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Re: *Automated reprocessing using a newly introduced high-level disinfectant*

Steris Corp. recently introduced onto the U.S. market *Resert XL HLD*, a high-level disinfectant labeled for manual and automated reprocessing of reusable semi-critical medical instruments, including flexible endoscopes. Resert's active ingredient is 2.0% hydrogen peroxide, and it is labeled to achieve high-level disinfection in 8 minutes (not longer) at room temperature with no heating (20° C; 68° F). Dispensed in a 4 liter container and ready to use without activation or dilution, Resert also contains furoic acid.

While its labeling indicates that it is compatible with many materials (including polypropylene, polyethylene, silicon rubber, Teflon, PVC, and 302 stainless steel), Resert is acidic, with a pH between 2.2 and 2.6. (For comparison, activated Cidex has a pH of 8.2 to 9.2, and Cidex OPA has a pH between 7.2 and 7.8.; a neutral pH is 7.0). Because of its acidity and a lack of available data, the compatibility of Resert with some of the materials and components used in the construction of the Custom Ultrasonics *System 83 Plus Washer-Disinfector* (and the endoscope) is unknown at this time.

Resert's labeling states that it is not compatible with and may corrode, for example, copper, brass, tungsten carbide, chromium-plated brass and nickel-plated steel. Therefore, Custom Ultrasonics Inc., does not endorse the use of Resert in the *System 83 Plus* at this time.

To prevent confusion in the event of damage caused by Resert to any of the materials used in the construction of the *System 83 Plus* or the endoscope, Custom Ultrasonics, Inc. further recommends that, before using it in the *System 83 Plus*, the medical facility first obtain a "letter of compatibility" from the endoscope's manufacturer indicating that Resert, as with any newly introduced high-level disinfectant, has been demonstrated to be compatible with all of the brands and models of endoscopes used by the medical facility.

In addition, Custom Ultrasonics has not performed itself any validation or verification testing to evaluate the compatibility of Resert with the *System 83 Plus*. Therefore, in addition to this letter, Custom Ultrasonics, Inc. requests that a facility obtain from Steris (Resert's manufacturer) a "letter of indemnification" as well. This letter from Steris would state that, in addition to whether it has determined that Resert is compatible with

all of the *System 83 Plus*'s components and materials, Steris will fully reimburse the facility for any damage – such as corrosion, tears, or discoloration of the scope's anodized finish, that might directly or indirectly be due to Resert (or any newly introduced high-level disinfectant) and/or may occur to any of the components or materials of the *System 83 Plus* or the endoscope.

Use of Resert in the *System 83 Plus* without the medical facility having obtained these letters (and provided both letters to Custom Ultrasonics, Inc. for its review), in addition to precluding Custom Ultrasonics, Inc. from sanctioning Resert's use, may void Custom Ultrasonics's warranty and, possibly, result in the medical facility incurring expensive repair costs.

Understandably, Custom Ultrasonics Inc. cannot be held financially responsible for materials' damage to the *System 83 Plus* or the endoscope caused by the use of a newly introduced high-level disinfectant.

Thank you for your cooperation.

Please contact Custom Ultrasonics, Inc. if you have any additional questions.