

## **Drug Recall**

DATE OF RECALL: September 6, 2023

**DRUG NAME:** Dianeal Peritonial Dialysis Solution with 1.5% Dextrose

**RECALLING FIRM:** Baxter Healthcare Corporation.

**REASON FOR RECALL:** This recall was issued due to Lack of Assurance of Sterility: Potential presence of leaks originating from the Luer component.

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FDA LINK: N/A

**OTHER DETAILS:** N/A

## **RECALLED PRODUCT:**

Product Description	NDC Number	Lot Number	<b>Expiration Date</b>
Dianeal Low Calcium (2.5 mEq/L)			
Peritonial Dialysis Solution with 1.5%	00941-0409-06	Y403948	. 09/30/2024
Dextrose, packaged in 2000mL per		Y406277	10/31/2024
Ambu-Flex II Container bag			
Dianeal Low Calcium (2.5 mEq/L)			
Peritonial Dialysis Solution with 1.5%	00941-0409-07	408790	11/30/2024
Dextrose, packaged in 5000mL per	00941-0409-07	408790	11/30/2024
Ambu-Flex II Container bag			
Dianeal Low Calcium (2.5 mEq/L) Peritonial Dialysis Solution with 1.5% Dextrose, packaged in 6000mL per Ambu-Flex II Container bag	00941-0409-01	Y403740	09/30/2024
		Y403740A	09/30/2024
		Y405638	10/31/2024
		Y405805	10/31/2024
		Y407304	10/31/2024
		Y407304A	10/31/2024
		Y407717	11/31/2024
		Y407717A	11/31/2024
		Y408554	11/31/2024
		Y420075	04/30/2025
Dianeal PD-2 Peritonial Dialysis			
Solution with 1.5% Dextrose, 5000 mL	00941-0411-07	Y06734	10/31/2024
AMBU-FLEX II Container with yellow	00341-0411-07	100734	10/31/2024
pull ring			