

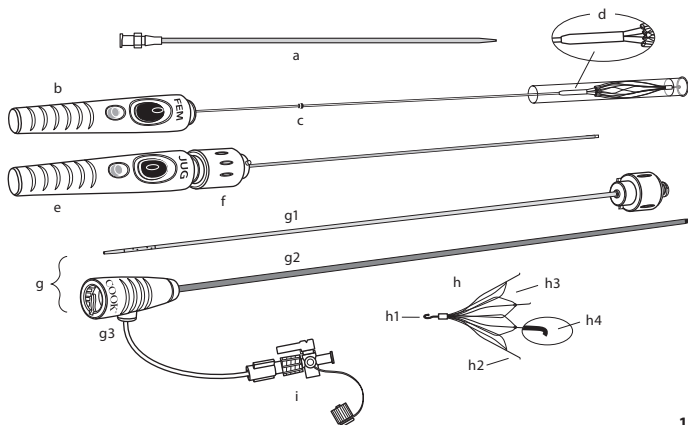
Günther Tulip® Vena Cava Filter Set for Femoral and Jugular Vein Approach

Instructions for Use

PATIENT I.D. CARD INCLUDED

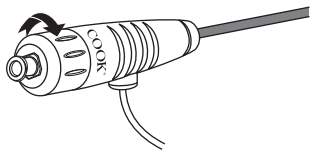
I-GTCFS-356-05EN



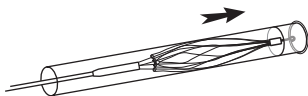


1

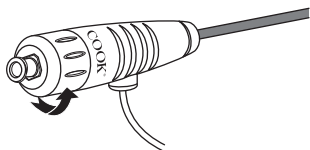
- a. Pre-dilator, radiopaque, hydrophilic coated, 10 French, 20 cm long
- b. Femoral filter introducer, preloaded with filter
- c. Tactile bump
- d. Femoral cup (metal mounting)
- e. Jugular filter introducer with protection sheath
- f. Protection sheath hub
- g. Coaxial introducer system consists of:
 - g1. Introducer dilator with 8 sideports and 2 radiopaque markers at the distal end
 - g2. Introducer sheath, 7 French, 65 cm long, with radiopaque band
 - g3. Introducer sheath hub with Check-Flo® valve
- h. Günther Tulip® Vena Cava Filter (supplied preloaded)
 - h1. Hook
 - h2. Primary legs
 - h3. Secondary legs
 - h4. Anchors
- i. Three-way stopcock, plastic



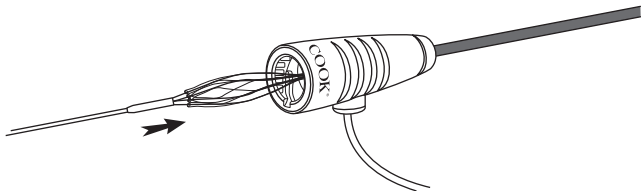
2



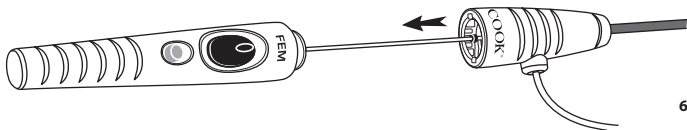
3



4



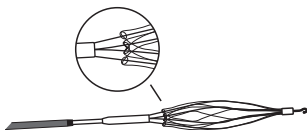
5



6

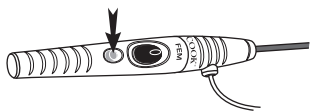


7

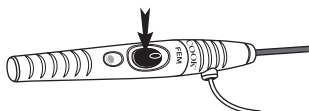


8

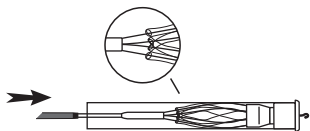
3



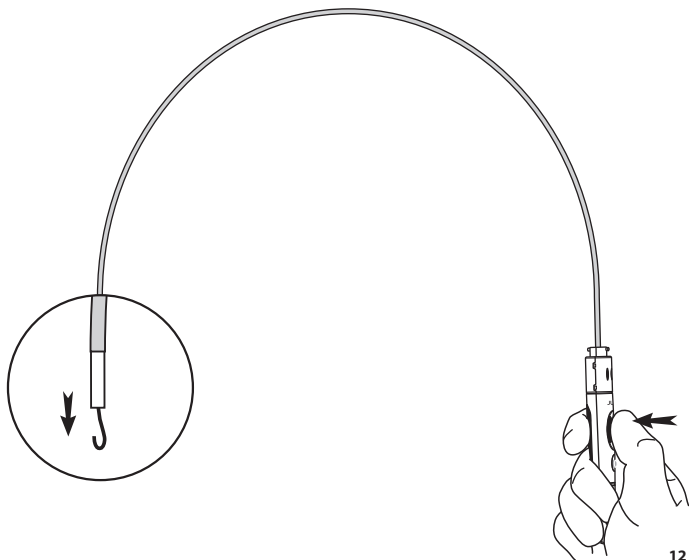
9



10



11



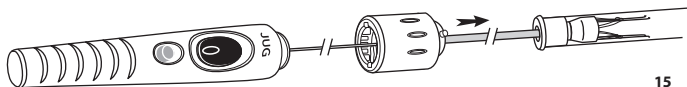
12



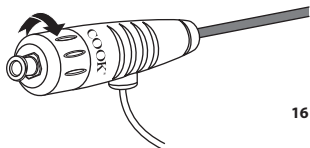
13



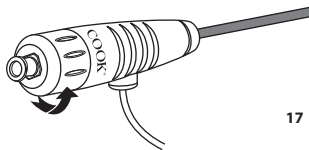
14



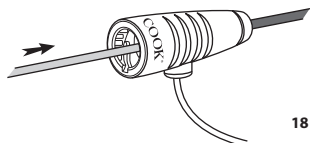
15



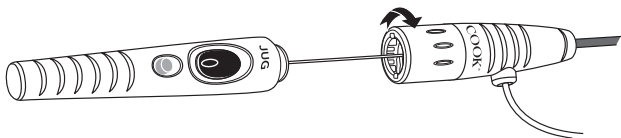
16



17



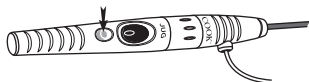
18



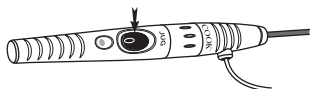
19



20



21



22

GÜNTHER TULIP® VENA CAVA FILTER SET FOR FEMORAL AND 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 Günther Tulip Filter Set consists of a filter composed of a paramagnetic cobalt chromium alloy (50 mm long when compressed to a diameter of 30 mm), preloaded on a femoral filter introducer; 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 femoral or jugular vein in adults. The femoral and jugular introducers are clearly identified on their respective handles.

The Günther Tulip Filter implant is designed to act as a permanent filter or retrievable filter. The Günther Tulip 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 Günther Tulip 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 Günther Tulip 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 femoral or 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 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.
- Excessive force should not be exerted to reposition (jugular approach) 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.
- When repositioning the filter (jugular approach), do not advance the introducer sheath over the anchors of the filter.

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 Günther Tulip 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 and nickel) 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 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.

Femoral 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 (metal mounting; indicated as position d in **Fig. 1**) is past the tip of the introducer sheath, the filter is fully exposed. Attempting to retract the filter at this point of the deployment sequence could damage the shape of the filter.

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



Non-clinical testing has demonstrated that the Günther Tulip Vena Cava 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 Günther Tulip Vena Cava Filter is expected to produce a maximum temperature rise of 5.2 °C after 15 minutes of continuous scanning.

The image artifact extends approximately 21 mm from the Günther Tulip Vena Cava Filter as found during non-clinical 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 USA |
| 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
- Postphlebotic 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

The safety of retrieving the Günther Tulip Vena Cava Filter was evaluated in a multicenter clinical study in the U.S. (IDE #G000242) in which filters were placed in 41 patients [female (n=19); male (n=22)]. The results of this and other references identified from a systematic literature search as providing safety and retrieval data pertinent to the Günther Tulip Vena Cava Filter are summarized below; the data support that the Günther Tulip Vena Cava Filter may be successfully retrieved:

| Reference | Filters Inserted, n | Retrieval Attempts, n | Successful Retrievals, n (%) | Range, days | Mean, days | Filter-Related Adverse Events ^a |
|--|---------------------|-----------------------|------------------------------|-------------|------------|--|
| Hoppe H, Nutting CW, Smouse HR, et al. Günther Tulip Filter Retrieval Study Multicenter Study Including CT Follow-up: Final Report. <i>J Vasc Interv Radiol.</i> 2006;17:1017-1023. ^b | 42 | 23 | 23 (100%) | 2-14 | 11.1 | Filter migration >2 cm after suprarenal placement (n=1), PE with filter in place and occlusive thrombus (n=1), and new IVC stenosis <20% after retrieval (n=1) |
| Smouse HB, Rosenthal D, Van Ha T, et al. Long-term Retrieval Success Rate Profile for the Günther Tulip Vena Cava Filter. <i>J Vasc Interv Radiol.</i> 2009;20:871-877. | 554 | 275 | 248 (90%) | 3-494 | 58.9 | Post-retrieval IVC stenosis at retrieval (n=1) and a small PE immediately after retrieval (n=1) |

| Reference | Filters Inserted, n | Retrieval Attempts, n | Successful Retrievals, n (%) | Range, days | Mean, days | Filter-Related Adverse Events ^a |
|---|------------------------|-----------------------|---|-------------|------------|--|
| Given MF, McDonald BC, Brookfield P, et al. Retrievable Gunther Tulip inferior vena cava filter: experience in 317 patients. J Med Imaging Radiat Oncol. 2008;52:452-457. | 322 | 205 | 188 (92%) | 1-309 | 76.95 | Insertion complications included: 1) filter penetration of IVC wall, 2) thrombus noted to extend superior to filter, and 3) iliac vein stent placed and caught on filter Breakthrough PE (n=1) while the filter was indwelling Five retrieval complications included: 1) two filters inserted, 2) cephalad filter descended and caught in caudal filter, 3) difficult/ unsuccessful retrieval with filter fracture and fragment embolized to lungs, 4) contrast extravasation with small IVC tears (n=2) and 5) IVC stenosis secondary to attempted retrieval Additionally, IVC narrowing/ stenosis at retrieval (n=10), with one balloon dilatation required |
| Marquess JS, Burke CT, Beecham AH, et al. Factors Associated with Failed Retrieval of the Günther Tulip Inferior Vena Cava Filter. J Vasc Interv Radiol. 2008;19:1321-1327. | 188 | 188 | 166 (88%) | 1-269 | 63 | Pericardial tamponade secondary to right ventricular injury from a guide wire (n=1), leg protrusion outside the IVC wall at retrieval (n=152), and intimal injury of the IVC wall during a difficult retrieval procedure (n=1) |
| Laborda A, Kuo WT, Ioakeim I, et al. Respiratory-Induced Haemodynamic Changes: A Contributing Factor to IVC Filter Penetration. Cardiovasc Intervent Radiol. 2015;38(5):1192-1197. | 101 (67 Günther Tulip) | 101 | 100 (99%) (No filter filter-type identified for failed retrieval) | 28-36 | 30.89 | Events specific to the Günther Tulip Filter – filter penetration ^c (n=9; 2 major [grade 3] and 7 minor [grade 2]), and filter migration >2 cm (n=1) |
| Lee MJ, Valenti D, de Gregorio MA, Minocha J, Rimon U, Pellerin O. The CIRSE Retrievable IVC Filter Registry: Retrieval Success Rates in Practice. Cardiovasc Intervent Radiol. 2015. | 628 (98 Günther Tulip) | 98 Günther Tulip | 86 (88%) Günther Tulip | <1-1056 | 76 | Minor complications (n=2; 2%) – details of complications were not provided and were not reported by filter type |

| Reference | Filters Inserted, n | Retrieval Attempts, n | Successful Retrievals, n (%) | Range, days | Mean, days | Filter-Related Adverse Events ^a |
|--|-------------------------|-----------------------|------------------------------|-------------|------------|---|
| Turba UC, Arslan B, Meuse M, et al. Gunter tulip filter retrieval experience: predictors of successful retrieval. <i>Cardiovasc Intervent Radiol.</i> 2010;33:732-738. | 92 | 92 | 87 (95%) | N/A | 43 | Filter migration ~2 cm (n=1), post-retrieval IVC stenosis 10-30% (n=16) and 30-50% (n=5), >1 cm filter strut penetration on venogram (n=50), and minor IVC irregularity post retrieval without intervention (n=3) |
| Yamagami T, Kato T, Hirota T, Yoshimatsu R, Matsumoto T, Nishimura T. Evaluation of retrievability of the Gunther tulip vena cava filter. <i>Cardiovasc Intervent Radiol.</i> 2007;30:226-231. | 86 | 80 | 77 (96%) | 8-108 | 19.7 | No serious complications, minor complications included: 1) transient mild dyspnea during the retrieval procedure (n=1), 2) transient back pain during and just after retrieval (n=2), and 3) mild subcutaneous hematoma at the retrieval insertion site (n=2) |
| Ray CE, Mitchell E, Zipser S, Kao EY, Brown CF, Moneta GL. Outcomes with Retrievable Inferior Vena Cava Filters: A Multicenter Study. <i>J Vasc Interv Radiol.</i> 2006;17:1595-1604. | 197 (143 Günther Tulip) | 73 Günther Tulip | 61 (84%) Günther Tulip | 1-139 | 15.6 | Events specific to the Günther Tulip Filter – recurrent PE (n=1) and IVC thrombosis (n=2; 1 confirmed and 1 suspected) |
| Ota S, Yamada N, Tsuji A, et al. The Gunther-Tulip retrievable IVC filter: clinical experience in 118 consecutive patients. <i>Circ J.</i> 2008;72:287-292. | 118 | 66 | 60 (91%) | 2-37 | 10.1 | Filter occlusion (n=3), strut penetration >3 mm on CT without extravasation or injury to adjacent organ (n=23), and filters were dropped in the IVC (n=2) during retrieval, but were successfully retrieved |

^aFilter-related adverse events are reported as described in the individual publications.

^bData collected under IDE #G000242.

^cFilter penetration was categorized according to the definitions in Oh JC, Trerotola SO, Dagli M, et al. Removal of retrievable inferior vena cava filters with computed tomography findings indicating tenting or penetration of the inferior vena cava wall. *J Vasc Interv Radiol.* 2011;22(1):70-74.

INSTRUCTIONS FOR USE

Femoral Approach

General

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. 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)
3. Remove the filter protection tube. (Fig. 3)

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 .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 femoral filter introducer with the preloaded filter into the Check-Flo valve of the introducer sheath, (Fig. 5) and advance it into

the introducer sheath 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.

13. 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 fully exposed, still connected to the filter introducer. (Fig. 8)

CAUTION: Attempting to retract the filter at this point of the deployment sequence could damage the shape of the filter.

14. 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 (metal mounting; indicated as position d in Fig. 1) is completely free of the introducer sheath. Use the radiopaque band of the introducer sheath for positioning.

15. 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.
16. When the filter position is correct, push the red safety button to prepare filter release. (Fig. 9)
17. 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.
18. 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.

Jugular Approach

General

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. It is assumed that the operator will use local anesthesia, sedation and analgesia as required.

Preparation

To prepare for jugular approach, the filter must be transferred from the femoral introducer to the jugular introducer.

1. On the femoral introducer system push the filter hook through the cap on the protection tube. (Fig. 11)
2. Push and hold the release button on the jugular introducer handle to advance the grasping hook beyond the protection sheath. While holding the jugular introducer in a soft bend according to illustration, (Fig. 12) catch the hook of the preloaded filter on the femoral introducer and release the button to firmly grasp the filter. (Fig. 13)
NOTE: Do not kink the jugular introducer while bending it.
3. Secure the lock on the jugular introducer handle by pushing the red knob on the back side. (Fig. 14)
4. To release the filter from the femoral introducer, push the red safety button followed by the release button on the femoral introducer handle. (Fig. 9 and 10)
5. Straighten the jugular introducer system and then advance the protection sheath hub on the jugular filter introducer until a confirmed stop is felt (approximately 6 cm). (Fig. 15) This ensures that the filter is inside the tip of the protection sheath.
The product is now prepared for use.
6. Flush the introducer sheath and the introducer dilator.
7. 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. 16)

Filter Placement

8. Access the chosen jugular vein using the Seldinger technique.
9. Perform diagnostic imaging to confirm a single IVC, measure the IVC diameter, check for thrombus, and establish the position of the renal veins.
10. Place a supportive .035 inch wire guide in the IVC.
11. If necessary, dilate the puncture site with the 10 French pre-dilator.
12. 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.

13. Remove the wire guide.
14. 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.

15. When correct position is established, twist the introducer dilator hub counterclockwise and remove the introducer dilator. (Fig. 17)
16. Place the jugular 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. 18)
WARNING: Do not rotate the preloaded filter inside the introducer system.
17. Connect the introducer sheath hub and protection sheath by twisting clockwise until a click is felt. (Fig. 19) 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 introducer system.
18. 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. 20)
WARNING: Do not rotate the expanded filter inside the vena cava. Doing so may compromise the performance of the filter.
19. If the filter is not in the desired position, carefully advance the introducer sheath over the filter until right before the anchors. 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.
WARNING: Do not advance the introducer sheath over the anchors of the filter. Doing so may cause particles to be scratched off the introducer sheath.
20. When the filter position is correct, push the red safety button to prepare filter release. (Fig. 21)

21. Push the release button completely to ensure proper release of the filter. (**Fig. 22**) 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.

22. 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 Günther Tulip 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:

- 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.



WILLIAM COOK EUROPE ApS

Sandet 6, DK-4632
Bjaeverskov, DENMARK
Phone: +4556868686

www.cookmedical.com

© COOK 2021

2021-10

I-GTCFS-356-05EN