Letters

Is sterilization of bronchoscopes and cystoscopes necessary?

Letter to the Editor from Dr. Thomas W. Fengler, Cleanical GmbH, Augusta Hospital, Scharnhorststr. 3, 10115 Berlin, Germany, and Bruno Amann, CSSD Manager, Leopoldina Krankenhaus, Gustav-Adolf-Str. 8, 97422 Schweinfurt, Germany, on: H. Martiny, O. Leiß Is sterilization of bronchoscopes and cystoscopes necessary?. Zentr Steril 2019; 27 (2): 110-113.

Important aspects of the German regulation for reprocessing flexible endoscopes have thankfully been collated and presented in the order of their importance in this publication. The current version of the German Medical Device 0perator Regulation (MPBetreibV), 67 pages of the KRINKO Recommendation from 2012 (with eight annexes and in Annex 8, dealing with endoscopy, eight further appendices) point to the need for a guide [1]. The publication also cites personal statements made by various manufacturers while listing the types of damage that can occur. While these appear plausible, in this form they cannot naturally be verified.

How critical is the, as generally "semi-critical" classified, use of heat-sensitive flexible endoscopes? That question has preoccupied the specialist organizations and many authors since the documented cases of infection caused by contaminated and therefore infectious, i.e. inadequately reprocessed, duodenoscopes in the USA. Unfortunately, to our knowledge there are only very few scientific epidemiological and comprehensive studies which are not case studies or single case reports.

We have learned about these incidents linked to the use of flexible endoscopes only thanks to the fact that such painstaking documentation and meticulous tracking were used in the cases described, bringing them to the attention of the courts and leading to convictions. Such routine investigations tend to be rare on a global scale since endoscopy generally involves short hospital visits where the patient and their problem disappear from sight after the examination, with the link between it and any infection going undetected.

The following remark, I do not understand: "The aforementioned statements regarding material damage and interactions with disinfectants have of course no implications if instead (?) of disinfection only (?) sterilization is carried out, as is often (?) the case outside Germany."

The question marks inserted here by the authors of this letter to the editor are intended as follows:

– instead:
Chemothermal disinfection is not necessarily omitted if low-temperature sterilization follows. In both cases damage may result from an interaction between the disinfectants/sterilants and the material surfaces, changing their characteristics (e.g. elasticity, porosity).

– only:
Sterilization is more time consuming than disinfection

– often:
"…outside Germany" is a vague global viewpoint that could also be suggestive of reduced time for reprocessing: hence, as many endoscopies as possible with the few, since very expensive, flexible endoscopes?

But if what is meant is that only sterilization was used, that would constitute reprocessing that did not comply with the WHO recommendations (see Table).

The authors then quickly conclude in the following "…that an appropriately reprocessed bronchoscope or cystoscope will not present any risk to the patient."

What does "appropriately" mean? The description of the requirement is equated here with fulfilment of the same. "As regards the final rinsing with sterile/sterile filtered water (manual) or with water of < 10 cfu/100 ml (automated), we believe that the requirement addressed to the total colony count is also below that actually needed." *It remains to be hoped that the microorganisms are willing to comply with the guidelines!*

This is followed by a comparison of disinfection versus sterilization. A more appropriate approach would be to compare (high-level) disinfection with subsequent sterilization.

The flexible endoscope does, of course, penetrate non-sterile mucosa. But (equally) incorrect (as in dentistry) is the underlying belief that it is rendered non-sterile immediately after penetration. In terms of the immune system response a distinction is made between foreign or resident microorganisms (foreign body response). What is also forgotten is that by the very latest the use of the

Table: Stages of reprocessing for flexible endoscopes (WHO)

Stage	Why
Bedside procedure (pre-clean)	To remove readily detachable organic matter. This will help to reduce the possibility of drying and causing channel blockages, especially if there is a delay before manual cleaning takes place.
Leak test	To ensure the integrity of the endoscope. Any damage to the outer surface could allow body fluids or chemicals into the internal workings of the endoscope.
Manual cleaning	Brushing of accessible channels and flushing of all channels to remove organic matter. This stage will also allow the detection of channel blockages.
Rinsing	To remove detergent residues that may affect the performance of the disinfectant.
Drying	To expel excess fluid that may dilute the disinfectant.
Desinfection	To eradicate potentially pathogenic microorganisms, i.e. bacteria, including mycobacteria and viruses.
Rinsing	To remove disinfectant residues that could cause a harmful effect to the patient.
Drying	To expel excess fluid before use on a patient or storage.

(hopefully sterilized) single-use biopsy forceps involves penetration of sterile tissue.

Sterile describes the body's state of homeostasis and integrity. Today, we know that the body is host to the most diverse resident flora (the intestinal flora alone weigh more than a person's brain). But just as I would not use the fork of my co-diner to eat in a restaurant without suitable reprocessing, so too should suitable reprocessing measures be taken to ensure that all microorganisms such as Helicobacter pylori are rinsed away or at least inactivated by means of a biocide.

When the authors refer here to a "physiologic microbiome" *that does not mean that a migrated, exogenous, microbial population could not present an infection risk. This is because during the irrigation steps undertaken during endoscopy infectious material can also be rinsed out from the insides of the flexible endoscopes into the bronchi or the renal pelvis.*

Both body regions represent "critical areas of application", involving "microbiomes" not anticipated there and triggering irritant reactions (or there has been no irritant immune response at all): many scenarios are likely but most of which are undesirable. Why do we continue to talk about prions and pyrogens?

Risk assessment means taking a close look at details, together with meticulous documentation, including traceability. We deem the likelihood of an interaction with the immune system to be sufficient grounds to contemplate further measures such as sterilization.

Besides, our own destructive tests on flexible ureteroscopes demonstrated that certain pathogenic bacteria belonging to the urogenital flora continued to grow for even months after damaged, unrepressed flexible ureteroscopes were stored in a dry condition (see our communication in the International FORUM Medical Devices & Processes 2017/18). Likewise, when endoscopes that were not, or not fully reprocessed, were sent for repair, the tests revealed persistent microbial growth [6].

On the other hand: The in the meantime increasingly formal aspirational "limbo" (more and more …) noted in the requirements applied to medical device reprocessing leads us to ever more complex arguments since the basic prerequisites for residue-free cleaning can only be verified to an extent!

Nor are limit values for irrigation tests with limited recovery rate of much use (especially if that does not include examination of the brushes). While one can investigate the comparative cleaning efficacy, to date it has not been possible to fully verify the cleaning results.

Therefore efforts aimed at an approach that reflects everyday practice are to be welcomed in principle, that enable users to actually implement legitimate requirements for effective reprocessing of flexible endoscopes.

So what are the objections then to sterilization? The rationale applied here must be based on an estimate of the risk of infection or of other hazards to the subsequent patient, regardless of whether we are mulling over what is considered to constitute (still) a semi-critical or (already) a critical encounter with the human body. With a high degree of probability what we are dealing with here is inadequate cleaning, and therefore, with a certain degree of probability, with a scenario where all flexible endoscopes are colonized with potentially resistant pathogenic microorganisms. Subsequent disinfection, or in the future also increasingly low-temperature sterilization, can at least assure comprehensive inactivation of pathogens, including on the inner surfaces.

Today, most German hospitals also dispose of low-temperature sterilization facilities, but which are often underutilized. Therefore, it is technically possible to enhance the process safety when reprocessing flexible endoscopes – and we renounce that possibility? I recall the debate conducted over decades about prions and the 18-min programme without any clinical or epidemiological evidence for that!

And to verify the process safety one can no doubt continue to devise microbiological, non-destructive test methods for flexible endoscopes used in the clinical setting. Why is the entire endoscope not filled, free of bubbles, with a nutrient solution, why are the brushes not also included in scope of the tests?

Within the framework of process validation, the authors believe that this type of spot checks conducted according to a fixed schedule for flexible endoscopes used in the clinical setting would be more useful than the use of (brand new) silicone test tubes contaminated with an artificial test soil. The latter approach is being called into question by various groups (inter alia, by the author at the meeting of the group responsible for compilation of the Guideline on validation of automated endoscope cleaning processes on 12 March 2015 in Hamburg, and by Dr W. Michels at the annual conference of the German Society of Sterile Supply (DGSV) in 2017 [3]). Similarly, protein limit values defined in terms of their plausibility or technical feasibility are but a snapshot of what we want to uncover.

But before formulating procedural rules, we need tests and results from which a test method can then be developed.

"Reduction" through cleaning processes definitely makes a contribution to disinfection that should not be underestimated, since in addition to soils, microorganisms too are washed away. But one must ensure that residues are then inactivated with a biocidal agent. Nonetheless, verification of the cleaning outcome appears to be fragmentary, since it is generally limited to protein substances or blood constituents: What about fats, mucus or saliva?

When weighing up the risks of an endoscopic procedure, these limitations to cleaning must also be taken into consideration and the clinician must be aware of this residual risk associated with flexible endoscopy. This means we need better informed endoscopists and, at the same time, better documentation going beyond the respective institution in order to at all enable traceability in the event of a complication.

How can one track the infection chain once the patient has returned home after endoscopy? And in the event of a complication attends another hospital? In general, no questions are asked that could pinpoint the flexible endoscope used and its infectious nature.

Flexible endoscope reprocessing procedures involving several manual steps are just as variable and susceptible to interference as are the bedside procedures conducted after endoscopy. From our consultancy work we know that there is much scope for improvement here.

We cannot agree with the authors' assertion that spores are not to be expected in bronchoscopes or cystoscopes. Why not, bearing in mind that reprocessing also extends to duodenoscopes and colonoscopes? Perhaps the obligatory precleaning is carried out in the same basin, perhaps without an intermediate disinfection step. Terminal low-temperature sterilization no doubt increases the safety of the reusable medical device when used on the next patient.

What about clostridia? Here we need not reflect on residues when we don't even try to use the available sterilants such as formaldehyde or ethylene oxide in the interest of risk minimization. And we also believe that office-based endoscopists would be well advised to outsource reprocessing to a specialist department (RUMED/CSSD, service provider) in order to concentrate with their staff on specific tasks around the patient.

Reprocessing processes for flexible endoscopes pursuant to *KRINKO 2012,* Annex 8

Status: 03/2019

Site of use, endoscope connected to unit

Pre-cleaning at site of use
Wipe off insertion tube with non-linting, disposable wipe impregnated with cleaning solution
Flush suction channel with cleaning solution
Flush air/water channel with sterile water from the optics cleaning bottle, fit cleaning valve
Connect and empty channels
Disconnect endoscope from unit fit cap (video)

Closed hygienic transportation from site of use to reprocessing site

Reprocessing site, unclean area

Leak test as per manufacturer's *Information for Use*
Leak tester contact points – always keep endoscope dry!
Leak tester stays continuously connected during all manual pre-cleaning steps (reprocessing site)!
1. *Perform leak test at a dry workstation*
2. *Perform leak test in cleaning solution, while filling the channels with cleaning solution*
3. *Observe leak tester manometer continuously during manual pre-cleaning*

Reprocessing site, unclean area

Manual Cleaning / Brushing at reprocessing site
Remove valves, caps and immerse in cleaning solution
Immerse endoscope fully in cleaning solution
Brush accessible channels with flexible double head brush
Clean outer surfaces with non-linting, disposable wipe
Brush valve seats with valve seat brush
Brush valves, caps

Reprocessing site, unclean area

Rinse off detergent solution / Intermediate rinse
Where?: An empty, cleaned and disinfected basin
Rinse thoroughly outer surfaces (shower)
Flush out thoroughly channels, valves, caps (water pistol)
Goal: To remove cleaning solution, dissolved soils from the outside and inside
Do not carry over to next process step!

Automated endoscope reprocessor (AER)	Disinfector *(semi-automatic machine)*	Manual disinfection
Give preference to	**Not recommended**	**Feasible**

Reprocessing site

Process description	Process description	Process description
• Leak test • Pre-cleaning • Cleaning • Rinsing • Disinfection • Rinsing • Final rinse (demin. H_2O) • Drying	• Leak test • Rinsing • Disinfection • Final rinse (demineralized H_2O) • Drying	• Leak test • Fully immerse endoscope in disinfectant solution • Fill channels with disinfectant solution • Observe exposure time • Manual final rinse with sterile, filtered demineralized H_2O • Drying

Closed hygienic transportation from reprocessing site to site of use

The most important precondition for improvement in medical device reprocessing is feedback from users in clinical practice. Without that feedback the manufacturer is well-intentioned but possibly clueless. For example, single-use valves are seen as an important option for infection prevention since, as experience shows, reusable valves are not reliably assigned to the same flexible endoscope and can often be found collected in a coffee cup in a drawer. Here, there is overall an enormous scope for innovation in flexible endoscopy, both in terms of endoscope design and implementation of the reprocessing procedures while assuring the same quality. Any mistakes must then be balanced out by our immune system – or the patient contracts a healthcare-associated infection.

With regard to the conclusions drawn by the authors of the cited publication, we would only agree with them, if we specify the exceptions for conduct of terminal sterilization in cases of doubt for a, as critical defined, flexible endoscope. These differentiating features have to be incorporated into the procedural instructions of the Health-Care Establishment. Thus, the endoscopist is informed about risk assessment (training, trainee's signature attesting to participation and perusal).

Risk management as an essential part of quality management calls for trusting cooperation between those responsible for the clinical processes and those producing the medical devices.

A selection of references for further reading:

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AUTHORS' REPLY:

We thank Dr Fengler and Mr Amann for their detailed letter to the editor on our article "Is sterilization of bronchoscopes and cystoscopes necessary?" We shall limit our reply to the points in which the authors have contradicted our statements or where we do not quite understand the issues raised by the authors. Unfortunately, in this letter to the editor, as also in that by Dr Fengler on our discussion article "Are drying cabinets necessary" [1; in German only], few reference sources are given, and the references are given as general recommendations for further reading and not as arguments or proof to a special topic.

With regard to cases of documented infection linked to duodenoscopes, authors Fengler/Amann express regret: "*Unfortunately, to our knowledge there are only very few scientific epidemiological and comprehensive studies which are not case studies or single case reports.*" If that statement refers in general to infections following endoscopy, attention is drawn to the recent study by Wang et al. on rates of infections after colonoscopy and osophagogastroduodenoscopy [2]. If the statement refers to infections after duodenoscopy, attention is drawn to

the study by Rauwers et al., which was carried out in the Netherlands on reprocessing of duodenoscopes [3]. However, just what the authors believe to be "scientific epidemiological, comprehensive studies" with regard to the question of whether following examinations with sterilized endoscopes fewer patients contract endoscopy-linked infection compared with after endoscopes that had only been disinfected is a mystery in practical and ethical terms.

Authors Fengler/Amann misinterpret our text "*The aforementioned statements regarding material damage and interactions with disinfectants have of course no implications if instead of disinfection only sterilization is carried out, as is often the case outside Germany.*" In that respect we have pointed to the KRINKO/BfArM Recommendation, which on page 1254 states with regard to sterilization "*In principle, sterilization is carried out after thorough cleaning and, for occupational health and safety reasons, obligatory disinfection of the medical devices.*" [4]. By virtue of the expression "in principle" omission of the disinfection step prior to sterilization is also permitted in Germany if the occupational health and safety of the staff entrusted with medical device reprocessing is assured by a means other than disinfection of the medical device.

The reference by authors Fengler/Amann to the WHO recommendations for endoscope reprocessing is not correct: Sterilization of flexible bronchoscopes/cystoscopes is not mentioned in the WHO recommendation, and the last step is the disinfection step. However, as per the WHO recommendation for rigid endoscopes sterilization is carried out immediately after cleaning, and no provision is made for a disinfection step [5].

Since in many countries the reprocessing steps may differ, at the beginning of our article we stated expressis verbis that our statements were based on German legislation.

We very much hope that authors Fengler/Amann essentially know when an endoscope is appropriately reprocessed as per the KRINKO/BfArM Recommendation and make every effort to ensure that the requirements are also met in the areas for which they are responsible. It is not the microorganisms but rather the employees entrusted with reprocessing the endoscopes who must comply with the regulations.

The accusation made by authors Fengler/Amann regarding the failure to mention "high-level disinfection" is untenable. A distinction between "low-level", "intermediate-level" and "high-level" disinfection does not apply in the Federal Republic of Germany; the spectrum of activity required in Germany for medical devices that do not undergo terminal sterilization does not include sporicidal activity.

As pointed out above, the study by Alfa et al. which we cited in our references was not at all paid any attention by authors Fengler/Amann. However, the following sentence is questionable: *"But (equally) incorrect (as in dentistry) is the underlying belief that it is rendered non-sterile immediately after introduction into a cavity"*. Still sterile even after contact with the mucosa? While biopsy forceps will have been sterilized, they are undoubtedly no longer sterile at the site of use – the lung in the case of bronchoscopy, the bladder in cystoscopy – because on the way to these sites the patient's mucus/body fluids are drawn into the distal end of the biopsy channel when air is supplied into the hollow organs. In 2002 Kinney et al. demonstrated that none of the sterile biopsy forceps which has been pushed through the biopsy channel of a colonoscope reprocessed with glutaraldehyde in accordance to American guidelines showed microbial growth. In contrast, all 10 sterile biopsy forceps pushed through the biopsy channel immediately after a colonoscopy showed high grade contamination [6]. In the interest of politeness we refrain from commenting on the definition of "sterile" proposed by authors Fengler/Amann.

Despite repeated perusal, we are unfortunately unable to grasp what authors Fengler/Amann wished to convey with their statements about the microbiome. To spare readers of this letter by authors Fengler/Amann the effort of having to search through the cited Forum journals for the study mentioned, (the authors did not bother to cite the exact source), we point out that this source makes no reference to the sterilization of endoscopes. Rather, it states that microbial growth continued to be detected in non-reprocessed endoscopes sent for repair after storage for at least four weeks. We would never have expected that!

In their letter to the editor authors Fengler/Amann also address various other issues, repeatedly drawing attention to the inability to guarantee or furnish proof of adequate cleaning. May we point out that this is part of process validation and if according to Fengler/Amann cleaning cannot be feasibly implemented, we ask ourselves on what basis are medical devices released by authors Fengler/Amann. But the following statement renders us speechless: *"With a high degree of probability what we are dealing with here is inadequate cleaning, and therefore, with a certain degree of probability, with a scenario where all flexible endoscopes are colonized with potentially resistant pathogenic microorganisms. Subsequent disinfection, or in the future also increasingly low-temperature sterilization, can at least assure comprehensive inactivation of pathogens, including on the inner surfaces"*. That conveys what we call the science of the last century: despite inadequate cleaning, disinfection and sterilization are supposed to prove successful and both disinfection and low-temperature sterilization processes are supposed to even be able to distinguish between apathogenic and pathogenic microorganisms? In our discussion article we cited a total of five studies that demonstrate that neither disinfection nor sterilization is effective without appropriate cleaning. The KRINKO/BfArM Recommendation, too, repeatedly stresses the need for thorough cleaning to ensure effective disinfection and sterilization. Authors Fengler/Amann do not address any of our 24 reference sources which we clearly and reproducibly cited to underpin our arguments, whereas their own statements simply amount to opinions and often have nothing at all to do with the respective topic.

Attention is drawn here to a recent publication by the European Hygiene Expert Forum in which the participating experts likewise unanimously agreed that sterilization of endoscopes is not necessary [7].

Finally, we would like to still unequivocally address an issue raised by authors Fengler/Amann: "So what are the objections then to sterilization?". That was not at all the issue addressed in our discussion article; rather, we

wanted to explore whether sterilization is mandatorily necessary. We do not want to prevent anyone from making use of underutilized low-temperature sterilizers or of increasing the number of endoscopes available in an endoscopy unit. Likewise, the issue of whether and when flexible endoscopes become damaged is for us of secondary importance from the viewpoint of preventing infection in patients undergoing endoscopy. But advocating sterilization because one believes that effective cleaning is not possible and that therefore ineffective disinfection measures can be improved through sterilization is hazardous to patients and therefore irresponsible!

Already for the past 25 years Section 4 (1) of the Medical Devices Directive has stipulated: *"It is forbidden to place on the market, install, commission, operate or use medical devices if 1. there is justified reason to believe to believe that, when properly employed and maintained and while observing the intended purpose, they could endanger the safety and health of the patients, users or third parties beyond a degree that can be justified by the existing stock of knowledge of medical science…"* [8]. Finally, we would like to thank authors Dr Fengler and Mr Amann for the effort put into their letter to the editor and for thus giving us the opportunity to eliminate existing inaccuracies.

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