2023 Circuit Disruption

Permission to print:	Yes
Category	Circuit disruption
Incident type	Good Catch No Harm Incident
Duration of incident:	hours
Description:	While performing an emergency bypass for a failed percutaneous MVR (This was an emergency and the patient was unstable), a Medtronic Affinity Fusion Oxygenator CB8111 leaked from the arterial temperature port (TMA) at the rate of one drop every 5 sec. This is a known problem with the current production of oxygenators (the TGA have made us aware of this problem) but normally only a problem either before the bypass run or after during disassembling the pump. At no time was the Temp probe put under torsion. Discussed changing out the oxygenator with team, however patient was found to be too unstable. It was deemed safer to continue and manage the patient's needs first. The leak was manageable, whilst the patient was warm and hemodynamically extremely unstable. Total blood loss from oxygenator during case approx 500 mls.
GOOD CATCH - what went well	Spare oxygenator was on hand for change out and sterile bone wax was ready to be applied to leak if it worsened
What could we do better	Although pre-bypass check was completed and the port inspected, I question if I missed the crystalloid leak. I question if somehow it was knocked as we had to urgently move equipment and personnel to a non-cardiac theatre.
Preventive actions	Have an Emergency Theatre on standby for the next Percutaneous MVR. Carefully inspect the oxygenator port before each pump run
Type of incident:	Equipment
Hospital incident filed:	Yes
Ext Authority Advised	Yes
Discussed with team:	Yes
Patient outcome variance f	Mild
Commentary	The Therapeutics Goods Authority and Medsafe NZ have issued safety alerts to Medtronic Fusion users regarding the Temperature Monitoring Adaptor- see attached. This is the first instance of a leak during CPB. With the potential for oxygenator changeout (“The investigation to date indicates reduced connection strength for TMA connections made in the past 17 months, resulting in detachment….” – Product Defect Alert) the consideration of a PRONTO line in the circuit for uninterrupted flow changeout (not available in this case - personal communication PIRS ed) is again strongly recommended. PIRS has received a relative recent report of a similar leak from the temperature port of the LivaNova Inspire oxygenator and while the cause of the problem may not be common to these devices, avoidance of excessive torque applied to temperature adaptors in any oxygenator is advised. PIRS ed.

Medtronic

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February 2023

URGENT – PRODUCT DEFECT ALERT

Affinity Fusion™ Oxygenator
Temperature Monitoring Adapter
TGA Reference: RC-2022-RN-01547-1

Product number	Product description	ARTG
BB811	Oxygenator with Balance Biosurface	182789
BB841	Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface	182790
CB811	Oxygenator with Cortiva BioActive Surface	223064
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	221965
Perfusion Tubing Packs	Any of the 4 Product Numbers listed above in this table may be contained inside a Tubing Pack.	NA

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, with 1 in Australia, 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 finalising the root cause investigation and will take appropriate actions as warranted.

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Product Scope:

Product Number	Product Description	Device Identification
BB811	Oxygenator with Balance Biosurface	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	
CB811	Oxygenator with Cortiva BioActive Surface	
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	
Perfusion Tubing Packs	Any of the 4 Product Numbers listed above in this table may be contained inside a Tubing Pack.	

Customer Action Required:

Medtronic records indicate that your facility has received at least one of the impacted serial numbers. The impacted devices will be replaced upon availability of the non-impacted devices. Medtronic is in the process to design new devices and anticipate the availability of unaffected devices by end of 2023. In the interim, Medtronic requests that you take the following actions:

- Continue to use 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 minimise manipulation of the TMA probe connection during the clinical procedure.

- Complete the enclosed Customer Confirmation Form, acknowledging that you have received this information, and email to rs.anzrecalls@medtronic.com.

- This notice must be passed on to all who need to be aware within your organisation or to any organisation 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.

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 a procedure.

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

Additional Information:

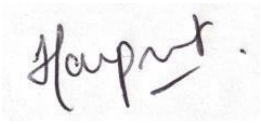
Medtronic is initiating this action in consultation with the Therapeutic Goods Administration.
The impacted devices will be replaced upon availability of the non-impacted devices.

Local contact details:

We are committed to patient safety and welcome any questions you may have regarding this communication. Please do not hesitate to contact your local Medtronic Sales Representative or contact Meredith Wank, ANZ Cardiac Surgery Business Manager on +61417065227 or email meredith.c.wank@medtronic.com.

We appreciate your cooperation and apologise for the inconvenience that this issue may cause.

Sincerely,



Harpreet Kaur
Pronouns: She/Her
Post-Market Vigilance Supervisor | Quality and Regulatory Affairs

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Enclosures:

- Customer Confirmation Form
- Attachment A: Identifying Affected Product

Medtronic

Attachment A: Identifying Affected Product
Affinity Fusion™ Oxygenator

Product Number	Product Description	Device Identification
BB811	Oxygenator with Balance Biosurface	All Fusion Oxygenator Serial Numbers between 8111483548 and 8113999999 (See Image 2 below)
BB841	Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface	
CB811	Oxygenator with Cortiva BioActive Surface	
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	
Perfusion Tubing Packs	Any of the 4 Product Numbers listed above in this table may be contained inside a Tubing Pack.	Tubing Packs – Locate the oxygenator SN inside the tubing pack.

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

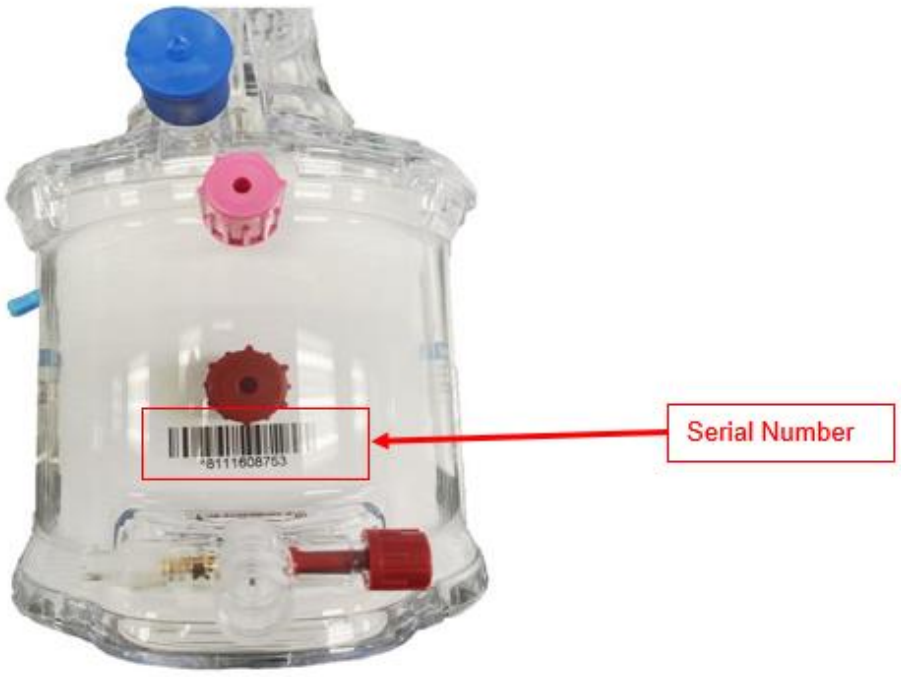

Image 2 – SN location on the Affinity Fusion Oxygenator

Medtronic

URGENT – PRODUCT DEFECT ALERT

Acknowledgement Form

TGA Reference: **RC-2022-RN-01547-1**

Product number	Product description	ARTG
BB811	Oxygenator with Balance Biosurface	182789
BB841	Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface	182790
CB811	Oxygenator with Cortiva BioActive Surface	223064
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	221965
Perfusion Tubing Packs	Any of the 4 Product Numbers listed above in this table may be contained inside a Tubing Pack.	NA

To assist us in this corrective action, please complete and sign this Acknowledgement Form.

By signing this acknowledgement form, I confirm that I have read and understood the URGENT - PRODUCT DEFECT ALEERT Notification regarding Affinity Fusion™ Oxygenator Temperature Monitoring Adaptor dated February 2023.

Please complete the form and email to rs.anzrecalls@medtronic.com to the attention of Recalls.

Hospital/Facility:_____

Hospital/Facility Address:_____

Customer Name:_____

Customer Title: _____

Customer Signature: _____

Date:_____

Telephone: _____

For questions, contact Meredith Wank on +61417065227 or email meredith.c.wank@medtronic.com.

Medtronic

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February 2023

URGENT - SAFETY ALERT

Affinity Fusion™ Oxygenator
Temperature Monitoring Adapter

Medsafe Reference# 30383

Product number	Product description	WAND
BB841	Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface	100618-WAND-6950VG
CB811	Oxygenator with Cortiva BioActive Surface	071009-WAND-77T9X4
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	071009-WAND-77T9XM
Perfusion Tubing Packs	Any of the 3 Product Numbers listed above in this table may be contained inside a Tubing Pack.	NA

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, with zero in New Zealand, 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 finalising 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, minimise 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 Instruction For Use, Emergency Oxygenator Replacement section. If the TMA comes detached after the procedure completion, no additional action is required.

Product Scope:

Product Number	Product Description	Device Identification
BB841	Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface	All Fusion Oxygenator Serial Numbers between 8111483548 and 8113999999 (Refer to Attachment A) Tubing Packs – Locate the oxygenator SN inside the tubing pack.
CB811	Oxygenator with Cortiva BioActive Surface	
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	
Perfusion Tubing Packs	Any of the 3 Product Numbers listed above in this table may be contained inside a Tubing Pack.	

Customer Action Required:

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, acknowledging that you have received this information, and email to rs.anzrecalls@medtronic.com.
- This notice must be passed on to all who need to be aware within your organisation or to any organisation 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 is initiating this action in consultation with Medsafe.

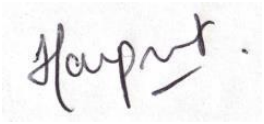
Medtronic

Local contact details:

We are committed to patient safety and welcome any questions you may have regarding this communication. Please do not hesitate to contact your local Medtronic Sales Representative or contact Lesley Beatrice Palmer on +6421339910 or +6499674660 or email lesley.palmer@medtronic.com.

We appreciate your cooperation and apologise for the inconvenience that this issue may cause.

Sincerely,



Harpreet Kaur
Pronouns: She/Her
Post-Market Vigilance Supervisor | Quality and Regulatory Affairs

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harpreet.kaur3@medtronic.com

Enclosures:

- Customer Confirmation Form
- Attachment A: Identifying Affected Product

Medtronic

Attachment A: Identifying Affected Product

Affinity Fusion™ Oxygenator

Product Number	Product Description	Device Identification
BB841	Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface	All Fusion Oxygenator Serial Numbers between 8111483548 and 8113999999 (See Image 2 below) Tubing Packs – Locate the oxygenator SN inside the tubing pack.
CB811	Oxygenator with Cortiva BioActive Surface	
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	
Perfusion Tubing Packs	Any of the 3 Product Numbers listed above in this table may be contained inside a Tubing Pack.	

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

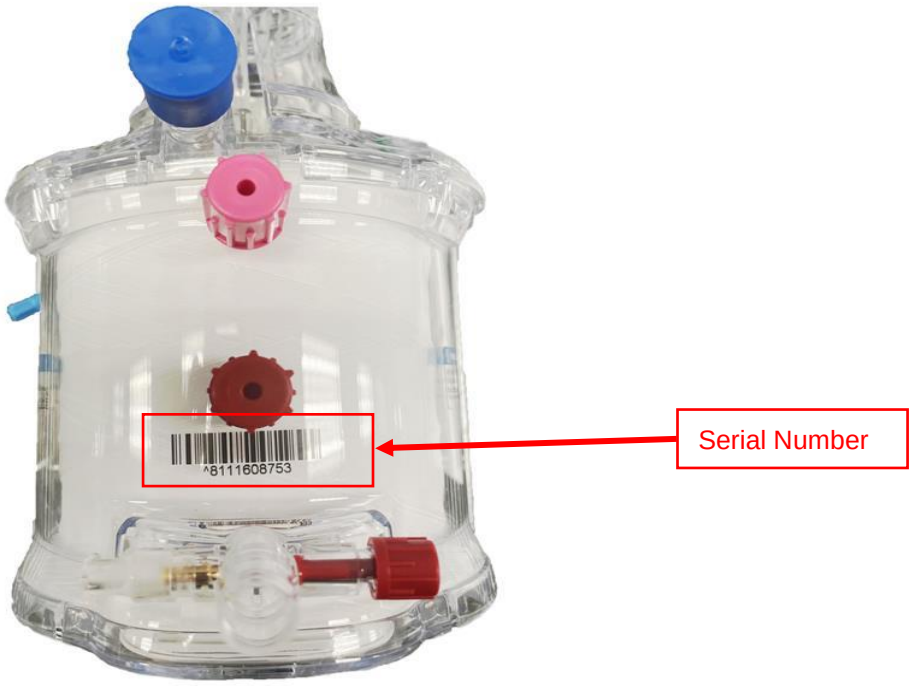

Image 2 – SN location on the Affinity Fusion Oxygenator

Medtronic

URGENT – SAFETY ALERT

Affinity Fusion™ Oxygenator

Temperature Monitoring Adapter

Medsafe Reference# 30383

Product number	Product description	WAND
BB841	Oxygenator and Cardiotomy/Venous Reservoir with Balance Biosurface	100618-WAND-6950VG
CB811	Oxygenator with Cortiva BioActive Surface	071009-WAND-77T9X4
CB841	Oxygenator with Cortiva BioActive Surface and Cardiotomy/Venous Reservoir with Balance Biosurface	071009-WAND-77T9XM
Perfusion Tubing Packs	Any of the 3 Product Numbers listed above in this table may be contained inside a Tubing Pack.	NA

To assist us in this corrective action, please complete and sign this Acknowledgement Form.

By signing this acknowledgement form, I confirm that I have read and understood the URGENT - SAFETY ALERT Notification regarding Affinity Fusion™ Oxygenator Temperature Monitoring Adaptor dated February 2023.
Please complete the form and email to rs.anzrecalls@medtronic.com to the attention of Recalls.

Hospital/Facility:_____

Hospital/Facility Address:_____

Customer Name:_____

Customer Title: _____

Customer Signature: _____

Date:_____

Telephone: _____

For questions, contact Lesley Beatrice Palmer on +6421339910 or +6499674660 or email lesley.palmer@medtronic.com.