

March 4, 2015

Updated Information for Healthcare Providers Regarding Duodenoscopes

- 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 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.
- FDA recommends the following:
 - Thoroughly clean and disinfect duodenoscopes, pursuant to the manufacturers' instructions;
 - Have a comprehensive quality program in place for reprocessing duodenoscopes;
 - If you suspect that a duodenoscope may be associated with a patient infection, take it out of service and meticulously clean and disinfect it until it is verified to be free of pathogens;
 - Inform patients of the benefits and risks associated with ERCP procedures, including the risk of possible infection;
 - Discuss with your patients what they should expect following the ERCP procedure and what symptoms (such as fever or chills, chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, or black or tarry stools) should prompt additional follow-up;
 - Submit a report to the manufacturer and to the FDA via [MedWatch](#) if you suspect problems have led to patient infections.