



## California Device Recall Information Sheet

### Fresenius Medical Care Holdings, Inc. Recalls Stay-Safe for NDL PCBA Leachables

Recall Date	Product Description	Recalling Firm	Recall Reason
4/3/2024	<b>Stay-Safe /Safe Lock Catheter</b> Ext. 12 in	<b>FRESENIUS MEDICAL CARE HOLDINGS, INC.</b> Waltham, Massachusetts	The peroxide cross-linked tubing has leachables identified as NDL PCBAs.
4/3/2024	<b>Stay-Safe /Luer Lock Adapter</b> 4 in	<b>FRESENIUS MEDICAL CARE HOLDINGS, INC.</b> Waltham, Massachusetts	The peroxide cross-linked tubing has leachables identified as NDL PCBAs.
4/3/2024	<b>Stay-Safe /Luer Lock Catheter</b> Ext. 12 in	<b>FRESENIUS MEDICAL CARE HOLDINGS, INC.</b> Waltham, Massachusetts	The peroxide cross-linked tubing has leachables identified as NDL PCBAs.
4/3/2024	<b>Stay-Safe /Luer Lock Catheter</b> Ext. 18 in	<b>FRESENIUS MEDICAL CARE HOLDINGS, INC.</b> Waltham, Massachusetts	The peroxide cross-linked tubing has leachables identified as NDL PCBAs.
4/3/2024	<b>Stay-Safe /Luer Catheter</b> Ext. 6 in	<b>FRESENIUS MEDICAL CARE HOLDINGS, INC.</b> Waltham, Massachusetts	The peroxide cross-linked tubing has leachables identified as NDL PCBAs.

Recall Class	Product Identification	Distribution	Affected Dates
I	<b>Stay-Safe /Safe Lock Catheter</b> Model Number: 050-95001; UDI/DI (Bag): 00840861100767; UDI/DI (Case): 10840861100764; All lots.	114982 Units Nationwide	January, 2024 and prior
I	<b>Stay-Safe /Luer Lock Adapter</b> Model Number: 050-95003; UDI/DI (Bag): 00840861100774; UDI/DI (Case): 10840861100771; All lots.	828954 Units Nationwide	January, 2024 and prior
I	<b>stay-safe /Luer Lock Catheter</b> Model Number: 050-95004; UDI/DI (Bag): 00840861100781; UDI/DI (Case): 10840861100788; All lots.	663221 Units Nationwide	January, 2024 and prior
I	<b>Stay-Safe /Luer Lock Catheter</b> Model Number: 050-95005; UDI/DI (Bag): 00840861100798; UDI/DI (Case): 10840861100795; All lots.	479978 Units Nationwide	January, 2024 and prior
I	<b>Stay-Safe /Luer Catheter</b> Model Number: 050-95013; UDI/DI (Bag): 00840861100804; UDI/DI (Case): 10840861100801; All lots.	105700 Units Nationwide	January, 2024 and prior

For additional information, please visit the [FDA website](#) [Safe Lock](#) , [Adapter](#) , [Luer Lock Catheter Ext. 12](#) , [Catheter Ext. 18 in](#) , [Catheter Ext. 6 in](#)

CDPH Food and Drug Branch  
MS 7602 • P.O. Box 997435 • Sacramento, CA 95899-7435  
(916) 650-6500 • (916) 650-6650 FAX  
Internet Address: [www.cdph.ca.gov](http://www.cdph.ca.gov)

