WHITE PAPER

Medical device recall and FDA letter to health care providers

FLEXIBLE UROLOGICAL ENDOSCOPES AND REPROCESSING METHODS

On Friday April 1, 2022 Karl Storz Endoscopy-America Inc. initiated an urgent medical device recall notice on certain Karl Storz flexible endoscopes for urological use. Shortly after that the Food and Drug Administration (FDA) issued a letter to health care providers ensuring that all relevant stakeholders were informed about the details of the urgent recall and understood their options.

Prior to the recall, supplemental validation testing of the efficacy of the manual high-level disinfection (HLD) process was performed showing that the required efficacy level of disinfection was not achieved. As a result, the manufacturer has now removed manual and automated HLD as well as liquid chemical sterilization (for specific models) from the Instruction for Use (IFU) of the affected endoscopes.

The FDA has provided recommendations to the end users of the affected devices[1,2]:

1. Do not use high-level disinfection methods or liquid chemical sterilization to reprocess affected urological endoscopes.
2. Sterilize affected urological endoscopes after each use by using sterilization methods recommended in the instructions for use specific to each device.
3. Do not use affected urological endoscopes if you do not have access to an appropriate sterilization method recommended in the instructions for use.
4. Discuss the benefits and risks associated with procedures involving reprocessed urological endoscopes with your patients.

As early as April 2021, FDA communicated about infections associated with reprocessed urological endoscopes providing recommendations for how to reprocess reusable urological endoscopes[3]. Based on over 450 Medical Device Reports (MDRs), which described patient infections post procedure or other possible contamination issues associated with reprocessing, FDA raised awareness about proper reprocessing processes according to the manufacturers' IFUs.

WHAT DOES THIS CHANGE IN REPROCESSING METHODS MEAN FOR THE USER AND FOR PATIENT SAFETY?

CURRENT PRACTICE AND UNMET NEEDS

In the United States, high-level disinfection (HDL) is the minimum recommended practice for the reprocessing of reusable flexible cystoscopes[4]. It includes seven separate steps associated with organizational and financial burden: Pre-cleaning, leak testing, manual cleaning, visual inspection, disinfection, storage, and documentation[4,5]. The overall cost of reprocessing one flexible endoscope with HLD without additional sterilization has been estimated to range between $114 and $280[6].

Sterilization of endoscopes is intended to add an additional safety margin relative to the current reprocessing methodology[7]. However, sterilization of endoscopes is an expensive and time-consuming process, which requires specific equipment, facilities, and trained staff[8]. Furthermore, some evidence suggests that sterilization of endoscopes may not solve the issues of infection and cross-contamination[9,10].

IMPLICATIONS OF STERILIZATION AS ONLY POSSIBLE REPROCESSING METHOD

Besides liquid chemical sterilization, other methods of sterilizing endoscopes include the traditional steam sterilization method via autoclave, hydrogen peroxide gas plasma sterilization, and Ethylene Oxide (EtO) sterilization. These methods all have different benefits and limitations. Since most reusable flexible cystoscopes are heat and moisture-sensitive, the traditional method of physical sterilization using steam is not a relevant solution to implement in current practices[4].

The EtO sterilization method was highlighted by both the FDA and the Environmental Protection Agency (EPA) to have a significant negative impact on the environment and human health. EPA has classified EtO as a hazardous air pollutant subject to tight restrictions within the Clean Air Act, and in general, EtO sterilization is under increasing scrutiny and pressure from both the FDA and the EPA[11,12].

In July 2019, FDA announced two innovation challenges aimed at developing new device sterilization methods and reducing emissions connected to EtO sterilization[12]. During the same year, the EPA issued a state EPA order to close a facility sterilizing medical products due to unacceptable levels of EtO in the air around the facility[13].

In addition to the environmental burden, the EtO sterilization method has a long turnaround time of approximately 2 hours and 30 minutes compared to 1 hour and 15 minutes for the conventional HLD method[6,14]. EtO sterilization has also been found to add an additional per procedure cost of $339 (2015 USD)[15].

We expect both health systems and manufacturers to continue to be challenged by the FDA and EPA to move away from EtO sterilization to solutions that are less harmful for the environment and human health.

Furthermore, the use of gases and chemicals to sterilize endoscopes are known to cause significant damage to the endoscopes. This imparts additional costs and leads to endoscopes being unavailable due to repairs[10,15,16].

Since all recommended sterilization methods may result in an increase in the turnaround time and higher repair rates, it must be assumed to negatively affect current reusable flexible cystoscopy capacity. Hence, it is expected that health care systems will experience additional costs associated with ensuring a bigger fleet of cystoscopes to perform the same amount of procedures, establishing new reprocessing procedures and training the staff accordingly.

HOW CAN A SINGLE-USE SOLUTION OFFER SUPPORT?

Sterilization of reusable urological endoscopes is cumbersome, costly and time-consuming, and it contributes to the deterioration of the endoscope. What, then could be an alternative that would still permit adequate patient treatment?

The implementation of a single-use cystoscopes is a solution that can allow health care providers to provide a an economically viable, safe and timely option for patient treatments and can be used in facilities where proper sterilization is not applicable.

The cost of implementing single-use cystoscope differs between facilities. However, the per procedure cost of a cystoscopy procedure has been found to range from $155-495, which makes single-use cystoscopes an economically sustainable solution[17–19]. The clinical performance of single-use cystoscopes has been found to be superior or comparable to reusable cystoscopes[20,21]. What is more, the continuous availability of single-use cystoscopes makes it possible to maintain your current procedure volume without adding additional resources even if you are affected by the recall, and it helps reduce the risk of procedure delays[19,22,23].

In conclusion, single-use cystoscopy is regarded as the preferred alternative to reusable flexible cystoscopy. It provides a safe and simple option for immediate patient treatment on an ongoing basis and/or when reusable endoscopes are unavailable for whatever reason. Single-use cystoscopes offer a superior or comparable clinical outcome, are cost transparent and enable institutions to retain maximum cystoscopy capacity. Due to potential workflow benefits and the elimination of reprocessing and repairs, single-use cystoscopes can free up resources to focus on patient care and other important tasks.

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