**Medical Device Hazard Report**

**UMDNS Terms:**
- Sterilizing Units, Germicidal Liquid [18006]

**Product Identifier:**
EVOTECH Endoscope Cleaners and Reprocessors (ECRs) used with Various Endoscopic Retrograde Cholangiopancreatography (ERCP) Endoscopes [Capital Equipment]

<table>
<thead>
<tr>
<th>ERCP Endoscope Manufacturers:</th>
<th>Model Nos.:</th>
<th>Elevators:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fujinon</td>
<td>ED-250XL5, ED-300XL5</td>
<td>Sealed</td>
</tr>
<tr>
<td>Olympus</td>
<td>TIF-Q180V</td>
<td>Sealed</td>
</tr>
<tr>
<td>Pentax</td>
<td>ED-310XU, ED-3200, ED-3270K, ED-3410, EG-3870UTK, JF-1T40</td>
<td>Open</td>
</tr>
</tbody>
</table>

- **Fujinon Elevators:**

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**Geographic Regions:** (Impact in additional regions has not been identified or ruled out at the time of this posting), U.S.

**Manufacturer(s):** Advanced Sterilization Products

33 Technology Dr, Irvine, CA 92618, United States

**Suggested Distribution:** Clinical/Biomedical Engineering, Infection Control, Gastroenterology, Central Sterilization Reprocessing

**Problem:**

In an April 3, 2014, Urgent Product Notification letter submitted by an ECRI Institute member hospital, ASP states that a recent article, “CDC: Superbugs can be spread via endoscopy” published on January 7, 2014, linked carbapenem-resistant Enterobacteriaceae (CRE) occurrences to the use of automated endoscope reprocessing systems to reprocess ERCP endoscopes. ASP is proactively communicating the potential risk associated with inadequate reprocessing in the elevator channel area. ASP emphasizes that it is not recalling ECRs and states that the reported occurrences are not connected to ASP products. ASP has not confirmed the information provided in the source material.

**Action Needed:**

Identify any affected ECRs that are used to reprocess the above ERCP endoscopes in your inventory. If you have affected ECRs and ECRP endoscopes, verify that you have received the April 3, 2014, Urgent Product Notification letter from ASP. ASP recommends the following:

1. Ensure that the elevator channel is manually cleaned according to the manufacturer's instructions before reprocessing the entire endoscope in affected ECRs. ASP states that it is aware of one endoscope model, Olympus TJF-Q180V, which includes specific instructions on manually cleaning the elevator channel. This information has been incorporated into the associated EVOTECH ECR connection diagram (CD-101551-001). ASP states that as the industry continues to investigate cross-contamination related to ERCP endoscopes, additional updates may be issued as a result.

2. Review and fully understand both the EVOTECH ECR labeling and the ERCP endoscope labeling as they relate to the cleaning and reprocessing of the elevator channel.

Inform all relevant personnel at your facility of the information in the Urgent Product Notification letter. Retain a copy of the letter with EVOTECH ECRs in your facility.

**For Further Information:**

Stericycle
Tel.: (877) 552-7141 (Reference Event No. 5205)
Website: [Click here](#)

ASP
Website: [Click here](#)

**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](#).

**Source(s):**

- 2014 Apr 8. Member Hospital. ASP letter submitted by an ECRI Institute member hospital. Reference No. CL-90098-041. [Download](#)