



EVOTECH[®]

Newly Published Data Demonstrate EVOTECH[®] Endoscope Cleaner and Reprocessor (ECR) Superior to Manual Cleaning of Endoscopes

Study Result Highlights:

- EVOTECH[®] ECR cleaning is superior to traditional manual cleaning.
- The EVOTECH[®] ECR provides an effective automated approach that provides greater assurance that flexible endoscopes are adequately cleaned.
- The EVOTECH[®] ECR provides effective removal of both organic material and bioburden from all channels and all surfaces of the flexible endoscopes evaluated.
- The EVOTECH[®] ECR achieved greater than 99 percent compliance with all benchmarks for surfaces and lumens.

First-of-its-Kind Study

Newly published data demonstrated the EVOTECH[®] ECR provides an automated approach superior to the manual cleaning required of traditional AERs. Published in the July 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.

Study Overview

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: $< 6.4 \mu\text{g}/\text{cm}^2$ of residual protein, $< 1.8 \mu\text{g}/\text{cm}^2$ of residual hemoglobin and $< 4 \text{Log}_{10}$ viable bacteria/cm².

Cleaning efficiency was validated for elective procedures, not emergency endoscopies, and only with bedside flushing.

Key data includes:

- The overall compliance of the EVOTECH[®] ECR cleaning with all benchmarks for surfaces and lumens was greater than 99 percent.
- In the clinical 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 clinical-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.¹

Based on the data, the study authors concluded the EVOTECH[®] ECR cleaning cycle provides an effective automated approach that ensures flexible endoscopes are adequately cleaned.

Helping Healthcare Facilities Raise the Standard of Care

- 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.²⁻⁸
- A recent study by ASP indicates that as much as 60 percent of scopes may not be processed correctly.⁹
- Improper reprocessing of flexible endoscopes can result in infection transmission and chemical colitis.¹⁰⁻¹⁵
- 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.¹⁶
- On December 3, 2009, the U.S. Food and Drug Administration (FDA) required all healthcare facilities to transition from the STERIS System 1[®] to a legally marketed reprocessing alternative.
- The EVOTECH[®] ECR, which is listed as a legally marketed alternative to the SS1[®], is the first commercially available system to eliminate manual cleaning when a cycle containing a wash stage is selected.
- Independent data now confirm the efficacy of the EVOTECH[®] ECR, providing all healthcare facilities with the opportunity to benefit from this new and more automated technology.

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

The EVOTECH[®] Endoscope Cleaner & Reprocessor (ECR) is the first commercially available system in the U.S. 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.aspjj.com.

STERIS System 1 is a registered trademark of the STERIS Corporation.

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

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