Medtronic
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USA
www.medtronic.com

Urgent Medical Device Recall
Medtronic Affinity Fusion® Oxygenator

BB811	BB8L58R3	HY1F66R18
BB841	BB8N94R4	HY7G33R8
BB5Z97R14	BB9B43R2	HY9D36R1
BB8A57R11	BB9G59R5	HY9L88R2
BB8C33R6	BB9L72R1	SSHY9M26R

November 2016

Dear Risk Manager or Healthcare Professional:

Medtronic is initiating a voluntary product recall for specific lot numbers of the above listed Affinity Fusion® Oxygenators with Balance®[1] Biosurface. (See Appendix A for affected lot numbers and additional instructions to identify if your product is impacted.) These are distributed as standalone devices, or as a combination unit with the Affinity Fusion Cardiotomy/Venous Reservoir, or as part of tubing packs. Medtronic has identified an out–of-specification condition exhibiting additional plastic (flash) in the arterial sampling port adjacent to the arterial outlet port of the oxygenator. Our testing has been unable to conclusively determine the absence of increased patient risk associated with the flash, therefore we are recalling the specific lots referenced in Appendix A.

This issue was identified during manufacturing. Through 08-Nov-2016, Medtronic has received no complaints or reports of patient injury or adverse events related to this issue.

Our records indicate that one or more listed oxygenators were distributed to your facility. As a result, Medtronic requests that you take the following actions:

1. Ensure all unused affected product in your inventory has been properly quarantined.
2. Return all affected product in your inventory to Medtronic. Contact Medtronic Customer Service at 800-848-9300 to initiate a product return and credit. Your local Medtronic Representative can assist you in the return and replacement of this product as necessary.
3. Complete the enclosed Customer Confirmation Certificate and fax it to Medtronic at 651-367-0612 to the attention of Customer Focused Quality or scan and email to RS.CFQFCA@medtronic.com.

For affected product that has been used, no action is necessary, and patients should continue to be managed in accordance with your standard patient management protocol.

Medtronic will replace this inventory as it is available to meet your needs, and has taken necessary action to prevent future occurrences. All applicable regulatory agencies have been notified of this issue, as required.

[1] Balance technology licensed under agreement from Biointeractions, Limited, United Kingdom.

Please share this notification with others in your organization as appropriate, and contact your Medtronic Representative with any questions related to this Urgent Medical Device Recall. If you require assistance in contacting your representative, please contact Medtronic's National Answering Service at 800-633-8766. We appreciate your cooperation and apologize for the inconvenience this may cause you; please be assured that patient safety and product quality remain our primary concern.

Sincerely,

Christopher D. Harrold
Vice President, Quality
Medtronic Coronary & Structural Heart

Appendix A

Affected Lot Numbers*

Model / Catalog No.	Lot #	Model / Catalog No.	Lot #
BB5Z97R14	211885289	**BB841**	13182978
BB811	13186543		13182979
BB8A57R11	211885327		13183344
BB8C33R6	212073805		13183378
BB8L58R3	211991198		13183553
BB8N94R4	211846421		13183609
BB9B43R2	211892942		13183727
BB9G59R5	211991385		13183944
BB9L72R1	212020797		13183963
HY1F66R18	211807907		13184174
HY7G33R8	212046220		13184206
HY9D36R1	211985748		13184587
HY9L88R2	212034498		13184871
SSHY9M26R	211914227		13184872
BB841	13182438		13184873
	13182603		13184952
	13182626		13185297
	13182721		13185542
	13182733		13185788
	13182822		13185992
	13182950		13186127
	13182977		

***Please note**: these lot numbers are only visible on the outer label located on the shipping box. If you have already opened this box, and removed the inner tray, please take the following steps:

- Note the serial number listed on the inner tray label (it will be a 10 digit number beginning with 811).
- Go to www.Medtronic.com > *Healthcare Professionals* > *Products* > *Product Performance & Advisories* > *Affinity Fusion Oxygenator* (http://www.medtronic.com/us-en/healthcare-professionals/products/product-performance.html and then click on Affinity Fusion Oxygenator)
- Input your serial number as found on the inner tray label
- If your serial number is shown to be **not** impacted, no further action is necessary.
- If your serial number is impacted, pay attention to the lot number that it is associated with (an 8 digit number beginning with 1318). That lot number will be required to initiate a return and credit.