Medtronic

URGENT FIELD SAFETY NOTICE
Duet® External Drainage and Monitoring System Patient Line Recall

Medtronic reference: FA624

June 2014

Dear OR Supervisor-Neurosurgery, ICU Manager and Risk Manager,

Medtronic Neurosurgery is initiating a voluntary recall of all unused units of the following Medtronic products:

- Medtronic Duet® External Drainage and Monitoring System, Interlink® Injection Sites, Catalog Number 46913
  - Lot Numbers: 206923217, 207096627, 207096630, 207187691, 207224897, 207269986, 207466017, 207565424, 207565425, 207659575, 207659576, 207739874, 207875274, 207945037, 207982847

- Medtronic Duet® External Drainage and Monitoring System, SmartSite® Injection Sites, Catalog Number 46914
  - Lot Numbers: 206843112, 206854300, 206875578, 206923218, 206951123, 206962974, 206986677, 207167084, 207246210, 207312741, 207441171, 207466011, 207466012, 207560684, 207632971, 207659577, 207716835, 207716836, 207766493, 207900255, 207945036, 207983301, 208008802

- Medtronic Duet® External Drainage and Monitoring System, Interlink® Injection Sites, Ventricular Catheter, Catalog Number 46915
  - Lot Numbers: 206923344, 206986678, 207096628, 207565426, 207659574, 207945035, 207982846, 208031201, 208055143

- Medtronic Duet® External Drainage and Monitoring System, SmartSite® Injection Sites, Ventricular Catheter, Catalog Number 46916
  - Lot Numbers: 206843114, 206854302, 206923345, 207167085, 207246211, 207466015, 207565607, 207716842, 207766492, 208031202

- Medtronic Duet® External Drainage and Monitoring System, Interlink® Injection Sites, Lumbar Catheter, Catalog Number 46917
  - Lot Numbers: 208031203

You are receiving this letter because our records indicate you have received one or more of the affected products. Medtronic is initiating this voluntary recall because the patient line tubing in the Duet® External Drainage and Monitoring Systems listed above may become disconnected from the patient line stopcock.

Disconnections of the patient line, if they occur, are more likely to occur during handling of the system by a healthcare professional. The event would likely be noticed immediately and could be addressed without exposing the patient to significant risk.

Potential hazards that may occur as a result of a patient line disconnection are pneumocephalus, underdrainage, overdrainage and infection. Of the affected lots identified in this field action, there have been no underdrainage, overdrainage or infection events reported and a 0.05% event occurrence rate for pneumocephalus.

All pneumocephalus events resolved without injury. Although the disconnection occurrence rate is low, Medtronic has decided to initiate this voluntary recall. Our investigation of this issue confirms that it is limited to the lot numbers listed above and potential risk for the patient is low. The production process has been improved and additional controls have been implemented which address the identified issue. Since the controls were implemented, we have not observed this issue and there have been no reports from customers. New product manufactured with these new processes and controls is available.

We ask that the following actions be initiated immediately:

1. Cease use of the listed product and return any unused units to Medtronic.
2. Account for product used.
3. If any of the indicated products are in use, verify all connections are secure and leak-free as stated in the Instructions for Use.

Medtronic has notified the Competent Authority of your country of this action. Please share this notification with others in your organization as appropriate or with any organization where the potentially affected devices have been transferred.

We appreciate your cooperation with this matter and apologize for the inconvenience that it may cause. Please contact your Medtronic representative for any questions you may have related to this product Recall.

Sincerely,