



本處檔號 OUR REF.: L/M (45) to DH/MDCO/20-10/9

來函檔號 YOUR REF.:

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Dear Healthcare Professionals,

**Risk of life-threatening embolism related to the use of air- or gas-pressurised spray devices
for application of sprayable fibrin sealants**

Your attention is drawn to a medical device alert issued by the Medicines and Healthcare products Regulatory Agency (MHRA), United Kingdom on the risk of life-threatening embolism associated with the use of air- or gas-pressurised spray devices for the application of sprayable fibrin sealants to achieve intra-operative haemostasis.

The MHRA is aware of fatal incidents of air or gas embolism occurring during, or immediately after, application of fibrin sealants using air- or gas-pressurised spray devices. These adverse events had occurred during surgical procedures such as arthroscopy, laproscopic partial nephrectomy, and vascular surgery. The cause of these events appears to be related to the use of spray devices to apply fibrin sealants when either the pressure setting is greater than recommended or when the device is held closer to the tissue surface than is recommended by the manufacturer, leading to the introduction of gas or air to bleeding tissue surfaces under pressure. So far, the Hong Kong Department of Health has not received any report of similar adverse events in Hong Kong.

To avoid these adverse events, all those preparing and/or using the air- or gas-pressurised spray system for these products should be well trained in their use. They should follow the manufacturer's instructions for use closely, particularly, with regard to the air or gas pressure used and the distance to the tissue. In addition, the spray device with gas alone should not be used to dry the tissue surface prior to application of the sealant.

For more details about the safety alert, please refer to the following link: <http://www.mhra.gov.uk/home/groups/dts-bs/documents/medicaldevicealert/con149680.pdf>

Thank you for your attention.

Yours faithfully,

(Dr. LEUNG Yiu-hong)
for Director of Health

竭誠服務 顧客為本 素質為先

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