

Urgent Product Notification
Cidex® Activated Glutaraldehyde Solution

Product Code: SCX145, CX250

3rd August 2015

Please distribute this information to appropriate personnel at your facility.

Dear Valued Customers,

Advanced Sterilization Products (ASP) recently determined, as part of its routine quality program, that it may lack the adequate data to support the entire 24-month shelf life of CIDEX® Activated Glutaraldehyde Solution.

Although ASP has received no complaints or adverse event reports related to this matter, we are proactively notifying customers of this issue.

DESCRIPTION OF ISSUE

ASP determined that data for CIDEX® Activated Glutaraldehyde Solution supports a 12-month shelf life. The CIDEX® Activated Glutaraldehyde Solution is currently labeled for a 24-month shelf life. While the product has a maximum 14-day reuse life, data shows that the pH level of the CIDEX® Activated Glutaraldehyde Solution may be below specification for up to 2 hours after activation. Use of CIDEX® Activated Glutaraldehyde Solution after 12 months may result in inadequate medical device reprocessing (disinfection/sterilization) or re-contamination if it is used for reprocessing within the first 2 hours of activation.

ASP has not received any reports relating to efficacy issues or adverse events of patients contracting infections from medical devices that were disinfected with CIDEX® Activated Glutaraldehyde Solution.

ASP has a corrective action in place to update the shelf life of CIDEX® Activated Glutaraldehyde Solution from 24 months to 12 months. In the meantime, ASP is recommending the actions below until that change takes effect.

PRODUCTS AFFECTED

Product Code	Product Description
SCX145	Cidex® Activated Glutaraldehyde Solution
CX250	Cidex® Activated Glutaraldehyde Solution

WHY ARE YOU BEING CONTACTED?



You are receiving this letter because our records indicate you have received Cidex® Solution. To report any complaints or suspected problems with Cidex® **Activated Glutaraldehyde** Solution related to this letter and Customer Acknowledgement Form, please contact your ASP representative.

WHAT ACTIONS ARE RECOMMENDED?

Customers may continue to safely use product in accordance with the instructions for use if the expiration date on any bottles of CIDEX® **Activated Glutaraldehyde** Solution currently in inventory is greater than 12 months from the present date.

ASP advises the customer to check the expiration date on all bottles of CIDEX® **Activated Glutaraldehyde** Solution currently in inventory and follow the instructions below:

1. For all bottles of CIDEX® **Activated Glutaraldehyde** Solution, subtract 12 months from the expiration date labeled on the container to achieve the new expiration date (see *Appendix 1* below of this customer letter).
2. For replacement of product that expired due to the change in expiration date, complete the attached Customer Acknowledgement Form indicating the number of expired bottles of CIDEX® **Activated Glutaraldehyde** Solution.
3. In the event your facility prefers not to subtract 12 months from the expiration date labeled on the container, follow the instructions for product return below for product replacement. Upon availability of product labeled with the correct shelf life, ASP will provide replacement.
 - Physically count all your inventory of affected products and record the data on the enclosed Customer Acknowledgement Form. It is very important that you complete the requested information on the enclosed Customer Acknowledgement Form and return it to your ASP representative. Incomplete Customer Acknowledgement Form cannot be processed.
 - Contact your ASP representative or call our customer service (Ridawati Rahmat) at 68276096 to return all unused Cidex® Solution Product. Attach a photocopy of the Customer Acknowledgement Form with the products.
4. While ASP conducts our corrective action, we recommend the following alternative biocide solutions to the Cidex® **Activated Glutaraldehyde** Solution: Cidex® OPA Solution (Note: Cidex® OPA is contraindicated for use with patients that have a history of bladder cancer) or an alternative Glutaraldehyde solution provided through another manufacturer.
5. Ensure anyone in your facility impacted by this notification reads this letter. In the event expired product was used, please note that the health hazard evaluation discussed the patient risk and due to the fact that prophylactic antibiotics are the standard of care and used in most surgeries, especially in the greatest risk population, the risk is considered to be acceptable.

6. Maintain a copy of this communication where CIDEX® **Activated Glutaraldehyde Solution** is stored.
7. Complete the **Customer Acknowledgement Form** and pass it to your ASP Representative or fax it to **6720 0750 within 2 business days.**
8. If you have distributed the affected product to other locations within your healthcare system, please notify them of this recall and ask them to contact ASP representative or customer service to arrange for return of product.
9. As with any medical device, adverse reactions or quality problems experienced with the use of this product should be reported as a complaint to Johnson & Johnson Medical Singapore following the usual procedure.

Any CIDEX® **Activated Glutaraldehyde Solution** products received after August of 2015 have the accurate 12-months shelf life.

We know that you place high value in our products. We appreciate your cooperation in this matter and value you as our customer. ASP is committed to maintaining your confidence in the safety and quality of our products.

Thank you for your cooperation and patience.

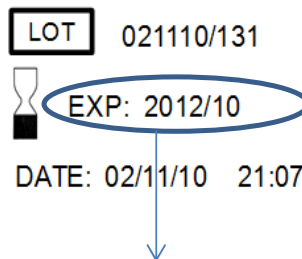
Yours sincerely,



Cherie Yip
Regulatory Affairs Specialist

Appendix 1

Sample



- Subtract 12 months from the expiration date labeled on the container.
 - If the calculated date occurs on or before the present date, the bottle is expired and should be disposed per your facility procedure and the Safety Data Sheet (SDS).

For example:

The bottle has the expiration date of 2016/05.

Subtracting 12 months from 2016/05 is 2015/05.

This calculated date is before the present date and therefore the bottle is expired and should be disposed.

- If the calculated date occurs after the present date, you may continue to safely use product in accordance with the instruction for use.

For example:

The bottle has the expiration date of 2017/02.

Subtracting 12 months from 2017/02 is 2016/02.

This calculated date is after the present date and the bottle may continue to be used until February of 2016.