March 5, 2015

Dear Valued Customer:

Re: Recent Media Coverage on the Olympus TJF-Q180V Duodenoscope

As you are aware, there has been recent media coverage about “superbug” bacterial infections in U.S. hospitals using duodenoscopes to perform endoscopic retrograde cholangiopancreatography (ERCP) procedures. As the leading manufacturer of duodenoscopes, Olympus has been highlighted in some of these articles. We would like to take this opportunity to provide you with additional clarity and context.

- Olympus as a medical device manufacturer continuously strives to improve our products for safe and effective use. This includes changes to device design.
- Olympus markets the TJF-Q180V duodenoscope in the U.S. based upon applicable 510(k) clearance guidelines. Olympus modified our 510(k)-cleared duodenoscope in 2010 and determined that the resulting TJF-Q180V did not require a new 510(k) application according to the FDA policy on modifications to 510(k)-cleared devices.
- The FDA subsequently requested a 510(k) application with information regarding the modified device. Olympus submitted a 510(k) to the FDA and the company continues to cooperate with the agency.
- In an FDA statement from February 23, 2015, Dr. William Maisel recognized, “The vast majority of ERCPs are conducted without incident and often to the patient’s great benefit. For most patients, the benefits of this potentially life-saving procedure far outweigh the risks of possible infection."
- In an update to their Safety Alert, on March 4, 2015, the FDA stated the following:
    - The FDA has received inquiries from healthcare providers about whether they should cancel ERCP procedures, based on the fact that one specific model duodenoscope manufactured by Olympus (the TJF-Q180V) does not currently have a 510(k) clearance. FDA is not recommending that healthcare providers cancel ERCP procedures for their patients who need them.
    - Olympus has a pending 510(k) application for this device, and the company continues to market the product while the application is under review. FDA is not taking action against Olympus regarding its device during our review of the application, because, based on the information currently available to the Agency, we believe that removal of the device from the market could lead to an insufficient number of available duodenoscopes to meet the clinical demand in the United States of approximately 500,000 procedures per year.
    - The FDA’s analysis indicates that the reported duodenoscope-associated infections have occurred in patients who have had procedures with duodenoscopes from all three manufacturers. At this time, FDA has no evidence that the lack of a 510(k) clearance was associated with the infections.
- According to industry estimates there are more than 500,000 ERCP procedures performed in the U.S. on an annual basis and while any complication affecting a patient’s health is a serious matter, the reported incidence of infections is extremely low.
- The emergence of drug-resistant microorganisms is a challenge to the entire healthcare community. Olympus is working with relevant medical societies and our customers in research of this emerging issue and the development of additional safeguards to prevent infection associated with endoscopic procedures including ERCP.

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- Olympus provides you, our customers, with many educational offerings to guide the proper cleaning and reprocessing of our duodenoscopes including but not limited to operation and reprocessing manuals, process reference materials, peer-to-peer on-site training, a Technical Assistance Center 1-800 number and professional education courses.

Olympus strives to keep you, our customers, as informed as possible, however, for practical reasons, we do not comment on active legal matters or speculation. We continue to monitor this issue closely and work with the FDA, relevant medical societies and customers to address concerns, including the consideration of alternative cleaning and reprocessing methods.

If you require additional information about the proper steps to clean and reprocess the TJF-Q180V, there are numerous ways to obtain this information:

- You can contact our Technical Assistance Center (TAC) at 1-800-848-9024, option 1. The TAC department can assist in answering questions on TJF-Q180V cleaning and reprocessing and obtaining additional copies of the TJF-Q180V Reprocessing Manual and supplemental educational materials.

- Olympus also has dedicated field personnel, called Endoscopy Support Specialists, who visit customer sites to assess and observe customer reprocessing methods and to provide reprocessing training and education. If you would like an ESS to visit your facility to review and train on TJF-Q180V cleaning and reprocessing instructions, please request a site visit by calling our TAC department at 1-800-848-9024, option 1.

- Olympus offers an extensive program of educational programs for endoscopy, with specific courses on endoscope reprocessing for both nurses and reprocessing specialists. Please visit our website at www.olympusuniversity.com or call the Olympus Registration help desk at 1-800-231-0016 to obtain more information.

- Olympus has a webpage dedicated to reprocessing information for Olympus endoscopy equipment at www.olympusamerica.com/msg_section/cds/index.asp.

- Your Olympus sales representative can serve as a resource in assisting you in obtaining reprocessing information.

Lastly, Olympus requests that you report any infections or persistent microbial colonization associated with Olympus endoscopes by calling our Technical Assistance Center (TAC) at 1-800-848-9024, option 1.

Thank you for your continued support.

Sincerely,

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President, Medical Systems Group, Olympus Corporation of the Americas