



CALIFORNIA DEVICE RECALL INFORMATION SHEET

Covidien Recalls Palindrome Precision Chronic Dialysis for Potential Leak due to Void in Component Resulting in Unanticipated Fluid Return

Recall Date	Product Description	Recalling Firm	Recall Reason
6/8/2022	Palindrome Precision Chronic Catheter Sterile, Single Use, Rx Only. For vascular access for acute and chronic hemodialysis, apheresis, and infusion	Covidien LLC, Mansfield, Massachusetts	There is a potential leaking condition within the hub of specific chronic dialysis catheters, due to an inter-lumen void in the hub component, which may result in unanticipated fluid return during use.
6/8/2022	Palindrome Precision H Chronic Catheter	Covidien LLC, Mansfield, Massachusetts	Potential leaking condition
6/8/2022	Palindrome Precision SI Chronic Catheter	Covidien LLC, Mansfield, Massachusetts	Potential leaking condition
6/8/2022	Palindrome Precision HSI Chronic Catheter	Covidien LLC, Mansfield, Massachusetts	Potential leaking condition
6/8/2022	Palindrome Chronic Catheter	Covidien LLC, Mansfield, Massachusetts	Potential leaking condition
6/8/2022	Palindrome H Chronic Catheter	Covidien LLC, Mansfield, Massachusetts	Potential leaking condition

6/8/2022	Palindrome SI Chronic Catheter	Covidien LLC, Mansfield, Massachusetts	Potential leaking condition
6/8/2022	Palindrome HSI Chronic Catheter	Covidien LLC, Mansfield, Massachusetts	Potential leaking condition
6/8/2022	Mahurkar Chronic Carbothane (Maxid) Catheter	Covidien LLC, Mansfield, Massachusetts	Potential leaking condition

Recall Class	Product Identification	Distribution	Affected Dates
I	Palindrome Precision Chronic Catheter Code Information organized as "Model No., Serial No., GTIN": 8888123400, 1729700111, 20884521012933 - 8888146044P, 2124600241, 20884521158464	213,589 units Worldwide, Nationwide incl. California	June 2022 and prior
I	Palindrome Precision H Chronic Catheter 8888119365P, 2119400168, 10884521157712 - 8888145071P, 1922100139, 20884521158457	26,675 units Worldwide, Nationwide incl. California	June 2022 and prior
I	Palindrome Precision SI Chronic Catheter 8888119368, 1925200090, 20884521012841 - 8888145066, 2019500162, 20884521013473	2,462 units Worldwide, Nationwide incl. California	June 2022 and prior
I	Palindrome Precision HSI Chronic Catheter 8888119369P, 2031800118, 10884521157736 - 8888145057P, 2124600235, 20884521158273	25,765 units Worldwide, Nationwide incl. California	June 2022 and prior

I	Palindrome Chronic Catheter 8888119360, 1916500132, 20884521012803 - 8888145061, 2012100135, 20884521013381	576,018 units Worldwide, Nationwide incl. California	June 2022 and prior
I	Palindrome H Chronic Catheter 8888119365, 1925200097, 20884521012810 - 8888145046C, 2026000091, 20884521056333	26,474 units Worldwide, Nationwide incl. California	June 2022 and prior
I	Palindrome SI Chronic Catheter 8888119368, 1925200090, 20884521012841 - 8888145066, 2019500162, 20884521013473	2,462 units Worldwide, Nationwide incl. California	June 2022 and prior
I	Palindrome HSI Chronic Catheter 8888119369, 2009300138, 10884521012875 - 8888145057C, 2026000161, 20884521083070	13,526 units Worldwide, Nationwide incl. California	June 2022 and prior
I	Mahurkar Chronic Carbothane (Maxid) Catheter 8888119362, 1928800230, 10884521056879 – 8888145254, 1903500127, 20884521014326	132,443 units Worldwide, Nationwide incl. California	June 2022 and prior

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