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FIRST-OF-ITS-KIND STUDY RELEASED AT THE SGNA 36th ANNUAL CONFERENCE REVEALS INCONSISTENCY IN GI ENDOSCOPE REPROCESSING

ST. LOUIS, MO. (May 18, 2009) — Preliminary results from the first-of-its-kind Clinical Evaluation and Assessment of Endoscope Reprocessing (CLEANR) study was released today at the Society of Gastroenterology Nurses and Associates, Inc. (SGNA) 36th Annual Conference in St. Louis, MO. The study indicated that while there are written endoscope reprocessing guidelines in place at the sites who participated in the study, significant variation in manual reprocessing takes place, leading to challenges with achieving consistent gastrointestinal (GI) endoscope reprocessing practices. The observational study was led by Cori L. Ofstead, MSPH, of Ofstead & Associates, Inc., a healthcare research firm, and sponsored by Advanced Sterilization Products (ASP). Other key employee-related findings included:

- Majority of experienced workers “disliked” some of the manual reprocessing tasks;
- 70% felt pressure to work quickly;
- More than half experienced discomfort associated with reprocessing;
- Employees indicated that using more automated systems provided increased consistency and better compliance-related documentation than manual processing.

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According to Cori L. Ofstead, MSPH, lead researcher, “This study shows that institutions have adopted written GI endoscope reprocessing guidelines, yet there are clearly suboptimal practices and wide variations in adherence within and between institutions. Our findings indicate the majority of employees experience occupational health problems attributed to reprocessing, and many of them dislike tasks associated with manual cleaning. We found that automation improves consistency and employee satisfaction. In accordance with CDC guidelines, every facility should reexamine their practices, and seek ways to improve occupational health and reduce infection risks for patients.”

Background on Study and Additional Findings

The CLEANR Study was conducted from October 2008 through April 2009 at six U.S. sites (only five provided data in the required time frame) including two gastroenterology centers, three multi-specialty hospitals, and one outpatient surgery center. Participating sites used a variety of reprocessing methodologies ranging from manual cleaning with brushes to automated channel irrigators and other automated systems including the ASP EVOTECH™ Endoscope Cleaner and Reprocessor. The EVOTECH System is the first commercially available system in the U.S. that both cleans and high-level disinfects endoscopes. It does not eliminate bedside precleaning in procedure room and no manual cleaning is required when selecting a cycle that has a wash stage.

Managers were interviewed and individuals tasked with the responsibility of cleaning endoscopes after a GI procedure were surveyed and their actions documented by an observer. Managers at every site stated that written reprocessing policies were in place. Study results indicated that GI endoscope reprocessing time varied by the individual, and its variability resulted in:

- Majority of endoscopes using traditional reprocessing techniques were not reprocessed in accordance with existing reprocessing guidelines.

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- Inconsistency in brushing, detergent flush, rinsing, alcohol flushes and forced-air drying times:
 - Brush times ranged from 10 seconds to 2:30 minutes.
 - Detergent flush times ranged from 18 seconds to 2:45 minutes.
 - Sites with consistent flush times were using an automated channel irrigator.
 - Rinsing times ranged from 76 seconds to 3:20 minutes.
 - Alcohol flushes were only documented in 39.5% of instances.
 - Forced air was used in 81.5% of instances.

“ASP realizes that ensuring proper GI endoscope reprocessing is a complex and challenging task, and not all facilities have these issues,” said Barbara Trattler, Director, Clinical Education at ASP. “ASP will continue to partner with our customers and industry to increase awareness of best practices in reprocessing. We are also dedicated to developing new technology solutions such as the EVOTECH™ Endoscope Cleaner and Reprocessor — the first commercially available system to eliminate the labor-intensive manual cleaning of endoscopes—to help improve compliance and increase employee satisfaction.”

About Ofstead & Associates, Inc.

Ofstead & Associates is an independent research organization that gathers, analyzes, interprets, and summarizes evidence-based scientific and clinical information for clinicians and healthcare industry executives. Since 1996, Ofstead has focused exclusively on providing customized research services for clients in the medical field. Ofstead is committed to fostering excellence in healthcare by combining tailored research services and medical insights with practical approaches for developing high-quality output.

About ASP

Advanced Sterilization Products (ASP), division of Ethicon, Inc., a Johnson & Johnson company, has a long track record of designing and delivering innovative infection prevention solutions. Our pioneering technology, global distribution, and established leadership position enable us to simplify the process of buying and operating infection prevention products and services every day, for thousands of medical facilities around the world. This in turn enables our customers to focus on what they do best – preventing infection and saving lives. www.evotechcr.com

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