

Field Safety Notice
Reminder to follow CIDEX® OPA Solution Instructions for Use
Product Code: 20490

Please distribute this information to appropriate personnel at your facility.

Dear Valued Customers,

Advanced Sterilization Products (ASP) is sending this letter to remind customers of the importance of reading the warnings and following the rinsing instructions of the CIDEX® OPA Solution IFU (Instruction For Use). Although the IFU remains unchanged, ASP has received reports of anaphylaxis following medical procedures involving a device disinfected with CIDEX® OPA Solution. In each of these cases, users failed to follow the IFU for proper rinsing.

Customers may keep their current inventory of CIDEX® OPA Solution and continue to safely use the product in accordance with the IFU, which contains the rinsing instructions.

DESCRIPTION OF ISSUE

ASP conducted a post-market surveillance review of two international complaints for anaphylaxis following medical procedures involving a device disinfected with CIDEX® OPA Solution. Subsequent investigation identified the user failed to follow the rinsing instructions to remove residual CIDEX® OPA Solution from the medical devices post-processing. Improper rinsing may result in the potential for anaphylaxis risk for patient populations beyond bladder cancer patients.

PRODUCTS AFFECTED

Product Code	Product Description
20490	ASP CIDEX® OPA Solution

WHY ARE YOU BEING CONTACTED?

You are receiving this letter because our records indicate you have received CIDEX® OPA Solution. To report any complaints or suspected problems with CIDEX® OPA Solution related to this letter, please contact your ASP representative.

WHAT ACTIONS ARE RECOMMENDED?

As a reminder, customers may keep their current inventory of CIDEX® OPA Solution and continue to safely use the product in accordance with the instructions for use.

- ASP advises the customer :
 1. Refer to WARNINGS, section 5 in the IFU for use of CIDEX® OPA Solution.
 2. Follow the DIRECTIONS FOR USE Rinsing Instructions (Part B) in the IFU completely and correctly for important information on rinsing when use CIDEX® OPA Solution.
 3. Refer to DIRECTIONS FOR USE Rinsing Instructions (Part B), part (a) manual processing, bullet number 5 of the section in the IFU for the risk of CIDEX® OPA Solution residues due to improper rinsing.

- Ensure anyone in your facility impacted by this notification reads this letter carefully.

- Maintain a copy of this communication where CIDEX® OPA Solution is stored.

ACTIONS REQUIRED FROM YOU

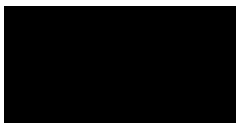
1. Complete the **Customer Acknowledgement Form** and pass it to your ASP Representative or fax it to **6720 0750 within 2 business days.**

2. 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.

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.

Thank you for your cooperation and patience.

Yours sincerely,



Lee Ching Hwee

Senior Regulatory Affairs Specialist