

*On behalf of the authors, STERIS is posting this abstract of the research paper "Effectiveness of the SYSTEM 1E Liquid Chemical Sterilant Processing System for Processing Duodenoscopes."  
The full manuscript has been accepted for publication.*

## **Effectiveness of the SYSTEM 1E<sup>®</sup> Liquid Chemical Sterilant Processing System for Processing Duodenoscopes**

**BACKGROUND:** Infection transmission events involving antibiotic resistant microbial pathogens have been associated with the use of duodenoscopes. The US Food and Drug Administration (FDA) has requested that manufacturers of endoscope reprocessing systems perform additional testing with duodenoscopes to establish greater confidence in the safe and effective use of those automated reproducers.

**OBJECTIVE:** STERIS was asked to provide additional simulated use data using varied duodenoscope designs to support the safety and effectiveness of STERIS's SYSTEM 1E Liquid Chemical Sterilant Processing System (S1E) as a low temperature sterilization option for duodenoscopes. The duodenoscopes tested were Olympus TJF-Q180V, Olympus TJF-160F and Pentax ED-3490TK, selected to represent both open and closed elevator guide-wire designs. The protocol incorporated more stringent parameters than previously performed for the premarket clearance of the system. The test approach was to first establish the load of spores achieved on each test site of each device using validated inoculation and recovery methods, then to determine the log reduction achieved at each site after processing through a "worst case" S1E cycle.

**STUDY DESIGN AND SETTING:** This study was conducted by STERIS Corporation and incorporated soiling conditions, spore loads, drying, no rinsing, and other stringent test parameters requested by FDA. All internal channels and the distal tip of each scope were inoculated with *Geobacillus stearothermophilus* in 400 ppm hard water with 5% serum, to achieve more than 6 log<sub>10</sub> of recoverable test organisms per site. Inoculated scopes were allowed to dry for an hour, followed by processing in S1E with 2.5 minutes exposure to sterilant. Neutralized samples were recovered from each site, filtered, and incubated on TSA for seven days to enumerate recoverable organisms.

**OUTCOMES AND MEASURES:** The testing established the recoverable load of *G. stearothermophilus* on each site of each device after the inoculation procedure, enabling the log reduction per site to be calculated after reprocessing. Reprocessing consisted of a "worst case" S1E test cycle using end of shelf life sterilant concentration, lowest flow conditions for the pump, lowest acceptable UV intensity, and worst case incoming water temperature, in addition to less than half of the standard 6-minute sterilant exposure time.

**RESULTS:** The protocols were completed and results submitted to FDA in October, 2015. In three consecutive trials for each of the three duodenoscopes, each channel and distal tip of every device demonstrated greater than a 6 log<sub>10</sub> reduction of spores at an exposure time less than half of the SYSTEM 1E's standard liquid chemical sterilization cycle.

### **CONCLUSIONS:**

SYSTEM 1E Liquid Chemical Sterilant Processing System is a fast, safe, and effective method for low temperature liquid chemical sterilization of duodenoscopes.