

**PENNSYLVANIA DEPARTMENT OF HEALTH**

**2015- PAHAN -302 - 02-24-ADV**

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



<b>DATE:</b>	2/24/2015
<b>TO:</b>	Health Alert Network
<b>FROM:</b>	Karen Murphy, Acting Secretary of Health
<b>SUBJECT:</b>	Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes: FDA Safety Communication - Design May Impede Effective Cleaning
<b>DISTRIBUTION:</b>	Statewide
<b>LOCATION:</b>	Statewide
<b>STREET ADDRESS:</b>	Statewide
<b>COUNTY:</b>	Statewide
<b>MUNICIPALITY:</b>	Statewide
<b>ZIP CODE:</b>	Statewide

**This transmission is a “Health Advisory”: provides important information for a specific incident or situation; may not require immediate action.**

**HOSPITALS:** PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, INFECTION CONTROL, NURSING, AND LABORATORY STAFF IN YOUR HOSPITAL

**EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE

**FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE

**LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE

**PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP

The Pennsylvania Department of Health is sharing the following Food and Drug Administration alert regarding infection risks from incompletely cleaned duodenoscopes.

<http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm434922.htm>

The FDA wants to raise awareness among health care professionals, including those working in reprocessing units in health care 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.

The FDA is closely monitoring the association between reprocessed duodenoscopes and the transmission of infectious agents, including multidrug-resistant bacterial infections caused by Carbapenem-Resistant Enterobacteriaceae (CRE) such as *Klebsiella* species and *Escherichia coli*. In total, from January 2013 through December 2014, the FDA received 75 medical device reports encompassing approximately 135 patients in the United States relating to possible microbial transmission from reprocessed duodenoscopes. It is possible that not all cases have been reported to the FDA. The agency is continuing to evaluate information about documented and potential infections from multiple sources, including medical device reports submitted to the FDA, the medical literature, the health care community, professional medical societies, and the Centers for Disease Control and Prevention (CDC). The FDA is actively engaged with other government agencies, including CDC, and the manufacturers of duodenoscopes used in the United States to identify the causes and risk factors for transmission of infectious agents and develop solutions to minimize patient exposure.

The FDA continues to actively monitor this situation and will provide updates as appropriate.

**BACKGROUND:** Duodenoscopes are flexible, lighted tubes that are threaded through the mouth, throat, stomach, and into the top of the small intestine (the duodenum). They contain a hollow channel that allows the injection of contrast dye or the insertion of other instruments to obtain tissue samples for biopsy or treat certain abnormalities.

**RECOMMENDATIONS:** See the [FDA Safety Communication](#) for additional information and recommendations for facilities and staff that reprocess ERCP duodenoscopes.

#### **Recommendations for Health Care Providers:**

- Inform patients of the benefits and risks associated with ERCP procedures.
- 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, as described below, if you suspect that problems with reprocessing a duodenoscope have led to patient infections.

#### **Recommendations for Patients:**

- Discuss the benefits and risks of procedures using duodenoscopes with your physician. For most patients, the benefits of ERCP outweigh the risks of infection. ERCP often treats life-threatening conditions that can lead to serious health consequences if not addressed.
- Ask your doctor what to expect following the procedure and when to seek medical attention. Following ERCP, many patients may experience mild symptoms such as a sore throat or mild abdominal discomfort. Call your doctor if, following your procedure, you have a fever or chills, or other symptoms that may be a sign of a more serious problem (such as chest pain, severe abdominal pain, trouble swallowing or breathing, nausea and vomiting, or black or tarry stools).

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: [www.fda.gov/MedWatch/report](http://www.fda.gov/MedWatch/report)
- [Download form](#) or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Further information about the prevention of CRE transmission is available in CDC's CRE toolkit (<http://www.cdc.gov/hai/organisms/cre/cre-toolkit/index.html>).

Categories of Health Alert messages:

**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; no immediate action necessary

<p>This information is current as of February 24, 2015, but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.</p>
---