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URGENT FIELD SAFETY NOTICE

Design update to the Ascenda™ Intrathecal Catheter

Models 8780, 8781, and 8784

Notification

May 2024

Medtronic Reference: FA1321

EU Manufacturer Single Registration Number (SRN): US-MF-000019977

Dear Health Care Professional,

The purpose of this letter is to inform you that Medtronic has received regulatory approval for a design update to the Model 8780, 8781, and 8784 Ascenda™ Intrathecal catheters (Ascenda catheter). The Ascenda catheter models are part of the Medtronic SynchroMed™ infusion system that stores and delivers parenteral drugs to the intrathecal space. The implanted infusion system components consist of a SynchroMed pump and an 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.

Issue Description

The Ascenda catheter design update focuses on improvement of the catheter connector seal quality to reduce the probability of tissue growth into the connector that attaches to the SynchroMed pump.

Medtronic is not recommending prophylactic replacement of the current Ascenda catheter design due to the low observed occurrence rate (0.06%) and the risks associated with replacement

surgery. Instead, Medtronic recommends re-emphasizing to patients and caregivers the signs and symptoms of withdrawal or return of underlying conditions.

From August 2016 through February 2024, Medtronic has received 72 complaints related to unexpected substance (tissue) in the catheter connector. Of these 72 complaints, 55 complaints presented as a return of symptoms (i.e., loss of therapy, withdrawal), and during surgical intervention to address these symptoms, the presence of tissue in the catheter connector was detected. One of these patients developed baclofen withdrawal syndrome which necessitated intensive care treatment. Additionally, in 15 complaints, patients were asymptomatic, however, the presence of tissue in the catheter connector was detected incidentally during planned surgical intervention (e.g., elective replacement/end of service). For the remaining 2 complaints, one noted tissue during a complete system explant and one found tissue through returned product analysis. In both of these cases, no return of symptoms was reported.

The presence of tissue in the catheter connector may result in a prolonged surgical procedure due to extended troubleshooting (i.e., cleaning and re-attaching the connector or replacing the pump connector). If the presence of tissue in the catheter connector causes an obstruction, it may lead to return of symptoms, loss of therapy and/or life-threatening baclofen withdrawal.

Clinician and Patient Recommendations

As noted in the Ascenda labeling, prior to implant, proper alignment, and full engagement of the Ascenda catheter connector to the catheter port on the pump is critical in ensuring the catheter is properly and completely connected to the pump (refer to Figure 1). When connecting the Ascenda catheter connector to the pump, keep the connector in line with the catheter port and do not angle the connector. If connected at an angle, the Ascenda connector could detach after surgery, or an occlusion could occur at the connection site. Be sure to firmly secure all connections.

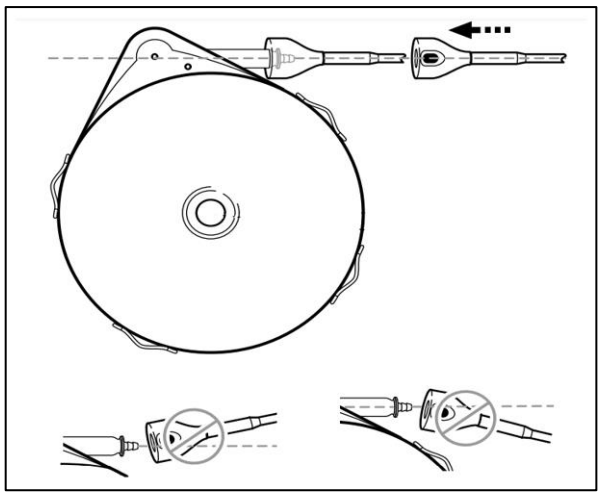

Figure 1: Picture of Ascenda catheter connecting to the pump

After implant, there are no clinician or patient recommendations to prevent this issue from occurring. Tissue growth into the catheter develops slowly, and physicians and patients are unable to differentiate return of symptoms due to tissue growth from other sources of catheter occlusion issues (e.g., kinks). Therefore, this issue is not detectable until encountered in a surgical procedure (i.e., elective replacement/end of service). Should an occlusion be suspected, surgical intervention may be warranted at which time the tissue growth into the connector could be detected as a possible cause.

Actions

Starting in May 2024, the Ascenda catheters will be manufactured with the design update. To ensure patients have access to uninterrupted therapy, the Ascenda catheters manufactured prior to this update will remain available. Once there is sufficient inventory of the updated Ascenda catheters, Medtronic will notify customers and retrieve any unused Ascenda catheters that were manufactured prior to the design update.

The following customer actions are requested:

- Complete the enclosed Customer Acknowledgement Form acknowledging that you have received this information.
- Share this notice with all those who need to be aware of this design update within or outside your organization or to any organization where the potentially affected product has been transferred or distributed and 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 questions related to this issue, please contact your local Medtronic representative at 01 511 1400.

Sincerely,

Bethany Moxon

Associate Regulatory Affairs Specialist UKI

Enclosure:
Customer Acknowledgement Form

Medtronic

FA1321 Customer Acknowledgement Form - Response is required.

Design Update Ascenda™ Intrathecal Catheter

Please complete this Form in its entirety.

Date: _____

Name of Person Completing this Form: _____

Title:_____

Direct Phone #:_____

Email:_____

Account Name:_____

Account Number:_____

Account Address:_____

City: _____Zip Code:_____

Country:_____

I have read and understand the instructions provided and acknowledge receipt of the **notification** regarding the use of the **Ascenda™ Intrathecal Catheter** by signing below. I also agree to further distribute and communicate this important information within my facility and to anyone whom I have further distributed **Ascenda™ Intrathecal Catheter** as required.

_____ _____ _____

Name: (print) Signature: Date:

If you have any questions regarding this notification, please contact your Medtronic sales representative.

PLEASE EMAIL THIS ACKNOWLEDGEMENT TO:

rs.regulatoryuk-ire@medtronic.com

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