COOK SOUTH EAST ASIA PTE. LTD.
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Urgent Field Safety Notice

Commercial name of the affected product: Inferior Vena Cava (IVC) Filter
Manufacturer : William Cook Europe
Cook Reference Number: 2019FA0001
Type of action: Field Safety Corrective Action (FSCA) – IFU update

Date: 26 February 2019

Attention: Health Care Provider / Chief Executive / Risk Management / Purchasing

Details on affected devices:

Product Brand Name	Catalogue Identifier
Günther Tulip® Vena Cava Filter Set Cook Celect® Vena Cava Filter Set Cook Celect® Platinum Vena Cava Filter Set	IGTCFS-65-1/2-FEM/JUG/UNI-TULIP/CELECT/CELECT-PT (See attached list)

You may have received the following affected devices which were manufactured between 1 January 2016 and 22 February 2019 (Expiry Date: Between 1 January 2019 and 22 February 2022):

- Cook Celect® Platinum Vena Cava Filter Set for Jugular Vein Approach (IGTCFS-65-2-JUG-CELECT-PT, G34310)
- Cook Celect® Platinum Vena Cava Filter Set for Femoral and Jugular Vein Approach (IGTCFS-65-2-UNI-CELECT-PT, G34504)

Description of the problem:
Cook Medical is sending you this communication to inform you about a global implementation of updated Cook Inferior Vena Cava (IVC) Filter product labeling from 25 February 2019.

The labeling updates are being made to ensure physicians are appropriately informed so to make the best decisions regarding patient care and are not related to feedback questioning device safety or performance. The updates are based on the most updated information available from post-market surveillance, data published in international standards and regulatory communications, and updated clinical data pertinent to the products. The added information is not reflective of a change in risk profile of the devices but is in line with common product safety knowledge.

The changes impact the device labels and the following sections of the IFUs: Device Description, Intended Use, Contraindications, Warnings, Precautions, MRI Safety Information, Potential Adverse Events, Clinical Studies, step-by-step Instructions for Use, and References. Updates are made to the patient card to reflect changes in the MRI Safety Information section of the IFUs. The table below highlights the changes in the IFUs.

The Instructions for Use (IFU) for each Cook IVC filter continues to highlight the importance of individual risk-benefit patient evaluation by Healthcare Professionals. Likewise, the IFUs continue to emphasize the importance of routine follow-up and IVC Filter retrieval when clinically indicated.

Based on the changes introduced to the Cook IVC Filter IFUs, as well as in accordance with recent regulatory communications, it is recommended that Healthcare Professionals are informed about the

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modifications to the product labeling, the potential risks associated with the devices, and the continued need for focus on routine follow-up and IVC Filter retrieval when clinically indicated.

Consequently, this Field Safety Notice is provided to reinforce the recommendations provided in the Cook IVC Filter IFUs. There is no change in the clinical procedure for IVC filter placement. However, the updates introduced to the Precautions, Potential Adverse Events and References sections are considered clinically relevant and important to the communications between Healthcare Professionals and patients.

Advise on action to be taken by the user:

1. No retrospective action for previously implanted products is warranted; however, compliance with current routine follow-up guidance is recommended.
2. Please read and understand the new IFUs provided for the abovementioned two devices to ensure full comprehension of the product's intended use.
3. The new IFUs and patient implant card for the abovementioned two devices in hardcopies are attached for your reference. If IFU of other devices listed in the Attachment (Global List) is required, please contact Cook Medical Sales Representative
4. Your Cook Medical Sales Representative will personally follow-up and provide corrected IFUs for your inventory.
5. Please complete the attached Customer Response Form within 5 business days of receiving this Field Safety Notice and return it to Cook Medical as directed on the form.

Summary of clinically relevant updates to the IFU by section

Device- Updated Section	**Description of update**
Cook Inferior Vena Cava Filters (Günther Tulip Vena Cava Filter Sets and Cook Celect/Celect Platinum Vena Cava Filter Sets) **– Precautions Section Updates**	The Precautions section is updated to include general precautions based on post-market surveillance (i.e., customer feedback, reports in the scientific literature, complaint history, etc.). New information on potential retrieval device; Cook CloverSnare® Vascular Retriever, is included. The safety and performance is confirmed by required product testing.
Cook Inferior Vena Cava Filters (Günther Tulip Vena Cava Filter Sets and Cook Celect/Celect Platinum Vena Cava Filter Sets) ***– Potential Adverse Events Section Updates***	The list of Potential Adverse Events is extended, based largely on the list in Section B.1 provided in ISO 25539-3:2011 "Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters", physician guidelines and post-market surveillance.
Cook Celect/Celect Platinum Vena Cava Filter Sets ***– Clinical Studies Section Updates***	The clinical study summary in the Clinical Studies section of the IFU is updated to include the final study data from the prospective, single-arm, multicenter, international study of the Cook Celect Vena Cava Filter. The IFU previously included a summary of interim results from the clinical study.
Cook Inferior Vena Cava Filters (Günther Tulip Vena Cava Filter Sets and Cook Celect/Celect Platinum Vena Cava Filter Sets) ***– References Section Updates***	The References section of the IFUs are updated to include references to relevant practice guidelines, standards, regulatory communications, and publications describing alternative retrieval techniques. A systematic literature search was performed to generate a list of citations describing alternative

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	retrieval techniques. These references are provided for reference only; moreover, it is communicated throughout the IFUs that the safety and effectiveness of these alternative retrieval techniques has not been established and that use of these techniques varies according to physician experience, patient anatomy, and filter position. While no specific safety or performance data related to the Cook IVC Filter Sets can be concluded from this published literature, these references are added to inform physician users, so they are equipped to make the best informed decisions regarding patient care.

Transmission of this Field Safety Notice:
Please share this notice with others in your organization who either use this device or follow patients treated with the device. If you need any further information or support concerning this notice, please contact your local Cook Medical Sales Representative.

Please kindly complete the acknowledgement of receipt attached and return to Cook Medical Sales Representative or the Regulatory Affairs Department. There will be another letter, a Dear Health Care Professional Letter (DHCPL) issued in consultation with Health Sciences Authority (HSA) shortly as well.

Reporting of Adverse Event:
Healthcare professionals are advised to report any adverse events and/or suspected adverse reactions associated with these devices to;

COOK South East Asia, Regulatory Affairs Department
Attn: Martin Ng/ Yu Hosokai
Tel: +65 6812 7461
Email: SNG-RegulatoryAffairs@CookMedical.com
Fax: +65 6812 7401

Alternatively, healthcare professionals may report the adverse events to the Vigilance and Compliance Branch, Health Products Regulation Group, HSA at Tel: 6866 3538, Fax: 6478 9069, or report online at www.hsa.gov.sg/ae_online. Events that are reported to COOK South East Asia will be investigated and subsequently reported to HSA.

We recognize this situation is a disruption to your normal operations and we sincerely apologize. Thank you again for your immediate assistance in this matter. Should you have any medical questions or concerns, please contact Cook South East Asia at +65 6812 7400. We look forward to your response.

Yours Sincerely

[redacted]

Martin Ng
Regulatory Affairs Specialist
Cook South East Asia Pte. Ltd.

CC: Chairman Medical Board
Relevant Head of Departments

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Attachment - Cook Medical - Field Action 2019FA0001 - IFU update (Global List)

Product code - RPN	GPN	Description	Remarks
IGTCFS-65-1-FEM-TULIP	G52917	Günther Tulip® Vena Cava Filter Set for Femoral Vein Approach	Not registered in Singapore
IGTCFS-65-1-JUG-TULIP	G52916	Günther Tulip® Vena Cava Filter Set for Jugular Vein Approach	Not registered in Singapore
IGTCFS-65-1-UNI-TULIP	G52918	Günther Tulip® Vena Cava Filter Set for Femoral and Jugular Vein Approach	Not registered in Singapore
IGTCFS-65-1-FEM-CELECT-PT	G34502	Cook Celect® Platinum Vena Cava Filter Set for Femoral Vein Approach	Not registered in Singapore
IGTCFS-65-1-JUG-CELECT-PT	G34309	Cook Celect® Platinum Vena Cava Filter Set for Jugular Vein Approach	Not registered in Singapore
IGTCFS-65-1-UNI-CELECT-PT	G34505	Cook Celect® Platinum Vena Cava Filter Set for Femoral and Jugular Vein Approach	Not registered in Singapore
IGTCFS-65-2-FEM-TULIP	G52925	Günther Tulip® Vena Cava Filter Set for Femoral Vein Approach	Nil
IGTCFS-65-2-JUG-TULIP	G52924	Günther Tulip® Vena Cava Filter Set for Jugular Vein Approach	Nil
IGTCFS-65-2-UNI-TULIP	G52926	Günther Tulip® Vena Cava Filter Set for Femoral and Jugular Vein Approach	Nil
IGTCFS-65-2-FEM-CELECT	G52920	Cook Celect® Vena Cava Filter Set for Femoral Vein Approach	Nil
IGTCFS-65-2-JUG-CELECT	G52919	Cook Celect® Vena Cava Filter Set for Jugular Vein Approach	Nil
IGTCFS-65-2-UNI-CELECT	G52921	Cook Celect® Vena Cava Filter Set for Femoral and Jugular Vein Approach	Nil
IGTCFS-65-2-FEM-CELECT-PT	G34501	Cook Celect® Platinum Vena Cava Filter Set for Femoral Vein Approach	Nil
IGTCFS-65-2-JUG-CELECT-PT	G34310	Cook Celect® Platinum Vena Cava Filter Set for Jugular Vein Approach	Nil
IGTCFS-65-2-UNI-CELECT-PT	G34504	Cook Celect® Platinum Vena Cava Filter Set for Femoral and Jugular Vein Approach	Nil

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Acknowledgement and Receipt Form

Please reply to this notification within **5 business days** of receipt, **even if you do not have any affected product.**

Please complete **all** information below regarding the **Field Safety Corrective Action (FSCA)** of **Cook Inferior Vena Cava (IVC) Filter product**

Customer information

Date:	Customer Account Number:	
Customer Name:	Street Address:	
City:	State:	
Postal Code:	Department:	Phone:
Form Completed By (Printed Name, Signature):		Date:

Actions Taken: Please provide a response for each of the following;

1. I have received the Inferior Vena Cava (IVC) Filter Field Safety Notice (2019FA0001) and understand the information provided in the letter. YES ☐ NO ☐
2. I have examined my inventory and have **no affected product**. YES ☐ NO ☐
3. I have examined my inventory and have affected product to be corrected by Cook Medical Sales Representative. YES ☐ NO ☐

Please complete the table below regarding affected products.

Part Number (GPN or RPN)	Lot Number	Quantity

4. I have experienced an adverse event associated with the affected product. YES ☐ NO ☐
   a. If yes, please explain the adverse event below:

Other Information:

- Please complete the Acknowledgement and Receipt Form within **5 business days** and send it via fax (65) 6812 7401, or email: SNG-RegulatoryAffairs@CookMedical.com
- Should you have any questions or concerns, please contact Customer Service (email: CookSEA.CS@CookMedical.com phone: 6320 7678/ 7677) or Cook Medical Sales Representative for more information.
- Once acknowledgement form is received, Cook Medical Sales Representative will arrange for correction of affected products.