Letters |

Does sterile reprocessing of thermolabile flexible endoscopes in endoscope washer-disinfectors increase the safety margin?

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Patient infections related to endoscopic procedures have been repeatedly reported in recent years. This has led to ongoing debates whether the current practice of cleaning and disinfection of semi-critical thermolabile endoscopes is sufficient for eliminating the high microbial load after use of the devices [6, 7]. Consequently, it has been discussed if a terminal sterilization on a routine basis for all semi-critical thermolabile endoscopes after their reprocessing in an endoscope washer-disinfector (EWD) provides a higher safety margin [8].

Within this framework, the U.S. Food and Drug Administration (FDA) proposed terminal sterilization of duodenoscopes after cleaning and disinfection or double High-Level Disinfection (HLD), among others [9]. Meanwhile first results are published, showing that neither double HLD, nor sterilization with ethylene oxide (ETO) always successfully eliminate all microorganisms/ remove multi-resistant pathogens [10–14].

Most flexible endoscopes are classified as semi-critical devices according to the Spaulding classification of medical devices, as they come into contact with intact mucous membranes and do not ordinarily penetrate sterile tissue. Consequently, they require cleaning and disinfection with disinfectants claiming to have bactericidal, fungicidal, mycobactericidal, and virucidal activity by application of relevant EN standards (which reflects the process of HLD in some countries) [1].

The common reprocessing procedure for most flexible endoscopes consists of precleaning and manual cleaning, followed by automated cleaning and disinfection in EWD complying with the relevant standard series of EN ISO 15883 [3–5]. To remove the disinfectant, rinsing with water of defined quality according to EN ISO 15883-4 and volume is integral part of the EWD program. Drying with air of defined quality according to EN ISO 15883-4 takes place either within the EWD, manually by using compressed filtered air (see Figure 1), or in a storage cabinet (see EN 16442) [17].

The quality of water and air used after disinfection is important to avoid recontamination with potentially pathogens (e.g. Pseudomonas *spp.,* Legionella *spp., atypical mycobacteria) and thus to maintain the microbial status of "disinfection".*

According to EN ISO 15883-4, the term "disinfection" is defined as the reduction of microorganisms present on a product to a level previously specified as appropriate for its intended further handling or use.
This means as a result of this process that pathogenic microorganisms are killed or inactivated to a level that does not represent any risk for the patient.

In practice, provided that precleaning and manual cleaning is carried out properly by trained personnel, and that every channel is properly connected with the EWD via adapters/channel separators, the EWD process leads to a successfully cleaned and disinfected endoscope.

For critical endoscopes, e.g. bronchoscopes, used e.g. for surgical opening of the pleural space with the specific purpose of taking a biopsy (for histology or culture), for aspiration of a loculated effusion or detachment of fibrin deposits, an additional step of sterilization is required. Depending on local regulation, for example in France, endoscopes such as cystoscopes and ureteroscopes are classified as critical, which means that these endoscopes can either be disinfected or sterilized. In case of disinfection, sporicidal activity of the disinfectant, followed by final rinsing with sterile water, is required in addition to the above mentioned levels of activity for semi-critical endoscopes.

According to EN ISO 11139, the term "sterilization" is defined as a "validated process used to render a product free from viable microorganisms" [16]. To maintain this sterile status until next use, the instrument needs to be packed in an appropriate packaging (sterile barrier) prior to sterilization (see Fig. 1).

Due to their design and materials, most of the flexible endoscopes currently used are not resistant to higher temperatures (> 60 °C). Therefore, for flexible endoscopes that require terminal sterilization, low temperature sterilization methods such as ETO sterilization, low-temperature steam formaldehyde (LTSF) or hydrogen peroxide are available. State of the art process and product requirements are described in relevant standards:

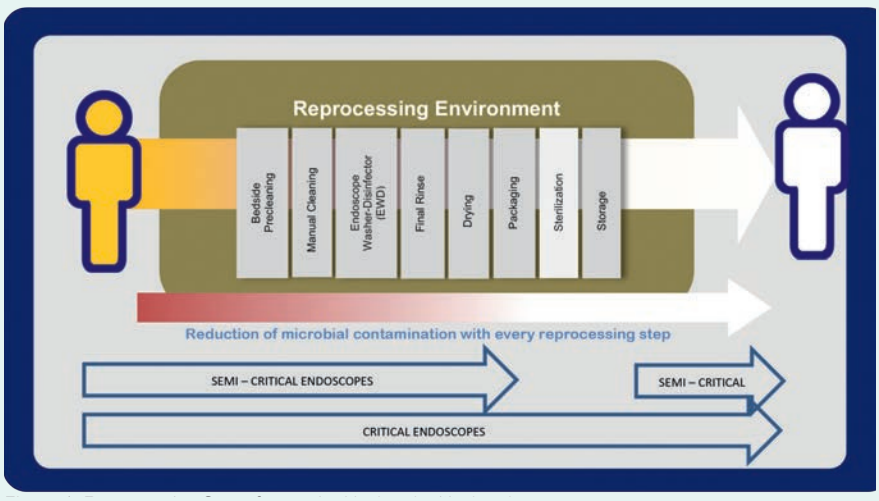

Figure 1: Reprocessing Steps for semi-critical and critical endoscopes

- *Ethylene Oxide Sterilization: EN 1422, EN ISO 11135:2014*
- *LTSF: EN 14180, EN ISO 25424*
- *Hydrogen Peroxide: prEN 17180:2017 (under discussion on ISO level)*

Some EWD manufacturers refer to Liquid Chemical Sterilization (LCS) and claim that their designated chemicals are not only suitable for disinfection, but also for LCS in EWD, using the same disinfectant with different parameters resulting in an increased consumption of resources, either chemicals, power and/or time [2]. LCS in EWD means that the disinfection step is replaced by a stage called "chemical sterilization".

This so-called sterility claim in EWD is often referred to EN ISO 14937 [15]. However, this standard does not apply to a specific sterilization method, but only defines general requirements for sterilization. In contrary to other sterilization methods, there is neither a process standard nor a product standard available that describes a LCS procedure and how to prove that it achieves the required sterility assurance level (SAL) of 10^{-6}.

Considering the above, claims for LCS need to be examined carefully.

Sterility in EWD?

Every step within the processing cycle has its justification, especially cleaning is key for process efficacy. If the cleaning step (incl. precleaning, manual cleaning and automated cleaning) is not performed properly, neither a successful disinfection nor sterilization result can be achieved. Reaching a higher safety margin by increasing one or more disinfection parameters (e.g. concentration, temperature, time) cannot be successful if the objective is to reach sterility [10–14]. Indeed, considering the connectors required to reprocess endoscope channels, there is a high risk that contact surfaces between endoscope and connectors were not submitted to the same disinfection efficacy level. Furthermore, maintaining the sterile status between end of cycle and the next patient use must be ensured. For sterilization this is achieved by sterile barrier packaging which is not possible to be realized with the existing EWD.

In the sense of patient safety, operators should assure that all critical aspects needed to achieve and preserve a cleanliness and disinfection level previously specified as appropriate for its intended further handling and use are considered and under control.

A safe reprocessing of semi-critical thermolabile flexible endoscopes can only be ensured when the instructions for precleaning and manual cleaning of the endoscope manufacturer are followed and when an EWD that meets the normative requirements as described in the EN ISO 15883 standard series is used.

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