

Date: 03 March 2025

Reference Number: SG-2503-426-H

الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

Medical Devices Sector

National Center for Medical Devices Reporting

Safety Communication

رسالة سلامة

To: Healthcare Provider	إلى: مقدمي الرعاية الصحية
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Title	Potential endotoxin contamination in Presource kits.	العنوان:
Medical Device Description	Cardinal Health Presource Kits, Orthopedic tray	اسم ووصف الجهاز/المستلزم الطبي:
Manufacturer	Cardinal Health 200	اسم المصنع
Authorized Representative	Medical Regulations Gate	الممثل المعتمد

Medical Devices Marketing Authorization (MDMA)	MDMA-1-2021-1293	إذن التسويق
Potential /Associated risks	Potential endotoxin contamination in non-sterile surgical strips and patties in Presource kits.	المخاطر المحتملة/ المرتبطة بالجهاز أو المستلزم الطبي
Recommendations	<ul style="list-style-type: none">Review your inventory immediately, stop using the affected product.Return all affected products to the local representative.	التوصيات:

For Reporting	 	للإبلاغ
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