Information Update - Health Canada informing healthcare professionals of safe use of fibrin sealants

PR Newswire

OTTAWA, March 15, 2013 /CNW/ - Health Canada and manufacturers are strengthening the labeling and instructions for the use of spray fibrin sealants following three deaths outside of Canada.

Fibrin sealants, also known as topical hemostatic agents, are used during surgery to help reduce local bleeding. The sealant solution is either dripped or sprayed onto bleeding tissue.

Efforts are ongoing to inform the medical community of the need to ensure that spray devices are always used at the manufacturer recommended pressure and distance from the tissue. Exceeding the maximum recommended pressure or spraying too close to the tissue increases the risk of an air or gas embolism (an air or gas bubble that blocks a vein or artery) in the patient.

Health Canada has received reports of incidents that occurred outside Canada of life-threatening air/gas embolisms associated with spray applications of fibrin sealants, including three deaths. The Department previously communicated [1] to healthcare professionals in 2010 regarding this risk. The most recent death occurred in the United Kingdom in January 2012. There have been no reports of life-threatening or fatal air/gas embolisms in Canada associated with fibrin sealant spray products.

While the current Canadian labelling for fibrin sealants provides instructions for their safe use, the international incidents have prompted regulators to request that manufacturers strengthen the instructions to further reduce the risk of misuse. Changes will include new labels stating the recommended pressure and distance for spraying on the device itself. The strengthened labelling is expected later this year.

Health Canada reminds healthcare professionals to always follow the instructions for the correct use of fibrin sealant spray devices, and to report any cases of air/gas embolism, or other serious adverse reactions, to the manufacturer or Health Canada.

Report a health or safety concern

- Call toll-free at 1-866-234-2345
- Visit Health Canada's Web page on Adverse Reaction Reporting [2] for information on how to report online, by mail or by fax

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[1] http://www.healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2010/14607a-eng.php
[2] http://www.hc-sc.gc.ca/dhp-mps/medeff/report-declaration/index-eng.php