衞生署 醫療儀器管制辦公室

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DEPARTMENT OF HEALTH MEDICAL DEVICE CONTROL OFFICE

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本署檔號 OUR REF. L/M(618) to DH/MDCO/20-10/8

來函檔號 YOUR REF.:

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Dear healthcare professional,

Health Canada Issued Important Safety Information on Central Vascular Access Devices

Your attention is drawn to a notice issued by Health Canada regarding the complications of catheter pinch-off associated with central vascular access devices and the recommendations on their use.

According to Health Canada, central vascular access devices (also known as central venous catheters or implantable ports) are considered to be safe and represent convenient means for providing patients with intravenous medication therapies, Health Canada is concerned about reports of catheter pinch-off (compression and fracture of the catheter), leading to subsequent embolization of the fractured distal fragments. Catheter pinch-off related problems can present as an inability to aspirate blood from a catheter line or injection port, or occasionally as chest pain or cardiac arrhythmias during infusion procedures. The presentation of catheter pinch-off related problems are quite variable as some patients with a fractured catheter can remain asymptomatic. Most of the reported cases involved migration of a fractured catheter to the pulmonary artery or the heart.

In order to minimize the risk of these complications associated with the use of central vascular access devices, Health Canada recommends the following:

- 1. Review the labelling of relevant devices, especially sections concerning warnings and implantation instructions.
- 2. Remain vigilant for early signs of catheter pinch-off problems. Stop using the catheter line when blood cannot be aspirated from the catheter, when the catheter cannot be flushed easily or whenever a catheter pinch-off related problem is suspected, and perform chest radiograph as needed to rule it out.
- 3. Consider a follow up with chest radiograph in patients with long-term central vascular access

devices. Educate patients to inform healthcare professionals when experiencing pain or other abnormal symptoms upon flushing or infusion of fluids through the catheter line.

For more details about the notice, please refer to the following links: http://hc-sc.gc.ca/dhp-mps/medeff/advisories-avis/prof/_2011/central_vascular-veineux_nth-aah-eng.php

Thank you for your attention.

Yours faithfully,

(Dr Addi CHAN)

for Director of Health