COOK®

Cook Medical Europe
O'Halloran Road,
National Technological Park,
Limerick, Ireland.
Phone: + 353 61 334440

Fax: + 353 61 334441

Urgent Field Safety Notice

Commercial name of the affected product: Cook Vacuum Pump™

Manufacturer : William A. Cook Australia Pty Ltd

Cook Reference : 2018FA0006 / QCR-82

Type of Action: Field Safety Corrective Action

Date: 08 March 2018

Attention: Chief Executive Officer of IVF Unit / Risk Management / Purchasing / Director of Nursing

Details on affected devices:

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

Description of the Problem:

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.

Field Action:

- Cook Medical is initiating a Field Safety Corrective Action 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.

Advise on action to be taken by the user:

1. Please complete the enclosed Customer Response Form within 5 business days to acknowledge receipt of this Field Safety Notice Letter.
2. Send the completed Customer Response Form via email to European.FieldAction@CookMedical.com or alternatively by fax to Cook Medical marked for the attention of European Customer Quality Assurance (fax number +353 61 334441).
3. Your authorised service agent will contact you to arrange for your device to be corrected.
4. Please report any adverse events to Cook Medical by contacting our Customer Support Department or your local COOK representative.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Contact reference person:

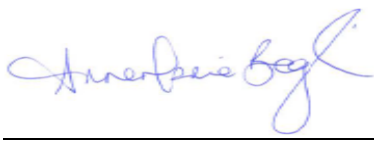
Michael Galvin
Regulatory Affairs Manager
COOK Ireland
O'Halloran Road, National Technology Park, Limerick, IRELAND

Or

Annemarie Beglin
Quality Systems Manager
COOK Medical Europe
O'Halloran Road, National Technology Park, Limerick, IRELAND

Should you have any questions, please feel free to contact us for more information (e-mail: European.FieldAction@CookMedical.com, phone +353 61 334440).

We confirm that this notice has been notified to the appropriate Regulatory Agency.



Annemarie Beglin
Quality Systems Manager