



Public Health Advisory
FDA Safety Communication
Endoscopic Retrograde Cholangiopancreatography (ERCP)
Duodenoscopes

February 23, 2015

Situation:

FDA Safety Communication: Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes - Design May Impede Effective Cleaning

The FDA wants to raise awareness among healthcare professionals, including those working in reprocessing units in healthcare facilities, that the complex design of ERCP endoscopes (also called duodenoscopes) may impede effective reprocessing. Reprocessing is a detailed, multistep process to clean and disinfect or sterilize reusable devices. Recent medical publications and adverse event reports associate multidrug-resistant bacterial infections in patients who have undergone ERCP with reprocessed duodenoscopes, even when manufacturer reprocessing instructions are followed correctly. Meticulously cleaning duodenoscopes prior to high-level disinfection should reduce the risk of transmitting infection but may not entirely eliminate it. Read more on the FDA website, <http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm434922.htm>.

A handwritten signature in blue ink that reads 'Joseph P. Iser'.

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Chief Health Officer
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Health Alert: conveys the highest level of importance; warrants immediate action or attention
Health Advisory: provides important information for a specific incident or situation; may not require immediate action
Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action
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