

**From:** [REDACTED]  
**Sent:** Wednesday, August 26, 2015 7:10 PM

**To:** [REDACTED]

**Subject:** Olympus Statement

Thank you for your inquiry and for your interest in providing your viewers with balanced coverage regarding duodenoscopes and the medical procedures they enable. We want to express our sympathy to those patients and to their families who have experienced or have been affected by infections believed to be related to procedures using Olympus duodenoscopes. This issue is receiving the highest level of attention at Olympus. We have partnered with physicians for more than 65 years to meet their needs by developing innovative, high-quality medical products that help advance procedures and therapies that improve clinical outcomes. Our commitment to the healthcare community, patients and social responsibility is at the cornerstone of everything we do.

We are working with government authorities and other stakeholders to better understand and address the potential root causes of the patient infections to continually enhance safeguards related to the use of our products. You can learn about our most recent actions, as well as gain a better understanding of the context of current events, on our website at <http://medical.olympusamerica.com/duodenoscope> however I am including some of the more pertinent facts below:

- ERCP is an endoscopic procedure – performed with a special endoscope known as a duodenoscope – to diagnose and treat conditions in the pancreas, bile duct and gallbladder. This includes life-threatening jaundice (caused by blockage of the bile duct by gall stones), and pancreatic and biliary cancers.
- Per industry estimates, duodenoscopes are routinely used in more than 600,000 ERCP procedures performed each year in the U.S. Specially trained gastroenterologists perform ERCPs. This technique provides physicians and their patients with a highly effective and minimally invasive alternative to open surgery or laparoscopic (percutaneous) surgery.
- The duodenoscope's special features - necessary for reaching the intended anatomy - while performance-changing for physicians, require meticulous manual cleaning around and under the actual moving parts during reprocessing. Thorough cleaning is essential before high-level disinfection because inorganic and organic material that remain on the surfaces of instruments can interfere with the effectiveness of other processes within the reprocessing procedure.
- 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.
- Reprocessing information pertaining to the TJF-Q180V duodenoscope can be found online here: <http://medical.olympusamerica.com/duodenoscope>.
- Olympus provides device-specific reprocessing manuals and instructions for use to all customers upon purchase of any new, user or certified pre-owned Olympus technology. Olympus also provides several training resources (in-person and online) for customers to reference over the life of their equipment. Details about specific resources and action items can be found here: <http://medical.olympusamerica.com/letter-from-olympus>

Best Regards,

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