COOK MEDICAL

CE 0088

Cook Celect® Platinum Vena Cava Filter Set for Femoral Vein Approach

Instructions for Use

PATIENT I.D. CARD INCLUDED

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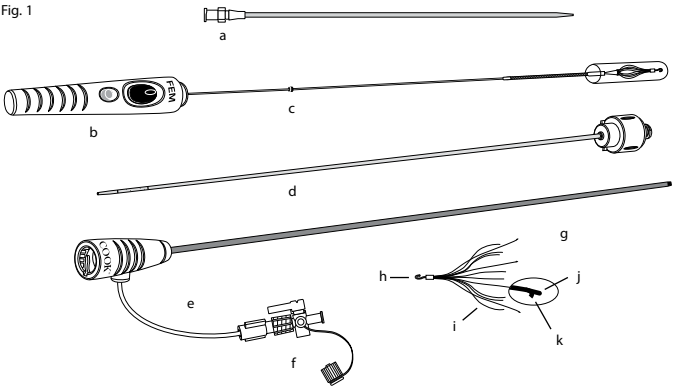
425-01

Fig. 1



a. Dilator Radiopaque hydrophilically coated 10.0 Fr, 20 cm long
b. Femoral preloaded filter introducer with flexible tip
c. Tactile Bump
d. Coaxial Introducer Sheath System Radiopaque introducer sheath, 7.0 Fr, 65 cm long, with radiopaque band and radiopaque introducer dilator with 2 radiopaque markers at the distal end
e. Check-Flo Valve
f. Three-way Stopcock Plastic
g. Cook Celect® Platinum Vena Cava Filter (supplied preloaded)
h. Hook
i. Primary Legs
j. Platinum markers
k. Anchors

Fig. 2

Fig. 3

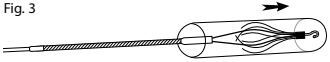


Fig. 4

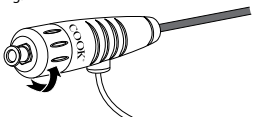


Fig. 5

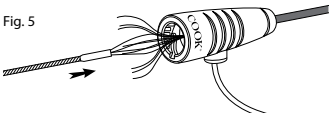


Fig. 6

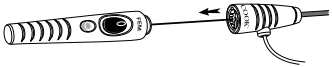


Fig. 7

Fig. 8

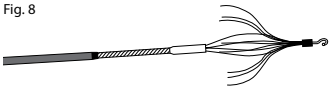


Fig. 9

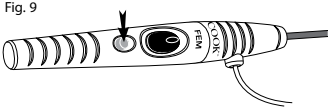
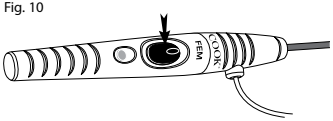


Fig. 10



COOK CELECT® PLATINUM VENA CAVA FILTER SET - FOR FEMORAL VEIN APPROACH

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEVICE DESCRIPTION

The Cook Celect Platinum Filter Set consists of a paramagnetic filter (30 mm diameter, 49 mm long) with platinum markers, preloaded on a femoral filter introducer with a flexible tip, a 7.0 Fr coaxial introducer system (compatible with a .035 inch wire guide) and a hydrophilically coated 10.0 Fr pre-dilator. The introducer dilator has 8 sideports and two radiopaque markers 30 mm apart (end-to-end).

INTENDED USE

The Cook 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 Cook Celect Platinum Filter implant may be retrieved. Please refer to the Instructions for Use provided with the Günther Tulip Vena Cava Retrieval Set (not included in the filter set).

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

CONTRAINDICATIONS

Filter Placement

- Megacava (diameter of the IVC > 30 mm).
- Diameter of the IVC < 15 mm.
- Extensive thrombus in the vein chosen for approach.
- Vena Cava filters should not be implanted in patients with risk of septic embolism due to the risk of infection. The decision should be based on the patient's individual risk/benefit profile.

Optional Filter Retrieval

- Retrieval of the filter with significant amounts of trapped thrombus (greater than 25% of the volume of the cone).
- Retrieval of the filter for patients with an on-going high risk for PE.

WARNINGS

Filter Placement

- Manipulation of products requires imaging control.
- When injecting contrast media, do not exceed maximum pressure rating of 1000 psi and flowrate of 20 ml/sec. Hand injection is also possible.
- **When placing the premounted filter via the femoral approach into the Check-Flo® valve of introducer sheath, hold the introducer with flexible tip near the end, close to the filter, to avoid kinking of the flexible tip.**
- Do not rotate the preloaded filter inside the introducer system.
- **Excessive force should not be exerted to place filter.** If severe resistance is met when advancing the wire guide, then retract the wire guide and choose a different approach.

Optional Filter Retrieval

- **Excessive force should not be exerted to retrieve the filter.**
- An inferior vena caval evaluation for residual captured thrombus should be performed prior to attempted retrieval.
- Available data from retrievals in a prospective, multicenter study demonstrate that the device can be safely retrieved. Please **refer to the Clinical Studies** section of this booklet for clinical study references to the retrieval of this filter.

PRECAUTIONS

- Possible allergic reactions should be considered.
- 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.

Filter Placement

- For placement of the filter, the right femoral vein is usually preferred due to the 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, anatomy and the location of the venous thrombosis.
- The filter for femoral vein approach is supplied preloaded on the filter introducer. Do not separate the preloaded filter introducer assembly to view or examine the components.
- Do not attempt to reload the filter onto the filter introducer. Any attempt to do so may damage the introducer or the filter.

- Before any injection of contrast media through the sheath, ensure that the sheath hub and handle are connected, or confirm by diagnostic imaging of the sheath tip (or radiopaque marker).
- Once the metal mount point is past the tip of the sheath, the secondary legs of the filter are expanded. The filter may be repositioned only by advancing the filter; retracting the filter could damage the secondary legs or caval wall.

Optional Filter Retrieval

- For filter retrieval, a right jugular vein approach is preferable. An approach via the left jugular vein is possible; however no data are available demonstrating the safety or effectiveness of filter retrieval via the left jugular vein.
- The filter has been designed to be retrieved with the Günther Tulip Vena Cava Filter Retrieval Set, (not included in the filter set). Cook has not performed testing to evaluate the safety or effectiveness of filter retrieval using other retrieval systems.
- Never re-deploy a retrieved filter.
- The decision to remove a filter should be based on the patient's individual risk/benefit profile. Retrieve the filter when feasible and clinically indicated.

MRI INFORMATION

Non-clinical testing has demonstrated that the Cook Celect Filter is MR Conditional according to ASTM F2503. The MR safety testing conducted on the Cook Celect filter is considered sufficient to support the MR safety of the Celect Platinum filter. A patient with this filter can be scanned safely after placement under the following conditions.

- Static magnetic field of 3.0 Tesla or 1.5 Tesla.
- Maximum spatial magnetic gradient of 1600 Gauss/cm (16.0 T/m) or less.
- Normal operating mode.
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning or less (i.e., per scanning sequence).

Static Magnetic Field

The static magnetic field for comparison to the above limits is the static magnetic field that is pertinent to the patient (i.e., outside of scanner covering, accessible to a patient or individual).

MRI-Related Heating

1.5 Tesla Temperature Rise

In non-clinical testing, the Cook Celect Filter produced a maximum temperature change of 3.7°C during 15 minutes of MRI (i.e., for one scanning sequence) performed in a 1.5 Tesla MR System (1.5 Tesla/64 MHz,Siemens Magnetom Avanto, NUMARIS/4 syngo MR B17 DHHS) at an MR system reported whole body averaged SAR of 2.05 W/kg (associated with a calorimetry measured whole body averaged value of 1.75 W/kg).

3.0 Tesla Temperature Rise

In non-clinical testing, the Cook Celect Filter produced a maximum temperature change of 4.2°C during 15 minutes of MRI (i.e., for one scanning sequence) performed in a 3.0 Tesla MR System (3.0 Tesla/128 MHz, Siemens Magnetom Trio, A Tim System, NUMARIS/4 syngo MR B17 DHHS) at an MR system reported whole body averaged SAR of 2.08 W/kg (associated with a calorimetry measured whole body averaged value of 1.71 W/kg).

Image Artifacts

MR image quality may be compromised if the area of interest is within approximately 21 mm of the position of the Cook Celect Filter as found during non-clinical testing using T1-weighted, spin echo and gradient echo pulse sequence in a 3.0 Tesla MR system (Excite, General Electric Healthcare, Milwaukee, WI). Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic filter.

For US Patients Only

Cook recommends that the patient register the MR conditions disclosed in this IFU with the MedicAlert Foundation. The MedicAlert Foundation can be contacted in the following manners:

Mail:	MedicAlert Foundation International 2323 Colorado Avenue, Turlock, CA 95382
Phone:	888-633-4298 (toll free) 209-668-3333 from outside the US
Fax:	209-669-2450
Web:	www.medicalert.org

POTENTIAL ADVERSE EVENTS

- Damage to the vena cava
- Pulmonary embolism
- Filter embolization
- Vena cava perforation/penetration
- Vena cava occlusion or thrombosis
- Hemorrhage
- Hematoma at vascular access site
- Infection at vascular access site
- Cardiac tamponade
- Filter malpositioning
- Postphlebitic syndrome
- Death

CLINICAL STUDIES

Previously published clinical studies for the Celect filter suggest probable clinical results for the successful retrieval of the Celect Platinum filter.

A prospective, international multicenter registry study to assess the safety, performance, and retrieval of the Cook Celect Filter in patients with a high risk of pulmonary thromboembolism (PE) was conducted. There were 28 female and 46 male patients enrolled. The average age of patients was 50 ± 20 years (range: 18 to 89 years). Indications for placement were: contraindication, complication or failure of anticoagulation with PE or DVT (n=26), severe trauma without PE or DVT (n=18), high-risk patients for PE or DVT (n=17), massive PE with DVT at risk for further PE (n=10), severe cardio-pulmonary disease and DVT (n=2), free-floating iliofemoral or IVC thrombus (n=1). Leading comorbidities for patients enrolled in this study included trauma (43%), current DVT (37%), current PE (37%), and pulmonary disease (24%).

The implantation procedure was uneventful, with filters successfully placed in a satisfactory location in all 74 patients. In one patient, a malfunction of the introducer resulted in a minor filter tilt of 6-10 degrees. In one patient, the filter was initially deployed in the right gonadal vein. The filter was snared and repositioned to the desired location within the IVC.

In the 74 patient cohort, follow-up was conducted at 1 month (60 of 69 possible patients), 3 months (50 of 58 possible patients) and 6 months (37 of 41 possible patients) consisting of clinical exam and imaging by X-ray and duplex ultrasound. No device related major adverse events (defined as hemorrhage, perforation, death, occlusion, filter fracture or significant filter migration) have occurred. X-ray imaging has not detected filter migration greater than 20 mm in any patient. Imaging by X-ray and duplex ultrasound has revealed no evidence of vena cava perforation. There have been 8 deaths (occurring from 1 to 295 days post-implant) that the independent Clinical Events Committee adjudicated 6 as not related to the device or the procedure; one death was attributed to pulmonary embolism adjudicated as device- or procedure-related, and one death was adjudicated as procedure-related.

Retrieval

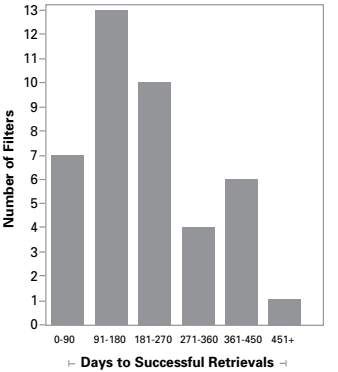
A later analysis on a subset of patients with intent to retrieve the filter was conducted.

Forty-three patients (12 female, 31 male) had retrieval attempts, and forty-one retrievals were successful.

Two filters were not retrieved (360 and 385 days following insertion) because the retrieval snare could not engage the filter hook that was embedded in tissue growth at the vena caval wall.

Time to retrieval ranged from 1-67 weeks.

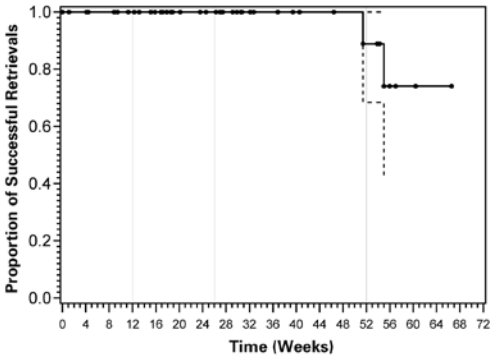
The following is a histogram of the days to successful retrieval for the forty-one patients, with the longest successful retrieval at 466 days after implant.



A Kaplan-Meier analysis predicts an 89% probability of a successful retrieval at 52 weeks (see following graph).

No adverse events relating to the filter retrieval procedure were reported in the retrieval group demonstrating the safety of filter retrieval in patients who no longer require a vena cava filter.

The following graph presents the Kaplan-Meier Analysis of Filter Retrieval Success showing the 95% Confidence Bounds.



INSTRUCTIONS FOR USE

Femoral Approach

General

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.

Preparation

1. Flush the introducer sheath and 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 (**Fig. 2**).
3. Remove the filter protection tube (**Fig. 3**).

Filter Placement

4. Access the chosen femoral vein using the Seldinger technique.
5. If the IVC anatomy is known from recent imaging, then proceed directly to filter placement.
6. If the IVC anatomy (i.e., dimensions and morphology) is not known, perform imaging to confirm a single IVC, measure the IVC diameter, check for thrombus, and establish the position of the renal veins.
7. Place a supportive .035 inch wire guide in the IVC.
8. If necessary, dilate the puncture site with the 10.0 Fr pre-dilator.
9. Remove the dilator and advance the coaxial introducer sheath system over the wire guide until the tip of the sheath lies just caudal to the renal veins.
10. Remove the wire guide.
11. Using either power or hand injection, perform diagnostic imaging to verify position below (caudal to) the renal veins.

    WARNING: When using a power injector, do not exceed maximum pressure rating of 1000 psi and flow rate of 20 ml/sec.

    WARNING: Before injecting contrast media through the introducer dilator, ensure that the sheath hub and handle are correctly connected, or confirm by diagnostic imaging of the sheath tip (or radiopaque marker).
12. When correct position is established, remove the introducer dilator by twisting the dilator hub counterclockwise (**Fig. 4**).
13. When placing the premounted filter via the femoral approach into the Check-Flo valve of introducer sheath, hold the delivery catheter near the end, close to the filter, to avoid kinking the flexible tip (**Fig. 5**).

    WARNING: Do not rotate the preloaded filter inside the introducer system.
14. Advance the filter introducer until the Check-Flo valve contacts the tactile bump. This will place the hook of the filter inside the sheath at the radiopaque band. Verify that the position of the hook is inside the introducer sheath and still below the renal veins (**Fig. 6**).

    WARNING: Excessive force should not be exerted to advance the filter through the delivery system.

15. Stabilize the introducer, and withdraw the introducer sheath and connect it to the handle. At this point the filter is expanded, still connected to the filter introducer (**Figs. 7** and **8**).

    WARNING: Repositioning is possible only by advancing the filter; retracting the filter could damage the secondary legs or the caval wall.
16. Proper position can now be verified by diagnostic imaging.

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

    CAUTION: Filter release or injection of contrast medium must not be made unless the metal mounting point is completely free of the sheath. Use the radiopaque band for positioning.
17. Verify that the sheath hub and handle are connected to ensure that the metal mounting point is completely free of the sheath before filter release.
18. When the filter position is correct, push the red safety button to prepare filter release (**Fig. 9**).
19. To release the filter, push the release button completely to ensure proper release of filter. Repositioning of the filter is no longer possible. The filter is now released (**Fig. 10**).
20. Perform diagnostic imaging to verify filter position, and then withdraw the introducer sheath.

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

Optional Retrieval Procedure

NOTE: The Cook Celect Platinum Filter implant may be retrieved. Please refer to the Instructions for Use provided with the Günther Tulip Vena Cava Retrieval Set (not included in the filter set).

HOW SUPPLIED

Supplied sterilized by ethylene oxide gas in peel-open packages. Intended for one-time use. Sterile if package is unopened or undamaged. Do not use the product if there is doubt as to whether the product is sterile. Store in a dark, dry, cool place. Avoid extended exposure to light. Upon removal from package, inspect the product to ensure no damage has occurred.

REFERENCES

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Cook sales representative for information on available literature.

Manufacturer
WILLIAM COOK EUROPE ApS
Sandet 6, DK-4632
Bjaeverskov, DENMARK

www.cookmedical.com