Recommendations by the quality task group (114)

Reprocessing flexible endoscopes – pros and cons of a RUMED close to or far from the site of use

Authors: B. Amann, U. Beilenhoff, A. Carter, D. Diedrich, S. Eberhardt, T. Fengler, A. Forster, K. Gehrmann, A. Hartwig, M. Hoppe, H. Hückinghaus, A. Jones, S. Krüger, J. Metzing, I. Mock, A. Papadopoulos, H. Pozo, P. Sauer, C. Schmid, M. Schreiner, D. Schricker, K. Wiese, U. Zimmermann

Introduction

Heat-sensitive flexible endoscopes are indispensable for diagnosis and treatment and are used in sterile and unsterile body regions.

RISK MANAGEMENT is the basis for the decision on which flexible endoscopes must be subjected to terminal sterilization .

Decision-making on which flexible endoscopes must be subjected to terminal sterilization comes within the scope of the premises operator's **RISK MANAGEMENT**, which is a part of quality management. The choice of sterilization method depends on the manufacturer's instructions for the respective medical device (e.g. ethylene oxide, formaldehyde, hydrogen peroxide).

Depending on how they are introduced into the human body, endoscopes and endoscopic ancillary instruments are classified as semi-critical or critical medical devices in accordance with the Spaulding classification system (see Table 1, *KRINKO/BfArM Recommendation* [1]). Accordingly, reprocessing featuring as its terminal step bactericidal, mycobactericidal, fungicidal and virucidal disinfection (semi-critical) or sterilization (critical) must be carried out. The responsibility for assigning the medical devices to risk groups is borne by the user/operator on site. If there is **UNCERTAINTY** or doubt, the flexible endoscope is assigned to the higher (more critical) risk level, e.g. semi-critical B is now classified as critical C.

IN CASE OF UNCERTAINTY, the flexible endoscope is assigned to the higher (more critical) risk level.

Endoscopic ancillary instruments that are repeatedly used are generally assigned to the *Critical* risk category and should preferably be reprocessed in a Reprocessing Unit for Medical Devices (RUMED) using thermal cleaning and disinfection processes. These medical devices (MDs) do not come within the remit of this present recommendation and will not be further addressed below.

Based on the *KRINKO/BfArM Recommendation*, both manual and automated reprocessing processes may be used for flexible endoscopes, but preference should be given to an automated process for reasons of reproducibility and process safety.

Flexible endoscopes are complex medical devices made of the most different materials. Therefore, reprocessing flexible endoscopes is an extremely demanding task and is more susceptible to errors than are standard surgical instruments. This arduous reprocessing task should only be entrusted to qualified personnel.

Training centres accredited by the German Society of Sterile Supply (DGSV) offer three-year training courses for qualification as a Medical Device Reprocessing Specialist (FMA) as well as technical training courses for reprocessing flexible endoscopes.

PRECLEANING immediately after endoscopy at the site of use is necessary in any case.

Pursuant to the *KRINKO/BfArM Recommendation* of 2012, Annex 8 and the respective manufacturer's instructions, flexible endoscopes should always be **PRECLEANED** immediately after endoscopy at the site of use.

The RUMED in which flexible endoscopes are later reprocessed may be situated within the endoscopy department or close to it. Flexible endoscopes can also be reprocessed in the central RUMED on the same premises or in an external RUMED. That must be decided by each individual medical institution. Hence, the choice of place where flexible endoscopes are reprocessed is also a location and logistical decision.

The entire specifications for reprocessing endoscopes in accordance with the *KRINKO/BfArM Recommendation* are given in the flowcharts below.

The Committee for Hygiene, Construction and Technology of the German Society of Sterile Supply (DGSV e.V.) has focused in depth on the **STRUCTURAL**

REQUIREMENTS for endoscope RUMEDs and issued specific recommendations to that effect [2].

In general, operators are driven by cost optimization. They aim to avoid long transportation and storage times between two endoscopy procedures, striving for the shortest possible turnaround times for the flexible endoscopes.

But reprocessing processes take time. If not enough time is allotted, the quality of the reprocessing results may be jeopardized, in turn presenting a hazard to the patient. Frenzied reprocessing activities can give rise to technical and functional defects as well as to avoidable costs for repairs and downtimes.

The use of a device-specific identification number for each endoscope assures batch-related documentation which can be used for costing purposes and calculation of the endoscope service life. Such an identification number also meets the requirements of the new Medical Device Regulation (MDR [3]) in respect of signs of material degradation or the maximum number of allowable reuses as well as the tracking requirements.

In the case of endoscopic examinations, in particular, issues around the economic feasibility can only be clarified on the basis of the recorded data, while the correct conclusions must be drawn with regard to the nature and number of endoscopes required.

Is central reprocessing advisable for utilization of existing resources or is the established model of reprocessing close to the site of use the concept of the future?

There are many pros and cons that must be considered in the individual case. But there is no general or universal solution. In this present recommendation, by comparing the reprocessing locations, we aim to outline the requirements applicable in each case and thus facilitate individual decision-making.

A precondition for such **DECISION-MAKING** is a (self)-critical cost-benefit calculation as well as assurance of the necessary structural quality and organizational prerequisites, while also taking account of any claims for damage, e.g. in the event of inadequate reprocessing conditions (and the impending threat of a claim for organizational negligence).

The cost calculation should include the following data, inter alia:

- Endoscopic procedures/specialist departments (daily/annual number, trend)
- Endoscope types and numbers (age, depreciation) incl. endoscopic ancillary instruments
- Structural requirements/possibly reconstructions
- Technical equipment/fittings
- Media supply
- Investments
- Consumables
- Normal staffing levels
- Personnel (qualifications)
- Arrangements for night, Sunday and public holiday shifts
- Functional and structural requirements (organization)
- Interfaces
- Additional transport costs
- Additional costs for QM and validation

The table below lists the preconditions, pros and cons of reprocessing “Close to the site of use” and “Far from the site of use”.

Compared here is decentral vs. central reprocessing. However, since there are no clear-cut dividing lines between these two entities, mixed solutions can also be contemplated. For example, a central reprocessing unit for endoscopes can be installed not just in the central RUMED but also, for example, within an endoscopy department. This means that for procedures performed within that department the endoscopes are reprocessed close to the site of use, whereas other endoscopy departments deliver their used endoscopes to this central reprocessing unit for endoscopes, which amounts to reprocessing far from the site of use. Appropriate logistical and timely transport arrangements must be made for the latter endoscopes.

STRUCTURAL REQUIREMENTS for endoscope RUMEDs are issued in specific recommendations by the Committee for Hygiene, Construction and Technology of the German Society of Sterile Supply.

DECISION-MAKING ON THE LOCATION OF ENDOSCOPE REPROCESSING requires a cost-benefit calculation as well as assurance of the necessary structural quality and organizational prerequisites.

Pros and cons of reprocessing performed "Close to the site of use" versus "Far from the site of use"		
Steps (to be undertaken as per the manufacturer's instructions)	**Reprocessing – Close to the site of use (within the endoscopy department)**	**Reprocessing – Farm from the site of use**
Precleaning at the site of use, clean the endoscope supply tube	No differences	
Transport in enclosed system (contaminated)	Guide time: 30 minutes * (source: ESGENA [4])	
	No additional compliance measures needed	Aspects to be noted and clarified include: ▪ Logistics ▪ Human resources ▪ Transport routes ▪ Transport system, Longer transport times may result in considerable damage
Inspection on delivery to reprocessing site (note model and delivery time)	No additional compliance measures needed	Further checks may be needed, e.g.: ▪ Damage assessment after transport ▪ Check for completeness
Leakage test	No differences	
Manual cleaning (incl. cleaning the endoscope channels with a brush)	No differences	
Further automated or manual reprocessing (cleaning and disinfection, possibly sterilization)	No differences Reprocess as per manufacturer's instructions	
Drying	Drying may not be needed if reused immediately	Drying mandatory
Care, inspection and release	No differences	
Return transport in a contamination-proof transport system	A contamination-proof transport system is needed if there is a change of room	Return transport necessary ▪ Must be protected against contamination and damage ▪ Medical device packaging for semi-critical B or critical C endoscopes, as well as transport packaging ▪ Delivery note and accompanying documentation required
Storage	Generally at the site of use	

* Longer transport//storage times may result in considerable costs for cleaning or may contraindicate cleaning

Template for reprocessing flexible endoscopes

Site of use, endoscope supply tube	**Precleaning at the site of use** Wipe off insertion tube with non-linting wipe impregnated with cleaning solution Purge suction channel with cleaning solution Rinse air/water channel with sterile water from the optics cleaning bottle, fit cleaning valve* Next, empty channels Disconnect endoscope from the supply tube, fit closing cap* (video)

Enclosed hygienic transport from the site of use to the reprocessing site

Reprocessing site, unclean area	**Leakage test as per the manufacturer's instructions*** *Remove all valves and distal caps before the leakage test!* *Always keep endoscope sites coming into contact with the leakage tester dry!* ***Leakage tester continues to be connected for all manual partial processes (reprocessing site)!*** 1. *Perform leakage test on a dry worktop* 2. *Perform leakage test in cleaning solution, while filling channels with cleaning solution* 3. *Observe leakage tester manometer during all manual partial processes*
Reprocessing site, unclean area	**Manual cleaning / brushing at reprocessing site** Remove valves, caps and place in cleaning solution Immerse endoscope fully in cleaning solution Brush accessible channels with flexible double-headed brush Clean distal ends and, if applicable, Albarran lever, with suitable brushes Clean outer surfaces with non-linting wipe Brush valve seat with valve-seat brush Brush valves and caps

Reprocessing site, unclean area	**Automated processing in EWD** is preferable	**Rinsing cleaning solution / intermediate rinse** *Carry out this task in an empty basin that has been cleaned and disinfected* Rinse outer surfaces thoroughly (shower) Rinse channels, valves and caps thoroughly (e.g. water pistol) *Purpose: to remove cleaning solution, dissolved soils from inner and outer surfaces* *Do not carry over to next partial process!*
Reprocessing site, clean area	**Automated processing in EWD** is preferable	*Final rinse to remove disinfectant residues* *Carry out this task in an empty basin that has been cleaned and once again disinfected* *Rinse thoroughly using fresh, microbiologically impeccable, water each time* *The water must be free of facultative pathogenic microorganisms*
Reprocessing site, unclean area	**Automated processing in EWD** is preferable	**Disinfection** *Disinfectant with demonstrable bactericidal, vircidal and fungicidal efficacy* *Disinfectant concentration and exposure as per the manufacturer's instructions* *Fill/purge all endoscope channels with disinfectant while avoiding air bubbles*
Reprocessing site, clean area	**Automated processing in EWD*** is preferable	**Drying** *Blow-dry endoscopes thoroughly with medicinal compressed air (note manufacturer's instructions!)*

*Step 7 can be performed in a drying cabinet

Summary

Currently, heat-sensitive flexible endoscopes are reprocessed in central RUMEDs, a RUMED situated within the endoscopy department as well as in decentral RUMEDs.

Before deciding where reprocessing is to be carried out, structural and technical prerequisites, manpower as well as organizational and logistical structures must be considered. Regardless of the choice of reprocessing site, reprocessing must meet the same quality requirements. Following manual precleaning and cleaning, flexible endoscopes should preferably undergo automated reprocessing in an automated endoscope reprocessor (AER) using validated processes (EN ISO 15883-4 [5]).

Depending on the type of endoscope used, validated reprocessing processes must meet various requirements and include manual precleaning , automated cleaning and disinfection in an AER, drying, and possibly sterilization and storage. That calls for personnel with commensurate specialist knowledge and qualifications.

The structural and technical facilities are the key to consistent separation between unclean and clean work steps, reprocessing safety and infection prevention.

If sterilization is indicated for medical and hygiene reasons for heat-sensitive components, a suitable low-temperature process should be chosen in accordance with the manufacturer's instructions.

References

1. 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)
2. Recommendations of the Committee for Hygiene, Construction and Technology of the German Society of Sterile (DGSV e.V))
3. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83 / EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223 / 2009 and repealing Council Directives 90/385 / EEC and 93/42 / EEC
4. Reprocessing of flexible endoscopes and endoscopic accessories used in gastrointestinal endoscopy: Position statement of the European Society of Gastrointestinal Endsocopy (ESGE) and European Society of Gastroenterology Nurses and Associates (ESGENA) – Update 2018. Endoscopy 2018; 50: 1205–1234.
5. Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2018); German version EN ISO 15883-4:2018
6. Flowchart, International FORUM Medical Devices & Processes, Band 33, 2018: 21