

Single use statement



Statement 27/03/2007

What does 'single use' mean?

The official definition of the single-use symbol given in EN 980 is 'Do not reuse'. For medical devices, it is also generally accepted that single use means 'for use on a single patient'. Guidance from the MHRA suggests that single use devices should only be used for a single procedure, however the term 'procedure' is not defined.

What does 'reuse' mean?

Reuse is another episode of use, or repeated episodes of use, for a medical device which has undergone some form of reprocessing between each episode.

What does 'reprocessing' mean?

Reprocessing is making a used device suitable for reuse by cleaning, disinfection, decontamination, sterilisation, refurbishment, or repacking.

Single use medical devices - summary

- for use on a single patient
- must not be reprocessed

Single patient medical devices

Some medical devices may be described as 'single patient'. This is not the same as single use. The term 'single patient' may be applied to products which may require reprocessing if they are used more than once. The method of reprocessing will be described in the instructions for use.

None of the above – repeated use

Some medical devices, such as breathing systems and carbon dioxide absorbent products, may not fall within any of the above categories if they are:

- not single-use or single-patient, as they can be used on more than one patient
- not reusable, as they cannot be reprocessed

These products can be used repeatedly on several patients, if a suitably validated single use respiratory filter is used between the product and each patient.



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