November 26, 2013

RE: Material Compatibility of Olympus Endoscopy Equipment Repaired by an Independent Service Organization (ISO)

Dear Health Care Professional:

The purpose of this letter is to highlight reprocessing compatibility and efficacy awareness amongst Olympus endoscope users utilizing Independent Service Organizations (ISOs). Please note that the instructions provided in the Olympus reprocessing manual have not been validated for Olympus devices repaired by an ISO. In the event that your device has been repaired by an ISO, please contact that repair facility for instructions regarding reprocessing.

Olympus does not support or authorize ISOs to repair Olympus equipment, nor does Olympus provide training or parts to ISOs to enable them to repair Olympus equipment to Olympus standards. As a result, Olympus has no knowledge of the specifications of the materials used by ISOs to repair Olympus equipment, nor the quality of such repairs. Olympus conducts a rigorous testing program to validate both compatibility of our instruments with specific reprocessing methods and agents, as well as the efficacy of such methods for reprocessing the device. Without knowledge of the materials used or the final quality of repair being provided by ISOs, Olympus is unable to validate the compatibility or reprocessing efficacy of the Olympus instructions provided in our product-specific reprocessing manuals. As a result, the instructions provided in our product-specific instruction manuals are invalid for Olympus equipment that has been repaired by an ISO. If your Olympus equipment was or is being repaired by an ISO, please contact that repair facility to obtain instructions on device compatibility and their recommended reprocessing procedures to ensure that your facility is following safe and validated reprocessing instructions.

We have recently revised many of our reprocessing manuals to include the above explanation of our policy.

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

Sincerely,

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