



For Information Contact:

Katie Sweet
ASP
949-789-3945 (U.S.)
ksweet@its.inj.com

NEWLY PUBLISHED DATA DEMONSTRATE ASP EVOTECH® ECR PROVIDES CLEANING THAT IS SUPERIOR TO MANUAL CLEANING OF FLEXIBLE ENDOSCOPES

Study Shows EVOTECH® Endoscope Cleaner and Reprocessor (ECR) Cleaning Cycle Provides Reliable Organic and Bioburden Removal from all Channels and Surfaces of Bronchoscopes, Duodenoscopes, Gastrosopes, and Colonoscopes.

IRVINE, CA, July 20, 2010 – Advanced Sterilization Products (ASP) announced today newly published data showing the ASP EVOTECH® Endoscope Cleaner and Reprocessor (ECR) provides an automated approach superior to the manual cleaning required when using traditional AERs. Published in the July 20, 2010 issue of *Biomed Central*, the combination clinical-use and simulated-use study was led by Michelle Alfa, Ph.D., FCCM, Medical Director, Microbiology Discipline Diagnostic Services of Manitoba (DSM) St. Boniface General Hospital Site.

"There have been a number of highly publicized endoscope cleaning incidents in both the USA and Canada that underscore the importance of improving the cleaning process for flexible endoscopes." said Dr. Alfa, study principal investigator and lead author. "While the EVOTECH® ECR technology is new, our recent in-use study evaluating the cleaning efficacy of the highly automated EVOTECH® ECR shows great promise as this system provided cleaning that was superior to manual cleaning for flexible endoscopes. Improved cleaning using a validated automated system is an important step in ensuring reliable reprocessing of flexible endoscopes and thereby reducing risk for patients."

As healthcare facilities transition to alternative systems for high-level disinfection, this data further supports that the EVOTECH® ECR eliminates manual cleaning while providing high-level disinfection.

In the United States each year, approximately 34 million gastrointestinal procedures alone are performed using flexible endoscopes.¹ Numerous studies of manual reprocessing indicate widespread difficulty in achieving endoscope manufacturers' recommended standards for manual cleaning and great variability in the manual cleaning performed.^{2,3,4,5,6,7,8} A recent study indicates that as much as 60 percent of scopes may not be processed correctly.⁹

-more-

ADVANCED STERILIZATION PRODUCTS®

Division of Ethicon, Inc.

a **Johnson & Johnson** company

33 Technology Drive • Irvine, CA • 92618 • United States

AD-090273-01-US_E



Despite the overall low rates of infection associated with flexible gastrointestinal procedures, flexible endoscopes are still the most common cause of healthcare-device-associated outbreaks.¹⁰

The EVOTECH® ECR is the first commercially available endoscope reprocessor to eliminate manual cleaning when a cycle containing a wash stage is selected.¹ This independent data not only confirms previous data that showed the EVOTECH® ECR cleaning cycle provides an effective automated approach comparable to that of manual washing and brushing, but also shows the EVOTECH® ECR cleaning cycle is superior to optimal manual cleaning even for the most difficult to clean channels such as the elevator guidewire channel.

“The study conducted by an independent researcher confirming the efficacy of the EVOTECH® ECR automated technology both validates and reaffirms ASP’s commitment to designing innovative infection prevention solutions,” said Marc Bellotti, Worldwide Vice President of Research and Development for ASP. “ASP will continue to partner with industry associations and key opinion leaders to ensure all healthcare facilities understand the benefits offered by this new and more automated technology.”

¹ Does not eliminate bedside precleaning.

About the Study

The objective of the study was to assess the efficacy of the EVOTECH® ECR cleaning for flexible colonoscopes, duodenoscopes, gastroscopes and bronchoscopes by simulated-use and clinical-use evaluation. The benchmarks for effective cleaning of all channels and surfaces tested were; < 6.4 µg/cm² of residual protein, < 1.8 µg/cm² of residual hemoglobin and < 4 Log₁₀ viable bacteria/cm².

Cleaning efficiency was validated for elective procedures, not emergency endoscopy procedures or where more than one hour has passed since the procedure, and only with bedside flushing. The EVOTECH® ECR and all funds for the study were sponsored by Advanced Sterilization Products.

About the Data

The study showed that:

- The EVOTECH® ECR cleaning cycle provides an effective automated approach that provides greater assurance that flexible endoscopes are adequately cleaned.
- The EVOTECH® ECR cleaning cycle provides effective removal of both organic material and bioburden from all channels and all surfaces of the flexible endoscopes evaluated.
 - The overall compliance of the EVOTECH® ECR cleaning with all benchmarks for surfaces and lumens was greater than 99 percent.
 - In the in-use study, 75 patient-used scopes were evaluated post cleaning with 98.8 percent of surfaces and 99.7 percent of lumens meeting or surpassing the cleaning endpoints for protein, hemoglobin and bioburden residuals.
 - 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 (hemoglobin not evaluated).
- The EVOTECH® ECR cleaning for endoscope surfaces and channels is superior to optimal manual cleaning.

ADVANCED STERILIZATION PRODUCTS®

Division of Ethicon, Inc.

a **Johnson & Johnson** company

33 Technology Drive • Irvine, CA • 92618 • United States

AD-090273-01-US_E



- The in-use study showed residuals for protein, hemoglobin and bioburden in the suction channel (L1) after EVOTECH[®] ECR cleaning are substantially better (99.7 percent met all benchmarks) compared to manual cleaning.¹¹

About EVOTECH[®] Endoscope Cleaner and Reprocessor (ECR)

The EVOTECH[®] ECR is the first commercially available system that both cleans and high-level disinfects endoscopes. Developed by ASP, the EVOTECH[®] ECR makes endoscope reprocessing a totally automated process by eliminating the tedious and sometimes inconsistent manual cleaning* required when using traditional AERs. The EVOTECH[®] ECR gives physicians and patients confidence that the scope used has been consistently cleaned.

Find more information regarding the EVOTECH[®] ECR from ASP at www.aspji.com.

*Manual cleaning of medical devices (endoscopes) is not required prior to placement in the EVOTECH[®] ECR when selecting those cycles that contain a wash stage. Does not eliminate bedside precleaning.

About Advanced Sterilization Products (ASP)

Advanced Sterilization Products (ASP) division of Ethicon, Inc., is a leading developer of innovative instrument sterilization, high-level disinfection, and cleaning technologies. The company is dedicated to protecting patients, healthcare workers, and the environment with products that focus as much on safety as they do on efficacy and cost-effectiveness. Utilizing advanced instrument processing technologies, these products help customers to promote positive patient outcomes while controlling costs, increasing productivity, and enhancing safety. The company is based in Irvine, California, USA.

For more information, please visit www.aspji.com.

###

¹ American Society for Gastrointestinal Endoscopy Web site: <http://www.asge.org/PressroomIndex.aspx?id=6858>. Accessed October 9, 2009.

² Gillespie EE, Kotsanas D, Stuart RL. Microbiological monitoring of endoscopes: 5-year review. *J Gastroenterol Hepatol*. 2008;23(7 Pt 1):1069-74.

³ Bisset L, Cossart YE, Selby W, et al. A prospective study of the efficacy of routine decontamination for gastrointestinal endoscopes and the risk factors for failure. *Am J Infect Control*. 2006;34(5):274-80.

⁴ Moses FM, Lee JS. Current GI endoscope disinfection and QA practices. *Dig Dis Sci*. 2004;49(11-12):1791-7.

⁵ Alfa MJ, Howie R. Modeling microbial survival in buildup biofilm for complex medical devices. *BMC Infect Dis*. 2009;9:56.

⁶ Vickery K, Pajkos A, Cossart Y. Removal of biofilm from endoscopes: evaluation of detergent efficiency. *Am J Infect Control*. 2004;32(3):170-6.

⁷ Vickery K, Quan-D N, Zou J, Cossart Y. The effect of multiple cycles of contamination, detergent washing and disinfection on the development of biofilm in endoscope tubing. *Am J Infect Control*. 2009 (in press).

⁸ Marion K, Freney J, James G, Bergeron E, Renaud FN, Costerton JW. Using an efficient biofilm detaching agent: an essential step for the improvement of endoscope reprocessing protocols. *J of Hosp Infect*. 2006;64(2):136-42.

⁹ Data on file, Advanced Sterilization Products.

¹⁰ Gillespie EE, Kotsanas D, Stuart RL. Microbiological monitoring of endoscopes: 5-year review. *J Gastroenterol Hepatol* 2008;23(7 Pt 1):1069-74.

¹¹ Alfa MJ, Degagne P, Olson N. Worst-case soiling levels for patient-used flexible endoscopes before and after cleaning. *Am J Infect Control*. 1999;27(5):392-401.

ADVANCED STERILIZATION PRODUCTS[®]

Division of Ethicon, Inc.

a Johnson & Johnson company

33 Technology Drive • Irvine, CA • 92618 • United States

AD-090273-01-US_E