

Safety Communication

رسالة سلامة

potential for serious injury due to balloon integrity and subsequent failure

Device/ Product Description:	Rashkind Balloon Septostomy Catheters	
Affected product:	Model	Lot Numbers
	007160	GFCT1699, GFCT2030, GFCW2430, GFCX2784, GFCY2476, GFCY3001, GFDN0247, GFDN3546, GFDR2901, GFDT2170, GFDT2200, GFDU2168, GFDV2177, GFDW2388, GFDW2389, GFDW2399, GFDX2709, GFDY1132, GFDZ1690, GFDZ1691, GFEN2173, GFEN2174, GFEQ2047, GFEQ2048, GFEQ2049, GFEQ2050
	007161	GFCR2342, GFCR2583, GFCX2785, GFCY3003, GFDN0248, GFDQ2501, GFDR2902, GFDS2211, GFDT2171, GFDT2201, GFDU2169, GFDV2178, GFDW2400, GFDX2710, GFDY1133, GFDY1134, GFES2327
	008764	GFCP2154, GFCR2591, GFCR2592, GFCS2156, GFCU2199, GFCV2587, GFCW1652, GFCW2431, GFCX2712, GFCY2997, GFDN0246, GFDN3553, GFDN3554, GFDN3555, GFDP2922, GFDQ2500, GFDR2919, GFDS2209, GFDS2210, GFDT2188, GFDT2189, GFDT2204, GFDT2205, GFDU2170, GFDU2171, GFDV2179, GFDV2180, GFDV2181, GFDW2390, GFDW2391, GFDW2392, GFDX2711, GFDX2712, GFDY1135, GFDY1136, GFDZ1692, GFDZ1693, GFEP1181, GFEP1182, GFEP1183, GFEP1184, GFER2080, GFER2081, GFER2082, GFES2328, GFES2329,
Manufacturer:	Medtronic	
Problem:	Complaints involving balloon integrity and subsequent failure. Material rupture / balloon failure during procedure can result in material embolization, balloon leak, balloon burst, inversion or stretching resulting in balloon failure, or surgical intervention.	
Recommendation /Actions:	<ul style="list-style-type: none"> Review this notice and ensure that all affected personnel within your organization are aware of the contents. 	

	<ul style="list-style-type: none"> • Inspect the inventory to identify and quarantine the affected products as listed in the table above. • Contact the Authorized Representative for the required corrective action. <p>For more information, please check the “FSCA”</p> <p>If you think you had a problem with your device or a device your patient uses, please report the problem to SFDA through: NCMDR Vigilance system 19999 unified call center</p>								
Authorized Representative Details	<table border="1"> <tr> <td data-bbox="386 478 743 516">AR name:</td> <td data-bbox="743 478 1520 516">Medtronic Saudi Arabia</td> </tr> <tr> <td data-bbox="386 516 743 554">Assigned Contact Person:</td> <td data-bbox="743 516 1520 554">Faisal Matbuli</td> </tr> <tr> <td data-bbox="386 554 743 592">Mobile/Phone:</td> <td data-bbox="743 554 1520 592">0555066900</td> </tr> <tr> <td data-bbox="386 592 743 630">Email:</td> <td data-bbox="743 592 1520 630">faisal.matbuli@medtronic.com</td> </tr> </table>	AR name:	Medtronic Saudi Arabia	Assigned Contact Person:	Faisal Matbuli	Mobile/Phone:	0555066900	Email:	faisal.matbuli@medtronic.com
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