COOK®

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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: 25 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)

Description of the problem:
Cook Medica! is sendingyou this communicatoin to inform you about a global implementationof updated Cook Inferior Vena *Cava* (IVC) Filter product labelingtrom 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 trom post-market surveillance, data published in international standards and regulatory communications, and updated clinical data pertinentto the products. The added information is not reflective of a change in risk profile of the devicesbut 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 tor Use, and References. Updates are made to the patient card to reflect changesin the MRI Safety Informationsectionof the IFUs. The table below highlights the changes in the IFUs.

The Instructions tor Use (IFU) tor each Cook IVC filter continues to highlight the importance of individual risk-benefit patient evaluation by Healthcare Professi onals. Likewise, the IFUscontinue 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 modifications to the product labeling, the potential risks associated with the devices, and the continued need tor 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 Filt er IFUs. There is no change in the clinical procedurefor IVC filt er placement. However, the updates introduced to the Precaution,sPotential 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 tor previously implanted products is warranted; however, compliance with current routine follow-up guidance is recommended.
2. Please read and understand the new IFU to ensure full comprehension of the product's intended use.
3. The electronic versions of the IFUs can be found on the Cook Medical Web https://ifu.cookmedica l.com/ifuPub/searchlfu.jsf by Catalogue Number (RPN) search.
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 rece iving 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 testina.
Cook Inferior Vena Cava Filters (Günther Tulip Vena Cava Filter Sets and Cook Celect!Ce/ect Platinum Vena Cava Filter Sets) - ***Potential Adverse Events Section Updates***	The list of Potent ial 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 trom the prospective, single-arm, multicenter, international study of the Cook Celect Vena Cava Filter. The IFU previously included a summarv of interim results trom the clinical studv.
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 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 techniqueshas 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 trom this published literature, these references are added to inform physician users, so they are equipped to make the best informed decisions reqardinq patient care.

Transmission of this Field Safety Notice:

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.

We apologize for any inconvenience this may cause, however we find it important to assure that you are aware of these recommendations tor optima! care of patients in your practice. If you need any further information or support concerning this information, please contact your local Cook Medical Sales Representative.

Contact reference person:

Thomas Hessner Kirk
Team Lead, Regulatory Reporting
Regulatory Affairs
William Cook Europe
Bjaeverskov, DENMARK

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 questions, please teel free to contact us for more information (e-mail: European.FieldAction@c ookmedical.com, phone +353 61 334440).

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

Thomas Hessner Kirk
Team Lead