Günther Tulip™ Vena Cava Filter

For Femoral Vein Approach

Instructions for Use

EN
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COOK® MEDICAL

Patient I.D. Card Included

I-IGTCFS-65-1-FEM-TULIP-0906-338-01EN

GÜNTHER TULIP™ VENA CAVA FILTER

For Femoral Vein Approach

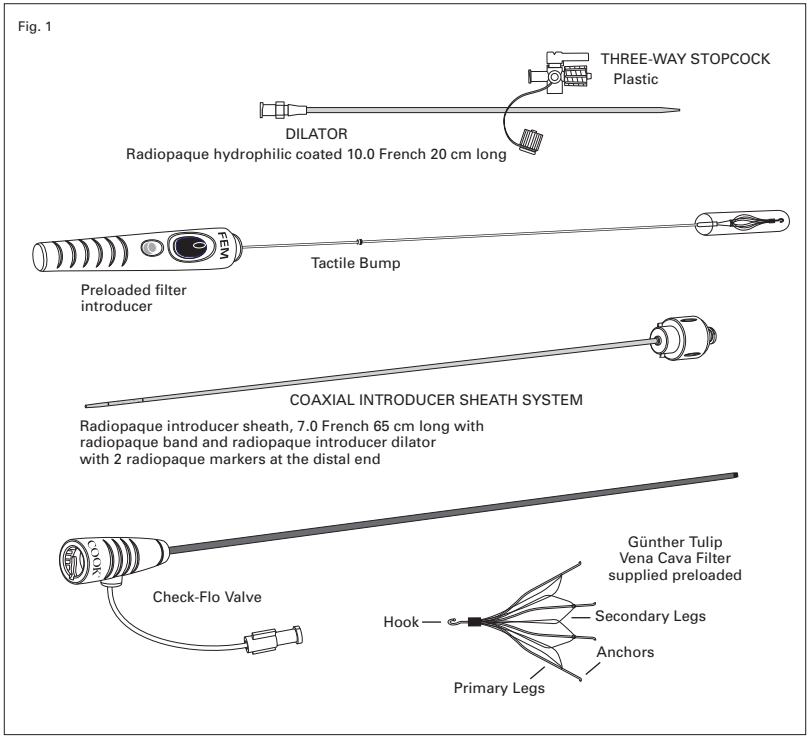
CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEVICE DESCRIPTION

The Günther Tulip Vena Cava Filter Set consists of a non-magnetic filter (30 mm diameter, 50 mm long), preloaded on a femoral filter introducer system, a 7.0 French coaxial introducer system (is compatible with a .035 inch wire guide), and a hydrophilic coated dilator. The introducer dilator has 8 sideports and two radiopaque markers 30 mm apart (end to end).

SET COMPONENTS

Fig. 1



INTENDED USE

The Günther Tulip Vena Cava Filter Set 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 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 embolism.

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).
- 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

- This Günther Tulip Vena Cava Filter Set is intended for femoral vein approach only and cannot be used for jugular vein approach.
- Manipulation of products requires fluoroscopic control.
- When injecting contrast medium, do not exceed maximum pressure rating of 1000 psi and flow rate of 20 ml/sec. Hand injection is also possible.
- **Excessive force should not be used to place 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.

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 (handle and sheath hub are connected).
- Once the metal mount point is past the radiopaque marker on 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, 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, GTRS- (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 Günther Tulip 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 525 Gauss/cm or less.
- Maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of scanning.

In non-clinical testing, the Günther Tulip Vena Cava Filter produced a temperature rise of less than 0.6°C at a maximum whole body averaged specific absorption rate (SAR) of 3.0 W/kg for 15 minutes of MR scanning in a 3.0 Tesla MR system using a transmit/receive body coil (Excite, Software G3.0-052B, General Electric Healthcare, Milwaukee, WI) 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 Günther Tulip 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
- Extravasation of contrast material at time of vena cavagram
- Hematoma at vascular access site
- Infection at vascular access site
- Thrombosis or stenosis at implant site
- 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.

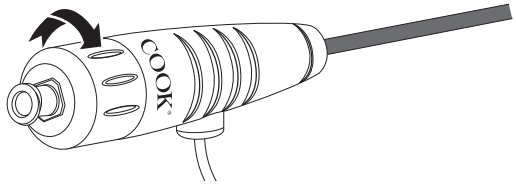
[1] *The unsuccessful retrievals did not result in adverse events; the device was left in place in place as a permanent implant.*

INSTRUCTIONS FOR USE

Preparation

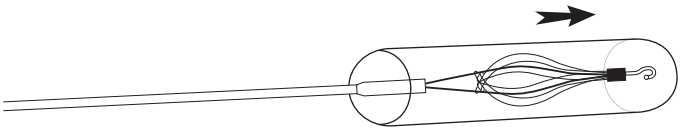
1. Flush the introducer sheath and dilator.

Fig. 2



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).

Fig. 3



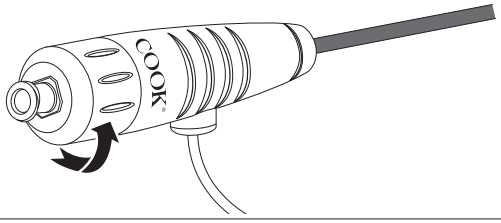
3. Remove the filter protection tube (Fig. 3).

Filter Placement

4. Puncture the femoral vein using the Seldinger technique.
5. Over the wire guide, dilate the puncture site with the dilator. Remove the dilator.
6. Advance the coaxial introducer sheath system over the wire guide.
7. Remove the wire guide.
8. Using either power or hand injection, perform cavography to verify position below (caudal to) the renal veins.

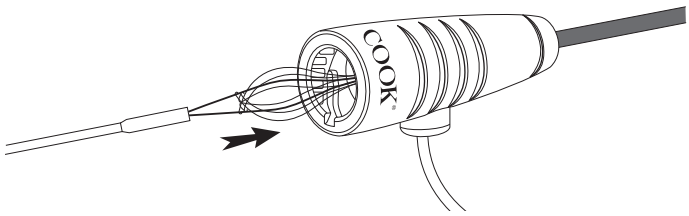
   WARNING: Do not exceed maximum pressure rating of 1000 psi and flow rate of 20 ml/sec.

Fig. 4



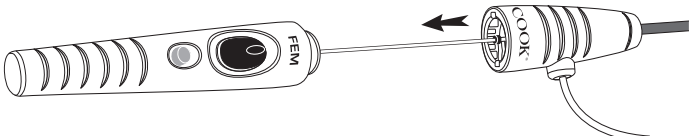
9. Remove the introducer dilator by twisting the dilator hub counter clockwise (Fig. 4).

Fig. 5



10. Place the filter introducer with the premounted filter into the hub of the introducer sheath and advance it into the sheath (Fig. 5).

Fig. 6



11. Advance the filter introducer until the silicone disc contacts the tactile bump. This will place the hook of the filter inside the sheath at the radiopaque band. Verify that the position of the hook is inside the sheath and still below the renal veins (Fig. 6).

Fig. 7

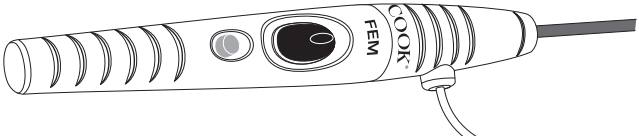
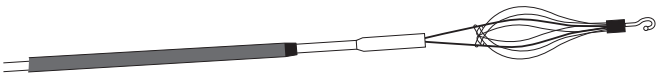


Fig. 8

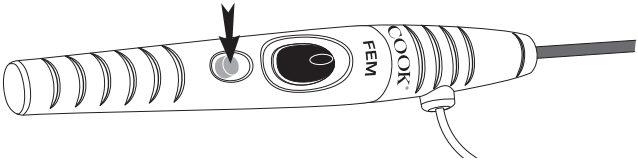


12. Stabilize the introducer, and withdraw the sheath and connect it to the handle. At this point the filter is expanded, still connected to the filter introducer (Figs. 7 and 8).
13. Proper position can now be verified by injection of contrast medium.

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

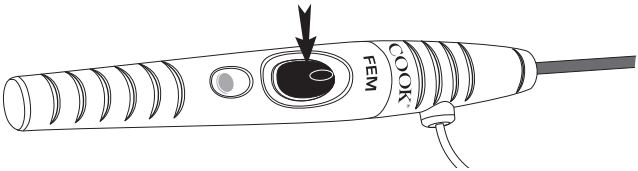
    CAUTION: Filter release or injection of contrast medium must not be made unless the metal mounting point is completely free of the sheath. Use the radiopaque band for positioning.

Fig. 9



14. When the filter position is correct, push the red safety button to prepare filter release (Fig. 9).

Fig. 10

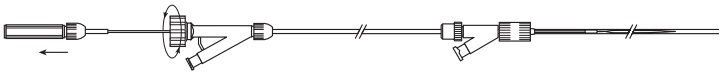


15. Verify that the sheath hub and handle are connected to ensure that the metal mount point is completely free of the sheath before filter release. To release the filter, push the release button completely to ensure proper release of filter. Repositioning of the filter is no longer possible. The filter is now released (Fig. 10).
16. Perform a cavagram to verify filter position, and then withdraw the introducer sheath.

Optional Retrieval Procedure

NOTE: If a 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. 11

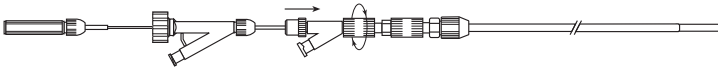


1. Hold the clear Y-fitting and pull back the plastic pin vise on the wire loop retriever to cover the loop. Tighten the screw of the clear Y-fitting to keep the loop inside the catheter (Fig. 11).
2. Puncture the right jugular vein using the Seldinger technique.
3. Position a flush catheter inferior to the filter and perform a diagnostic vena cavagram.
4. Exchange the flush catheter for the coaxial retrieval sheath system, advancing it over the wire guide.

Fig. 12

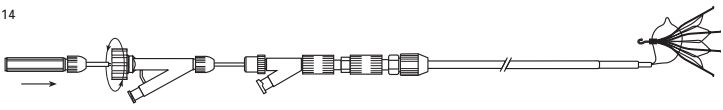
5. Remove the red inner dilator and the wire guide. Verify the position by injection of contrast medium (Fig. 12).

Fig. 13



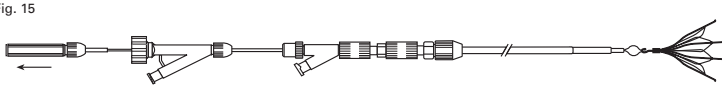
6. Introduce the retrieval loop system through the coaxial retrieval sheath system, advance and connect the white Tuohy-Borst side-arm adapter of the loop system to the sheath system. The Tuohy-Borst adapter can be tightened around the catheter to prevent loss of blood (Fig. 13).

Fig. 14



7. Loosen the screw of the clear Y-fitting to enable advancement of the loop inside the catheter. Hold the clear Y-fitting and push the pin vise forward. Advance until the loop has fully expanded inside the vena cava and surrounds the filter (Fig. 14).

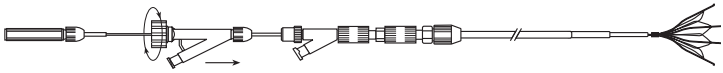
Fig. 15



8. Pull back the loop until it engages the hook of the filter (Fig. 15).

   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.

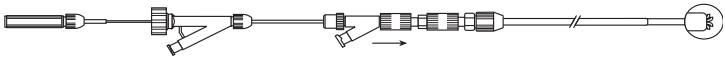
Fig.16



9. Hold the wire loop 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. 16).

   NOTE: If the retrieval wire loop is losing 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.

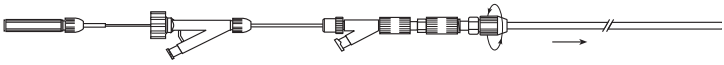
Fig.17



10. While holding steady the retrieval loop system with the clear Y-fitting, advance the white Tuohy-Borst side-arm adapter and the black inner sheath with the coaxial retrieval system. The filter collapses and the hooks disengage from the caval wall (Fig. 17).

    CAUTION: Advance the inner sheath over the filter to collapse it. Do not retract the loop snare. This may cause damage to the caval wall.

Fig.18



11. When the tip of the coaxial retrieval system is at the anchors, loosen the hub of the outer sheath, advance the outer sheath forward to cover the whole filter, and retrieve the complete assembly (Fig. 18).

    CAUTION: If the outer sheath is not advanced over the inner sheath to cover the anchors, the anchors may scratch or damage the caval wall.

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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