COOK MEDICAL EUROPE LTD.
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FSN Ref: QCR-2023-09/2023FA0011 FSCA Ref: QCR-2023-09/2023FA0011

24 January 2024

Updated
Urgent Field Safety Notice
MINC+ Benchtop Incubator

For Attention of: Chief Executive Officer, Director of IVF Unit and Purchasing Officers/Stores Manager

Contact details of local representative (name, e-mail, telephone, address etc.)
Cook Medical Europe Ltd. O'Halloran Road National Technology Park Limerick, Ireland E-mail: European.FieldAction@CookMedical.com Phone: Please refer to the attached Country Contact List. For any further information or support concerning the information within this FSN please contact your local Cook Medical Sales Representative or Cook Medical Europe Ltd.

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Updated
Urgent Field Safety Notice (FSN)
MINC+ Benchtop Incubator
Risk addressed by FSN

1. **Information on Affected Devices**	
1.	1. Device Type(s)
	The MINC+ Benchtop Incubator is intended to store and preserve gametes and/or embryos close to body temperature. The MINC+ uses a sterile, disposable humidification flask (K-MINC-2000-HF) for each incubation chamber. The MINC+ Benchtop Incubator is supplied non-sterile but comes with two sterile K-MINC-2000-HF humidification flasks.
1.	2. Commercial name(s)
	MINC+ Benchtop Incubator
1.	3. Primary clinical purpose of device(s)
	The MINC+ Benchtop Incubator is intended to store and preserve gametes and/or embryos close to body temperature. The MINC+ Benchtop Incubator is intended to be used by clinical embryologists within an IVF laboratory.
1.	4. Device Model/Catalogue/part number(s)
	RPN: K-MINC-2000 GPN: G44429
1.	5. Affected serial or lot number range
	List of affected lot numbers

2 **Reason for Field Safety Corrective Action (FSCA)**	
2.	1. Description of the product problem
	In November/December 2023, it was communicated that the MINC+ device is susceptible to losing temperature control if electrostatic discharge (static electricity) is applied to the lid of the device. Update 24 January 2024: During further testing on the MINC+ device, it was also identified that the MINC+ is susceptible to losing temperature control when exposed to high levels of radiofrequency emissions in the range of 710-930MHz, which includes mobile phones/wireless IT platforms.
2.	2. Hazard giving rise to the FSCA
	If there is a drop or increase in device temperature, it may then lead to a hazardous situation which is an unsuitable environment for culturing embryos. The hazardous situation may lead to embryo degeneration necessitating an additional medical procedure for the patient.

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2.	3. Probability of problem arising
	The HRA for electrostatic discharge concludes that in a worse case, there is a high probability (≥2.50% - ≤10%) of minor harm if the temperature of the K-MINC+ drops due to device malfunction as a result of exposure to electrostatic discharge. The HRA for radiofrequency emissions concludes that there is a remote probability (≥0.05% - <2.50%) that the use of the MINC+ device will cause a negligible adverse health consequence as a result of interference from radiofrequency emitting devices.
2.	4. Predicted risk to patient/users
	There have been three related complaints, but no harm was reported. The device produces audible and visual alerts to indicate a malfunction and the drop/increase in temperature was evident to the user. The device has only shown susceptibility to direct contact discharge on the lid (i.e., from a staff member touching the metallic surface of the lid), or use of radiofrequency emitting devices in the vicinity of the MINC+ device. Therefore, these issues are only likely to occur when staff are present in the IVF laboratory. The probability of a hazardous situation leading to harm relies on several cascading factors including: 1) Static applied to the lid of the device or mobile phones/wireless IT platforms are used near the MINC+ device. 2) The user must be unaware of the temperature drop or increase (unaware of the audible/visual alarms) 3) The user is unable to transfer the embryos to another incubator when there is a temperature drop or increase.

	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Other You can continue to use your MINC+ device, but William A. Cook Australia advises you to be vigilant and monitor for device alerts. If the device produces audible and visual alerts to indicate an error with temperature, immediately move any dishes to another incubator. If no other incubators are available, the device can be reset to normal operation by switching off mains power to the device for ten seconds then turning the power back on, ensuring there are no other radiofrequency emitting devices used in the vicinity of the MINC+ device. The risk of applying electrostatic discharge to the device can be reduced by: • Limiting physical contact with the stainless-steel magnet plate on top of the device • Touching an earthed component such as the incubator's braided gas hose prior to operating the device. The risk of interference from radiofrequency emitting devices can be reduced by: • Ensuring no mobile phones or wireless IT platforms are used near the MINC+ device.	
3.	**2. By when should the action be completed?**	Immediately

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3.	**3. Is customer Reply Required?** (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ On-site device modification/inspection An authorised service agent will contact you or you may reach out to capitalservice@cookmedical.com to arrange for your device to be corrected at your facility. The service agent will be updating the software/firmware of the device. The updated software/firmware will be available from 15 April 2024 (please note the change in correction of devices to 15 April 2024 from the previously communicated date of 01 February 2024, due to the additional test failure and updated software/firmware is not currently available).	

	4. General Information	
4.	1. FSN Type	Update
4.	2. Further advice or information already expected in follow-up FSN?	No
4.	3. Manufacturer information (For contact details of local representative refer to page 1 of this FSN)	
	a. Company Name	William A Cook Australia Pty Ltd
	b. Address	95 Brandl Street Brisbane Technology Park Eight Mile Plains QLD 4113 Australia
	c. Website address	www.cookmedical.com.au
4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	List of affected lot numbers Country Contact List
4.	6. Name/Signature	Nicole Burke Manager, Quality Engineering William A Cook Australia

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	Transmission of this Field Safety Notice
	This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate) Please transfer this notice to other organisations on which this action has an impact. (As appropriate) Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action. Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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Updated
Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	2023FA0011
FSN Date	24 January 2024
Product/ Device name	MINC+ Benchtop Incubator
Product Code(s)	RPN: K-MINC-2000 / GPN: G44429
Batch/Serial Number (s)	As per attached list.

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Department/Unit	
Shipping address if different to above	
Contact Name	
Title or Function	
Telephone number	
Email	

3. Customer action undertaken on behalf of Healthcare Organisation		
☐	I confirm receipt of the Field Safety Notice and that I read and understood its content.	
☐	The information and required actions have been brought to the attention of all relevant users and executed.	
Print Name		
Signature		
Date		

4. Return acknowledgement to sender	
Email	European.FieldAction@CookMedical.com
Customer Helpline	Please refer to the attached Country Contacts List
Fax	+ 353 61 239294
Deadline for returning the customer reply form	Please return this form within 5 business days of receipt.

It is important that your organisation takes the actions detailed in the FSN and confirms that you have received the FSN.

Your organisation's reply is the evidence we need to monitor the progress of the corrective actions.