Position Paper

Medical Device Reprocessing Requirements

Manufacturer responsibilities and operator responsibilities

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German Electrical and Electronic Manufacturers´ Association

Background

With a population of 81 million people, Germany has an estimated one million cases of healthcare-associated infections annually. The annual number of deaths resulting from these infections alone is put at 40,000 (DGKH [German Society for Hospital Hygiene] estimates). The figures show the great importance of proper hygiene in hospitals and community healthcare facilities. Medical devices for multiple reuse at different patients are always associated with a high risk of contamination with a variety of pathogens. This imposes responsibilities on medical device operators and manufacturers alike.

Discounting single-use devices, ZVEI member companies primarily market medical devices containing electronic parts. Due to their sensitivity and complex design, these devices pose a special challenge in terms of reprocessing. Manufacturers address this by providing suitable instructions and information to operators.

Requirements pertaining to cleaning, disinfection and sterilisation are increasingly being directed at manufacturers - in calls for tenders, for instance - which manufacturers are unable to meet in full or at all.

This document shows the extent and the limits of the support electromedical device manufacturers can provide to device operators. The document is based on the legal requirements directed both at operators and manufacturers. Electromedical equipment manufacturers have an interest in clarifying and outlining the demarcation of responsibilities between operators and manufacturers.

Requirements

The requirements for operators and manufacturers with regard to medical device reprocessing (cleaning, disinfection, sterilisation) are based on various legal provisions.

Section 4 of the Medical Devices Operator Ordinance (MPBetreibV) requires medical device operators to reprocess medical devices in accordance with the manufacturer's instructions using appropriate validated methods. Compliance with the requirement is assumed if the joint recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute and the Federal Institute for Drugs and Medical Devices (KRINKO-BfArM guideline) is followed.

§ 4 Reprocessing medical devices

(1) Medical devices that are intended for use in an almost sterile or sterile state must be reprocessed using appropriate, validated methods, taking account of the information and instructions provided by the manufacturer, in such a way that the success of these methods is traceable and guaranteed and the safety and health of patients, users and third parties are not endangered. This also applies to medical devices that are disinfected or sterilized prior to first use.

(2) Proper reprocessing as per subsection 1, sentence 1 is assumed if the joint recommendation of the Commission for Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute and of the Federal Institute for Drugs and Medical Devices regarding the hygiene requirements for the reprocessing of medical devices is observed. The reference is published by the Federal Ministry of Health in the Federal Gazette.

(3) ...

This is commonly misinterpreted as meaning that the manufacturer has to validate the operator's preferred method, including the operator's preferred cleaning agents and disinfectants.

Medical device manufacturers are required to comply with the German Medical Devices Act (MPG) and the European Medical Devices Directive (MDD). The MPG requires manufacturers to ensure compliance of their product with the Essential Requirements set forth in the MDD. This includes the obligation to provide information on suitable reprocessing methods in the Instructions for Use (Annex I 13.6 (h)):

"If the device is reusable, information on the appropriate processes to allow reuse, including cleaning, disinfection, packaging and, where appropriate, the method of sterilisation of the device to be resterilised is required, and any restriction on the number of reuses;

Where devices are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilisation must be such that, if correctly followed, the device will still comply with the requirements in section 1; ..."

These requirements are specified in greater detail in DIN EN ISO 17664 "Sterilisation of medical devices - Information to be provided by the manufacturer

for the processing of resterilisable medical devices". This standard also applies if the process ends after disinfection and does not include sterilisation.

How many methods does a manufacturer need to validate?

Section 3 of DIN EN ISO 17664 stipulates that at least one validated method for complete reprocessing needs to be specified. This indicates that a manufacturer can validate several methods but is only obliged to validate a single method. There are a number of recognized methods for each step in reprocessing (cleaning, disinfection, sterilisation). The standard stipulates that one validated manual method has to be specified for cleaning and one for disinfection. The standard calls in addition for a validated automated method unless the medical device is not a suitable candidate for such a method. Methods would include automatic cleaning, immersion disinfection and EtO sterilisation.

Operators are responsible in accordance with the Medical Devices Operator Ordinance and KRINKO-BfArM recommendation to validate their actual reprocessing procedure on site.

What information and instructions does the manufacturer have to provide on the cleaning agent and disinfectant?

Manufacturers are required to validate a cleaning and disinfection method with a specific cleaning agent and disinfectant for their medical device. If the operator uses the same method but with a different cleaning agent or disinfectant, the operator needs to be aware of possible implications in terms of material compatibility.

Medical device manufacturers will usually have tested several agents for material compatibility. The list of approved agents and their ingredients gives an indication of material compatibility with other agents containing the same substances. Operators who use an agent that the manufacturer has not listed are responsible for verifying material compatibility. In this case, the operator is liable for any resultant harm to patients or damage to the medical device.

What information and instructions does the manufacturer have to provide on the sterilisation method, if sterilisation is required?

As already stated, manufacturers are required to validate a method that is effective when used on their medical device. Manufacturers should indicate a number of validated sterilisation methods, if possible. In many cases, a medical device's design and material is not compatible with certain methods. Examples would include thermolabile medical devices or medical devices containing electronic parts. The effectiveness of an additional sterilisation method could in principle be demonstrated during on-site validation. However, there is always a risk of material incompatibility in such cases.

Conclusion

The methods and agents indicated by the manufacturer in the Instructions for Use are tested for effectiveness and material compatibility on the basis of the applicable legal requirements. Operators who deviate from these requirements assume liability for any resultant harm to patients or damage to the medical device. Operators should therefore consult the manufacturer before making any such decision.

Relevant documents

Legal requirements

Operators
Ordinance on the setting up, operation and use of medical devices (Medical Devices Operator Ordinance - MPBetreibV)

Manufacturers
Council Directive 93/42/EEC concerning medical devices (MDD)
Medical Devices Act (MPG)

Standards

Operators
DIN EN 15224 Health care services - Quality management systems. Requirements based on EN ISO 9001; German version EN 15224

Manufacturers
DIN EN ISO 17664 Sterilisation of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664); German version EN ISO 17664

Guidelines

Operators
Hygiene requirements for the reprocessing of medical devices; recommendation of the Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM) - Bundesgesundheitsbl 2012, 55:1244-1310

Hygiene requirements for the cleaning and disinfection of surfaces; recommendation of the Commission on Hospital Hygiene and Infectious Disease Prevention at the Robert Koch Institute (RKI) - Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 2004, 47: 51-61

Relevant documents as of September 2016, as amended.

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