COOK®
MEDICAL

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

Instructions for Use

PATIENT I.D. CARD INCLUDED

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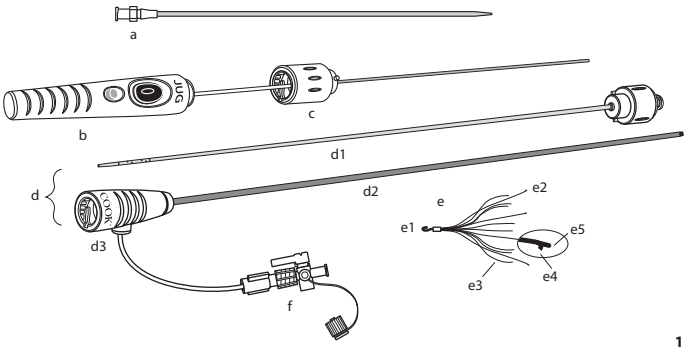
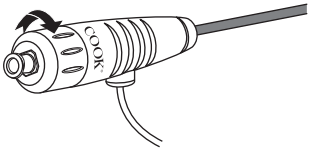
427-04EN



1

a. Pre-dilator, radiopaque, with hydrophilic coating, 10 French, 20 cm long
b. Jugular filter introducer with protection sheath
c. Protection sheath hub
d. Coaxial introducer system consists of:
d1. Introducer dilator with 8 sideports and 2 radiopaque markers at the distal end
d2. Introducer sheath, 7 French, 65 cm long, with radiopaque band
d3. Introducer sheath hub with Check-Flo® valve
e. Cook Celect® Platinum Vena Cava Filter (supplied preloaded)
e1. Hook
e2. Primary Legs
e3. Secondary Legs
e4. Anchors
e5. Platinum markers
f. Three-way Stopcock, plastic



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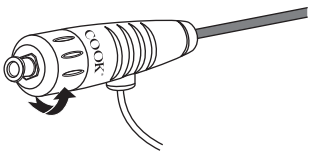

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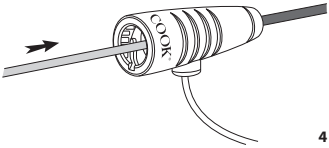

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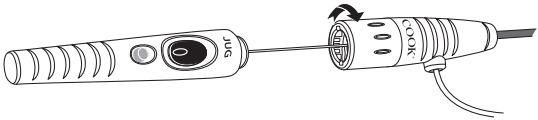

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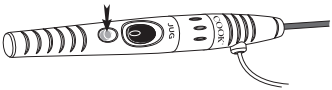

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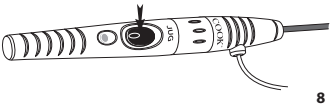

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COOK CELECT® PLATINUM VENA CAVA FILTER SET FOR JUGULAR VEIN APPROACH

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

DEVICE DESCRIPTION

The Cook 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 jugular filter introducer; a 7 French coaxial introducer system (compatible with a .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 jugular vein in adults.

The Cook Celect Platinum Filter implant is designed to act as a permanent filter or retrievable filter. The Cook Celect Platinum Filter implant may be retrieved if clinically indicated; please refer to the "**Optional Filter Retrieval**" section of the Instructions for Use for more information.

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 if clinically indicated; please refer to the "**Optional Filter Retrieval**" section of the Instructions for Use for more information.

The product is intended for percutaneous placement via a jugular 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.
- Patients with risk of septic embolism.
- Use in pregnant women.
- Use in minors/pediatric patients.

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 for PE.

WARNINGS

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.
- Do not attempt to rotate the preloaded filter inside the introducer system.
- 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.
- Excessive force should not be exerted to reposition or retrieve the filter, as it may lead to filter breakage and/or harm to the patient. If repositioning or retrieval of the filter is complicated, it may require additional interventions or surgical removal.

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.
- Please refer to the "**CLINICAL STUDIES**" section of the Instructions for Use for further information on filter retrieval from published clinical literature.

MRI

- Follow the MRI safety information to avoid excessive heating, torque, and/or deflection, which may cause injury to the vessel.

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 Cook 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 smaller or 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.

Filter Placement

- For placement of the filter, the right jugular vein is usually preferred due to its straighter route to the vena cava. An approach via the left jugular vein may be possible, depending on the patient's size and anatomy, and the location of any venous thromboses.
- The filter may be repositioned prior to final deployment by carefully advancing the introducer sheath over the filter; repositioning the system as desired; and again withdrawing the introducer sheath by reattaching it to the protection sheath hub, completely exposing the filter.

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 the "**REFERENCES**" section of the Instructions for Use 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.
- Available retrieval data from a prospective, multicenter study demonstrate that the device can be safely retrieved (refer to Lyon et al. (2009) in the "**REFERENCES**" section of the Instructions for Use). These data for the Cook Celect Filter suggest that in similar patient populations the probability of successfully retrieving a Cook Celect Platinum Filter is greater than 90.0% up to 52 weeks post placement.
- 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.** The "**REFERENCES**" section of the Instructions for Use includes citations that describe alternative retrieval techniques; this information is provided as reference.

MRI

- Image artifacts may occur, which may prolong diagnostic time and/or require additional imaging.

MRI SAFETY INFORMATION

Nonclinical testing has demonstrated that the Cook Celect Platinum Filter is MR Conditional. A patient with this device may be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla or 3.0 Tesla only.
- Maximum spatial gradient magnetic field of 1600 Gauss/cm (16.0 T/m) or less.
- Maximum MR system reported, whole-body-averaged specific absorption rate (SAR) of ≤ 2.0 W/kg (Normal Operating Mode) for 15 minutes of continuous scanning.

Under the scan conditions defined above, the Cook Celect Platinum Filter is expected to produce a maximum temperature rise of 4.2 °C after 15 minutes of continuous scanning.

The image artifact extends approximately 21 mm from the Cook Celect Platinum Filter as found during nonclinical testing when imaged with a gradient echo pulse sequence and a 3.0 Tesla MR system.

For U.S. Patients Only

Cook recommends that the patient register the MR conditions disclosed in these Instructions for Use 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

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 or filter fragment embolization
- Filter fracture
- Filter migration
- Filter malpositioning
- Hemorrhage
- Hematoma at vascular access site
- 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 perforation
- Vena cava penetration
- Vena cava occlusion or thrombosis
- Vena cava stenosis

CLINICAL STUDIES

A previous publication for the Cook Celect Filter suggests probable clinical results for the successful retrieval of the Cook Celect Platinum Filter (refer to Lyon et al. (2009) in the "**REFERENCES**" section for a summary of the retrievability portion of the study described herein).

A prospective, single-arm, multicenter, international study was conducted to assess the safety and performance of the Cook Celect Vena Cava Filter as both a permanent and retrievable filter. 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.

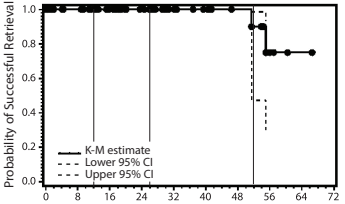
All filters (n=129) were successfully placed. Two placement procedures were associated with deployment difficulties and were subsequently repositioned and deployed in the correct location without complication: one was attributed to malfunction of the introducer (n=1) and the other to sheath movement 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 Figure 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.

Kaplan-Meier Plot



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

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.

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**)

Filter Placement

3. Access the chosen jugular vein using the Seldinger technique.
4. Perform diagnostic imaging to confirm a single IVC, measure the IVC diameter, check for thrombus, and establish the position of the renal veins.
5. Place a supportive .035 inch wire guide in the IVC.
6. If necessary, dilate the puncture site with the 10 French pre-dilator.
7. Remove the pre-dilator and advance the coaxial introducer system over the wire guide until the tip of the introducer sheath lies approximately 5 cm caudal to the lowest renal vein.
8. Remove the wire guide.
9. Perform diagnostic imaging to verify position of the introducer sheath tip (or radiopaque marker) approximately 5 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.
10. When correct position is established, twist the introducer dilator hub counterclockwise and remove the introducer dilator. (**Fig. 3**)
11. Place the filter introducer, with the protection sheath containing the preloaded filter, into the Check-Flo valve of the introducer sheath. Advance the filter introducer with the protection sheath into the introducer sheath. (**Fig. 4**)

    WARNING: Do not rotate the preloaded filter inside the introducer system.
12. Connect the introducer sheath hub and protection sheath by twisting clockwise until a click is felt. (**Fig. 5**) The filter is now positioned at the radiopaque band of the introducer sheath. The hook of the filter should be caudal to the renal veins.

    WARNING: Do not exert excessive force to advance the filter through the delivery system.
13. Stabilize the filter introducer system, and withdraw the introducer sheath and protection sheath until the protection sheath and jugular introducer handle are in contact with one another. At this point the filter is expanded, still connected to the filter introducer. (**Fig. 6**)

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

14. If the filter is not in the desired position, carefully advance the introducer sheath over the filter. Reposition the system as desired, and again withdraw the introducer sheath and protection sheath until the protection sheath and jugular introducer handle are in contact with one another, completely exposing the filter.
15. When the filter position is correct, push the red safety button to prepare filter release. (**Fig. 7**)
16. Push the release button completely to ensure proper release of the filter. (**Fig. 8**) Repositioning of the filter is no longer possible. The filter is now released.

    NOTE: Excessive tension during deployment may prevent the filter from releasing when the release mechanism is activated.
17. 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.

Optional Retrieval Procedure

The Cook 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).

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. 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, 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.
- Caplin et al. Society of Interventional Radiology Standards of Practice Committee. Quality improvement guidelines for the performance of inferior vena cava filter placement for the prevention of pulmonary embolism. J Vasc Interv Radiol 2011; 22:1499–1506.
- 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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