Medtronic

Urgent Field Safety Notice

Rashkind Balloon Septostomy Catheters

Recall

Product Number	Product Description	Lot Identification
007160	5F Rashkind Balloon Catheter Single Lumen	Refer to Table 1
007161	4F Rashkind Balloon Catheter Single Lumen	
008764	6F Rashkind Recessed Balloon Catheter	

September 2020

Medtronic reference: FA927

Dear Risk Managers or Healthcare Professional,

In August 2020, Medtronic initiated a verbal communication about an Urgent Field Safety Notice for a subset of Rashkind Balloon Septostomy Catheters (Product 008764 lots GFDY1136 and GFDV2179) to associated accounts. After completing the risk assessment, it has been determined that the scope of this recall be expanded to include all model and lot numbers listed in Table 1.

Through August 31, 2020, Medtronic has received nine (9) complaints involving balloon integrity and subsequent failure that involved one patient death and one patient material embolization. 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. As a result of these complaints and the potential for serious injury, Medtronic is initiating a product recall of Rashkind Balloon Catheters lots per Table 1.

Customer Instructions:

Medtronic records indicate that your facility has received one or more of the affected Rashkind Balloons Catheters. As a result, Medtronic requests that you immediately take the following actions:

- Identify and quarantine all unused Rashkind Balloon Catheters as listed in the table below
- Return all unused affected product in your inventory to Medtronic. Your local Medtronic Representative can assist you in the return of this product.
- Please forward this notice to all those who need to be aware within your organization.

Note: If you have already taken action as a result of the previous notification, please ensure you are now taking action on the expanded scope.

There are no actions required for patients where the Rashkind Balloon Catheter was used during a procedure. These patients should continue to be monitored in accordance with your medical facility's standard care protocols.

The Competent Authority of your country has been notified 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 Field Representative.

Sincerely,

Raed Yamout,
Senior Business Manager, Coronary, APS

Medtronic

Table 1: Rashkind Balloon Catheter Affected Lots

Rashkind Balloon Catheter Affected Model Numbers and Lot Identification Numbers	
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,