

Recommendations by the Quality Task Group (81)

Management of loan instruments (Part 2)

| Processing loan instruments

«Loan instruments» are intended for different applications. Whereas loan instruments used as replacement for repairs, i. e. for the establishment's own instruments currently undergoing repairs, can be processed using the same process and standard operating procedures as the original instruments, for new instrument types the feasibility and suitability of the processing procedure will have to be assessed on the basis of the manufacturer's reprocessing instructions. Enough time must be made available to that effect. Certain aspects may have to be queried and/or requalification of the modified process may be necessary (QM).

| Terms

Loan instruments for repairs

Loan instruments from the same manufacturer should not be any problem since these can be processed in exactly the same way.

Consigned goods

Instruments that are crucial for implantation of loan prosthetic devices are often supplied as consigned goods. The hospital enters into consignment contracts with several suppliers for instruments and prostheses. There must be enough time to review the corresponding documentation before use and ensure that the instruments can be processed with the existing facilities and using validated processes.

Short-term loan instruments

If short-term use of loan instruments is intended, the dates for ordering and use must be chosen such that there will be enough time to check that the instruments can be processed using the existing facilities and with validated processes. Only in the case of instruments with which the establishment is familiar can the existing standard operating procedures, with defined processing methods, be used.

Instruments for trying out

In the case of instruments on loan for the purpose of trying them out, a timely check must be carried out to ensure that the instruments can be processed using the existing facilities and with validated processes, so that there will be enough time for any queries or for making changes to the processing procedure. Accordingly, the instruments must be ordered and dates set for their use well in advance of their actual use.

Responsibilities

The operator is responsible for ensuring that the provisions of the Medical Devices Act and of the Medical Devices Operator Ordinance (MPBetreibV) are implemented in the prescribed fashion. This responsibility extends to all medical devices (MDs) in his possession. This also includes loan, leased and test equipment.

As dictated by quality management, loan and test instruments must be handled in a responsible manner, and coordination of all deadlines is vital.

| Processing

Consideration is given here only to loaning of instruments between the manufacturer/lender and customer, and not between customers. The latter is not recommended because of the more exacting quality assurance needed and for liability reasons.

Pursuant to the Medical Devices Act, the manufacturer or lender is viewed as the person/institution placing the device on the market and must ensure that instruments are supplied in impeccable condition to the user. The manufacturer or lender is certified accordingly.

To shorten the time needed to process the device after delivery before it is used, it would be beneficial if the manufacturer / lender would supply the loan instruments in a sterile state, and as such ready for use, and once returned would reprocess them using a validated process, perform functional testing, then pack and sterilize the instruments and supply them to the next customer. The lender's competence to render such services, including transport, would have to be certified by a Notified Body.

Many users find it difficult to conduct equally good validated, automated processing, for, among others, the following reasons:

- there are no adapters, or these are not ideal,
- separate processing without external contamination cannot be carried out because of a lack of time,
- the process chemicals are unsuitable,
- regular testing of the chemical and microbiological quality of the water is not carried out etc.

Below are specifications and tips for an enhanced processing procedure, with additional comments and explanations (Table 1).

Table 1: Enhanced Procedure for the management of loan instruments		
Specifications	Enhanced procedure	Comments and explanations
Ordering	<ul style="list-style-type: none"> – Inform CSSD about delivery date, OR date and return date. – If necessary, allow enough time for checking and processing MD before initial use. 	
Incoming inspection <i>If the incoming inspection is done by the CSSD, details for processing MD before and after use can be defined immediately</i>	The condition of the instrument must be checked during incoming inspection and must be recorded. Inspection must focus on the following: <ul style="list-style-type: none"> – Completeness – Functionality – Cleanliness – Maintenance condition – Processing instructions – Dismantling instructions – Condition of transport packaging – Condition of sterile barrier system – Lender's evidence that MD decontaminated 	If the instruments are not clean, or conclusive evidence is not provided that they had been decontaminated, they must be processed before first used. To process instruments/medical devices of a different design or with delicate materials, needing different chemical products, requalification (validation) will be required: <ul style="list-style-type: none"> – only sterilization before initial use – for multiple use – check that processing instructions before and after use are implemented as per DIN EN ISO 17764
Cleaning and disinfection	Gross soiling must first be removed as per the manufacturer's instructions and the KRINKO Recommendation [1]. The prescribed pre-processing measures must be taken for the loan instruments and this documented. Processing should be preferably carried out in a washer-disinfector (WD) using validated processes.	Support systems are very helpful; these can be used for cleaning and disinfection as well as for sterilization without having to unpack the MDs. If instruments have to be connected to the cleaning system in the WD, the manufacturer must provide the corresponding adapters. Avoid protein-fixing agents as well as contact with corrosive substances (e.g. chlorides) (see AKI* Red Brochure, Issue 10, Chapt. 5 Preparation) When inspecting for cleanliness, pay attention to the manufacturer's information on any particularly critical areas
Functional test	Functional testing is done as per the manufacturer's/lender's instructions	Contact the lender if there are any complaints
Sterilization	The user may employ only a sterile barrier system that has been checked for compatibility with the validated (sterilization) process and the medical device.	The sterilization process must be suitable and qualified and subjected to annual requalification. The parameters specified for sterilization of the loan tray must be observed. Often, e.g. the minimum holding time is different from the 5 min (at 134 °C) normally used in Germany. If necessary, check with validation engineer or lender.
Drying	The sterilizer drying phase must be designed such that the total weight of the sterile supplies does not rise by more than 0.2 % (EN 868-8). It is particularly hard to assure this limit value for synthetic trays as well as for instruments with a high synthetic content, so such cases must be checked in particular.	
Release	The persons responsible for release must have the required expertise and be appointed to discharge this task (KRINKO Recommendation, Annex 6) [1]).	If the loan instruments are to be used for other applications, they are decontaminated and sterilized and this is recorded.
Return	If a validated decontamination process is used, sterilization can be omitted before returning the instrument; this must be agreed with the lender. The set(s) is/are checked for completeness and integrity. The results are recorded. Evidence of decontamination is enclosed with the returned instrument.	If necessary, check with validation engineer or lender.
[1] KRINKO/BfArM Recommendation: Recommendation for hygienic processing practices for medical devices, jointly compiled by the Commission for Hospital Hygiene and Infection Prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM); Bundesgesundheitsblatt – Gesundheitsforschung – Gesundheitsschutz 2012; 55 (10): 1244–1310. * Working Group Instrument Preparation		