COOK MEDICAL EUROPE LTD.
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FSN & FSCA Ref: 2021FA0006

Date: 15Sep2021

Urgent Field Safety Notice

Inferior Vena Cava (IVC) Filter

For Attention of:Chief Executive / Risk Management / Purchasing

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 Contacts 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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Inferior Vena Cava (IVC) Filter

Risk addressed by FSN

1. **Information on Affected Devices**	
1.	1. Device Type(s)
	The CE-marked Günther Tulip Vena Cava Filter Set and the Cook Celect Platinum Vena Cava Filter Set are in the scope of this FSN: The Günther Tulip Vena Cava Filter Set (IGTCFS-65-2-UNI-TULIP) includes the Günther Tulip Vena Cava Filter implant and the introducer system components. The Günther Tulip IVC filter implant is composed of a paramagnetic cobalt chromium alloy (50 mm long when compressed to a diameter of 30 mm) and is supplied preloaded on a femoral filter introducer. A jugular introducer, introducer system, and pre-dilator are also supplied. The Günther Tulip Vena Cava Filter implant is designed to act as a permanent or retrievable filter. The Günther Tulip Vena Cava Filter implant may be retrieved if clinically indicated; the IFU provides more information about optional filter retrieval. The Cook Celect Platinum Vena Cava Filter Sets (IGTCFS-65-2-FEM/JUG/UNI(-FT)-CELECT-PT) includes the Cook Celect Platinum Vena Cava Filter implant and the introducer system components. The Cook Celect Platinum Vena Cava filter implant is composed of a paramagnetic cobalt chromium alloy (49 mm long when compressed to a diameter of 30 mm) with platinum markers and is supplied preloaded on a femoral or jugular filter introducer. An introducer system, and pre-dilator are also supplied. The Cook Celect Platinum Vena Cava Filter implant is designed to act as a permanent or retrievable filter. The Cook Celect Platinum Vena Cava Filter implant may be retrieved if clinically indicated; the IFU provides more information about optional filter retrieval.
1.	2. Commercial name(s)
	Günther Tulip® Vena Cava Filter Set for Femoral and Jugular Vein Approach, Cook Celect® Platinum Vena Cava Filter Set for Femoral Vein Approach, Cook Celect® Platinum Vena Cava Filter Set for Jugular Vein Approach, Cook Celect® Platinum Vena Cava Filter Set for Femoral and Jugular Vein Approach Cook Celect® Platinum NavAlign Uniset Vena Cava Filter Set

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1. 3. Primary clinical purpose of device(s)

The Günther Tulip and Cook Celect Platinum Vena Cava Filters are intended to capture blood clots traveling in the infrarenal inferior vena cava in the clinical situations detailed in the Indications for Use section of the IFU.

The Günther Tulip and Cook Celect Platinum Vena Cava Filter implants may be retrieved if clinically indicated, see the "Optional Filter Retrieval" section of the IFU for more information.

1. 4. Device Model/Catalogue/part number(s)

Product code - RPN	GPN	Description
IGTCFS-65-2-UNI-TULIP	G52926	Günther Tulip® Vena Cava Filter Set for Femoral and Jugular Vein Approach
IGTCFS-65-2-FEM-CELECT-PT	G34501	Cook Celect® Platinum Vena Cava Filter Set for Femoral Vein Approach
IGTCFS-65-2-JUG-CELECT-PT	G34310	Cook Celect® Platinum Vena Cava Filter Set for Jugular Vein Approach
IGTCFS-65-2-UNI-CELECT-PT	G34504	Cook Celect® Platinum Vena Cava Filter Set for Femoral and Jugular Vein Approach
IGTCFS-65-2-UNI-FT-CELECT-PT	G35581	Cook Celect® Platinum NavAlign Uniset Vena Cava Filter Set

2 Reason for Field Safety Corrective Action (FSCA)

2. 1. Description of the product problem

The purpose of this Field Safety Notice (FSN) is to inform you about updated product labeling (specifically, updated Instructions for Use) for the William Cook Europe ApS Günther Tulip Vena Cava Filter Set and Celect Platinum Vena Cava Filter Set.

The IFU updates are described in the table below. The updates are not related to device safety, device performance, or product design changes. The updated information is not reflective of newly identified hazards and/or harms or of a change in risk profile of the devices. Rather, the added information reflects well-known safety information associated with endovascular procedures requiring anesthesia and contrast media.

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Summary of Labeling Updates:

Section of IFU	Description of Changes
Device Description	Further clarify that the product is intended for percutaneous placement via a femoral or jugular vein in adult patients
Intended Use / Indications for Use	Modified to better reflect existing clinical evidence.
Contraindications	1. Updated to contraindicate use in minors/pediatric patients and pregnant patients. Note: Use in these patient populations was previously addressed in a Precaution statement; therefore, this update reinforces previously communicated information. 2. The IFU for the Günther Tulip IVC filter implant now includes a Contraindication for use in vena cava below 15 mm in diameter, aligning with existing Celect Platinum use specifications.
Warnings and Precautions	Clarified language and added new warnings and precautions to provide further emphasis related to existing topics in the IFU.
Potential Adverse Events	Aligned with the available post-market surveillance evidence. No new potential adverse events were added. One potential adverse event (coagulopathy) was removed from the list.
How Supplied	Text was added to mitigate the risk of resterilization of the final device.

2. 2. Hazard giving rise to the FSCA

No specific feedback regarding device use, device safety or device performance gave rise to this update. Rather, the updates to device labeling were to ensure alignment with ongoing regulatory requirements and best practices.

The target population for the Günther Tulip and Celect Platinum Vena Cava Filter Sets remains unchanged; specifically, these devices are intended for patients at risk for PE. However, the IFU updates includes contraindications for two specific patient groups (i.e., minors/pediatrics and pregnant women). While healthcare professionals may assess the potential benefit of IVC filter placement to outweigh the potential risk in these patients, this update reinforces the fact that safety and performance of the Günther Tulip and Celect Platinum IVC filter implants have not been established in these patients

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	3. Type of Action to mitigate the risk	
3.	**1. Action To Be Taken by the User** ☒ Take note of amendment/reinforcement of Instructions for Use (IFU) ☒ Other 1. No retrospective action for previously implanted products is warranted 2. The electronic versions of the IFUs can be found on the Cook Medical Web https://ifu.cookmedical.com/ifuPub/searchIfu.jsf by Catalogue Number (RPN) search 3. A Cook Medical Sales Representative will personally follow-up and provide corrected IFUs for customer's inventory. 4. Please complete the Customer Response Form within 5 business days of receiving the Field Safety Notice and return it to Cook Medical as directed on the form.	
3.	2. Particular considerations for: Implantable device Is follow-up of patients or review of patients' previous results recommended? No Compliance with current routine follow-up guidance is recommended.	
3.	3. Is customer Reply Required? (If yes, form attached specifying deadline for return)	Yes
3.	**4. Action Being Taken by the Manufacturer** ☒ IFU or labelling change ☒ Other Customers will be contacted by a Cook Medical Sales Rep for the purpose of swapping IFUs from old IFUs to new updated IFUs on all impacted unused devices in the customers possession.	

	4. General Information	
4.	1. FSN Type	New
	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 Cook Europe
	b. Address	Sandet 6 4632 Bjaeverskov Denmark

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4.	4. The Competent (Regulatory) Authority of your country has been informed about this communication to customers.	
4.	5. List of attachments/appendices:	Reply form Country Contacts List
4.	6. Name/Signature	 Lissi Walmann Manager, Regulatory Reporting, Quality Assurance William Cook Europe

	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.

Field Action Customer Reply Form

1. Field Safety Notice (FSN) information	
FSN Reference number	**2021FA0006**
FSN Date	15Sep2021
Product/ Device name	Günther Tulip® Vena Cava Filter Set and Cook Celect® Platinum Vena Cava Filter Set
Product Code(s)	1. IGTCFS-65-2-UNI-TULIP 2. IGTCFS-65-2-FEM-CELECT-PT 3. IGTCFS-65-2-JUG-CELECT-PT 4. IGTCFS-65-2-UNI-CELECT-PT 5. IGTCFS-65-2-UNI-FT-CELECT-PT
Batch/Serial Number (s)	Please refer to the attached list of affected lot numbers

2. Customer Details	
Account Number	
Healthcare Organisation Name	
Organisation Address	
Contact Name	
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.	
☐	I have affected unused devices for IFU swap - enter Lot number and quantities in table below.	
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

If you have any unused affected products, please indicate the part number, lot number and quantity:

Product Part Number	Product Lot Number	Quantity

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.