



## California Device Recall Information Sheet

## Food and Drug Branch - Device Recalls

Avanos Medical, Inc. Ballard Closed Suction Catheters

Recall Date	Product Description	Recalling Firm	Recall Reason
04/16/2025	Brand Name: Ballard Product Name: Closed Suction Catheters Model/Catalog Number: 198 Software Version: N/A Product Description: Ballard Closed Suction System for Neonates/Pediatrics, 8 F, Y- Adapter Component: No  Brand Name: Ballard Product Name: Closed Suction Catheters Model/Catalog Number: 210 Software Version: N/A Product Description: Ballard Closed Suction System for Neonates/Pediatrics, 10 F, Elbow Component: N/A	Avanos Medical, Inc.	Lack of sterility assurance for closed suction catheter systems
	Brand Name: Ballard Product Name: Closed Suction Catheters Model/Catalog Number: 20083 Software Version: N/A Product Description: Ballard Closed Suction System for Neonates/Pediatrics, 8 F, Elbow Component: N/A		

Brand Name: Ballard

Product Name: Closed Suction

Catheters

Model/Catalog Number:

220135

Software Version: N/A
Product Description: Ballard
Closed Suction System for
Adults, 14 F, T-Piece
Component: N/A

Brand Name: Ballard

Product Name: Closed Suction

Catheters

Model/Catalog Number: 2210-5

Software Version: N/A

Product Description: Ballard Closed Suction System for

Adults, 14 F, DSE Component: N/A

Brand Name: Ballard

Product Name: Closed Suction

Catheters

Model/Catalog Number:

2271418-5

Software Version: N/A Product Description: Ballard Turbo-Cleaning Closed Suction System for Adults, 14 F, DSE,

MDI

Component: N/A

Brand Name: Ballard

Product Name: Closed Suction

Catheters

Model/Catalog Number: 227-5

Software Version: N/A

Product Description: Ballard Turbo-Cleaning Closed Suction System for Adults, 14 F, DSE

Component: N/A

Brand Name: Ballard

Product Name: Closed Suction

Catheters

Model/Catalog Number:

22714183-5 Software Version: N/A Product Description: Ballard Turbo-Cleaning Closed Suction System for Adults, 14 F, DSE, MDI Component: N/A	
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Recall Class	Product Identification	Distribution	Affected Dates
	Lot/Serial Number(s): 1561168 Each: 00609038938264 DSP: 10609038938261 Case: 20609038938268  Lot/Serial Number(s): 1561165 Each: 00609038938349 DSP: 10609038938346 Case: 20609038938343  Lot/Serial Number(s): 1555215, 1555217 Each: 00609038938311 DSP: 10609038938318 Case: 20609038938315  Lot/Serial Number(s): 1555453, 1564227 Each: 00609038944920 DSP: 10609038944927 Case: 20609038944924  Lot/Serial Number(s): 1555424 Each: 00609038983103 DSP: 10609038983107 Case: 20609038983107	Nationwide	Affected Dates  March and prior
	Lot/Serial Number(s): 1555430 Each: 00609038982632 DSP: 10609038982639 Case: 20609038982636		
	Lot/Serial Number(s): 1555468 Each: 00609038989655 DSP: 10609038989652		

Case: 20609038989659	
Lot/Serial Number(s): 1555426 Each: 00609038982649 DSP: 10609038982646 Case: 20609038982643	

For additional information, please visit: <u>FDA Website (198)</u>, <u>FDA Website (210)</u>, <u>FDA Website (20083)</u>, <u>FDA Website (220135)</u>, <u>FDA Website (2210-5)</u>, <u>FDA Website (2271418-5)</u>, <u>FDA Website (2271418-5)</u>, and <u>FDA Website (22714183-5)</u>.