Recommendations by the Quality Task Group (100)

Tracking the reprocessing process

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1. Introduction

Measures must always be in place to ensure tracking of the process used to reprocess medical devices (MDs) for initial use or reuse.

➜ **EFFECTIVE TRACKING** must be assured.

The following preconditions must be met for ➜ **EFFECTIVE TRACKING**:

- Unambiguous identification of the MD
- Documentation of the reprocessing process (IT-based state of the art)
- Data archival and data backup
- Reprocessing with validated processes

2. Regulatory framework

In Germany, the regulatory framework consists essentially of the following:

- The Medical Devices Act (MPG)
- The Medical Devices Operator Ordinance (MPBetreibV) Section 3/Section 4/Section 5/Section 10
- KRINKO/BfArM Recommendations* 2.2.6 /2.2.8
- EN ISO 13485:2016 Para. 7.5.9
- EN ISO 9001:2015 Para. 8.5.2 (see below)
- Reversal of the burden of proof as enshrined in the German Civil Code (BGB) Section 630 a – h
- Patient Rights Act
- Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM)

3. Identification/labelling

Medical device labelling (e.g. of needle holders in a basic tray), as well as of each set (e.g. basic tray) is required for unambiguous identification. ➜ **UNAMBIGUOUS IDENTIFICATION**, in turn, is required for documented tracking of each and every reprocessing process. The label must feature the following:

➜ **UNAMBIGUOUS IDENTIFICATION** is required for documented tracking.

- Article number on each MD **(MD manufacturer)**
  This is needed for assignment of the manufacturer's instructions
- Serial number if required **(MD manufacturer)**
  Overview of previous cycles for MDs with restriction of total number of reprocessing cycles
  Servicing intervals of motor systems
- Set code (individual code assigned by operator)
  Tracking of a set (e.g. basic tray, other tray, individually wrapped instruments)

4. Tracking batches and instruments

Pursuant to the KRINKO/BfArM Recommendation, the results of the reprocessing process must be documented in such a manner as to permit tracking.

➜ **FOR CRISTICAL C RISK GROUP MDs** tracking of each individual instrument is required.

For MDs belonging to the ➜ **CRITICAL C RISK GROUP** tracking of each individual instrument is required.

For all other risk groups tracking can be implemented via the set code. One set can contain several MDs (e.g. in a basic tray or other tray) or also only a single instrument (e.g. needle holder in a sterilization pouch).
An ➜ **UNAMBIGUOUS CODE** (set code) is assigned to the set and the contents are recorded on a packing list. Coding should be assigned with e.g. "basic tray 4711" rather than "basic tray" to ensure clear coding of several basic trays.
Loaned instruments, too, must be integrated into the system.

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5. Processes and documentation

Medical device utilization

The ➜ **SET CODE** also records which MD was used on a patient. This means that the reprocessing process can be traced back to the individual patient.

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Precleaning immediately after use

If the MD manufacturer specifies in the reprocessing instructions that the MD be precleaned immediately after use, conduct of precleaning must also be documented.

Arrival of MD in the RUMED

The state of the art is assured by a computerized system with facilities to record the arrival of an MD in the Reprocessing Unit for Medical Devices (RUMED). Each incoming MD can be recorded as "arrived". This helps to check the downtime of an MD (when its handover in the OR is recorded).

Manual pretreatment

For ➜ **COMPLEX MDs**, for which manual pretreatent is needed to ensure effective reprocessing, a specific standard operating instruction (SOP) and release may be advisable. Compliance with that SOP can be confirmed through "imminent release" at the time of loading the washer-disinfector (WD). Here "imminent release" is understood to mean that by starting the WD process the respective staff member confirms having carried out manual precleaning.
The personnel entrusted with such tasks must have the necessary expertise.

➜ **FOR COMPLEX MDs** specific SOPs and immanent release are advisable.

Automated cleaning and disinfection
The documentation must contain at least the following points:

- Batch loading
- Programme used
- Correct WD loading pattern based on validation load
- Actual values of cleaning/disinfection process
- Person entrusted with release

Packing area

The documentation related to the set assembly area must contain at least the following points:

- Set code
- When packed
- Super- and subsets
- Cycle counter (number of reprocessing cycles) for MDs with restriction of total number of reprocessing cycles
- Final result (only disinfected or also sterilized)
- Sterilization process
- Person entrusted with release

Release of the following individual steps, which are also carried out for the packing process, are accorded "imminent status" by printing out and affixing the label:

- Correct set selected
- Visual inspection, maintenance, functional testing
- Packaging process properly implemented

Sterilization

The documentation related to the sterilization area must contain at least the following points:

- Which sets/MDs were included in the batch (load)
- Correct sterilizer loading pattern based on validation load
- Actual values
- Release decision (released or embargoed)
- Person entrusted with release

➜ **ROUTINE CHECKS** must be documented separately.

Periodic ➜ **ROUTINE CHECKS** (BD, vacuum test, etc.) must be documented separately.

Outgoing MDs/consignment store

It may be useful to record to which storage place or by which transport medium the set/ MD was dispatched or how the set/MD exited the RUMED. In larger institutions, in particular, it is advisable to record storage or dispatch.

6. Potential difficulties with tracking

Potential sources of errors

- Manual scanning tasks may be forgotten. Measures should be taken to ensure that such mistakes are detected. In such cases the documentation gaps must be eliminated before the next reprocessing step can be executed (e.g. packing must be postponed if cleaning has not been documented).
- Data must be saved and continue to be legible for the prescribed tracking period.
- A concept must be devised to counter any failure of the electronic documentation system.
- While in the case of implants delivered in an unsterile state the respective process can be identified, in the absence of unambiguous coding it will not be possible to gain any insight into the number of previous reprocessing cycles or ensure assignment to the patient.
- Migration of similar MDs between sets is possible. However, certain countries stipulate that this be documented or avoided, e.g. due to concerns about CJD transmission.

7. Typical questions arising during audits (tips for verifying tracking)

Questions to check the system and to verify tracking

It should be possible to provide answers to the following questions (verify through spot checks):

- Are you able to demonstrate which MDs in a load were reprocessed and on which patient had they been used?
- Starting with a patient: has reprocessing of all MDs used been fully recorded?
- Are you able to implement recall of loads (locate the MDs)?
- How do you ensure that data have been archived and continue to be legible?
- For which patient have certain MDs been used?

8. Outlook

Prospects for the future

It may be possible to simplify tracking by exploiting innovative technical facilities.
The American Unique Device Identification (UDI) system provides for universal coding of MDs from different manufacturers. The UDI system, involving laser marking, can be used to mark e.g. implants and bone screws.
Radio frequency identification (RFID) can make data registration much easier. The RFID system consists of a transponder, which is fitted in or on an MD and features a unique code, and a reader for reading the (transponder) code. ■