

URGENT MEDICAL DEVICE NOTICE
Rapicide PA Part A – Lot #628309

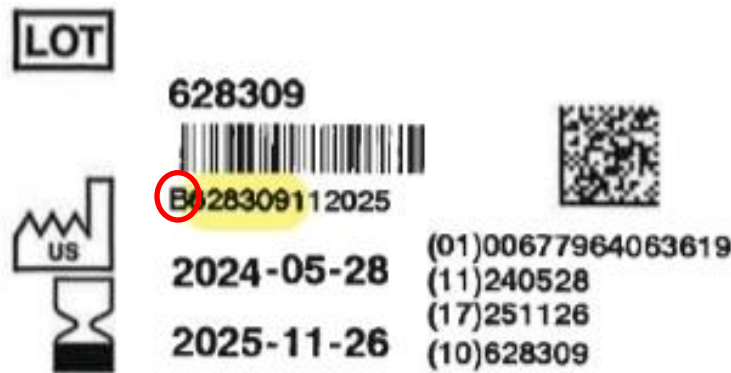
July 26, 2024

ATTN: MATERIALS MANAGEMENT OR STERILE PROCESSING DEPARTMENT

Dear Valued STERIS Customer:

STERIS is providing this notice to make you aware of a labeling issue that was recently identified for Rapicide PA Part A – Lot #628309. This lot was distributed between July 15-22, 2024. Our records indicate that your facility purchased product from this lot.

STERIS has confirmed that the barcode for this lot contains an error, specifically, the starting character should be an “A” instead of a “B”.



When scanning the barcode, this error will prevent the Advantage Plus AERs from accepting the bottle for use. **It is important to note there is nothing wrong with the chemistry, the bottle, or any other part of the label other than the first character.**

User Action – Users can continue to use the Rapicide PA as normal. Your AER is equipped with the ability to manually enter the barcode information (instead of scanning it). Please follow the instructions outlined on the following page for the manual entry process. DSD Edge users should simply enter an “A” as the first character.

If you are a distributor, and have further distributed affected product, please provide this letter to your Customers.

We apologize for any inconvenience this matter may cause, and as always, STERIS is dedicated to supporting our products and valued Customers. If you have questions regarding this matter, please contact your local STERIS Representative.

Sincerely,



Daniel Davy
Director, Quality & Regulatory Compliance
STERIS

Rapicide PA Replacement to correct barcode error

Step 1 – Replace Component Bottle:

When either Rapicide PA Part A or B containers are empty, the Advantage Plus machine will stop and prompt you to replace them.

1. Remove the empty component container.
2. Replace it with the correct component.
Part A has a blue & white label; the internal uptake tubing cap is blue.
Part B has a black & white label; the internal uptake tubing cap is white.

Step 2 – Manually enter information into the Advantage Plus:

1. Press the Menu button 
2. Scan the Operator's barcode 
3. Select **Replace Fluids** from the Main Menu; confirm by pressing 
4. Select **Component A** from the Replace Fluids Menu; confirm by pressing 
5. Scan the disinfectant lot number from Component A bottle. If the leading letter in the barcode is "B," **connect an external keyboard or pull up the onscreen keyboard, delete the letter "B" and replace with the letter "A," leaving the numeric part of the scanned barcode unchanged. After verifying that the information is correct, confirm by pressing** 
6. Follow steps in Replace Fluids Menu to replace Component B, if necessary.
7. Press the START button to resume the cycle. 

For reference on the location of the onscreen keyboard for the Advantage Plus and the Advantage Plus Pass Thru, please refer to the following images:

