

Medtronic

Medtronic International, Ltd. (Singapore Branch)

(Co.Reg.No. S98FC5604C)

50 Pasir Panjang Road

#04-51

Mapletree Business City

Singapore 117384

Tel: 165.6870.5300

Fax: 65.6482.0300

www.medtronic.com

URGENT: MEDICAL DEVICE RECALL

Retrieval of the Ascenda™ Intrathecal Catheters Manufactured on or before 09-May-2024

Models 8780, 8781, and 8784

06 March 2025 | 16:30 SGT

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Customer/Distributor:

In May 2024, Medtronic notified you of a design update to the Model 8780, 8781, and 8784 Ascenda™ Intrathecal catheters (Ascenda catheter). The intent of the design update is to reduce the potential for tissue growth into the Ascenda catheter connector which may potentially lead to catheter occlusion. As of 10-May-2024, all Ascenda catheters are manufactured with the updated design. At this time, Medtronic has sufficient inventory of the Ascenda catheters with the updated design and is voluntarily recalling the prior configuration.

With this communication, there is no new information regarding the safety or performance of the catheter. No action is required for catheters that have been implanted. Medtronic is not recommending prophylactic replacement of the current Ascenda catheter design due to the low observed occurrence rate (0.06%) of occlusion and the risks associated with replacement surgery. In general, Medtronic recommends re-emphasizing to patients and caregivers the signs and symptoms of withdrawal or the return of underlying conditions to evaluate for potential catheter issues.

Actions

Please review all inventory of Ascenda Catheter(s) and take the following actions:

- Identify the Ascenda catheter product manufactured on or before 09-MAY-2024 that does not have the updated design. The following provides an example of the symbols used to identify the Manufacturing date on the outer packaging of the Model 8780, 8781, and 8784 Ascenda kits:



Date of manufacture on or before 2024-05-09

- Return affected product per the return instructions in the enclosed Customer Confirmation Form.
- Complete and return the Customer Confirmation Form to your local Medtronic field representative, even if you do not have any affected product.
- This notice should 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.

Additional Information

Medtronic is communicating this information to the appropriate regulatory agencies.

Adverse events or quality problems experienced with this product should be reported to Medtronic through your local Medtronic field representative.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact your local Medtronic field representative.

Sincerely,

Signed by:



 Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 06 March 2025 | 16:30 SGT
90D0724C9B1C402A99B286449A1644B8

Quality and Regulatory Affairs Director

Southeast Asia

Enclosure:

Customer Confirmation Form

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Customer Confirmation Form

Urgent Medical Device Recall

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Models 8780, 8781, and 8784

For completion by Medtronic Customers Only - Please complete all fields below and return all pages immediately even if you do not have any product to return.

Customer Contact Details		Medtronic Contact Details	
Distributor/Hospital/Clinic/Patient name:		Name:	
		Contact:	
Address:		Email:	
Phone no:	Email:		

If you have no affected stock to be returned, please tick the appropriate box, and sign off the form.

Do you have remaining inventory of the affected units? (Please select only ONE):

no, **NONE** of the affected inventory to be returned. I have examined our inventory for product/s covered by this and confirm that all affected was/were previously consumed.

YES, affected inventory to be returned. I have examined our inventory and have the affected product/s listed in the following table that remain/s unconsumed and is to be returned.

Model/Product Number	Lot/Serial Number	Quantity to be returned (in units)

By signing this form, I confirm that I have read the Urgent Medical Device Recall Notification Letter, dated 06 March 2025 | 16:30 SGT from Medtronic regarding the retrieval of the Ascenda Catheter Models 8780, 8781, and 8784 manufactured on or before 09-May-2024 and have taken appropriate action.

In the event you no longer implant and/or manage patients with Ascenda Catheters please provide a detailed explanation in the space below so that Medtronic's records can be updated accordingly. Thank you!

Please complete all fields and sign the form as indicated below and hand or scan then email back to your local Medtronic representative.

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

