

**GÜNTHER TULIP™**  
**VENA CAVA FILTER**  
***RETRIEVAL SET***

*for Jugular Vein Approach*

Instructions for Use  
Optional Retrieval Procedure

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# GÜNTHER TULIP™ VENA CAVA FILTER RETRIEVAL SET

## For Jugular Vein Approach

These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgement concerning patient care.

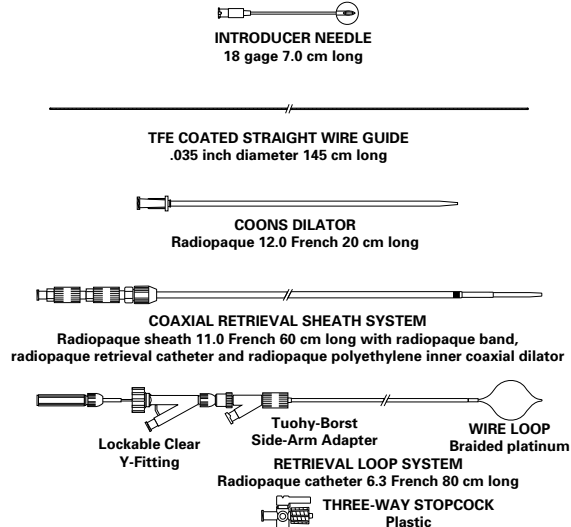
**CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).**

## 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 Vena Cava Filter is designed to act as a permanent filter. When clinically indicated, the filter 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 an implanted Günther Tulip Vena Cava Filter in patients who no longer require a filter.

Retrieval of the filter can be performed only by jugular approach.

## GENERAL USE INFORMATION

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.

Upon removal from package, inspect the product to ensure no damage has occurred.

## 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 device can be safely retrieved (mean of 11.4 days, range 2-20 days). Please refer to the "Clinical Experience" 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

- 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 is no available data which demonstrates 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.

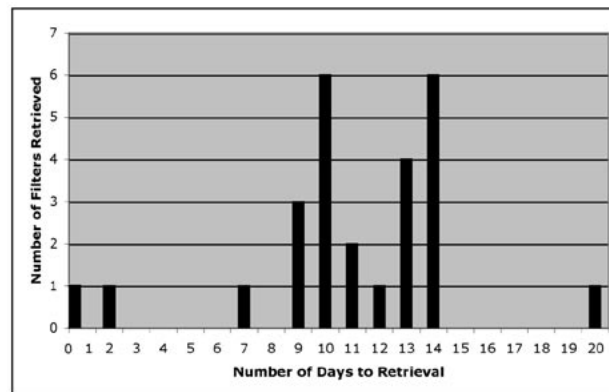
## CLINICAL EXPERIENCE

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 **Figure A** on next page 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.

## Günther Tulip Filter Time to Retrieval



**Figure A**

In addition, the following published sources demonstrate that the Günther Tulip Vena Cava Filter may be safely retrieved:

1. Ivanovic V, Bjarnason H, Johnson CM, "Retrievable IVC Filter Placement: Indications and Outcomes," Abstract submitted to Radiological Society of North America 2003.
2. Given M, Lyon S, Foster A, McGrath F, Lee M, "Retrievable Günther Tulip Filter: Experience in 41 Patients," Paper. 2002 Annual Meeting Radiological Society of North America. 2002.
3. Dumbleton S, Ryan J, Smith T, "A Single US Center's Initial Experience with the Retrievable Günther Tulip Filter," Paper. 2002 Annual Meeting Radiological Society of North America. 2002.
4. Nadkarni S, Macdonald S, Cleveland TJ, Gaines PA, "Placement of a Retrievable Günther Tulip Filter in the Superior Vena Cava for Upper Extremity Deep Venous Thrombosis," *Cardiovasc Intervent Radiol* 2002 Nov-Dec;25(6):524-6.
5. Tay KH, Martin ML, Fry PD, Webb JG, Machan LS, "Repeated Günther Tulip Inferior Vena Cava Filter Repositioning to Prolong Implantation Time," *J Vasc Interv Radiol* 2002 May;13(5):509-12.
6. Brenner C, Molloy M, McEniff N, "Use of Inferior Vena Cava Filters in Thromboembolic Disease Two Case Reports," *Ir Med J* 2001 Oct;94(9): 267-8.

7. Millward SF, Oliva VL, Bell SD, Valenti DA, Rasuli P, Asch M, Hadziomerovic A, Kachura JR, "Günther Tulip Retrievable Vena Cava Filter: Results from the Registry of the Canadian Interventional Radiology Association," J Vasc Interv Radiol 2001 Sep;12(9):1053-8.
8. Millward SF, "Günther Tulip Retrievable Filter: Why, When and How?" Can Assoc Radiol J 2001 Jun;52(3):188-92.
9. Lin M, Soo TB, Horn LC, "Successful Retrieval of Infected Günther Tulip IVC Filter," J Vasc Interv Radiol 2000 Nov-Dec;11(10):1341-3.
10. Millward SF, Bhargava A, Aquino J Jr, Peterson RA, Veinot JP, Bormanis J, Wells PS, "Günther Tulip Filter: Preliminary Clinical Experience with Retrieval," J Vasc Interv Radiol 2000 Jan;11(1):75-82.
11. Ponchon M, Goffette P, Hainaut P, "Temporary Vena Caval Filtration. Preliminary Clinical Experience with Removable Vena Caval Filters," Acta Clin Belg 1999 Aug;54(4):223-8.
12. Abbott, G, "Prophylactic Use of Temporary IVC Filters for Prevention of Pulmonary Thromboembolization in a District General Hospital." Poster No. 210. 1999 Society of Cardiovascular & Interventional Radiology. 1999 March.
13. Linsenmaier U, Rieger J, Schenk F, Rock C, Mangel E, Pfeifer KJ, "Indications, Management, and Complications of Temporary Inferior Vena Cava Filters," Cardiovasc Intervent Radiol 1998 Nov-Dec;21(6):464-9.
14. Capasso P, Bianchi D, Meuwly J-Y, Schnyder P, "Perioperative Thromboembolic Protection Using the Günther Tulip Inferior Vena Cava (IVC) Filter as a Temporary Prosthesis," Paper. CIRSE 98 Annual Meeting of Cardiovascular & Interventional Radiological Society of Europe. 1998: 21(1).
15. Lorch H, Zwaan M, Siemens H-J, Wagner T, Weiss H-D, "Temporary Vena Cava Filters and UHSK Thrombolysis Therapy," Paper. CIRSE 98 Annual Meeting of Cardiovascular & Interventional Radiological Society of Europe. 1998:21(1).
16. Khong PL, John PR, "Technical Aspects of Insertion and Removal of an Inferior Vena Cava IVC Filter for Prophylactic Treatment of Pulmonary Embolus," Pediatr Radiol 1997 Mar;27(3):239-41.
17. Owen RJ, Krarup KC, "Case Report: The Successful Use and Removal of the Günther Tulip Inferior Vena Caval Filter in Pregnancy," Clin Radiol 1997 Mar;52(3):241-3.
18. Neuerburg JM, Günther RW, Vorwerk D, Dondelinger RF, Jager H, Lackner KJ, Schild HH, Plant GR, Joffre FG, Schneider PA, Janssen JH, "Results of a Multicenter Study of the Retrievable Tulip Vena Cava Filter: Early Clinical Experience," Cardiovasc Intervent Radiol 1997 Jan-Feb;20(1):10-6.

## INSTRUCTIONS FOR USE - OPTIONAL RETRIEVAL PROCEDURE

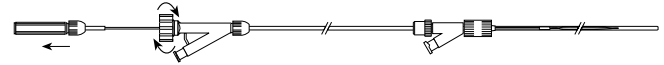


Fig. 1

1. Hold the clear Y-fitting and pull back the plastic pin vise on the wire loop retriever 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.
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 by injection of contrast medium. **(Fig. 2)**

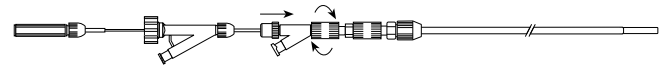


Fig. 3

6. Introduce the retrieval loop system through the coaxial retrieval sheath system, advance and connect the white 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. 3)**

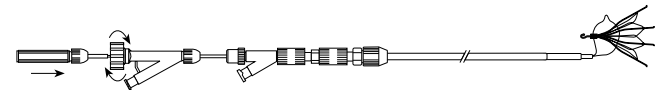


Fig. 4

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

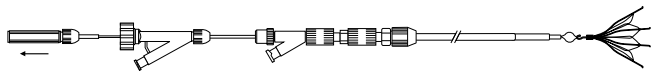


Fig. 5

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.**

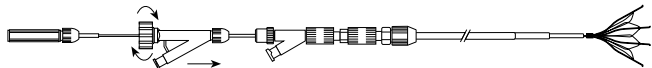


Fig. 6

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. To snare the filter in this position make sure to firmly lock the screw of the clear Y-fitting on the wire loop. (Fig. 6)

**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.**

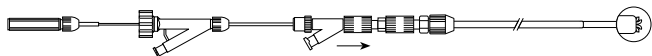


Fig. 7

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. 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.**

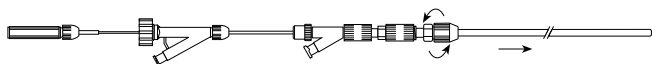


Fig. 8

11. When the tip of the coaxial retrieval system is at the barbed hooks, loosen the hub of the 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 dark, dry, cool place. Avoid extended exposure to light.

