Medtronic

Urgent Field Safety Notice

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

Models 8780, 8781, and 8784

March 2025

Medtronic Reference: FA1321

<For use in countries that follow EU MDR: EU Manufacturer Single Registration Number (SRN): 000019977>

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.

Product Names	Manufacturer's Product Number/Catalog Number	GTIN
Ascenda Catheter, 45" length	8780	00643169793972 00643169793989 00643169794009 00643169793996 00643169794016 00643169999633 00643169999657

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		00643169999640 00763000077150 00763000125998 00763000126001 00763000126018 00763000421045 00763000421052 00763000421069 00763000862510 00763000051112 00643169202122 00643169783027
Ascenda Catheter, 55" length	8781	00643169370586 00643169794061 00643169794023 00643169794047 00643169794030 00643169794054 00643169999664 00643169999671 00643169999688 00763000077174 00763000126032 00763000126025 00763000126049 00643169061132 00763000421076 00763000421083 00763000421090 00763000862558 00763000051129 00643169202139 00643169359154
Ascenda Catheter, Pump Segment Revision Kit	8784	00643169794122 00643169794139 00643169794146 00643169999725 00643169999732 00763000077211 00643169999749 00763000126087 00763000126094 00763000126100 00763000421137

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		00763000421144 00763000051143 00643169202153 00643169359178

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 unused, affected product in your inventory to Medtronic. Your Medtronic representative can assist you in the return of affected product as necessary.
- 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 has notified the Competent Authority of your country of this action.

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 Medtronic Representative.

Sincerely,

Enclosures:

- May 2024 Medical Device Correction Notification