Recall detail

Type of Product[i]	Medical Device
TGA Recall Reference[ii]	RC-2014-RN-01009-1
Product Name/Description[iii]	Codman Neuro EDS 3 CSF External Drainage Systems (indicated for draining cerebrospinal fluid (CSF) and other fluids when the insertion of a permanent internal shunt is not indicated) EDS 3CSF External Drainage System with Ventricular Catheter Part number: 82-1730 ARTG: 123236 EDS 3CSF External Drainage System (no Ventricular Catheter) Part number: 82-1731 ARTG:122785 Lumbar Drainage Catheter Kit II with EDS 3System Part number: 82-1738 All lot numbers affected ARTG: 123489
Recall Action Level[iv]	Hospital
Recall Action Classification[v]	Class I
Recall Action Commencement Date[vi]	22/09/2014
Responsible Entity[vii]	Johnson & Johnson Medical Pty Ltd T/A Depuy Australia
Reason / Issue[viii]	The tubing within the system that drains CSF may leak or disconnect from the joints. Leakage and tube separations may result in over- or under-drainage of CSF from the ventricular system or introduction of air into the ventricular system (pneumocephalus). This may result in collapsed ventricles, subdural bleeding, or an inability to properly control elevated intracranial pressure. The tubing disconnection or leakage may also increase the risk of ventriculitis. If undetected or untreated each of these events may cause severe brain injury, which may lead to coma, stroke or death. These systems are most often used on neurocritical care floors and these issues are likely to be detected immediately.
Recall Action[ix]	Recall

Recall Action Instructions[x]	Johnson & Johnson Medical Pty Ltd (JJM) is issuing a two stage recall action to mitigate the risk of shortage for these devices in the market place. STAGE 1 - INFORM: Inform customers regarding the product issues and what actions need to be undertaken in the interim. STAGE 2 - RECALL: Customers should return affected product to JJM once they have sourced alternate product. In the case where no substitute drainage system is immediately available, the EDS 3 System may continue to be used until an alternative product can be obtained. Manipulation of tubing should be minimised and extra vigilance (identified in the customer letter) is required for early detection of leakage and/or disconnection. After the alternative products have been sourced by customers, affected products should be quarantined for returning it to JJM.
Contact Information[xi]	1800 252 194 - JJM Customer Service

Footnotes

[i] Type of Product: Medicine, Medical Device, or Biological

[ii] TGA Recall Reference: Unique number given by the TGA

[iii] Product Name/Description: Brand name (including active ingredient for medicines) and may include generic reference for the kind of medical devices. Includes all necessary information such as affected: catalogue / model and / or batch / serial numbers.

[iv] Recall Action Level: The level to which the recall action is to be undertaken. This is based on the significance of the risk and the channels through which the goods have been distributed. The recall action levels are / Wholesale / Hospital / Retail / Consumer.

- Wholesale - includes wholesalers and state purchasing authorities.
- Hospital - includes nursing homes and institutions, hospital pharmacists, ambulance services, blood and tissue banks and laboratories as well as wholesale as appropriate.
- Retail - includes retail pharmacists, medical, dental and other health care professionals as well as wholesale and hospital as appropriate.
- Consumer - includes patients and consumers, as well as wholesale, hospital and retail levels as appropriate.

[v] Recall Action Classification: Recall actions of therapeutic goods are classified based on the potential risk the deficiency poses to patients / consumers. They are classified as Class I, Class II or Class III.

- Class I recall action occurs when the product deficiency is potentially life-threatening or could cause a serious risk to health.
- Class II recall action occurs when the product deficiency could cause illness, injury or result in mistreatment, but are not Class I.
- Class III recall action occurs when the product deficiency may not pose a significant hazard to health, but action may be initiated for other reasons eg. quality related issues.

[vi] Recall Action Commencement Date: The date the recall strategy and communication was agreed by the TGA.

[vii] Responsible Entity: Sponsor / Supplier / Importer responsible for the recall actions.

[viii] Reason / Issue: Reason for the recall action.