

Product Bulletin

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Date: **November 28, 2015**

RE: INTERCEPT® Detergent use throughout endoscope cleaning process

Endoscope Technology Hazard

Flexible medical endoscopes are extremely useful instruments in providing diagnostic and therapeutic patient care; however, they also carry a high level of risk related to their condition, their ability to be consistently cleaned and subsequently disinfected, and for the entire process to be adequately documented. As identified in recent patient fatalities associated with Carbapenem-resistant Enterobacteriaceae (CRE) infections that attracted national media attention, endoscopes are very complex medical devices that require a high degree of specialized training and reprocessing expertise. These events resulted in the ECRI Institute elevating flexible endoscope reprocessing as the #1 Health Technology Hazard in 2016.

It is now the responsibility of industry in conjunction with healthcare professionals, to raise the standard of reprocessing using new technologies, processes and education to enhance the standard of cleaning of flexible endoscopes, and to emphasize the importance of endoscope condition in the success of this process.

INTERCEPT Cleaning Detergent

Medivators strongly recommends the use of INTERCEPT Detergent and Cleaning products for all steps of the endoscope cleaning and disinfection process.

Using the full line of INTERCEPT Detergent and Cleaning products throughout the entire cleaning process will:

- Increase compliance with manual or automated cleaning standards
- Ensures the same mechanism of cleaning action is always used
- Standardize and provide consistency in the cleaning process
- Improve reprocessing efficiencies
- Deliver a best practices approach to endoscope cleaning

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The INTERCEPT® Detergent family of products includes Bedside Kits, Detergent and Wipes, and are uniquely designed for use on endoscopes and other medical devices. INTERCEPT Detergent also delivers superior cleaning performance and aids in the physical removal of biofilms.

INTERCEPT Detergent is required for the ADVANTAGE PLUS® automated endoscope reprocessor's cleaning cycle. INTERCEPT Detergent is fully validated to meet the FDA requirements for cleaning of flexible, immersible endoscopes when used in the ADVANTAGE PLUS (AER) cleaning cycle to enhance the manual cleaning process of endoscopes prior to placement in the AER. This is documented in the indications for use statement in the FDA 510(k) ADVANTAGE PLUS (AER) cleaning claim.

INTERCEPT Detergent has a fast 1-minute contact time compared to a standard 2-minute contact time with most enzymatic detergents, and it has no endoscope material compatibility issues which results in less endoscope downtime and reduces endoscope repair costs.

The INTERCEPT Detergent family of products meets society guidelines for effective manual and automated cleaning, and is recommended for use in all steps of the endoscope cleaning process.

If you have any questions related to this bulletin, please contact Medivators technical services department on 1-800 444 4729.