Health Canada Santé Canada

Health Products and Food Branch
Direction générale des produits de santé et des aliments

The Marketed Health Products Directorate (MHPD) of the Health Products and Food Branch (HPFB) posts on the Health Canada Website safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories are prepared in collaboration with other Directorates in the HPFB which includes pre-market and post-market areas as well as market authorization holders and other stakeholders. Although the HPFB grants market authorizations or licenses for therapeutic products, we do not endorse either the product or the company. Any questions regarding product information should be discussed with your health professional.

This is duplicated text of a letter from **Abbott Laboratories, Limited.**
Contact the company for a copy of any references, attachments or enclosures.

IMPORTANT SAFETY INFORMATION REGARDING THE USE OF SEVORANE AF (SEVOFLURANE) IN CONJUNCTION WITH ANESTHESIA MACHINES

Quality Health Care Worldwide
Au service de la santé dans le monde entier

Faxbulletin™

November 17, 2003

Dear Healthcare Professional,

Abbott Laboratories, Limited ("Abbott") would like to make you aware of rare, isolated reports of smoke/fire or extreme heat which have been observed in anesthesia machines where SEVORANE AF* (sevoflurane) is used in conjunction with a desiccated carbon dioxide (CO_2) absorbent. Although ongoing investigations have not yet identified the exact etiology, Abbott considers it important to inform anesthesia providers of the existence of these rare occurrences, which can result in patient injury.

Based on available information, it is important to highlight that in most cases reported to Abbott, desiccated CO_2 absorbents were in use. It is also well documented that the exothermic reaction that occurs between all inhalational agents, including sevoflurane, and the CO_2 absorber is increased when the absorber becomes desiccated, such as after an extended period of dry gas flow through the absorbent canister.

Please remember to continue to follow your best practices with respect to maintaining your anesthesia machines, such as:

- If you suspect that the CO_2 absorbent may be desiccated because it has not been in use for an extended period of time, replace it.
- Although the exact conditions under which absorbent may become desiccated are not well defined, a low fresh gas flow rate over an extended period of non-use may contribute to unexpected desiccation of CO_2 absorbent materials on the anesthesia machine. Therefore, completely shut off the anesthesia machine at the end of clinical use or after any case when a subsequent extended period of non-use is anticipated.
- Turn off all vaporizers when not in use.

- Verify the integrity of the packaging of new CO_2 absorbents prior to use.
- Periodically monitor the temperature of the CO_2 absorbent canisters.
- Monitor the correlation between the sevoflurane vaporizer setting and the inspired sevoflurane concentration. An unusually delayed rise or unexpected decline of inspired sevoflurane concentration compared to the vaporizer setting may be associated with excessive heating of the CO_2 absorbent canister.

In addition, please consider the following:

- The colour indicator of most CO_2 absorbents does not necessarily change as a result of desiccation. A lack of significant colour change should therefore not be taken as an assurance of adequate hydration. CO_2 absorbents should be replaced routinely regardless of the state of the colour indicator.

- If excessive heat from the CO_2 absorbent canister is noted, the clinical situation should be evaluated and disconnecting the patient from the anesthesia circuit should be considered.

- The following findings have been reported in association with the rare events of fire and extreme heat:

  - Failed inhalation induction or inadequate anesthesia with sevoflurane
  - Patient signs of airway irritation, such as coughing
  - Oxygen desaturation, increased airway pressures, and difficult ventilation
  - Severe airway edema and erythema
  - Elevated carboxyhemoglobin levels

- Current information indicates that typically these cases of fire or extreme heat were the first case of the day for the specific anesthesia machine, and the reported cases indicated that Baralyme® CO_2 absorbent was used. However, cases of extreme heat have been reported in association with desiccated soda lime.

- When desiccated CO_2 absorbents are used with sevoflurane under extreme experimental conditions, flammable degradation products, including formaldehyde and methanol, may be present even in the absence of fire. The potential risk to patients receiving sevoflurane anesthesia due to these breakdown products has not been evaluated.[1] Similar to other potent inhalational anesthetic agents, sevoflurane, when exposed to desiccated CO_2 absorbents, produces carbon monoxide.[2]

SEVORANE AF* (sevoflurane) has been available in Canada since its initial launch in 1995. Although these events are rare and isolated, they can result in patient injury. Abbott will continue to investigate the causative and preventive factors surrounding the issues of fire, extreme heat, and potential breakdown products associated with the use of sevoflurane and desiccated CO_2 absorbents. Abbott will continue to provide timely guidance as relevant information becomes available.

Please review the steps to reduce the risk of fire and extreme heat included in this letter with your anesthesia associates. As with all medical products, healthcare professionals are strongly encouraged to report any adverse events that occur with the use of SEVORANE AF*. If you

have additional questions regarding SEVORANE AF*, please contact Abbott Laboratories, Limited.

Sincerely,

original signed by
Mauricio Ede, MD, PhD
Medical Director
Abbott Laboratories, Limited

* TM

References:

1. Holak EJ, Mei DA, Dunning MB III, et al. Carbon monoxide production from sevoflurane breakdown: modeling of exposures under clinical conditions. *Anesth Analg*. 2003;96:757-64.
2. Wissing H, Kuhn I, Warnken U, Dudziak R Carbon monoxide production from desflurane, enflurane, halothane, isoflurane, sevoflurane with dry sodalime. *Anesthesiology* 2001;95:1205-12.

Abbott Laboratories, Limited/Laboratoires Abbott, Limitée
P.O. Box/C.P. 6150, Station/succursale Centre-ville
Montréal (Québec) H3C 3K6

Any suspected adverse incident can also be reported to:
Health Products & Food Branch Inspectorate
HEALTH CANADA
Address Locator: 3002C
OTTAWA, Ontario, K1A 0K9
Tel: The Medical Devices Hotline 1-800-267-9675