

Rec'd SSD

APR 14 2010

URGENT DEVICE RECALL NOTICE: Action Required

November 9, 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:

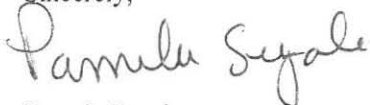
Medtronic Spine LLC has conducted an investigation into complaints received for KyphX HV-R Bone Cement characteristics observed during preparation. The issues reported include an extended time to reach the proper viscosity (doughy state) and inconsistency or lack of homogeneity during cement preparation, 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 at [866 959-7466 or for geography] 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 and completion of the information on Page 3 of this communication. We also ask that you report any associated complaints to our Quality Assurance Group at 1-800-399-9636 (Medtronic Spine complaint line). We apologize for any inconvenience this may cause you. If you have any questions about this notification, please do not hesitate to contact me via email, pamela.n.segale@medtronic.com, or phone at (408) 548-5235. Thank you for your prompt attention to this matter.

Sincerely,



Pamela Segale
Sr. Director, Regulatory Affairs

Lot Numbers of Affected Product
Affected Lots of C01A, KyphX HV-R Bone Cement
and C01B, KyphX HV-R Bone Cement with Kyphon Mixer

C01A, KyphX HV-R Bone Cement				
Catalog Number	Lot Number (EL)		Catalog Number	Lot Number (EL)
C01A	15106		C01A	22908
C01A	15406		C01A	23008
C01A	15706		C01A	23508
C01A	16006		C01A	23608
C01A	16406		C01A	23708
C01A	16506		C01A	24008
C01A	16806		C01A	24108
C01A	17006		C01A	24208
C01A	17307		C01A	24408
C01A	17507		C01A	24508
C01A	17607		C01A	24608
C01A	17707		C01A	25008
C01A	17807		C01A	25108
C01A	18007		C01A	25408
C01A	18307		C01A	25508
C01A	18407		C01A	26409
C01A	18707		C01A	26509
C01A	18907			
C01A	19207			
C01A	19507			
C01A	19807			
C01A	20007			
C01A	20107			
C01A	20307			
C01A	20407			
C01A	20507			
C01A	20607			
C01A	20808			
C01A	20908			
C01A	21008			
C01A	21208			
C01A	21308			
C01A	21608			
C01A	21708			
C01A	21908			
C01A	22008			
C01A	22108			
C01A	22308			

**C01B, KyphX HV-R Bone Cement
with Kyphon Mixer**

C01B	J6092716		C01B	0000802774
C01B	J6100426		C01B	0000802775
C01B	J6101208		C01B	0000819410
C01B	J6101808		C01B	0000825149
C01B	J6103009		C01B	0000828632
C01B	J6110310		C01B	0000828633
C01B	J6110906		C01B	0000828633
C01B	J6112008		C01B	0000828633
C01B	J6112712		C01B	0000841918
C01B	J6120108		C01B	00841918
C01B	J6121203		C01B	0000841918
C01B	J6121902		C01B	0000841918
C01B	J6121903		C01B	0000841919
C01B	J6121904		C01B	0000841919
C01B	J6121905		C01B	0000841919
C01B	J7010201		C01B	0000842869
C01B	J7011907		C01B	0000842871
C01B	J7012506		C01B	0000848666
C01B	J7020624		C01B	0000848670
C01B	J7022202		C01B	0000858673
C01B	J7022702		C01B	0000858673
C01B	J7030605		C01B	0000858673
C01B	J7031401		C01B	0000892106
C01B	J7031506		C01B	0000898859
C01B	J7032702		C01B	0000911555
C01B	J7041301		C01B	0000922990
C01B	J7050101		C01B	0000922990
C01B	J7050405		C01B	0000922990
C01B	J7051107		C01B	0000922990
C01B	J7051801		C01B	0000925894
C01B	J7052511		C01B	0000930458
C01B	J7060205		C01B	00930458
C01B	J7062109		C01B	0000931993
C01B	J7070210		C01B	0000945996
C01B	J7071602		C01B	0000952887
C01B	J7072702		C01B	0000958800
C01B	J7080702		C01B	0000966732
C01B	J7081815		C01B	0000966734
C01B	J7081816		C01B	0000972324
C01B	J7082816		C01B	0000972324
C01B	J7091106		C01B	0000972324
C01B	J7091205		C01B	0000972325
C01B	J7091206		C01B	0000975787
C01B	J7100606		C01B	0000975787
C01B	J7101704		C01B	0000975787
C01B	J7101705		C01B	0000982884

C01B	J7110523		C01B	0000994176
C01B	J7111216		C01B	0000994176
C01B	J7111608		C01B	0000994176
C01B	J7112823		C01B	0001008470
C01B	J7120314		C01B	0001008472
C01B	J7122101		C01B	0001008472
C01B	J8010201		C01B	0001008472
C01B	J8010402		C01B	0001008598
C01B	J8010918		C01B	0001008598
C01B	J8010919		C01B	0001008598
C01B	J8012213		C01B	0001033988
C01B	J8020117		C01B	0001034877
C01B	J8021910		C01B	0001045184
C01B	J8030517		C01B	0001045187
C01B	J8030518		C01B	0001050788
C01B	J8031202		C01B	0001050788
C01B	J8041401		C01B	0001050788
C01B	J8041705		C01B	0001050789
C01B	J8042401		C01B	0001056101
C01B	J8051203		C01B	0001056101
C01B	J8051204		C01B	0001056101
C01B	J8052915		C01B	0001056102
C01B	J8052916		C01B	0001060659
C01B	J8060205		C01B	0001060662
C01B	J8060410		C01B	0001067884
C01B	J8061208		C01B	0001067884
C01B	J8061209		C01B	0001067884
C01B	0001040177		C01B	0001067884
C01B	0000776598		C01B	0001067886
C01B	0000790377		C01B	0001081545
C01B	0000790377		C01B	0001081546
C01B	0000790377		C01B	0001104034
C01B	0000790377			
C01B	0000790380			
C01B	0000794905			
C01B	0000794997			
C01B	0000794998			
C01B	0000794998			
C01B	0000794998			
C01B	0000794999			
C01B	0000795000			

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.

URGENT DEVICE RECALL 2nd NOTICE: Action Required

Rec'd SSD

APR 14 2010

January 14, 2010

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:

As a recipient of this notice, our records indicate that as of January 14, 2010, we have not yet received your written acknowledgement to the Urgent Device Recall Notice that was sent to you on November 9, 2009. Please complete the response form included with this letter and return by fax to (408) 543-6192 so that we can be assured of your understanding of this notification.


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 at [866 959-7466 or for geography] 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 2nd Recall Notice. There is no additional follow-up recommended for patients as a result of this 2nd 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 2nd Notice and completion of the information on the response form included with this communication. We also ask that you report any associated complaints to our Quality Assurance Group at 1-800-339-9636 (Medtronic Spine complaint line). We apologize for any inconvenience this may cause you. If you have any questions about this notification, please do not hesitate to contact me via email at michael.armstrong@medtronic.com, or phone at (408) 548- 5296. Thank you for your prompt attention to this matter.

Sincerely,


Michael Armstrong
Sr. Director, Quality Assurance

APR 14 2010

URGENT DEVICE RECALL NOTICE: Action Required

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)

Hospital Name: Texas Tech Univ Hlth Science

Hospital Address: 3601 - 4th Street Stop 7113

Lubbock, TX 79430

The hospital has inventory of the Affected Product and will return the product to Medtronic Spine.

Reference the RA Number obtained from Customer Service: _____;

OR

The hospital does not have any inventory of the Affected Product

I have read Medtronic Spine LLC's Notice regarding the characteristics observed during preparation of KyphX HV-R Bone Cement. I understand that Medtronic Spine LLC is requesting acknowledgement of this Notice. I understand that Medtronic Spine LLC is requesting a return of any Affected Product that the above listed hospital may have in inventory and that Medtronic Spine LLC will replace the product at no charge to the hospital.

Name (Hospital Representative)

Title

Signature

Date

Please copy for your records and then RETURN the COMPLETED FORM to Medtronic Spine LLC.

Fax: To Medtronic Spine LLC (408) 543-6192

Mail: Medtronic Spine LLC
Attn: Peter Taylor
Recall Coordinator
1221 Crossman Avenue
Sunnyvale, CA 94089

For any questions associated with the issue, please contact Pamela Segale, Sr. Director, Regulatory Affairs, via email, pamela.n.segale@medtronic.com, or phone at (408) 548-5235 or Michael Armstrong, Sr. Director, Quality Assurance, via email, michael.armstrong@medtronic.com, or phone at (408) 548- 5296.