



IMPORTANT PRODUCT NOTICE

HemosIL® Rinse Solution, Part Number 0020302400

September 30, 2024

Dear Valued HemosIL Rinse Solution Customer:

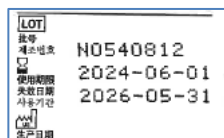
This notification is intended to advise your facility regarding a reported labeling issue with HemosIL Rinse Solution (Part No.: 0020302400, UDI: 08426950515395) that is applicable to the following impacted lots with the correct manufactured date and expiration date:

Lot Number	Manufactured Date	Expiration Date
N0540766	2024-05-01	2026-04-30
N0540770		
N0540789	2024-06-01	2026-05-31
N0540794		
N0540799		
N0540808		
N0540812		
N0641749		
N0641754		
N0641759		
N0641763		
N0641769		
N0641774	2024-07-01	2026-06-30
N0641782		
N0641804		
N0641809		
N0641814		
N0641818		
N0641823		
N0641827		
N0742616		

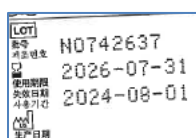
- **Issue Description and Impact**

Recently we have received complaints concerning HemosIL Rinse solution (P/N 0020302400), indicating that the manufactured date and the expiration date on the container label were reversed.

Incorrect:



Correct:



An internal investigation has confirmed the complaint findings for HemosIL Rinse solution. There is no potential for patient harm, as incorrect labeling does not impact patient results. You may continue to use impacted lots of HemosIL Rinse Solution based on its labeled intended use.

Please refer to the above table for the impacted lots and correct manufactured/expiration dates.

- **Mandatory Customer Actions**

Based on the above, please take the following **immediate** actions:

- **Continue** to use impacted lots of HemosIL Rinse Solution based on its labeled intended use. Refer to the above table for the correct manufactured and expiration dates.
- **Share** this notification with your laboratory staff and follow your internal procedures.
- **Forward** this notification to all affected locations within your facility.
- **Retain** a copy of this notification for your records.

Your prompt attention to this important Field Safety Notification is greatly appreciated.

Sincerely,

Anuja Khan

Regulatory Affairs Manager II
Instrumentation Laboratory Co.