

COOK® Celect® Filter Set For Femoral Vein Approach

Instructions for Use

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COOK®



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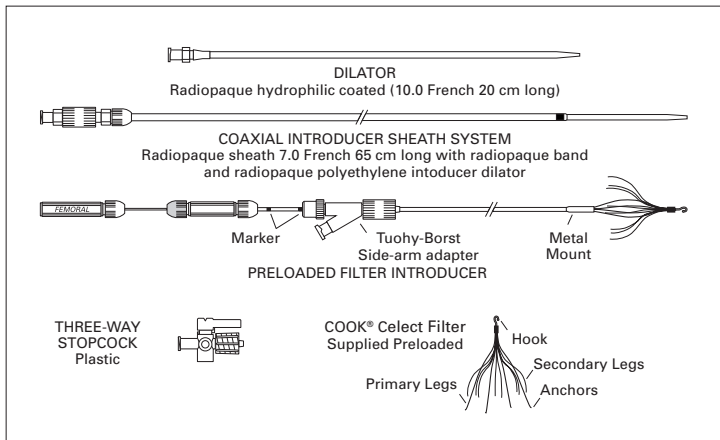
Cook® Celect® Filter Set

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 Celect Filter consists of a non-magnetic filter (30 mm diameter, 48 mm long) preloaded on a femoral filter introducer, an 8.5 French coaxial introducer system (compatible with a .035 inch wire guide) for introduction and a hydrophilic-coated dilator.



INTENDED USE

The Celect Filter 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 pulmonary embolism where anticipated benefits of conventional therapy are reduced; and
- Chronic, recurrent pulmonary embolism where anticoagulant therapy has failed or is contraindicated.

The Cook Celect Vena Cava Filter may be retrieved according to the instructions supplied in the section labeled "Optional Retrieval Procedure."

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

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.

CONTRAINDICATIONS

Filter Placement

- Megacava (diameter of the IVC > 30 mm).
- Diameter of the IVC < 15 mm.
- Vena cava filters should not be implanted in patients with risk of septic embolism.

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 pulmonary embolism.

WARNINGS

Filter Placement

- Manipulation of products requires fluoroscopic control.
- Do not rotate the pre-loaded filter inside the introducer system.
- Excessive force should not be used to place the filter.

Optional Filter Retrieval

- Excessive force should not be used to retrieve the filter.
- An inferior vena cavagram evaluation for residual captured thrombus should be performed prior to attempted retrieval.
- Available data from retrievals in multicenter and single center studies 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.

Femoral Filter Placement

- For placement of the filter, the right femoral vein is preferable. An approach via the left femoral vein is possible.
- 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.
- Any attempt to reload may damage the introducer or filter.
- Use the radiopaque band of the sheath to ensure that the filter is completely out of the sheath before injection of contrast medium in the vena cava, and at the same time ascertain that the sheath and the Tuohy-Borst side-arm adapter are withdrawn to the proximal marker on the filter introducer.
- Once the metal mount point is past the radiopaque marker, 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, there are no available data which demonstrate 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).
- Cook has not performed testing to evaluate the safety or effectiveness of filter retrieval using other retrieval systems.
- Never re-deploy a retrieved filter.

MR COMPATIBILITY

Non-clinical testing has demonstrated that the Cook Celect Vena Cava Filter is MR Conditional. It can be scanned safely immediately after placement under the following conditions:

- Static magnetic field of 3.0 Tesla or less
- Spatial gradient field of 330 Gauss/cm or less
- Maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of scanning.

In non-clinical testing, the Cook Celect Vena Cava Filter produced a temperature rise of less than 0.2 degrees C at a maximum whole body averaged specific absorption rate (SAR) of 2.0 W/kg for 15 minutes of MR scanning in a 3.0 Tesla MR system using a transmit/receive body coil MR scanner. MR image quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Cook Celect Vena Cava Filter. Therefore, it may be necessary to optimize MR imaging parameters for the presence of this metallic implant.

POTENTIAL ADVERSE EVENTS

- Damage to the vena cava
- Pulmonary embolism
- Filter embolization
- Vena cava perforation
- Vena cava occlusion or thrombosis
- Hemorrhage
- Hematoma at vascular access site
- Infection at vascular access site
- Death

CLINICAL STUDIES

Placement

A prospective, international multicenter registry study to assess the safety, performance, and retrieval of the Cook Celect Vena Cava 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

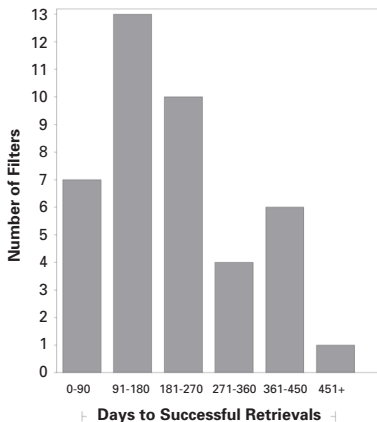
A later analysis on a subset of patients with intent to retrieve the filter was conducted.

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.

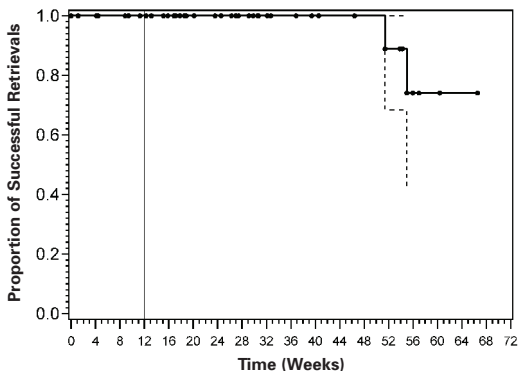
A histogram of the days to successful retrieval for the forty-one patients is presented below, with the longest successful retrieval at 466 days after implant.



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

Fig. 1



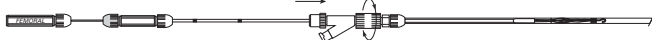
1. Remove the filter protection tube. (Fig. 1)
2. Puncture the femoral vein using the Seldinger technique.
3. Over the wire guide, dilate the puncture site with the dilator. Remove the dilator.
4. Advance the coaxial introducer sheath system over the wire guide.
5. Remove the wire guide and introducer dilator.
6. With a hand injection, perform cavography to verify position below (caudal to) the renal veins.

Fig. 2



7. Place the filter introducer with the pre-mounted filter into the hub of the introducer sheath and advance it into the sheath. (Fig. 2)

Fig. 3



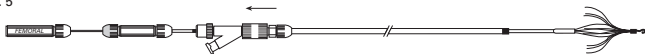
8. Advance the Tuohy-Borst side-arm adapter to connect it to the sheath. (Fig. 3) The Tuohy-Borst adapter can be tightened around the filter introducer to prevent loss of blood.

Fig. 4



9. Advance the filter introducer until the distal marker reaches the Tuohy-Borst side-arm adapter. This will place the hook of the filter inside the sheath at the radiopaque band. Verify position of the hook inside the sheath (Fig. 4), still below the renal veins.

Fig. 5



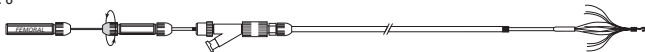
10. When correct position has been verified, withdraw the sheath, including the Tuohy-Borst side-arm adapter, until the proximal part of the adapter reaches the proximal marker on the filter introducer. This ensures the metal mounting point and filter are completely free of the sheath. Tighten the Tuohy-Borst side-arm adapter to secure position. (Fig. 5) Proper position can now be verified by injection of contrast medium.

WARNING: The pre-exposed filter can be advanced, but never pulled back into the sheath; doing so will damage the shape of the filter.

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.

Fig. 6



11. Loosen the red hub half a turn to prepare filter release. (Fig. 6)
12. Keep the filter introducer in position by holding the proximal pin vise. Preparation for filter release is now complete. Check again the proximal marker on the filter introducer and the radiopaque band to ensure that the metal mounting point is completely free of the sheath before filter release.

Fig. 7

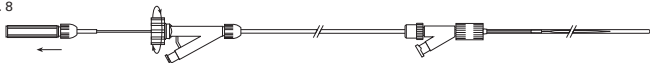


13. To release the filter, in one quick controlled motion pull the red hub until it contacts the pin vise. The filter is now released. (Fig. 7)
14. Perform a cavagram to verify filter position, then withdraw the entire system.

Optional Retrieval Procedure

NOTE: If filter retrieval is going to be performed, please refer to Instructions For Use provided with the Günther Tulip Vena Cava Filter Retrieval Set (not included) for device description and caution statement.

Fig. 8



1. Hold the clear Y-fitting and pull back the plastic pin vise on the wire loop retriever to cover the loop. Tighten the screw of the clear Y-fitting to keep the loop inside the catheter. (Fig. 8)
2. Puncture the right jugular vein using the Seldinger technique.
3. Position a flush catheter inferior to the filter, and perform a diagnostic vena cavagram to identify any residual thrombus.
4. Exchange the flush catheter for the coaxial retrieval sheath system, advancing it over the wire guide.

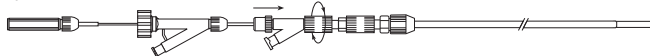
WARNING: If more than 25% of the cone is filled with thrombus, do not remove the filter.

Fig. 9



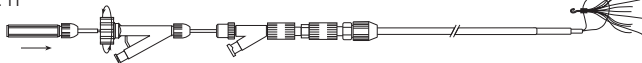
5. Remove the red inner dilator and the wire guide. Verify the position by injection of contrast medium. (Fig. 9)

Fig. 10



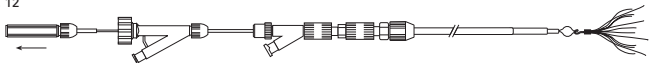
6. Introduce the retrieval loop system through the coaxial retrieval sheath system, advance and connect the white Tuohy-Borst sidearm adapter of the loop system to the sheath system. The Tuohy-Borst adapter can be tightened around the catheter to prevent loss of blood. (Fig. 10)

Fig. 11



7. Loosen the screw of the clear Y-fitting to advance the loop inside the catheter. Hold the clear Y-fitting and push forward the pin vise. Advance until the loop has fully expanded inside the vena cava and surrounds the filter. (Fig. 11)

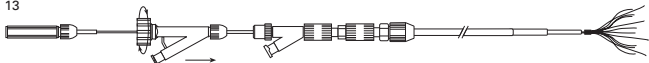
Fig. 12



8. Pull back the loop until it engages the hook of the filter. (Fig. 12)

CAUTION: Do not pull on the filter beyond what is required to keep tension on the loop. Doing so may cause damage to the caval wall.

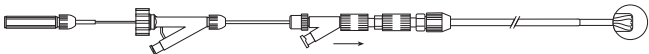
Fig. 13



9. Hold the loop wire steady with the pin vise, then push the clear Y-fitting with the catheter forward until it touches the hook. To snare the filter in this position make sure to firmly lock the screw of the clear Y-fitting on the wire loop. (Fig. 13)

NOTE: If the retrieval wire loop loses its shape during the attempt to engage the hook of the filter, it can be removed and gently reshaped. After reshaping, clean loop and proceed from step 6.

Fig. 14



10. While holding steady the retrieval loop system with the clear Y-fitting, push forward the white Tuohy-Borst sidearm adapter with the coaxial retrieval system. The filter collapses and the anchors disengage from the caval wall. (Fig. 14)

Fig. 15



11. When the tip of the coaxial retrieval system is at the anchors, loosen the hub of the outer sheath, and advance the outer sheath forward to cover the whole filter, and retrieve the complete assembly. (Fig. 15)

POST-RETRIEVAL CARE

After retrieval of filter, hospital standard of care should be followed for removing the sheath and providing hemostasis to prevent bleeding at the vascular access site.

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.

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