




Date: 2 Jan 2023

Reference Number: SG-2301-401-H

قطاع الأجهزة والمستلزمات الطبية  
المركز الوطني لبلاغات الأجهزة والمستلزمات الطبية

Medical Devices Sector  
National Center for Medical Devices Reporting

رسالة سلامة  
Safety Communication

To: Healthcare Provider		إلى: مقدمي الرعاية الصحية										
Title	A potential leaking condition within the hub of specific chronic hemodialysis catheters											
Medical Device Description	Palindrome™ Precision Chronic Hemodialysis Catheters Palindrome™ Chronic Hemodialysis Catheters Mahurkar™ Chronic Carbothane Catheters											
Medical Device Products Identifier	<table border="1"> <tr> <td>Palindrome Precision Chronic Catheter</td> <td>Palindrome Chronic Catheter</td> </tr> <tr> <td>Palindrome Precision H Chronic Catheter</td> <td>Palindrome H Chronic Catheter</td> </tr> <tr> <td>Palindrome Precision SI Chronic Catheter</td> <td>Palindrome SI Chronic Catheter</td> </tr> <tr> <td>Palindrome Precision HSI Chronic Catheter</td> <td>Palindrome HSI Chronic Catheter</td> </tr> <tr> <td colspan="2">Mahurkar™ Chronic Carbothane Catheters</td> </tr> </table> <p>For the above product families, affected lots will start with 17144xxxxx through 22038xxxxx. <u>Example</u>: 1714400164. If your Lot number is outside this range, your product is not impacted</p>	Palindrome Precision Chronic Catheter	Palindrome Chronic Catheter	Palindrome Precision H Chronic Catheter	Palindrome H Chronic Catheter	Palindrome Precision SI Chronic Catheter	Palindrome SI Chronic Catheter	Palindrome Precision HSI Chronic Catheter	Palindrome HSI Chronic Catheter	Mahurkar™ Chronic Carbothane Catheters		الأرقام للجهاز/المستلزم الطبي
Palindrome Precision Chronic Catheter	Palindrome Chronic Catheter											
Palindrome Precision H Chronic Catheter	Palindrome H Chronic Catheter											
Palindrome Precision SI Chronic Catheter	Palindrome SI Chronic Catheter											
Palindrome Precision HSI Chronic Catheter	Palindrome HSI Chronic Catheter											
Mahurkar™ Chronic Carbothane Catheters												
Manufacturer	Covidien LLC											
Authorized Representative	شركة ميدترونك العربية السعودية											
Medical Devices Marketing Authorization (MDMA)	GHTF-2017-0153, GHTF-2016-0151											
Potential /Associated risks:	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											
Recommendations	1. Immediately quarantine and discontinue use for specific lots of chronic hemodialysis catheters 2. Return specific lots of chronic hemodialysis catheters											
For Reporting	  	للإبلاغ:										