Medtronic

Urgent Field Safety Notice

KYPHON® Express Directional Bone Filler

Model F06B, Specific Lot Numbers

Recall

December 2017

Medtronic reference: FA793

Dear Risk Manager,

The purpose of this letter is to inform you that Medtronic is initiating a field corrective action for specific lot numbers of KYPHON® Directional Bone Filler Device, Model Number F06B (see Appendix A).

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. Per the product's Instructions for Use supplied with all KYPHON® Express Directional Bone Filler devices, the following adverse events may occur as a result of incorrect use of this instrument:

- Nerve injury including puncture of the spinal cord or nerve roots potentially resulting in radiculopathy, paresis or paralysis
- Embolism of fat, thrombus or other materials resulting in symptomatic pulmonary embolism or other clinical sequelae
- Hemothorax or pneumothorax
- Deep or superficial wound infection
- Unintended puncture wounds including vascular puncture and dural tear
- Bleeding or hemorrhage
- Hematoma
- Pain

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 at <XXXXX>.

Sincerely,

Medtronic

Appendix A: List of affected Lot Numbers

Product Name	Product Number	Lot Numbers
KYPHON® Express Directional Bone Filler	F06B	WI424428, WI428822, WI435227, WI439940, WI442555, WI446722, WI449819, WI455595, WI459477, WI463434, WI472175, WI472178, WI472176, WI472177, WI474575