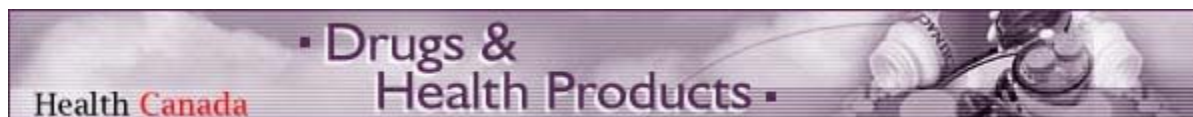


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A-Z IndexContact us
Consultations Help
Media RoomSearch
It's Your
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Home[About Health Canada](#)[Consumer Product
Safety](#)[Diseases &
Conditions](#)[Drugs & Health
Products](#)[Adverse Reaction
Information](#)[Advisories, Warnings &
Recalls](#)[Biologics, Radio-
pharmaceuticals &
Genetic Therapies](#)[Compliance &
Enforcement](#)[Controlled Substances &
Precursor Chemicals](#)[Drug Products](#)[International Activities](#)[MedEffect](#)[Medical Devices](#)[Medical Use of
Marihuana](#)[Natural Health Products](#)[Progressive Licensing](#)[Public Involvement &
Consultations](#)[Regulatory Requirements
for Advertising](#)[Special Access to Drugs
& Health Products](#)[Veterinary Drugs](#)[Legislation & Guidelines](#)[Reports & Publications](#)[Emergencies &
Disasters](#)[Environmental &
Workplace Health](#)[First Nations & Inuit
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Pages: 03, Size: 54 K, Date: 2007-05-30

The Health Products and Food Branch (HPFB) posts on the Health Canada web site safety alerts, public health advisories, press releases and other notices as a service to health professionals, consumers, and other interested parties. These advisories may be prepared with 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.

NOTICE TO HOSPITALS
**Health Canada Issued Safety Information on Bone Cements Used in
Vertebroplasty and Kyphoplasty Procedures**

POSTED BUT NOT FAXED**This notice supersedes the Notice to Hospitals issued by Health Canada on February 9, 2007, as Health Canada has revised information**

May 30, 2007

To: Hospital Chief of Medical StaffPlease distribute to the relevant Departments of Radiology, Orthopaedic Surgery, Neurosurgery, and other involved professional staff and **post this NOTICE** in your institution.**Subject: Complications Associated with the Use of Bone Cements in
Vertebroplasty and Kyphoplasty Procedures**

Health Canada has been made aware of reports relating to serious complications, including deaths, associated with the use of bone cement in Vertebroplasty and Kyphoplasty procedures and wishes to alert healthcare professionals to this safety information.

Vertebroplasty and Kyphoplasty are relatively new procedures that are being increasingly used in the treatment of patients with vertebral compression fractures. Advocates of both procedures claim to offer advantages over the conservative therapy in immediate pain relief and mechanical stabilization of the vertebral body. Vertebroplasty is performed by percutaneously injecting bone cement into the vertebral bodies under fluoroscopic and/or computed tomography guidance. Kyphoplasty includes an attempt to expand the vertebra

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with an inflatable balloon prior to the injection of bone cement. Currently, only certain polymethylmethacrylate (PMMA) bone cements are licensed by Health Canada for use in these procedures.

Serious complications associated with the use of the bone cements in these procedures have been reported. They include:

- Death due to sudden blood pressure drop that may be related to the release of the PMMA monomer into the vascular system;
- Bone cement extravasation into the spinal canal leading to neurologic deficit, with compression of the spinal cord and/or nerve roots;
- New fractures, usually of adjacent non-augmented vertebrae;
- Pulmonary embolism of the PMMA.

These adverse events can result in neurologic complications ranging from minor motor and sensory loss to paraplegia. Further intervention (surgical correction, rehabilitation therapy) is required in many cases. Deaths due to sudden blood pressure drop, PMMA embolism and other factors related to pre-existing cardiovascular disease, have been reported internationally.

Though the available data does not allow for a direct comparison of the rates of new fracture after vertebroplasty, kyphoplasty and conservative treatment, there is evidence to suggest that the occurrence of new vertebral fractures after vertebroplasty and kyphoplasty may be nonlinear, with the majority of cases diagnosed within the first few months after augmentation. Augmentation of the vertebral body with PMMA cement increases the strength and stiffness of the vertebrae and may dispose the adjacent vertebral bodies to new fractures.

In order to minimize the risk of these and other complications associated with the use of bone cements in Vertebroplasty and Kyphoplasty procedure, Health Canada recommends the following:

- A period of conservative therapy should be considered in all patients having acute osteoporotic vertebral body fractures.
- Only qualified physicians who are thoroughly trained in performing Vertebroplasty and Kyphoplasty should perform these procedures.
- Use only bone cements indicated for Vertebroplasty and Kyphoplasty procedures, and carefully review and follow the Instructions for Use.
- Monitor the procedures with high quality imaging systems to allow recognition of PMMA leakage.
- Closely monitor patients' blood pressure during and immediately after the procedures; multiple-level treatment may increase the risk of sudden drop in blood pressure related to the release of PMMA monomer into the circulation.
- Careful diagnosis and special precautions should be taken when the procedures are performed in treating patients with spinal tumours that have eroded the posterior vertebral body wall.
- Traumatic burst fractures with disruption of the posterior vertebral body should be a relative contraindication to Vertebroplasty or Kyphoplasty.

Managing marketed health product-related adverse incidents depends on health care professionals and consumers reporting them. Reporting rates determined on the basis of spontaneously reported post-marketing adverse incidents are generally presumed to underestimate the risks associated with health product treatments. Any cases of serious or unexpected adverse incidents in patients treated with Vertebroplasty and Kyphoplasty procedures should be reported to the marketing authorization holder or to Health Canada at the following address:

Health Products and Food Branch Inspectorate
HEALTH CANADA
Address Locator: 2003D
Ottawa, Ontario K1A 0K9
Tel: The Inspectorate Hotline 1-800-267-9675

The [Reporting Form](#) and [Guidelines](#) can be obtained from the Health Canada web site.

For other inquiries related to this communication, please contact Health Canada at:
Marketed Health Products Directorate (MHPD)
E-mail: mhpd_dpdc@hc-sc.gc.ca
Tel.: (613) 954-6522
Fax.: (613) 952-7738

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