

Hygienic requirements for the reprocessing of medical devices

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Medical devices

- contaminated with pathogens (bacteria, viruses, prions, spores/ *C. difficile*) are a potential risk for infections in patients. This holds especially true for the reuse of all complex medical devices and is not only a matter of the reuse of „single use“ devices.
- Every day, thousands of flexible endoscopes are only manually cleaned and disinfected

Major questions are

- Is it possible to reprocess a medical device properly? If yes:
- Under which conditions (personnel/training, technical prerequisites/validation protocols, equipment) is it possible to reprocess a medical device properly?
- With respect to the prevention of disease transmission, the ability to clean a medical device is the central problem

Consequently: The (re)use of medical devices

- requires adequate (re)processing which has to meet defined specifications.
- Major regulations for manufacturers acting on the european market are
 - - the European Medical Device Directive
 - and
 - - the european standard EN ISO 17664
- The reprocessing of MD by the operator is regulated on a national level

The german Ministry of health asked
the responsible national subordinate
authorities to develop a guideline
concerning the:
Hygienic Requirements for the
reprocessing of medical devices

- > Recommendations by the german
Commission for Hospital Hygiene and
Infection Prevention at the Robert Koch-
Institute and the German Federal Institute
for Drugs and Medical Devices (2001)

National legal regulations

In accordance with §4 of the Medical Devices Operator Ordinance, the cleaning, disinfection and sterilisation of medical devices are to be carried out with **suitable, validated procedures** in a way, that the result is comprehensively guaranteed and the safety and health of patients, users and third parties is not endangered.

The reprocessed device must meet

- its **intended function** to its full extent and
- ensure all **safety relevant requirements** without limitation.

In other words:

The reprocessing procedures have to ensure that further use of the device does not pose any danger of an injury to health, especially in terms of:

- Infections
- pyrogen-related reactions
- allergic reactions
- toxic reactions or
- altered technical or functional properties of the device.

The legal regulations refer to the
state of science and technology.

According to §4 of the (national)
Medical Devices Operator Ordinance
that means to observe

- the National-Guideline (RKI/BfArM)
as well as
- the harmonized (technical) European
Standards (EN)

On the basis of a **risk assessment and classification** of the device, the operator (owner/user) must record

- **whether**
- with which **method** and
- under which **conditions** (e.g. rooms, equipment, personnel qualification)
- medical devices which are operated in his responsibility are reprocessed and stored.

Validation is a precondition for reprocessing

- to prove:
 - the **suitability** (i.e. product compatibility to guarantee for functional and safety relevant properties) and
 - **effectiveness**
 - of the applied reprocessing procedures.
-
- This is usually be done by the manufacturer resulting in data to be provided according to EN ISO 17664

In the context described here,
the parameters defined in the
process of validation are

- the design parameters of the medical device that guarantee technical and functional safety (i.e. suitability of the reprocessing procedure) as well as
- the parameters to guarantee the effective cleaning, disinfection and sterilisation.
- **It has to be considered that the effective cleaning may be impossible
> single use**

Risks emanating from reprocessed medical devices are determined by unintended effects that may result from

- **previous use** (residues, e.g. blood)
- **previous processing** (residues, e.g. disinfectants; alterations in physical, chemical, functional properties)
- **transport and storage** (e.g. mechanical damage).

According to the kind of subsequent use devices can be classified as

- non-critical
 - semi-critical and
 - critical
-
- medical devices
-
- In case of doubt about the correct classification, the device should be classified to the higher risk level.

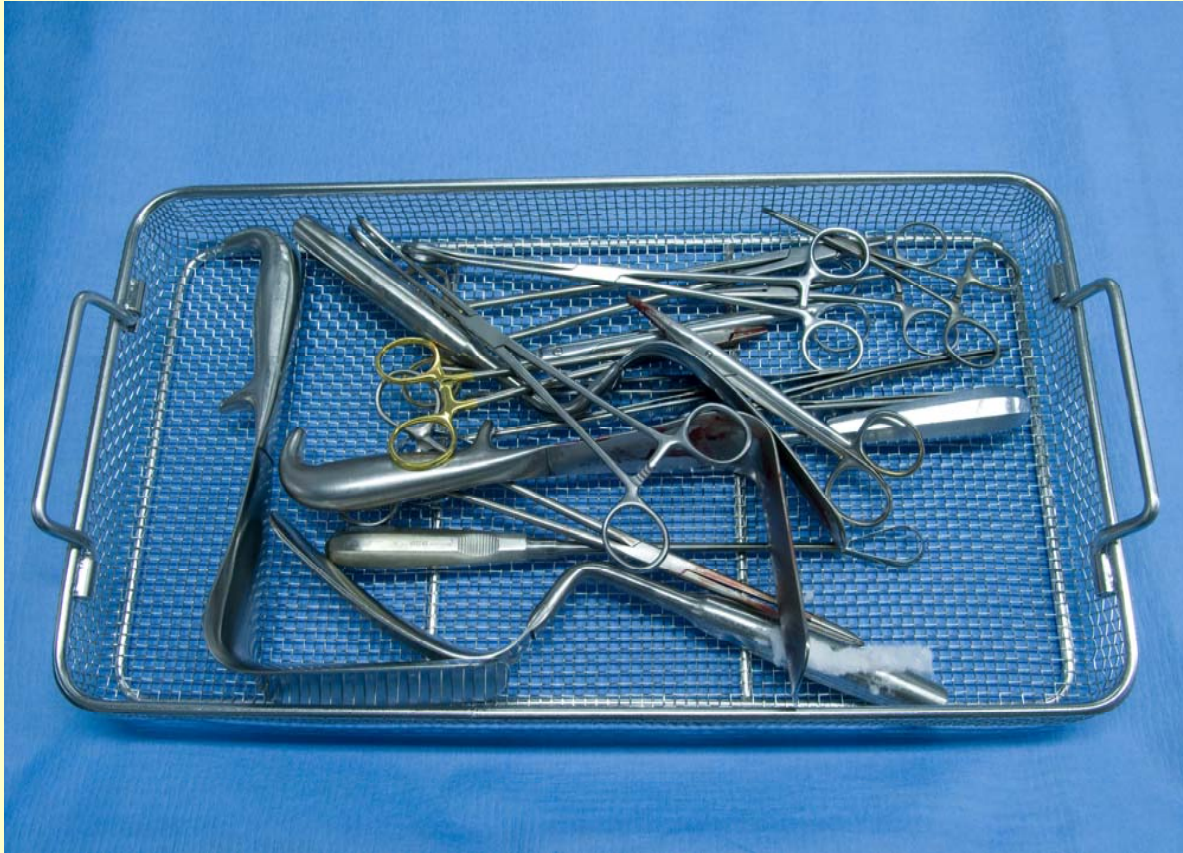
However, structural and material details of the device's design can increase the requirements for proper reprocesing.

- Consequently, it has been necessary to further specify this classification.

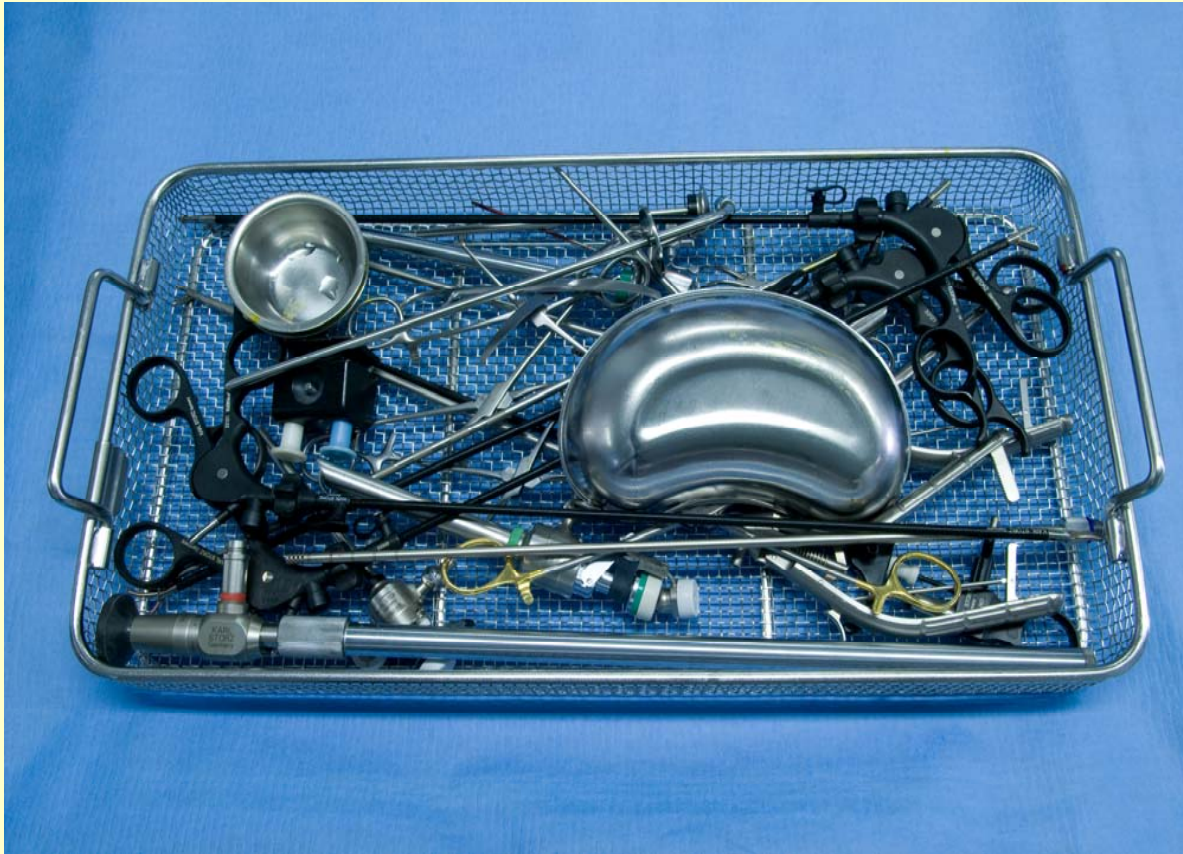
Semi-critical devices and critical devices can be further classified into devices with

- no special requirements (**group A**) or
- increased reprocesing requirements (**group B**).

Medical devices „Critical A“



Medical devices „Critical B“



Critical devices can furthermore classified as those

- for which reprocessing has to meet
especially high requirements (**group C**).

Medical devices with increased requirements for reprocessing are those

- in which the efficiency of the cleaning procedure cannot be directly evaluated by means of inspection (e.g. due to long, narrow lumina), hardly to access and therefore hardly to rinse complex surfaces or
- in which effects of reprocessing on the device (function, material) influencing functional safety cannot be excluded

– or

- In which the number of uses or the number of reprocessing procedures is limited by the manufacturer

Consequently:

- Any device declared for single use is at least classified as a device with increased requirements for reprocessing (group B)

Within the group of critical medical devices with increased requirements for reprocessing (**critical B**) it has to be further distinguished between

- thermostable (i.e. steam sterilizable, 134° C) and
- thermolabile (i.e. devices that can not be sterilized by steam (134° C)) devices.

**The latter group (i.e. critical B
and thermolabile) has to be
classified as critical C**

- i.e. Medical devices with especially high requirements for reprocessing

**The reprocessing of critical devices
with especially high requirements
(critical C)
is subject to external quality control.**

The quality assurance system for the reprocessing of these medical devices shall be **certified** to meet the requirements stated in **DIN EN ISO 13485, 14971, 17664** and those formulated in this (RKI/BfArM) guideline by a **notified body** accredited by the responsible national authority (ZLG).

When performing the risk assessment of the devices to be reprocessed, the critical process steps and potential hazards have to be defined. These are then the basis for measures aimed at the minimisation of risks or the decision not to reprocess the device.

Any deviation from the manufacturer's specifications has to be justified and documented and it has to be insured that

- the functionality to fulfil the purposes of the product and
- the application safety of the reprocessed medical device
- is guaranteed to its full extent.

Confidence is good, control is better.

- The german parliament instructed the 16 german states to implement a system to control/supervise proper reprocessing of medical devices
- (Bundestagsdrucksache 14/7331, 7.11.2001, S.52)

According to § 25 MPG any facility that reprocesses MD for others has to declare this

- The respective declaration is made on forms developed and supported by DIMDI

These „reprocessors“

- are specifically supervised by the responsible local authorities.
- **In case that they reprocess „critical C“ MD, the quality assurance system has to be certified by a notified body taking into account the „RKI-guideline“ and the respective european standards, especially EN ISO 13485, 14971 (and 17664)**

In order to realise unforeseen risks
there is a
Medical device safety plan
(§ 29 MPG, MPSV)

- i.e. a legal regulation to report and register any incident associated with the use of a medical device
- Responsible authority: Federal institute for drugs and medical devices (BfArM) in collaboration with DIMDI (German Institute for MD Information)

Thank You for Your Attention

National (german) authorities with responsibility in the field of medical device reprocessing

- Federal Ministry of health
- German Federal Institute for Drugs and Medical Devices in collaboration with DIMDI (German Institute for Medical Documentation and Information)
- Robert Koch-Institute (Hygienic requirements)
- Ministries of health on the state level (N=16)
- ZLG (Central authority of the states for the accreditation of Notified bodies; §15 MPG)
- Local responsible administrative bodies for the supervision of MD reprocessing