WHITE PAPER

INFECTION CONTROL IN ENDOSCOPY

Endoscopic retrograde cholangiopancreatography (ERCP) is a therapeutic, potentially life-saving endoscopic procedure that relieves pressure in the bile or pancreatic ducts. ERCP is common for pancreatic cancer patients and is considered much safer than invasive surgery.

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THE SAFEST SOLUTION POSSIBLE

While considered very rare, ERCP does carry a risk for patients of developing pancreatitis or a secondary infection, both of which are dangerous for the immunosuppressed. ERCP is also performed using a duodenoscope, one of the most difficult medical devices to clean and disinfect. That's due to its delicate nature, complex design, and an elevator mechanism on the distal end which has been proven to harbor dangerous organisms – sometimes even antibiotic-resistant ones.

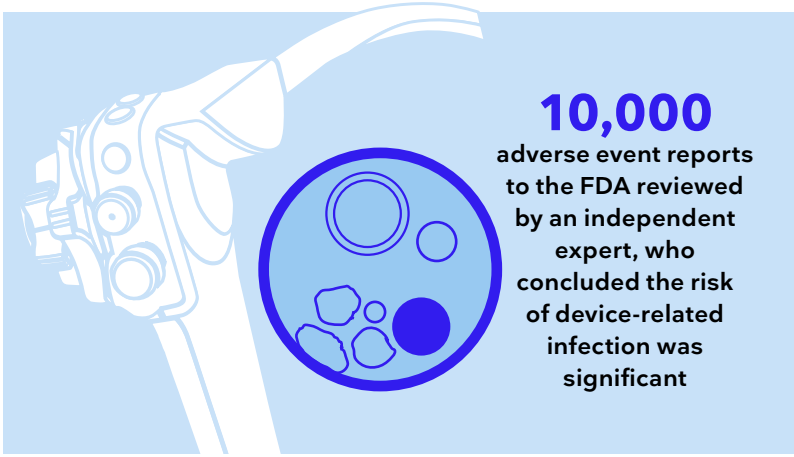
Duodenoscopes, however, are not the only types of flexible endoscopes that carry a risk for cross-contamination related patient infections. These devices are used in a variety of clinical settings and are the most common instruments traced back to device-related infection.

After a recent comprehensive review of more than 10,000 adverse event reports to the U.S. Food and Drug Administration (FDA) concerning six different types of endoscopes, Dr. Lawrence F. Muscarella – an independent infection prevention and safety expert – concluded the risk of device-related infection from these devices was too great to maintain the status quo.

Inadequate cleaning and improper maintenance of flexible endoscopes puts too many patients at risk of device-related infection, especially considering the potential to exposure of multidrug-resistant bacteria, according to Muscarella, who advises hospitals, the public and manufacturers, including Ambu Inc.

The published analysis noted the number of reports to the FDA that outlined actual or potential contamination of a flexible endoscope has increased exponentially since 2014. This increase was particularly alarming during COVID-19-era lockdowns, when many elective endoscopic procedures were put on hold.

As increased attention is paid to infection control in hospitals, investments in single-use technology have surged. Sterile, single-use flexible endoscopes offer hospital systems the opportunity to provide every patient with the safest solution possible for routine, therapeutic, and emergency care.



PATIENT AND STAFF FACE INFECTION RISKS

Endoscopes allow physicians the opportunity to view, sample, or perform treatments in hallow cavities of the body without the risk of invasive surgery. Comprised of long, often flexible, working channels and delicate distal ends, endoscopes are notoriously difficult to clean. Typical reprocessing is a complex process that includes more than 100 steps for preparing, cleaning, and disinfection or sterilization – and if not started immediately following a procedure, it could ultimately be rendered useless in removing harmful contaminants and biofilms.

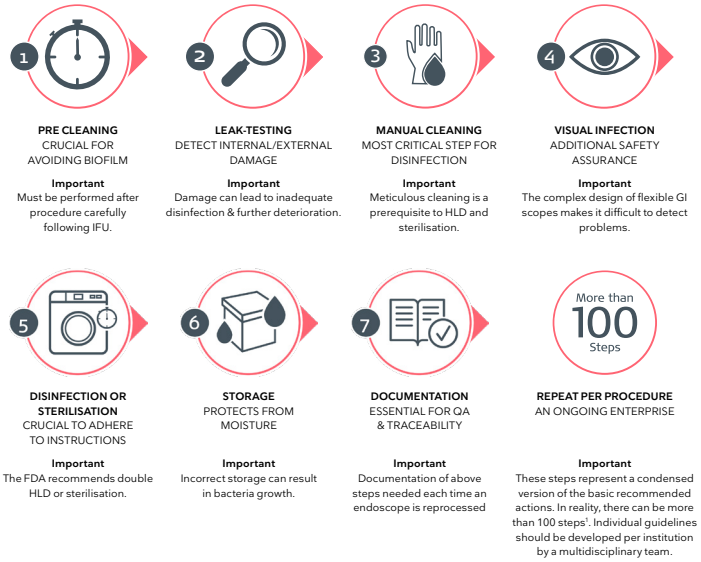


Figure 1: Simplified illustration of the endoscope reprocessing cycle.

Decades of research point to reprocessing errors as one of the key drivers of patient infection risk in endoscopy, which can result from poor training of and high turnover rates for reprocessing technicians or the inherently difficult nature of the two-hour process that is highly susceptible to inconsistencies and oversight. Time may also play a factor, in that reprocessing is often hurried and vital steps are rushed or skipped to meet growing procedural demands.

Reusable endoscopes also pose a potential infection threat to reprocessing personnel. From the moment a procedure ends until the endoscope is removed from an automated endoscope reprocessor after high-level disinfection, anyone handling the device is at risk for exposure either to the organisms on the scope itself or the dangerous chemicals used to clean them.

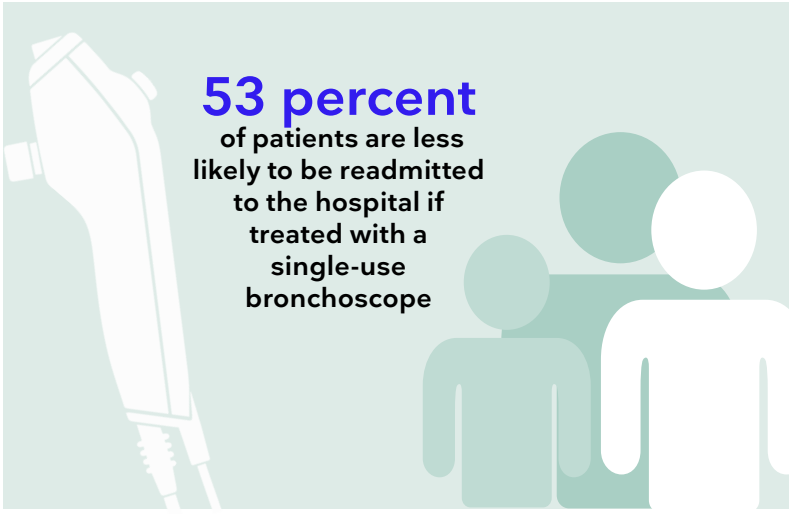
FDA PUSHES SINGLE-USE

In the last three years, the FDA has released several updated safety recommendations regarding the potential for cross-contamination in endoscopy – first addressing duodenoscopes but now including other scopes.

The most recent communications from the FDA have also pointed to the potential infection risk posed by bronchoscopes, used to treat and diagnose diseases in the lungs, and cystoscopes and ureteroscopes, devices used to treat and diagnose disease in the urinary tract. As time passes, the agency has increasingly recommended industry switch to partially disposable or fully single-use devices.

Coupling the FDA recommendations, the global COVID-19 pandemic has heightened patient awareness of hospital-acquired infection, and how hospital systems are working to prevent it. From the early days of the pandemic, leading bronchoscopy societies encouraged single-use technology to be used when bronchoscopy was deemed necessary for coronavirus diagnosis or treatment. Society guidelines highlighted the security single-use devices provide future patients and reprocessing staff if they are immediately disposed of following procedures.

Now, two years into the global pandemic, studies show the potential impact single-use bronchoscopes had on preventing the spread of COVID-19 infection, particularly to healthcare staff. Additionally, a recent retroactive study of bronchoscopy data concludes that patients are 53 percent less likely to be readmitted to the hospital if treated with a single-use bronchoscope, as compared with a reusable one – an impactful finding as readmissions are a key CMS Quality Metric.



A new, highly anticipated update to standards for reprocessing reusable endoscopic medical devices classifies flexible endoscopes – including duodenoscopes, bronchoscopes, ureteroscopes, cystoscopes, and others – as "high-risk," necessitating sterilization rather than high-level disinfection to rid the scopes of contaminants that could harm patients.

The document, ANSI/AAMI ST91:2021, *Flexible and semi-rigid endoscope processing in health care facilities*, states that high-level disinfection (HLD) may not "reliably inactivate" certain types of microorganisms. All flexible endoscopes should undergo sterilization to lower the risk of biofilm formation and enhance patient safety, according to the updated guidelines from the Association for the Advancement of Medical Instrumentation (AAMI). Cleaning verification tests should be performed after each use of these scopes.

Other updates include revisions to guidance on disinfecting and sterilization, drying, and storage of flexible endoscopes, as well as suggested quality control procedures.

Still to come: Updated guidelines for flexible endoscope reprocessing from the Association of periOperative Registered Nurses, or AORN. Its guidelines were up for public comment this spring and are expected to publish in September.

MAKING THE SWITCH

While device-related infection is still considered rare across the healthcare space, continued research is providing a growing body of evidence that there is a safer way to perform endoscopy. The risks of infection following inadequate reprocessing are too great to ignore – especially when there are sterile, single-use alternatives available. And to keep device-related infections rare, healthcare systems are forced to devote significant amounts of resources in equipment, people, time, and oversight.

In an editorial published in the American Journal of Biomedical Science & Research, Dr. Caroline A. Miller and Dr. Michael J. Kennelly explored "a new era" of flexible endoscopy for urologists utilizing cystoscopy to prevent, diagnose, and treat a range of diseases. This era, they write, is taking shape against a backdrop of minimizing patient cross-contamination, concerns heightened by COVID-19 and new levels of awareness of infection risks.

Disposable cystoscopes were part of "a flourish of technological advancement."

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> With a different endoscope used for each patient, patient cross-contamination is all but eradicated and infection risk due to inadequate reprocessing techniques is prevented," Miller and Kennelly add. "Although in its early stages of clinical application, single-use cystoscopy may have its place in medicine and afford opportunities for increased patient efficiency and safety."

A clean record is more important than ever for hospital systems, especially in an era of heightened awareness of patient safety within hospital walls. Sterile, single-use endoscopes provide high-quality patient care with greatly reduced potential for adverse outcomes from hospital-acquired infection.

Today, Ambu's line of single-use endoscopes includes duodenoscopes, gastroscopes, rhinolaryngoscopes, bronchoscopes and cystoscopes. Ambu, the world's leading single-use endoscope provider, plans to continue expanding single-use offerings with new product launches in the coming years.

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

REFERENCES

1. Rex DK, Sieber M, Lehman GA, Webb D, Schmitt B, Kressel AB, et al. A double-reprocessing high-level disinfection protocol does not eliminate positive cultures from the elevators of duodenoscopes. Endoscopy. 2018 Jun;50(6):588–96.