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Date: **October 13, 2008**

Subject: Staining after use of Intercept on endoscopes disinfected with OPA

We have received customer reports of a black discharge from endoscopes that had been high-level disinfected with OPA after commencing the use of Intercept.

OPA (orthophthalaldehyde) is an organic dialdehyde that reacts with the amino acids in proteins, producing a highly colored (blue to light purple) derivative. Research indicates that OPA acts partly by binding with proteins on the cell wall of microorganisms (although it is soluble in the bacterial membrane and may penetrate into the cell to cause further damage). Once reacted, the proteins may fragment but the coloration remains and may intensify with time. If endoscopes are not properly cleaned and rinsed prior to reprocessing, these stained proteins will dry onto endoscope and reprocessor surfaces.

Enzymatic detergents act by breaking internal chemical bonds in proteins and in some cases carbohydrates. Soil is removed from the biofilm surface inwards. Improper use of enzymatic detergents can result in residual protein on endoscope surfaces, leaving an endoscope with a protein residual which would promote the formation of permanent bacterial biofilms.

Intercept, a non-enzymatic detergent, removes soil by breaking the bonds between the soil and surface of the endoscope. This mechanism results in more complete soil removal under most conditions. Continued use of Intercept will remove any residual soil from endoscope surfaces, preventing the formation of bacterial biofilms. Biofilms on medical devices have been implicated as sources of nosocomial infections.

When Intercept is used on endoscopes that have been disinfected with OPA, a dark liquid may be observed exiting the endoscope distal tip. This is a direct result of Intercept removing protein accumulation from endoscope surfaces which has reacted with OPA, forming a black material which stains surfaces. Regular use of Intercept will remove biofilms and the reacted protein. When all residuals have been removed, the discharge of dark liquid will cease and basin staining will be reduced.

A copy of this product bulletin is available on the Medivators website located at www.minntech.com/medivators by selecting "Medivators Reprocessing Systems" followed by "Resource Center." If you have any questions regarding this Product Bulletin, please contact Medivators Customer Support at 1-800-444-4729.