COOK®
MEDICAL

Celect Platinum® Vena Cava Filter Set for Femoral Vein Approach

Instructions for Use

I-IGTCFS-425-05EN

ENGLISH

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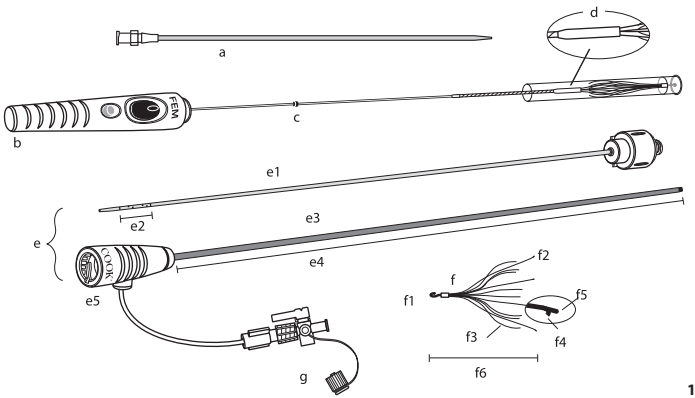

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a. Pre-dilator, radiopaque, with hydrophilic coating
b. Femoral filter introducer with flexible tip, preloaded with the Celect Platinum® filter
c. Tactile Bump
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e. Coaxial introducer system consists of:
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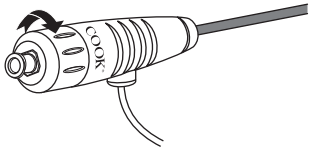

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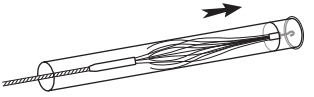

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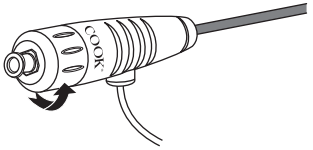

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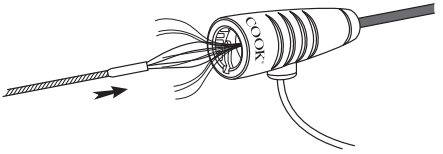

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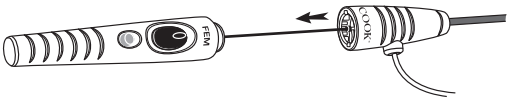

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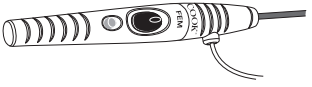

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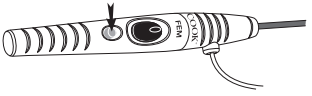

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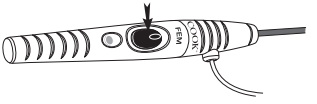

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ENGLISH

CELECT PLATINUM® VENA CAVA FILTER SET FOR FEMORAL VEIN APPROACH

Read all instructions carefully. Failure to properly follow the information provided may lead to the device not performing as intended or injury to the patient.

STERILE – DO NOT RESTERILIZE – SINGLE USE ONLY.

CAUTION: US federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

1. DEVICE DESCRIPTION

The Celect Platinum Filter Set consists of a filter composed of a paramagnetic cobalt chromium alloy (49 mm long when compressed to a diameter of 30 mm) with platinum markers, preloaded on a femoral filter introducer with a flexible tip; a 7 French coaxial introducer system (compatible with a 0.035 inch wire guide); and a 10 French pre-dilator with hydrophilic coating for vessel access. The introducer dilator has eight sideports and two radiopaque markers 30 mm apart (end-to-end). The product is intended for percutaneous placement via a femoral vein in adults.

The Celect Platinum Filter implant is designed to act as a permanent filter or retrievable filter. The Celect Platinum Filter implant may be retrieved if clinically indicated; please refer to **Section 5.2, Optional Filter Retrieval** for more information.

2. INTENDED USE

The Celect Platinum Filter implant is intended for the prevention of recurrent pulmonary embolism (PE) via placement in the vena cava in the following situations:

- Pulmonary thromboembolism when anticoagulant therapy is contraindicated;
- Failure of anticoagulant therapy in thromboembolic diseases;
- Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent PE where anticoagulant therapy has failed or is contraindicated.

The Celect Platinum Filter implant may be retrieved if clinically indicated; please refer to **Section 5.2, Optional Filter Retrieval** for more information.

The product is intended for percutaneous placement via a femoral vein for filtration of inferior vena cava (IVC) blood to prevent PE.

3. CONTRAINDICATIONS

3.1 Filter Placement

- Megacava (diameter of the IVC >30 mm).
- Diameter of the IVC <15 mm.
- Extensive thrombus in the vein chosen for approach.
- Patients with risk of septic embolism.
- Use in pregnant women.
- Use in minors/pediatric patients.

3.2 Optional Filter Retrieval

- Filters with significant amounts of trapped thrombus (greater than 25% of the volume of the cone).
- Patients with an ongoing high risk of PE.

4. WARNINGS

4.1 Filter Placement

- If severe resistance is met when advancing the wire guide or the introducer system, then retract and choose a different approach. Excessive force should not be exerted.
- When power injecting contrast media, do not exceed the maximum pressure rating of 68 bar/1000 psi and flow rate of 20 mL/sec. Hand injection is also possible.
- When inserting the preloaded filter into the Check-Flo® valve of the introducer sheath, hold the introducer with flexible tip near the end, close to the filter.
- Do not attempt to rotate the preloaded filter inside the introducer system.
- Do not re-sheath the expanded filter during femoral approach.
- Do not attempt to rotate, advance, or retract the expanded filter inside the vena cava.
- Excessive force should not be exerted in placement of the filter. If deployment of the filter is not possible, it may require a replacement of the device. If a replacement of the device is not possible, or if the filter does not expand correctly, it may require additional interventions or surgical removal.
- During diagnostic imaging evaluate that the filter does not show any signs of damage or defect. If the filter is damaged, it may affect the clot trapping ability of the filter or cause an obstruction of the blood flow.

4.2 Optional Filter Retrieval

- An inferior vena caval imaging evaluation for residual captured thrombus should be performed prior to attempted retrieval.
- Never attempt to re-deploy a retrieved filter.

- Excessive force should not be exerted to retrieve the filter, as it may lead to filter breakage and/or harm to the patient. If retrieval of the filter is complicated, it may require additional interventions or surgical removal.
- Please refer to **Section 8, CLINICAL STUDIES** for data regarding filter retrieval in the Cook IVC Filter (CIVC) Study.

5. PRECAUTIONS

- The product is intended for use by physicians trained and experienced in diagnostic and interventional endovascular techniques.
- Standard techniques for placement of vascular access sheaths, angiographic catheters, and wire guides should be employed.
- The Celect Platinum Filter Set should be used in patients with vessel diameters compatible with the associated device components.
- Product (filter or introducer system) modification or alteration is not recommended, as the product's safety and effectiveness has not been established following any modifications.
- Manipulation of products (e.g., placement and retrieval) requires imaging control.
- Before injecting any contrast media (by either power or hand injection) through the introducer dilator, ensure that the introducer sheath hub and introducer dilator are correctly connected.
- Possible allergic reactions (e.g., to cobalt, chromium, nickel, and platinum) should be considered.
- Ensure that the patient does not have impaired tolerance to general, regional, or local anesthesia to avoid adverse reactions associated with the anesthetic procedure.
- Ensure that the patient is not allergic/sensitive to contrast media since the use of contrast media during the procedure and/or during postoperative imaging may cause an allergic reaction and/or other contrast-induced harms.
- Placement in the suprarenal position have been reported. The safety and effectiveness of the filter has not been established in these patients.
- Filter tilt has been reported. Potential causes may include filter placement in IVCs with diameters larger than those specified in these Instructions for Use; improper deployment; manipulations near an implanted filter (e.g., a surgical or endovascular procedure in the vicinity of a filter); and/or a failed retrieval attempt. Excessive filter tilt may contribute to difficult or failed retrieval; vena cava wall penetration/perforation; and/or result in loss of filter efficiency.
- Vena cava wall penetration/perforation has been reported and may be either symptomatic or asymptomatic. Potential causes may include improper deployment; and/or excessive force or manipulations near an in situ filter (e.g., a surgical or endovascular procedure in the vicinity of a filter).
- Filter fracture has been reported and may be either symptomatic or asymptomatic. Fracture of a filter leg may be due to repetitive motion on a filter leg in an unusual, stressed position, such as a filter leg penetrating/perforating the IVC; or a filter leg being caught in a side branch (e.g., a renal vein). Other potential causes of filter fracture may include excessive force or manipulations near an implanted filter (e.g., a surgical or endovascular procedure in the vicinity of a filter). Retrieval of a fractured filter or filter fragments (including embolized fragments) using endovascular techniques has been reported.
- Filter or filter fragment migration and/or embolization (e.g., movement to the heart or lungs) has been reported. Filter or filter fragment movement has occurred in both the cranial and caudal direction and may be either symptomatic or asymptomatic. Potential causes may include filter placement in IVCs with diameters smaller or larger than those specified in these Instructions for Use; improper deployment; deployment into thrombus; dislodgement due to large thrombus burdens; and/or excessive force or manipulations near an in situ filter (e.g., a surgical or endovascular procedure in the vicinity of a filter).
- Increased friction and/or compression at the access site during the procedure may lead to increased risk of thrombosis at the access site.
- Follow the instructions thoroughly to ensure successful deployment, and to avoid any harm to the patient or damage to the device.
- If the introduction system or parts of the introduction system malfunctions prior to or during procedure, the device should be replaced. If the device malfunctions during procedure, perform careful replacement to avoid injuries to the access site and vessel.
- Failure to store the device correctly may result in material degradation and/or damage to the device.

5.1 Filter Placement

- For placement of the filter, the right femoral vein is usually preferred due to its straighter route to the vena cava. The left femoral vein can be used, but is more tortuous. Prior to choosing an approach, assess the patient's size and anatomy, and the location of any venous thromboses.

- The filter implant is supplied preloaded on the femoral filter introducer. Do not attempt to separate the preloaded filter introducer.
- Do not attempt to reload the filter onto the femoral filter introducer. Any attempt to do so may damage the introducer and/or the filter.
- Once the femoral cup (indicated as position d in **Fig. 1**) is past the tip of the introducer sheath, the secondary legs of the filter are expanded. Attempting to retract the filter at this point of the deployment sequence could damage the secondary legs or caval wall.

5.2 Optional Filter Retrieval

- Physician practice guidelines and published guidance from regulatory agencies recommend that patients with indwelling filters undergo routine follow-up. The risks/benefits of filter retrieval should be considered for each patient during follow-up. Refer to **Section 11, REFERENCES** for citations that include recommendations related to filter follow-up and retrieval.
- Once protection from PE is no longer necessary, filter retrieval should be considered. Filter retrieval should be attempted when feasible and clinically indicated. Filter retrieval is a patient-specific, clinically complex decision; the decision to remove a filter should be based on each patient's individual risk/benefit profile (e.g., a patient's continued need for protection from PE compared to their experience with and/or ongoing risk of experiencing filter-related complications). For all retrievable IVC filters, retrieval becomes more challenging with time, and this is commonly due to encapsulation of the filter legs or hook (in a tilted filter) by tissue ingrowth.
- Data from the Cook IVC Filter Study (CIVC) study demonstrate the Celect Platinum filter can be safely retrieved (refer to **Section 8, CLINICAL STUDIES**).
- The filter is designed to be retrieved with the Günther Tulip® Vena Cava Filter Retrieval Set. It may also be retrieved with the CloverSnare® Vascular Retriever. Cook has not performed testing to evaluate the safety or effectiveness of filter retrieval using other retrieval systems or techniques.
- For filter retrieval, the right jugular vein is usually preferred due to its straighter route to the vena cava.
- The published clinical literature includes descriptions of alternative techniques for filter retrieval; use of these techniques varies according to physician experience, patient anatomy, and filter position. **The safety or effectiveness of these alternative retrieval techniques has not been established. Section 11, REFERENCES** includes citations that describe alternative retrieval techniques; this information is provided as reference.

6. MRI SAFETY INFORMATION

MR Conditional

A patient with the Celect Platinum Vena Cava Filter may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Notes
[1] **Item Name/Identification**	Celect Platinum Vena Cava Filter
[2] **Item Manufacturer**	Cook Medical
[3] **Static Magnetic Field Strength [T]**	1.5 T or 3.0 T
[4] **Maximum Spatial Field Gradient [T/m and gauss/cm]**	20 T/m (2000 gauss/cm)
[5] **RF Excitation**	Circularly Polarized (CP)
[6] **RF Transmit Coil Type**	Whole body transmit coil, Head RF transmit-receive coil
[7] **RF Power**	Normal Operating Mode
[8] **Maximum Whole Body SAR [W/kg]**	2.0 W/kg
[9] **Scan Duration**	2.0 W/kg whole body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks). Under the scan conditions defined above, the Celect Platinum Vena Cava Filter is expected to produce a maximum temperature rise of less than 4.2 °C after 15 minutes of continuous scanning.
[10] **MR Image Artifact**	The presence of this implant may produce an image artifact of 24 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	
Follow the MRI safety information to avoid excessive heating, torque, and/or deflection, which may cause injury to the vessel.	
Image artifacts may occur, which may prolong diagnostic time and/or require additional imaging.	

For US Patients Only

It is recommended that patients register the conditions under which the implant can be safely scanned with the Medic Alert Foundation (medicalert.org) or an equivalent organization.

7. POTENTIAL ADVERSE EVENTS

Potential adverse events that may occur include, but are not limited to, the following:

- Access site thrombosis/occlusion
- Air embolism
- Arrhythmia
- Back or abdominal pain
- Blood loss
- Branch vessel occlusion
- Cardiac damage
- Cardiac tamponade
- Damage to the vena cava
- Death
- Deep vein thrombosis
- Edema
- Extravasation of contrast material
- Failure of filter expansion/incomplete expansion
- Filter fracture
- Filter malpositioning
- Filter migration
- Filter or filter fragment embolization
- Hematoma at vascular access site
- Hemorrhage
- Infection at vascular access site
- Intimal tear
- Obstruction of blood flow
- Pneumothorax
- Postphlebitic syndrome
- Pulmonary embolism
- Retrieval failure
- Trauma to adjacent structures
- Unacceptable filter tilt
- Vascular trauma
- Vena cava occlusion or thrombosis
- Vena cava penetration
- Vena cava perforation
- Vena cava stenosis

8. CLINICAL STUDIES

Overview of clinical studies

The Celect Platinum Vena Cava Filter was subject of a multicenter, single arm, Investigational Device Exemption (IDE) study, the Cook IVC Filter Study (CIVC). As described in **Section 8.1**, the CIVC study results support the safety and effectiveness of the Celect Platinum Vena Cava Filter. In addition, the Celect Platinum Vena Cava Filter is supported by results from a multicenter, single-arm, study which confirmed the safety and performance of the Cook Celect Vena Cava Filter. The results from this multicenter study are described in **Section 8.2** and suggest probable clinical results for the successful retrieval of the Celect Platinum Vena Cava Filter.

8.1 CIVC Study

8.1.1 Objectives and Design

The Cook IVC Filter Study (CIVC) was a multi-center, prospective, single arm, Investigational Device Exemption (IDE) study of Cook's commercially available permanent and retrievable IVC filters (specifically the Günther Tulip and Celect filters) that were placed in subjects for the prevention of pulmonary embolism (PE). Subjects were stratified based upon the type of filter they received (i.e., Celect or Günther Tulip). The study enrolled 473 subjects at 28 sites in the US, UK, and Australia; the Celect stratum included 324 subjects and the Günther Tulip stratum included 149 subjects. All treated subjects were scheduled for evaluation at procedure and at 3, 6 (telephone), 12, 18 (telephone), and 24 months post-procedure.

The primary objective of this IDE study was to evaluate the safety and effectiveness of Cook's commercially available permanent and retrievable IVC filters (specifically the Günther Tulip and Celect filters) in subjects in need of temporary or permanent IVC filter placement for the prevention of PE. The primary safety and effectiveness endpoints were evaluated for the Celect filter stratum. Secondary study outcomes were evaluated for each stratum and for the combined patient set.

The primary safety endpoint was the 12-month rate of freedom from major adverse events and was evaluated for the Celect stratum. Major adverse events were defined as:

- Clinical perforation: protrusion of filter legs through the wall of the IVC causing hemorrhage or hematoma or touching, impressing, or perforating another organ (e.g., liver, bowel, aorta, psoas muscle, vertebral body, lymph nodes); documented using CT and confirmed by core laboratory.
- Clinical migration: caudal or cranial movement of a filter resulting in surgical or endovascular intervention; confirmed by core laboratory.
- Clinical fracture: a loss of structural integrity (breakage or separation) of the filter identified by imaging and associated with clinical sequelae and/or requiring intervention; confirmed by core laboratory.
- Embolization of the filter or filter fragments to the heart or lungs: post-placement movement of the filter or its components to the heart or lungs; documented by imaging or autopsy and confirmed by core laboratory.
- IVC thrombotic occlusion: presence of an occluding thrombus in the IVC occurring after

filter placement (may be symptomatic or asymptomatic); documented by appropriate imaging or autopsy and confirmed by core laboratory.

- New symptomatic DVT while a filter is indwelling (confirmed by appropriate imaging and confirmed by core laboratory).
- Access site complications with clinical sequelae: arteriovenous fistula, hematoma, or bleeding requiring transfusion (≥2 units), hospitalization (either admission or extended stay), or further treatment.
- Procedure-/device-related death: death directly attributable to the filter or filter placement or retrieval procedure itself, documented by clinical findings, imaging, or autopsy, or as adjudicated by a Clinical Events Committee.

The hypothesis for the primary safety endpoint was that at 12 months post-procedure, the rate of freedom from major adverse events will be above the prespecified performance goal of 80%.

The primary safety endpoint was tested using the Z-statistic, with Kaplan-Meier estimate for freedom from major adverse events. The primary safety endpoint was additionally tested post-hoc using the one-sided exact binomial test. Success would be considered if the lower limit of the one-sided 97.5% exact binomial confidence interval was above the performance goal.

The primary effectiveness endpoint was the rate of technical placement success (defined as deployment of a filter in a location suitable to provide sufficient mechanical protection against PE with no filter deformation, fracture, premature release, or clinical migration) and 12-month freedom from new symptomatic PE (documented by appropriate imaging and confirmed by core laboratory) while a filter is indwelling and was evaluated for the Celect stratum.

The hypothesis for the primary effectiveness endpoint was that the rate of technical placement success and 12-month freedom from new symptomatic PE while a filter was indwelling will be above the prespecified performance goal of 90%.

The primary effectiveness hypothesis was tested using the one-sided exact binomial test. Success would be considered if the lower limit of the one-sided 97.5% exact binomial confidence interval was above the performance goal.

The secondary endpoints included the rate of technical placement success and 12-month freedom from new symptomatic PE while a filter is indwelling; the rate of 12-month freedom from MAEs; and the rate of 12-month freedom from Grade 2 (i.e., filter strut entirely outside of the IVC lumen and within the retroperitoneum as evidenced by a "halo" of retroperitoneal fat around axially viewed strut) or Grade 3 (i.e., filter strut is touching, impressing, or perforating another organ) filter leg interaction with the IVC, filter migration, filter fracture, and filter embolization. Secondary endpoints were evaluated for the individual stratum and the combined patient population. Various secondary measures, including several device safety measures, placement procedure related measures, and filter retrieval measures, were also evaluated.

8.1.2 Subject Accountability

In total, 473 patients were enrolled; all patients had IVC filters placed. Patient accountability is shown in **Table 1**.

Subjects with IVC filter retrieval: Sixty-seven percent (67%) of 473 subjects underwent filter retrieval prior to 2-years of follow-up (318/473), and compliance with the 1-month post retrieval visit was 83.8% (254/303). Thirty-four percent (34.6%) of these filter retrievals took place prior to the 3-month follow-up visit (110/318) and 94% occurred prior to 12 months of follow-up (298/318).

Subject deaths: A total of 73 deaths occurred during study follow-up (73/473; 15.4%). Seventy-five percent (75%) of these deaths occurred prior to 12 months of follow-up (55/73). Deaths were assessed for relatedness; 59 deaths were determined to be not related to the device or procedure, 13 deaths were unable to be determined, and one patient death was determined to be related to the device.

Consent withdrawal or lost-to-follow-up: Eleven percent (11%) of subjects withdrew consent or were lost-to-follow-up (51/473), with 41% occurring prior to 12 months (21/51). Over the course of the study, 22 subjects withdrew consent and 29 were lost to follow-up.

Twenty percent (20%; 97/473) of subjects remained in the study with a filter in place at 12 months. Just under 10% (9.7%; 46/473) of subjects remained in the study with a filter in place at 24 months; 87% of those completed the final study visit (40/46).

Table 1 – Patient Accountability

Patient Censoring	Procedure (n[a]=473)	3 Months (n=324)	6 Months (n=177)	12 Months (n=97)	18 Months (n=68)	24 Months (n=46)	Retrieval Procedure (n=318)	1-Month Post-Retrieval (n=303)	Total
Death	29	11	15	9	7	1	0	1	73
Filter Retrieval	110	127	61	14	6	0	0	0	318
Withdrew Consent/ Lost to Follow-Up	10	8	3	6	7	4	4	9	51
Other Endpoint[b]	0	0	1	0	0	1	11	8	21
Total	**149**	**146**	**80**	**29**	**20**	**6**	**15**	**18**	**463**

All counts in the table reflect subject disposition at the end of the respective visit window.

[a] At each time, n reflects the number of patients eligible for the follow-up.

[b] Other endpoint included study filter retrieved and replaced (n=4), study filter retrieved and 1-month post-retrieval follow-up not done (n=12), patient(s) in long term care facility or hospice and unable to complete follow-up visit (n=2), patient(s) cancelled/missed follow-up (1 month, 2 year, etc.) appointment (n=3).

8.1.3 Results

Baseline Demographics

The mean age of subjects was 61 years, 57% were male, and 77% were white. Baseline venous thromboembolism status was characterized as: current DVT in 62%, current PE in 30%, a history of DVT in 34%, and history of PE in 24%. The baseline demographics were similar between the Celect and Günther Tulip stratum. **Table 2** shows patient baseline demographics.

Table 2 – Baseline Demographics

Characteristic	Total (N=473)	Celect (N=324)	Günther Tulip (N=149)
Age, Yrs. [Mean (SD, Range)]	61.1 (16.1; 18 - 94)	60.7 (16.4; 18 - 94)	61.9 (15.4; 20 - 92)
Gender, Male (%, n)	271 (57.3%)	184 (56.8%)	87 (58.4%)
Race			
White	364 (77.0%)	244 (75.3%)	120 (80.5%)
Black	57 (12.1%)	40 (12.3%)	17 (11.4%)
Other	52 (10.9%)	40 (12.3%)[a]	12 (8.1%)[b]
Baseline Venous Thromboembolism Status[c]			
History of DVT	161 (34.0%)	106 (32.7%)	55 (36.9%)
Current DVT	279 (n=453; 61.6%)	199 (n=309; 64.4%)	80 (n=144; 55.6%)
History of PE	115 (24.3%)	79 (24.4%)	36 (24.2%)
Current PE	141 (29.8%)	92 (28.4%)	49 (32.9%)

[a] Other race includes: Hispanic or Latino (31), Asian (5), Black/Hispanic or Latino (2), Hispanic or Latino/White (1), and Asian/White (1).

[b] Other race includes: Hispanic or Latino (12).

[c] Subject could have more than baseline venous thromboembolism status.

Indication for Filter Placement

Table 3 summarizes the indication for filter placement, the majority of which were for current DVT (48.4%) and/or PE (20.7%) with additional indicator(s) for filter placement.

Table 3 – Indication for Filter Placement

Indication Details[a]	Total (N=473)	Celect (N=324)	Günther Tulip (N=149)
Current DVT	48.4% (229)	50.0% (162)	45.0% (67)
Current PE	20.7% (98)	19.1% (62)	24.2% (36)
Complication to anticoagulation	4.9% (23)	4.9% (16)	4.7% (7)
Contraindication to anticoagulation	40.4% (191)	37.3% (121)	47.0% (70)
Failure of anticoagulation	1.5% (7)	1.9% (6)	0.7% (1)
No contraindication to anticoagulation, but with added risk	21.4% (101)	23.5% (76)	16.8% (25)
Poor compliance with anticoagulation	0.8% (4)	1.2% (4)	0% (0)
No VTE; considered at risk:	30.9% (146)	30.9% (100)	30.9% (46)
History of prior VTE	14.8% (70)	13.6% (44)	17.4% (26)
Hypercoagulable	4.4% (21)	3.7% (12)	6.0% (9)
Recent Trauma	8.2% (39)	10.5% (34)	3.4% (5)
Surgery	20.9% (99)	18.5% (60)	26.2% (39)
Other medical condition	3.2% (15)	2.5% (8)[b]	4.7% (7)[c]
Contraindication to anticoagulation	16.9% (80)	15.4% (50)	20.1% (30)

[a] Subject could have more than one indication for filter placement.

[b] Other medical conditions included bleeding on anticoagulation (1), history of PE or DVT (1), immobilized in bed (1), metastatic cancer (1), strong family history of DVT and PE (1), previous massive PE (1), and profound anemia (2).

[c] Other medical conditions included cancer (1), previous DVT (1), myelofibrosis (1), prolonged immobilization (2), rectus sheath hematoma (1), and renal cell carcinoma (1).

8.1.4 Endpoint Results

Primary Safety Endpoint Results

The prespecified performance goal for the primary safety endpoint was 80%. All subjects (n=324) in the Celect stratum were evaluated for the primary safety endpoint. This analysis included all safety events (i.e., MAEs) occurring through
12 months, regardless of final patient status. Patients without a safety event through 12 months were censored in the event of filter retrieval, lost to follow-up, withdrawal, death, or an "other" endpoint. The 12-month freedom from MAE rate was 81.5% with a lower 95% confidence interval of 72.6%, failing to meet the performance goal (**Table 4**). The analysis failed to reject the null hypothesis [p=0.369], although the estimate for the 12-month freedom from MAE was above 80%. Many subjects were censored in the Kaplan-Meier analysis due to successful filter retrieval in the absence of a safety event (n=204), making the 12-month estimate less precise. In the post-hoc analysis, a successful filter retrieval in the absence of a safety event through 12 months was considered a successful safety result, mirroring clinical practice in which a filter is considered to have performed safely if it is placed, remains indwelling during an at-risk period, and is successfully retrieved without a safety event. In this analysis, the 12-month rate from MAE was 86.7%, with a lower 95% confidence interval of 82.5%, meeting the performance goal (**Table 4**).

Table 4 – Primary Safety Endpoint Results (Celect Stratum)

Primary Safety Endpoint	Rate (Number at risk, Number of events OR n/N)	95% CI*
12-month freedom from MAE*	81.5% (57, 32)	(72.6%, 90.4%)
Post-hoc: 12-month freedom from MAE**	86.7% (281/324)	(82.5%, 90.2%)

* The Z-statistic was used for analyses, with Kaplan-Meier estimate for freedom from major adverse events.

** The Exact binomial test model was used for analyses. The denominators are the number of subjects evaluable for the endpoint.

Primary Effectiveness Endpoint Results

The predefined performance goal for the primary effectiveness endpoint rate was 90%. All subjects (n=324) in the Celect stratum were evaluated for the primary effectiveness endpoint. The primary effectiveness endpoint rate for the Celect stratum was 97.8%, with a lower 95% confidence interval of 95.6%, meeting the performance goal (**Table 5**).

Table 5 – Primary Effectiveness Endpoint Results (Celect Stratum)

Primary Effectiveness Endpoint	Rate*	95% CI*
Technical placement success and freedom from new symptomatic PE	97.8% (317/324)	(95.6%, 99.1%)

* The Exact binomial test model was used for analyses. The denominators are the number of subjects evaluable for the endpoint.

Secondary Endpoints

In support of the primary measures for safety and effectiveness, the secondary endpoints included evaluation of the primary safety and effectiveness endpoints for the individual stratum and the combined patient population through 12 months; outcomes for the individual elements of the endpoints were also determined. In addition, the secondary endpoints included evaluation of a 12-month composite endpoint defined as freedom from Grade 2 or Grade 3 filter leg interaction with IVC, filter migration, filter fracture, and filter embolization.

Table 6 presents the secondary endpoints for the Celect stratum, the Günther Tulip stratum, and the total population. The outcomes support the safety and effectiveness of the Cook IVC filters. Of primary interest is whether the noted safety events occurred during the time period of filter use, which consists of the time from filter placement to filter retrieval, patient death, or a decision to leave the filter as permanent. The denominators included in **Table 6** represent how many subjects contributed to the evaluations. For the majority of the subjects, the 12-month follow-up was not performed because the filter was no longer in place (filter retrieval; 65.9%; 312/473) or evaluation was no longer possible (patient withdrew consent, lost to follow-up or death unrelated to the filter; 19.2%; 91/473). Thus the rates presented should be interpreted as representing the absence of the noted event within the time period of filter use, with a 12-month maximum.

Table 6 – Secondary Endpoints (Total Population, Celect Stratum, Günther Tulip Stratum)

Primary Safety Event	Total Population	Celect Stratum	Günther Tulip Stratum
12-month Freedom from MAE	87.9% (416/473)	86.7% (281/324)	90.6% (135/149)
Freedom from clinical perforation	93.4% (442/473)	92.7% (301/324)	94.6% (141/149)
Freedom from clinical migration	99.8% (472/473)	99.7% (323/324)	100% (149/149)
Freedom from clinical fracture	100% (473/473)	100% (324/324)	100% (149/149)
Freedom from embolization of the filter or filter fragments to the heart or lungs	100% (473/473)	100% (324/324)	100% (149/149)
Freedom from IVC thrombotic occlusion	99.6% (471/473)	99.4% (322/324)	100% (149/149)
Freedom from new symptomatic DVT while the filter is indwelling	95.1% (450/473)	94.8% (307/324)	96.0% (143/149)
Freedom from access site complications with clinical sequelae	100% (473/473)	100% (324/324)	100% (149/149)
Freedom from procedure-device-related death	100% (473/473)	100% (324/324)	99.3% (148/149)
Technical placement success and 12-month Freedom from new symptomatic PE while a filter is indwelling	98.1% (464/473)	97.8% (317/324)	98.7 (147/149)
Technical placement success	98.9% (468/473)	98.8% (320/324)	99.3% (148/149)
12-month freedom from new symptomatic PE while a filter is indwelling	96.9% (127/131)	96.6% (85/88)	97.7% (42/43)
12-month Freedom from Grade 2 or Grade 3 filter leg interaction with IVC, filter migration, filter fracture, and filter embolization	85.6% (405/473)	84.6% (274/324)	87.9% (131/149)

The bolded endpoints were prespecified secondary endpoints in the study protocol. The other categories were individual components of the endpoints.

Secondary Measures

The secondary measures reported include individual components of the primary effectiveness endpoint and primary safety endpoint, as well as other device-related measures. These individual outcome measures included freedom from new symptomatic pulmonary embolism, freedom from clinical perforation, freedom from symptomatic clinical perforation, freedom from a filter leg perforating an adjacent organ, freedom from a filter with a leg >5 mm beyond the column of contrast, freedom from filter embolization, freedom from IVC thrombotic occlusion, freedom from new symptomatic DVT while a filter is indwelling, freedom from procedure- and device-related death, freedom from access site complications with clinical sequelae, freedom from filter fracture, and freedom from filter migration >20 mm. **Table 7** shows Kaplan-Meier estimates for the total study population, as well as the number of patients at risk and the number of events, for these secondary measures at protocol-defined follow-up time points; Kaplan-Meier analysis provides an estimate of cumulative survival (i.e., the probability that a patient is event-free over time). For freedom from clinically significant pulmonary embolism, Kaplan-Meier analysis indicated a 99.5% probability that a patient is free from experiencing a new symptomatic pulmonary embolism at 3 months (with 360 patients at risk or still in the study and not yet experienced a new symptomatic pulmonary embolism, and 2 events of new symptomatic pulmonary embolism through 3 months) and a 98.5% probability that a patient is free from experiencing new symptomatic pulmonary embolism at 24 months (with 26 patients at risk and 4 events of new symptomatic pulmonary embolism through 24 months). **Table 8** and **Table 9** show Kaplan-Meier estimates for the Celect stratum and Günther Tulip stratum, respectively; outcomes were similar between the two strata.

Finally, filter retrieval measures were reported. In total, 335 retrieval attempts were reported and 318 retrieval attempts were successful. Failed retrieval attempts (17 attempts in 15 patients) were attributed to hook embedded in the vessel (n=11), hook oriented towards the vessel wall and unable to grasp (n=9), excessive growth at the filter legs (n=2), and other (n=3; included ingrowth of intima into struts of the filter, unable to reach the filter hook with the snare,

and hook oriented towards vessel wall and patient intolerant of procedure). One patient required surgical retrieval of a Celect filter following multiple unsuccessful endovascular retrieval attempts.

Table 7 – Secondary Measures (% Patients Free from Experiencing Each Event) - Total Population

	Kaplan-Meier Estimate (Number of patients at risk, Number of events)				
Endpoint	**3 months**	**6 months**	**12 months**	**18 months**	**24 months**
Freedom from new symptomatic pulmonary embolism while a filter is indwelling	99.5 (360, 2)	99.1 (187, 3)	98.5 (96, 4)	98.5 (60, 4)	98.5 (26, 4)
Freedom from clinical perforation	98.4% (358, 7)	97.2% (186, 11)	89.1% (90, 20)	60.5% (38, 45)	50.1% (16, 49[a])
Freedom from symptomatic filter leg interaction with the IVC	99.8% (362, 1)	99.8% (189, 1)	99.0% (98, 2)	99.0% (62, 2)	99.0% (28, 2)
Freedom from a filter with a leg perforating another organ	100% (362, 0)	99.7% (188, 1)	99.7% (98, 1)	97.4% (61, 3)	91.7% (28, 5)
Freedom from a filter with a leg >5 mm beyond the column of contrast	99.5% (361, 2)	99.5% (188, 2)	98.6% (97, 3)	91.7% (56, 9)	89.1% (27, 10[b])
Freedom from filter embolization	100% (362, 0)	100% (189, 0)	100% (98, 0)	100% (62, 0)	100% (28, 0)
Freedom from IVC thrombotic occlusion	99.1% (360, 4)	98.8% (186, 5)	97.5% (94, 7)	97.5% (60, 7)	97.5% (27, 7)
Freedom from new symptomatic deep vein thrombosis	96.5% (350, 15)	93.8% (174, 22)	93.2% (89, 23)	89.4% (54, 26)	89.4% (23, 26)
Freedom from procedure or device related death	99.8% (362, 1)	99.8% (189, 1)	99.8% (98, 1)	99.8% (62, 1)	99.8% (28, 1)
Freedom from access site complications with clinical sequelae	100% (362, 0)	100% (189, 0)	100% (98, 0)	100% (62, 0)	100% (28, 0)
Freedom from filter fracture	100% (362, 0)	100% (189, 0)	100% (98, 0)	98.9% (61, 1[c])	98.9% (27, 1)
Freedom from filter migration >20mm	100% (358, 0)	100% (186, 0)	99.0% (95, 1)	98.0% (58, 2[d])	98.0% (26, 2)

[a] One additional event of clinical perforation occurred after 24 months, for a total of 50 events in the study.

[b] Four (4) additional observations of a filter with a leg >5 mm beyond the column of contrast occurred after 24 months, for a total of 14 observations by the core laboratory.

[c] One (1) filter fracture was reported during a filter retrieval procedure; the retrieval attempt included use of the Günther Tulip Retrieval Set, the loop snare technique, and forceps. A filter strut subsequently embolized to the right ventricle.

[d] Caudal movement of a Celect and Gunther Tulip IVC filter ≥20 mm was observed on 12-month follow-up imaging, without clinical sequelae.

Table 8 – Secondary Measures (% Patients Free from Experiencing Each Event) - Celect Stratum

Endpoint	Kaplan-Meier Estimate (Number of patients at risk, Number of events)				
	3 months	6 months	12 months	18 months	24 months
Freedom from new symptomatic pulmonary embolism while a filter is indwelling	99.6 (256, 1)	99.0% (132, 2)	98.2% (69, 3)	98.2% (40, 3)	98.2% (15, 3)
Freedom from clinical perforation	98.0% (254, 6)	96.4% (131, 10)	89.2% (66, 16)	60.6% (28, 34)	47.1% (11, 38[a])
Freedom from symptomatic filter leg interaction with the IVC	99.7% (257, 1)	99.7% (134, 1)	98.5% (71, 2)	98.5% (42, 2)	98.5% (17, 2)
Freedom from a filter with a 3C (perforating) filter leg	100% (257, 0)	99.6% (133, 1)	99.6% (71, 1)	96.3% (41, 3)	88.1% (17, 5)
Freedom from a filter with a leg >5 mm beyond the column of contrast	99.3% (258, 2)	99.3% (134, 2)	98.0% (70, 3)	91.4% (38, 7)	87.7% (17, 8[b])
Freedom from filter embolization	100% (257, 0)	100% (134, 0)	100% (71, 0)	100% (42, 0)	100% (17, 0)
Freedom from IVC thrombotic occlusion	99.0% (255, 3)	98.6% (131, 4)	96.7% (67, 6)	96.7% (40, 6)	96.7% (16, 6)
Freedom from new symptomatic deep vein thrombosis	96.7% (249, 10)	93.4% (123, 16)	92.6% (63, 17)	89.5% (36, 19)	89.5% (13, 19)
Freedom from procedure or device related death	100% (257, 0)	100% (134, 0)	100% (71, 0)	100% (42, 0)	100% (17, 0)
Freedom from access site complications with clinical sequelae	100% (257, 0)	100% (134, 0)	100% (71, 0)	100% (42, 0)	100% (17, 0)
Freedom from filter fracture	100% (257, 0)	100% (134, 0)	100% (71, 0)	100% (42, 0)	100% (17, 0)
Freedom from filter migration >20mm	100% (254, 0)	100% (132, 0)	100.0% (70, 0)	98.6% (39, 1c)	98.6% (15, 1)

[a] One additional event of clinical perforation occurred after 24 months, for a total of 39 events in the Celect stratum.

[b] Two (2) additional observations of a filter with a leg >5 mm beyond the column of contrast occurred after 24 months, for a total of 10 observations by the core laboratory.

[c] Caudal movement of a Celect IVC filter ≥20 mm was observed on 12-month follow-up imaging, without clinical sequelae.

Table 9 – Secondary Measures (% Patients Free from Experiencing Each Event) - Günther Tulip Stratum

Endpoint	Kaplan-Meier Estimate (Number of patients at risk, Number of events)				
	3 months	6 months	12 months	18 months	24 months
Freedom from new symptomatic pulmonary embolism while a filter is indwelling	99.3% (104, 1)	99.3% (55, 1)	99.3% (27, 1)	99.3% (20, 1)	99.3% (11, 1)
Freedom from clinical perforation	99.2% (104, 1)	99.2% (55, 1)	88.4% (24, 4)	59.8% (10, 11)	59.8% (5, 11)
Freedom from symptomatic filter leg interaction with the IVC	100% (105, 0)	100% (55, 0)	100% (27, 0)	100% (20, 0)	100% (11, 0)
Freedom from a filter with a 3C (perforating) filter leg	100% (105, 0)	100% (55, 0)	100% (27, 0)	100% (20, 0)	100% (11, 0)
Freedom from a filter with a leg >5 mm beyond the column of contrast	100% (106, 0)	100% (56, 0)	100% (27, 0)	92.6% (18, 2)	92.6% (10, 2[a])
Freedom from filter embolization	100% (105, 0)	100% (55, 0)	100% (27, 0)	100% (20, 0)	100% (11, 0)
Freedom from IVC thrombotic occlusion	99.3% (105, 1)	99.3% (55, 1)	99.3% (27, 1)	99.3% (20, 1)	99.3% (11, 1)
Freedom from new symptomatic deep vein thrombosis	96.2% (101, 5)	94.6% (51, 6)	94.6% (26, 6)	89.6% (18, 7)	89.6% (10, 7)
Freedom from procedure or device related death	99.3% (105, 1)	99.3% (55, 1)	99.3% (27, 1)	99.3% (20, 1)	99.3% (11, 1)
Freedom from access site complications with clinical sequelae	100% (105, 0)	100% (55, 0)	100% (27, 0)	100% (20, 0)	100% (11, 0)
Freedom from filter fracture	100% (105, 0)	100% (55, 0)	100% (27, 0)	96.3% (19, 1[b])	96.3% (10, 1)
Freedom from filter migration >20mm	100% (104, 0)	100% (54, 0)	96.3% (25, 1[c])	96.3% (19, 1)	96.3% (11, 1)

[a] Two (2) additional observations of a filter with a leg >5 mm beyond the column of contrast occurred after 24 months, for a total of 4 observations by the core laboratory.

[b] One (1) filter fracture was reported during a filter retrieval procedure; the retrieval attempt included use of the Günther Tulip Retrieval Set, the loop snare technique, and forceps. A filter strut subsequently embolized to the right ventricle.

[c] Caudal movement of a Gunther Tulip IVC filter ≥20 mm was observed on 12-month follow-up imaging, without clinical sequelae.

8.1.5 Study Conclusions and Strengths/ Limitations

The CIVC Study provides safety and effectiveness data for up to two years of follow-up on 473 subjects treated with Celect or Günther Tulip vena cava filters. This large, multicenter study was intended to address FDA questions related to observed safety events for IVC filters.

The prespecified analysis for the primary safety endpoint was hindered by extensive censoring due largely to IVC filter retrieval, and less so due to patient death and subject lost-to-follow-up. The post-hoc analysis provided a clinically meaningful reflection of the primary safety rate. The 12-month freedom from MAE rate was 81.5%, with a lower 95% confidence interval of 72.6%, failing to meet the performance goal of 80%. The post-hoc primary safety endpoint rate was 86.7% (281/324).

The primary effectiveness endpoint rate was 97.8% (317/324) and met the prespecified performance goal of 90%. Of note, the 12-month rate of freedom from new symptomatic PE was 96.6% (85/88) and contributed to the primary effectiveness outcome.

The CIVC Study results largely confirm previously reported expected rates for filter complications, including filter embolization, clinically significant perforation, new DVT, IVC thrombotic occlusion, and SAEs.

8.2 Cook Celect Vena Cava Filter Single Arm Study

The Celect Platinum Vena Cava Filter is supported by results from a prospective, single-arm, multicenter, international study conducted to assess the safety and performance of the Cook Celect Vena Cava Filter as both a permanent and retrievable filter. The results from this study suggest probable clinical results for the successful retrieval of the Celect Platinum Vena Cava Filter. Refer to Lyon et al. (2009) in **Section 11, REFERENCES** for more regarding the retrievability portion of the study described herein.

The primary study endpoint was the composite rate of major adverse events (MAE), defined as: hemorrhage, perforation (i.e., protrusion of filter struts through the wall of the IVC causing hemorrhage or hematoma); PE; procedure-related death; IVC occlusion; significant migration (i.e., migration >20 mm); and filter fracture. An independent Clinical Events Committee (CEC) was used to adjudicate adverse events and a Data Safety Monitoring Board provided study oversight of patient safety.

In total, 129 patients with a high risk of pulmonary thromboembolism (pulmonary embolism; PE) were enrolled at six clinical study sites. Registry A included 34 patients with a permanent need for an IVC filter (10 men; mean age of 52 ± 19 years) and Registry B included 95 patients with a temporary need for an IVC filter (61 men; mean age: 51 ± 19 years). The primary reason for IVC filter placement in Registry A was evidence of PE or deep vein thrombosis (DVT) and a contraindication, complication, or failure of anticoagulation (n=18) or massive PE with residual DVT and risk for further PE (n=12). The primary reasons for IVC filter placement in Registry B were evidence of PE or DVT and a contraindication, complication, or failure of anticoagulation (n=40), high-risk (n=29; e.g., immobilized, prophylactic preoperative placement), and severe trauma without documented PE or DVT, with a closed head injury, spinal cord injury, or multiple long bone pelvic fractures (n=23).

Patients were followed up at 30 days, 3 months, 6 months, and 12 months. Patients in Registry B maintained the same follow-up schedule until filter retrieval (which was attempted when deemed clinically appropriate); subsequent to filter retrieval, patients in Registry B were followed at 3 months post-retrieval.

All filters (n=129) were successfully placed. Two placement procedures were associated with deployment difficulties and were subsequently repositioned and deployed in the correct location without complication: one was attributed to malfunction of the introducer (n=1) and the other to sheath movement resulting in a suboptimal deployment position (n=1). Significant tilt (i.e., tilt >15°) was observed in six patients based on venographic images taken after filter placement.

Among patients in Registry A, the MAE rate was 3% (1/34); one patient experienced a PE. Among patients in Registry B, the MAE rate was 2.1% (2/95); two patient deaths were CEC adjudicated as potentially device-related, one was within 24 hours of the procedure and one was associated with a recurrent PE. Two events of vascular injury were reported: a non-occlusive thrombus of the left external iliac vein and leg ulcers with edema. There were no reports of access site complications, filter fracture, filter embolization, significant filter migration, or IVC occlusion in this study.

Filter retrieval was attempted in 58 patients (mean indwell time to attempted retrieval: 185.6 days; range 5-466 days). Based on venographic imaging at retrieval, no IVC perforations were noted and 21 cases of IVC penetration (i.e., transmural incorporation) were noted; there were no patient-reported symptoms (e.g., pain). Among the 58 patients with imaging data at placement and retrieval, five had observations of significant tilt at placement and two had observations of significant tilt at retrieval. Fifty-six (56) retrievals (96.6%) were successful (mean indwell time for successful retrievals: 179 days; range 5-466 days). The two unsuccessful retrievals were attributed to

an inability to capture the filter hook due either to excessive filter tilt (360 days) or to tissue growth causing the hook to become embedded in the endothelium (without tilt; 385 days), respectively. There were no MAEs associated with the filter retrieval procedure. A Kaplan-Meier product limit estimate (see **Table 10** below) indicates the estimated probability of successful retrieval of the Cook Celect Filter based on the study data; the probability of successful retrieval remains at 100% at up to 50 weeks post-implant and at 75% after 55 weeks post-implant.

Table 10 – Estimated Probability of Successful Retrieval Cook Celect Filter

Filter Indwell Time Weeks	Kaplan-Meier Estimated Probability of Successfully Retrieving the Celect Filter	Standard Error
0	100%	0.00
4	100%	0.00
12	100%	0.00
26	100%	0.00
52	90%	0.09
60	75%	0.16

9. INSTRUCTIONS FOR USE

The product is intended for use by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for placement of vascular access sheaths, angiographic catheters, and wire guides should be employed. It is assumed that the operator will use local anesthesia, sedation, and analgesia as required.

9.1 Preparation

1. Flush the introducer sheath and the introducer dilator.
2. Advance the introducer dilator through the middle of the Check-Flo® valve on the introducer sheath. Secure the introducer dilator to the introducer sheath by twisting the dilator hub clockwise until a click is felt. (**Fig. 2**)
3. Remove the filter protection tube. (**Fig. 3**)

9.2 Filter Placement

4. Access the chosen femoral vein using the Seldinger technique.
5. Perform diagnostic imaging to confirm a single IVC, measure the IVC diameter, check for thrombus, and establish the position of the renal veins.
6. Place a supportive 0.035 inch wire guide in the IVC.
7. If necessary, dilate the puncture site with the 10 French pre-dilator.
8. Remove the pre-dilator and advance the coaxial introducer system over the wire guide until the tip of the introducer sheath lies approximately 1 cm caudal to the lowest renal vein.
9. Remove the wire guide.
10. Perform diagnostic imaging to verify the position of the introducer sheath tip (or radiopaque marker) approximately 1 cm caudal to the lowest renal vein.

    CAUTION: Before injecting contrast media by either power or hand injection through the introducer dilator, ensure that the introducer sheath hub and introducer dilator are correctly connected.

    WARNING: When using a power injector, do not exceed the maximum pressure rating of 68 bar/1000 psi and flow rate of 20 mL/sec.
11. When correct position is established, twist the introducer dilator hub counterclockwise and remove the introducer dilator. (**Fig. 4**)
12. Place the preloaded filter into the Check-Flo valve of the introducer sheath. (**Fig. 5**)

    WARNING: Hold the filter introducer near the end, close to the filter, to avoid kinking the flexible tip.
13. Advance the filter introducer until the Check-Flo valve contacts the tactile bump on the filter introducer. This will place the hook of the filter inside the introducer sheath at the radiopaque band. Verify that the position of the hook is inside the introducer sheath and still caudal to the renal veins.

WARNING: Do not rotate the preloaded filter inside the introducer system.

WARNING: Do not exert excessive force to advance the filter through the introducer system.

14. Stabilize the filter introducer, withdraw the introducer sheath, (**Fig. 6**) and connect it to the handle of the femoral introducer. (**Fig. 7**) At this point the filter is expanded, still connected to the filter introducer. (**Fig. 8**)

    CAUTION: Attempting to retract the filter at this point of the deployment sequence could damage the secondary legs or caval wall.

15. Proper position can now be verified by diagnostic imaging.

    WARNING: Do not rotate the expanded filter inside the vena cava. Doing so may compromise the performance of the filter.

    CAUTION: Injection of contrast medium must not be performed unless the femoral cup (indicated as position d in Fig. 1) of the filter is completely free of the introducer sheath. Use the radiopaque band for positioning.

16. Verify that the introducer sheath hub and femoral introducer handle are connected to ensure that the femoral cup is completely free of the introducer sheath before filter release.
17. When the filter position is correct, push the red safety button to prepare filter release. (**Fig. 9**)
18. Push the release button completely to ensure proper release of the filter. (**Fig. 10**) Repositioning of the filter is no longer possible. The filter is now released.
19. Perform diagnostic imaging to verify filter position.

    NOTE: Hospital standard of care should be followed for removing the introducer sheath and providing hemostasis to prevent bleeding at the vascular access site.

9.3 Optional Retrieval Procedure

The Celect Platinum Filter implant may be retrieved. The filter was designed to be retrieved with the Günther Tulip Vena Cava Filter Retrieval Set. It may also be retrieved with the CloverSnare Vascular Retriever. Please refer to the Instructions for Use provided with the Günther Tulip Vena Cava Filter Retrieval Set or the CloverSnare Vascular Retriever (not included in the filter set).

10. HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Do not resterilize. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Keep the device dry and away from sunlight. Upon removal from package, inspect the product to ensure no damage has occurred.

11. REFERENCES

These instructions for use are based on experience from physicians and/or their published literature, IVC filter guidelines, ISO 25539-3, and regulatory safety communications regarding IVC filters. Refer to your local Cook sales representative for information on available literature.

Recommendations related to filter follow-up and retrieval:

- Lyon et al. Short- and long-term retrievability of the Celect vena cava filter: results from a multi-institutional registry. J Vasc Interv Radiol. 2009 Nov;20(11):1441-8.
- Kaufman JA, Barnes GD, Chaer RA, et al. Society of Interventional Radiology clinical practice guideline for inferior vena cava filters in the treatment of patients with venous thromboembolic disease: developed in collaboration with the American College of Cardiology, American College of Chest. J Vasc Interv Radiol. 2020;31(10):1529-1544.
- ARC-SIR-SPR 2021 practice guideline for the performance of inferior vena cava (IVC) filter placement for the prevention of pulmonary embolism. Published online 2021:1-17.
- ISO 25539-3:2011 "Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters".
- Removing Retrievable Inferior Vena Cava Filters: FDA Safety Communication; Issued May 6, 2014.
- Retrievable inferior vena cava (IVC) filters - serious complications associated with attempted IVC filter retrieval. MHRA Medical Device Alert; Issued May 2, 2013.

Filter retrieval is a patient specific, clinically complex decision; the decision to remove a filter should be based on each patient's individual risk/benefit profile (e.g., a patient's continued need for protection from PE compared to their experience with and/or ongoing risk of experiencing filter-related complications). For all retrievable IVC filters, retrieval becomes more challenging with time, and this is commonly due to encapsulation of the filter legs or hook (in a tilted filter) by tissue ingrowth.

The following references include descriptions of alternative techniques for filter retrieval. **The safety or effectiveness of these alternative retrieval techniques has not been established**. Use of these techniques varies according to physician experience, patient anatomy, and filter position.

- Al-Hakim et al. The hangman technique: a modified loop snare technique for the retrieval of inferior

vena cava filters with embedded hooks. J Vasc Interv Radiol. 2015; 26(1):107-10.
- Cho et al. Failed inferior vena cava filter retrieval by conventional method: Analysis of its causes and retrieval of it by modified double-loop technique. Phlebology. 2015; 30(8):549-56.
- Foley et al. A "fall-back" technique for difficult inferior vena cava filter retrieval. J Vasc Surg. 2012; 56(6):1629-33.
- Kuo et al. Excimer laser-assisted removal of embedded inferior vena cava filters: a single-center prospective study. Circ Cardiovasc Interv. 2013; 6(5):560-6.
- Stavropoulos et al. Retrieval of Tip-embedded Inferior Vena Cava Filters by Using the Endobronchial Forceps Technique: Experience at a Single Institution. Radiology. 2015; 275(3):900-7.

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