ANGEL®
CATHETER

Angel® Catheter

Femoral Approach

Instructions for Use

Catalog No.: AC3930A

CAUTION: Federal (United States) law restricts this device to sale by or on the order of a physician.

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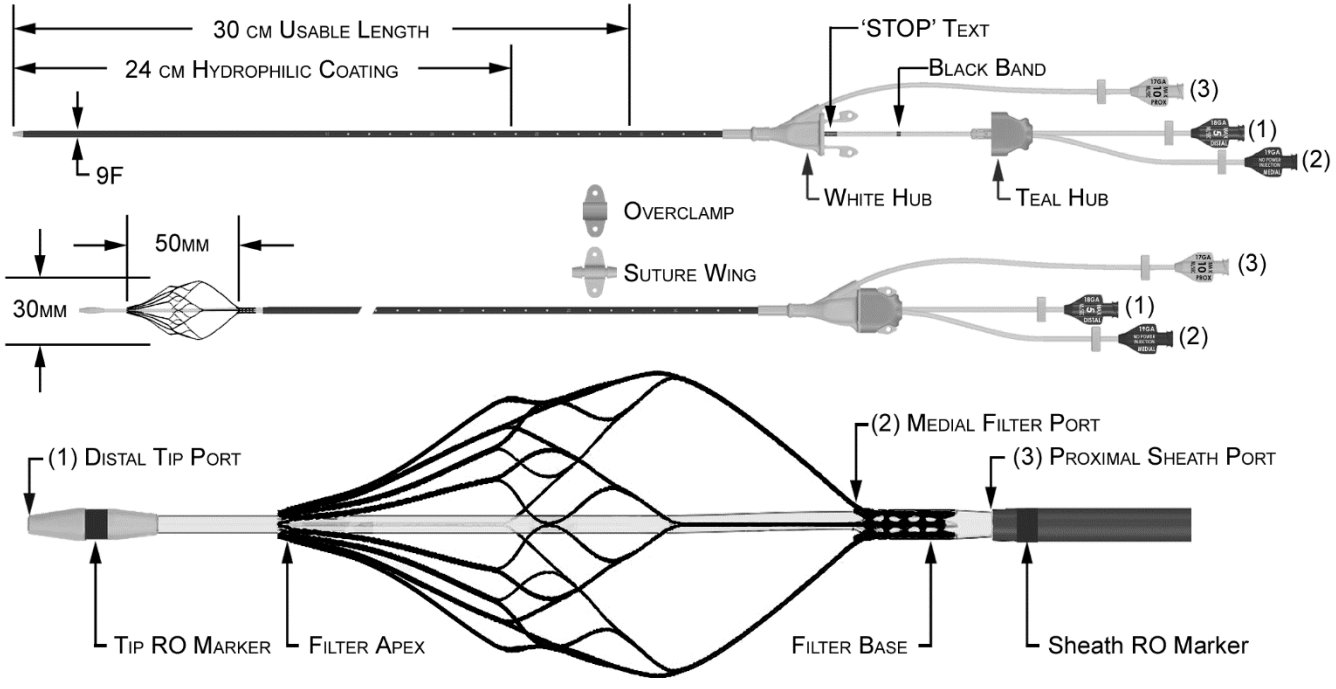
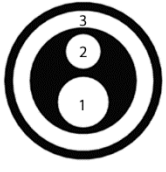


Catheter Cross Section



(1) Distal Tip Port (Brown)
(2) Medial Filter Port (Blue)
(3) Proximal Sheath Port (White)

Figure 1: Angel® Catheter Design Overview

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Device Description

The Angel® Catheter combines the functions of an inferior vena cava (IVC) filter and a multi-lumen central venous catheter (CVC) (see figure 1). The sterile, single use device is designed to be placed in the inferior vena cava, via the femoral vein, for the prevention of Pulmonary Embolism (PE), and for access to the central venous system.

The IVC filter is permanently attached to the multi-lumen central venous access catheter. The filter is intended to be placed in the IVC and serve as an emboli filtration device. The conical, self-expanding, Nitinol filter has wide proximal openings that allow the capture of clots in the distal end of the filter. The filter is 50 mm long at its maximum expanded/ unconstrained diameter of 30 mm

The 9F multi-lumen catheter has a 30 cm usable length and provides the means for delivering, deploying, and retrieving the filter. It also provides 3 lumen access to the central venous system for administering nutrient fluids, sampling or delivering blood, infusion of multiple fluids and therapeutic agents, and monitoring venous pressure. The distal tip port (1) and proximal sheath port (3) may be used for power injection of contrast media. The outer sheath of the Angel® Catheter has '1 cm' depth markers indicating the depth the Angel® Catheter has been inserted into the patient.

The Angel® Catheter is coated with a hydrophilic coating, applied to the outer diameter up to the 24 cm depth marker.

Intended Use

The Angel® Catheter is intended to provide the combined functions of an inferior vena cava (IVC) filter and a multi-lumen central venous catheter.

The Angel® Catheter is intended for short-term use for the prevention of clinically significant pulmonary embolism (PE) in critically ill patients at high risk for PE or recurrent PE, and recognized contraindications to standard pharmacological thromboprophylaxis therapy.

The Angel® Catheter is also intended to provide access to the central venous system.

Contraindications

- Patients with a known IVC with a diameter of >30 mm (megacava)
- Patients with a known IVC with a diameter of <15 mm
- Patients with risk of septic embolism
- Patients with known allergic reactions to nickel

MRI Safety Information

MR Conditional

Non-clinical testing has demonstrated that the Angel® Catheter is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3 Tesla, with
- Maximum spatial gradient magnetic field of 4,000 Gauss/cm (40 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Under the scan conditions defined above, the Angel Catheter is expected to produce a maximum temperature rise of less than 4°C after 15 minutes of continuous scanning. The Angel® Catheter has not been tested in simultaneous combination with other devices.

In non-clinical testing, the image artifact caused by the device extends approximately 4.0 mm from the Angel® Catheter when imaged with a gradient echo pulse sequence and a 3 Tesla MR system.

Warnings

General Warnings

- Prior to use read all package insert warnings, precautions, and instructions. Failure to do so may result in severe patient injury or death.
- The Angel® Catheter is designed for femoral approaches ONLY. Never use the Angel® Catheter for superior approaches (e.g., jugular, subclavian or antecubital vein).
- Do NOT use the device or accessories after the “Use By” date.
- Contents are supplied sterile. Do NOT use if the product sterilization barrier or its packaging is compromised.
- Do NOT use if device is damaged.
- The Angel® Catheter has been designed for single use only. Reusing the Angel® Catheter bears the risk of cross-patient contamination as medical devices, particularly those with long and small lumen, joints, and/or crevices between components, are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biological material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.
- Do NOT resterilize the Angel® Catheter. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing, and/or resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

Catheter Placement Warnings

- Do NOT cut or alter catheter in any way. Doing so will compromise the integrity and functionality of the Angel® Catheter.
- Do NOT withdraw the guidewire back into the needle as this may result in separation of the guidewire. The needle should be removed first.
- Ensure that the filter has been collapsed prior to removal from packaging. Not doing so may result in damage to the catheter and/or filter.
- The healthcare provider must be aware of potential air embolism associated with leaving open needles or catheters in central venous puncture sites or as a consequence of inadvertent disconnects. To lessen the risk of disconnects, only use securely tightened luer-lock connections with this device. Follow hospital protocol to guard against air embolism for all catheter maintenance.
- Failure to dilate the access site may lead to difficulties in catheter placement that may result in damage to the catheter and/or filter.
- Do NOT use excessive force when advancing the dilator.
- Do NOT use excessive force when placing the Angel® Catheter.
- Do NOT use excessive force when deploying the filter.
- Do NOT torque or twist the device.
    - Do NOT apply relative torque between the inner (multi-lumen assembly) and outer (sheath assembly) of the catheter. Application of relative torque between the inner (multi-lumen assembly) and outer (sheath assembly) of the catheter, while the filter is constrained, could cause the filter to twist about its central axis, possibly resulting in damage to the catheter and/or filter.
    - Do NOT apply torque to the inner (multi-lumen assembly) after deployment of the filter. Application of torque to the inner (multi-lumen assembly), while the filter is deployed in the vena cava, could cause the filter to twist about its central axis, possibly resulting in damage to filter and/or damage or irritation to the lining of the vena cava.
- Incorrect securement of the Angel® Catheter to the patient may result in movement of the filter within the vena cava.
- After filter placement, any catheterization procedure requiring passage of a device through the filter may be impeded and/or compromise filter integrity.
- Failure to ensure patency of catheter lumen prior to power injection may result in catheter failure.
- Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.
- Use of lumens not indicated for or exceeding indicated maximum lumen flow rates for power injection of contrast media may result in catheter failure.
- Exceeding maximum power injection pressure of 300psi may result in catheter failure.

Catheter Removal Warnings

- Do NOT retrieve filter if significant amount of thrombus (greater than 25% of the volume of the filter) is observed without attempting to mitigate with clinically acceptable means.
- Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.
- Retrieval of the filter with a filter fracture present may result in complications that require surgical intervention to remove the Angel® Catheter.
- Do NOT use excessive force when collapsing the filter into the outer sheath.

Catheter Removal Warnings (continued)

- Do NOT completely withdraw the Angel® Catheter from the patient prior to collapsing the filter.
- Holding BOTH the inner catheter and WHITE outer sheath hub is important to prevent potential re-deployment of the filter during removal.
- Do NOT use excessive force when withdrawing the Angel® Catheter from the patient.
- After use, the Angel® Catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

Precautions

General Precautions

- This product is intended for use by healthcare providers trained and experienced in diagnostic and/or interventional techniques.
- Do NOT use acetone or alcohol on the Angel® Catheter. Always allow alcohol and acetone applied to skin to dry completely prior to applying dressing.
- Store in a cool, dark, dry place.
- Do NOT expose the Angel® Catheter to organic solvents.
- The safety and effectiveness of this device has NOT been established for pregnant patients.
- The safety and effectiveness of this device has NOT been established for suprarenal placement.
- Procedures or activities that lead to changes in intra-abdominal pressure could affect the integrity or stability of the filter.
- In patients with continued risk of pulmonary embolism, patients should be returned to anti-thrombotic therapy as soon as it is deemed safe.
- If strong resistance is met during any stage of the procedure, discontinue the procedure and determine the cause before proceeding. It is the responsibility of the healthcare provider to use his/her judgment, based on patient safety and clinical experience, regarding the acceptability level of any resistance and whether to continue.

Catheter Placement Precautions

- Use maximal sterile barrier precautions, including a cap, a mask, a sterile gown, sterile gloves, and full body drape during the insertion of the device.
- Exercise caution when handling and inserting the catheter to prevent pinching, crushing, or kinking. This type of damage may prevent proper function of the device.
- Anatomical variances, left sided access and/or patients with higher BMIs, may complicate filter insertion and deployment, and may also require post placement adjustments to be properly positioned in the IVC.
- If ultrasound guidance is available, its use is recommended because it can increase the likelihood of success for gaining intravenous (IV) access. However, ultrasound guidance is not required for placement of the Angel® Catheter.
- If resistance is encountered during a femoral insertion procedure, do not force the guidewire. At no time should the guidewire be advanced or withdrawn when resistance is met. Determine the cause of resistance and take appropriate actions before proceeding.
- Ensure the catheter is dry prior to placement of the suture wing to provide secure grip between the catheter and the suture wing. The suture wing should be placed between the 24cm mark and strain relief. Placement of the suture wing on the hydrophilic coating, at or below the 24 cm depth marker, may result in catheter slippage.

- In agitated patients, use hospital protocol precautions to prevent accidental retrieval/removal of the device.

Catheter Placement Precautions (continued)

- Maintain the access site regularly using aseptic technique per hospital protocol.
- Maintain catheter lumen per hospital protocol. It is recommended that catheter lumen be flushed a minimum of every 8-12 hours or have a continuous infusion to Keep Vein Open (KVO).
- Ensure that the slide clamp on the catheter extension line is disengaged prior to injecting.
- Discontinue power injections if catheter deformation is observed or if catheter lumens have been subjected to a maximum of ten (10) power injections.

Catheter Removal Precautions

- To minimize the risk of inadvertently cutting the catheter, do NOT use scissors to remove the dressing.

Potential Adverse Events

- Accidental catheter removal
- Acute proximal deep vein thrombosis
- Air embolism
- Arrhythmia
- Arterial puncture
- Arteriovenous fistula
- Back or abdominal pain
- Branch vessel occlusion
- Catheter colonization
- Catheter movement
- Catheter-related blood stream infection
- Catheter-related thrombosis
- Caval injury or damage
- Caval occlusion
- Caval perforation
- Caval penetration
- Caval stenosis
- Death
- Deep vein thrombosis
- Embolization
- Extravasation of contrast material at time of vena cavogram
- Failure of filter expansion/incomplete expansion
- Filter fracture
- Filter movement
- Filter thrombosis
- Guidewire entrapment
- Hematoma
- Hemorrhage
- Infection
- Insertion failure
- Intimal tear
- Major bleeding
- Malposition
- Nerve injury
- Obstruction of blood flow
- Pain
- Phlegmasia
- Phlegmasia cerulean dolens
- Postphlebitic syndrome
- Post procedure bleeding
- Pulmonary embolism
- Retrieval complications
- Retrieval failure
- Retroperitoneal hematoma
- Separation of the filter from Angel® Catheter
- Sepsis
- Septic embolism
- Thrombophlebitis
- Vascular trauma
- Venous ulceration

Clinical Experience

Study Design: A single arm, multicenter, prospective study, was conducted to assess the safety and effectiveness of the Angel® Catheter, a combination central venous catheter and inferior vena cava filter, for the prevention of clinically significant PE in critically ill patients. The primary effectiveness endpoint was the freedom from clinically significant PE or fatal PE at the time of discharge or up to 72 hours after removal of the device, whichever occurred first. Freedom from clinically significant PE was formally compared against a performance goal (PG), which was derived based on published reports of clinical trials evaluating the use of pharmacological thromboprophylaxis in patients at high risk of VTE, as well as historical control studies evaluating the risk of VTE and PE among patients not treated with pharmacological thromboprophylaxis. The assessment of the hypotheses was carried out on all per-protocol subjects by comparing the one-sided 95% confidence interval (CI) of the primary endpoint rate to the PG of 94% with a statistical power of 80% to detect a type I error (α) level of 0.05 (one-sided). Additionally, several secondary safety endpoints using descriptive statistics were also evaluated. These included acute proximal DVT, catheter-related thrombosis, catheter-related bloodstream infections (CRBSI), severe bleeding events, and averted PEs defined by the trapping of a significant thrombus in the IVC filter (>25% of the volume of the filter). The independent Clinical Events Committee adjudicated all primary and secondary endpoints, as well as all serious adverse events (SAEs).

A clinically significant PE was defined as a high-risk PE in subjects with systemic hypotension or an intermediate-risk PE in subjects with no hypotension but with right ventricular dysfunction as confirmed by echo or spiral computed tomography of the chest and with myocardial injury as confirmed by elevated levels of troponin I or troponin T. A fatal PE was defined as unexpected death within 24 hours of the onset of the acute event. The treatment period began with the insertion of the device and ended 72 hours after removal or discharge from the hospital, whichever occurred first.

Subject Enrollment: A total of 172 subjects were consented at 20 clinical sites in the United States. Nine subjects did not undergo device implantation as their eligibility changed after screening and before Angel® Catheter insertion (n=6), or; there was an inability to obtain femoral access (n=3). The device was successfully placed in 163 eligible subjects [intention-to-treat (ITT) population], 151 of these subjects had the device in place for at least 48 hours [per-protocol (PP) population].

Indications for Device Placement: The most common indication for placement of the device was recognized contraindication to the use of anticoagulation in 160/163 (98.2%) of subjects (Table 1).

Table 1. Indications for Angel® Catheter Placement

Subject Characteristics	ITT Population (N=163)	PP Population (N=151)
Subject has recognized contraindications to standard pharmacological thromboprophylaxis including	98.2% (160/163)	98.0% (148/151)
Active bleeding or at high risk for bleeding	95.6% (153/160)	95.3% (141/148)
Hypersensitivity to pharmacological thromboprophylaxis	0.0% (0/160)	0.0% (0/148)
History of severe heparin induced thrombocytopenia	0.0% (0/160)	0.0% (0/148)
Severe thrombocytopenia	0.6% (1/160)	0.7% (1/148)
Other	6.9% (11/160)	7.4% (11/148)
Subject has a confirmed acute proximal lower extremity DVT or a confirmed acute PE as diagnosed by site with recognized contraindication to anticoagulation	4.9% (8/163)	5.3% (8/151)
Subject requires a temporary interruption (>24 hours from last dose) of pharmacological thromboprophylaxis for a surgical or medical procedure	6.2% (10/162)	6.7% (10/150)
Prophylactic use of the Angel® Catheter*	98.2% (160/163)	98.0% (148/151)

* Defined as subjects without a confirmed ongoing PE.

Subject Baseline Characteristics: The mean (±SD) age of the subjects was 44±19 years. The vast majority of the study population had high risk factors for VTE events and bleeding. Seventy-eight percent (78%) of the subjects required mechanical ventilation, 24.5% required vasopressors and 72% had another central venous catheter before the insertion of the device. Active bleeding was present in 67/163 (41%), in most of these subjects 56/67 (83.6%) the severity of the bleeding was reported as major. A total of 151/163 (92.6%) of the subjects were admitted to the critical care unit with trauma and the severity of trauma was considered critical in 92/151 (61%). The remaining non-trauma patients enrolled were classified as 2/163 (1.2%) surgical, 6/163 (3.7%) medical, and 4/163 (2.5%) neurological. The mean injury severity score (ISS) was 27.38. The baseline patient characteristics are listed in Table 2.

Table 2. Baseline Characteristics of the Intention to Treat (ITT) and Per Protocol Populations (PP)

Subject Characteristics	ITT Population (N=163)	PP Population (N=151)
Age (yrs) (Mean±SD)	44.07±18.66	44.46±18.56
Male Gender	74.8% (122/163)	74.2% (112/151)
Body Mass Index (BMI) (Mean±SD (N))	28.23±5.63 (163)	28.46±5.56 (151)
Primary ICU Admission Diagnosis		
Trauma	92.6% (151/163)	93.4% (141/151)
Surgical	1.2% (2/163)	0.7% (1/151)
Medical	3.7% (6/163)	3.3% (5/151)
Neurological	2.5% (4/163)	2.6% (4/151)
Summary of Trauma Diagnoses		
Head/Spinal Trauma	85.4% (129/151)	85.1% (120/141)
Head Bleed	79.0% (102/129)	78.3% (94/120)
Chest	41.7% (63/151)	40.4% (57/141)
Abdomen	27.2% (41/151)	25.5% (36/141)
Lower Extremity Trauma	35.8% (54/151)	34.0% (48/141)
More than one area affected	53.0% (80/151)	51.8% (73/141)
Injury Severity Score (ISS) for Trauma Admissions		
Mean±SD (N)	27.68±11.94 (151)	27.38±11.85 (141)
Minimal (1-9)	4.6% (7/151)	5.0% (7/141)
Moderate (10-15	7.3% (11/151)	7.1% (10/141)
Severe (16-24)	27.2% (41/151)	27.7% (39/141)
Critical (25+)	60.9% (92/151)	60.3% (85/141)

Procedural Results: The device was inserted in the critical care unit in 157/163 (96.3%) patients and in all of the subjects without fluoroscopic guidance; the mean time for the insertion was 14.48 ± 12.15 min. Ultrasound guidance was used in 159/163 (97.5%) of the subjects and no serious adverse events were reported as a result of the device insertion. Approximately 80% (130/163) of the devices were placed in the right femoral vein and the remaining 33 placed in the left femoral vein. There were 36/159 (22.6%) repositionings to achieve optimal filter position (apex of the filter up to 3 cm above the L1-2 intervertebral space and up to 5 cm below). Of these repositionings, 28 were peri-procedural adjustments and 8 were post-procedural. The post-procedural repositioning rate was 8/159 (5.03%). There were no clinical sequelae as a result of catheter repositioning.

The mean duration of use of the study device was 6.5 days (range 2-22 days). Device removal was attempted in 143/163(88%) of the inserted devices. Twelve (8%) were subject self-removals and the remaining 131 (80.4%) were retrieved according to the protocol. The remaining twenty devices (12.3%) were not removed as the subjects died with the device in place. None of the deaths were device related. The device was successfully retrieved in 100% of the patients exiting the study in per protocol group. The most common reasons for the device retrieval were: clinical need no longer present or medical thromboprophylaxis was initiated. A pre-removal cavogram was performed in 98.4% that had the catheter retrieved according to the protocol. The mean duration of the removal procedure was 13.7±15.3 minutes.

Study Endpoints: Freedom from clinically significant PE and fatal PE were reported for all subjects (i.e., no clinically significant or fatal PEs were reported in any of the study subjects as determined by the CEC). Thus, the primary effectiveness endpoint of the study was met (Table 3). Of the secondary safety endpoints there were 30/163; 18.40% ITT (30/151; 19.87% PP) acute proximal DVT including the 20/163; 12.27% ITT (20/151; 13.25% PP) catheter-related DVTs, 0/163; 0.00% ITT (0/151; 0.00% PP) catheter-related blood stream infection, and 5/163; 3.07% ITT (4/151; 2.65% PP) rate of major bleeding events (Table 4). In addition, the averted PE rate was 14/163; 8.59% ITT (14/151; 9.27% PP). The study device had no reported events related to filter fracture, migration or embolization.

Table 3: Primary Endpoint Analyses

	ITT Population		PP Population	
	Devices Inserted (N=163)	**Exact 95%CI**	**Devices Inserted (N=151)**	**Exact 95%CI**
Freedom from clinically significant pulmonary embolism (PE) or fatal PE at the time of discharge or up to 72 hours post device removal*, %(n/N)	100.00% (163/163)	[97.76%,100.00%]	100.00% (151/151)	[97.59%,100.00%]
Freedom from Clinically Significant PE, %(n/N)	100.00% (163/163)	[97.76%,100.00%]	100.00% (151/151)	[97.59%,100.00%]
Freedom from Fatal PE, %(n/N)	100.00% (163/163)	[97.76%,100.00%]	100.00% (151/151)	[97.59%,100.00%]

* The primary endpoints are presented for the PP population, i.e., subjects who (1) Have the indwelling Angel® Catheter for at least 48 hours or (2) have experienced clinically significant PE within 24-48 hours from the Angel® Catheter insertion.

Table 4: Secondary Endpoints*, %(n/N)

	ITT Population (N=163)	PP Population (N=151)
Acute Proximal Deep Vein Thrombosis	18.40% (30/163)	19.87% (30/151)
Catheter-related Thrombosis	12.27% (20/163)	13.25% (20/151)
Catheter-related Blood Stream Infections	0.00% (0/163)	0.00% (0/151)
Major Bleeding Events	3.07% (5/163)	2.65% (4/151)
PE Averted**	8.59% (14/163)	9.27% (14/151)

* The secondary endpoints (except for PE averted) are reported for the follow-up period from the catheter insertion until 72 hours following catheter removal or hospital discharge (whichever is first).
** PE averted is defined if a thrombus greater than 25% filter volume was reported by the CORE radiology lab.

Instructions for Use—Angel® Catheter

Procedure for Angel® Catheter Placement, Femoral Approach

Catheter Insertion

WARNING: Do NOT cut or alter catheter in any way. Doing so will compromise the integrity and functionality of the Angel® Catheter.

CAUTION: Use maximal sterile barrier precautions, including a cap, a mask, a sterile gown, sterile gloves, and full body drape during the insertion of the device.

CAUTION: Exercise caution when handling and inserting the catheter to prevent pinching, crushing, or kinking. This type of damage may prevent proper function of the device.

CAUTION: Anatomical variances, left sided access and/or patients with higher BMI's may complicate filter insertion and deployment, and may also require post placement adjustments to be properly positioned in the IVC.

1. Prepare and drape the femoral access site per hospital protocol.
    a. Insert an 18 Ga. needle into the femoral vein and stabilize the needle with the other hand (observe for non-pulsatile blood return).
    b. Verify venous return and access into the femoral vein.
    c. Advance an 0.035" (6mm J Tip) wire into the needle and the vessel lumen, withdraw the needle.
    d. Enlarge access site with a scalpel.

CAUTION: If ultrasound guidance is available, its use is recommended because it can increase the likelihood of success for gaining intravenous (IV) access. However, ultrasound guidance is not required for placement of the Angel® Catheter. Access the femoral vein by using the Seldinger technique.

CAUTION: If resistance is encountered during a femoral insertion procedure, do not force the guidewire. At no time should the guidewire be advanced or withdrawn when resistance is met. Determine the cause of resistance and take appropriate actions before proceeding.

WARNING: Do NOT withdraw the guidewire back into the needle as this may result in separation of the guidewire. The needle should be removed first.

2. Prepare the Angel® Catheter for insertion:
    a. Prior to removing the catheter from package, flush each of the three lumens with 2-5 cc of saline. Use the slide clamps to clamp the Proximal Sheath Port and Medial Filter Port. Leave the Distal Tip Port unclamped to allow for guidewire passage.
    b. Collapse the expanded filter into the sheath by pinching the WHITE tabs on the proximal end of the catheter hub and pulling back on the TEAL colored proximal hub until 'STOP' text can be seen and the WHITE tip of the catheter is seated in the outer sheath.

WARNING: Ensure that the filter has been collapsed prior to removal from packaging. Not doing so may result in damage to the catheter and/or filter.

WARNING: The healthcare provider must be aware of potential air embolism associated with leaving open needles or catheters in central venous puncture sites or as a consequence of inadvertent disconnects. To lessen the risk of disconnects, only use securely tightened luer-lock connections with this device. Follow hospital protocol to guard against air embolism for all catheter maintenance.

3. Dilate the access site with a 9F dilator over the guidewire. Remove the dilator from the access site.

WARNING: Failure to dilate the access site may lead to difficulties in the placement procedure that may result in damage to the catheter and/or filter.

WARNING: Do NOT use excessive force when advancing the dilator.

4. Pull on the WHITE hub to remove the Angel® Catheter from the packaging.
5. Advance the Angel® Catheter over the 0.035" guidewire.
   a. Ensure complete wetting of the external surface of the catheter to activate the hydrophilic coating.
   b. Advance catheter all the way to the hub.

WARNING: Do NOT use excessive force when placing the Angel® Catheter.

Filter Deployment

6. Hold the TEAL hub stationary in one hand and retract the WHITE hub with the other hand to deploy the filter, ensuring that the hub is securely locked together.

WARNING: Do NOT use excessive force when deploying the filter.

WARNING: Do NOT torque or twist the device.

- **Do NOT apply relative torque between the inner multi-lumen assembly and outer sheath assembly of the catheter. Application of relative torque between the inner multi-lumen assembly and outer sheath assembly of the catheter, while the filter is constrained, could cause the filter to twist about its central axis, possibly resulting in damage to the catheter and/or filter.**
- **Do NOT apply torque to the inner multi-lumen assembly after deployment of the filter. Application of torque to the inner multi-lumen assembly, while the filter is deployed in the vena cava, could cause the filter to twist about its central axis, possibly resulting in damage to filter and/or damage or irritation to the lining of the vena cava.**

7. Following placement of the Angel® Catheter, it is recommended to confirm proper position of the filter via an abdominal radiograph (KUB). The filter apex should be positioned in the region at or below L1. The filter base should be above L5. Figure 2 can be used as a reference for the targeted placement zone for the IVC filter.

NOTE: The KUB may be performed after the catheter securement to confirm filter position.

   a. Note the indwelling catheter length per the centimeter mark closest to the access site, once initial satisfactory placement has been achieved, to ensure no unintentional catheter movement in subsequent catheter securement steps.

8. In some patients adjustment of filter position may be required for optimal placement:
   a. Collapse filter into the sheath by pinching the WHITE tabs on the proximal end of the catheter hub and pullback on the TEAL colored hub until the BLACK band on the multi-lumen is visible, indicating that the filter is collapsed. The 'STOP' text indicates that the filter has been fully retrieved into the outer sheath.
   b. Relative to depth marker noted at time of initial KUB, adjust the catheter depth to obtain desired filter position in the inferior vena cava.
   c. Redeploy filter by holding the WHITE hub stationary while advancing the TEAL hub until the hub is locked together.
   d. Repeat KUB to confirm proper filter position.

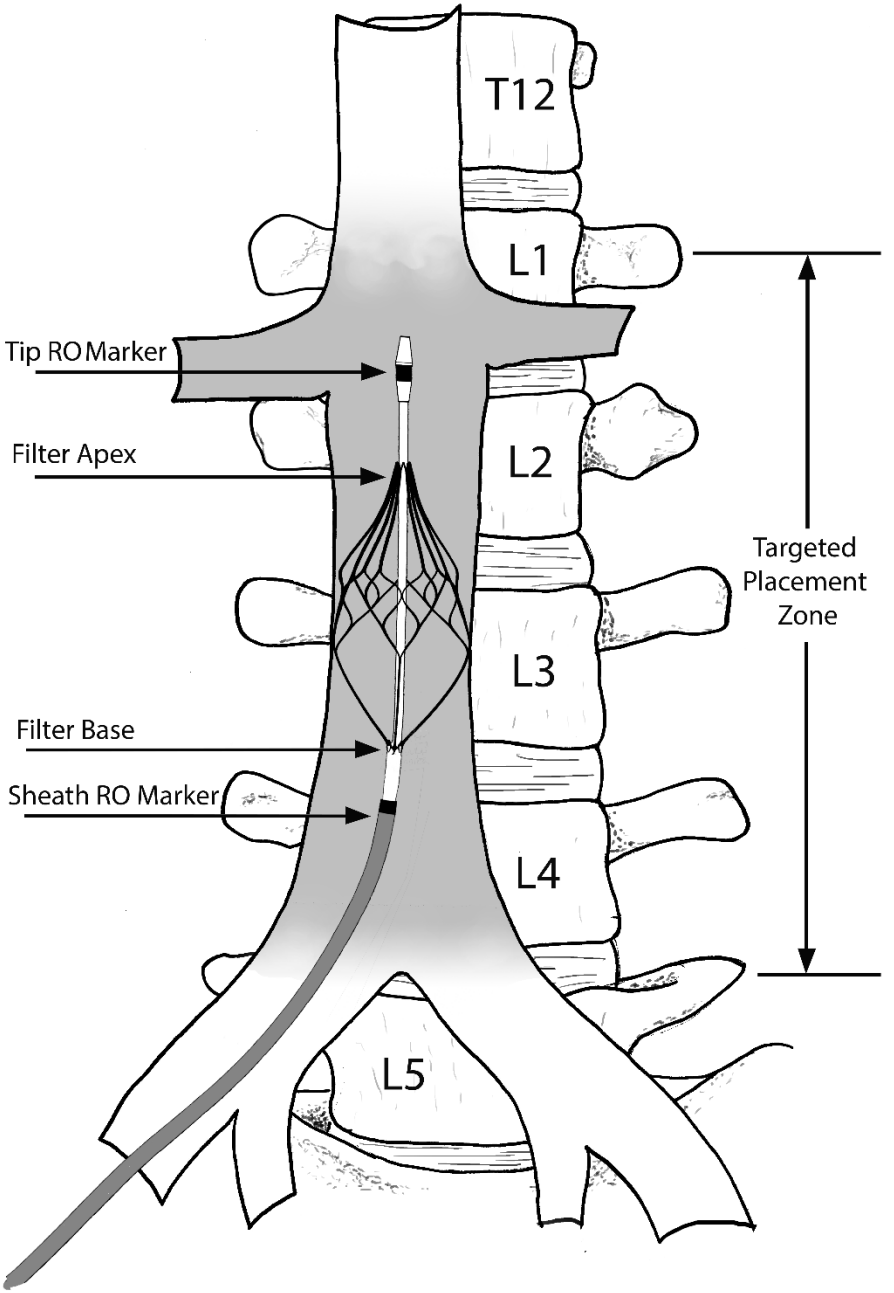


Figure 2: Reference for the targeted placement zone for the IVC filter

9. Remove the guidewire.
10. After removing the guidewire, verify venous blood can be aspirated and flush each lumen.
11. Engage the slide clamps after flushing to prevent blood loss.
12. Allowing space for proper positioning of a BIOPATCH®, or alternate anti-infective dressing, around the catheter at the access site, place the suture wing onto the catheter and lock it into position with the over-clamp (Figure 3).

CAUTION: Ensure the catheter is dry prior to placement of the suture wing to provide secure grip between the catheter and the suture wing. The suture wing should be placed between the 24 cm mark and strain relief. Placement of the suture wing on the hydrophilic coating, at or below the 24 cm depth marker, may result in catheter slippage.

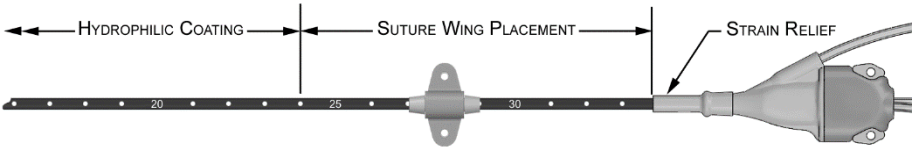


Figure 3: Suture wing placement

13. Suture the suture wing and over-clamp to the skin.
14. Place sutures through the loops of the catheter hub to reduce possibility of inadvertent decoupling of the catheter hub (Figure 4).

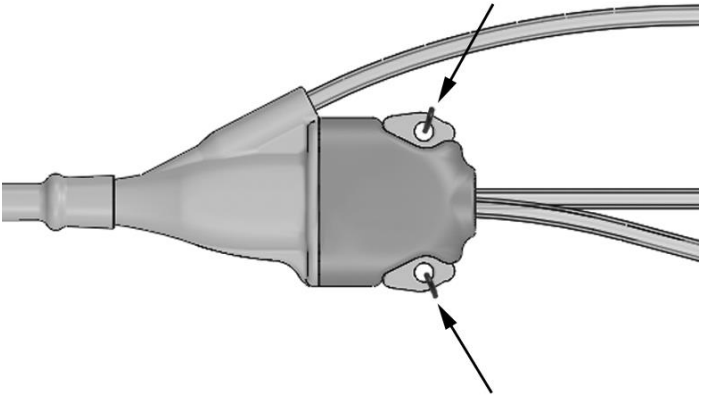


Figure 4: Sutures through catheter hub loops

CAUTION: In agitated patients, use hospital protocol precautions to prevent accidental retrieval/removal of the device.

WARNING: Incorrect securement of the Angel® Catheter to the patient may result in movement of the filter within the vena cava.

15. Place recommended BIOPATCH®, or alternate anti-infective dressing, around the catheter at the access site.
16. Apply Tegaderm™ dressing over access site and dress the access site per hospital protocol.

WARNING: After filter placement, any catheterization procedure requiring passage of a device through the filter may be impeded and/or compromise filter integrity.

17. Record indwelling catheter length, per the centimeter mark closest to the access site, on the patient's chart. Regular visual assessment of catheter position should be made to ensure that the catheter has not moved.

CAUTION: Maintain access site regularly using aseptic technique per hospital protocol.

CAUTION: Maintain catheter lumen per hospital protocol. It is recommended that catheter lumen be flushed a minimum of every 8-12 hours or have a continuous infusion to Keep Vein Open (KVO).

18. Clearly indicate on patient chart, and at the patient's bedside, that patient has an IVC filter attached to a central venous catheter (Angel® Catheter).

19. Maintain the Angel® Catheter and access site per standard hospital protocols for central line catheters. The standard of care in each institution should follow guidelines for the prevention of intravascular catheter-related infections.

Power Injection Procedure

20. Ensure patency of catheter lumen prior to power injection.

WARNING: Failure to ensure patency of catheter lumen prior to power injection may result in catheter failure.

21. Warm contrast media to body temperature prior to power injection.

WARNING: Failure to warm contrast media to body temperature prior to power injection may result in catheter failure.

22. Connect power injector and perform power injection taking care not to exceed labeled maximum flow rates:

- Proximal Sheath Port (WHITE): 10mL/sec
- Distal Tip Port (BROWN): 5mL/sec
- Medial Filter Port (BLUE): DO NOT POWER INJECT

WARNING: Use of lumen not indicated for or exceeding indicated maximum lumen flow rates for power injection of contrast media may result in catheter failure.

WARNING: Exceeding maximum power injection pressure of 300psi may result in catheter failure.

CAUTION: Ensure that the slide clamp on the catheter extension line is disengaged prior to injecting.

CAUTION: Discontinue power injections if catheter deformation is observed or if catheter lumen has been subjected to a maximum of ten (10) power injections.

23. Disconnect power injector and maintain catheter per hospital protocol.

Procedure for Angel® Catheter Removal

Filter Retrieval

24. Utilize the Angel® Catheter Proximal Sheath Port to perform a contrast vena cavagram, or alternate acceptable imaging means to check for thrombus and take appropriate precautions.

WARNING: Do NOT retrieve filter if significant amount of thrombus (greater than 25% of the volume of the filter) is observed without attempting to mitigate with clinically acceptable means.

WARNING: Filter fractures are a known complication of vena cava filters. There have been some reports of serious pulmonary and cardiac complications with vena cava filters requiring the retrieval of the fragment utilizing endovascular and/or surgical techniques.

WARNING: Retrieval of the filter with a filter fracture present may result in complications that require surgical intervention to remove the Angel® Catheter.

NOTE: If the decision to place a traditional temporary/permanent IVC filter is made at the time of removal, see recommendation at the end of this document.

25. Remove the suture wing and over-clamp from the catheter.

CAUTION: To minimize the risk of inadvertently cutting the catheter, do NOT use scissors to remove the dressing.

26. Collapse the expanded filter into the sheath by pinching the WHITE tabs on the proximal end of the catheter hub and pulling back on the TEAL colored proximal hub. The BLACK band (Figure 5) on the multi-lumen indicates that the filter (without thrombus burden) has been collapsed. The 'STOP' text (Figure 6) indicates that the filter has been fully retrieved into the outer sheath.

WARNING: Do NOT use excessive force when collapsing the filter into the outer sheath.

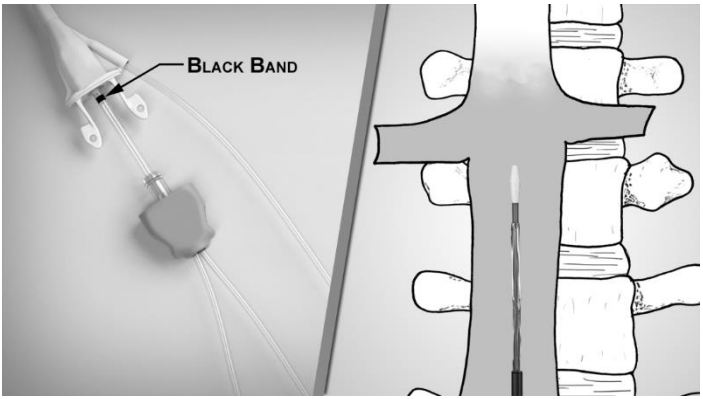


Figure 5: BLACK band indicating filter (without thrombus) is collapsed.

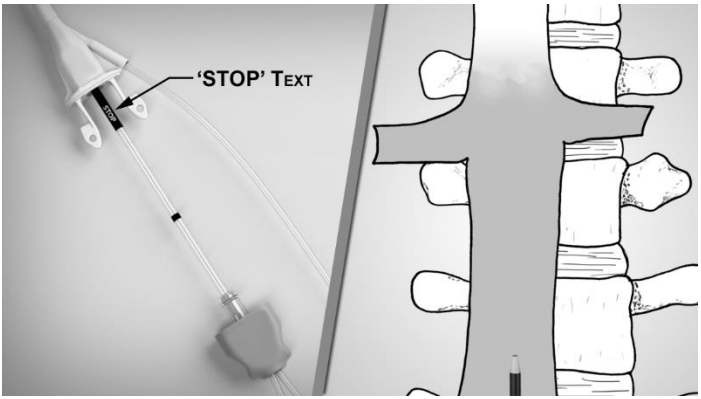


Figure 6: 'STOP' text indicating filter is fully retrieved into outer sheath.

Catheter Withdrawal

WARNING: Do NOT completely withdraw the Angel® Catheter from the patient prior to collapsing the filter.

27. Grasping BOTH the inner catheter and WHITE outer sheath hub, withdraw the Angel® Catheter as one unit from the patient (Figure 7).

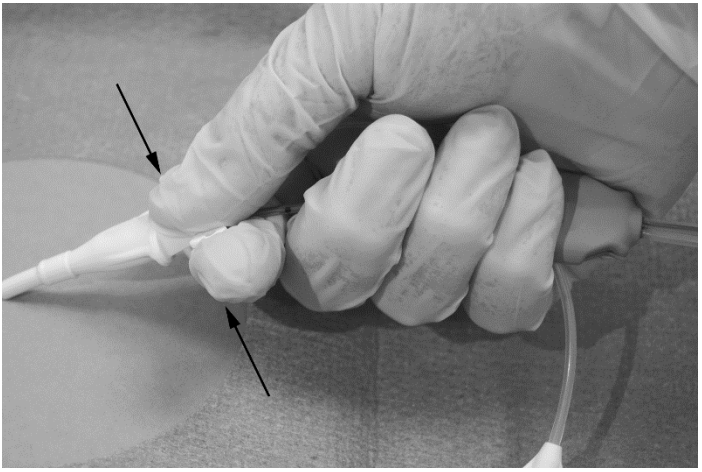


Figure 7: Grasp BOTH the inner catheter and WHITE outer sheath hub during catheter withdrawal

WARNING: Holding BOTH the inner catheter and WHITE outer sheath hub is important to prevent potential re-deployment of the filter during removal.

28. After withdrawal ensure that the entire Angel® Catheter has been withdrawn from the patient.

WARNING: Do NOT use excessive force when withdrawing the Angel® Catheter from the patient.

WARNING: After use, the Angel® Catheter may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable laws and regulations.

Post Catheter Withdrawal Care

After retrieval of filter and withdrawal of the Angel® Catheter, hospital standard of care should be followed for providing hemostasis to prevent bleeding at the vascular access site.

Recommendation for Placement of IVC Filter at Time of Angel® Catheter Removal

If the decision to place a traditional temporary/permanent IVC filter is made at the time of Angel® Catheter removal, it is recommended to partially withdraw the expanded filter to allow for placement of the traditional filter in the IVC. The expanded filter/Angel® Catheter should be positioned to allow for unobstructed delivery and placement of the traditional filter.

WARNING: After filter placement, any catheterization procedure requiring passage of a device through the filter may be impeded and/or compromise filter integrity.

Storage and Handling

The Angel® Catheter is supplied sterilized by ethylene oxide gas in a peel-open package. It is intended for one-time use only. The Angel® Catheter is 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.

WARNING: Contents are supplied sterile. Do NOT use if the product sterilization barrier or its packaging is compromised.

WARNING: Do NOT use if device is damaged.

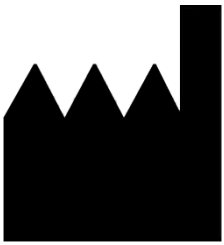
Symbols Glossary

Symbol	Title of Symbol	Standard and Symbol Reference
	Caution, see Instructions for Use	ISO 15223-1 5.4.4
	Do Not Reuse	ISO 15223-1 5.4.2
	Do Not Resterilize	ISO 15223-1 5.2.6
	Keep Dry	ISO 15223-1 5.3.4
	Keep Away From Sunlight	ISO 15223-1 5.3.2
	Do Not Use If Package is Damaged	ISO 15223-1 5.2.8
	Sterilized Using Ethylene Oxide	ISO 15223-1 5.2.3
	Catalog Number	ISO 15223-1 5.1.6
	Use By Date	ISO 15223-1 5.1.4
	MR Conditional	ASTM F2503-13
	Batch Code	ISO 15223-1 5.1.5
	Manufacturer	ISO 15223-1 5.1.1
	Non-Pyrogenic	ISO 15223-1 5.6.3
	Prescription Use Only	N/A

The symbols used in Angel® Catheter labeling are contained in the following recognized standards: ISO 15223-1:2012 Medical devices—Symbols to be used with medical devices labels, labeling, and information to be supplied—Part 1: General requirements, and ASTM F2503-13 Standard Practice For Marking Medical Devices And Other Items For Safety In The Magnetic Resonance Environment.

ANGEL® CATHETER

Patents https://www.mermaidmedical.com/patents/



Angel® Catheter
Catalog No.: AC3930A

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mermaid medical®