



September 2010

Dear Valued Customer:

Advanced Sterilization Products (ASP) wishes to further respond to published statements by the Society for Gastrointestinal Nurses and Associates (SGNA) and the American Society for Gastrointestinal Endoscopy (ASGE) regarding our claim that the EVOTECH<sup>®</sup> Endoscope Cleaner and Reprocessor (ECR) eliminates labor-intensive manual cleaning of endoscopes.\*

In the 2009 SGNA Practice Guidelines & Position Statement, *Standards of Infection Control in Reprocessing of Flexible Gastrointestinal Endoscopes*, SGNA writes:

“While the introduction of automated, brushless washing of endoscope channels represents a potentially significant advancement ... users are cautioned about dispensing with manual cleaning endoscope reprocessing and brushing steps before the capabilities of the new machines are confirmed in independent studies and in clinical practice.”

Similarly, in the Technology Status Review report on automated endoscope reprocessors published in *Gastrointestinal Endoscopy (Volume 69, No. 4 : 2009)*, ASGE writes:

“One device (EvoTech System; Advanced Sterilization Products, Irvine, Calif) has received labeling clearance for use after bedside precleaning only, without prior manual cleaning and channel brushing. However, only limited proprietary bench data are available for this machine ... manual cleaning remains the standard of care before disinfection.”

While we respect the efforts of SGNA and ASGE to promote redundant manual cleaning along with automated cleaning as an extra level of safety — and we by no means discourage these efforts— ASP continues to stand behind our claim that manual cleaning of endoscopes is not necessary with the EVOTECH<sup>®</sup> ECR, when used in accordance with its User’s Guide.

We hope the following information reassures our customers that, even though automated cleaning technology is still a relatively new development, the EVOTECH<sup>®</sup> ECR can be trusted to provide effective cleaning of endoscopes — helping you save time, increase productivity, and free up staff to focus on patient care:

- **ASP validated cleaning efficacy.** Data from internal laboratory studies and endoscopes used on patients were collected through rigorous, systematic research involving multiple analytical methods. These studies demonstrated that cleaning in the EVOTECH<sup>®</sup> ECR is non-inferior to manual cleaning, using worst-case conditions for the EVOTECH<sup>®</sup> ECR and best-case conditions for manual cleaning. This data served as the basis for the system’s clearance in 2006, and is still valid today.
- **Published Data Demonstrate EVOTECH<sup>®</sup> ECR Superior to Manual Cleaning of Endoscopes.** Recently published data from by Michelle Alfa, Ph.D., FCCM, Medical Director, Microbiology Discipline Diagnostic Services of Manitoba (DSM), St. Boniface General Hospital Sitedemonstrated that EVOTECH<sup>®</sup> ECR cleaning is superior to the manual cleaning required of traditional AERs.

CO-1003814

CL-101263 Rev. C (10/10)

**ADVANCED STERILIZATION PRODUCTS<sup>®</sup>**

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Published in the July 2010 issue of *BioMed Central*, this peer-reviewed article demonstrates overall compliance of the EVOTECH® ECR cleaning with all benchmarks for surfaces and lumens was greater than 99 percent.

- **Using the EVOTECH® ECR as directed reduces the inconsistency and safety risks of manual cleaning.** Peer-reviewed results from a first-of-its-kind study entitled “Endoscope Reprocessing Methods: A Prospective Study on the Impact of Human Factors and Automation” published in the July/August 2010 issue of *Gastroenterology Nursing* showed that while there are written endoscope reprocessing guidelines in place at each of the study sites, only one in 69 (1.4%) endoscopes reprocessed manually was reprocessed in accordance with existing guidelines. In comparison, 75.4% of endoscopes reprocessed using the EVOTECH® ECR were completed according to guidelines. Automation also resulted in reduced occupational health issues and time pressure for staff.

To learn more about the EVOTECH® ECR of ASP, download the copies of the manuscripts at [www.aspji.com](http://www.aspji.com), or contact ASP Professional Services at 888-783-7723 to request copies.

Sincerely,

ASP Professional Services

\*Does not eliminate bedside precleaning in procedure room and no manual cleaning is required when selecting a cycle that has a wash stage.