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THE REBOUND — HOW A TRANSITION TO SINGLE-USE ENDOSCOPY WILL HELP INSTITUTIONS OVERCOME UNPRECEDENTED BACKLOGS AND PATIENT SAFETY CONCERNS

Experts estimate it will take the U.S. healthcare system two years to work through surgical backlogs created by shutdowns and elective procedure postponements in 2020. That is, if institutions can operate at 10 to 20 percent above historic levels, while facing an industry-wide $200 billion in projected deficits.[i]

WHITE PAPER

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Also halted at the height of the COVID-19 pandemic were elective endoscopies – minimally invasive procedures used to diagnose and treat ailments in hollow cavities of the body, including the lungs, upper and lower digestive tract, urinary system, and uterus. More than 75 million endoscopies are performed annually in the U.S. in inpatient and outpatient settings, under normal circumstances.[ii]

In the face of unprecedented procedural backlogs and heightened patient awareness of hospital-acquired infections (HAIs), institutions will need to adopt infrastructure or new workflow approaches that enable more efficient care and also guarantees patient safety, all while lowering costs. Hospitals will have to become more productive and will need to eliminate, where possible, time- and resource-intensive processes.

Single-use flexible endoscopes, with their portable display units, are ready for use in a fraction of the time compared to reusable endoscopes, do not require sterile processing between uses, and eliminate the need for costly repairs.[iii] Ultimately, a transition to single-use endoscopy eliminates risk for patient cross-contamination and increases patient throughput in a cost-effective way.

STERILE, STRAIGHT FROM THE PACK

Endoscopes are complex instruments comprised of long, often flexible, working channels with cameras on the distal end. Given their delicate nature and complex design, endoscopes are notoriously difficult to disinfect, and thus carry a risk for patient cross-contamination and subsequent infection.[iv]

The 100-plus-step disinfection process for reusable endoscopes has been the subject of intense scrutiny, even before the COVID-19 pandemic heightened public awareness of infection control in the healthcare space. U.S. Food and Drug Administration (FDA) post-market surveillance studies of flexible endoscopes point to several reasons for inconsistencies in reprocessing success, chief among them the complexity of reprocessing such delicate instruments as well as the time pressures on technicians that may cause vital steps to be skipped or performed inadequately.[v] In a recent editorial for Gastroenterology & Endoscopy News, two gastroenterologists describe reprocessing as inherently prone to error as it is "driven by humans, who may not be able to comply with these complex processes for a variety of reasons."[vi]

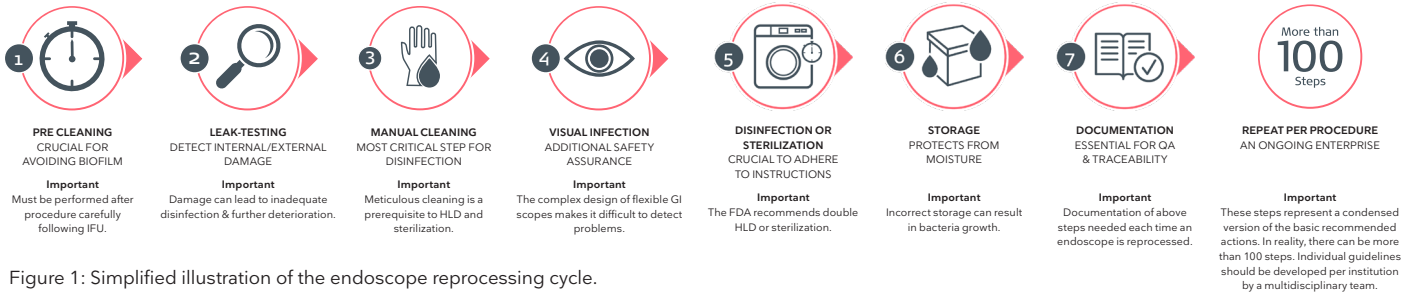


Figure 1: Simplified illustration of the endoscope reprocessing cycle.

While endoscope-associated patient infection is considered low under normal circumstances, more HAIs are linked to flexible endoscopes than any other medical device.[vii] Experts have also acknowledged that the available data may present a false picture of the true infection rate, due to a lack of surveillance or tracing infections back to contaminated endoscopes.[viii] It is worth noting that multidrug-resistant bacterial infections have been traced back to patient-ready duodenoscopes[ix x], bronchoscopes[xi], cystoscopes[xii], and gastroscopes[xiii].

Following high-profile media reports exposing duodenoscope-associated infections and related deaths, the FDA in August 2019 recommended an industry switch to partially disposable or fully disposable duodenoscopes for use in endoscopic retrograde cholangiopancreatography (ERCP). The agency also issued a letter in April 2021 detailing a new investigation into urological endoscope-associated patient infections that resulted in three deaths outside of the U.S.[xiv]

In a time of heightened infection prevention awareness, sterile, single-use endoscopes provide an added layer of safety for both patients and healthcare workers. Unlike their reusable counterparts, single-use endoscopes are opened from a sterile package at point-of-care moments before the procedure preparation and discarded after use. This means healthcare workers are at a reduced risk of infection from handling contaminated endoscopes during point-of-care pre-cleaning, transport, and reprocessing.

These infection prevention benefits were immediately recognized by the American Association for Bronchology and Interventional Pulmonology in the early months of the COVID-19 pandemic in 2020.[xv] A recent retrospective analysis from the Northwestern University Feinberg School of Medicine outlined how Ambu A/S single-use bronchoscopes were a part of infection prevention efforts that kept healthcare workers safe from contracting COVID-19, despite treating hundreds of patients.[xvi]

EFFICIENCY IMPROVES WORKFLOW

As patient volumes rebound in outpatient clinics post-pandemic (an industry segment that saw 900 million outpatient visits in 2019 alone[xvii]), single-use endoscopes enable a more complete spectrum of care on location – helping healthcare systems deliver care where patients live and work. This is largely because disposable endoscopes do not require sterile processing units on site, making routine procedures such as flexible cystoscopy or laryngoscopy possible in expanding satellite operations.

Faster setup times, and eliminating the need for complex, time-consuming disinfection between procedures, reduces patient wait times and increases procedural volume both on the hospital floor and in outpatient clinics. Clinicians benefit from portability and the ability to immediately administer care. [xviii] A sterile, single-use option also guarantees endoscope availability on nights and weekends when sterile processing resources may be limited.

Single-use endoscopes boost institutional efficiency with their portable, compact video monitors and image processors.[xix] Typically, both outpatient and inpatient video endoscopies require large image processing towers and display systems – equipment that costs tens of thousands of dollars and may not be in every procedural room of the ICU, OR, emergency department or clinic.

The result? The ability of clinicians using reusable endoscopes to perform endoscopy may be limited by the availability or location of these towers.

TRANSPARENCY FOR THE BOTTOM LINE

These image processing systems are just one of the big-ticket capital investments required for reusable flexible endoscopy – this financial outlay also encompasses the endoscopes, reprocessing equipment, drying cabinets, and other cleaning equipment. All these depreciating assets require regular maintenance and repair. Endoscopes are delicate and may be damaged easily in use, in transport, or even during sterile processing.[xx]

The operationally burdensome reprocessing of endoscopes between uses also adds to procedural expenses. These include equipment repair and maintenance, the chemicals used, the personal protective equipment worn by cleaning personnel, and ongoing training and labor costs for sterile processing personnel.

Another cost driver worthy of consideration is the possible cross-contamination of endoscopes due to improper reprocessing and the costs of treating patient infections that may result. A patient infection could lead to a prolonged ICU stay or readmission, both of which can result in considerable costs. This

kind of scenario due to endoscope contamination is not just a patient safety concern: The potential impact on institutional reputation is a big financial risk.

Most of the costs associated with reusables are largely fixed: depreciating capital investments, reprocessing operations, and repair contracts. These costs are not variable with the ups and downs of patient volumes – and this is especially concerning during the COVID-19 pandemic. Why? This can create scenarios where revenue decreases, but costs do not decline accordingly.

Single-use costs, by contrast, vary with procedure volume, resulting in predictable margins. Single-use endoscopes are considered supplies, and as a result they do not depreciate and stay on a balance sheet for years like reusables.

Single-use endoscopy offers cost transparency for some of the most common procedures performed in hospitals and outpatient clinics today. Without reprocessing, repair, and training expenses tied up in multiple service contracts, institutions gain a clearer idea of output per expenditure. Considering the operational benefits of single-use endoscopes and the reduced risk of exogenous patient infection, single-use emerges as a clear and cost-effective solution.

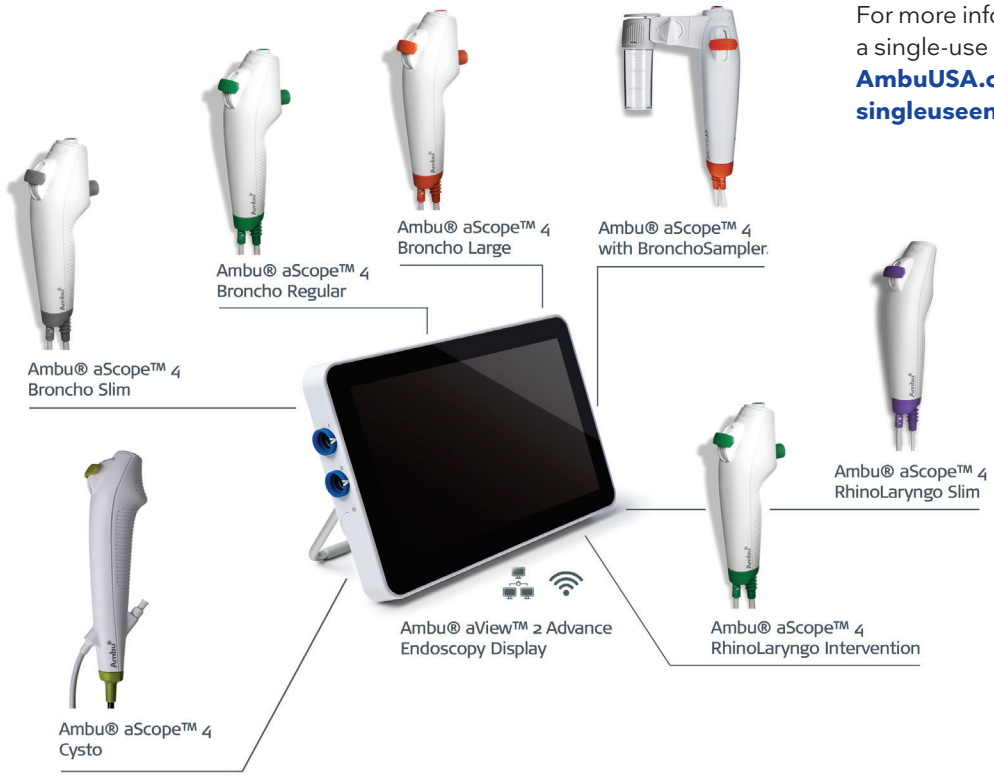
CONCLUSION

A transition to single-use endoscopy allows for quality patient care across clinical settings while minimizing routine and emergency endoscopy delays. This will be especially important as institutions work through unprecedented backlogs and patients bring a heightened infection control awareness to the healthcare marketplace.

Ambu A/S, headquartered in Ballerup, Denmark, created the world's first single-use video endoscope in 2009, forever changing the possibilities for sterile, efficient, and cost-effective care in endoscopy. Today, Ambu's complete line of single-use endoscopes and video display systems includes 2021 Red Dot Award-winning duodenoscopes and cystoscopes as well as rhinolaryngoscopes and fourth-generation bronchoscopes. More than 1 million Ambu single-use endoscopes were sold in fiscal year 2020.

Ambu, named the "most innovative single-use endoscopy player in the market" by Frost & Sullivan in 2021, is poised to launch more than 20 new flexible endoscopy products in the next three years, bringing more than a decade's worth of single-use endoscopy experience and expertise to additional clinical areas, including colonoscopy, gastroscopy, and ureteroscopy.

By leveraging a single-use innovation cycle and delivering solutions with short development and product life cycles (two to three years), Ambu is able to facilitate rapid adoption of new technologies and design improvements – and is adding new manufacturing capacity to do just that, with a fourth manufacturing facility being built in Mexico to support the U.S. market.



For more information about transitioning a single-use endoscopy platform, visit **AmbuUSA.com or singleuseendoscopy.com**.

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