Manufacturer Reminds Users about Risk of Inadequate Reprocessing in Elevator Channel Area

**Medical Device Hazard Report**

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

**ERCP Endoscope Manufacturers:**
- Fujinon
- Olympus

<table>
<thead>
<tr>
<th>Manufacturer</th>
<th>Model Nos.:</th>
<th>Elevators:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fujinon</td>
<td>ED-250XL5, ED-250XT5, ED-450XL5, ED-530XT</td>
<td>Sealed</td>
</tr>
<tr>
<td>Olympus</td>
<td>TJF-Q180V</td>
<td>Sealed</td>
</tr>
</tbody>
</table>

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

**Problem:**
Manufacturer states that its EVOTECH Endoscope Cleaners and Reprocessors (ECRs) used with various ERCP endoscopes may not be adequately reprocessed in the elevator channel area. This may lead to potential risk of infection for patients.

**Action Needed:**
- Verify that you have received the September 27, 2011, Urgent Device Recall letter dated September 27, 2011. The manufacturer has not confirmed the information provided in the source material.
- FDA’s Center for Devices and Radiological Health (CDRH) states that the manufacturer initiated a recall by Urgent Device Recall, and the regulatory agency also states that the manufacturer initiated a recall by Urgent Device Recall.
- Leads in the above devices may short, potentially resulting in shocks and burns.

**Distributor:**
- LifeWatch—LifeStar Ambulatory Cardiac Telemetry Systems: Leads May Short, Potentially Resulting in Minor Shocks and Burns

**Device Recall Letter:**
- Mailer
- Identity, isolate, and discontinue use of any affected product in your inventory.
- Verify that you have received the September 27, 2011, Urgent Device Recall letter, prepaid mailer, and new device kit from LifeWatch.

**For Further Information:**
- Regulatory Agency: Designation:
  - FDA
  - CDRH
  - FDA’s Center for Devices and Radiological Health (CDRH)
  - FDA’s Center for Devices and Radiological Health (CDRH) also states that the manufacturer initiated a recall by Urgent Device Recall, and the regulatory agency also states that the manufacturer initiated a recall by Urgent Device Recall.

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Manufacturer(s): Advanced Sterilization Products Technology Dr, Irvine, CA 92618, United States

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

Summary:
This Report provides new information based on a November 21, 2014, Product Notification Update letter submitted by ECRI Institute member hospitals regarding Hazard Report Accession No. H0230. ASP expanded its notification regarding the use of the above reprocessors to include additional ERCP endoscopes, bolded above.

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 November 21, 2014, Product Notification Update letter from ASP. The following actions are those listed in Hazard Report Accession No. H0230. The firm recommends that you review the labeling for both EVOTECH ECR and ERCP endoscopes regarding the cleaning and reprocessing of the elevator channel; specifically, that you 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. 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.

Source(s):
- 2014 Dec 1. Member Hospital. ASP letter submitted by ECRI Institute member hospitals. Reference No. CL-90098-051. Download

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