Recommendations by the quality task group (117)

Transport between the site of use and reprocessing department

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Introduction

Increasing centralization of medical device reprocessing is presenting ever greater challenges, especially in logistics. In principle, it must be ensured that transport and storage do not adversely affect the medical device characteristics.

The KRINKO/BfArM Recommendation* underlines the imperative need for a well-established quality management system (QMS) to guarantee consistent and demonstrably high quality.

Sterilized medical devices (MDs) must be protected against contamination when transported between the reprocessing department and the site of use (sterile barrier system); used MDs harbour potentially infectious contaminants against which the environment must be protected (use suitable packaging to transport the used MDs).

Risk assessment must be conducted to determine whether, depending on the storage site, e.g. with direct link to the site of use or external storage, used MDs should be transported in closed or open systems. If the transport routes intersect with public corridors/rooms or other hygiene zones closed transport systems must be used in general. It must be ensured that personnel or third parties are not endangered when **MAKING PROVISION FOR MD TRANSPORTATION**. Occupational health and safety regulations must be observed. Sterilized MDs must be transported separately from non-sterilized MDs to rule out contamination/mix-up.

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The economic operator is responsible for provision of an appropriate means of transport and storage areas (see DIN 58953, Part 8, *Logistics of sterile medical devices*).

DIN 58953 also states that **PERSONNEL ENTRUSTED WITH LOGISTICS** must participate in training at least yearly. In addition to receiving information on hygiene rules, in these training courses logistics staff should be taught how to handle potentially infectious materials, taking account of the Accident Prevention Regulations (UVV). Training records must be kept for all staff members involved in loading the transport containers and trolleys as well as in organizing transport procedures.

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The German Load Handling Regulation (*LasthandhabV*), "Regulation on occupational health and safety requirements for manual handling of loads"), prohibits in general the **HANDLING OF LOADS OF MORE THAN 10 KG**. Only under defined circumstances and in exceptional cases is handling of loads of more than 10 kg permitted (for men of a certain age, see also Hettinger table). The weight of an item to be sterilized is also of relevance when drying in a steam sterilization process, as explained in DIN 58953 Part 9, Section 8.

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1. Planning the transportation process – Set assembly

The packaging system generally consists of a sterile barrier system and protective packaging as per DIN EN ISO 11607-2. "Set" is an umbrella term used to denote a defined selection of MDs, including the tray/securing aids, sterile barrier system and, as applicable, protective packaging. The nature and duration of transportation should be considered already when selecting the **STERILE BARRIER SYSTEM**, securing aids, etc. for set assembly.

The nature and duration of transportation should be considered when selecting the **STERILE BARRIER SYSTEM**.

* KRINKO/BfArM Recommendation: Hygiene requirements for processing medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (KRINKO) and the Federal Institute for Drugs and Medical Devices (BfArM)

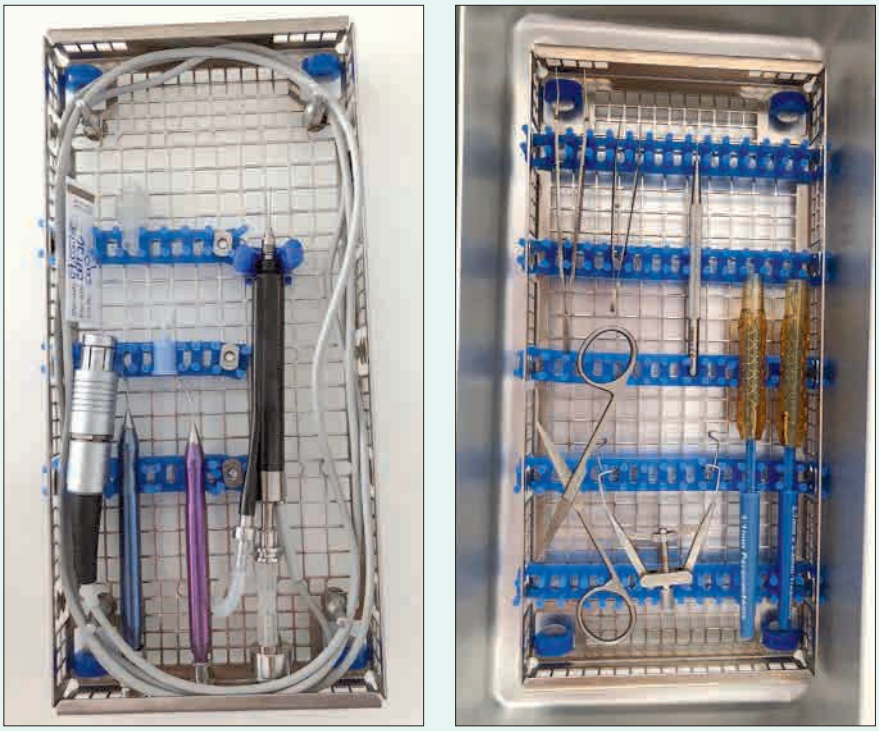

Figure 1 and 2: Examples of securing aids

Planning transport processes and set assembly are interface tasks. The interfaces and competent persons are defined in the QMS interface descriptions. These interface descriptions also specify the competent persons for the various partial processes as well as for their implementation. The appointed competent persons sign the interface descriptions (e.g. operating room (OR) management, RUMED and/or logistics department).

In general the OR management together with the surgeon and in collaboration with the RUMED management specify the tray contents list. The packaging type, accessories, e.g. securing aids (Fig. 1 and 2), transport protection as well as issues such as tray weight are discussed and defined in collaboration with the RUMED management.

Note: The manufacturer must also provide instructions for reprocessing medical device accessories (Medical Device Regulation [MDR] Art. 2(2). These instructions must be observed (including any limit on the maximum number of reprocessing cycles).

2. Transport for supply and collection of reprocessable medical devices

THE TRANSPORT TROLLEYS MUST FEATURE A LABEL showing whether they contain sterilized or contaminated MDs.

The transport trolleys must feature a **LABEL** on the outside showing whether they contain sterilized or contaminated MDs. These transport systems/trolleys must be amenable to, preferably automated, cleaning and disinfection.

The European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) contains important information on transport. It is a comprehensive basic guide to classification, packaging, labelling and documentation of dangerous goods, with information on handling during transport and on the vehicles used:

ADR 2.2.62.1.5.9

… With the exception of
(a) Medical waste (UN No. 3291);
(b) Medical devices or equipment contaminated with or containing infectious substances in Category A (UN No. 2814 or UN No. 2900); and
(c) Medical devices or equipment contaminated with or containing other dangerous goods that meet the definition of another class, medical devices or equipment potentially contaminated with or containing infectious substances which are being carried for disinfection, cleaning, sterilization, repair, or equipment

evaluation are not subject to provisions of ADR other than those of this paragraph if packed in packagings designed and constructed in such a way that, under normal conditions of carriage, they cannot break, be punctured or leak their contents. Packagings shall be designed to meet the construction requirements listed in 6.1.4 or 6.6.4. These packagings shall meet the general packing requirements of 4.1.1.1 and 4.1.1.2 and be capable of retaining the medical devices and equipment when dropped from a height of 1.2 m. The packagings shall be marked "USED MEDICAL DEVICE" or "USED MEDICAL EQUIPMENT". When using overpacks, these shall be marked in the same way, except when the inscription remains visible.

2.1. Transport within buildings:

If MDs are transported between different **HYGIENE ZONES**, this must be done in a closed system even within the same buildings. Closed transport trolleys or transport containers (with matching lid) are used to that effect. The type of transport system used will depend on factors such as the quantity, weight and shape or size of the MDs and the packaging used to transport the used MDs.

If MDs are transported between different **HYGIENE ZONES**, this must be done in a closed system.

2.2. Transport outside buildings

If transported outside buildings, **MDS** and/or their sterile barrier system **ARE AT HIGHER RISK OF DAMAGE** from mechanical stress or humidity following temperature fluctuations. These aspects must be taken into account at the planning stage.

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3. Making provision for MD transportation

3.1. Used/contaminated MDs (client, user → RUMED)

Danger to personnel or third parties must be ruled out when preparing contaminated medical devices for transport.

The procedural instructions for precleaning the MDs at the site of use and for collecting/preparing them for unclean transport must be defined in accordance with the QMS (e.g. standard operating procedures (SOPs) procedural instructions, interface descriptions or also service instructions).

When collecting and transporting the used MDs it is important to create **FAVOURABLE PRECONDITIONS** for subsequent cleaning and disinfection. If necessary, contaminated MDs must be precleaned immediately after use, see extract from the KRINKO/BfArM Recommendation (page 1252):

"*Remove course soils from the MDs immediately after use. Pre-empt as far as possible drying of blood and tissues by specifying suitable processes and procedures (e.g. wiping off external soils and rinsing working channels immediately after use; define times for collection of used MDs), especially to avoid adversely affecting the cleaning performance (drying of infectious pathogens enclosed in protective colloids).*"

To create **FAVOURABLE PRECONDITIONS** for subsequent cleaning and disinfection, if necessary, contaminated MDs must be precleaned immediately after use.

In compliance with occupational health and safety, **POINTED OR SHARP MDS** should be made safe for transport, while also avoiding rough handling of MDs and excessively tight winding of cables to prevent damage.

POINTED OR SHARP MDS should be made safe for transport.

Avoid precleaning with chloride solutions as this leads to corrosion. When arranging the used MDs for transport, cables should in principle be placed above the devices to prevent damage to the insulation. The cables should not be wound too tightly (e.g. manufacturer's instructions for fibre optic cables: form loops with diameter of at least 15–20 cm). Remove liquids before transport.

Specify the transport times in accordance with the internal supply requirements (QMS). Arrange the **TRANSPORT TIMES** between the site of use and reprocessing department such that the used/contaminated, reprocessable MDs undergo a validated cleaning and disinfection process in compliance with the *Six-Hour Rule* recommended in the *Red Brochure* published by the Working Group Instrument Preparation (AKI), Edition 11, chapter 5, page 31) (KRINKO/BfArM Recommendation, manufacturer's information for use). This will positively impact all subsequent validated partial reprocessing processes.

Arrange **TRANSPORT TIMES** such that MDs undergo a validated cleaning and disinfection process within six hours.

If the used MDs cannot be reprocessed within this specified time, e.g. standby service, external reprocessing, the pretreatment process must be adapted accordingly. Because soils will have been allowed to dry out on the used MDs for prolonged

periods of time, due attention must be paid to this by classifying the cleaning results for such MDs as a worst-case load at the time of validation of automated cleaning and disinfection processes. Such procedures must be set out in the QM system.

3.2. Reprocessed MDs (RUMED → client, user)

Transport trolleys must be labelled to show their contents. Damage to personnel or third parties must be ruled out when preparing MDs for transport. The provisions of occupational health and safety as well as fire safety regulations must be observed and measures taken for MD value retention.

TRANSPORT STERILIZED MDS separately from u sed MDs.

TRANSPORT STERILIZED MDS separately from used MDs to exclude contamination/mix-up. The following points must be noted to prevent mechanical damage to the sterile barrier system:

Figure 3: Example of disorderly transport

MDs which together with their tray are wrapped in fleece packaging should be placed in baskets (basket/tray system). MDs wrapped in foil/paper (reels or pouches) should be placed in a basket or in a suitable transport box. In sterilization containers, trays filled with MDs can be safely stacked, provided that there is no contact to the tray stored above. To ensure safe stacking. the tray must be equipped with a stacking frame.

All racks, inserts or modules must be securely fitted in the transport trolleys/system to prevent displacement of supplies during transport and ensure nothing falls out when opening the doors (Fig. 3).

If soils are allowed to dry out on the used MDs for prolonged periods of time, due attention must be paid to this by classifying the cleaning results for such MDs as a **WORST-CASE LOAD** at the time of validation of automated cleaning and disinfection processes.

Do not bundle foil packaging to avoid damage. Sterilization containers can be stacked.

Because soils will have been allowed to dry out on the used MDs for prolonged periods of time, due attention must be paid to this by classifying the cleaning results for such MDs as a **WORST-CASE LOAD** at the time of validation of automated cleaning and disinfection processes. In accordance with the KRINKO/BfArM Recommendation, it must be ensured in principle that the MD characteristics will not be adversely affected during transport to the RUMED.

3.3. Transport protection

The extent of the MD transport protection measures needed as well as a suitable choice of transport system (transport trolleys, transport containers) will depend on the distance and the ground conditions (vibration from ramps, joints or similar) between the reprocessing department and the site of use. In the case of external reprocessing different road conditions and abrupt braking must be taken into account (Guideline: “Storage of reprocessed medical devices and transport of reprocessable medical devices for supply and collection between the RUMED and user”).

Use **SECURING AIDS** to prevent damage to MDs during transport.

Slipping and sliding in the trays can damage the MDs and should be prevented, e.g. by means of **SECURING AIDS** such as silicone mats or straps.

Note: If the securing aids are later reprocessed together with the MDs in the washer-disinfector (WD), it must be ensured that securing aids that will not adversely impact the mechanical action of the water are used (e.g. use lattice silicone mats with adequately large holes). Drying in the WD must be adapted as needed.

4. Packaging

The type of packaging used for supply and collection of MDs must be described and defined in the QMS e.g.:

From the site of use to the reprocessing department	From the reprocessing department to the site of use
▪ In the original sterile supply container ▪ In a special container for used MDs ▪ In special plastic transport boxes ▪ Wrapped in the original soft packaging in a transport basket and closed transport trolley	▪ In the sterile supply container ▪ Soft packaging with transport basket or plastic transport boxes

References

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