



Urgent Field Safety Notice

Ascenda™ Intrathecal Catheters / Revision Kit Specific Serial numbers of Models 8780, 8781, and 8784 Device Removal

July 2014

Medtronic reference: FA629

Dear Customer,

Medtronic is conducting a voluntary removal of specific serial numbers of the Ascenda™ Intrathecal Catheters and Ascenda™ Revision Kits. Ascenda™ catheters are used with the implantable Medtronic SynchroMed® drug infusion pump. This voluntary removal is being conducted due to a single component of the catheter, the retainer ring. Medtronic has not received any complaints due to this issue and is investigating the possibility of unintentional disconnection of the catheter from the pump, or difficulty in disconnecting the catheter from the pump during a revision procedure. Medtronic is conducting this removal to minimize potential patient risk as we work with our component supplier to conclude our investigation.

Your action is only required for Ascenda™ catheter model numbers and serial numbers identified in this removal notice which are listed below and in Attachment 1:

Model #	Product Description
8780	Ascenda™ Intrathecal Catheter with an 86 cm spinal segment
8781	Ascenda™ Intrathecal Catheter with a 66 cm spinal segment
8784	Ascenda™ Intrathecal Catheter pump segment revision kit with a sutureless pump connector

Action Required for Healthcare Professional:

Our records indicate that your facility has received affected product and you are identified as an implanting or managing physician who has potentially implanted 1 or more affected catheters. Patient management recommendations are provided below:

- At this time we are not recommending the removal of catheters from patients. Medtronic has not completed all the testing to accurately characterize potential failure modes and / or potential frequencies of failures, if any. One potential failure mode is the possibility of unintentional disconnections of the catheter from the pump. We will provide updates as the investigation progresses.
- Medtronic recommends that patients implanted with affected catheters identified in this recall be monitored for symptoms associated with drug withdrawal.

Medtronic will provide additional information regarding the potential for impact to product performance as it becomes available.

Action Required for Risk/Inventory Manager:

Attached is a list of affected Ascenda™ product serial numbers.

- Immediately identify and quarantine all affected unused inventory.
- Return all affected product in your inventory to Medtronic. Your Medtronic representative will visit you to assist with this process and will also be able to assist with ordering replacement product as they become available.



Additional Information:

Medtronic has notified the Competent Authority of your country of this action. Please share this notification with others in your organization as appropriate or with any organization where the potentially affected devices have been transferred.

We appreciate your assistance with this matter and apologize for the disruption and inconvenience. Our field team is prepared to help with the removal process and we will strive to facilitate an efficient process. If you have questions, please contact your sales representative at Gulf Medical Tel Gulf Medical +966 2 651 2828 x-304

Sincerely,

Ayman Doughan
NeuroModulation Business Manager
Middle East and North Africa

Country/BU manager

Enclosed:

List of affected serial numbers

ATTACHMENT 1

Ascenda™ Intrathecal Catheters Specific Serial Numbers of Models 8780, 8781, and 8784 Affected Product Serial Number List Distributed in May 2014 - July 2014

0208400011	0208422585	0208422700	0208423311	0208448076	0208452115	0208453913	0208477579
0208404256	0208422586	0208422701	0208430409	0208448077	0208452432	0208453914	0208477580
0208408588	0208422587	0208422702	0208430410	0208448078	0208452436	0208453916	0208477585
0208408589	0208422588	0208422703	0208430411	0208448079	0208453197	0208453917	0208477586
0208408590	0208422589	0208422704	0208430412	0208448343	0208453198	0208453918	0208479311
0208408591	0208422590	0208422705	0208430413	0208448344	0208453199	0208453919	0208479318
0208408592	0208422591	0208422706	0208438523	0208448347	0208453580	0208453920	0208482807
0208408593	0208422592	0208422707	0208438524	0208448360	0208453581	0208456065	0208482808
0208408594	0208422593	0208422708	0208438530	0208448361	0208453600	0208456066	0208483028
0208408595	0208422594	0208422713	0208438532	0208448370	0208453601	0208457223	0208489023
0208408598	0208422595	0208422714	0208438594	0208448371	0208453602	0208457240	0208490257
0208409021	0208422596	0208422715	0208439140	0208448372	0208453603	0208457241	0208493199
0208409022	0208422597	0208422718	0208439141	0208448373	0208453605	0208457242	0208493200
0208409023	0208422598	0208422719	0208439142	0208448374	0208453606	0208460808	0208493233
0208409024	0208422599	0208422780	0208439143	0208448375	0208453607	0208461923	0208493234
0208409031	0208422600	0208422781	0208439144	0208448376	0208453608	0208461924	0208493415
0208409033	0208422602	0208422782	0208439146	0208448379	0208453612	0208461948	0208493484
0208409034	0208422603	0208422783	0208439147	0208448422	0208453615	0208463831	0208501349
0208409035	0208422604	0208422784	0208439148	0208448423	0208453620	0208466272	0208506987
0208409036	0208422605	0208422793	0208439149	0208448424	0208453621	0208466273	0208506988
0208409039	0208422620	0208422794	0208439150	0208448425	0208453622	0208466982	
0208409041	0208422621	0208422795	0208439151	0208448426	0208453900	0208469564	
0208409042	0208422622	0208422799	0208439157	0208448427	0208453901	0208474584	
0208421471	0208422625	0208422800	0208439164	0208448435	0208453904	0208474585	
0208421802	0208422626	0208422801	0208439165	0208448436	0208453905	0208474586	
0208422192	0208422627	0208422802	0208439174	0208448439	0208453906	0208474822	
0208422553	0208422628	0208422803	0208439178	0208448460	0208453907	0208474827	
0208422564	0208422629	0208422804	0208439179	0208448461	0208453908	0208477573	
0208422580	0208422630	0208422805	0208439200	0208448462	0208453909	0208477574	
0208422582	0208422632	0208422807	0208448073	0208448463	0208453910	0208477576	
0208422583	0208422638	0208422808	0208448074	0208448464	0208453911	0208477577	
0208422584	0208422639	0208422809	0208448075	0208452114	0208453912	0208477578	