



**Medical Devices Control Division**  
**Ministry of Health Malaysia**  
 Level 5, Plot 3C4,  
 No. 26, Jalan Persiaran Perdana,  
 Precint 3, 62675 Putrajaya  
 Malaysia  
 Tel: 603-8885 0778 / 603-8885 0773  
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**Medical Device / Equipment RECALL**

**Date Issued : 28 JANUARY 2010**

**Ref:MDB/R/2010/001**

<b>IMMEDIATE ACTION</b>	✓
<b>ACTION</b>	
<b>UPDATE</b>	
<b>INFORMATION REQUEST</b>	

*\*The dissemination of this information is based on the Notice Of Recall Letter by Medtronic International Ltd. Malaysia Branch.*

<b>PRODUCT</b>	<b>KYPHX HV-R BONE CEMENT</b>
<b>CLASS</b>	Not Mentioned
<b>USE</b>	Bone Cement
<b>SOURCE OF MEDICAL DEVICE RECALL / ALERT</b>	<b>E-mail communication from Medtronic International Ltd. Malaysia Branch, via their Regulatory Affair Specialist.</b>
<b>RECALLING / ALERTING FIRM</b>	<b>Medtronic International Limited-Malaysia Branch</b>
<b>REASON FOR RECALL/ALERT</b>	<b>- Refer attachment for details-</b>
<b>SCENARIO IN MALAYSIA</b>	<b>Customers have been notified by the responsible representative.</b>
<b>ACTION</b>	<i><b>*any healthcare facilities possessing the abovementioned device are advised to respond to this communication immediately.</b></i>
<b>RECOMMENDATION</b>	<p><b>Users of the abovementioned device <u>should contact the distributors/supplier of this device/product</u> and inform the Medical Devices Control Division, Ministry of Health providing the following information:-</b></p> <p align="center">a. Name of healthcare centre/hospital/clinic</p>

	<p>b. Contact person and contact number  c. Numbers of units available  d. Name of the supplier(s)</p>
<b>CONTACT/ENQUIRIES</b>	<p>Miss Debra Anne Anthony Peter,</p> <p><b>F-39-7 CREST,  3 Two Square,  No. 2, Jalan 19/1,  46300 Petaling Jaya  Selangor Darul Ehsan.</b></p> <p><b>Tel:- 03-79534800  Fax:- 03- 79582202</b></p>
<b>REFERENCES FOR DETAILS</b>	<p><i>Attached together is the Urgent Device Recall Notice and the Key information on the preparation and use of KyphX HV-R Bone Cement.</i></p>

NOTIFICATION BY MEDICAL DEVICE BUREAU 2010