ASGE Emphasizes Steps in Endoscope Reprocessing

In late 2006 the FDA approved new labeling for an automated endoscope reprocessor (the EvoTech System) manufactured by Advanced Sterilization Products (ASP), a division of Johnson & Johnson Company. This machine was originally approved for high level disinfection of GI Endoscopes in 2005. The new labeling clears the machine as a washer-disinfector, for use after bedside pre-cleaning only, without prior manual washing and channel brushing. ASP recently began marketing for a June release in the United States. The new labeling and current marketing raise concerns regarding maintenance of optimal reprocessing practices. In order to understand the FDA basis for approval and the capabilities of the recently approved machine, the Technology Committee of the ASGE and representatives of the Society for Gastrointestinal Nurses and Associates (SGNA) recently met with representatives of the manufacturer. Technology Committee members also met with the FDA.

High level disinfection (HLD) refers to treatment of medical devices to remove all viable micro-organisms except some spores when present in a significant load. National consensus standards for endoscope reprocessing emphasize: a) bedside cleaning and aspiration of enzymatic detergent through the suction channel, b) manual washing and brushing of accessible channels, c) subsequent disinfection via immersion for an appropriate duration in a liquid chemical germicide of appropriate concentration, followed by d) a water rinse, alcohol flush and air drying of all channels. The manual washing and brushing of all accessible channels has always been a critical step prior to performing HLD. This new labeling of the Evotech System represents a break from this consensus standard.

Automated endoscope reprocessors are FDA cleared for high level disinfection of flexible endoscopes when used according to manufacturer's recommendations. All currently available systems are labeled for HLD following manual washing, as outlined by the Society for Gastrointestinal Nurses and Associates.

In the studies submitted for clearance the EvoTech machine reduced residual organic carbon to acceptable levels, as determined by the FDA. To our knowledge, to date, only proprietary data have been generated for this machine, applied to an incomplete selection of currently available endoscopes. At the present time no independent confirmatory data and no clinical data from production devices have been released or published. The machine is designed to detect channel obstruction but no claims are made regarding detection of partial compromise of lumens or of retained objects, two of the benefits of manual brushing.

While the introduction of automated, brushless washing of endoscope channels represents a potentially significant advancement, the Technology Committee of the ASGE emphasizes the existing Multi-Society Guidelines and other international standards, all of which highlight the importance of manual washing and brushing for the overall efficacy of HLD. The redundancy achieved by *adding* an automated washing step following manual washing can undoubtedly provide an extra level of safety. Members are cautioned about dispensing with manual washing

and brushing steps before the capabilities of the new machine are confirmed in independent studies and in clinical practice. Lastly, all currently used machines in the United States are labeled specifically for use only after manual washing with mechanical brushing. Diligence in application of all steps of washing and disinfection remains paramount in the safe delivery of endoscopic services.

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