March 2, 2009

RE: Compatibility of Olympus Flexible Endoscopes with Sporox and Sporox II (Covered Models: All fiberoptic and videoendoscopes)

Dear Healthcare Professional:

Olympus issued technical bulletins in April and November 1998 indicating that Sporox II Sterilizing and Disinfecting Solution manufactured by Reckitt & Colman may cause cosmetic changes but does not cause functional damage to the majority of Olympus flexible endoscopes. Those statements were based upon extensive laboratory testing of solutions provided by Reckitt & Colman. However, since the introduction of Sporox to the market in the spring of 1998, Olympus has received and investigated several reports of Sporox-associated damage to Olympus flexible endoscopes. In addition, Olympus has also continued laboratory testing of Sporox and a modified formulation, Sporox II. **The purpose of this letter is to inform you that after evaluating the data obtained from current investigations, Olympus cannot list Sporox or Sporox II as compatible with Olympus flexible endoscopes.**

After receiving a number of reports of damage to flexible rhinolaryngoscopes and colonoscopes, Olympus interviewed personnel at the reporting facilities, as well as other facilities that were using Sporox but not reporting problems, in order to iderltify factors that could be contributing to the damage attributed to Sporox. Laboratory studies were also performed with Sporox and Sporox II.

Field Reports

Beginning in late 1998, Olympus received several reports of damage to the insertion tubes of flexible endoscopes. The damage to colonoscopes (e.g., CF-140L) was restricted to buckling of the resin composing the bulk of the insertion tube and cracking of the clear polymer coating ("clear coat"), which covers the insertion tube. The damage observed on rhinolaryngoscopes was to the clear coat of the insertion tube as well as to the underlying insertion tube resin, but there was no sign of buckling. Subsequent interviews of the 28 facilities reporting damage indicated that the average time that Sporox was in use was 8.6 months (Range 5 to 16). Other than the use of Sporox, there were no other remarkable reprocessing materials or techniques noted. These data strongly suggested that the use of Sporox was associated with damage to the insertion tubes of Olympus flexible endoscopes.

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Laboratory Studies

The reports of damaged endoscopes in clinical settings prompted a re-examination of previous compatibility studies performed with intact endoscopes. This review suggested that there might be reason to believe that damage could be confirmed if tested under the most challenging laboratory conditions. In order to gain insight into the recent clinical reports, isolated insertion tube materials were soaked in Sporox and Sporox II. In a preliminary experiment consisting of 500 hours of exposure of the outer portion of the insertion tube material, the material displayed damage similar to that previously seen at clinical facilities. Additional laboratory testing of Sporox II for 250 hours showed damage to the insertion tube clear coat, glues and some paints. Taken together, these laboratory studies indicate that Sporox and Sporox II are capable of damaging the insertion tube materials used in Olympus flexible endoscopes under controlled laboratory conditions.

The results of interviews and clinical inspections suggest that incomplete rinsing (at times leaving a white residue) and elevated temperature may play a role in damage or at least accelerate the damage. However, the new laboratory results confirmed that insertion tube damage can also occur at room temperature.

At the present time it is not possible to predict if all models of Olympus flexible endoscopes or all clinical sites using Sporox will experience durability problems. However, the results of current investigations of damage to rhinolaryngoscopes and colonoscopes, and observations of damage to gastroscopes and flexible cystoscopes, form the basis for the current decision not to list Sporox or Sporox II as a compatible sterilantl/disinfectant for any Olympus flexible endoscope.

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Illustrations of Endoscope Damage After Repeated Exposure to SPOROX@ Sterilizing & Disinfecting Solution

Severe buckling of the insertion tube on a CF-140L colonoscope. The outer covering of the insertion tube has detached from the metal substructure below. This results in a loose, wrinkled outer cover. The wrinkles are particularly evident when the insertion tube is flexed.

Cosmetic damage to an ENF-P3 rhinolaryngoscope. The black anodized coating on various parts of the control section has been removed, resulting in a silvery and/or golden tinge. Similar loss of anodization is usually observed on portions of the light guide connector.

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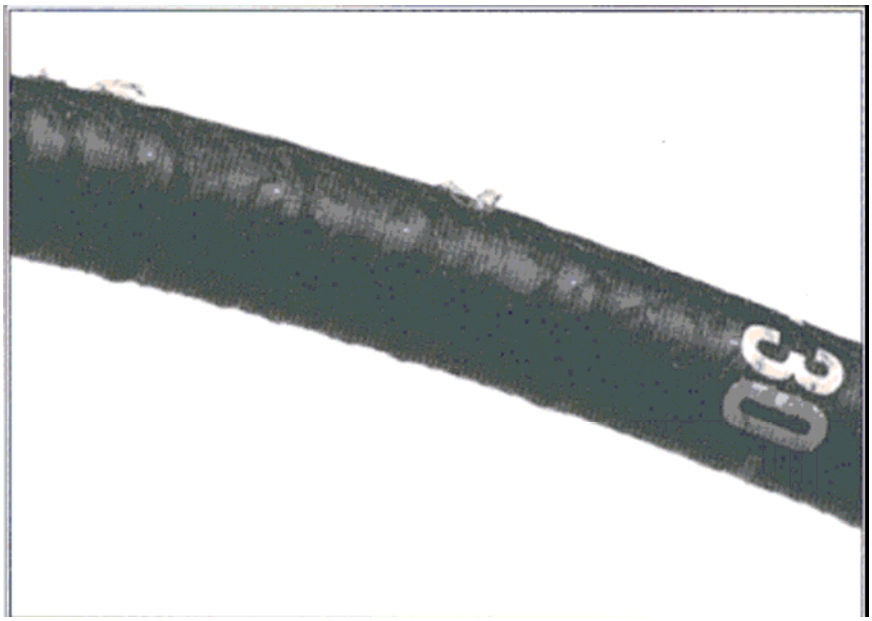
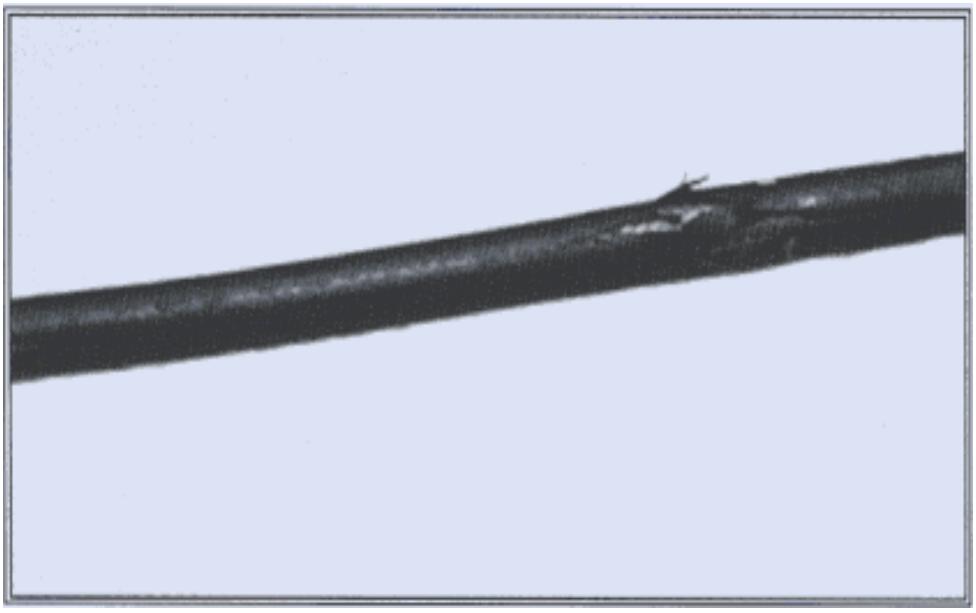


The normally smooth, shiny, clear outer coating on this GIF-140 gastroscope is now cracked and crazed. The topcoat of the insertion tube has started to peel as it deteriorates.



The insertion tube on this ENF-P3 shows erosion of the top shiny layer. Deterioration of the resin results in a roughened surface, erosion of the white markers, and finally tears in the coating itself.

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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

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