Supplemental Measures to Enhance Duodenoscope Reprocessing [Update]

**Summary:**
This report provides updated information based on FDA source material regarding Supplemental Measures to Enhance Duodenoscope Reprocessing, which was published on May 7, 2015.

**Problem:**
In an August 4, 2015, Safety Communication, FDA provided a list of supplemental duodenoscope reprocessing measures that emerged from an agency-led panel meeting earlier in 2015. FDA states that hospitals and healthcare facilities that use duodenoscopes can, in addition to meticulously following manufacturer reprocessing instructions, take one or more of these additional steps to further reduce the risk of infection and increase the safety of these medical devices:

- Microbiological culturing
- Ethylene oxide (EtO) sterilization
- Use of a liquid chemical sterilant processing system
- Repeat high-level disinfection

**ECRI Institute Perspectives:**

While the August 4, 2015, FDA Safety Communication referenced above discusses different disinfecting or sterilizing methods to be considered, the most important message the guidance presents reiterates two key points made by ECRI Institute in Alert Accession Nos. H0245 01 and H0245 02.

- Regardless of the disinfecting or sterilization method used, if the duodenoscope is not first thoroughly cleaned the disinfecting end goal cannot be assured.
- Duodenoscope microbiological culturing can be used to help assess the adequacy of reprocessing, but for it to be effective culturing must be done in conjunction with a well-conceived surveillance strategy.

**References:**

**United States:**

**Comments:**
This alert is a living document and may be updated when ECRI Institute receives additional information. In circumstances in which we...
determine that it is appropriate for customers to repeat their review of an issue (e.g., when additional affected product has been identified), we will post a separate update alert. In other cases, we may add information, such as additional commentary, recommendations, and/or source documents, to the original alert. For additional information regarding the format of this alert, refer to our HDA Format Guide.

- This Hazard Report and other technology management, patient safety, and risk management guidance articles and recommendations are publicly available in ECRI Institute’s CRE and Duodenoscope Resource Center, located at www.ecri.org/cre.

**Source(s):**
- 2015 Aug 7. FDA. Download
- 2015 Aug 7. FDA. Download