Medtronic

60 Middletown Avenue
North Haven, CT 06473
USA
www.medtronic.com

MEDICAL DEVICE CORRECTION
Covidien superDimension™ Navigation System Labeling Error

May XX, 2018

Dear Valued Customer:

The purpose of this letter is to advise you that Medtronic China is voluntarily conducting a field correction in relation to three (3) superDimension navigation systems due to incorrect labels on the outer carton and on the device. These incorrect labels are the result of a labeling error that occurred at our distribution center. There are no device performance issues related to this correction. Accordingly, there are no patient safety implications related to this action.

This voluntary recall affects only the item code and serial numbers listed below:

Item Code	Description	Affected Serial Numbers		
AAS00161-02	superDimension™ Navigation System	504236	504352	504370

Medtronic China has the corrected labels available for the affected devices. A Medtronic representative will come to your facility to apply the correct label to your device.

Actions you should take:

1. Please complete form even if you have no inventory of the affected serial numbers listed above.
2. Please contact Customer Service at XXX_XXX-XXXX to schedule an appointment with a Medtronic Representative to come to your facility to apply the correct product label.

This action is being taken with the knowledge of regulatory authorities. We request that you contact your Medtronic China representative if you have any questions related to this action.

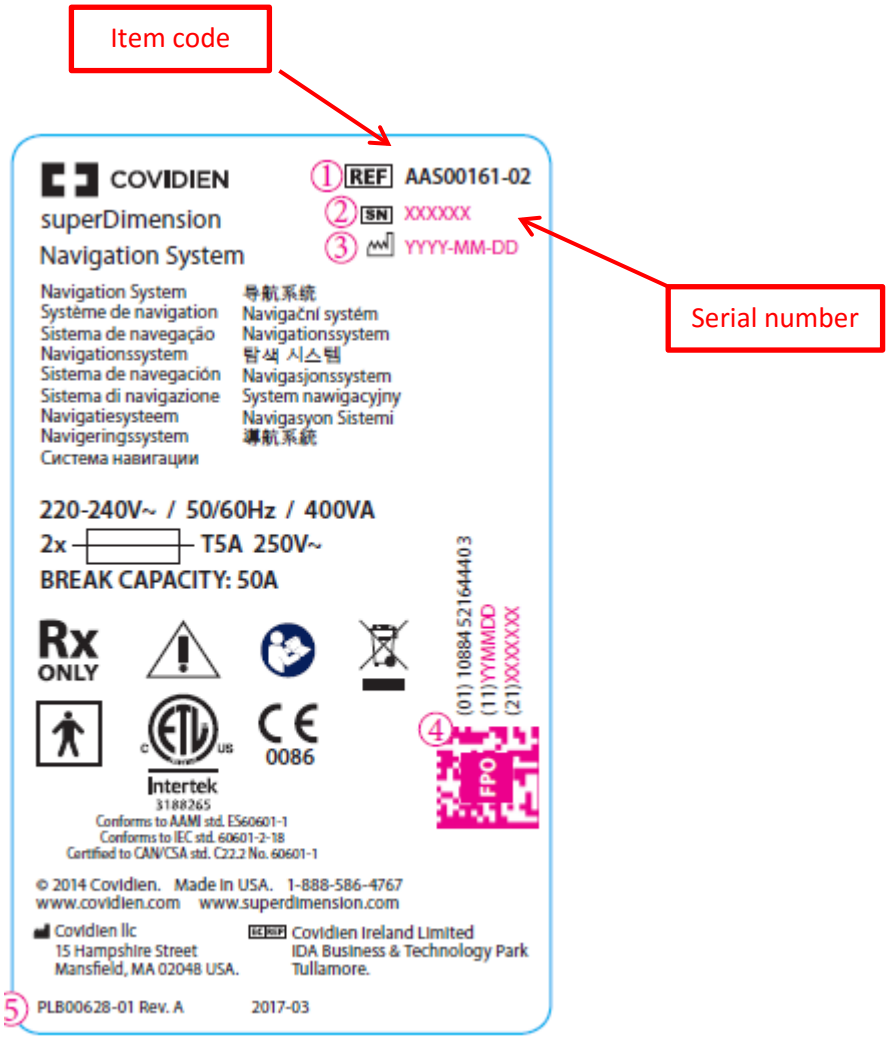
We apologize for this inconvenience. If you have any questions regarding this communication, please contact your Medtronic representative or Customer Service at XXX-XXX-XXXX, option 2.

Sincerely,

Joyce Wang
Vice President, QA/RA, Greater China
China Chief Operating Officer Quality

Medtronic

Attachment A



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FIELD CORRECTION ACKNOWLEDGEMENT FORM

Covidien superDimension™ navigation system

Customers must complete the form even if you do not have inventory.

Date:

Name of Person Completing this Form: Title:

Direct Phone #: Email:

How did the account purchase this product? (Please complete **ONLY** A or B)

Direct from Medtronic (Complete A): **From a Distributor (Complete B):**

A. Direct Customers:

Account Name:

Primary Account #:

Account Address:

City:

State: Zip Code:

B. From a Distributor:

Distributor:

Customer Information:

Customer Name:

Address:

City:

Stat Zip:

No Inventory (Please check):

Item Code	Serial Number	Qty	Case or Each

I acknowledge receipt of the superDimension™ navigation system field correction notification dated May XX, 2018, and understand the recall instructions provided.

Signature

PLEASE EMAIL OR FAX THIS ACKNOWLEDGEMENT TO:

Product purchased directly from Medtronic: China email or fax to (XXX) XXX-XXXX.
Product purchased through distributor: China email or fax it to (XXX) XXX-XXXX.