



Field Safety Notice – Updated Product Information

Reference: 2014FA0009

November 2014

Dear Health Care Provider:

Cook Medical is sending you this important safety communication to inform you that there is updated clinical information contained in our retrievable inferior vena cava (IVC) filter labeling (IFUs). This notification is not due to any increase in complaints or adverse events associated with Cook retrievable IVC filters.

Affected Products: Günther Tulip® Vena Cava Filter Set
Cook Celect® Vena Cava Filter Set
Cook Celect® Platinum Vena Cava Filter Set

Specifically, please note that these product IFUs include the current clinical study results as they relate to IVC filter retrieval timeframes. The intention of this notice is to inform you that we now provide this clinically significant, safety-related updated information in summary form. Accordingly, the following 'Precaution' is contained in the products' IFUs:

“The clinical study data suggest that the optimal retrieval period is between 0 and 12 weeks [for Tulip filters] and between 0 and 52 weeks [for Celect filters], during which time the probability of successfully retrieving the filter is greater than 90%. Filter retrieval is a patient-specific, clinically complex decision; a filter should only be retrieved when feasible and clinically indicated. For all IVC filter types, retrieval becomes more challenging with time. This is due to encapsulation of the filter legs or hook (for a tilted filter) by tissue in-growth. Please refer to the “Clinical Studies” section of this booklet for further details related to filter retrieval and the reference to the clinical study describing the retrievability of this filter.”

This additional precaution does not include any new clinical study data, or describe any new risks to the patient, end user or other person. There is no action required from you as there is no product recovery necessary. As existing inventory is used, new devices will include this IFU update.

Please transfer this notice to others in your organization on which this action may have an impact. Please also note that Cook Medical has informed the relevant competent authorities about this Field Safety Notice and the updated product information.

We apologize for any inconvenience this may cause, however we find it important to assure that you are aware of these recommendations for optimal 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.

Sincerely,

Anna Bjerg Jessen, MSc
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