Medtronic

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**URGENT: MEDICAL DEVICE RECALL**

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

24 January 2024 | 09:38 SGT

**Attention: Risk Management Director and O.R Materials Management**
**CC: The Chairman Medical Board and relevant Head of Departments**

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).

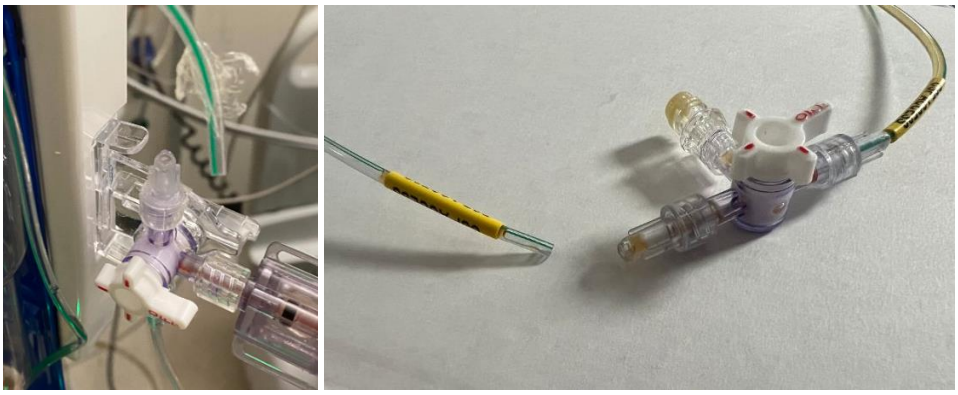

*Figure 1: Duet EMDS catheters disconnected from Luer connectors*

If a tubing disconnection occurs, potential harm to patients may include infections, cerebrospinal fluid leakage, over drainage of cerebrospinal fluid, and abnormality of the ventricles. Uncontrolled over drainage 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:

- 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.

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**Return Instructions**:

| Customers with affected product | Where to send the completed customer confirmation form |
|---|---|
| • Complete the Customer Confirmation Form.<br>• Work with your Medtronic Rep for any product returns or credit note. | • Complete and return the Customer Confirmation Form, *even if you do not have any unused affected product to return.*<br>• Return the form or scan then email to your local Medtronic field representative within 30 days ofreceipt. |

**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 your local Medtronic field representative.

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 local Medtronic field representative.

Sincerely,

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 24 January 2024 | 09:38 SGT
90D0724C9B1C402A99B286449A1644B8

**Quality and Regulatory Affairs Director**
Mainland and Island Southeast Asia

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## Appendix A – FCA Affected Products

| Brand Name | CFN | GTIN | Serial 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 |
| 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, 222393929, 221955231, 221955230, 221916164, 221915125, 221915124, 221873428, 221873427, 221744549, 221744158, 221687765, 221648854, 221520718, 221482529 |
| 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 |
| 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, |

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| Brand Name | CFN | GTIN | Serial Number |
|---|---|---|---|
| | | | 224852795, 224032609, 223999043, 223999042, 223956150, 223907225, 223907224, 222082062, 221873429, 221612695, 221343119 |
| | | 00763000406011 | 227307931, 227007688, 226899371, 226420635, 225749841, 225675930, 224387126, 224128508, 222480772, 222480771, 221873431 |
| Medtronic Duet® External Drainage and Monitoring System, Interlink® Injection Sites, Lumbar Catheter | 46917 | 00613994445407 | 226665395, 226571115, 226546799, 225198822, 224990871, 224990870, 224990852, 224973997, 224302820, 222277587 |
| | | 00763000406028 | 226756273, 224301720, 223999040 |

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## Customer Confirmation Form

## URGENT: MEDICAL DEVICE RECALL

## Duet EDMS Tubing Disconnection from Patient Line Stopcock

## Model Numbers: 46913, 46914, 46915, 46916, and 46917

***For completion by Medtronic Customers Only – Please complete all fields below and return all pages immediately.***

| Customer Contact Details | | Medtronic Contact Details |
|---|---|---|
| **Distributor / Hospital / Clinic / Physician / Patient name:** | | **Name:** |
| | | **Contact:** |
| **Address:** | | **Email:** |
| **Phone no:** | **Email:** | |

**If you have no affected stock to be returned, please tick the appropriate box, and sign off the form.**

**Do you have remaining inventory of the affected units?** (Please select only ONE):

☐ no, **NONE** of the affected inventory to be returned. I have examined our inventory for product/s covered by this and confirm that all affected was/were previously consumed.

☐ **YES**, affected inventory to be returned. I have examined our inventory and have the affected product/s listed in the following table that remain/s unconsumed and is to be returned:

**How did you purchase this product?** (Please select only ONE):

☐ direct from Medtronic ☐ from a distributor [Distributor Name: _____]

| Product Number / Item Code | Lot Number(s) | Quantity for return (in eaches) |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

*If this table is not enough, please use the additional page provided. Additional page and/or attachments must be signed and dated.

**Return Instructions:**

1. Identify and quarantine any unused impacted product(s).
2. Contact your local Medtronic representative to coordinate your returns.

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3. Return all unused inventory to Medtronic for replacement product or credit note. Your local Medtronic representative will assist you in initiating and coordinating the return and replacement of the product.
4. If purchased from a distributor, contact your local distributor directly to arrange for return of the product back to your distributor.

By signing this form, I confirm that I have read the Urgent Medical Device Recall Notification Letter, dated 24 January 2024 | 09:38 SGT, from Medtronic regarding Duet EDMS Model Numbers 46913, 46914, 46915, 46916, and 46917 and taken appropriate action.

Please complete and sign the form as indicated below and hand or scan then email back to your local Medtronic representative. If you no longer manage Duet EDMS products, please provide the details requested above so that Medtronic's records can be updated accordingly.

Name (print): _____ Signature: _____ Stamp: _____ Date: dd Mmm yyyy

***Note: The addressee may continue to receive reminders of this notice until a response is received.***

For questions, contact your local Medtronic representative.