COOK®
MEDICAL

# Günther Tulip® Filter Set For Femoral Vein Approach

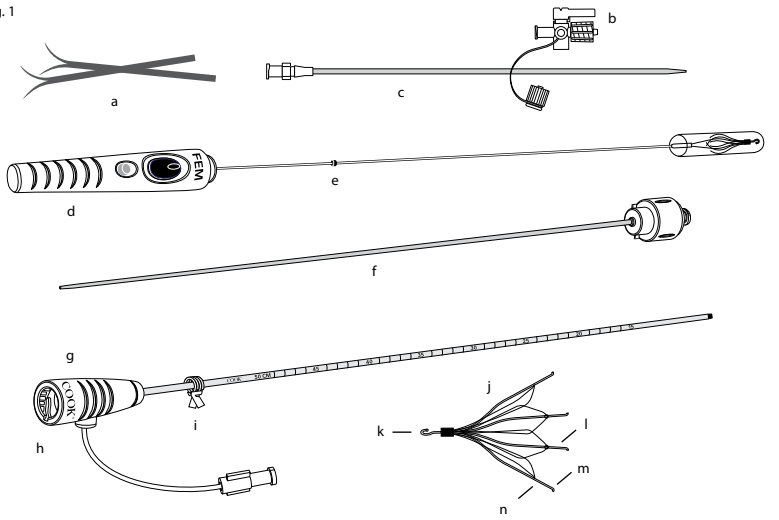
Instructions for Use

**PATIENT I.D. CARD INCLUDED**

I-IGTCFS-1203-400-01EN

400-01EN

Fig. 1




a. 8.5 Fr Peel-Away® sheaths
b. Three-way stopcock Plastic
c. Dilator, radiopaque, hydrophilically coated, 10.0 Fr, 20 cm long
d. Filter introducer handle
e. Tactile bump
f. 8.5 Fr introducer dilator
g. 8.5 Fr, 65 cm long introducer sheath with centimeter markers, radiopaque tip and a sheath clip
h. Check-Flo® Valve
i. Sheath clip
j. Günther Tulip Filter (supplied preloaded)
k. Hook
l. Primary legs
m. Anchors
n. Secondary legs

Fig. 2

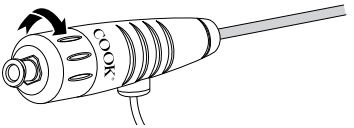



Fig. 3

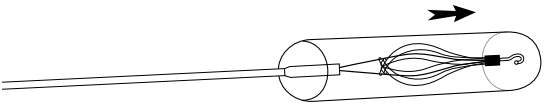


Fig. 4

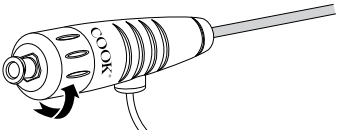


Fig. 5

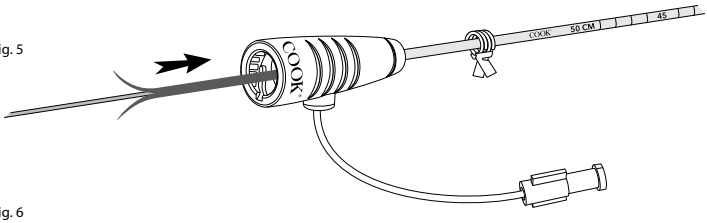



Fig. 6

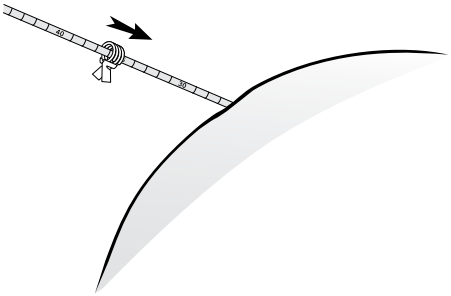


Fig. 7

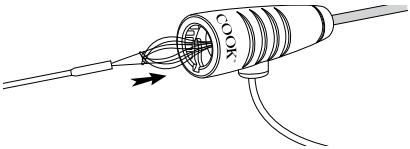



Fig. 8

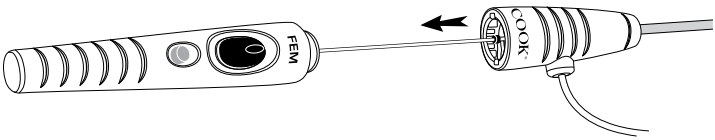



Fig. 9

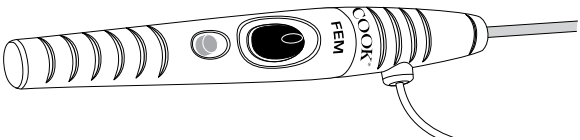


Fig. 10

Fig. 11

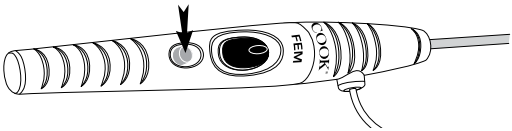
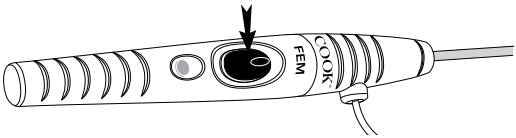



Fig. 12




## GÜNTHER TULIP® 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 Günther Tulip filter set consists of a paramagnetic filter (30 mm diameter, 50 mm long) preloaded on a femoral filter introducer, an 8.5 Fr coaxial introducer sheath system with markers and sheath clip (sheath system compatible with .035 inch wire guide). Also including hydrophilically coated dilator, a Three-way plastic stopcock and 8.5 Fr Peel-Away® sheaths.

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

The Günther Tulip Filter implant may be retrieved. Please refer to the Instructions for Use provided with the Günther Tulip Vena Cava Filter 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 pulmonary embolism.

### CONTRAINDICATIONS

#### Filter Placement

- Megacava (diameter of the IVC > 30 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 ongoing high risk for pulmonary embolism.

### WARNINGS

#### Filter Placement

- This Günther Tulip Filter Set is intended for femoral vein approach only and cannot be used for jugular vein approach.
- Manipulation of products requires imaging control.
- Do not rotate the preloaded filter inside the introducer system.
- **Excessive force should not be exerted to place filter.**

#### 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 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.

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 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.
- When the filter introducer is inside the sheath, ensure that the sheath hub and handle are connected, before any injection of contrast media through the sheath.
- 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 available data is 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 redeploy 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 Günther Tulip Vena Cava Filter is **MR Conditional** according to ASTM F2503. 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 Günther Tulip Vena Cava Filter produced a maximum temperature change of 3.8 °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 Günther Tulip Vena Cava Filter produced a maximum temperature change of 5.2 °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 Günther Tulip Vena Cava Filter, as found during non-clinical testing using $T^1$-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<br>2323 Colorado Avenue, Turlock, CA 95382 |
| Phone: | 888-633-4298 (toll free)<br>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

To evaluate the safety of retrieving the Günther Tulip Vena Filter, a clinical study was conducted in which 41 patients [female (n=19); male (n=22)] were enrolled for possible retrieval of the filter. The results of this and other published and presented sources listed below demonstrate that the Günther Tulip Vena Cava Filter may be safely retrieved:

| Reference | Filters Inserted | Retrieval Attempts [1] | Successfull Retrievals | Range (Days) | Mean (Days) | Adverse Events |
|---|---|---|---|---|---|---|
| Hanno Hoppe, et al. "Günther Tulip Filter Retrievability Multicenter Study Including CT Follow-up: Final Report". JVIR 2006; 17:1017-1023 | 41 | 26 | 26 | 2-20 | 11.4 | None |
| Kachura JR "Inferior Vena Cava Filter Removal After 475-day Implantation". JVIR 2005 16: 1156-1158. | 1 | 1 | 1 | 475 | 475 | None |
| Binkert CA, Bansal A, Gates JD, "Inferior Vena Cava Filter Removal After 317 day Implantation." JVIR 2005; 16:1395-1398. | 1 | 1 | 1 | 317 | 317 | Mild caval stenosis following 317-day retrieval; follow-up OK |
| Lyon SM, "Retrievable Günther Tulip Filter – Experience in 188 Cases." Paper. 2005 Annual Meeting Society of Interventional Radiology." | 182 | 122 | 110 | 1-309 | 59.6 | 1. Mild IVC Stenosis 2. Filter fractured during retrieval and small filter fragment embolized to lung. |
| Piano G, et al. "Safety, Feasibility, and Outcome of Retrievable Vena Cava Filters in High-risk Surgical Patients." J Vasc Surg 2007; 45:784-788 | 60 | 54 | 52 | 32-162 | 63 | One patient had non-fatal PE with filter in place. Three patients required second retrieval attempt. All three were successful. |
| Terharr OA, Lyon SM, Given MF, Foster AE, Mc Grath F, Lee MJ. "Extended Interval for Retrieval of Günther Tulip Filters." JVIR 2004; 15:1257-1262. | 53 | 19 | 16 | 7-126 | 34 | None |
| Morris CS, Rogers FB, Najarian KE, Bhave AD, Shachford SR. "Current Trends In Vena Caval Filtration with the Introduction of a Retrievable Filter at a Level 1 Trauma Center," J Trauma, 2004; 57(1):32-36. | 58 | 14 | 13 | 11-41 | 19 | One patient had a non-fatal PE after filter retrieval. |

[1] The unsuccessful retrievals did not result in adverse events; the device was left in place in place as a permanent implant.

## INSTRUCTIONS FOR USE

### Preparation

1. Flush the introducer sheath and dilator.
2. Advance the introducer dilator through the middle of the silicone 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 femoral vein using the Seldinger technique.
5. Advance a dilator over the wire guide and dilate the puncture site. Remove the dilator, leaving the wire guide in place.
6. Advance the coaxial introducer sheath system over the wire guide.
7. Remove the introducer dilator by twisting the dilator hub counterclockwise, leaving the wire guide in place if using an imaging catheter **(Fig. 4)**.
8. When using an imaging catheter, place the Peel-Away sheath over the tip of the imaging catheter and advance the Peel-Away sheath and the imaging catheter together over the wire guide and through the center of the silicone valve until the imaging catheter has been introduced into the introducer sheath. Remove the Peel-Away sheath **(Fig. 5)**.

   **CAUTION:** Ensure that the tip of the imaging catheter is more than 5 cm beyond the sheath tip prior to any fluoroscopic contrast imaging.
9. Perform diagnostic imaging of the vena cava and the location of the renal veins.
10. Confirm appropriate anatomy and vena caval diameter, and ensure that there is no thrombus which might preclude filter placement.
11. Place the introducer sheath tip below (caudal to) the renal veins. Slide the sheath clip into position at the insertion site. Note the inserted length, using the markers on the introducer sheath, and confirm that the inserted length is consistent with the distance to the renal veins **(Fig. 6)**.
12. If using an imaging catheter, remove the imaging catheter and wire guide.
13. Place the filter introducer with the preloaded filter into the hub of the introducer sheath, and advance it into the sheath **(Fig. 7)**.
14. Advance the filter introducer until the tactile bump is in contact with the silicone disc in the Check-Flo valve. (Fig. 8). This will place the hook of the filter inside the sheath at the distal tip of the introducer sheath. Note the position of the sheath clip and markers to confirm the proper location of the introducer sheath.
15. Hold the position of the filter introducer handle steady. Withdraw the introducer sheath and connect it to the filter introducer handle. At this point, the filter is still connected to the filter introducer **(Figs. 9** and **10)**.

    **WARNING:** The pre-exposed filter can be advanced, but never pulled back into the sheath; retracting the filter could damage the secondary legs or caval wall.

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

    **CAUTION:** Filter release or injection of contrast medium must not occur unless the metal mounting point is completely beyond the sheath tip. Ensure the filter introducer sheath and the filter introducer handle are connected or use the radiopaque tip of the sheath for positioning.
16. When the filter position is correct, push the red safety button completely down to prepare the filter release **(Fig. 11)**.
17. Verify that the sheath hub and handle are connected to ensure that the metal mounting point is completely free of the sheath and that the sheath clip is 7-8 cm from the insertion site, before filter release.
18. To release the filter, push the release button completely to ensure proper release of the filter **(Fig. 12)**. Remove the filter introducer. Repositioning of the filter is no longer possible.
19. Proper positioning can now be verified by diagnostic imaging.
20. Remove 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 Günther Tulip Filter implant may be retrieved. Please refer to the Instructions for Use provided with the Günther Tulip Vena Cava Filter 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

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