Reprocessing bronchoscopes – is it time for a change?

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Introduction
The enormous progress in processes and technologies have in recent years led to bronchoscopes being increasingly also used for interventional treatment procedures together with instruments that otherwise penetrate sterile tissues and could therefore be contaminated by non-sterile bronchoscopes.

In addition to stenosis treatment and airway recanalization, stent implantation is in the meantime very important. Likewise, bronchoscopic procedures have become established for the treatment of emphysema (placement of valves) or of asthma through ablation of muscle strands or nerve tracts, or are to be soon offered as a treatment option to defined, larger patient groups [1].

A glance at the international guidelines confirms the trend reversal in the recommendations for reprocessing flexible endoscopes. In recent times several major hospital centers and societies have started to recommend sterilization as a standard for reprocessing this group of instruments.

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The implementation of such recommendations does, of course, presuppose the compatibility of flexible bronchoscopes with suitable low-temperature-sterilization processes.

The trend towards sterilizability of bronchoscopes has in recent years been driven by the manufacturers’ growing awareness of the more stringent hygiene requirements in hospitals, as reflected in the new guidelines, as well as by the consensus among manufacturers and hospitals on the need for effective reprocessing in light of the growing emergence of multidrug-resistant pathogens (e.g. MDR or XDR tuberculosis) [1].

In Germany, the reprocessing of flexible bronchoscopes is regulated by the KRINKO/BfArM Recommendation: “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)” (2012). As a first step, the recommendation stipulates that risk assessment and classification (of the medical devices) be conducted as instructed. This means that a decision must be taken already in advance on the reprocessing steps needed after using the device on a patient. Annex 8, Appendix 6 “Reprocessing flexible cystoscopes and bronchoscopes” describes on page 1308 of the KRINKO/BfArM Recommendation special aspects of risk assessment for these two specific instrument groups. Based on that description, both groups can be assigned to the semi-critical B risk group if they are subsequently used only for diagnostic purposes [2]. Hence, pursuant to the guideline, only – preferably automated – cleaning and disinfection are needed.

However, the KRINKO/BfArM Recommendation simultaneously states that bronchoscopes and cystoscopes are used in a sterile body cavity or are advanced into normally sterile areas of the bronchial system, thus implying more stringent requirements in terms of a low microbial count (sterility). See Table 1, Index 2 of the Recommendation [2].

Hence, the final responsibility and decision-making on risk classification of these medical devices rest with the user/premises operator.

Keywords
- Heat-sensitive endoscopes
- Bronchoscopes
- Reprocessing
- Sterilization

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Section 1.2.1 of the KRINKO/BfArM Recommendation “Risk assessment and classification of medical devices before
reprocessing” clearly states on page 1247 how risk classification should be carried out in cases of uncertainty and doubt: “Where there is doubt about classification, the medical device must be assigned to the higher (more critical) risk level (QM)”.

Advanced Sterilization Products (ASP) has addressed the question of the practices in place in German hospitals that dispose of a H₂O₂ gas plasma process for reprocessing flexible cystoscopes and bronchoscopes. To that effect, a survey was conducted in the Central Sterile Supply Department (CSSD)/Reprocessing Unit for Medical Devices (RUMED) of 31 German hospitals on current practices with regard to terminal sterilization of flexible cystoscopes and bronchoscopes following cleaning and disinfection.

Methods
To obtain an overview of the current situation with regard to reprocessing of flexible bronchoscopes, i.e. the focus topic, in particular also compared to cystoscopes, the Scientific Product Support Department at ASP devised a questionnaire. This was jointly answered and completed in face-to-face discussions held from April to August 2018 between the Clinical Education Consultants (CECs) and the CSSD/RUMED managements as well as the infection control physicians and nurses.

The following main topics were addressed in the questionnaire:
- Who in your institution is responsible for risk classification of medical devices?
- In addition to your own instruments, do you also reprocess instruments as a service provider for other hospitals?
- When acting as a service provider, do you take charge of all reprocessing activities, including cleaning/disinfection, or just of sterilization?
- Are the following instrument groups sterilized in your hospital: flexible cystoscopes/flexible bronchoscopes?
- Cystoscopes
  - How many cystoscopes are there?
  - Manufacturer/type
  - Are the cystoscopes compatible with the STERRAD® process?
  - Number of cystoscopes sterilized per day/week?
- Bronchoscopes
  - How many bronchoscopes are there?
  - Manufacturer/type?
  - For which examinations/treatments are bronchoscopes used?
  - Which treatments are classified as “therapeutic”?
  - What is the ratio of therapeutic to diagnostic application (%)?
  - Are only those bronchoscopes used for therapeutic purposes sterilized?
  - Is classification as a semi-critical or critical medical device (disinfection or sterilization) done before the scheduled procedure or after use?
  - What implications does extension of the storage period have on decision-making regarding sterilization?
  - What are the reasons/objectives in your opinion for sterilization of bronchoscopes?
  - What role do economic, hygiene and logistic aspects play?
  - What do you believe is the reason why cystoscopes are sterilized in most hospitals, but often the bronchoscopes are not?
  - How many batches are sterilized in STERRAD®/day?
  - Are the bronchoscopes already compatible with the STERRAD® process?
  - Do you have, if necessary, still reserves for additional cycles/day?

Different types of hospitals, primary, secondary and tertiary care as well as university hospitals, were covered by the survey. In terms of their geographic distribution, the hospitals were in the German Federal States of Bavaria, Baden-Württemberg, Hesse, Lower Saxony, North Rhine-Westphalia, Saxony and Saxony-Anhalt.
All hospitals surveyed disposed of at least one STERRAD® sterilizer in their CSSD/RUMED and, as such, had facilities for low-temperature sterilization of critical C instruments with the H₂O₂ gas plasma process.

Results
The topic was deemed to be highly topical and worthy of discussion.

The survey of the current reprocessing practices employed for the various instrument groups of flexible cystoscopes and bronchoscopes demonstrated that, of the 31 hospitals surveyed, 30 (97%) confirmed that flexible cystoscopes were sterilized. By contrast, that applied to only 13 of flexible bronchoscopes (42%).

In all 31 hospitals surveyed the CSSD/RUMED management, at times in collaboration with the hospital infection control team, was responsible for risk classification of the medical devices. 51% of these hospitals reprocessed not just their own medical devices but also acted as service providers for other hospitals. The proportion of hospitals acting as service providers that sterilized flexible bronchoscopes was as high as 69%.

The hospitals surveyed which sterilize flexible bronchoscopes mainly used the instruments for both diagnostic and interventional purposes. Only 23% of these establishments stated they provided only diagnostic services.

In the CSSD of 19 hospitals (61%) no information was available on the ratio of diagnostic to therapeutic application of the bronchoscopes.

As reasons why flexible bronchoscopes were not sterilized, the following points were mentioned by the hospitals concerned:
- Cystoscopes and ureterorenoscopes (URS) are inserted into aseptic body cavities, while bronchoscopes are not.
- Difficulty in differentiating between diagnostic and therapeutic applications, therefore the RKI “bridge” was used for semi-critical classification for diagnostic applications
- Poor hygiene awareness among decision-makers
- Lack of clear guidelines
- Decentralized reprocessing of bronchoscopes in the automated endoscope reprocessor (AER) outside the CSSD

Sterilizability of certain bronchoscopes not assured
- Lack of sterilization capacity and high instrument throughput
- Concerns about the higher costs incurred for sterilization

The responsible CSSD/ RUMED managers justified the reasons for terminal sterilization as follows:
- Difficulty in unambiguously differentiating between diagnostic and therapeutic use, therefore as a rule consistent classification as critical C instruments in the CSSD
- Often, information on the intended or actual use was not passed on to the CSSD
- Most bronchoscopes were now already compatible with modern low-temperature sterilization processes
- There was no longer a need to reprocess once again rarely used bronchoscopes that were stored for long periods, which meant they were always available in a sterile state when needed
- The CSSD had suitable sterilizers available
- Highest hygiene standards and maximization of patient safety had absolute priority.
- Compliance with the provisions of the KRINKO/BfArM Recommendation

For 88% of the CSSDs/RUMEDs surveyed, and which commented on the role of these aspects, the desire to enhance hygiene and patient safety was the main concern, followed by logistic decisions, which generally ranked second. In no case were economic aspects given top priority when making decisions about sterilization of bronchoscopes. In 56% of cases that consideration ranked last.

Evaluation
There are increasing reports about healthcare-associated infections (HAIs) linked to contaminated bronchoscopes (Fig. 1) [3, 4]. In addition to drug-resistant pathogens, some of the recently reported outbreaks were also caused by:

- Non-pseudomonas bacteria
- Pseudomonas
- Fungi
- Mycobacteria

Figure 1: Reports of HAIs associated with contaminated bronchoscopes [4]
by disinfectant-resistant pathogens [5, 6]. For example, following a major outbreak after surgical or bronchoscopy procedures in Brazil over 3,000 patients became infected with bacteria that had proved to be highly resistant to glutaraldehyde [5].

Therefore, healthcare institutions are now reviewing as a matter of urgency current practices with regard to reprocessing flexible bronchoscopes. Is the safety level afforded by cleaning and disinfection sufficient or should theaim be to assure the highest standard of patient care through terminal sterilization of bronchoscopes?

In terms of the reasons and arguments put forward so far by the majority of hospitals for not performing terminal sterilization of flexible bronchoscopes, in addition to classification as a semi-critical medical device, these relate to logistics, capacity and economic factors.

When deciding in favour of terminal sterilization of the bronchoscopes, the main drivers were assurance of the highest hygiene safety, in particular when no reliable information was available on how the bronchoscope was used, as well as storage considerations.

That viewpoint is also reflected by our experiences and reactions to the discussions held in the hospitals on that topic. In many cases the preconditions, or compatibility of the bronchoscopes with the sterilization processes available as well as the possibility of logistical integration into the working practices had already been verified and, in some cases, implemented.

The reasons given for deciding to sterilize cystoscopes were relatively consistent. The instruments were introduced into sterile body cavities and therefore classified as a Critical C medical devices. Due to the local, generally clearly defined use in urology and a manageable number of instruments, the logistics around transportation to the CSSDs/RUMEDs as well as reprocessing, including cleaning, disinfection and terminal sterilization, were clearly regulated.

By contrast, bronchoscopes are instruments that are used very frequently in various disciplines (OR, anaesthesia, ENT/pneumology, endoscopy, thoracic surgery, emergency medicine, etc.) and were often used and reprocessed in a very rapid instrument turnaround time. On the one hand, decisions on reprocessing methods were mainly based on technical and logistical capacities rather than on costs. On the other hand, it appears to be very difficult to distinguish clearly between diagnostic and therapeutic application or to opt for a uniform reprocessing method.

At the same time must ask whether a fundamental distinction between diagnosis and treatment for the purpose of classification into risk groups is at all appropriate. The diagnostic procedures that can be carried out with modern flexible bronchoscopes include, inter alia, sampling of bronchial fluid as well as transbronchial needle puncture. To that effect, the bronchial wall is deliberately pierced in the direction of the lymph nodes of the mediastinum or of the deeper airways. Likewise, diagnostic procedures include, for example, taking a tissue sample. Here instruments are used to take a biopsy of the mucosa, which may result in minor bleeding.

Experiences from several of the CSSDs/RUMEDs surveyed showed that on inspection of bronchoscopes used for such “diagnostic” purposes clear traces of blood could be identified on and in the working channel, thus endorsing the indication for classification as critical instruments. Furthermore, when asked users confirmed that in many cases it was not clear before an examination whether use for sole diagnostic purposes was really adequate, since often the need for a further therapeutic intervention manifested only during the procedure.

If reprocessing entails only high level disinfection patients are exposed in such cases to an avoidable infection risk. If a flexible bronchoscope is really to be defined as a “semi-critical B” instrument, then the term “Diagnostic application” should be expressed more precisely as “Visualization diagnostic application”.

**Conclusion and outlook**

In summary, it can be stated that compatible flexible bronchoscopes are appropriately reprocessed by means of sterilization, thus assuring the highest level of hygiene safety, regardless of whether they are intended for critical or semi-critical use. That dispenses with the need for repeat reprocessing of bronchoscopes that are rarely used and stored for long periods, thus helping to reduce the additional workload.

If it is not possible to sterilize all bronchoscopes because of a very high instrument throughput, inadequate technical capacity or the lack of material compatibility, “pooling” constitutes a useful and practical compromise. By selecting material-compatible flexible bronchoscope intended for therapeutic purposes, terminal sterilization can be specified in principle for this group, thus ensuring that sterile bronchoscopes will always be available when needed.

**References**

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