

Medtronic

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Urgent Field Safety Notice

Pedicle Access Kit (PAK) Needles

Model 8670009, Lot Number 0521148W

Recall

May 2017

Medtronic reference: FA763

Dear Risk Manager, OR Manager,

The purpose of this letter is to advise you that Medtronic is initiating a voluntary product removal for one lot number of Pedicle Access Kit (PAK) Needles (see above). Medtronic has discovered that the packaging may incorrectly include two bevel-tipped needles or two trocar-tipped needles instead of one trocar-tipped needle and one bevel-tipped needle.

Possible risks of using the incorrect needle include inadvertent pedicle breach resulting in nerve root injury, which may present surgical delay and increased patient exposure time. Also, per the Instructions for Use supplied with all Medtronic Sterile Instruments, the following complications may result due to the misuse of these instruments:

- Nerve damage, paralysis, pain, or damage to soft tissue, visceral organs or joints.
- Pain, discomfort, or abnormal sensations resulting from the presence of the device.
- Nerve damage due to surgical trauma.
- Dural leak in cases of excessive load application.
- Impingement of close vessels, nerves and organs by slippage or misplacement of the instrument.
- Damage due to spontaneous release of clamping devices or spring mechanisms of certain instruments.
- Bony fracture, in cases of deformed spine or weak bone.
- Tissue damage to the patient, physical injury to operating staff and/or increased operating time that may result from the disassembly of multi-component instruments occurring during surgery

Please locate and remove the impacted products from normal storage locations and do not use this product.

Your Medtronic 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,