COOK INCORPORATED
750 DANIELS WAY, P.O. BOX 489
BLOOMINGTON, IN 47402-0489 U.S.A.
PHONE: 812.339.2235 TOLL FREE: 800.457.4500
WWW.COOKMEDICAL.COM

Date: November 19, 2015

# URGENT: MEDICAL DEVICE RECALL

ATTENTION: Risk Management/Recall Administration/Customer Representative

**Details on affected devices:**
**Brand Name:** VentriClear® II Ventricular Drainage Catheter Set
**Catalog Number:** 50318 (5 pack)
**GPN Number:** G44130
**Lot Numbers:** F4365351X, F4692818X, NS5274254X, NS5667436X, NS5727900X, NS6079165X, NS6079166X

**Description of the problem:**

Cook Medical is initiating a voluntary recall of specific lot numbers of the VentriClear® II Ventricular Drainage Catheter Set listed above. This product is distributed by Medtronic Neurosurgery.

The VentriClear® II Ventricular Drainage Catheter Set is intended for obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume. The catheter is impregnated with the antimicrobial agents, minocycline and rifampin, which may reduce the risk of catheter colonization and catheter-related infection during use.

Cook Medical has discovered internally that these specific lot numbers have been sterilized a total of two (2) times before shipment. The concentrations/amounts of minocycline and rifampin present on each catheter are known to decrease after each sterilization cycle. There have been no reports of illness or injury associated with this event. There is a high probability of the minocycline and rifampin coating being less than what is indicated. Therefore, the potential exists for the minocycline and rifampin catheter coating to be less than what is indicated on the Instructions for Use/Labeling .

Medtronic Neurosurgery indicates your facility has received devices distributed in May 2014.

**Action to be taken:**

1. Please review the affected product and lot numbers shipped to your account, and quarantine any affected product that remains unused.

2. Please complete the attached Recall Response Form.

3. Immediately collect and return all unused affected products to Medtronic as soon as possible for credit (See attached Recall Response Form for instructions).

4. Contact your local Medtronic Representative at ***Gulf Medical*** for replacement product.

**Transmission of this Notice:**

This notice must be passed on to appropriate personnel, including down to the user level, within your organization or to any organization where the potentially affected devices have been transferred.

We regret the inconvenience this may cause you. Thank you again for your immediate assistance in this matter.

Should you have any questions or concerns, please do not hesitate to contact your Medtronic Representative.

We look forward to your response.

Cook Medical

Rita A. Harden

Rita A. Harden
Director, Customer Relations & Regulatory Reporting