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Date: May 6, 2010

RE: Material Compatibility of Rapicide PA HLD with Fujinon EC450 HL5 Colonoscope

A study was conducted to evaluate the material compatibility effect of an endoscope reprocessing cycle using Medivators Rapicide PA on an Fujinon EC450 HL5 colonoscope. The tests were conducted at 32 ± 0 C and included colonoscope exposure to a 0.3% solution of Intercept detergent.

The EC450 HL5 was subjected to five hundred (500) high level disinfection (HLD) cycles in an automated endoscope reprocessor (AER), to simulate approximately 1 year of endoscope usage and reprocessing. The endoscope was evaluated at the beginning and the conclusion of the study by Surgical Repair Technologies to identify and describe any significant cosmetic changes or operating functions of the endoscope.

The AER HLD cycles were performed as follows:

- Flush rinse (0.5 minutes, fresh water only)
- Detergent inject (13 second @3 ml/second)
- Soak (exposure to detergent, 30 seconds)
- Rinse/Soak (rinse detergent residues from interior and exterior of endoscope)
- High Level Disinfection (5 minute exposure to Rapicide PA at 32 ± 0 C)
- Rinse (fresh water, 30 seconds)
- Alcohol inject (3 seconds @3 ml/second)
- Alcohol (30 second exposure)
- Air purge (60 seconds, using air filtered through a 0.2 micron bacteria retentive filter)

After 500 cycles, the endoscope was sent to Surgical Repair Technologies for evaluation.

Results and conclusion

The Instrument Inspection Report (available upon request) indicated that no visual or functional changes to the Fujinon EC450 HL5 colonoscope due to chemical exposure during the 500 cycle test period were detected. The conclusion of this study is that Rapicide PA HLD, when used as directed in a Medivators AER, is compatible with Fujinon endoscopes. Minntech Corporation Study Protocol QP-202474 describes the test parameters, methodology, and results in more detail, and is also available upon request.

Any questions or requests for additional information should be directed to Medivators Technical Support at 1-800-444-4729.

Endoscope reprocessing the way it should be

MEDIVATORS

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