

# **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<sup>TM</sup> 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   9422140     9421114   942221     9421115   942222     9421117   942223     9421200   942224     9421201   9422230     9421202   9422310     9421203   9422330     9421220   9422330     9421230   9422331     9421230   9422331     9421240   9422332     9421250   9422333     9421300   9422334     9421300   9422340     9421512   9422350     9421522   9422360     9421532   942300     9421533   9423020     9421542   9423110     9421543   9423210     9421543   9423210     9421543   9423230     9421540   9423230     9421532   942300     9421533   9423210     9421543   9423230     9421543   9423230     9422000   9423230     9422010   9423320     942202	<u>Model nu</u> m	bers contai
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9421114     9422210       9421115     9422221       9421117     9422223       9421200     9422224       9421201     9422230       9421202     9422310       9421220     9422320       9421230     9422330       9421230     9422330       9421230     9422331       9421240     9422332       9421300     9422333       9421300     9422334       942152     9422350       9421512     9422350       9421522     942360       9421532     9423010       9421533     9423020       9421542     9423110       9421543     9423210       9421543     9423220       9422010     9423230       9422020     9423310       9422030     9423320	9421112	9422130
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