



March 23, 2009

Re: Compatibility of Olympus Flexible GI Endoscopes with Compliance™ Sterilizing & Disinfecting Solution

Dear Healthcare Professional,

Metrex Research Corporation has recently launched a new sterilizing and disinfecting solution under the trade name Compliance™. The active ingredients in Compliance™ are 7.35% hydrogen peroxide and 0.23% peracetic acid. Compliance™ has a 15-minute high-level disinfection claim and a 3-hour sterilization claim in the United States.

As a screening study prior to more detailed and time-consuming simulated-use testing to investigate whether or not Compliance™ is compatible with Olympus GI endoscopes, Olympus immersed several insertion tubes (models CF-Q160AI & PCF-140I) in the solution for an extended period of time. Within 165 hours of immersion, one of the test insertion tubes had failed due to a swelling and loosening of the black polymer layer of the tube. The polymer layer of the insertion tube lost its adherence to the underlying metal substructure resulting in the creation of ridges and folds in the polymer layer of the tube. Due to the loss of a firm bond between the polymer layer and the underlying metal substructure, the insertion tube lost its normal elasticity and handling characteristics. This “buckling” of the insertion tube worsened with further contact with Compliance™ (refer to Figure 1) and was seen in the other test samples as well.

Conclusion

Due to the early failure of the test insertion tubes, Olympus has concluded that:

COMPLIANCE™ IS NOT COMPATIBLE WITH OLYMPUS GI ENDOSCOPES.

Warranty

The use of Compliance™ on Olympus endoscopes will not automatically void the standard Olympus warranty covering original materials and workmanship. However, Olympus does not endorse the use of Compliance™ on Olympus endoscopes and will not assume any liability for chemical damage to any endoscope as a result of its use.



FIGURE 1. This insertion tube was immersed continuously in Compliance™ for 263 hours at room temperature. The deterioration that caused an early failure of the insertion tube has become even more obvious. The black polymer layer of the insertion tube is swollen and has loosened from the metal mesh below. The white markings have yellowed. The insertion tube has lost its normal elasticity and handling characteristics.

If you have any additional questions, please contact your local Olympus Sales Representative or the Olympus Technical Assistance Center at 1-800-848-9024 (United States) or 1-800-387-0437 ext 703211 (Canada). Thank you.

Sincerely,

Olympus