

# ADVANCED STERILIZATION PRODUCTS

Division of Cilag GmbH International  
a *Johnson & Johnson* company

Date

## **URGENT-PRODUCT RECALL:** **CIDEX® Activated Glutaraldehyde Solution** **Product Code SCX145**

Dear Valued Customers,

Advanced Sterilization Products (ASP) recently was notified that a limited quantity of expired units and beyond shippable date units of CIDEX® Activated Glutaraldehyde Solution product, product code SCX145, lot 020315018, were shipped to customers in Singapore.

CIDEX® Activated Glutaraldehyde Solution is a liquid chemical sterilant and a high level disinfectant for reprocessing heat sensitive medical/dental devices such as endoscopes, respiratory therapy equipment and ultrasonic transducers. CIDEX® Solution is intended for use in manual systems as well as in automated endoscope re-processors.

**Sterilant:**

CIDEX Solution is a sterilant when used or reused, according to the Directions for Use, at or above its Minimum Effective concentration (MEC) as determined by the CIDEX® Solution Test Strip, at 25°C (77°) with an immersion time of at least 10 hours with a reuse period not to exceed 14 days.

**High Level Disinfectant:**

CIDEX Solution is a high level disinfectant when used or reused, according to the Directions for Use, at or above its Minimum Effective Concentration (MEC) as determined by the CIDEX® Solution Test Strip, at 25°C (77°) with an immersion time of at least 45 minutes with a reuse period not to exceed 14 days.

### **Description of the Issue**

ASP has concluded that the issue is bounded to nine (9) bottles (4 expired and 5 beyond shippable life) of CIDEX® Activated Glutaraldehyde, lot 020315018, shipped to three (3) customers in Singapore. This issue is limited to this specific lot and customers only.

Please note that a field notification letter was attached to each of the bottles with the instructions to subtract 12 months from the product expiration date.

### **What Actions Are Recommended?**

- Ensure anyone in your facility impacted by this notification reads this letter. In the event expired product was used, ASP recommends that healthcare facilities follow their risk management procedures as it relates to this notification.
- ASP advises the customer to check your current inventory of CIDEX® Activated Glutaraldehyde Solution, product code SCX145. If you have inventory of lot 020315018, DO NOT USE the product and immediately return the affected products by following the instructions in the section below for product return and replacement.
- Maintain a copy of this communication where CIDEX® Activated Glutaraldehyde Solution is stored and used until all affected products are returned to Johnson & Johnson Private Limited.
- Please complete and return the attached Business Reply Form to your ASP representative or fax it to +65 6720 0750 within (2) two business days of receipt of the Field Safety Notice.

### **Product Return and Replacement Instructions:**

Complete the following steps for product return and replacement:

1. Physically count all bottles of CIDEX® Activated Glutaraldehyde Solution product, product code SCX145, lot 020315018 from your current inventory.
2. Record total number of CIDEX® Activated Glutaraldehyde Solution bottles of this lot 020315018 on the enclosed Business Reply Form (BRF) and return the completed form to your ASP representative or fax it to +65 6720 0750. Incomplete Business Reply Forms cannot be processed.

Gubelstrasse 34, 6300 Zug, Switzerland



*protecting lives against infection*

CL-90098-090

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3. Return all CIDEX® **Activated Glutaraldehyde** Solution bottles indicated on the Business Reply Form (BRF) by contacting your ASP representative or calling our customer service at 68276096, and attaching a photocopy of the Business Reply Form with the products. Johnson & Johnson Private Limited will issue credit/replacement for returned products, if applicable.

## Why you are being contacted:

You are receiving this letter because our records indicate you have received CIDEX® **Activated Glutaraldehyde** Solution, product code SCX145, lot 020315018. To report any complaints or suspected problems with CIDEX® **Activated Glutaraldehyde** Solution related to this letter, please contact your ASP representative or call our customer service at 68276096. For questions regarding the business reply form, please contact your ASP representative or call our customer service at 68276096.

We know 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.

Sincerely,



Przemyslaw Szafran  
ASP Manager, EMEA/APAC Supplier Quality, EMEA Quality and Regulatory Compliance  
Advanced Sterilization Products- a Division of Cilag Management Representative

Gubelstrasse 34, 6300 Zug, Switzerland



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