Medtronic International Ltd. - Malaysia Branch
(993966-P)
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3 Two Square,
No. 2, Jalan 19/1,
46300 Petaling Jaya,
Selangor Darul Ehsan, Malaysia.
Tel: 603-7953 4800 (10 lines) Fax: 603-7958 2202

December, 2009.

To:
DIRECTOR OF MEDICAL DEVICE BUREAU
MINISTRY OF HEALTH MALAYSIA
Level 5, No. 26, Boulevard Plot 3C4,
Precinct 3,
Federal Government Administration Centre,
62675 Putrajaya,
Malaysia

Dear Sir,

NOTICE OF RECALL: KYPHX HV-R BONE CEMENT.

This letter is to inform you on the Field Corrective Action being carried out by Medtronic on the product KyphX HV-R Bone Cement.

The communication letters are sent to the respective physicians and the Hospitals/Institutions where the affected lots of the products have been distributed. The letter is as attached, to provide further insights into this field action.

Do consult us should you require additional information.

Yours Sincerely,

Debra Anne Anthony Peter
REGULATORY AFFAIRS SPECIALIST
MEDTRONIC INTERNATIONAL, LTD.

Attachment: Customer Communication Letter

URGENT DEVICE RECALL NOTICE:
Action Required

December 2009

Re:	**Bone Cement Characteristics Observed During Preparation**
Product:	**C01A KyphX HV-R Bone Cement** **C01B KyphX HV-R Bone Cement with Mixer**
Lot Numbers:	**(refer to attached table)**

Dear Sir/Madam:

Medtronic Spine LLC has conducted an investigation into complaints received for KyphX HV-R Bone Cement characteristics observed during preparation. The issues reported include an extended time to reach the proper viscosity (doughy state) and inconsistency or lack of homogeneity during cement preparation, as well as, when waiting to deliver the bone cement with the delivery device (e.g. Bone Filler Device). Our medical review of this matter concludes that the risk to patients is low but the risk of bone cement extravasation may be increased if the bone cement is used if it has not reached the proper state of viscosity (doughy state) prior to delivery, as described in the Instructions for Use. To ensure that our customers have product that meets their expectations, **we are requesting that the Affected Lots on the attached page(s) be returned to Medtronic Spine.**

Your hospital has been identified as having received one or more of the Affected Product. The Affected Product may still be in your hospital's possession if not already used during the procedure. **Please do not use any Affected Product** that you may have received with the **Lot Numbers provided on the attached page(s)**. Medtronic Spine will replace any Affected Product in your inventory at no cost to you. Please contact your Medtronic Spine sales representative or customer service for assistance with replacement of the product.

In addition, for our customer's convenience, we are providing key information on the preparation and use of KyphX HV-R Bone Cement as a separate page attached to this Recall Notice. There is no additional follow-up recommended for patients as a result of this Recall Notice except for what is already recommended in the Instructions for Use: "Long-term follow-up is advised for all patients on a regularly scheduled basis."

Medtronic Spine LLC is requesting confirmation that you have received this Notice by completing and returning the attached confirmation slip. We apologize for any inconvenience this may cause you. If you have any questions about this notification, please do not hesitate to contact Medtronic. Thank you for your prompt attention to this matter.

Sincerely,

Pamela Segale
Sr. Director, Regulatory Affairs

Key Information on the Preparation and Use of KyphX HV-R Bone Cement

- Store product below 25°C. Keep the product at a temperature of 23 ± 1°C for a period of 24 hours prior to use.
- The handling characteristics of bone cements are affected by operating room conditions, including the room temperature, temperature of the cement components prior to mixing, humidity, the geometry of the mixing apparatus, time spent mixing, and the geometry of the delivery device. Any change in one or more of these conditions can alter the handling characteristics of the bone cement, including the time it takes for bone cement to reach the doughy state (the handling period), the time the bone cement remains in the doughy state (the working time), and the time the bone cement hardens (the setting time). The user must be aware of these factors and adjust technique to account for variability in operating room conditions.
- DO NOT mix more than one vial of liquid and one packet of powder together at any one time. Never modify the ratios between the liquid and solid components. Doing so could affect bone cement properties, including handling characteristics.
- KyphX HV-R® Bone Cement is provided in finished form with all the necessary components for use. The addition of radiopacifier, e.g. barium; antibiotics; or other drugs or materials to KyphX HV-R® Bone Cement is not recommended. Never add other substances or foreign bodies to the acrylic resin. The safety and effectiveness of adding such drugs or materials has not been evaluated and may cause patient harm.

- Handling Characteristics of KyphX HV-R® Bone Cement at 22°C and 23°C in our Laboratory:

Period	Activity	Approximate Cumulative Time From Initiation of Mixing
Mixing	Mix liquid and powder	0-2 minutes
Handling	Transfer into delivery system	2-8 minutes
Working (doughy state)	Fill cavity in vertebral body	8-16 minutes
Setting	Wait before completing procedure	16-20 minutes

Note: These cumulative time periods will vary depending on temperature and other factors. For example, the colder the environment, the longer the time necessary for the cement to develop the required doughy consistency. Warmer temperatures require more rapid preparation and handling. Ensure the cement's viscosity is high enough (doughy) before delivery begins.

- **Do not insert** the bone cement into the cavity of the vertebral body until the bone cement has reached the **doughy state**.
- Before delivery, dispense a small sample of the bone cement from the delivery device to ensure proper viscosity (doughy state). The bone cement is not ready to deliver until it remains attached to the end of the KYPHON® Bone Filler Device and does not drip, does not stick to surgical gloves and has lost its sheen.