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Medtronic

Urgent Field Safety Notice

Affinity Fusion™ Oxygenator with Integrated Arterial Filter and CVR

Specific lot Numbers of Model BB841

Recall

November 2016

Medtronic reference: FA746

Dear Health Care Professional, Risk Manager,

Medtronic is initiating a voluntary product recall for specific lot numbers of the 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 devices are distributed as a combination unit with the Affinity Fusion Cardiotomy/Venous Reservoir. 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. Medtronic testing has not conclusively ruled out a potential impact of the flash, therefore we are recalling the specific lots referenced in Appendix A.

This issue was identified during manufacturing. Through 8 November 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. Your Medtronic Representative can assist you in the return and replacement of this product as necessary.

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.

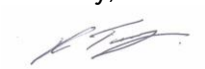
[1] Balance technology licensed under agreement from Biointeractions, Limited, United Kingdom.

The Competent Authority of your country has been notified of this action.

Please share this notification with others in your organisation as appropriate and contact your Medtronic Representative Directly or via 01923 212213 with any questions related to this Urgent Field Safety Notice.

We appreciate your cooperation and apologise for the inconvenience this may cause you; please be assured that patient safety and product quality remain our primary concern.

Sincerely,



Keith Taverner
Regulatory Affairs Manager UK & Ireland

Appendix 1: List of affected Lot Numbers*:

Lot number					
13182438	13182822	13183344	13183944	13184871	13185542
13182603	13182950	13183378	13183963	13184872	13185788
13182626	13182977	13183553	13184174	13184873	13185992
13182721	13182978	13183609	13184206	13184952	13186127
13182733	13182979	13183727	13184587	13185297	

***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 is associated with it (an 8 digit number beginning with 1318). That lot number will be required to initiate a return and credit.