

# Second-Generation, Optional Vena Cava Filter

A 90-day update on the safety and performance of a second-generation, optional vena cava filter in an animal model.

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There are 650,000 cases of pulmonary embolism (PE) annually in the US, and PE remains the first or second most common cause of death in most age groups. The highest recognized incidence of PE occurs in hospitalized patients, with 60% of hospitalized patients having had a PE. However, the diagnosis of PE is missed in approximately 70% of those patients.

Most patients with deep vein thrombosis (DVT) or PE do not require inferior vena cava (IVC) interruption if they can safely undergo anticoagulation. Moreover, once ambulatory, most trauma or surgical patients are at low risk for DVT and/or PE, and do not require IVC interruption. Therefore, a temporary vena cava filter (VCF) is an attractive alternative to permanent filter placement in those

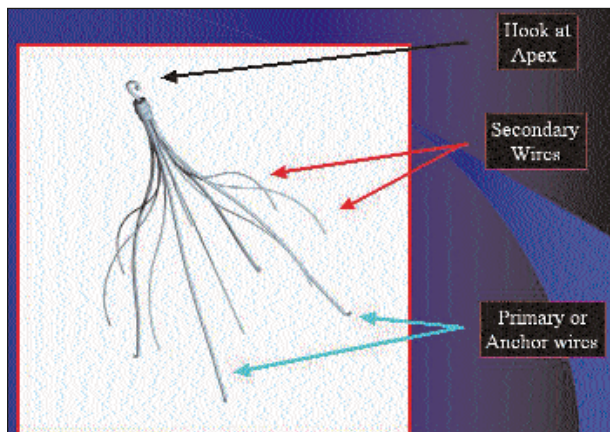


Figure 1. The Cook second-generation optional VCF with hook and primary and secondary wires.

TABLE 1. FOLLOW-UP PERIODS AFTER VCF IMPLANTATION FOR THE SIX GROUPS OF SHEEP

| Group | Follow-Up       |
|-------|-----------------|
| 1     | 30 d (+30 d)    |
| 2     | 60 d (+30 d)    |
| 3     | 90 d (+30 d)    |
| 4     | 180 d (+30 d)   |
| 5     | 360 d (+30 d)   |
| 6     | 4 back-up sheep |

patients who will eventually be at low risk for PE once their medical condition improves.

There are three commercially available optional VCFs in the US—the Günther-Tulip (Cook Incorporated, Bloomington, IN), the OptEase (Cordis, a Johnson & Johnson company, Miami, FL), and the Recovery (C.R. Bard, Murray Hill, NJ). All VCFs confer a high degree of recurrent PE protection, with a relatively high degree of successful removal. However, there have been reported cases of filter migrations, filter thromboses, and unsuccessful filter retrievals, resulting in further research to develop improved optional VCFs.

## STUDY DESIGN

A second-generation, optional-type VCF has been developed by Cook. It is undergoing animal testing at the Purdue animal lab and is expected to receive FDA approval in early 2005 (Figure 1). This article is an update on the development and testing of this second-generation VCF.

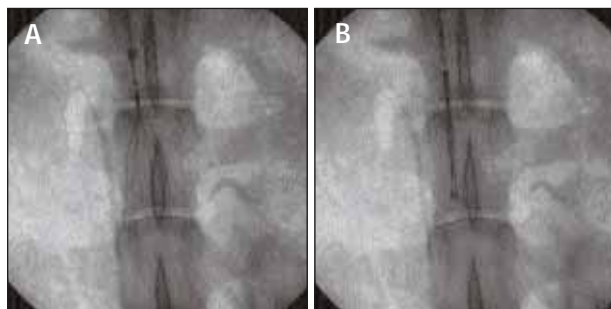


Figure 2. Resheathing (A) and unsheathing (B) the VCF.

The study was designed to test the safety and retrievability of the VCFs out to 360 days and involved the implantation of 48 VCFs into 24 sheep (two filters per IVC). The animals were followed in six groups of four sheep each (Table 1).

To date, groups 1 through 3 have been evaluated at times ranging from 30 through 120 days. Two sheep from each group had both of their filters removed and were sacrificed immediately. The two remaining sheep from each group had only one of their filters removed and then were sacrificed 30 days later. That is, group 1 included retrievals at 30 days with evaluations at 30 and 60 days, group 2 retrievals at 60 days with evaluations at 60 and 90 days, and group 3 retrievals at 90 days with evaluations at 90 and 120 days.

Variables evaluated included performance and ease of use of delivery and retrieval systems; successful filter retrievals and force used in retrieving the filters; filter migration, deformation, fracture, pitting, and thrombosis; vena cava injury; foreign-body response and granuloma formation; and systemic toxicity. Thrombus loading was performed with one filter to determine if filter dislodgement was a risk. This was performed at the Dotter Institute in Portland, Oregon, and will not be submitted to the FDA.

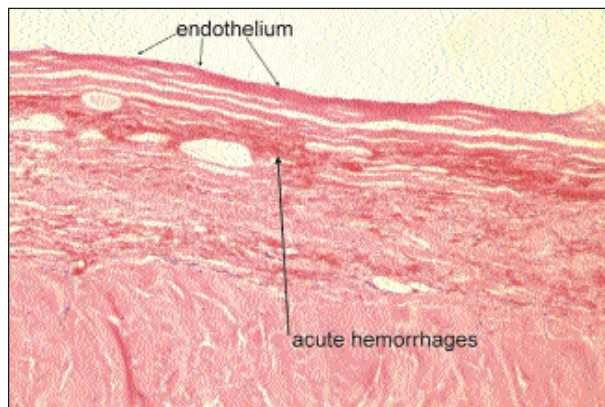


Figure 3. Subintimal hemorrhage at 60 days.

### FILTER DESIGN

The second-generation VCF is made of Elgiloy (Elgiloy Limited Partnership, Elgin, IL)—an amalgam of cobalt, nickel, and chromium—is conical-shaped with a hook at the apex and has four primary anchor wires and eight secondary wires. The anchor wires have a 55° bend at the tips of the wires that contact the IVC preventing migration. The secondary wires are thinner than the anchor wires and provide lateral stability and orientation along the long axis of the IVC preventing tilting (Figure 1). The primary and secondary wires do not touch each other and the tips of the secondary wires do not touch the IVC: only the curved portions of the wires touch the IVC. The deployment and retrieval are identical to the Günther Tulip VCF, with unsheathing of the filter for deployment and snare capture for resheathing the filter (Figure 2).

### RESULTS TO DATE (90-DAY RETRIEVAL DATA)

#### Deployment and Retrieval

All filters were deployed without difficulty and with accurate placement. Four of 18 filters had minor tilting during deployment that did not impair filter retrieval (one tilt-

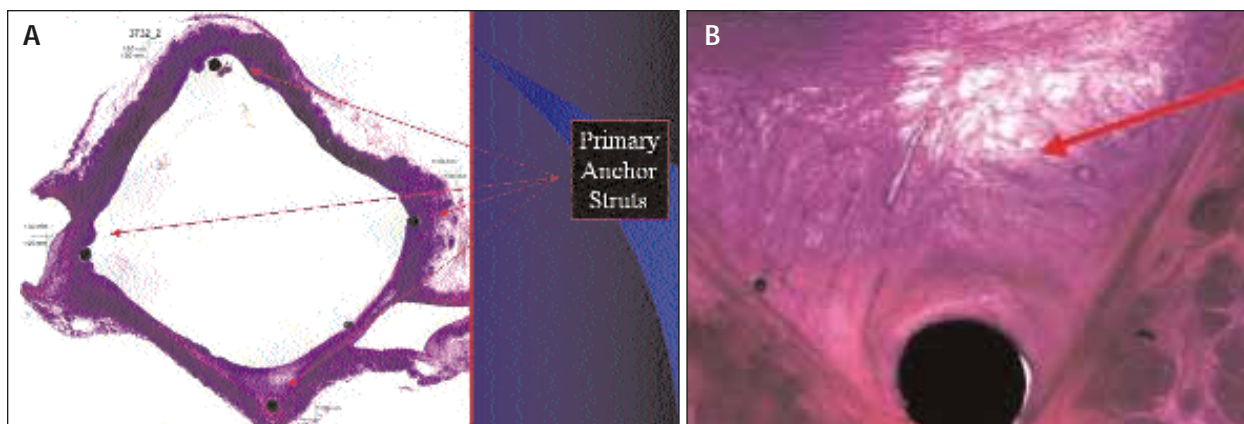


Figure 4. The primary anchor struts (A). A photomicrograph of primary anchor strut (B).

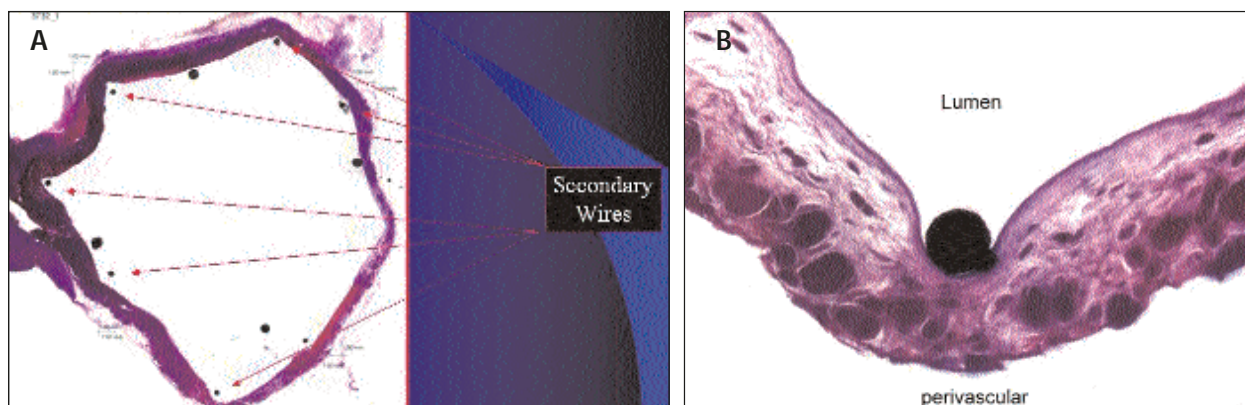


Figure 5. The secondary wires (A). A photomicrograph of secondary wire indenting of the IVC (B).

ing occurred from operator error and one filter had righted itself by the scheduled retrieval date). Successful retrieval of the VCFs occurred in 18 of 18 attempts. The force used to retrieve the second-generation VCF was considered to be less than or equal to the force used to retrieve the Günther-Tulip filter in 14 of 18 retrievals, and greater than (but acceptable) the force used to retrieve the Günther-Tulip filter in three of 18 retrievals.

### Filter Evaluation

There were no filter migrations or thromboses. The filters themselves were intact without fracture, corrosion, or pitting. A secondary wire deformed in two VCFs from inserting the filters through the hemostatic valve of the delivery sheath without using a peel-away sheath, as recommended by the manufacturer.

### Histopathology

Histopathology demonstrated one localized subintimal hemorrhage of the IVC at a retrieval site at 60 days that was considered insignificant (Figure 3). There were no other IVC injuries and no vessel wall perforations. There were no foreign-body responses, inflammatory changes, or granuloma formations. At the anchor points, there was neovascular overgrowth securing the anchor wires to the IVC as early as 30 days (Figure 4). This overgrowth did not impede filter removal out to 90 days. At the level of maximum expansion of the filter's secondary wires, there was indentation of the IVC wall without incorporation of the wires into the wall of the IVC (Figure 5). There were no IVC injuries from the secondary wires.

### Necropsy Results

No systemic toxicity was found in any organ system.

### Clot Loading

To test whether thrombus would dislodge the second-generation VCF, a total of more than 60 mL of

autologous thrombus was injected into a single VCF *in vivo* over a 30-minute time period. Although this amount of clot nearly occluded the IVC, there was no filter movement or migration up to 1 hour after thrombus loading.

### CONCLUSIONS

There were no safety problems with the second-generation VCF. All filters were easily implanted, and all were removed without difficulty. There were no VCF migrations immediately after implantation or to at least 90 days (and 120 days in two sheep). The anchor regions were imbedded in neointimal tissue as early as 30 days, providing sufficient resistance to filter migration.

There were no significant IVC injuries *in situ* or after VCF removal. No VCFs were dislodged by large thrombus loads. Based on gross and microscopic evaluation, the secondary wires did not incorporate into the IVC. There were no premature animal deaths, vessel ruptures, or injuries. ■

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