



September 6, 2019

Dear Valued Customer:

As you are aware, the FDA recently published a Safety Communication and Press Release recommending the transition from fixed endcap to disposable endcap duodenoscopes and announced results of the 522 order for postmarket surveillance studies. We are writing to you because we value our relationship with you and understand the importance of the decisions you will make in the future as you consider FDA guidance.

Olympus shares your concern about patient safety. We are supportive of the FDA's recommendation of a gradual transition to duodenoscopes with disposable components, and we recognize that a full transition away from conventional duodenoscopes to newer models will take time. Accordingly, we are working with the FDA to bring our disposable endcap duodenoscope to the U.S. market as soon as possible. In the meantime, we will be working closely with you to develop plans for transitioning away from current fixed endcap models.

The FDA's recommendation for a transition to duodenoscopes with disposable components is based in part on findings from the 522 Order for the postmarket surveillance of duodenoscopes, issued in October 2015 to Fujifilm, Pentax, and Olympus. We were told to investigate the following: Human Factors: 1) Whether it is possible for the products to be reprocessed in accordance with the instructions for use; Sampling and Culturing: 2) Whether bacteria remain on the duodenoscopes after healthcare facilities reprocess them; and, 3) If bacteria remain, the cause of this and steps for elimination.

The FDA has published final results of the Human Factors Study and interim results of the Sampling and Culturing Study. The Human Factors Study shows that some nurses and technicians had difficulty with the multi-step tasks involved in reprocessing duodenoscopes. The Sampling and Culturing Study shows a 4.1% residual contamination rate for high-concern organisms on the TJF-Q180V and a 6.1% residual contamination rate for high-concern organisms on TJF-160F/VF duodenoscopes. Because the JF-140F and the PJF-160 duodenoscopes are used infrequently, Olympus has been unable to obtain the required number of samples to complete the 522 Postmarket Surveillance Study for both of these models. Upon the FDA's recommendation, we will be modifying the labeling on our duodenoscopes to include the contamination rate shown in the Sampling and Culturing Study.

It is important to note that contamination rate does not equal infection rate, and that rates of patient infection associated with duodenoscopes have always been relatively low and have more recently declined due to enhanced efforts to improve patient safety. Even so, we understand and share the agency's concern about these findings, and we are devoting significant resources to address these concerns. The initiatives underway to support duodenoscope reprocessing and enhance infection prevention include:

- Consulting third-party experts on options to enhance our instructions for use in order to improve user adherence;
- Providing additional customer support through enhanced training, including technician retraining, and more frequent scope inspections;
- Making additional reprocessing resources available to technicians, including introduction of a Visual Reprocessing Guide for the TJF-Q180V, which provides detailed illustrations of reprocessing steps; and
- Evaluating design changes to enhance reprocessing efficacy.

We are continuing our root cause analysis of the 522 Order findings, and with patient safety top of mind, we are using the results to inform new product development and as the basis for planning future studies.

We know that you have come to depend on the image quality and precise handling of Olympus duodenoscopes because the excellence of these features could mean the difference in saving a patient's life, for example by helping patients to avoid cancer or by allowing their physicians to conduct treatment in difficult to access anatomies. We are as committed to this excellence as ever during this process of improving infection control around the devices. Through our continued collaboration with governmental authorities and stakeholders such as yourselves, we are dedicated to providing innovative, life-saving products and supporting their safe and effective use.

We are aware that there are other options available to you in meeting your patient needs. Olympus considers it an honor to serve you, and we are committed to making every effort to maintain your trust in our products. We rely on individual relationships with our customers to maintain high levels of customer and patient satisfaction, and we want to serve you on that individual level. Should you have any questions, please do not hesitate to ask me directly.

Sincerely,

A handwritten signature in black ink, appearing to read 'K+MH' with a horizontal line extending from the end.

Kurt Heine
Group Vice President
Olympus America Inc.