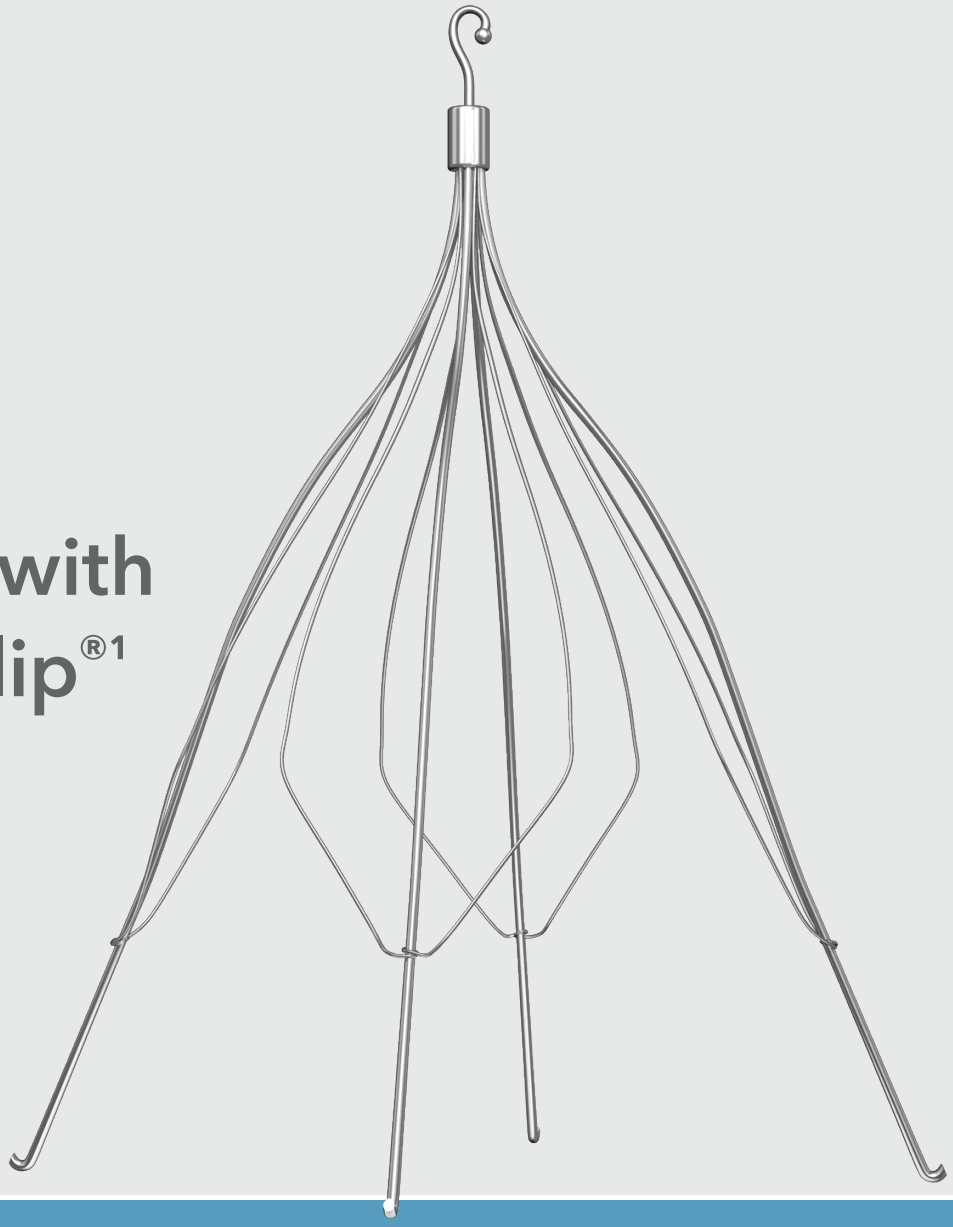
Reliable PE prevention with Günther Tulip®[1]



Günther Tulip®
VENA CAVA FILTER

Effective at preventing PE while also being highly retrievable[1]

Clinical data show successful filter retrieval attempts at 94.3% within study duration (99 successful attempts/105 total attempts).[1]

Freedom from new symptomatic pulmonary embolism while the filter was indwelling was 99.3% (27,1) at 12 months and 99.3% (11,1) at 24 months.[1*]

Accurate, controlled deployment

The Navalign™ delivery system helps to deploy the filter precisely, easily providing control with accurate deployment.

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*Kaplan-Meier estimate (number of patients at risk, number of events).

Global Product Number	Order Number	Filter Max Diameter mm	Filter Length mm	Introducer Sheath Fr	Introducer Sheath Length cm
Femoral					
G52917	IGTCFS-65-1-FEM-TULIP	30	50	7.0	65
Jugular					
G52916	IGTCFS-65-1-JUG-TULIP	30	50	7.0	65
UniSet					
G52918	IGTCFS-65-1-UNI-TULIP	30	50	7.0	65

Global Product Number	Order Number	Retrieval Loop Catheter Fr	Retrieval Loop System Length cm	Retrieval Sheath Fr	Retrieval Sheath Length cm
Günther Tulip® Vena Cava Filter Retrieval Set (Filter Not Included)*					
G13287	GTRS-200-RB	6.3	80	11.0	60

*Set contains the following: coaxial sheath system, retrieval loop system, Coons dilator, needle, wire guide, and 3-way stopcock.

Please follow any step-by-step instructions carefully, including the risk and technical information provided in the IFU.
Note that some products or part numbers may not be available in all markets; consult your Cook representative for details.

1. Van Allan RJ, Smouse HB, McWilliams RG, et al. Two-year outcomes from the Cook Inferior Vena Cava Filter (CIVC) study. *J Vasc Interv Radiol.* 2025;36(4):583–593.e3.

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

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

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 **Optional Filter Retrieval** in the **PRECAUTIONS** section below 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 of 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 **Section 8, CLINICAL STUDIES** in the complete Instructions for Use for data regarding Günther Tulip filter retrieval.

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 has 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 the complete 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 the complete 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** in the complete Instructions for Use) 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 **Section 11, REFERENCES** in the complete 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. • **Section 8, CLINICAL STUDIES** in the complete Instructions for Use includes data that supports the safety of Günther Tulip filter retrieval. • 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. Section 11, REFERENCES** in the complete Instructions for Use includes citations that describe alternative retrieval techniques; this information is provided as reference.

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 fracture • Filter malpositioning • Filter migration • Filter or filter fragment embolization • Hematoma at vascular access site • Hemorrhage • Infection at vascular access site • Intimal tear • Obstruction of blood flow • Pneumothorax • Postphlebitic syndrome • Pulmonary embolism • Retrieval failure • Trauma to adjacent structures • Unacceptable filter tilt • Vascular trauma • Vena cava occlusion or thrombosis • Vena cava penetration • Vena cava perforation • Vena cava stenosis

See Instructions for Use for full product information.

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