

The Impact of Automated Endoscope Reprocessing on Cleaning and Infection Prevention

— ACHIEVING THE HIGHEST STANDARD OF CARE

by Charles Roberts and Barbara Trattler



Automated brushless systems are an important step in raising the standard of care for flexible endoscope reprocessing.

Each year in the United States alone, approximately 34 million gastrointestinal procedures are performed using flexible endoscopes.¹ The most recent estimate of the risk of infection from this type of procedure is one in 10 million.² However, despite the low overall rates of infection associated with flexible gastrointestinal procedures, flexible endoscopes are still the most common cause of healthcare-device-associated outbreaks, according to the American Society for Gastrointestinal Endoscopy (ASGE).³ Moreover, the Emergency Care Research Institute (ECRI) ranked flexible endoscope cross contamination as the No. 1 hazard in today's healthcare facilities.⁴

It is apparent that improper reprocessing of flexible endoscopes can result in the transmission of infection and chemical colitis, and the real-world impact of these challenges has been demonstrated recently in endoscope contamination incidents in both the United States and Canada.

An outpatient surgery facility in Southern California reported that endoscopic equipment used in patient care may not have been properly disinfected, and in June 2010, the facility issued an endoscope contamination warning to 3,400 patients. The facility also stated that steps recommended by the manufacturer were not always completed when disinfecting equipment.⁵

In February 2009, the Veterans Affairs (VA) Hospital began warning nearly 10,000 former patients in Georgia, Tennessee and Florida—some who had colonoscopies and other endoscopic procedures as far back as 2003—that they may

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have been exposed to infections, including HIV and hepatitis.⁶

In April of this year, 500 patients who underwent endoscopic retrograde cholangiopancreatography at Victoria General Hospital in Canada were issued letters warning them of potential bloodborne virus infections. According to the hospital, a review of endoscopes revealed residual biological material on one scope that could have resulted in the transmission of infection.⁷

These incidents underscore the importance of improving the cleaning process for flexible endoscopes. Data indicate that the manual reprocessing of flexible endoscopes may be a significant contributor to the challenges with the current standard of care. Numerous studies of manual reprocessing indicate widespread difficulty in achieving endoscope manufacturers' recommended standards for manual cleaning and show great variability in the manual cleaning performed.⁸⁻¹⁴ In fact, a recent study indicates that as much as 60 percent of scopes may not be processed correctly.¹⁵

Additionally, manual endoscope reprocessing requires meticulous work that may cause strain injuries to employees and the potential human error can lead to inadequate cleaning and high-level disinfection.¹⁶ In addition to the physical demands, the need to handle high volumes of endoscopes with quick turnaround to avoid procedural delays can place significant stress on staff.¹⁷

Endoscope Cleaning and Reprocessing

In order to address some of the challenges with manual reprocessing, Michelle Alfa, PhD, FCCM, performed a study to assess the efficacy of automated endoscope cleaning reprocessor for flexible

colonoscopes, duodenoscopes, gastroscopes and bronchoscopes using the EVOTECH® Endoscope Cleaner and Reprocessor (ECR) from Advanced Sterilization Products (ASP). Key results from the data indicate that the overall compliance of the EVOTECH ECR cleaning, with all benchmarks for surfaces and lumens, was greater than 99 percent.

Published in *BMC Infectious Diseases* in July 2010, the article titled "EVOTECH® Endoscope Cleaner and Reprocessor (ECR) Simulated-Use and Clinical-Use Evaluation of Cleaning Efficacy" determined that the cleaning achieved using the EVOTECH ECR was superior to that achieved using optimal manual cleaning. In the clinical-use study, 75 patient-used scopes were evaluated post-cleaning and 98.8 percent of surfaces and 99.7 percent of lumens met or surpassed the cleaning endpoints set for protein, hemoglobin and bioburden residuals.

The clinical-use study showed that after automated cleaning, residuals for protein, hemoglobin and bioburden in the suction channel (L1) were substantially better (99.7 percent met all benchmarks) compared to manual cleaning. Also, in the simulated-use study 100 percent of the Olympus colonoscopes, duodenoscopes and bronchoscopes evaluated met or surpassed all benchmarks for protein and bioburden residuals. For all phases, cleaning efficiency was validated with bedside flushing for elective procedures, but not emergency endoscopy procedures or where more than one hour has passed since the procedure.

Raising the Standard of Care

Dr. Alfa's data demonstrate that an automated process can provide optimal endoscope reprocessing, and give physicians and patients confidence that the scopes have been consistently cleaned. The ASGE and Society of Gastroenterology Nurses and Associates (SGNA) have noted that automated brushless systems are an important step in raising the standard of care for flexible endoscope reprocessing,^{18,19} and this data offers support that manual cleaning of endoscopes is not necessary with an automated process like the EVOTECH® ECR. Today, the reality is endoscopy departments are expected to increase the number of



procedures performed daily with the same or sometimes less resources. Automating endoscope reprocessing can allow facilities to utilize valuable staff resources in other patient-related activities and reduce occupational health problems associated with reprocessing.

Although there are a number of guidelines in place related to endoscope reprocessing, including those from the government, third parties and manufacturers, a recent study revealed that GI endoscopes were generally not reprocessed in accordance with guidelines.²⁰ In line with this, only one of 69 endoscopes in the study was reprocessed properly when manual reprocessing methods were used. In contrast, an automated endoscope cleaner and reprocessor resulted in better compliance with guidelines.

As noted previously, and as recognized by the Centers for Disease Control (CDC), contaminated endoscopes are the most common cause of medical-device-associated healthcare outbreaks.²¹ In its 2008 guideline for “Infection Control During GI Endoscopy,” the ASGE points out that the efficacy of the cleaning and disinfection processes are personnel dependent. Furthermore, the SGNA states that there is a “narrow margin of safety” in the process for flexible endoscope reprocessing and that “any slight deviation” from the recommended protocol can lead to an increased risk of infection. To put it simply, given the potential for infection of potentially life-threatening illnesses, there is no room for human error in flexible endoscope reprocessing. For facilities striving to achieve the highest standard of care, automation can standardize reprocessing procedures and eliminate human shortcomings.

For More Information

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4. Advanced Sterilization Products EVOTECH® ECR - <http://www.aspii.com> [<http://www.aspii.com/us/products/evotech-ecr/publication>]

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