Medtronic

# URGENT FIELD SAFETY NOTICE
# FlexCath® Select Steerable Sheath
# Model Number: 990065
# Recall

Medtronic reference: FA644

February 2015

Dear Physician, Risk Manager, Health Care Professional:

Through 20 February 2015, Medtronic received four (4) reports where clinicians observed debris appearing to originate from the hemostasis valve on the proximal end of Model 990065 FlexCath® Select Steerable Sheath (10 Fr), outside of the patients' bodies. **There have been no reports of patient injury or death associated with this issue, nor are any predicted.**

As a result of this issue, Medtronic is recalling seven lots of Model 990065 FlexCath® Select Steerable Sheaths. This issue does not affect other Medtronic sheaths or delivery catheters.

Following lot numbers are affected by this recall: 54790, 54860, 54876, 54877, 54878, 72417, 72419.

This sheath is indicated for percutaneous catheter introduction into the vasculature; it is not implanted in the body. The hemostasis valve on the sheath remains outside of the patient body during use. While no patient injuries have been reported to date, nor are any predicted, potential harms include embolization of debris to the brain resulting in a transient ischemic attack (TIA) or stroke; or to coronary arteries resulting in cardiac ischemia, which may require medical intervention. Medtronic has stopped distributing the Model 990065 FlexCath Select Steerable Sheaths (10 Fr) while the root cause investigation for this issue continues.

Our records show that your facility has received one or more of these sheaths.

As such, Medtronic requests that you:

- Immediately quarantine all unused Medtronic Model 990065 FlexCath Select Steerable Sheaths.
- Return all affected product in your inventory to Medtronic. Your sales representative will assist you with this process.
- If replacement product is needed, your Medtronic field representative can assist you with identifying suitable replacement product.

For affected product that has been used, no action is necessary and patients should continue to be managed in accordance with your standard patient management protocol.

Medtronic has notified the Competent Authority of your country of this issue.

Please share this notification with others in your organization as appropriate. If any FlexCath Select Steerable Sheaths within scope of this issue have been sent to another facility, please notify that facility of this issue and facilitate the retrieval of these sheaths.

We appreciate your cooperation and apologize for the inconvenience that this issue may cause. Please be assured that patient safety and product quality remain our primary concern.

Sincerely,

Country/BU manager