COOK SOUTH EAST ASIA PTE. LTD.
238A THOMSON ROAD, #12-08 NOVENA SQUARE
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CO. REGN: 198602196G
WWW.COOKMEDICAL.COM

06th March 2018

URGENT: PRODUCT DEFECT CORRECTION
COOK K-MAR-5200

Device Registration No. (Singapore): DE0002557

Attention: Director of IVF Unit

Product owner and manufacturer, William A. Cook Australia Pty Ltd is issuing a Product Defect Correction Notice for the products listed below. Our records indicate that you may have received the affected product K-MAR-5200 Vacuum Pump:

Product Name	Reference Part Number	Global Product Number	Lot Numbers
Cook Vacuum Pump ™	K-MAR-5200	G49275	All lots
	K-MAR-5200-US	G51067	All lots

During a recent design review of the K-MAR-5200 Vacuum Pump, William A. Cook Australia Pty Ltd identified that the internal mains wiring does not fully comply with the requirements of the medical electrical equipment standard IEC60601-1 Edition 3.0.

IEC60601-1 states that conductors and connectors of medical electrical equipment shall be secured or insulated so that accidental detachment shall not result in a hazardous situation. The K-MAR-5200 mains wiring is secured, but the mechanism is not considered suitable under IEC60601-1.

The potential hazardous situations which could arise due to K-MAR-5200 mains wiring detaching from the terminals include;

- Failure of the device to operate.
- Electric shock or burn to the user.

There have been no reports of harm associated to this fault since the release of the device. There has been one occurrence of a device failing to operate, which resulted in a minor inconvenience to the user. No harm was reported in this instance.

Cook Medical is initiating a product defect correction to replace the mains wiring components in all devices in the field. This will ensure that the devices fully comply with the requirements of IEC60601-1 Edition 3.0. Any new devices will have the correct mains wiring installed.

Cook Medical will be replacing the mains wiring for each unit either at your premises or as a back to base repair. An authorised service agent will contact you to arrange for impacted devices to be corrected.

Cook Medical recommends whilst waiting for the device correction that a residual current device (RCD), also known as a ground fault circuit interrupter (GFCI), ground fault interrupter (GFI), or an appliance leakage current interrupter (ALCI) is fitted to the mains electricity supply to mitigate the risk of a hazardous situation.

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Action to be Taken:

1. Please complete the Acknowledgement and Receipt Form within **5 business days** and return it via email to **SNG-RegulatoryAffairs@CookMedical.com**. If you no longer have affected product in your inventory, complete the Acknowledgement and Receipt Form and return it via email to **SNG-RegulatoryAffairs@CookMedical.com**.

2. Your authorised service agent will contact you to arrange for your device to be corrected.

3. Report adverse events to;

   Cook South East Asia, Regulatory Affairs Department
   Yu Hosokai Tel:+65 6812 7486
   Jennifer Chin Tel:+65 6812 7461
   Email: SNG-RegulatoryAffairs@CookMedical.com
   Tel (main): +65 6812 7400
   Fax (main): +65 6812 7401

Transmission of This Notice:

Please pass this notice on to the appropriate personnel, including down to the user level, within your organisation or to any organisation where the potentially affected devices have been transferred.

Please retain this letter in a prominent position for one month should there be any product in transit.

Thank you for your immediate attention to this matter. We recognise this disrupts your normal operations and for this, we sincerely apologise. Should you have any questions or concerns, please contact your local field representative at Cook Medical for more information.

Sincerely

[redacted]

Yu Hosokai
Regulatory Affairs Manager - SEA
Cook South East Asia Pte Ltd

CC: Chairman of Medical Board and Relevant Head of Departments

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IMPORTANT: PLEASE RETURN THIS FORM

Acknowledgement of Receipt

I hereby acknowledge the receipt of the **URGENT: PRODUCT DEFECT CORRECTION COOK K-MAR-5200** dated 06 March 2018.

(please select one and fill in the blank if applicable)

☐ I have _____ units at my premises.

☐ I no longer have affected products in my inventory.

Signature _____ Date _____

Name:

Designation:

Organization: