Günther Tulip™ Vena Cava Filter Retrieval Set

for Jugular Vein Approach

Instructions for Use
Optional Retrieval Procedure

COOK®
MEDICAL

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GÜNTHER TULIP™ VENA CAVA FILTER RETRIEVAL SET

For Jugular Vein Approach

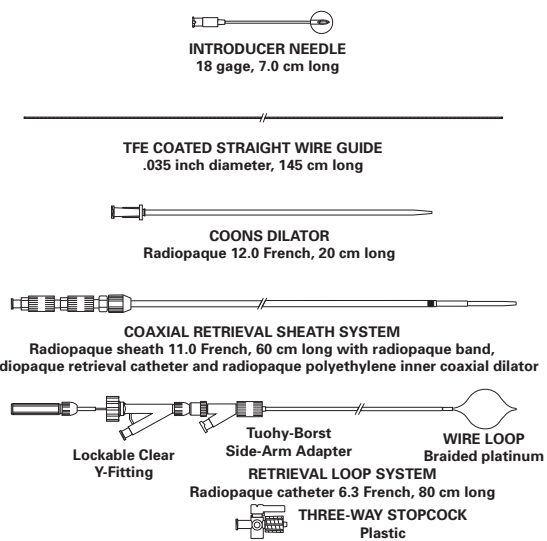
CAUTION: U.S. federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

DEVICE DESCRIPTION

The Günther Tulip Vena Cava Filter Retrieval Set (GTRS-) for jugular approach consists of a retrieval loop system with a braided platinum wire loop, a coaxial retrieval sheath system, an entry needle, a wire guide and a dilator. Radiopaque band provided on the outer sheath identifies precise location of the distal tip of the sheath for positioning accuracy. Refer to label for further information.

The Günther Tulip and Cook Celect Vena Cava Filters are designed to act as permanent filters. When clinically indicated, the filters may be retrieved after implantation according to the instructions provided using the Günther Tulip Vena Cava Filter Retrieval Set (GTRS-) for jugular approach.

SET COMPONENTS



INTENDED USE

The product has been designed for retrieval of implanted Günther Tulip and Cook Celect Vena Cava Filters in patients who no longer require a filter. Retrieval of the filter can be performed only by jugular approach.

CONTRAINDICATIONS

- 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 (PE).

WARNINGS

- **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 a 41-patient study suggest that the Günther Tulip filter can be safely retrieved (mean of 11.4 days, range 2-20 days). Please refer to the "Clinical Studies" section of this booklet.
- Available data from retrievals in a 43-patient study suggest that the Cook Celect filter can be safely retrieved (range 1-67 weeks). Please refer to the "Clinical Studies" section of this booklet.
- **This product contains NATURAL RUBBER LATEX which may cause allergic reactions. The latex component is in the Side-Arm Adapter.**
- Other possible allergic reactions should be considered.
- Never re-deploy a retrieved filter.

PRECAUTIONS

- This 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.
- Manipulation of product requires fluoroscopic control.
- 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.

POTENTIAL ADVERSE EVENTS

- Acute damage to the inferior vena cava
- Acute pulmonary embolism (PE)
- Extravasation of contrast material at time of vena cavagram
- Hematoma at retrieval vascular access site
- Hemorrhage
- Thrombosis or stenosis at implant site
- Wound infection at retrieval vascular access site
- Death

CLINICAL STUDIES

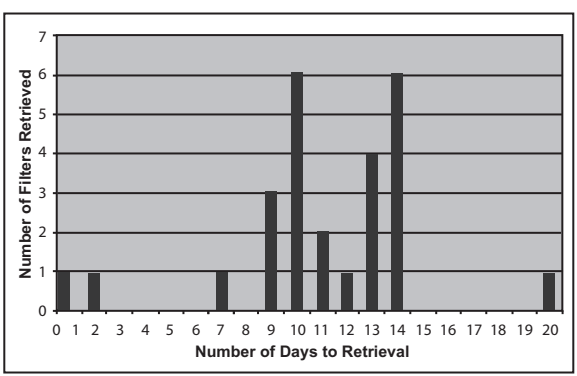
Günther Tulip Filter

To evaluate the safety of retrieving the Günther Tulip Vena Cava Filter, a clinical study was conducted in which 41 patients [female (n=19); male (n=22)] were enrolled for possible retrieval of the filter. Mean age of patients was 47.7 years and age range was 20.1-73.0 years.

Indications for placement of retrievable filter in the study included: bleeding while anticoagulated (n=2), recent bleeding not anticoagulated (n=0), prophylactic pre-op (n=12), prophylactic post-op (n=3), failure of anticoagulation resulting in recurrent PE (n=1), failure of anticoagulation resulting in extension of DVT (n=0), prophylaxis following PE (n=3), prophylaxis with extensive DVT (n=3), trauma (n=13) and other (n=4).

Retrieval was not attempted in 15 patients due to the continued need for permanent implantation of the filter. A total of 26 attempted retrievals in 26 patients were successful [n=number of filters retrieved]. Retrieval of filter immediately after deployment at Day 0 (n=1), Day 2 (n=1), Day 7 (n=1), Day 9 (n=3), Day 10 (n=6), Day 11 (n=2), Day 12 (n=1), Day 13 (n=4), Day 14 (n=6), Day 20 (n=1). Please see histogram in Table 1 depicting time to retrieval. No adverse events were reported in the retrieved filter group. 23 patients in whom a filter was retrieved were followed for three months post retrieval with no abnormalities reported, except 1 patient with left iliac vein non-occluding thrombus from inguinal ligament to near confluence of iliac veins; 3 patients were lost to follow-up. Results from the clinical study showed that the filter could be safely retrieved up to 14 days or longer in patients who no longer required an inferior vena cava filter. Time to retrieval ranged from 2-20 days with a mean implantation time of 11.4 days.

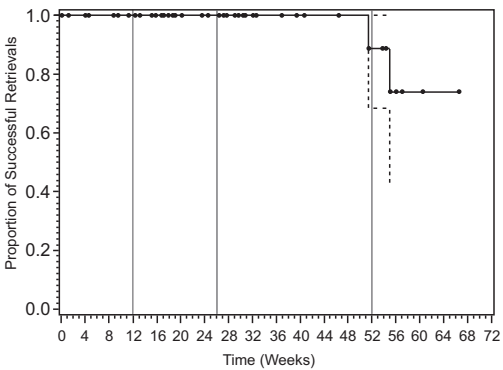
Table 1: Günther Tulip Filter Time to Retrieval



Cook Celect Filter

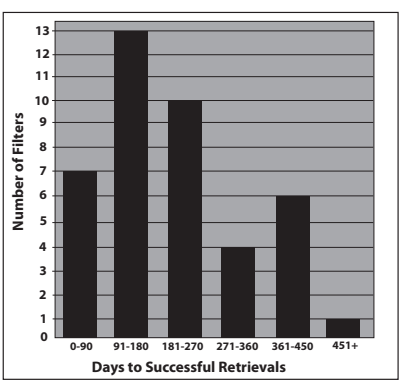
To evaluate the safety of retrieving the Cook Celect Vena Cava Filter, a clinical study was conducted in which filter retrieval was attempted in 43 patients (12 female, 31 male), and 41 retrievals were successful. Time to retrieval ranged from 1-67 weeks. See the Kaplan-Meier graph depicting success over time for retrieval of Celect filter (Table 2). No adverse events relating to filter retrieval were reported in the retrieval group, demonstrating the safety of filter retrieval in patients who no longer require a vena cava filter.

Table 2: Kaplan-Meier Analysis of Filter Retrieval Success with 95% Confidence



Please see histogram in Table 3 depicting time to retrieval.

Table 3: Celect Filter Time to Retrieval



Patient follow-up was conducted at 1 month, 3 months and 6 months or until filter retrieval, and 30 days post-retrieval consisting of clinical exam, and imaging by X-ray and duplex ultrasound. No device-related major adverse events (defined as hemorrhage, perforation, death, occlusion, filter fracture or significant filter migration) have occurred. X-ray imaging has not detected filter migration greater than 20 mm in any patient. Imaging by X-ray and duplex ultrasound has revealed no evidence of vena cava perforation. There were no adverse events associated with the filter retrieval procedure.

INSTRUCTIONS FOR USE

Optional Retrieval Procedure

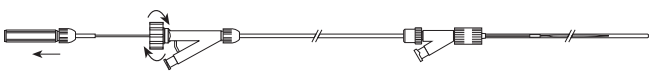


Fig. 1

1. Hold the clear Y-fitting and pull back the plastic pin vise on the wire loop to cover the loop. Tighten the screw of the clear Y-fitting to keep the loop inside the catheter. **(Fig. 1)**
2. Puncture the right jugular vein using the Seldinger technique. Dilate the puncture site with the Coons dilator over the wire guide. Remove the dilator.
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. 2

5. Remove the red inner coaxial catheter and the wire guide. Verify the position of the introducer by injection of contrast medium. **(Fig. 2)**

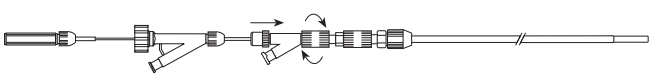


Fig. 3

6. Introduce the retrieval loop system through the coaxial retrieval sheath system, advance and connect the white side-arm adapter of the loop system to the sheath. The white side-arm adapter can be tightened around the catheter to prevent loss of blood. **(Fig. 3)**

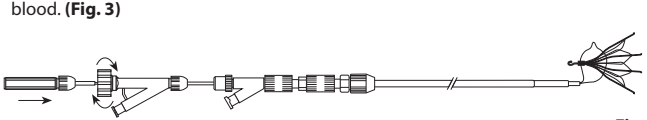


Fig. 4

7. Loosen the screw of the clear Y-fitting to enable advancement of the loop inside the catheter. Hold the clear Y-fitting and advance the pin vise. Advance until the loop has fully expanded inside the vena cava and surrounds the filter. **(Fig. 4)**

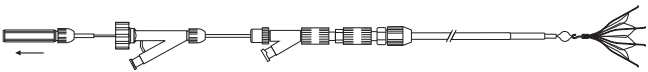


Fig. 5

8. Pull back the loop until it engages the hook of the filter. **(Fig. 5)**

   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.

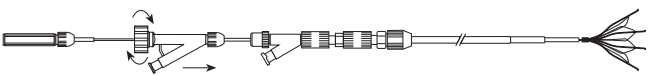


Fig. 6

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. Lock the clear Y-fitting to secure the snare around the filter hook. **(Fig. 6)**

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

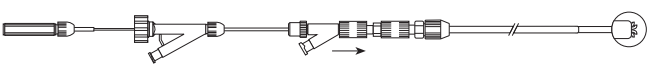


Fig. 7

10. While holding the retrieval loop and clear Y-fitting steady, advance the white Tuohy-Borst side-arm adapter with the coaxial retrieval system. The filter collapses and the hooks disengage from the caval wall. **(Fig. 7)**

    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.

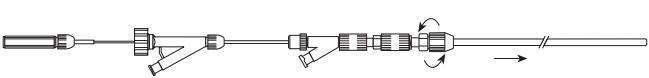


Fig. 8

11. When the tip of the coaxial retrieval system is at the barbed hooks, loosen the hub of the blue outer sheath, advance the outer sheath forward to cover the whole filter, and retrieve the complete assembly. **(Fig. 8)**

CAUTION: If the outer sheath is not advanced over the inner sheath to cover the barbed hooks, the barbed hooks 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.

Keep dry

Keep away from sunlight

Manufacturer
COOK INCORPORATED
750 Daniels Way
Bloomington, IN 47404 U.S.A.

EC Representative
WILLIAM COOK EUROPE ApS
Sandet 6, DK-4632
Bjaeverskov, DENMARK

www.cookmedical.com

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