Medtronic

Urgent Field Safety Notice

Affinity Fusion™ Oxygenator Temperature Monitoring Adapter

Notification

February 2023

Medtronic Reference: FA1302

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

Dear Healthcare Professional,

The purpose of this letter is to inform you that Medtronic recently identified an upward trend of complaints related to the Temperature Monitoring Adapter (TMA) located on the Affinity Fusion Oxygenator.

Issue Description:

The complaints indicate that the TMA (see Image 1 for the TMA location) had come loose from the oxygenator either during pre-procedure perfusion set-up or post-procedure when disassembling the perfusion circuit.

Image 1 – TMA location on the Affinity Fusion Oxygenator

Since 02 August 2021, there have been 83 complaints globally of TMA separation from the oxygenator, with 70 reported from 07 November 2022 to 26 January 2023. The investigation to date indicates reduced connection strength for TMA connections made in the past 17 months, resulting in detachment prior to or

after the procedure. In all instances, the TMA separation only occurred pre- or post-procedure, and there were no adverse patient impacts reported. To date, no TMA events have been reported during a procedure.

The potential harms related to the TMA detaching during use are: infection (contamination due to handling of TMA), neurological dysfunction (reversible), neurological dysfunction (irreversible), hypovolemia, and exsanguination. Medtronic is providing device use recommendations (below) to minimize TMA loosening or detachment. Medtronic is finalizing the root cause investigation and will take appropriate actions as warranted.

Device Use Recommendations:

Regarding use of the Affinity Fusion Oxygenator, please take either of the following actions:

- Option 1: Continue to use the Affinity Fusion Oxygenator without using the TMA – use other conventional perfusion circuit temperature monitoring methods; or
- Option 2: Continue to use the Affinity Fusion Oxygenator and the TMA for arterial temperature monitoring. Ensure there is minimal torque applied to the oxygenator TMA when attaching or detaching the Temperature Probe (Product Number ATP210). Also, minimize manipulation of the TMA-probe connection during the clinical procedure.

Important Note: Although Medtronic has not received any reports of the TMA separating from the oxygenator during a clinical procedure, this risk exists if the TMA is manipulated during procedure.

If the TMA comes detached before the procedure setup or priming, discard the product. If the TMA comes detached during the procedure and an oxygenator replacement is decided, follow the Instructions for Use (IFU), Emergency Oxygenator Replacement section. If the TMA comes detached after the procedure completion, no additional action is required.

Product Scope:

Product Number	Product Description	GTINs (UDI-DI)	Device Identification
BB811	Oxygenator with Balance Biosurface	00643169178168, 00643169178175	All Fusion Oxygenator Serial Numbers between 8111483548 and 8113999999 (Refer to Attachment A) Tubing Packs – Locate the oxygenator SN inside the tubing pack.
BB841	Oxygenator and Cardiotomy/ Venous Reservoir with Balance Biosurface	00643169354869, 00643169354883	
CB811	Oxygenator with Cortiva BioActive Surface	00763000225476, 00763000225483	
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	00763000225452, 00763000225469	
Perfusion Tubing Packs	Any of the 4 Product Numbers listed above in this table may be contained inside a Tubing Pack. The tubing packs will have unique GTINs.		

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Customer Actions:

Medtronic records indicate that your facility has received at least one of the impacted serial numbers. As a result, Medtronic requests that you take the following actions:

- Complete the enclosed Customer Confirmation Form please return the form to rs.ranordic@medtronic.com
- This notice must be passed on to all who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Patients previously supported with the Affinity Fusion Oxygenators face no additional risk from the issue described in this communication and should continue to be monitored by your practice's normal follow-up procedures.

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,

Local / BU Manager

Enclosures:

- Attachment A: Identifying Affected Product

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Attachment A: Identifying Affected Product

Affinity Fusion™ Oxygenator

Product Number	Product Description	GTINs (UDI-DI)	Device Identification
BB811	Oxygenator with Balance Biosurface	00643169178168, 00643169178175	All Fusion Oxygenator Serial Numbers between 8111483548 and 8113999999 (See Image 2 below) Tubing Packs – Locate the oxygenator SN inside the tubing pack
BB841	Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface	00643169354869, 00643169354883	
CB811	Oxygenator with Cortiva BioActive Surface	00763000225476, 00763000225483	
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	00763000225452, 00763000225469	
Perfusion Tubing Packs	Any of the 4 Product Numbers listed above in this table may be contained inside a Tubing Pack. The Tubing Packs will have unique GTINs.		

At time of set up, locate the serial number on the affected product by referring to the image below.

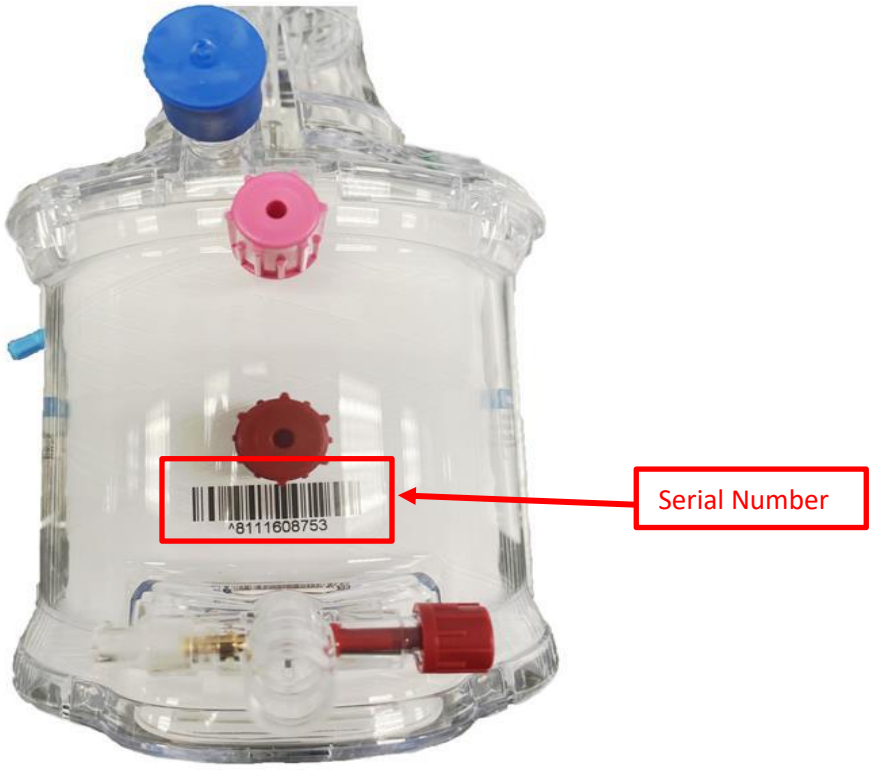

Image 2 – SN location on the Affinity Fusion Oxygenator