

Devices designated as Single Use by the Do Not Reuse symbol should only be used on a single patient during a single procedure and then discarded.

A Single Use device should not be reprocessed and used again, even on the same patient because there are risks associated with this reuse, for example: the device design may be such that thorough decontamination and/or resterilisation is not possible, or reprocessing may alter the device characteristics so that it fails to satisfy the original specification, performance and/or intended function.

Single Use devices lack the evidence, test data or validation required to confirm their safety and performance if reused. The potential risks of reuse include:

Potential for Cross Infection

The risk of cross infection may be increased due to reprocessing procedures being unable to completely remove viable micro-organisms, which can remain on the device and be transferred to the next patient/user. Design features such as narrow lumens, the type of material used in the device (e.g. heat sensitive materials), etc. may contribute to this risk.

Inability to adequately Clean and Decontaminate the Device

Cleaning processes need to be validated to ensure that they consistently provide results that comply with predetermined specifications; cleaning processes must access all parts of a device to allow complete decontamination and all cleaning agents need to be completely removed at the end of the cleaning process. Design features such as acute angles, coils, long or narrow lumens, specialist surface coatings, etc. may make cleaning difficult and make it not possible to validate a cleaning process.

Residues from Chemical Decontamination Agents

Some materials used in device manufacture can absorb or adsorb certain chemicals, which can then gradually leach from the material over time and cause a reaction in the patient or user. For example, disinfectants like glutaraldehyde may be absorbed by plastics and leach out during use, resulting in chemical burns or a risk of sensitisation.

Material Alteration

Exposure to chemical agents, such as cleaning and decontamination agents and chemical sterilants, can damage some devices. Such agents may cause corrosion and/or changes in the materials of the device. Exposure to elevated temperatures or pressure during sterilisation processes may also alter the device properties or cause degradation of the device material, for example, plastics may soften, crack or become brittle.

Mechanical Failure

Some devices may experience stress during each cycle of reuse and/or during repeated reprocessing and these stresses may lead to fatigue-induced failure and fracturing.

Reaction to Endotoxins

Endotoxins are Gram-negative bacterial breakdown products that can be a significant problem if the device has a heavy bacterial load after use which cannot be adequately removed by cleaning; even if they have been effective in killing the bacteria, the decontamination and sterilisation processes cannot inactivate these toxins.

Prion diseases

The abnormal proteins associated with prion diseases, e.g. Creutzfeldt-Jacob disease (CJD) and variant-CJD (v-CJD), are very resistant to all conventional methods of decontamination and in order to reduce the risk of transmission of prion proteins during surgical procedures, the Department of Health has issued advice (Health Service Circular 1999/178) which states that 'devices designated for single use must not be reused under any circumstances whatsoever'.