



COOK ASIA (MALAYSIA) SDN. BHD.
CO. REG. NO. 199001015417
UNIT 1602, LEVEL 16, UPTOWN 1,
NO. 1, JALAN SS21/58, DAMANSARA UTAMA,
47400 PETALING JAYA, SELANGOR, MALAYSIA
PHONE: +603 7669 3889, FAX: +603 7669 3898
WWW.COOKMEDICAL.COM

Date: 05-May-2022
Manufacturer Field Action Reference Number: FAR-2022-012

URGENT: MEDICAL DEVICE RECALL

Hilal Embolization Microcoil **Nester® Embolization Microcoil** **Tornado® Embolization Microcoil**

For Attention of: Chief Executive / Risk Management / Purchasing
Our records indicate that you have received affected products.

Patient safety and customer satisfaction are Cook Medical's highest priorities. We appreciate your time and attention in reading this important notice.

Contact details of Local Authorised Representative

Cook Asia (Malaysia) Sdn Bhd
Unit 1602, Level 16, Uptown 1
No. 1 Jalan SS21/58 Damansara Utama
47400 Petaling Jaya, Selangor
Malaysia.
E-mail: RA-Malaysia@CookMedical.com
Phone: +60 3 7669 3889
Fax: +60 3 7669 3898

For any further information or support concerning the information within this Field Safety Notice, please contact your local Cook Medical Sales Representative or Regulatory Affairs department, Cook Asia (Malaysia) Sdn Bhd.



Manufacturer Field Action Reference Number: FAR-2022-012

URGENT: MEDICAL DEVICE RECALL

Hilal Embolization Microcoil **Nester® Embolization Microcoil** **Tornado® Embolization Microcoil**

Purpose of this Letter

The purpose of this letter is to inform you that Cook Medical is voluntarily recalling specific lots of Hilal Embolization Microcoils, Nester® Embolization Microcoils, and Tornado® Embolization Microcoils.

Reason for Voluntary Recall

Cook Medical identified during manufacturing an unintended small stainless-steel cannula may be contained in the loading cartridge of these devices. This loading cartridge is manufactured by an external supplier.

Product Information

See Attachment 1 for a complete list of affected products.

Market Impact

This recall is strictly specific to lots listed in Attachment 1. These devices will continue to be accessible on the market for purchase based on availability.

Risk to Health

Potential adverse events that may occur if an affected product is used include difficult advancement and/or removal of the device leading to increased procedural time, future imaging complications (from magnetic resonance imaging if foreign cannula is unnoticed), and/or entrance of the foreign body (small stainless-steel cannula) into the patient, potentially being life-threatening.

To date, Cook Medical has not received customer complaints related to the adverse patient effects listed above for the affected lots. However, please be advised that the presence

Action To Be Taken by the Customer

1. Examine inventory immediately to determine if you have affected product(s) and quarantine any affected product that remains unused. Immediately cease all further distribution and use of the affected products.
2. Return the affected product(s) to Cook Medical with a copy of the Acknowledgement and Receipt Form to receive a product credit. Refer to the Acknowledgement and Receipt Form for return instructions.
3. Please complete the Acknowledgement and Receipt Form within **5 business** days of receiving this letter regardless of whether you have affected product(s) on hand. You may return the Form via fax (+60 3 7669 3898) or email (RA-Malaysia@CookMedical.com).
4. This notice must be shared with appropriate personnel, including down to the user level, within your organization or with any organization where the potentially affected devices have been transferred.
5. Please immediately report adverse events to Cook Asia (Malaysia) Sdn Bhd by phone at +60 3 7669 3889, Monday through Friday between 8:30am and 5:00pm or by email to:
6. RA-Malaysia@CookMedical.com.
7. Physicians should practice their standard patient monitoring following the procedure for an early identification of any complications to mitigate their severity.



COOK ASIA (MALAYSIA) SDN. BHD.
CO. REG. NO. 199001015417
UNIT 1602, LEVEL 16, UPTOWN 1,
NO. 1, JALAN SS21/58, DAMANSARA UTAMA,
47400 PETALING JAYA, SELANGOR, MALAYSIA
PHONE: +603 7669 3889, FAX: +603 7669 3898
WWW.COOKMEDICAL.COM

Action being Taken by Cook Medical

Cook Medical is removing potentially affected products from the market. Additionally, a supplier investigation has been opened to determine the appropriate corrective action(s) to prevent reoccurrence of a similar issue.

We recognize that this situation is a potential disruption to your normal operations, and we sincerely apologize. Thank you for your immediate assistance in this matter. If you have any questions or concerns, please contact Cook Asia (Malaysia) Sdn Bhd at +60 3 7669 3889.

Sincerely,

A handwritten signature in black ink that reads "Claire".

Claire Chong
Regulatory Affairs Specialist
Cook Asia (Malaysia) Sdn Bhd