

## Recommendations by the Quality Task Group (73)

# Medical device reprocessing logistics

This recommendation replaces Recommendation 2 from *Central Service 6/1998* «Transport from OR to CSSD»

→ **TRANSPORT** is of paramount importance for successful reprocessing and for preserving the value of MDs.

→ **THE NATURE OF THE PROBLEMS** arising during transport can vary and apply to both internal and external reprocessing .

<sup>1</sup> Recommendation by the RKI and BfARM: Hygiene requirements for medical device reprocessing German Federal Law Gazette (BGBl) 2001; 44: 1115–1126.

### 1 Medical device transportation within the medical devices circuit

Medical device (MD) → **TRANSPORTATION** is of paramount importance for successful reprocessing and for preserving the value of the MDs. In recent years it is not only MD transportation from the OR to the Central Sterile Supply Department (CSSD) that is important, rather all transport routes traversed by a MD within the medical devices circuit must be coordinated and defined. Measures must be in place to ensure that MD transportation is organised such that patients can be treated as scheduled. Such measures are often designated as transport or sterile supply logistics. Logistics is generally defined as the integrated planning, organisation, management, processing and control of the entire flow of materials and goods, including the associated information flows, for a specific organisational unit. Another definition commonly used is the Plowman definition: «Logistics must ensure that the right product is supplied in the right quantity, right condition, at the right place, at the right time and at the right cost to the right customer».

The majority of reusable medical devices are reprocessed in a CSSD. In general all critical, most semi-critical, rarely also non-critical medical devices (classification based on the provisions of the recommendation issued by the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices<sup>1</sup>) are reprocessed internally at a central location within the hospital or by an external service provider. Hence transportation within and outside the hospital is needed. Preference should always be given to dry transport.

### 2 Problems associated with medical device transportation

Here a distinction must be made between the transport → **PROBLEMS** typically encountered with regard to internally reprocessed MDs and those arising during transport for external reprocessing.

#### 2.1 Transport problems related to internal and external reprocessing

- Competencies have not been properly assigned
- The collection and delivery service has other priorities
- There are no delivery or consignment notes, or these are not properly filled out
- Infection protection for transport personnel (transport staff have no personal protective equipment in the event of a container being damaged during transport).
- Transport support mechanisms are not adequate, damage is inflicted on MDs during transport
- Infectious materials are not labelled as per the Protection against Infection Act (IfSG)
- Instruments are collected (after use) but not reprocessed in a timely manner (there are very busy peak working times; a balanced workload is not assured)

#### 2.2 Other possible transport problems arising from external reprocessing

- Distance between site of use and reprocessing department
- Transport time
- Effects of external temperature (summer/winter) on MD transport.

Since in most cases these problems stem from the organisational measures taken for transport and, sometimes, from the structural conditions, changes cannot often be made overnight. However, alone for economic reasons, such as continuous utilisation of equipment in the CSSD as well as to protect transport personnel, the aforementioned problems should be kept to a minimum or preferably eliminated.

### 3 How can medical device transportation be improved before and after reprocessing?

The German Medical Devices Operator Ordinance stipulates in Article 4, Maintenance, that all tasks must be discharged in a reproducible manner so as to ensure that patients, users or third parties are not harmed. Therefore a **→ QUALITY MANAGEMENT (QM)** system must be introduced to regulate reprocessing and related interfaces, while setting out the different sequences and activities in Procedures and Instructions (standard operating procedures – SOPs). The quality management system governing the CSSD must cover the «medical device transportation» interface. The establishment and implementation of a transport logistics system for medical devices that takes account of all responsible parties is a suitable tool for enhancing the transport situation. The following points must be borne in mind:

#### 3.1 Observe reprocessing requirements

Cleaning is a prerequisite for effective disinfection and sterilisation. But cleaning is all the more difficult, the longer blood, tissue, mucosal and other residues are left to dry. Therefore efforts must be made to ensure that the used MDs are **→ REPROCESSED** as soon as possible. This calls for a commensurate logistics system, i. e. organisation of the flow of goods from all sites of use to the reprocessing department. After reprocessing, the medical devices are transported to the user once they have cooled down to room temperature, have been released and packed.

#### 3.2 Observe user requirements

Operations are performed according to the OR schedule. Assuming that sequences are regulated at the interfaces, instruments should be available for procedures on time and free of any transport damage.

#### 3.3 Make provision for transport

- Support systems tailored to the respective transport routes should be available
- Provision must be made for ergonomic support systems to be used for transport
- These support systems used for transport must be reprocessed (e. g. in a container tunnel washer)
- If necessary, a suitable vehicle should be available for road carriage, e. g. a truck with appropriate ventilation and air-conditioning facilities.

#### 3.4 Define transport sequences

In a «Medical device **→ TRANSPORTATION**» standard operating procedure competencies and sequences are described and defined:

- Transport times
- Transport routes
- Communication channels/contact partners
- Visible labels on transport containers (e. g. CLEAN/used medical device [see 4.2])
- Collection points
- Delivery points

The sequences must be agreed with the internal or external service providers organising transport. To that effect service level agreements and/or quality assurance agreements are needed. These should be included in the service contract.

#### 3.5 Induction and training

**→ TRAINED PERSONNEL** is a basic prerequisite for ensuring problem-free transport of contaminated and reprocessed medical devices.

**→ QUALITY MANAGEMENT REGULATIONS** are needed for medical device transportation just as for reprocessing.

**→ REPROCESSING REQUIREMENTS**, too, must be observed when compiling transport regulations.

**→ PROVISION MUST BE MADE FOR TRANSPORT** and for precisely defined sequences.

**→ INDUCTION AND TRAINING** of transport personnel is imperative.

### 3.5.1 Training transport personnel

The transport service personnel must be made aware of the value and importance of their role. Staff members must participate in infection control training, including compliance with the requirements for handling contaminated and sterile medical devices and this must be documented. The content of training is set out, inter alia, in the Technical Regulation TRBA 250 – Biological Agents in Healthcare and Welfare Facilities<sup>2</sup> and in DIN 58953, Part 8 – logistics for sterile medical devices<sup>3</sup>.

### 3.5.2 Training users of medical devices

Before the individual medical devices are released for transportation, measures must be taken as per the manufacturer's instructions for dismantling, pre-cleaning and safe storage. To that effect, a standard operating procedure is normally compiled for transportation of used medical devices to the reprocessing site.

Both the time factor and transport safety must be borne in mind for transportation of the used medical devices. Timely transport and immediate start of medical device cleaning are crucial to assure the success of subsequent steps. The Working Group Instrument Preparation (AKI) recommends the following: «For both transportation methods (i. e. transportation in a wet or dry state), avoid long waiting times until reprocessing, e. g. overnight or throughout the weekend because this poses a risk of corrosion and hampers cleaning. Experiences show that when MDs are transported dry, they can tolerate waiting times of up to six hours without any problem»<sup>4</sup>.

## 4 Further points to be borne in mind

### 4.1 General

The aforementioned details apply for medical device transportation from OR areas to the CSSD and back since in most cases it is the OR departments who are the CSSD's principle clients. Just like for the OR areas, so too must regulations be drafted for all other areas within the hospital which use medical devices. Appropriate procedures must be compiled to that effect.

### 4.2 Multilateral agreement M 232

For transportation of contaminated medical devices, the provisions of → **MULTILATERAL AGREEMENT M232**, ADR 2011 (European Agreement Concerning the International Carriage of Dangerous Goods by Roads), must be observed. This stipulates, inter alia, in 1. c that a label stating «used medical device or used medical equipment»<sup>5</sup> should be affixed to such hazardous devices. The agreement describes other preconditions for transportation of contaminated medical devices. ■

→ **MULTILATERAL AGREEMENT M 232** for transport of contaminated medical devices must be observed.

<sup>2</sup> TRBA 250 – Biological Agents in Healthcare and Welfare Facilities

<sup>3</sup> DIN 58953, Part 8 – logistics for sterile medical devices

<sup>4</sup> Proper Maintenance of Instruments, 9. Issue 2009, [www.a-k-i.org](http://www.a-k-i.org)

<sup>5</sup> Internet site of German Federal Ministry of Transport, Building and Urban Development Multilateral Agreements