



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Cook Incorporated Recalls Blue Rhino G2-Multi Series Percutaneous Tracheostomy Products For Unsecure Connection Between 15mm Cap And Circuit Components And Accessories

Recall Date	Product Description	Recalling Firm	Recall Reason
5/17/2023	Blue Rhino G2-Multi Percutaneous Tracheostomy Introducer Set Reference Part Numbers C-PTIS-100-HC-G-EU-FLEX7.5 (G57695), C-PTIS-100-HC-G-EU-FLEX8.5 (G57696), C-PTIS-100-HC-G-NA-FLEX7.5 (G57691), C-PTIS-100-HC-G-NA-FLEX8.5 (G57692)	COOK INCORPORATED Bloomington, Indiana	There were reports from customers that the tracheostomy in the sets and trays is not making a secure connection with the 15mm cap and other 15mm circuit components and accessories. This resulted in an unsecure connection between the device connector and circuit components, cap, or accessories.
5/17/2023	Blue Rhino G2-Multi Percutaneous Tracheostomy Introducer Tray Reference Part Numbers C-PTISYJ-100-HC-G-EU-FLEX8.5 (G57725), C-PTISYJ-100-HC-G-NA-FLEX7.5 (G57720), C-PTISYJ-100-HC-G-NA-FLEX8.5 (G57721), C-PTISY-100-HC-G-NA-FLEX8.5 (G57717), C-PTISY-100-HC-G-NA-FLEX7.5 (G57716)	COOK INCORPORATED Bloomington, Indiana	Unsecure Connection

Recall Class	Product Identification	Distribution	Affected Dates
I	<p>Blue Rhino G2-Multi Percutaneous Tracheostomy Introducer Set C-PTIS-100-HC-G-EU-FLEX7.5 (G57695): UDI-DI 00827002576957, Lot Number 14842940; C-PTIS-100-HC-G-EU-FLEX8.5 (G57696): UDI-DI 00827002576964, Lot Numbers 14727192-14742873; C-PTIS-100-HC-G-NA-FLEX7.5 (G57691): UDI-DI 00827002576919, Lot Numbers 15063922-14221180; C-PTIS-100-HC-G-NA-FLEX8.5 (G57692): UDI-DI 00827002576926, Lot Numbers 14608362-15136113</p>	3053 Units Nationwide	April 2023 and Prior
I	<p>Blue Rhino G2-Multi Percutaneous Tracheostomy Introducer Tray C-PTISYJ-100-HC-G-EU-FLEX8.5 (G57725): UDI-DI 00827002577251, Lot Numbers 14351912, 14345668; C-PTISYJ-100-HC-G-NA-FLEX7.5 (G57720): UDI-DI 00827002577206, Lot Numbers 14210437-14365703; C-PTISYJ-100-HC-G-NA-FLEX8.5 (G57721): UDI-DI 00827002577213, Lot Numbers 14705461-14345633; C-PTISY-100-HC-G-NA-FLEX7.5 (G57716): UDI-DI 00827002577169, Lot Numbers 15032438-15141529</p>	25161 Units Nationwide	April 2023 and Prior

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