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WHITE PAPER
Single-use flexible Bronchoscopes

FLEXIBLE BRONCHOSCOPES AND THE FDA'S UPDATED RECOMMENDATIONS FOR REPROCESSING

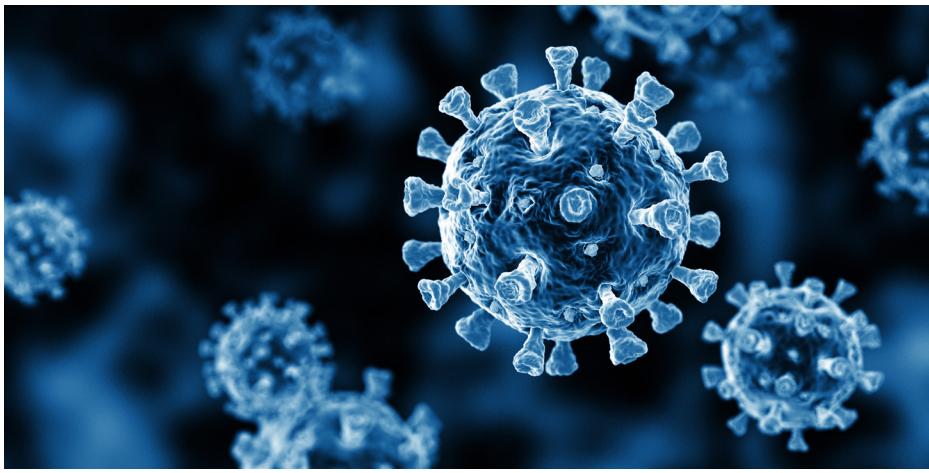
A complete transition to single-use bronchoscopy is a foolproof — and cost-effective — solution for the pervasive infection prevention challenges that the U.S. Food and Drug Administration is addressing with its latest safety communication regarding reusable bronchoscopes.

EXECUTIVE SUMMARY

The latest safety communication from the U.S. Food and Drug Administration (FDA) regarding reusable bronchoscopes confirms that the current industry standard for disinfection is not enough to ensure patient safety in bronchoscopy.[i]

For the first time, the FDA recommended a transition to single-use bronchoscopes for select patient populations – namely, those at high risk for transmitting infection, or patients needing a bronchoscopy when immediate reprocessing is unavailable.

The agency also suggests institutions consider using sterilization, rather than high-level disinfection (HLD), when reprocessing reusable flexible bronchoscopes, and directs caregivers to consult the American Association for Bronchology and Interventional Pulmonology (AABIP) recommendations for treating COVID-19 patients.



For this latest safety communication, published June 25, 2021, the FDA analyzed more than 800 recent medical device reports (MDR) relating to infections or device contamination associated with reusable bronchoscopes. The agency noted there were seven deaths reported in the latest MDRs collected between 2015 and 2021, though it remains unknown if contaminated bronchoscopes contributed to the fatalities or if comorbidities were a factor.

The 867 MDRs represent an almost eight-fold increase in the number of reported incidents related to bronchoscope-related infection or cross-contamination compared with the number received from 2010 to 2015.[ii] But while the number of MDRs has increased dramatically in recent years, the FDA and the U.S. Centers for Disease Control and Prevention (CDC) have been tracking bronchoscope-related contamination and subsequent patient infection incidents for decades.[iii]

If institutions implement sterilization practices and adopt single-use technology for high-risk cases, as the FDA suggests, there will undoubtedly be improved patient safety in the ICU, OR, and the bronch suite. However, a complete transition to single-use bronchoscopy is a full-proof – and cost-effective – solution for these pervasive infection prevention challenges.

SAFEGUARDING AGAINST INFECTION

Flexible bronchoscopes are a type of endoscope that include a thin, lighted tube with a camera on the distal end. This working channel is inserted down a patient's nose or mouth for clinicians to diagnose and treat ailments in the throat, larynx, trachea, and lower airway.

Patients may get sick from the movement of their own flora (by the bronchoscope) during a procedure or, as the MDRs have been demonstrating, because microorganisms were present on the bronchoscope used.[iv] There is also risk of infection transmission to healthcare workers handling reusable bronchoscopes.[v]

Reports of bronchoscope-related infection transmission date at least as far back as the 1970s.[vi] Still, these incidents are considered rare, given that approximately half a million bronchoscopies are performed in the U.S. annually (and research suggests bronchoscopes are actually utilized in a million or more procedures per year). Experts, however, say a perceived low prevalence rate could be due to poor reporting and surveillance.[vii]

Institutions safeguard against bronchoscope-associated infection transmission by implementing complex sterile processing protocols that include staff and resources spanning multiple departments and budgets. Despite this, potentially fatal outbreaks can occur – including instances where strict adherence to disinfection practices are reported.[viii]

THE COST AND COMPLEXITY OF MOVING TO STERILIZATION

Flexible bronchoscope reprocessing requires a series of sequential subtasks under the categories of:

- Bedside pre-cleaning
- Leak testing
- Manual cleaning
- Visual inspection
- HLD or sterilization
- Drying
- Storage
- Documentation

HLD is the current standard for flexible bronchoscopes, and the minimum requirement for semi-critical devices. Ethylene oxide (EtO) sterilization and low temperature hydrogen peroxide sterilization – alternatives to HLD for flexible endoscopes – add additional cost to reprocessing and therefore have not traditionally been preferred by institutions.

Studies comparing HLD and sterilization on GI flexible endoscopes have found sterilization may not eliminate all contaminants from devices if they are not properly cleaned in earlier reprocessing stages.[ix] Gas sterilization methods can also damage these endoscopes over time.[x]

The FDA says one of the primary causes of unsuccessful decontamination is a failure to meticulously follow manufacturer reprocessing instructions. Other reasons for reprocessing failures documented in literature include biofilms shielding microorganisms during disinfection[xi], damage to bronchoscope channels[xii], contaminated or broken automated reprocessing equipment[xiii], inadequate drying[xiv], and mishandling devices after reprocessing.[xv]

Why would the FDA specify lack of "immediate reprocessing" in their recommendation for single-use bronchoscopes?

Biofilm

Bedside cleaning in the minutes following a procedure, followed by a transition to manual cleaning within the hour, reduces the risk of biofilm formation. Biofilm can shield microorganisms against HLD or sterilization and once formed, it is incredibly difficult to remove. That is why immediate attention to cleaning is so crucial to disinfection success.

Reasons for Reprocessing Failure	
Human Factors	Reprocessing is a complex procedure with between 50 and 100 individual steps that vary per endoscope being reprocessed. The complexity and time constraints on reprocessing personnel may lead to inadequate performance of tasks, or even some steps being skipped.
Reprocessing Equipment Failure	Automated endoscope reprocessors (AERs) require regular cleaning and maintenance. Biofilm on AERs, or contaminated rinse water, can lead to recontamination of bronchoscopes during HLD.
Biofilm	Biofilm is a complex microstructure of cells that can shield mircoorganisms during HLD.
Damaged Bronchoscopes	Microorganisms can form inside and be protected by grooves in working channels created by procedural accessories.
Improper Drying	Lingering moisture in bronchoscope working channels helps facilitate new bacterial growth.
Mishandling of Devices Post-Reprocessing	Using dirty PPE to handle bronchoscopes, dropping equipment, or improper storage can lead to recontamination of devices.

FDA: SINGLE-USE FOR HIGH-RISK PATIENTS

Given these challenges, it is no wonder there was heightened concern for both patient and healthcare worker safety regarding the use of flexible bronchoscopes in the early days of the COVID-19 pandemic. In March 2020, AABIP recommended providers use single-use devices if bronchoscopy was deemed necessary when treating potential or confirmed novel coronavirus patients.[xvi]

The FDA now encourages providers to continue to heed that advice and further stated providers should use single-use bronchoscopes for other high-risk patient populations, including immunocompromised patients and those with prion disease.

The 2021 FDA safety communication also included patients suffering from infections caused by multidrug-resistant organisms (MDRO) among those requiring single-use devices. Though potentially underreported, studies have traced MDRO-related outbreaks back to flexible bronchoscopes worldwide.[xvii]

MDROs known to have been transferred during bronchoscopy include *P. aeruginosa*, and *M. tuberculosis*, leading to patients contracting sepsis, pneumonia, bronchitis, lung tuberculosis, and pulmonary infections.[xviii] Global mortality rates for *P. aeruginosa* infection are 20 percent, and the bacteria causes infections such as hospital-associated pneumonia and ventilator-associated pneumonia.[xix] This waterborne organism is also one of the most common bacteria found on different types of endoscopes.[xx]

STERILE, COST-EFFECTIVE CARE

Single-use bronchoscopes were proven to be successful infection prevention assets during the height of the COVID-19 pandemic.[xxi] These safety benefits during crises easily translate to routine patient care.

Single-use bronchoscopes eliminate the need for – and expenses, labor, and training associated with – sterile processing. Single-use bronchoscopes, with their portable display units, also set up in a fraction of the time and do not require maintenance or repair.

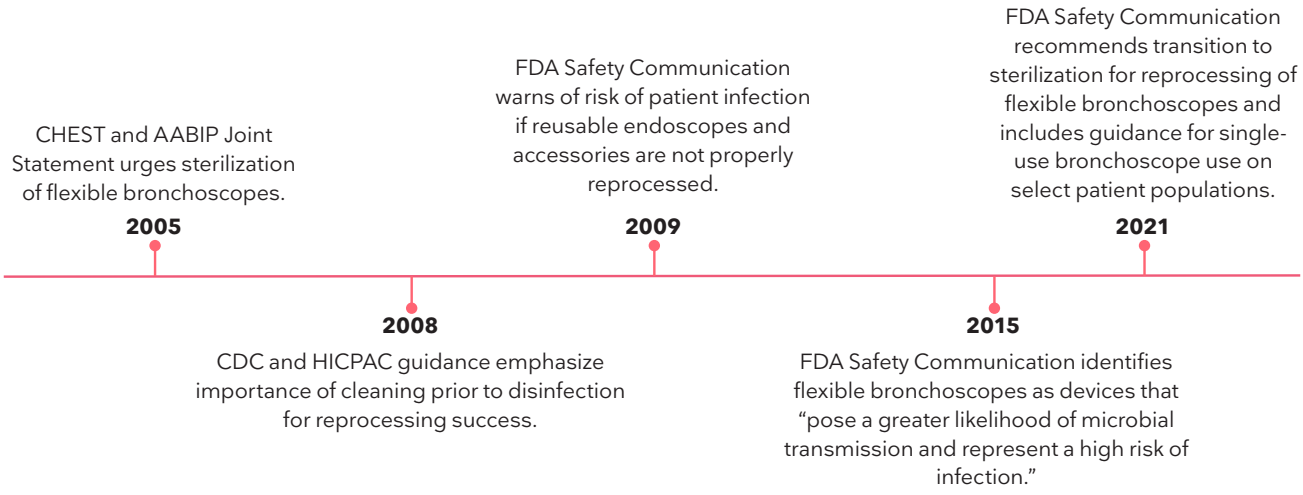
Physicians benefit from the ability to immediately administer care at any time, regardless of reusable scope availability. This allows for increased patient throughput without incurring additional expenses.

Additionally, reusable bronchoscopy has another cost driver worthy of consideration: treating any infections that result from cross-contamination.[xxii] MDRO infections, especially, are becoming increasingly expensive to treat as bacteria continue to evolve against antibiotics.[xxiii] The potential impact on institutional reputation from a bronchoscope-related outbreak is also a big financial risk.

Single-use bronchoscopes provide a cost-effective infection prevention solution for all patient populations, regardless of immunocompromised status.

Most importantly, single-use bronchoscopes guarantee clinicians and patients the sterility they desire and expect during routine and emergency bronchoscopy, regardless of a patient's immunocompromised status. Unlike their reusable counterparts, single-use bronchoscopes are opened from a sterile package at the point of care before the procedure preparation and discarded after use. This means healthcare workers are also at a reduced risk of infection from handling contaminated bronchoscopes during that vital, immediate step of point-of-care pre-cleaning for reusable devices.

REGULATORY GUIDANCE: REPROCESSING FLEXIBLE BRONCHOSCOPES



CONCLUSION

Current standard reprocessing methods cannot sufficiently ensure a complete elimination of microorganisms on flexible bronchoscopes between every use, despite the staff resources and expenses that go into implementing them. Liquid chemical sterilization and EtO sterilization, while perhaps more effective than HLD as suggested by the FDA, are costly to implement and still rely on human factors for success.

The only way to remove the potential for patient-to-patient contamination from flexible bronchoscopes for all patient populations is to utilize single-use devices. At the same time, disposable bronchoscopes offer additional financial and workflow benefits for consistent, cost-effective patient care.

Ambu A/S created the world's first video endoscope in 2009. The Denmark-based company continues to advance single-use bronchoscopy technology and was named the "most innovative single-use endoscopy player in the market" by Frost & Sullivan in 2021.

During the company's 2020 fiscal year, Ambu was a vital partner for institutions facing unprecedented infection prevention challenges during the COVID-19 pandemic and sold more than 1 million single-use endoscopes worldwide. With plans to release up to 20 new endoscopy products in the next three years, Ambu's research and development pace remains unmatched in the market.

Today, Ambu's fourth-generation single-use bronchoscopes are used in 96 percent of the top 500 hospitals in the U.S.

For more information about transitioning to a single-use bronchoscopy platform, visit ambuUSA.com.

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