Medtronic

Medtronic International, Ltd. (Singapore Branch)
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Urgent: Medical Device Recall
1882900 DRILL MINI-TREPHINATION 2.0mm

2 April 2019

Attention: Risk management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

Dear Customer/Risk Manager:

The purpose of this letter is to advise you that Medtronic is voluntarily recalling the listed Mini-Trephination 2.0mm Drill model 1882900.

Issue Description:

The Frontal Sinus 2.00mm Mini-Trephine Drill is an interchangeable drill bit intended for use with the Xomed XPS System and Drill Guide with Skin Protector. The 2.0mm reusable drill is packaged singly and provided sterile for first time convenience. The Frontal Sinus MiniTrephination Drill is indicated for use in incising or removing bone and tissues in ear, nose, and throat, including sinus and rhinology surgery.

The issue is that the drill may not cut properly. The hazardous situation that may occur if the Mini-Trephination Drill does not function properly is that the procedure being performed may be delayed, causing extended exposure to anesthesia for the patient.

Product Scope:

CFN	GTIN	Lot Number
1882900	00681490047241	0215115425
1882900	00681490047241	0215115426
1882900	00681490047241	0215142888
1882900	00681490047241	0216403765
1882900	00681490047241	0216439625

Requested Actions

1. Please quarantine and discontinue use of the affected item codes and lots listed.

2. Please complete the attached Customer Confirmation Form in its entirety and revert back to your local Medtronic Representative.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations.

Please communicate this important information within your facility and or other facilities as required. We request that you contact Medtronic if you experienced any other quality problems or adverse events.

If you have any questions or concerns regarding this Field Action, please do not hesitate to contact your local Medtronic representative.

We appreciate your attention to this matter and apologize for any inconvenience this issue may have caused. We are committed to patient safety and appreciate your prompt attention to this matter.

Sincerely,

Diana Teo
QRA Manager

South East Asia
Medtronic

Enclosure: Customer Confirmation Form

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Customer Confirmation Form

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ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Physician / HCP :	**Name:**
	Contact:
Address:	**Email:**
Phone no:	
E-mail:	

Indicate in the columns below all serial numbers you have in your facility.

Product Number	Lot Number or Serial number	Qty Shipped (units)	Qty On-hand (units)	Should the unit be transferred to another facility, please list address if any

Product disposition Instructions:

Please check as appropriate:

____ The above devices could not be located in our facility (enter zero in "Qty On-hand" box above).

____ The devices have been confirmed as used or destroyed (enter zero in "Qty On-hand" box above).

_____ I have the above Qty On-hand and will scrap the Qty On-hand in my facility

By signing this form, I confirm that I have received and understand attached information: **Urgent: Medical Device Recall 1882900 Drill Mini-Trephination 2.0mm,** dated on 2 April 2019.

Name: _____ (print) Signature: _____ Stamp: _____ Date:_____