Medtronic

Urgent Field Safety Notice

Duet EDMS Tubing Disconnection from Patient Line Stopcock
Model Numbers: 46913, 46914, 46915, 46916, and 46917

Recall

January 2024

Medtronic Reference: FA1400

EU Manufacturer Single Registration Number (SRN): US-MF-000023270

Dear Healthcare Professional/Risk Manager:

The purpose of this letter is to advise you that Medtronic is recalling the Duet® External Drainage and Monitoring System (EDMS) products due to the potential for catheter disconnection from the patient line stopcock connectors. Please refer to the attached list of products that are affected. With the impacted Duet® External Drainage and Monitoring Systems, disconnections at the stopcock connection may occur at any point along the patient line.

Issue Description:
Medtronic received customer complaints alleging instances of the Duet catheter tubing disconnecting at the stopcock or Luer connector (Figure 1).

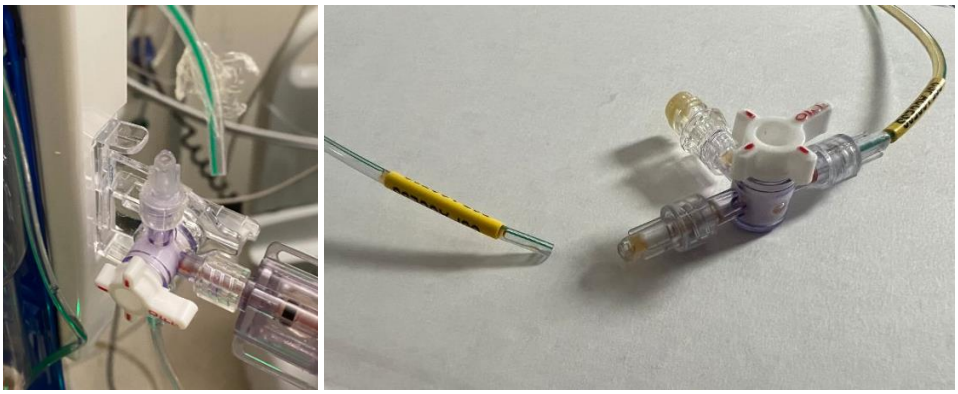

Figure 1: Duet EMDS catheters disconnected from Luer connectors

If a tubing disconnection occurs, potential harm to patients may include infections, cerebrospinal fluid leakage, overdrainage of cerebrospinal fluid, and abnormality of the ventricles. Uncontrolled overdrainage of cerebral spinal fluid could lead to neurological injury or death if the disconnection is undetected. The types of patient harms that have been reported in the complaints include cerebrospinal fluid (CSF) leakage and infection. No serious neurological injuries or patient deaths have been reported.

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Actions:
Our records show that your facility has received the impacted product. Medtronic requests that you immediately take the following actions:

- Identify and quarantine any unused impacted product(s). Refer to ***Appendix A - Affected Products*** for impacted products.

Patient Management Recommendations:

- As stated in the Duet® External Drainage and Monitoring System Instructions for Use section titled, "System Setup," check all components for damage and that all connections are secure and leak-free.
  - If a patient is currently connected to an impacted Duet EDMS and a leak or disconnection is detected, the device should be changed to a new alternative device utilizing a sterile technique.
  - It is not recommended to remove or replace a Duet system device that is connected to a patient and has been examined and found to be working as intended.
- Used product should not be returned to Medtronic and should be disposed of by the healthcare facility in accordance with the healthcare facility's policies and practices.

Unused Product:

- Return all unused and non-expired product(s) in your inventory to Medtronic. Your Medtronic Sales Representative can assist in returning any affected inventory, if applicable.
- This notice should be distributed to all others in your organization who should be aware, or to any organization where the potentially affected devices have been transferred. Please maintain a copy of this notice in your records.

Regulatory Notification:
Medtronic is communicating this information to the appropriate regulatory agencies. Adverse events or quality problems experienced with this product should be reported to Medtronic.

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 / OU manager

Enclosures:

- Appendix A – FCA Affected Products

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Appendix A – FCA Affected Products distributed to Denmark

Brand Name	CFN	GTIN	Serial Number
Medtronic Duet® External Drainage and Monitoring System, Interlink® Injection Sites	46913	00613994445360	225336442, 221795478, 221614450, 221482527
		00763000406004	227289114, 227289113, 225559818, 225234318, 224990662, 224949836, 221955229, 221744547, 221744157, 221687764, 221569956
Medtronic Duet® External Drainage and Monitoring System, SmartSite® Injection Sites	46914	00613994445377	226490979, 226490978, 226420630, 226366037, 222999296, 222530273, 222346067, 222204094, 222061755, 222015665, 221916163, 221827827, 221795479
		00763000395971	227289117, 227289116, 226951461, 226899370, 226756270, 226616246, 226420631, 226111272, 225587872, 225587871, 225500028, 225234319, 224387139, 224342656, 224173197, 223251949, 223165962, 223165960, 223130156, 222543362, 222393930, 222393929, 221955231, 221955230, 221916164, 221915125, 221915124, 221873428, 221873427, 221744549, 221744158, 221687765
Medtronic Duet® External Drainage and Monitoring System, Interlink® Injection Sites, Ventricular	46915	00613994445384	225468102, 224303374, 222204097
Medtronic Duet® External Drainage and Monitoring System, SmartSite® Injection Sites, Ventricular Catheter	46916	00613994445391	226899380, 226899379, 226335146, 226111239, 225500036, 225198821, 224990846
Medtronic Duet® External Drainage and Monitoring System, Interlink® Injection Sites, Lumbar Catheter	46917	00613994445407	225198822