Urgent Field Safety Notice

Palindrome™ Precision Chronic Hemodialysis Catheters
Palindrome™ Chronic Hemodialysis Catheters
Mahurkar™ Chronic Carbothane Catheters

Recall

June 2022

Medtronic reference: FA1244

Dear Risk Manager/Healthcare Professional,

The purpose of this letter is to advise you that Medtronic has initiated a voluntary recall for specific lots of chronic hemodialysis catheters. You are receiving this letter as Medtronic records indicate your facility may have at least one of the chronic hemodialysis catheters identified for recall in Appendix 1 (attached). Medtronic initiated this action to prevent the usage of potentially affected chronic hemodialysis catheters that may impact patients.

Issue Description:
During the production process, Medtronic has identified a potential leaking condition within the hub of specific chronic hemodialysis catheters. Flushing one extension tube may result in unanticipated fluid return through the adjacent extension tube (in addition to the anticipated flow of fluid through the distal tip of the catheter). The condition is the result of an inter-lumen void formed in the hub component of the catheter during the manufacturing process. During use, this observed condition could translate to cross-communication of the blood circuit.

To date, Medtronic has received one reported complaint and has not received any reports of patient injury or death related to this issue.

Risk to Health:
Utilization of a product with this manufacturing defect could introduce the potential for patient harm(s) including embolism, thrombosis, hemolysis, infection, and inadequate treatment. Replacement of an implanted catheter could introduce the potential for patient harm(s) including infection, delay to treatment/ therapy, and unintended radiation exposure due to the placement of an additional catheter.

Patient Recommendation:
For patients with affected lots of chronic hemodialysis catheters currently in place, a replacement procedure may not be necessary. Clinicians should continue to follow facility specific policies and procedures for routine assessment of the hemodialysis access device for patency, function, and efficacy. To identify the potential interlumen communication of fluid, while flushing one extension tube, the clinician should assess for the unanticipated simultaneous fluctuation of

fluid in the adjacent extension tube. If detected, the patient's medical team should use their clinical judgement in determining the necessity and timing of a replacement catheter.

Required Actions:

1. Immediately quarantine and discontinue use for specific lots of chronic hemodialysis catheters (see Appendix 1).
2. Return specific lots of chronic hemodialysis catheters as indicated in Appendix 1.
3. If you have distributed the specific lots of chronic hemodialysis catheters listed in Appendix 1, please promptly forward the information from this letter to those recipients.
4. Please complete the Customer Acknowledgment Form even if you **do not** have unused inventory.
5. Share this notice with those who need to be aware within your organization.
6. Retain this notification for your records regarding the retrieval of the unused product identified above.

	Customer with inventory	**Customer with zero inventory**	**Where to send the completed form**
Purchased **directly** from Medtronic	Please complete the attached Customer Acknowledgment Form in its entirety. Upon receiving your form, Medtronic Customer Care will contact you to organize the return of your products. You will receive credit for unused device(s) that you return	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to the Medtronic contact provided on the verification form.
Purchased from a **distributor**	Complete **all** fields on the form and contact your distributor directly to arrange for return of product.	Complete form and check the box indicating "no inventory"	E-mail or fax the completed form to your Distributor and to the Medtronic contact provided on the verification form.

Additional Information:

Medtronic has notified the Competent Authority of your country of this action.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your Medtronic representative.

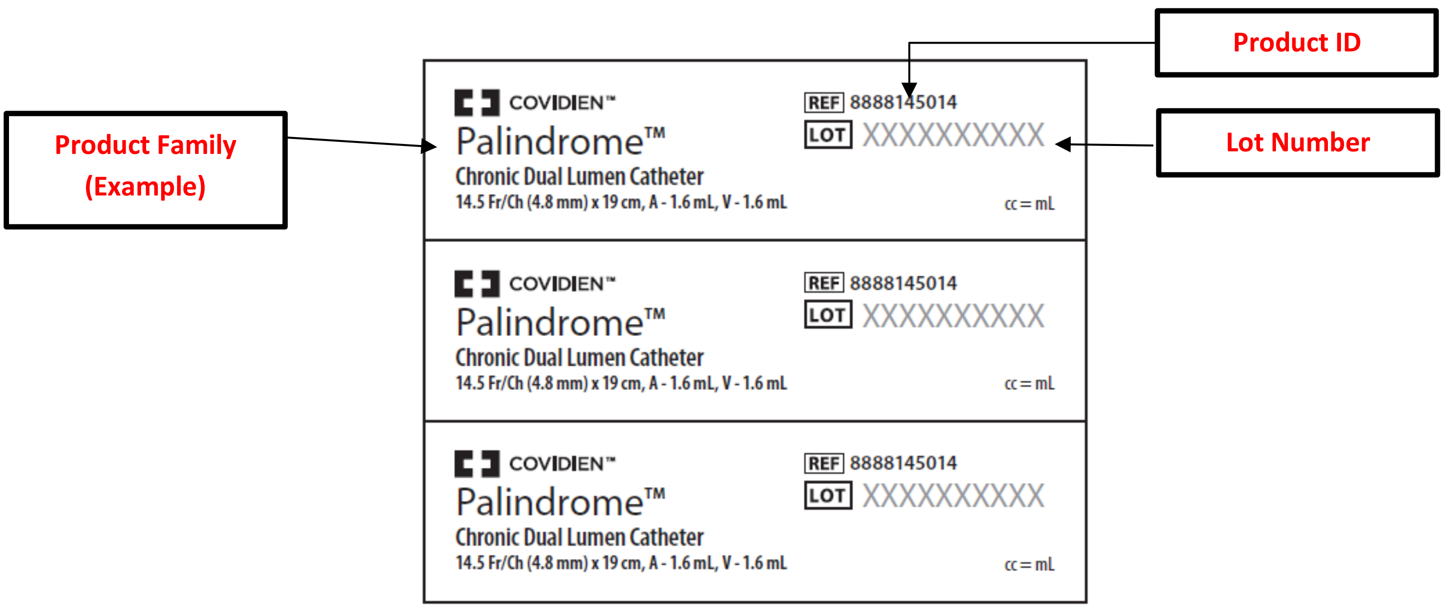
Sincerely,

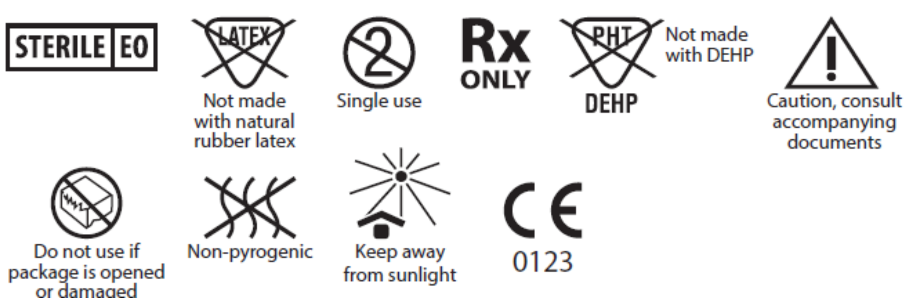
Local / BU Manager

Appendix 1

- Palindrome Precision Chronic Catheter
- Palindrome Precision H Chronic Catheter
- Palindrome Precision SI Chronic Catheter
- Palindrome Precision HSI Chronic Catheter
- Mahurkar™ Chronic Carbothane Catheters
- Palindrome Chronic Catheter
- Palindrome H Chronic Catheter
- Palindrome SI Chronic Catheter
- Palindrome HSI Chronic Catheter

For the above product families, affected lots will start with **17144**xxxxx through **22038**xxxxx. Example: **17144**00164. If your Lot number is outside this range, your product is not impacted.





Affected Products by Product ID/ GTIN:

Product Name	Product ID	GTIN
Palindrome Chronic Catheter	8888145015	20884521013169, 10884521013162
Palindrome Chronic Catheter	8888145016	20884521013176, 10884521013179
Palindrome Chronic Catheter	8888145017	20884521013190, 10884521013193
Palindrome Chronic Catheter	8888145040	20884521056661, 10884521056664
Palindrome Chronic Catheter	8888145041	20884521056678, 10884521056671
Palindrome Precision Chronic Catheter	8888145015P	20884521157986, 10884521157989
Palindrome Precision Chronic Catheter	8888145016P	20884521157993, 10884521157996
Palindrome Precision Chronic Catheter	8888145017P	20884521158006, 10884521158009
Palindrome Precision Chronic Catheter	8888145018P	20884521158013, 10884521158016
Palindrome Precision Chronic Catheter	8888145039P	20884521158020, 10884521158023
Palindrome Precision Chronic Catheter	8888145040P	20884521158037, 10884521158030
Palindrome Precision Chronic Catheter	8888145041P	20884521158044, 10884521158047
Palindrome Precision Chronic Catheter	8888145042P	20884521158051, 10884521158054
Palindrome Precision Chronic Catheter	8888146044P	20884521158464, 10884521158467
Palindrome Precision H Chronic Catheter	8888145043CP	20884521158068, 10884521158061
Palindrome Precision H Chronic Catheter	8888145044CP	20884521158082, 10884521158085
Palindrome Precision H Chronic Catheter	8888145045CP	20884521158105, 10884521158108
Palindrome Precision H Chronic Catheter	8888145046CP	20884521158129, 10884521158122

Affected Products by Lot Numbers:

1715100162	1715100163	1716500191	1717900134	1717900198	1718400086	1718600102	1720000112
1720700116	1721300148	1722300119	1725600112	1725600118	1726300128	1727100081	1727700143
1730500132	1730500133	1731900209	1733700131	1734000168	1800300138	1801700121	1801700138
1803100124	1805900122	1805900123	1805900126	1805900134	1806600085	1808600074	1808600081
1810400152	1810400153	1812200186	1812900133	1813600095	1815000190	1815000191	1815000194
1815000195	1817700210	1818500198	1819000135	1820700097	1824700126	1826200148	1826200163
1826200175	1826800139	1826800144	1828200130	1828900130	1828900135	1829500109	1833800160
1835100108	1901400122	1902100140	1903500124	1906000143	1906700175	1906700186	1907700095
1907800079	1907800083	1908400308	1908800155	1908800173	1908800177	1908800181	1908800184
1908800198	1909400128	1909400129	1909400131	1910600252	1912600105	1913000185	1913000187
1914000291	1914000292	1914800211	1914800213	1914800216	1916500104	1917600143	1918300138
1921300031	1923400225	1924000147	1924000149	1924600100	1926100280	1927500053	1927500061
1927500062	1929400083	1929400084	1929400093	1935100102	1935100104	1935100105	1935100106
1935100107	2001400116	2001400120	2002100138	2007800076	2009300084	2014900162	2017500123
2019500278	2021000086	2021000087	2022000046	2023300131	2023300138	2023300140	2023300154
2023300164	2026000065	2026000066	2026000069	2026000071	2026000072	2026000094	2026000123
2026000124	2026000125	2026000132	2026000133	2026000139	2027200191	2027200230	2027200250

2028200155	2028200166	2028200194	2028200197	2028200209	2031800135	2031800145	2034200075
2034400108	2034400119	2034400148	2102500098	2104600107	2104600108	2104600114	2104600118
2106900101	2110900108	2110900112	2110900114	2110900145	2113400062	2113400067	2113400090
2113400091	2119400129	2119400136	2119400144	2119600124	2119600125	2119700085	2119700086
2119700087	2124500095	2124500109	2124500118	2124500120	2124600237	2124600241	2124600245
2125800093	2127200527						