.

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5. Evidence Base

The Medicines and Healthcare products Regulatory Agency (MHRA) provide detailed advice in 'Single-use Medical Devices: Implications and Consequences of Reuse' DB 2006(04) v2.0 (Re-issued in Dec. 2011).

6. Key Definitions

Medical device – Any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, together with any accessories, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of conception

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Single-use – The medical device is intended to be used on an individual patient during a single procedure and then discarded. It is not intended to be reprocessed and used on another patient.

This symbol is used on medical device packaging indicating 'do not reuse' and may replace any wording.



Some single-use devices are marketed as non-sterile which require processing to make them sterile and ready for use. The manufacturer of the device will include appropriate processing instructions to make it ready for use.

Single-patient use - The medical device may be used for more than one episode of use on one patient only. The device may undergo some form of reprocessing between each use (as defined and specified by the manufacturer).

7. References

Single-use Medical Devices: Implications and Consequences of Reuse DB 2006(04) v2.0 (Re-issued in Dec. 2011)