Medtronic

Field Safety Notice

AsterX™ Expandable Corpectomy System

Product Recall

December 2019

Medtronic reference: FA898

Dear customer,

The purpose of this letter is to inform you that Medtronic is issuing a Field Safety Notice (FSN) for the **AsterX™ Expandable Corpectomy System** (see page 2 for the model numbers) in Switzerland.

Issue Description & Potential Health Hazard(s):
Swissmedic has requested communication of this FSN due to reports of device migration that in some cases led to a revision surgery. The individual cases represent several unique circumstances that do not indicate any systematic issues or correlating factors for product failure but involved factors that are associated to procedural issues determined by user application. Each case resulted in an associated patient severity experience that aligns with known adverse events currently documented per the Instructions for Use. There are no additional known risks with the use of this product. Medtronic is removing all AsterX devices from the Swiss market to prevent the risk of additional events of device migration.

For products that have been implanted, no action is necessary, and patients should continue to be managed in accordance with your standard patient management protocol. If device migration is experienced or any other adverse health consequence with the use of this product, it should be reported to Medtronic.

Actions:

1. Please locate and remove the impacted products from normal storage locations. Do not use these products.
2. Your Medtronic representative will support the return AsterX™ Expandable Corpectomy System products and is available to support evaluation of other Medtronic therapies.

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please maintain a copy of this notice in your records.

We sincerely apologise for any inconvenience this action may cause. If you have any questions regarding this communication, please contact your Medtronic Representative.

Sincerely,

Medtronic (Schweiz) AG

Medtronic

List of affected models:

Kit models:
SPS01729 and SPS01730

Model numbers contained in the kits (all lot numbers are affected):

9421111	9422120
9421112	9422130
9421113	9422140
9421114	9422210
9421115	9422221
9421116	9422222
9421117	9422223
9421200	9422224
9421201	9422230
9421202	9422310
9421220	9422320
9421230	9422330
9421240	9422331
9421250	9422332
9421260	9422333
9421300	9422334
9421400	9422340
9421512	9422350
9421522	9422360
9421532	9423010
9421533	9423020
9421542	9423110
9421543	9423210
9421600	9423220
9422010	9423230
9422020	9423310
9422030	9423320
9422110	9423330