



December 8, 2009

Re: STERIS Reliance™ EPS Endoscope Processing System and  
Olympus Flexible Endoscopes

Dear Health Care Professional:

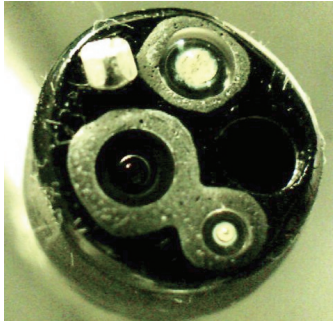
The purpose of this letter is to provide Olympus America Inc. (“Olympus”) customers with important information regarding the reprocessing of Olympus flexible gastrointestinal and pulmonary endoscopes with the STERIS Reliance™ EPS Endoscope Processing System (“Reliance EPS”). Olympus has not performed formal studies to evaluate the compatibility of the Reliance EPS with Olympus flexible endoscopes. As a result, Olympus does not list the Reliance EPS as a compatible reprocessing method for Olympus gastrointestinal and pulmonary flexible endoscopes.

STERIS Corporation provides a Technical Data Monograph on their website ([www.steris.com](http://www.steris.com)) containing information on the compatibility of flexible endoscopes with the Reliance EPS up to 300 cycles. No data on functional or performance compatibility of flexible endoscopes with the Reliance EPS is provided beyond 300 cycles. Please contact STERIS with any questions regarding the stated compatibility for up to 300 cycles and the Reliance EPS Technical Monograph.

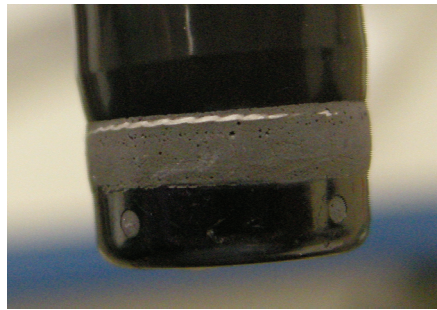
Olympus has received customer reports indicating degradation of flexible endoscope adhesives after use with the Reliance EPS. These reports note that repeated Reliance EPS processing of these Olympus flexible endoscopes causes damage and deterioration to specific materials used in the construction of the endoscope. In particular, the epoxy adhesives used to seal the endoscope against water infiltration and to fix certain components (e.g., bending section, objective lens) of the endoscope have been reported to deteriorate with repeated exposure to the Reliance EPS process. Examples of adhesive damage that may be observed following repeated Reliance EPS processing of Olympus flexible endoscopes are provided in the figure below.

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Telephone: (484) 896-5000  
[www.olympusamerica.com](http://www.olympusamerica.com)

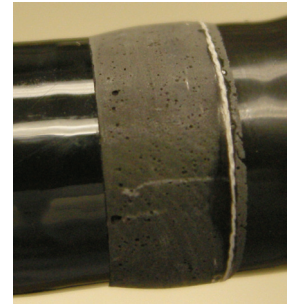
Deterioration and pitting of adhesive around lenses.



Deterioration and pitting of adhesive at bending section and distal end junction



Deterioration and pitting of adhesive at bending section and insertion tube junction



**Health care facilities using the Reliance EPS to reprocess their endoscopes are advised to inspect their endoscopes prior to each use for adhesive damage and to repair any endoscopes with missing or deteriorated adhesive prior to further patient use. Refer to the Endoscope's Reprocessing Manual for instructions on proper endoscope handling and reprocessing.**

Nothing contained in this letter alters, extends, or modifies in any way the authorized Olympus warranty applicable to your Olympus product(s). The use of the Reliance EPS does not by itself void the Olympus new product warranty for damage caused by faulty materials or workmanship. However, chemically-induced damage, such as blistering or peeling of the insertion and light guide tubes, degradation or discoloration of adhesives, and unexplained fluid entry into the endoscope resulting from the use of liquid chemical germicides that are not listed as compatible with Olympus endoscopes is considered non-warranty damage.

If you have any additional questions, please contact your local Olympus sales representative or the Olympus Technical Assistance Center at 1-800-848-9024.

Sincerely,



Bradley J. Catalone, PhD  
Director of Clinical Affairs

Reliance is a registered trademark of STERIS Corporation

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