

Medtronic CSF  
Cranial and Spinal Technologies  
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Fort Worth, TX 76137  
United States  
www.medtronic.com

**URGENT: MEDICAL DEVICE RECALL**  
**Duet EDMS Tubing Disconnection from Patient Line Stopcock**  
**Model Numbers: 46913, 46914, 46915, 46916, and 46917**

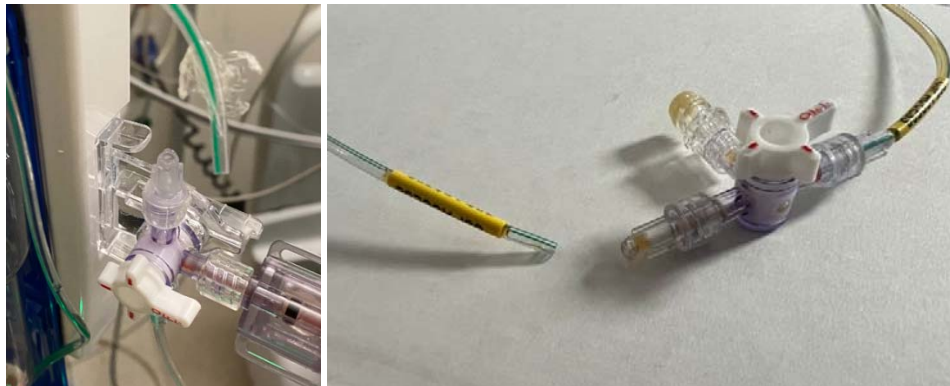
February 2024

Dear Healthcare Professional/ Risk Manager:

The purpose of this letter is to advise you that Medtronic is voluntarily 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 EDMS 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.

**Actions:**

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

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- 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 following the instructions in the enclosed Customer Confirmation Form. Your Medtronic Sales Representative can assist in returning any affected consignment and loaner inventory, if applicable.
- Complete the Customer Confirmation Form enclosed with this letter (even if you have no product to return), acknowledging that you have received this information.
- 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.

**Return Instructions:**

Customers with affected product	Where to send the completed customer confirmation form
<ul style="list-style-type: none"> <li>• Complete the Customer Confirmation Form.</li> <li>• Work with your Medtronic Rep to receive an RGA# or contact us at 1-800-874-5797, Option 1, to coordinate inventory replacement/credit. Reference <b>FA1400, Lot Number, and Product Number</b>.</li> <li>• Reference the RGA# in the attention line when returning the affected product. Credit for products returned without an RGA# may be delayed.</li> <li>• Return unopened affected units to: Medtronic Attention: [Insert RGA #] 4340 Swinnea Rd Building B, Returns cage Memphis, TN 38118</li> </ul>	<ul style="list-style-type: none"> <li>• Complete and return the Customer Confirmation Form, <u>even if you do not have any unused affected product to return.</u></li> <li>• Return the form via email to <a href="mailto:neuro.quality@medtronic.com">neuro.quality@medtronic.com</a> within 30 days of receipt.</li> </ul>

**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 and the FDA MedWatch Adverse Event Reporting program via:

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- Online at <http://www.fda.gov/Safety/MedWatch/HowToReport/default.htm>
- FDA telephone at 1-800-FDA-1088 (1-800-332-1088)

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,



Alison Webster  
VP Quality CST  
Medtronic, Inc

**Enclosures:**

- Customer Confirmation Form
- Appendix A - FCA Affected Products

## Appendix A - FCA Affected Products

Brand Name	CFN	GTIN	Lot Number
Medtronic Duet® External Drainage and Monitoring System, Interlink® Injection Sites	46913	00613994445360	226899374, 225468101, 225336443, 225336442, 224333656, 222274125, 222274124, 222240560, 222240559, 222240558, 222186495, 222186494, 222186493, 222121358, 222082061, 221795478, 221614452, 221614451, 221614450, 221482527
		00763000406004	227289115, 227289114, 227289113, 226738257, 226738256, 226738255, 226738254, 226711357, 226711356, 226711355, 226665392, 226665391, 226665390, 226517900, 226335061, 226111273, 226091713, 225749838, 225587870, 225587869, 225559818, 225559817, 225558567, 225422438, 225419717, 225375798, 225375797, 225279760, 225234318, 225035261, 224990848, 224990662, 224949837, 224949836, 224918533, 224302821, 224277483, 224255795, 224218028, 224218026, 224197127, 224032596, 223999039, 222580925, 222322813, 222322812, 222322811, 222061754, 222061753, 221955229, 221955228, 221873430, 221744547, 221744157, 221687764, 221569957, 221569956
		00763000624767	227194730, 227188106, 227187465, 227187464, 227136769, 227136768, 227136767, 226689508, 226650894, 226650893, 226571113, 226571112, 226546794, 226546791, 226517896, 226517895, 226490966, 226467306, 226335062, 226288880, 226242271, 226242270, 224990886, 224990868, 224990867, 224990850, 224990849, 224990663, 224973999, 224973998, 224918536, 224918535, 224918534, 224878533, 223818450, 223778508, 223734520, 223659558, 223659557, 223564705
		00613994445384 (Lots included inside Kit CFN 46915)	226951468, 226951467, 226951465, 226899377, 226665394, 226517901, 226490981, 226420633, 226366038, 225468102, 225336444, 224303374, 224303373, 224083877, 222817387, 222817386, 222816525, 222766470, 222766469, 222724792, 222724791, 222658561, 222658560, 222439029, 222439028, 222439027, 222204097, 222204095,

Brand Name	CFN	GTIN	Lot Number
			222163788, 222163787, 222163140, 222125124, 222121359, 221827829, 221604935
		00763000396008 (Lots included inside Kit CFN 46915)	226951469
		00763000624781 (Lots included inside Kit CFN 46915)	227194736, 227194735, 227188108, 227136777, 226732001, 226665650, 226665648, 226665647, 226665646, 226665405, 226665404, 226665403, 226665401, 226665400, 226665399, 226665393, 226634690, 226634689, 226634688, 226632942, 226625848, 226571114, 226546796, 226420634, 226242272, 223956932, 223954944, 223818452, 223818451
		00613994445407 (Lots included inside Kit CFN 46917)	226665395, 226571115, 226546799, 225198822, 224990871, 224990870, 224990852, 224973997, 224302820, 222277587
		00763000406028 (Lots included inside Kit CFN 46917)	226756273, 224301720, 223999040
		00763000624804 (Lots included inside Kit CFN 46917)	226734689, 226734688, 226665388, 226517899, 226490967, 223734523, 223698572, 223580362, 223565027
Medtronic Duet® External Drainage and Monitoring System, SmartSite® Injection Sites	46914	00613994445377	226490979, 226490978, 226420630, 226366037, 225558568, 224990661, 224990659, 224990658, 224949833, 223999041, 222999296, 222999295, 222970858, 222970857, 222970856, 222580924, 222530273, 222346067, 222345105, 222345104, 222204094, 222061755, 222015665, 221916163, 221827828, 221827827, 221795479
		00763000395971	227289117, 227289116, 226951462, 226951461, 226899370, 226756270, 226616246, 226420631, 226111272, 225749839, 225587872, 225587871, 225500028, 225468089, 225279761, 225234319, 224387139, 224342656, 224173197, 223251949, 223165962, 223165961, 223165960, 223130156, 223070846, 222543363, 222543362, 222393930,

Brand Name	CFN	GTIN	Lot Number
			222393929, 221955231, 221955230, 221916164, 221915125, 221915124, 221873428, 221873427, 221744549, 221744158, 221687765, 221648854, 221520718, 221482529
		00763000624774	227387373, 227307929, 227188107, 227136770, 227007687, 227006497, 226951464, 226951463, 226899372, 226810274, 226756272, 226756271, 226616244, 226567492, 226567490, 226567489, 226567488, 226517898, 226517897, 226420632, 226335065, 226335064, 226335063, 226288882, 226288881, 226242269, 226242268, 226242267, 226242266, 225749840, 225587874, 225587873, 225422433, 225035347, 224990888, 224990887, 224990869, 224990851, 224990665, 224990664, 224990656, 224918537, 224878535, 224878534, 224877792, 224852794, 224852793, 224852792, 224032597, 223778509, 223734522, 223734521, 223698571, 223659560, 223659559, 223621055, 223620063, 223580360
		00613994445391 (Lots included inside Kit CFN 46916)	226899380, 226899379, 226899378, 226899375, 226756274, 226517902, 226335148, 226335146, 226111239, 225686835, 225675932, 225500037, 225500036, 225198821, 224990846, 224990660, 224949835, 224949834, 224878536, 224852796, 224852795, 224032609, 223999043, 223999042, 223956150, 223907225, 223907224, 222082062, 221873429, 221612695, 221343119
		00763000406011 (Lots included inside Kit CFN 46916)	227307931, 227007688, 226899371, 226420635, 225749841, 225675930, 224387126, 224128508, 222480772, 222480771, 221873431
		00763000624798 (Lots included inside Kit CFN 46916)	227188109, 227136780, 226899373, 226734686, 226734645, 226734643, 226734641, 226734639, 226734637, 226616245, 226567491, 226420636, 226366036, 226335147, 226288883, 226242273, 224990889, 224990847, 224990657, 223659561, 223621056, 223618474, 223580378, 223580361, 223565026

Brand Name	CFN	GTIN	Lot Number
Medtronic Duet® External Drainage and Monitoring System, Interlink® Injection Sites, Ventricular	46915	00613994445384	226951468, 226951467, 226951465, 226899377, 226665394, 226517901, 226490981, 226420633, 226366038, 225468102, 225336444, 224303374, 224303373, 224083877, 222817387, 222817386, 222816525, 222766470, 222766469, 222724792, 222724791, 222658561, 222658560, 222439029, 222439028, 222439027, 222204097, 222204095, 222163788, 222163787, 222163140, 222125124, 222121359, 221827829, 221604935
		00763000396008	226951469
		00763000624781	227194736, 227194735, 227188108, 227136777, 226732001, 226665650, 226665648, 226665647, 226665646, 226665405, 226665404, 226665403, 226665401, 226665400, 226665399, 226665393, 226634690, 226634689, 226634688, 226632942, 226625848, 226571114, 226546796, 226420634, 226242272, 223956932, 223954944, 223818452, 223818451
Medtronic Duet® External Drainage and Monitoring System, SmartSite® Injection Sites, Ventricular Catheter	46916	00613994445391	226899380, 226899379, 226899378, 226899375, 226756274, 226517902, 226335148, 226335146, 226111239, 225686835, 225675932, 225500037, 225500036, 225198821, 224990846, 224990660, 224949835, 224949834, 224878536, 224852796, 224852795, 224032609, 223999043, 223999042, 223956150, 223907225, 223907224, 222082062, 221873429, 221612695, 221343119
		00763000406011	227307931, 227007688, 226899371, 226420635, 225749841, 225675930, 224387126, 224128508, 222480772, 222480771, 221873431
		00763000624798	227188109, 227136780, 226899373, 226734686, 226734645, 226734643, 226734641, 226734639, 226734637, 226616245, 226567491, 226420636, 226366036, 226335147, 226288883, 226242273, 224990889, 224990847, 224990657, 223659561, 223621056, 223618474, 223580378, 223580361, 223565026
Medtronic Duet® External Drainage and Monitoring System, Interlink®	46917	00613994445407	226665395, 226571115, 226546799, 225198822, 224990871, 224990870, 224990852, 224973997, 224302820, 222277587
		00763000406028	226756273, 224301720, 223999040

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Brand Name	CFN	GTIN	Lot Number
Injection Sites, Lumbar Catheter		00763000624804	226734689, 226734688, 226665388, 226517899, 226490967, 223734523, 223698572, 223580362, 223565027