Medtronic Ltd
Building 9
Croxley Park
Hatters Lane
Watford
Herts WD18 8WW
Tel: 01923 212213
Facsimile: 01923 241004

Medtronic

Urgent Field Safety Notice

KYPHON® Directional Bone Filler

Model F04C, All Lot Numbers

Recall

May 2017

Medtronic reference: FA768

Dear Risk Manager,

This letter is to inform you that Medtronic is conducting a recall of KYPHON®Directional Bone Void Filler, Product # F04C. The scope of this action includes all lot numbers.

Medtronic has discovered the directional arrow at the proximal end of the instrument may not correctly align with the cut-out opening on the distal end of the instrument. Using affected bone void filler may result in the injected cement being placed in a direction unintended by the surgeon. Possible risks associated with this misalignment include cement extravasation into the spinal canal with a potential result of paralysis or nerve injury with risk of pulmonary embolism or cardiac arrest. Medtronic has received two reports of this misalignment. To date there have been no associated patient injuries resulting from this issue.

Required actions:

1. Please locate and remove the impacted product from normal storage locations. Do not usethis product.
2. Your Sales Representative will contact you to facilitate the return of any impacted products you may have in your possession

Please disseminate this information to additional personnel within your facility as appropriate and maintain a copy of this notice in your records.

The Competent Authority of your country has been notified of this action.

We sincerely apologise for any inconvenience this action may cause but it is necessary to assure that our high standard of quality is maintained. If you have any questions regarding this communication, please contact your Medtronic Representative directly or via tel no: 01923 212213.

Sincerely,

Keith Taverner. Regulatory Affairs Manager UK &Ireland