Summary of Safety and Clinical Performance
Angel® Catheter

Language: *en*

Scope

Summary of safety and clinical performance (SSCP) according to Regulation (EU) 2017/745 (MDR) article 32 and MDCG 2019-9 Rev.1. This SSCP (Reference number SSCP-003) is intended to provide public access to an up-to-date summary of the main aspects of the safety and clinical performance of the Angel® Catheter device. This SSCP is not intended to replace the Instructions for Use (IFU) as the main document to ensure the safe use of the device, nor it is intended to provide diagnostic or therapeutic suggestions to intended users or patients. The IFU contains all that is needed to directly find this SSCP in the EUDAMED public website once the mandatory usage date occurs. The official web address of the EUDAMED public website is https://ec.europa.eu/tools/eudamed.

The following information is intended for users/healthcare professionals. A supplemental SSCP with information for patients was not established since the Angel® Catheter is not an implantable device for which patients are provided an implant card, nor is the device intended to be used directly by patients.

This SSCP has been validated by the Notified Body and reflects the Validation Language as English per the recommendations of MDCG 2019-9 Section 9.

Revision history

SSCP Rev #	Date Issued	Change Description	Revision Validated by Notified Body
SSCP-003 Rev.01	2-December-2025	Initial Release of SSCP.	☒ Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices for which the SSCP is not yet sampled for validation by the NB)

1. Device identification and general information

1.1. Device trade name(s) covered by this SSCP:

Product Trade Name
Angel® Catheter

Catalog Number
The Angel® Catheter is offered in one size identified by catalog number: AC3930A

1.2. Manufacturer's name and address:

Manufacturer's name
Mermaid Medical A/S

Address of Manufacturer
Frydensbergvej 25
DK-3660 Stenløse
Denmark

Website
https://www.mermaidmedical.com/

1.3. Manufacturer's single registration number (SRN):

DK-MF-000033308

1.4. Basic UDI-DI:

5711055ACPX

1.5. Medical device nomenclature description / text:

In accordance with the Explanatory note on MDR codes guidance, MDCG 2019-14, the following MDR codes were identified for the Angel® Catheter:

- MDN 1203 - Non-active non-implantable guide catheters, balloon catheters, guidewires, introducers, filters, and related tools
- MDS 1005 - Devices in sterile condition
- MDT 2008 - Devices manufactured in clean rooms and associated controlled environments
- MDT 2011 - Devices which require packaging, including labelling

Additional medical device nomenclature applied to the Angel® Catheter is in the table below:

European Medical Device Nomenclature Number (EMDN)	C01050101: VENA CAVA FILTERS, RETRIEVABLE
Global Medical Device Nomenclature Code (GMDN)	41587: Vena cava filter, temporary/permanent
Universal Medical Device Nomenclature System (UMDNS)	11718
United Nations Standard Products and Services Code (UNSPSC)	42203414
Harmonized System Code (HS)	90189099

1.6. Class of device:

Per EU MDR 2017/745, Article 51, Annex VIII, Rule 7, the Angel® Catheter is classified as a Class III device.

The Angel® Catheter is surgically invasive and intended for short term use (up to 30 days). The device is intended specifically to control (interpreted in this context as “to prevent”) a defect of the central circulatory system through direct contact within the vena cava for the prevention of embolization of significant pulmonary embolism, is intended to administer medicines when needed via the central venous catheter functionality and is intended for use in direct contact with the central circulatory system.

1.7. Year when the first certificate (CE) was issued covering the device:

CE certificate number 573203 was awarded by BSI May 2012. Certificate expired May 2022.

1.8. Authorized representative if applicable; name and the SRN:

An authorized representative is not applicable since the manufacturer, Mermaid Medical A/S, has a registered place of business in Denmark, part of the European Union.

1.9. NB’s name (the NB that will validate the SSCP) and the NB’s single identification number:

Notified Body
BSI Group, The Netherlands B.V.

NB’s single identification number
2797

2. Intended use of the device

2.1. Intended purpose:

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's primary function as an inferior vena cava (IVC) filter is to prevent pulmonary embolism (PE) via placement in the inferior vena cava. The device incorporates a multi-lumen central venous catheter (CVC) to provide access to the central venous system.

The Angel® Catheter is intended for short-term (less than 30 days) vascular access via femoral vein.

2.2. Indication(s) and target population(s):

Indications for Angel® Catheter IVC filter Placement:

- Pulmonary thromboembolism when anticoagulants are contraindicated;
- Failure of anticoagulant therapy in thromboembolic disease;
- Emergency treatment following massive PE where anticipated benefits of conventional therapy are reduced; and/or
- Critically ill patients at high risk of pulmonary embolism not receiving medical thromboprophylaxis due to either increased risk of bleeding, active bleeding or heparin induced thrombocytopenia.

Indications for Angel® Catheter CVC use:

- Administration of nutrient fluids;
- Blood sampling/delivery;
- Venous pressure monitoring; and/or
- Infusion of multiple fluids, therapeutic agents.

Target populations

Adults who fall under the indications.

2.3. Contraindications:

- Pregnant patients when fluoroscopy may endanger the fetus. Risks and benefits should be assessed carefully.
- Patients with a known IVC with a diameter of >30mm (megacava).
- Patients with a known IVC with a diameter of <15mm.
- Patients with risk of septic embolism.
- This device contains a Nitinol alloy, composed of nickel and titanium. Patients with known sensitivities to these metals may suffer an allergic reaction. Patients should consult their healthcare provider prior to implantation for the potential allergy/hypersensitivity to these materials.

3. Device description

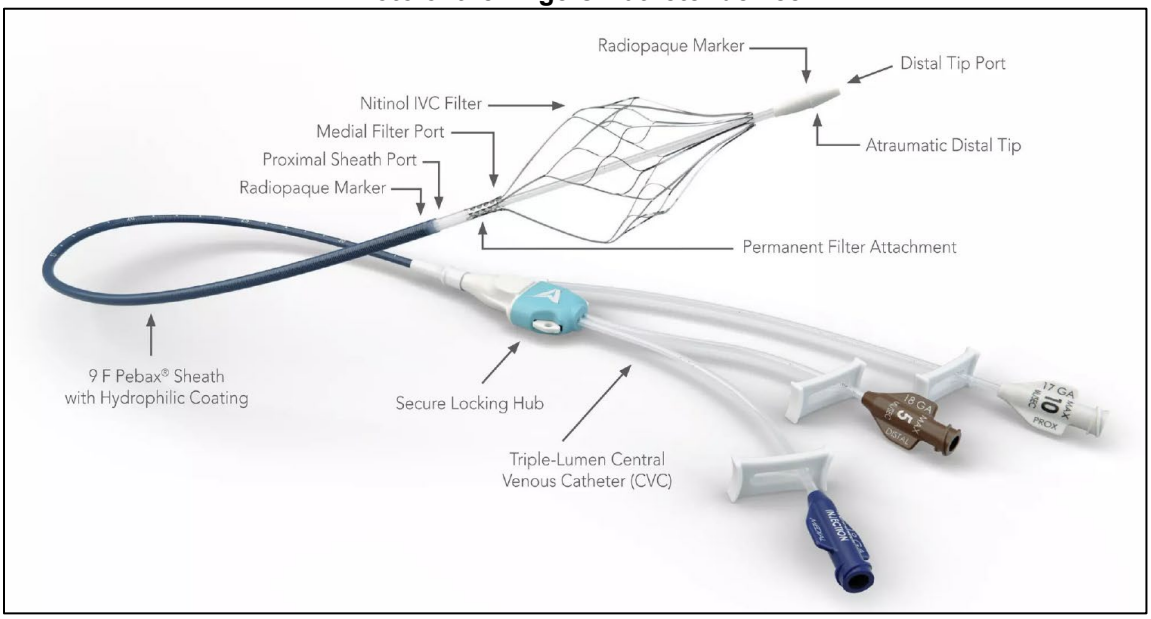
3.1. Description of the device:

The Angel® Catheter combines the functions of an inferior vena cava (IVC) filter and a multi-lumen central venous catheter (CVC). The 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 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 filter is not anchored to the vena cava wall with hooks; instead, it is permanently attached to the multi-lumen catheter to ensure secure positioning. The distal end of the filter is free floating on the central venous catheter so that the filter can expand to the diameter of the vena cava.

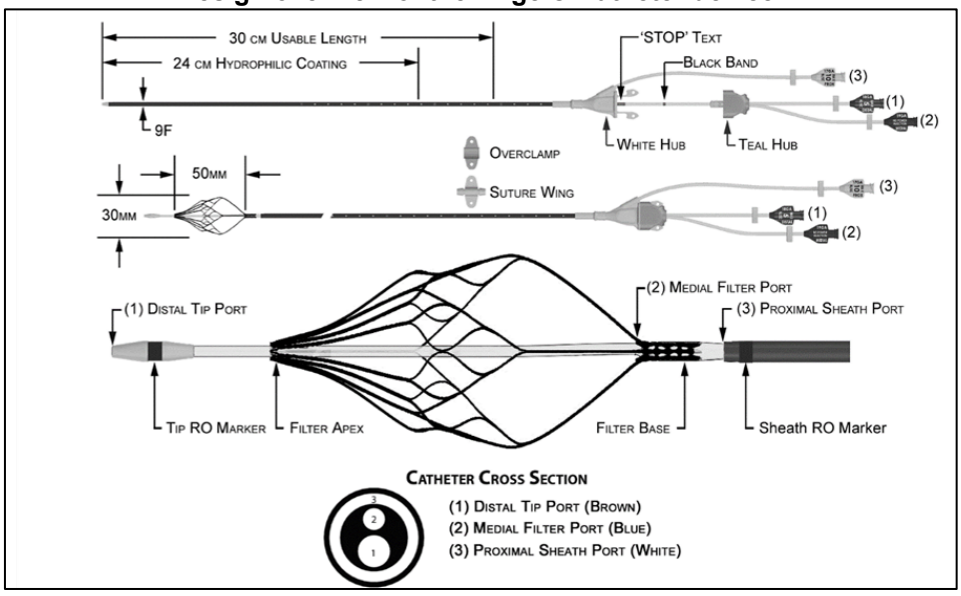
The catheter element of the Angel® Catheter consists of a 30 cm long (usable length), 9F sheath. It is designed to constrain the IVC filter in an unexpanded state for delivery to the IVC and to function as the sheath for retrieval of the IVC filter. The sheath contains coil reinforcement for improved flexibility. The second component of the catheter element is a multi-lumen central venous catheter that delivers the filter to its intended location and remains permanently attached to the IVC filter; it also provides 3-lumen access to the central venous system for administering nutrient fluids, sampling or delivering blood, infusing multiple fluids and therapeutic agents, and monitoring venous pressure. The multi-lumen central venous catheter has a large central lumen that is used for placement via an 0.035″ guidewire. There is one smaller lumen, with a distal opening in the proximal aspect of the filter. Additionally, the annular space between the multi-lumen central venous catheter and the outer sheath, serves as the third lumen for delivery of fluids and/or therapeutic agents needed for the treatment of critically ill Subjects.

The multi-lumen catheter and sheath connections are standard luer fittings, compatible with current ICU pressure monitoring equipment and other accessories. The outer sheath of the Angel® Catheter has '1 cm' depth markers indicating the depth the catheter has been inserted into the patient. The Angel® Catheter is coated with a hydrophilic coating, applied to the outer diameter. The Angel® Catheter is intended to be a temporary device (remaining in place for less than 30 days).

Photo of the Angel® Catheter device.

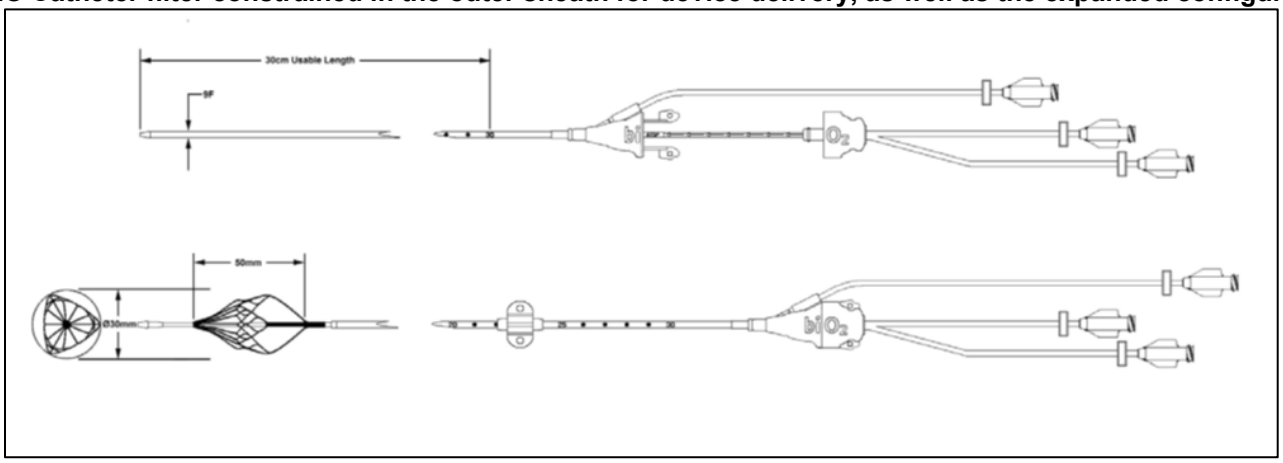


Design overview of the Angel® Catheter device.

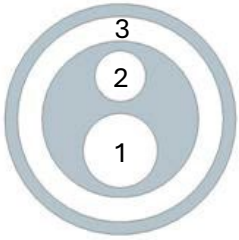


Summary of Safety and Clinical Performance
Angel® Catheter

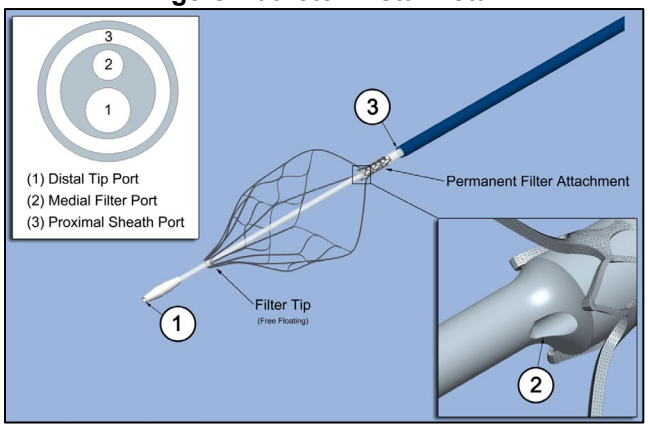
Angel® Catheter filter constrained in the outer sheath for device delivery, as well as the expanded configuration.



Cross section of the Angel® Catheter including lumen information.

Suggested Lumen Use(s)			
Catheter Cross-Section: 			
Lumen/Port Description	**Suggested Use(s)**	**Flow Rate* (ml/min)**	**Equivalent Gauge**
(1) Distal Tip Port	Blood sampling/delivery, administration of nutrient fluids & therapeutic agents, any situation requiring greater flow rate, Central Venous Pressure (CVP) monitoring, and as a 0.035" guidewire lumen.	27	18
(2) Medial Filter Port	CVP monitoring, delivery of therapeutic agents	8	19
(3) Proximal Sheath Port	Blood sampling/delivery, administration of therapeutic agents, any situation requiring greater flow rate, CVP monitoring.	38	17
*Lumen flow rates measured in accordance with ISO 10555-3, using 22°C±2°C deionized water with a head height of 1m.			

Angel® Catheter Distal Detail.

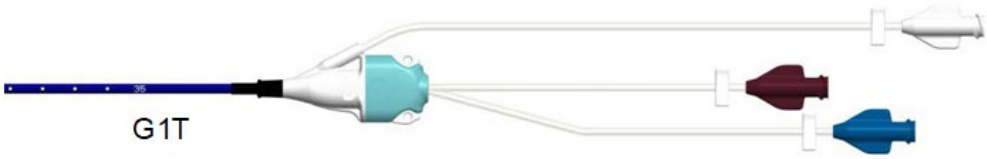
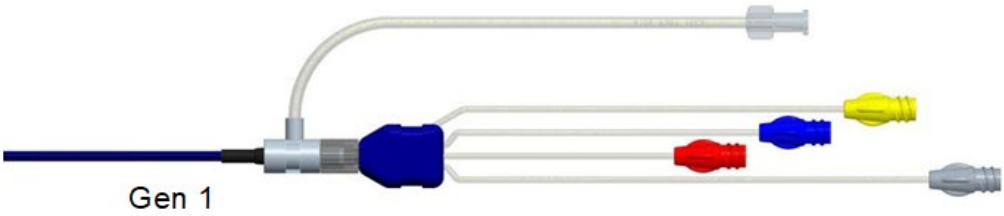


3.2. A reference to previous generation(s)/variants, and a description of the differences:

The original GEN1 Angel® Catheter was developed in 2009. The version currently on the market is the second-generation of the device, G1T, developed in 2012. The modifications made to GEN1 involved the following design and process related improvements:

- ergonomic catheter hub design,
- decrease the number of lumens from five to three,
- over molded catheter luers,
- reduced the usable length from 35cm to 30cm,
- Over molded catheter tip with a positive stop,
- strain relief material changed from polyolefin to silicone; and
- infusion port hole array removed.

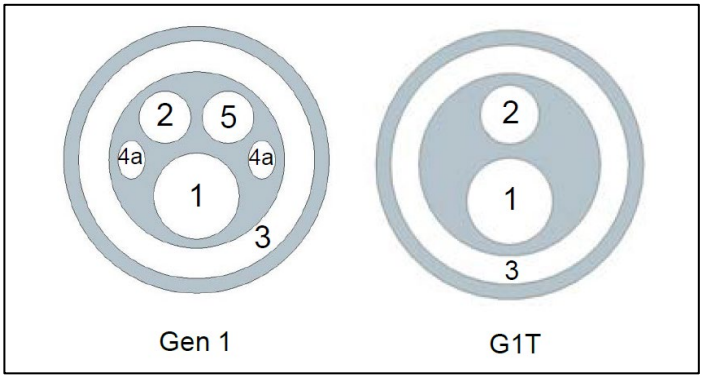
The enhancements to the design were driven by outcomes from design verification testing and clinical feedback obtained during the GEN1 Angel® Catheter first-in-man study. A summary of similarities between the two generations is presented below.

Version		Model	Date (MM-YYYY)
Current		G1T	04-2012
Previous		GEN1	09-2009

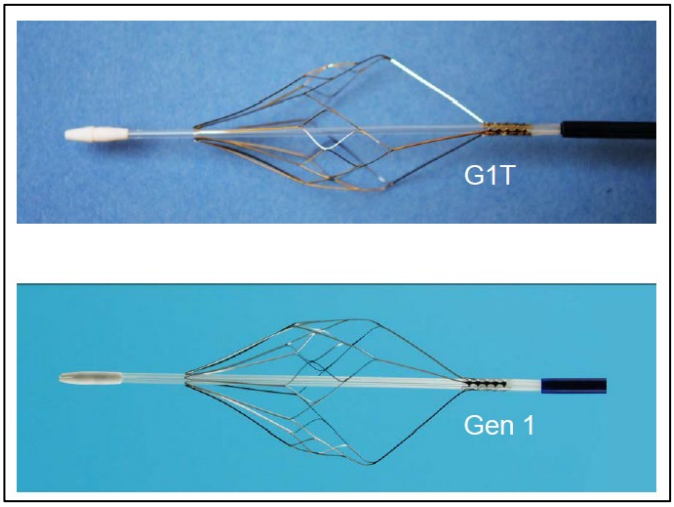
Technical characteristics	**Evaluation**
Technology	Similar
Design and dimension	Similar
Used under the same conditions of use	Same
Principles of operation	Same
Total technical characteristics	**Similar**
Biological characteristics	
Materials in contact with user	Similar
Duration of contact	Same
Body sites in contact with material	Same
Total biological characteristics	**Similar**
Clinical characteristics	
Intended use	Same
Medical indication	Same
Used in the same way	Same
Target population	Same
User	Same
Body site	Same
Total Clinical characteristics	**Same**
Summary	
Assessment of technical, biological, and clinical characteristics confirms that the design and process modifications did not alter the intended purpose, indications, or claims, and had no negative impact on device safety or performance.	

A visual comparison of the Angel® Catheter generations is provided below.

Multi-lumen cross section of G1T vs. GEN1.



Distal Section of G1T vs. GEN1.



3.3. Description of any accessories which are intended to be used in combination with the device:

No accessories are packaged and sold with the Angel® Catheter. The multi-lumen catheter and sheath connections are standard luer fittings, compatible with current ICU pressure monitoring equipment and other accessories that can be utilized with the Angel® Catheter. The Distal Tip Port and Proximal Sheath Port may be used for power injection of contrast media. Pad printing on the luers indicate maximum power injection rates.

The Percutaneous Access Kit, AK9035A is compatible with the Angel® Catheter. The kit provides accessories needed for the percutaneous placement of a catheter and is available for purchase separately.

3.4. Description of other devices and products intended to be used in combination with the device:

The Angel® Catheter is intended to be connected to other device(s) for monitoring/servicing of the device. Connections are color coded and labeled with their respective functions and are standard female luer connections that are commonly used in medical applications.

Connected equipment (by third party)
Connected equipment may include ICU Pressure monitoring equipment, ultrasound, power injector, contrast vena cavagram, radiograph.

Required supplies (by third party)
Required supplies may include cap, mask, sterile gown, sterile gloves, full body drape, BIOPATCH, Tegaderm, and temporary/permanent IVC filter.

4. Risks and warnings

4.1. Residual risks and undesirable effects:

The side effects are mentioned in the IFU. Clinical data for the Angel® Catheter is provided in the Clinical Evaluation Report and compared with literature data from meta-analysis and clinical studies of similar devices. The incidences found for the Angel® Catheter are in the range or even lower compared to literature data from meta-analysis and clinical studies of competitor devices.

Complications

The risks associated with use of the Angel® Catheter for its intended use were identified through the completion of a thorough risk analysis. Many of the identified risks (e.g., tip/filter embolization, filter durability/fatigue fracture, capture efficiency, filter migration, filter retrieval ability/force) were able to be adequately evaluated through nonclinical studies (i.e., bench and animal studies) which were reviewed for the previous BSI CE certification approval and the FDA 510(k) clearance for the Angel® Catheter. The potential clinical risks associated with the Angel® Catheter are consistent with those typically observed with the use of IVCFs or CVCs. It is crucial to recognize that some of these complications may result in fatal outcomes, given the critically ill nature of the patient population. Their clinical condition inherently carries a heightened likelihood of adverse events. Patient safety risks of the Angel® Catheter of major concern include (but are not limited to) catheter–related vein thrombosis, pulmonary emboli and the risk of catheter related blood stream infection (CRBSI). Data associated with these risks were collected in the post market data. In the tables below, relevant harms of residual risks are displayed and their occurrence described in the complaints and literature is reported.

Possible complications associated with the use of IVCFs

Stage	Complications	Definition	Rates from Literature	Frequency of Occurrence Rates (TPLC)	Internal Complaints	Angel® Catheter Clinical Studies
Immediate	Insertion problems	Incomplete filter opening, filter tilt more than 15 degrees from the IVC axis, misplacement of filter outside the intended area, or prolapse of filter components	5%-23% [84][37]	0.1%	-	1.7%
	Filter malposition	Placement of the filter outside the vena cava or outside of the proper and intended final position	1%-9% [84]	0.2%	-	3.4%
	Air embolism	Air embolism of the pulmonary arteries developing after filter insertion	0.2% [84]	-	-	-
	Arterial puncture	Artery puncture developing after filter insertion	0.04% [84]	-	-	-
	Arteriovenous fistula	An abnormal connection, either spontaneous or surgically created, between an artery and a vein	0.02% [84]	-	-	-
	Intimal tear	Dissection or rupture of the endothelial wall of the IVC.	-	-	-	-
	Failure of filter expansion/incomplete expansion	Failure of the filter to expand (open) after deployment	-	-	-	-
	Pain	An unpleasant feeling often caused by intense or damaging stimuli	-	0.1%	-	-
	Hematoma	Blood accumulation in soft tissues that is diagnosed clinically or by imaging	0.6% [84]	0.01%	-	-
	Hemorrhage/ Major bleeding event	Fatal bleeding or bleeding that requires diagnostic studies, hospitalization or treatment by a healthcare professional	-	0.03%	-	0.4%
Early	Infection	Invasion of a host organism's bodily tissues by disease-causing organisms, their multiplication, and the reaction of host tissues to these organisms and the toxins they produce	-	-	-	-
Late	Filter migration	Movement of the filter >2 cm from its initial placement position	0-18% [83][84][37]	0.1%	-	1.7%
	Unintended movement	Movement of the catheter as a result of the subject changes in positions and/or manipulations by medical personnel	-	0.4%	-	0.8%
	Organ injury	Trauma or failure of an essential system in the body	-	0.2%	-	-
	Caval penetration or perforation	Filter component extending >3 mm beyond the caval wall or into an adjacent structure	0-41% [83][84][85]	0.2%	-	-
	Filter thrombosis	Blood clot that has been captured or formed in the vena cava filter	2%-30% [83][85][37]	0.2%	-	0.4%
	Recurrent DVT	Thrombosis of proximal lower extremities after filter insertion	5%-35% [37][82][84]	-	-	11.4%
	PE	Blockage of the pulmonary artery or one of its branches. PE most commonly results from a DVT	0.5%-6% [37][82][84]	0.03%	-	0.4%

Stage	Complications	Definition	Rates from Literature	Frequency of Occurrence Rates (TPLC)	Internal Complaints	Angel® Catheter Clinical Studies
	Post- thrombotic syndrome	Post-thrombotic syndrome of the proximal lower-extremity vessels developing after filter insertion	15%-40% [84]	-	-	-
	Filter fracture	Filter fracture (Any loss of a filter's structural integrity (i.e. breakage or separation))	2%-10% [83][84]	0.3%	-	1.3%
	Caval occlusion	Presence of an occluding thrombus in the IVC after filter insertion	2%-30% [83][84]	0.3%	-	-
	Embolization	The process by which a blood vessel or organ is obstructed by an embolus or other mass, preventing normal blood flow	0.1% [83][84]	0.03%	-	-
	Death	The total and permanent cessation of all the vital functions	0.1% [85][37]	0.01%	-	-
	Obstruction of blood flow	Blockage of normal blood flow	-	-	-	-
	Branch vessel occlusion	Partial or complete obstruction of a collateral vein	-	0.3%	-	-
	Retrieval failure	Inability to retrieve the filter	0-10%[37]	0.3%	0.09%	0.80%
	Other		0	0.6%	-	-

Numerous potential complications can occur during the procedural femoral placement of a central venous catheter. Ultrasound guidance has been shown to decrease the risk of complications at all central line access sites. Possible complications associated with the use of CVCs include, but are not limited to, the following:

Possible complications associated with the use of CVCs

Stage	Complications	Definition	Reported rates
Immediate	Arterial puncture	Puncture of the femoral artery	0.5-3.7% [57] 4.2-9.3% [58] 0.5-11.0% [62]
	Catheter retention	Catheter becomes stuck or difficult to remove after insertion	1.5% [57]
	Catheter colonization	Growth of microorganisms, such as bacteria or fungi, on the surface of the catheter	14.2% [61]
	Catheter-related thrombosis	Formation of blood clots (thrombi)	21.5-29.0% [57][61] 25.0% [62] 8.5% (Angel® Catheter Clinical Studies)
	Mechanical complications	Detected perioperatively and were related to a procedure	17.2% [61]
	Major Mechanical complications	Complications requiring a specific therapeutic procedure	1.4% [61]
	Retained Guidewire	Failure to remove the guidewire after catheter placement, often due to procedural error or distraction.	0.05–0.1% [57]
Delayed	Central line-associated bloodstream infections (CLABSI/CRBSI)	Occur when bacteria or other germs enter the bloodstream	15.3 per 1,000 catheter days [57] 80-189 per 100,000 patient years [58] 2.0 per 1,000 catheter days [59] 1.5% [61]
	Catheter damage	Catheter fracture and embolization	0.5-3.0% [57]
	Loss of functionality of ports/lumen	Loss of functionality of one or more catheter ports/lumen for the delivery and/or withdrawal of fluids	14.0-36.0% [97] 8.1% (Angel® Catheter Clinical Studies)

4.2. Warnings and precautions:

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.

<u>Catheter Placement Warnings</u>

- 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.
- 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.

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.
- 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.

4.3. Other relevant aspects of safety, including a summary of any FSCA, including FSN:

This device has never been recalled in any market, nor has any field safety corrective action be initiated. No CAPAs have been initiated for the Angel ® catheter device due to safety or performance of the device. The serious incident rate for the Angel® Catheter is 0.09%, a risk level registering within the established tolerance threshold.

5. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

5.1. Summary of clinical data related to equivalent device:

The device proposed to be considered similar to the Angel® Catheter is OPTEASE™ Retrievable Vena Cava Filter (Cordis), as it is intended to be used for the same indications and patient population, employ the same design, construction, and materials. The Optease™ filter was briefly referenced by name in several SOTA articles, providing no substantial details or added insights beyond its acknowledgment.

Frequency of complications reported with potentially retrievable devices [100]

Complication	Optease™ filter %	Angel® Catheter %	Reduction in complication compared to Optease™ filter %
Fracture	8.4	1.3	84.5
Migration	24.3	1.7	93.0
Limb embolization	1.9	0	100.0
Tilt	5.6	0	100.0
IVC penetration	1.9	0	100.0
VTE/PE	0.9	0.4	55.6
IVC thrombus	6.5	0.4	93.8
Placement issues	30.8	5.9	80.8
Other	19.6	12.6	35.7

The above table provides a detailed comparison of the frequency of complications associated with the similar device Optease™ filter and the Angel® Catheter [100]. On average, the Optease™ filter complication rate is 15.6 times higher (relative values range from 1.6 to 56 times higher) than the Angel® Catheter.

Optease™ filter require close follow-up and timely retrieval to prevent complications [102]. Angel® catheter studies highlight its reliability and lower risk profile, particularly for patients requiring long-term venous access. The Angel® Catheter IVC filter is permanently attached to the catheter, so removing the central venous catheter (CVC)

necessitates the removal of the filter, reducing the likelihood of the filter remaining in place post-discharge. In contrast, regular non-tethered IVC filters, such as Optease™ filter, lack external visibility and can only be detected through imaging. These filters are typically placed while the patient is hospitalized and are removed during a follow-up visit at a hospital or outpatient clinic, often weeks or months later. However, some patients may not return for their follow-up, resulting in the filter remaining in place beyond the recommended duration or even indefinitely. In comparison, it is much less likely for a patient to leave the hospital with a CVC still in place, as the catheter is externally visible and potentially uncomfortable due to its exposed hub and luers at the femoral access site. Additionally, to minimize infection risks, most hospital protocols mandate the removal of CVCs, particularly femoral ones, prior to discharge.

While both devices are effective in their respective applications, the Angel® catheter demonstrates a safer profile with fewer complications and higher reliability. The Optease™ filter, though effective, requires advanced techniques for retrieval and careful monitoring to mitigate long-term risks.

5.2. Summary of clinical data from conducted investigations of the device before the CE-marking:

A comprehensive evaluation was conducted on 254 Angel® Catheter devices, representing 23% of total sales (1,087). These clinical studies spanned a seven-year period, from 2012 to 2019, and involved 41 sites across 5 countries, demonstrating a broad and diverse testing scope. The five studies demonstrated that 9% (23) of the filters effectively captured thrombi, thereby preventing potentially life-threatening PE. The data provides substantial support for its reliability in mitigating PE risks, affirming its clinical value and contribution to patient safety. A majority of these malfunctions were associated with the loss of functionality of one or more catheter ports/lumen for the delivery and/or withdrawal of fluids. Partial or complete occlusion of catheter lumen as a result of fibrin sheath or tail forming is an anticipated physiological response to central venous catheters. There was no indication of any Unanticipated Adverse Device Effect (UADE) based on the clinical data provided.

Angel® Catheter Clinical Study Data

Study Name	NCT number	Study Type	Year(s)	Sites(s)	Location	Subjects	Indwelling Days	Averted PE	Complications	Appraisal Rank
FIM Study (Pilot)	NCT01403090	Prospective [Interventional]	2012	2	CO	8	~4 (2-6)	1 (13%)	0	87.5%
Early Feasibility Study	NCT01847196	Prospective [Interventional]	2013-2014	4	US	5	~5 (1-10)	1 (20%)	2 (40%)	87.5%
Pivotal Study	NCT02186223	Prospective [Interventional]	2015	26	US	163	~7 (1-22)	14 (9%)	20 (12%)	87.5%
Post-Market Registry Study	NCT02917135	Observational [Patient Registry]	2013-2014	8	DE, GB, IT	60	~7 (1-14)	2 (3%)	2 (3%)	80.0%
Cedars Sinai	NA	Retrospective [case series]	2017-2019	1	US	18	~6 (1-19)	5 (28%)	1(6%)	100.0%
5 studies performed on the Angel Catheter			**2012-2019**	**41**	**5 countries**	**254**	**~6 days (1-22 days)**	**23 (9%)**	**25 (10%)**	**High Quality (89%)**

First-in-man (pilot) Clinical Trial

A first-in-man (pilot) clinical trial was conducted at two large academic medical centers in Medellin, Colombia. Recruitment started in December 2011 and concluded in March 2012. Eight critically ill patients in the Intensive Care Unit were included in this study. The principal diagnosis for admission to the ICU was trauma in 7 patients (87%) and subarachnoid hemorrhage in one patient (13%). Six of the trauma patients had multiple bone fractures and abdominal trauma and one had a traumatic brain injury. At the time of device insertion, three patients had ongoing bleeding, and one had a pulmonary embolism. The Angel® Catheter was placed via the femoral vein with ultrasound guidance in 5/8 (62.4%) and advanced to the infrarenal IVC without fluoroscopic guidance. This study confirmed the ease of bedside placement of the Angel® Catheter, with or without ultrasound guidance, into the IVC

via the femoral vein. In one of the patients the filter trapped a large venous clot and prevented PE. The mean length of time before retrieval was 4 days (±1.6). In all the patients, the devices were inserted and retrieved without complications. No diagnosis of new pulmonary embolism, major bleeding or blood stream catheter related infection was made in any of the patients. This pilot study supports the safety of the Angel® Catheter.

Early Feasibility Clinical Trial

The Angel® Catheter Early Feasibility Clinical Study was a single arm, multi-Center, Phase I (early feasibility) study to obtain initial insights into the safety of the Angel® Catheter. Subjects were followed daily during hospitalization until one week after removal of the Angel® Catheter or until hospital discharge, whichever occurred first. This Early Feasibility Study was conducted in four (4) U.S. medical centers, with a potential for up to six (6) sites to place one or more Angel® Catheters. Subject screening was initiated in November 2014 and concluded in June of 2014.

During this Early Feasibility study, the Angel® Catheter was placed in five (5) critically ill subjects with high risk of VTE disease AND who were not receiving pharmacological thromboprophylaxis. All subjects presented a variety of medical and surgical conditions including trauma and/or active or high risk of bleeding, temporary contraindications to anticoagulation, and were at high risk of PE. At the time of device insertion, two (2) subjects had subarachnoid and subdural bleeding, three (3) had traumatic brain injuries, three (3) had hepatic trauma, one (1) had a spinal injury, four (4) had musculoskeletal fractures, two (2) had spleen or kidney lacerations, and four (4) were in respiratory distress. The Angel® Catheter was placed successfully in all five (5) subjects via the femoral vein using ultrasound guidance. The Angel® Catheter was inserted as the first central line in three (3) of the five (5) subjects, and, per clinical indication, additional CVCs were not utilized for these three (3) subjects during their participation in this study. The other two (2) subjects had a CVC in place at the time of the Angel® Catheter insertion. One was removed shortly after Angel® Catheter placement but was replaced three days later. The other remained in place until three days post-removal. The final position of the catheter, as verified by KUB, was between L1 and L3-4 for three (3) of the five subjects and at L1 for the other two (2). Repositioning was required and successfully performed in two (2) subjects. The Angel® Catheter was maintained for an average of 4.1 days ± 3.3 indwelling days.

To assess the presence of clots in the filter and surrounding venous structures, pre-removal imaging was performed in four of the five subjects prior to filter retrieval. Pre-removal imaging was not performed in one subject due to Accidental Catheter Removal (ACR). Three of the four filters were patent (no evidence of trapped thrombus) and retrieved uneventfully. The fourth had significant clot (>25%) within the filter. Imaging confirmed proper deployment of the filter in the infrarenal IVC and the absence of IVC penetration in all four (4) subjects with available imaging. Angel® Catheter removal occurred for all five (5) subjects without complications.Twenty-eight (28) adverse events (AEs) were reported in the five critically ill subjects. No CRBSI, death, major bleeding, or vena cava perforation occurred. Two (2) AEs, both migration >2 cm, were reported as definitely related to the Angel® Catheter, but neither event resulted in clinical harm. No unanticipated adverse device effects (UADEs) were reported. One event of migration was considered unanticipated by the site. However, it did not qualify as a UADE because it was not serious. A total of six (6) serious adverse events (SAEs) were reported. Two SAEs, both DVT, were reported as possibly associated with the Angel® Catheter. However, the Core Lab confirmed that a fibrin sheath was present at the time of catheter removal. Fibrin sheath formation is a well-documented physiological reaction occurring between the catheter, vein wall, and blood elements. The remaining four SAEs were associated with another concurrent illness or injury, or evolution thereof, for which the subject was admitted to the hospital.

In conclusion, during Early Feasibility study the Angel® Catheter was placed in five (5) critically ill subjects with high risk of VTE disease AND who were not receiving pharmacological thromboprophylaxis. The delivery and removal of the Angel® Catheter was successful in all five cases. Maintenance was successful in three of the five cases. In one subject no complications were described after the accidental self-removal of the device. There were no adverse events associated with any of the delivery or removal of the Angel Catheter. There were no unanticipated adverse

device effects observed. The movement of the Angel® Catheter in 2 subjects did not lead to any adverse effects. Catheter coating modifications were implemented for the pivotal investigation which is expected to prevent future occurrences of catheter movement. The observed development of thrombosis in this critically ill subject population who were not anticoagulated was not unexpected, and the capture of thrombi by the Angel® Catheter suggested that the catheter potentially averted a clinically significant PE. A minor PE occurred despite the presence of a commercial filter after removal of the Angel® Catheter. This study supported initial safety of the Angel® Catheter in subjects at high risk of VTE disease AND who were not receiving pharmacological thromboprophylaxis, reference Angel Catheter Early Feasibility Clinical Study Report.

Pivotal Clinical Trial

A U.S. Pivotal Clinical Trial was conducted under an expansion of the Early Feasibility Investigational Device Exemption (IDE) study. The study was conducted to support a planned FDA 510(k) application for the Angel® Catheter G1T product under different indications for use and a power injection rating. A pivotal clinical trial titled "The Angel® Catheter Clinical Trial: Prevention of PE in High-Risk Subjects" was conducted at 26 centers in the United States. This prospective, multicenter study demonstrates that the bedside insertion of the Angel® catheter is safe and that this device is an effective alternative for the prevention of clinically significant PEs in a high-risk population of critically ill patients with contraindications to anticoagulation.

A single arm, multicenter, prospective study, NCT02186223, 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 (a) 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.

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]. The most common indication for placement of the device was recognized contraindication to the use of anticoagulation in 160/163 (98.2%) of subjects.

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.		

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.

Baseline Characteristics of the Intention		
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	67.5% (102/129)	66.7% (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)

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%) repositioning's 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 repositioning's, 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 6.79 days (range 1-22 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.

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. 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. 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.

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.				

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.		

5.3. Summary of clinical data from other sources:

Post Market Registry Study

The Post Market Registry Study was a European, observational, retrospective multi-center study designed to gather information on the usefulness and performance of the Angel® Catheter in general clinical practice and was intended to answer specific questions regarding usefulness and performance (i.e., residual risks) of the Angel® Catheter in general clinical use when used in accordance with its approved labeling.

During the course of this study, retrospective data was collected on the clinical use of the Angel® Catheter in a total of sixty (60) patients at eight (8) centers across the European Union over the course of sixteen (16) months, from March 23, 2013 to September 1, 2014. Patient data was gathered from the time of attempted Angel® Catheter placement through discharge from the hospital (46 patients), death (12 patients) or at least 30 days post retrieval (2 patients).

Prophylactic use of the Angel® Catheter was most common with placement occurring for the prevention of PE in (51/85%) patients at high risk of PE not receiving medical thromboprophylaxis. The remaining (9) patients had diagnosed PE at the time of Angel® Catheter placement, but were unable to receive medical thromboprophylaxis and were at high risk of a recurrent PE. Specifically, the indications reported for Angel® Catheter placement included: (39/65%) patients at high risk of PE not receiving medical thromboprophylaxis including (3) with a diagnosed PE, (6/10%) patients with an existing PE and contraindications to anticoagulation, (3/5%) critically ill patients requiring a ≥24 hour interruption of medical thromboprophylaxis, and in the remaining (12/20%) patients, the placement indication was associated with the nature of their disease and/or injuries, and included brain trauma, multiple trauma, stroke, intracerebral hematoma post-neurosurgery, and deep vein thrombosis. Although these (12) patients did not fit into one of the specified indications, per the investigator and treating physician's discretion, they would still benefit from placement of an IVC filter. Prior to Angel® Catheter insertion, (13/21.7%) patients had diagnosed venous thromboembolism (VTE). (9/15%) of these patients had a diagnosed PE, (7/11.7%) patients had diagnosed deep vein thrombosis, and (3/5%) patients had a diagnosed PE and DVT. At the time of Angel® Catheter placement, (58/96.7%) patients had either temporary or permanent contraindications to medical thromboprophylaxis. Baseline characteristics are summarized and the indications for placement are summarized below:

Baseline Characteristics of the Patient Population.	
Characteristic	**Angel® Catheter**
Age (yrs)	44.1 ± 17.9
Male sex (%)	39 (65%)
Body mass index†	26.5 ± 5.8
Length of Hospital Stay (days)	34.9±43.3
Main ICU diagnosis before insertion of the Angel® Catheter-- no (%)	(N = 60)
Severe Trauma	33 (55%)
Intra-cerebral Bleeding or Stroke	9 (15%)
Venous Thromboembolism	9 (15%)
Active Bleeding	6 (10%)
Burns	1 (1.7%)
Not reported	2 (3.3%)
Classification of Severe Trauma&	(N = 33)
Head or brain injury	22 (66.7%)
Multiple > 2 long bone fractures	10 (30.3%)
Pelvic Fracture	12 (36.4%)
One long bone fracture	6 (18.2%)
Severe Trauma with associated PE	3 (9.1%)
Thoracic or abdominal trauma	2 (6.1%)
Spinal Injury with or without paralysis	2 (6.1%)

Classification of Venous Thromboembolic (VTE) Disease	(N=60)
Patients with VTE Disease before insertion of the Angel® Catheter	13 (21.7%)
Acute Pulmonary Embolism	9 (15%)
Deep Vein Thrombosis	7 (11.7%)
Characteristic	**Angel® Catheter**
Pulmonary embolism & Deep Vein Thrombosis¶	3 (5%)
Anticoagulation Use at the time of Angel® Catheter Insertion	(N = 60)
Temporary contraindicationsΩ	55 (91.7%)
Permanent contraindicationsΩ	3 (5%)
Not contraindicated	2 (3.3%)
†Body mass index was calculated as weight in kilograms divided by the square of the height in meters. & There are 17/33 (51.5%) subjects with severe trauma that fall in at least 2 categories ¶ Refers to patients with both diagnoses Ω Includes patients with contraindications to either prophylactic or therapeutic doses	

Indications for Angel® Catheter Placement	
Indication for placement	**Angle® Catheter (N = 60)**
PE when anticoagulants are contraindicated	6 (10%)
Critically ill patient at high risk of PE, not receiving medical thromboprophylaxis due to either increased risk of bleeding, active bleeding, or heparin induced thrombocytopenia	39 (65%)
Patient is critically ill requiring (≥24 hours) interruption of medical thromboprophylaxis	3 (5%)
Other	12 (20%)
Coverage for endovascular procedure	2 (3.3%)
Trauma	7 (11.7%)
Active bleeding (includes a post-operative and a stroke patient)	2 (3.3%)
Deep vein thrombosis	1 (1.7%)
Prophylactic use of the Angel® Catheter	51 (85%)

There was one reported PE event, one (1) occurring after Angel® Catheter placement, which was considered not clinically significant. This PE was reported as unrelated to either the Angel® Catheter or a failure of the device. The event was not life threatening and no further medical treatment or follow-up was performed for this event. There was two reported Angel® Catheter complications involving filter migration >2 cm. One incident was the result of an ambulating patient, and neither event was life threatening nor resulted in harm to the patient. There were no reports of catheter-related bloodstream infections, catheter- related thrombosis, or DVT in the cumulative 381 catheter days, or other device-related complications.

Overall, the Angel® Catheter was successfully inserted and later retrieved in each case without the occurrence of any serious or device-related complications. This study found no significant safety concerns and suggests that early bedside placement of the Angel® Catheter can provide an effective alternative to short-term PE prophylaxis in high-risk patients with contraindications to anticoagulation.

Clinical data from literature/SOTA

The medical condition identified for Angel® Catheter is the cardiovascular disease venous thromboembolism (VTE), clinically presenting as pulmonary embolism (PE). VTE is a medical condition characterized by the formation of blood clots within the veins, which can lead to partial or complete obstruction of blood flow. VTE is a broad term that encompasses deep vein thrombosis (DVT) and PE, which are two interrelated but distinct entities.

In the developed Western world, an estimated 8% of people will develop VTE in their lifetime [8]. The incidence can vary depending on the population studied, geographical location, and the criteria used to define VTE. An American Heart Association report from 2023 estimated that approximately 1,036,000 total cases of VTE occur in the USA annually [9], with a similar incidence in the USA and Europe (0.96–3.0 per 1,000 and 0.75–2.69 per 1,000, respectively) [28]. This estimate was based on previously unpublished data from the National Inpatient Sample

and showed ~370,000 cases of PE in 2016. A modelling study estimated that the annual VTE incidence in six countries in Europe (total population 310.4 million) was 296,000 cases of pulmonary embolism [8]. As of January 2025, according to the CDC [55], up to 900,000 people in the United States are affected by venous thromboembolism (VTE, a blood clot), each year. An estimated 60,000–100,000 Americans die of VTE each year (370,000 in Europe [28]) and many others have long-term complications from a VTE. Sudden death is the first symptom in about one quarter (25%) of people who have a PE. VTE is a leading cause of preventable hospital death in the United States and is the third leading cause of vascular mortality globally [24]. In clinical practice, about two-thirds of VTE episodes manifest as DVT and one-third as PE with or without DVT [24].

PE is not a disease in and of itself rather, it is a complication of underlying venous thrombosis. PE occurs when a blood clot (thrombus) travels from the deep veins to the lungs, where it becomes lodged in an artery in the lung and obstructs blood flow in the pulmonary arteries. PE usually arises from a thrombus that originates in the deep venous system of the lower extremities; however, it rarely also originates in the pelvic, renal, upper extremity veins, or the right heart chambers. After traveling to the lung, large thrombi can lodge at the bifurcation of the main pulmonary artery or the lobar branches and cause hemodynamic compromise. Anticoagulation with unfractioned heparin (UFH), low-molecular-weight heparin (LMWH), fondaparinux, vitamin K antagonists (VKA) or direct oral anticoagulants (DOACs) represents the first-line treatment for VTE. However, when anticoagulant therapy is contraindicated, alternative therapeutic strategies must be considered. In this context, caval filter placement in the inferior vena cava (IVC) is considered standard practice for preventing embolization from the lower limbs to the pulmonary circulation. [53].

IVCFs are used to prevent PE in patients with VTE who cannot undergo anticoagulation therapy. They trap clots before they reach the pulmonary arteries [15]. IVCFs have been used for 50 years. The first percutaneous IVC filter, the Greenfield filter, was created in 1973 [3]. Since then, caval filter insertion has become the most common VTE treatment in patients with contraindications to anticoagulation. These filters are placed in the inferior vena cava, which is the large vein that carries blood from the lower body back to the heart. IVC filters are designed for their physical properties, clot-trapping effectiveness, ability to preserve flow in the IVC, and ease of placement.

Critically ill and trauma patients alike are considered as a high-risk population for developing PE as a result of immobility and injury. Anticoagulants may be contraindicated if there's active bleeding or a high risk of bleeding from their injuries. Due to contraindications or delays in starting pharmacological prophylaxis among trauma patients with a high risk of bleeding, an IVC filter is recommended. Additionally, two retrospective studies showed a reduced incidence of symptomatic and fatal PE in trauma patients treated with prophylactic vena cava filters [49][50]. The complexity of managing trauma patients involves balancing the risks of bleeding with the need to prevent or treat thromboembolic events.

All major international guidelines agree that caval filter placement is indicated in cases of VTE associated with an absolute contraindication to anticoagulation. The European Society of Cardiology, in its guidelines, recommends the use of caval filters in patients with acute PE and an absolute contraindication to anticoagulant therapy. Another suggested indication is the progression of PE despite appropriate anticoagulant therapy [1]. According to the NICE guidelines, caval filter placement is also indicated in patients with recurrent VTE despite adequate anticoagulation or in the context of clinical trials [71].

Data generated through PMS

The evaluation of the collected PMS information is in accordance with the EU Medical Device Regulation (MDR), Articles 83-86, Annex III, Annex XIV Part B. Information collected and reviewed include serious incidents, field safety corrective actions (FSCAs), corrective and preventive actions (CAPA), nonconformances, and trend reports, and feedback and Complaints from users, distributors and importers. Between 2018 and 2024, four Corrective and Preventive Actions (CAPAs) were initiated, all stemming from audit findings. Two of these CAPAs addressed issues with document control, while the remaining three focused on incomplete technical file documentation for the device.

A search on the TPLC and MAUDE databases was performed on 21-November-2024 in the period between 2012-2024. In the TPLC database for device problems, the search resulted in 370 hits. In the MAUDE database, the search resulted in 251 hits. The search on the TPLC database provides an overview of the events related to the Angel® Catheter, while the search in the MAUDE database provides more detailed information about the events related to the Angel® Catheter. A search on the FDA TPLC (Total Product Life Cycle) database on the product code PNS (short-term intravascular filter catheter) and DTK (filter, intravascular, cardiovascular), gives a representation of the most frequently reported adverse events for a products life cycle.

Top 10 device problems PNS & DTK, TPLC 2012-2024

Rank	Device Problems	Product Code PNS Qty	Product Code DTK Qty	Total Qty	Frequency of occurrence (%)	Cumulative Frequency of occurrence (%)
1	Unintended Movement		72	72	19%	19%
2	Difficult to Remove	1	58	59	16%	35%
3	Fracture	4	54	58	16%	51%
4	Failure to Align		46	46	12%	64%
5	Difficult to Insert		14	14	4%	67%
6	Material Puncture/Hole		14	14	4%	71%
7	Therapeutic or Diagnostic Output Failure		13	13	4%	75%
8	Occlusion Within Device		11	11	3%	78%
9	Therapy Delivered to Incorrect Body Area		11	11	3%	81%
10	Migration		10	10	3%	83%
	Total	**5**	**303**	**308**	**83%**	**83%**

The TPLC database reported (40) device problems, across (370) incidents of device failure in the period between 2012-2024. By calculating the individual frequency of occurrence for each failure mode (the number of reported events divided by the total number of events) and the cumulative frequency of occurrence for the failure modes (sum of the individual frequencies sorted in descending order), one can readily observe that the (10) top failure modes represent (83%/308) of the total reported events.

The majority of the contribution made by the TPLC problem report data involved similar device Optease™ filter. The Angel® Catheter cases were only (3%) of the problems reported, with the device fracturing being the source of all (5) cases related to the Angel® Catheter. Since this data is reported by end users, the device problem groups overlap.

No recalls were reported under product code PNS representing the Angel® Catheter. Product recalls for the code DTK representing the Optease™ filter were retrieved from the TPLC database. The product recalls from the last 12 years consist of a total of (2) recalls, none of which pertains to the Angel® Catheter.

Specific cases show that the Angel® Catheter successfully captured a substantial amount of clot, preventing potential complications. Surveys collected from healthcare professionals indicate high satisfaction with the device's performance, design, and safety. The feedback underscores the device's reliability and effectiveness in clinical

settings, with no incidents reported during its use. The data collected does not indicate any new or emerging risks that significantly impact the overall benefit-risk profile of the Angel® Catheter. The reported issues are manageable and do not detract from the device's overall safety and effectiveness.

The device's safety and effectiveness remain stable, with no new or unexpected adverse events reported. The performance data aligns with previous findings, showing no significant deviations or new issues. PMS activities, including adverse event reporting and trend analysis, have successfully monitored the device's safety and performance, indicating no emerging risks. The device continues to meet all regulatory requirements, with low complaint and vigilance rates, demonstrating its consistent performance in the market. The combined clinical evidence supports a favorable risk-benefit profile, ensuring a high level of health and safety protection. Therefore, the findings justify that the device's safety and effectiveness are unaffected.

Actions taken by the manufacturer, as described in Article 83 (3) MDR
Since there are no emerging risks or trends related to performance/safety issues during the period reviewed, no actions need to be taken at this moment. Based on the analysis of the collected data, it is concluded that the benefit-risk profile of the Angel® Catheter has not been adversely impacted and remains unchanged.

5.4. An overall summary of the clinical performance and safety:

The safety and performance claims, along with the demonstrated clinical benefits of the device, provide clear evidence of conformity with GSPR 1. These elements confirm that the device achieves its intended purpose under normal conditions of use without compromising the health or safety of patients and/or users. The clinical data presented in this report substantiate the device's favorable benefit-risk profile and support its continued safe and effective use in the target population.

Safety Claim	**The Angel® Catheter achieves a one-sided 95% lower confidence bound for freedom from major complications that exceeds 94%, based on SOTA reported complications.**	
Evaluation Criteria	**Results**	**Criteria Met**
The one-sided 95% lower confidence bound for freedom from major complications exceeds 94%.	There is a 95% confidence that at least 99.49% of patients would not experience complications with the Angel® Catheter device. This result provides quantitative evidence that the device not only meets but exceeds the predefined safety threshold.	☑ Yes
The observed complication rates for the Angel® Catheter are lower than or comparable to the representative benchmark rates reported in the SOTA literature.	The Angel® Catheter demonstrates a freedom from major complications rate of 99.91%, which exceeds the representative benchmark of 89% derived from SOTA literature by a margin of 11%.	☑ Yes

Inferential statistical analysis was conducted using a confidence interval approach to estimate the population proportion. The resulting safety outcome aligns with findings from clinical investigations, literature review, and post-market clinical data. This consistency across multiple sources supports the conclusion that the Angel® Catheter maintains a favorable safety profile. The observed rate of major complications further substantiates that the device performs at least as safely as, and potentially safer than, comparable devices or interventions currently in clinical use.

Performance Claim 1	The Angel® Catheter effectively prevents clinically significant PE, meeting or exceeding the 94% prevention rate attained by SOTA treatments.
Results	**Criteria Met?**
The Angel® Catheter demonstrated strong performance in preventing clinically significant pulmonary embolism (PE). No adverse events or complaints related to PE were reported. Across clinical studies, only 0.4% of patients developed PE following IVC filter placement, indicating a 99.6% prevention rate. Additionally, the device successfully intercepted thrombi and averted PE in 9% of patients, preventing potentially life-threatening events. These findings support the Angel® Catheter's effectiveness in PE prevention, exceeding the 94% prevention rate observed with state-of-the-art (SOTA) treatments by 6%.	☑ Yes
Performance Claim 2	**The Angel® Catheter demonstrates the capability to provide central venous access for the delivery of therapies, meeting or exceeding the observed 64% success rate achieved by SOTA treatments.**
Results	**Criteria Met?**
The Angel® Catheter demonstrated reliable central venous access performance with no reported adverse events or complaints related to the CVC component. In clinical studies, the CVC functionality was rated as 'Acceptable' to 'Good,' with only an 8% loss of functionality. This corresponds to a 92% success rate, representing a 28% improvement over the benchmark success rates observed in state-of-the-art (SOTA) treatments. Additionally, bench testing—including aspiration, leakage, and flow rate — confirmed the device's capability to deliver therapies effectively. These findings support the Angel® Catheter's superior performance in providing central venous access under real-world clinical conditions.	☑ Yes
Performance Claim 3	**The Angel® Catheter achieves a retrieval success rate meeting or exceeding the 90% rate observed by SOTA treatments.**
Results	**Criteria Met?**
The Angel® Catheter demonstrated a high retrieval success rate, with a combined retrieval failure rate of 0.89% based on clinical studies and reported complaints. This corresponds to a 99% retrieval success rate, which significantly exceeds the 90% benchmark observed with state-of-the-art (SOTA) treatments, an improvement of over 9%. This result supports the Angel® Catheter's superior performance, surpassing the expected standards of comparable devices.	☑ Yes

The observed clinical performance of the Angel® Catheter meets or exceeds the representative benchmark rates reported in the SOTA literature, thereby fulfilling the predefined performance objective. This outcome is further supported by consistent findings across clinical investigations, literature review, and post-market clinical data, reinforcing the conclusion that the Angel® Catheter maintains a favorable and reliable clinical performance.

Based on the current clinical evidence, the clinical benefits achieved with Angel® Catheter outweigh the individual and collective risk profiles of the device. The safety and performance claims were developed within the context of the published literature for benchmark/competitive devices and alternative treatments and was evaluated when used as intended. The clinical evidence meets these objectives, and the Angel® Catheter presents an acceptable risk-benefit profile versus the SOTA. The anticipated clinical benefits are outlined in the IFU, in accordance with GSPR 23.4(c).

5.5. Ongoing or planned post-market clinical follow-up:

The PMCF report from the assessment conducted in 2024 provides clinical evidence for the safety and performance of the Angel® Catheter when used for its intended use, therefore the clinical data is satisfactory and establishes conformity of the device with the General Safety Performance Requirements (GSPR) of the Medical Device Regulation (EU) 2017/745 (MDR). According to MEDDEV 2.12/2 rev 2, the decision to conduct PMCF studies should be based on the identification of possible residual risks and/or unclarity on long term clinical performance that may impact the benefit/risk

ratio. There have been no significant changes to the device or to its intended use nor has any new information been presented resulting in new/increasing risks or harms, such as new complaints, adverse events, clinical studies, or literature to suggest additional clinical follow-up. None of the clinical studies performed on the device found significant safety concerns, and all suggest that early bedside placement of the Angel® Catheter can provide an effective alternative to short-term PE prophylaxis in high-risk patients with contraindications to anticoagulation. Thus, previous clinical studies conducted on the device support the intended use on severely ill patients. The results from the clinical use of the Angel® Catheter are consistent with the clinical risks and benefits identified previously, and results of the literature search do not introduce information affecting the initial conclusions which would necessitate the need for a new PMCF at this time. A summary table of the different PMCF activities foreseen by Mermaid Medical is provided below:

Number of activity	Description of activity	Aim of the activity	Rationale & known limitations of the activity
1	Screen scientific literature and other sources of clinical data	The purpose of this activity is to help identify adverse events associated with the device that were not detected in previous clinical trials, to prevent any serious health deterioration using the device, and to develop comparators or provide context for the real-world performance of the device.	The measurable safety and performance objectives for the device were established based upon the requirement that the device perform in accordance with the context of the literature reports for similar devices and alternative treatments to the Angel® Catheter. The analysis will be screened for information on compliance with general safety and performance requirements, as well as the Angel® Catheter having an adverse event rate similar or inferior to that reported from the state of art. Appraisal of articles are quantitively assessed for suitability and contribution and will be ranked by compound weight and Clinical Evidence.
2	Survey from health care professional(s)	The purpose of this activity is to identify any potential safety or performance issues with the device, and to ensure that the device is still meeting the needs of users and/or patients.	Surveys provide essential real-world evidence for assessing the device's safety and performance in clinical practice. Surveys can be an effective way to collect post market information on the device. The effort involved in collecting this evidence, as well as designing questions that are appropriate are known challenges of this activity. The survey is scientifically justified and specifically designed to fill identified gaps in clinical evidence, incorporating well-defined endpoints and eligibility criteria. Its questions are clinically pertinent, targeting key aspects such as performance, safety, usability, and the validation of product claims.
3	Review of customer complaints which may reveal misuse or off-label use	The purpose of this activity is to identify possible systematic misuse or off-label use of the device, with a view to verifying that the intended purpose is correct.	Systematic misuse or off-label use should be identified and determined whether there is a genuine need in the medical community for the newly identified use in relation to the specific medical purpose/indication.
4	Collect data from existing data sources (such as registries)	The purpose of this activity is to increase the knowledge on the device contributing to improve the quality of patient care that continuously collects relevant data, evaluates meaningful outcomes and comprehensively covers the population.	Clinical experience data provides valuable real-world experience obtained in larger, heterogeneous and more complex populations, with a broader (and potentially less experienced) range of end-users. Data collection from existing data sources such as a device registry or medical records has known limitations and can be prone to bias and confounding. However, appropriate study designs and statistical methods will be considered when analyzing the data.

6. Possible diagnostic or therapeutic alternatives

The choice of a therapeutic alternative often depends on factors like efficacy, safety, patient preferences, and contraindications. Alternative treatments that employ different principals of operation from an IVC filter, offer other devices or therapies based on patient needs or clinical circumstances which may be used to prevent PE. Comparison of possible interventions for PE is presented in the Table below:

Comparison of key features of treatment methods.

Treatment	Safety Benefits	Harms/Risks	Comparative Analysis
Mechanical Thromboprophylaxis (Mechanical Prophylaxis) [88, 90, 91, 94, 96]	- The CLOTS trial showed that intermittent pneumatic compression (IPC) reduced the primary outcome of proximal DVT from 12.1% (no prophylaxis) to 8.5% in stroke patients. Adjusted odds ratio: 0.65 (95% CI 0.51-0.84, p<.01) - A randomized control study included in a meta-analysis found that IPC reduced DVT rates (3.80% vs. 19.28%, p<.01), PE rates (0% vs. 9.64%, p<.01), and non-sudden cardiac death (1.26% vs. 7.23%, p<.01) compared to no prophylaxis. - In intensive care units (ICUs), compliance rates with Mechanical thromboprophylaxis protocol compliance was 85% (n=85). - The use of intermittent pneumatic compression (IPC) reduced DVT from 28% in the control group (no treatment) to 5% in the IPC group in neurooncological patients. - The Venowave device reduced the risk of DVT by 79% in hospitalized neurosurgery patients.	- Higher compliance rates were observed in cases where ICU staff were aware of thromboprophylaxis protocols, emphasizing the importance of staff training, unaware staff 60%. - Mortality was significantly higher in the IPC group (50.6%) compared to the pharmacologic group (34.3%, p<.01). - Gaspard et al. found that patients receiving IPC had significantly higher rates of DVT (12 cases vs. 1 case) and PE (1 case vs. 0 cases) compared to those receiving pharmacologic prophylaxis (p<.01). Odds ratio for VTE: 9.9 (p = .028). - Wearing IPC devices for extended periods (at least 18 hours per day) can lead to skin irritation or pressure injuries. Improper sizing or placement of IPC devices can increase pressure in certain areas, causing skin damage, especially around bony prominences like the shin, ankles, heel, and Achilles tendon. About 34.5% of pressure ulcers in American hospital settings are device-related. - Asymptomatic DVTs developed in 20% of patients in both groups using alternate sequential compression devices (ASCD) and simultaneous sequential compression devices (SSCD). - In a study of 3,060 patients undergoing hip/knee arthroplasty, 0.75% experienced DVT, and 5 patients experienced PE following the use of mobile compression devices.	**Effectiveness:** Both methods are effective in reducing DVT and PE rates, but the Angel® Catheter offers lower complication rates and better outcomes in clinical studies. **Safety:** Mechanical thromboprophylaxis devices like IPC are associated with higher risks of skin damage, pressure injuries, and mortality compared to the Angel® Catheter. **Risks:** Angel® Catheter minimizes risks like recurrent DVT and PE, while mechanical thromboprophylaxis devices pose risks of asymptomatic DVTs and device-related pressure ulcers. The Angel® Catheter provides a safer and more reliable option for mechanical thromboprophylaxis, with lower complication rates and better clinical outcomes. Mechanical thromboprophylaxis devices, while effective in reducing DVT and PE, are associated with higher risks of skin damage, pressure injuries, and mortality, making the Angel® Catheter a preferable choice in certain clinical scenarios.
Mechanical Thrombectomy (Pulmonary Thrombectomy/ Percutaneous thrombectomy/ Aspiration Thrombectomy) [7, 18, 92]	-The Aspirex catheter (Straub Medical, Switzerland) is an 11-French device that aspirates thrombus through a flexible catheter tip. The catheter shaft contains a high-speed rotating coil, which creates negative pressure for aspiration and also serves to macerate clot that is brought into the catheter. Two European case series have been reported, with complete thrombus clearance observed in 83% to 88% of patients with intermediate- and high-risk PE. -The overall procedural success rates for mechanical thrombectomy, have been reported at 87% in studies, though these results may be subject to publication bias.	-Intracranial hemorrhage was rare in studies, but the rate of severe and moderate bleeding complications was 10% in one cohort. -Complications such as wire- and balloon-induced injury, intrapulmonary bleeding, and reperfusion lung injury are possible.	**Effectiveness:** Mechanical thrombectomy is highly effective in thrombus clearance (83%-88%) and procedural success (87%), while the Angel® Catheter focuses on preventing DVT and PE rather than removing existing thrombi. **Safety:** Angel® Catheter has lower complication rates, including bleeding and procedural risks, compared to thrombectomy. **Risks:** Mechanical thrombectomy poses higher risks of bleeding complications, procedure-related injuries, and requires specialized expertise, whereas the Angel® Catheter minimizes risks like recurrent DVT and PE. Mechanical thrombectomy is a highly effective treatment for intermediate- and high-risk PE, offering direct thrombus removal but with higher risks of bleeding and procedural complications. The Angel® Catheter, on the other hand, provides a safer option for preventing DVT and PE, with lower complication rates and broader applicability. The choice between the two depends on the clinical scenario—thrombectomy for acute

Treatment	Safety Benefits	Harms/Risks	Comparative Analysis
			thrombus removal and Angel® Catheter for prophylaxis and prevention.
Catheter-Based Thrombolytic Therapy (Ultrasound-assisted catheter-directed thrombolysis/ Catheter-Directed Thrombolysis (CDL)/ Catheter-directed fibrinolysis) [7, 18, 19, 89, 93]	-The risk of major bleeding in patients undergoing CDT is 1.4% in intermediate-risk PE and 6.7% in high-risk PE. -Targeted therapy reduces systemic bleeding risks. -A retrospective comparative case series of 25 patients with acute massive PE compared ultrasound-enhanced CDT (UE-CDT; n=11) and CDT alone (CDT; n=14). It reported a significant difference between the 2 groups in the rate of complete thrombolysis (>90% removal) at angiography assessment performed 12 to 48 hours after the start of treatment (UE-CDT 100% [11 out of 11] and CDT 50% [7 out of 14]; p=0.01). The study also reported that there was a significant difference in the mean overall infusion time between the 2 treatment groups (UE-CDT group 17.4±5.23 hours, CDT group 26.7±8.64 hours; p=0.03). -In a systematic review of 7 studies (n=197), 3 studies assessed the right-to-left ventricular dimension (RV/LV) ratio using a chest CT scan or echocardiography, before and after UE-CDT. The pooled mean RV/LV ratio decreased from 1.36 to 1.03, indicating an improvement in right heart strain following treatment. -The pooled mean pulmonary artery pressure decreased from 31.3±9.0 mmHg to 22.7±6.9 mmHg. -The pooled mean cardiac index increased from 2.2±0.7 l/min/m^2 to 3.1±1.3 l/min/m^2. -A pooled mean relative reduction in pulmonary occlusion score was 41% (range: 32% to 69%).	-Two cases of recurrent PE were reported: one treated with rescue thrombolysis and another resulting in death due to non-compliance with anticoagulant treatment. - Overall mortality at 3 months was 4% (7 out of 197 patients) in a systematic review. Causes included multi-organ failure, haemorrhage, cardiogenic shock, and recurrent PE. -A retrospective case series reported a 14% mortality (19 out of 22 patients) at 180-day follow-up. -Mortality was 9% in the UE-CDT group and 14% in the CDT group in a comparative study. -Major bleeding complications occurred in 4% (7 out of 197 patients), including bleeding from the access site, intra-abdominal haemorrhage, and intrapulmonary bleeding. -Minor bleeding complications occurred in 11% (21 out of 197 patients), including puncture site haematomas and non-fatal haemoptysis.	**Effectiveness:** CDT is highly effective in thrombolysis (100% with UE-CDT) and reducing right heart strain, while the Angel® Catheter focuses on preventing DVT and PE rather than treating existing thrombi. **Safety:** Angel® Catheter has lower complication rates, including bleeding and mortality, compared to CDT, which carries risks of major and minor bleeding and long-term mortality. **Risks:** CDT poses higher risks of bleeding complications and recurrent PE, whereas the Angel® Catheter minimizes risks like recurrent DVT and PE. Catheter-Based Thrombolytic Therapy is an effective treatment for acute thrombolysis, particularly in high-risk PE patients, but it carries significant risks of bleeding and long-term mortality. The Angel® Catheter, on the other hand, provides a safer option for preventing DVT and PE, with lower complication rates and broader applicability. The choice between the two depends on the clinical scenario—CDT for acute thrombolysis and Angel® Catheter for prophylaxis and prevention.
Thrombolytic Therapy (Systemic thrombolysis/ Fibrinolytic Therapy) [7, 18, 19, 20, 21, 92]	-The primary composite outcome of 7-day all-cause mortality or clinical deterioration was significantly reduced by ST (2.6% versus 5.6%, odds ratio 0.44; P=0.015), but this outcome was primarily driven by 3-fold reduction in clinical deterioration (1.6% versus 5.0%; P=0.002), with statistically similar all-cause 7-day mortality (1.2% versus 1.8%; P=0.43). Notably, 4.6% of patients in the placebo arm, compared with 0.8% in the Tenecteplase arm, required open-label rescue thrombolysis; this may have underestimated the observed benefit of thrombolysis. -Thrombolytic therapy reduced the incidence of death compared to heparin alone (OR 0.57, 95% CI 0.37 to 0.87, P = 0.01, low-quality evidence). -Thrombolytic therapy reduced the recurrence of PE compared to heparin alone (OR 0.51, 95% CI 0.29 to 0.89, P = 0.02, low-quality evidence).	-The risk of major bleeding in patients undergoing systemic thrombolytic therapy for acute PE is associated with a major bleeding risk of up to 20%. -A metaanalysis of ST trials, to which PEITHO contributed more than half of patients, demonstrated reduced mortality in intermediate- risk PE (odds ratio, 0.48; 95% confidence interval, 0.25–0.92) but a modest absolute risk reduction (number needed to treat of 65 to prevent 1 fatality). -Meta-analysis data identified an overall intracranial hemorrhage rate of 1.46% with ST versus 0.19% with anticoagulation (odds ratio, 4.63; 95% confidence interval, 1.78–12.04), corresponding to a number needed to harm of 79.30 There is a 3-fold increased risk of major bleeding in patients ≥65 years. -40% of type-4 or type-5 patients of the PE Severity Index (PESI) present with contraindications for both surgical embolectomy and fibrinolytic therapy;	**Effectiveness:** Thrombolytic therapy is highly effective in reducing mortality and PE recurrence, while the Angel® Catheter focuses on preventing DVT and PE rather than treating existing thrombi. **Safety:** Angel® Catheter has significantly lower risks of major and minor bleeding compared to thrombolytic therapy, which carries a high risk of bleeding complications, especially in older patients. **Applicability:** Thrombolytic therapy is contraindicated in a significant portion of patients (e.g., PESI type-4 or type-5), whereas the Angel® Catheter is broadly applicable for prophylaxis. Thrombolytic therapy is an effective treatment for acute PE, particularly in reducing mortality and recurrence, but it carries significant risks of major bleeding and contraindications in certain patient populations. The Angel® Catheter, on the other hand, provides a safer

Treatment	Safety Benefits	Harms/Risks	Comparative Analysis
		-When excluding studies at high risk of bias, the effect on mortality was not statistically significant (OR 0.66, 95% CI 0.42 to 1.06, P = 0.08). -Thrombolytic therapy increased the incidence of major bleeding events compared to heparin alone (OR 2.90, 95% CI 1.95 to 4.31, P < 0.001, low-quality evidence) -Thrombolytic therapy increased the incidence of minor bleeding events compared to heparin alone (OR 3.03, 95% CI 1.60 to 5.73, P < 0.001, very low-quality evidence).	option for preventing DVT and PE, with lower complication rates and broader applicability. The choice between the two depends on the clinical scenario—thrombolytic therapy for acute treatment and Angel® Catheter for prophylaxis and prevention.
Surgical Thrombectomy (Surgical Embolectomy/ Surgical pulmonary Embolectomy) [7, 18, 28, 92]	-In a study of 174,322 patients hospitalized with PE, surgical embolectomy showed comparable 30-day mortality rates to thrombolysis (13% vs. 15%) but had a lower risk of stroke and re-intervention at 30 days. -No difference was found in terms of 5-year actuarial survival, but thrombolytic therapy was associated with a higher rate of recurrent PE requiring readmission compared with surgery (7.9 vs. 2.8%).	-The procedure is complex and requires expertise, typically performed in specialized centers. -40% of type-4 or type-5 patients of the PESI present with contraindications for both surgical embolectomy and fibrinolytic therapy. -Historically, SPE had high mortality rates ranging from 16% to 64%, however recent studies report early mortality rates of 6% to 29%. -Takahashi et al. reported a 12.5% in-hospital mortality rate for 24 patients undergoing SPE. -Leacche et al. reported a 6% perioperative mortality rate in a series of 47 patients. -An analysis of the Society of Thoracic Surgery Database with multicentre data collection, including 214 patients submitted for surgical embolectomy for high- (n = 38) or intermediate-risk (n = 176) PE, revealed an in-hospital mortality rate of 12%, with the worst outcome (32%) in the group experiencing pre-operative cardiac arrest. - Among patients who presented with intermediate-risk PE (n = 28), high-risk PE without cardiac arrest (n = 18), and PE with cardiac arrest (n = 9), the in-hospital and 1 year survival rates were 93 and 91%, respectively. -Two recent studies suggest in-hospital mortality rates 6.6% to 11.7% based on high- and intermediate-risk PE cohorts, with a third reporting overall 4.6% 30-day mortality. - A meta-analysis of 56 studies (1965–2015) involving 1,579 patients undergoing SPE showed in-hospital all-cause mortality of 26.3%. Long-term all-cause mortality rate of 6.5 deaths per 100 person-years. Among these patients, one-third had cardiac arrest before surgery, and one-third required preoperative ECMO support.	**Effectiveness:** Surgical thrombectomy is effective for acute PE treatment, particularly in high-risk cases, while the Angel® Catheter focuses on preventing DVT and PE rather than treating existing thrombi. **Safety:** Angel® Catheter has significantly lower risks of mortality and complications compared to surgical thrombectomy, which carries risks of in-hospital mortality, preoperative cardiac arrest, and ECMO dependency. **Applicability:** Surgical thrombectomy is limited to specialized centers and high-risk PE cases, whereas the Angel® Catheter is broadly applicable for prophylaxis. Surgical thrombectomy is a life-saving procedure for high-risk PE patients, particularly those with contraindications to thrombolysis, but it carries significant risks of mortality and complications. The Angel® Catheter, on the other hand, provides a safer option for preventing DVT and PE, with lower complication rates and broader applicability. The choice between the two depends on the clinical scenario—surgical thrombectomy for acute treatment in specialized settings and Angel® Catheter for prophylaxis and prevention.
Extracorporeal Membrane Oxygenation (ECMO) [95]	The study analyzed the outcomes of Veno-Arterial Extracorporeal Membrane Oxygenation (VA-ECMO) in 18 patients with high-risk PE treated at Lausanne University Hospital from 2008 to 2020. -Overall ICU survival was 22% (4 out of 18 patients).	-Massive bleeding was the most frequent complication, occurring in 72% of patients (13 out of 18), and was the direct cause of death in 3 patients who had received systemic thrombolysis.	**Effectiveness:** ECMO is a life-saving intervention for patients with refractory shock or cardiac arrest due to PE, while the Angel® Catheter focuses on preventing DVT and PE rather than treating existing thrombi. **Safety:** Angel® Catheter has significantly lower risks of complications compared to ECMO,

Treatment	Safety Benefits	Harms/Risks	Comparative Analysis
	-Hospital survival was 42% for patients treated with VA-ECMO for refractory shock (3 out of 7 patients).		which carries high risks of massive bleeding and mortality. **Applicability:** ECMO is limited to advanced care centers and critical cases, whereas the Angel® Catheter is broadly applicable for prophylaxis in hospitalized patients. ECMO is a critical intervention for high-risk PE patients with refractory shock or cardiac arrest, providing life-saving support but with significant risks of bleeding and low survival rates. The Angel® Catheter, on the other hand, offers a safer option for preventing DVT and PE, with lower complication rates and broader applicability. The choice between the two depends on the clinical scenario—ECMO for acute, life-threatening cases and Angel® Catheter for prophylaxis and prevention.

7. Suggested profile and training for users

The Angel® Catheter is not intended for use by lay persons and is only available for use by a licensed physician and medically trained healthcare professionals. This device is intended for use by healthcare providers trained and experienced in diagnostic and/or interventional techniques. Instructions for use (IFU) are provided to users in addition to providing user training as applicable.

8. Reference to any harmonized standards and CS applied

There are no common specifications to comply with. The Angel® Catheter is in compliance with the following standards:

Harmonized standards that apply:

- BS EN ISO 13485:2016+A11:2021 Medical devices - Quality management systems - Requirements for regulatory purposes
- BS EN ISO 14971:2019+A11:2021 Medical devices - Application of risk management to medical devices
- BS EN ISO 15223-1:2021 Medical devices. Symbols to be used with information to be supplied by the manufacturer — General requirements
- EVS EN ISO 11607-1:2020+A11+A1:2023 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- EVS EN ISO 11607-2:2020+A11+A1:2023 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
- BS EN ISO 11135:2014 +A1:2019 Sterilization of health-care products. Ethylene oxide. Requirements for the development, validation and routine control of a sterilization process for medical devices
- BS EN ISO 11737-1:2018+A1:2021 Sterilization of health care products. Microbiological methods — Determination of a population of microorganisms on products
- EVS EN ISO 11737-2:2020 Sterilization of health care products. Microbiological methods — Tests of sterility performed in the definition, validation and maintenance of a sterilization
- BS EN ISO 10993-10:2023 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity
- DS/EN ISO 10993-15:2019 Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys
- DS/EN ISO 10993-17:2023 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents

International standards that apply:

- FDA CFR 21 § 820 Code of Federal Regulations for medical devices
- ISO 8573-1:2010 Compressed Air Pt 1: Contaminants and purity classes
- ISO 8573-7:2003 Compressed Air Pt 7: Test method for viable microbiological contaminant content
- DS/EN ISO 11138-1:2017 Sterilization of health care products. Biological indicators — General requirements
- DS/EN ISO 11138-2:2017 Sterilization of health care products. Biological indicators — Biological indicators for ethylene oxide sterilization processes
- EVS-ISO 10555-1:2023 Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements
- ISO 10555-3:2013 Intravascular catheters — Sterile and single-use catheters
- EVS EN ISO 10993-1:2020 Biological evaluation of medical devices — Evaluation and testing within a risk management process
- DS/EN ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
- DS/EN ISO 10993-4:2017 Biological evaluation of medical devices — Selection of tests for interactions with blood
- DS/EN ISO 10993-5:2009 Biological evaluation of medical devices — Tests for in vitro cytotoxicity
- EVS EN ISO 10993-7:2022 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (Amendment 1:2019 and BS AMD 1:2023 N/A as for limits on neonates/infants)
- DS/EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
- BS EN 62366-1:2015+A1:2020 Medical devices - Application of usability engineering to medical devices
- BS EN 868-5:2018 Packaging for terminally sterilized medical devices - Part 5: Sealable pouches and reels for porous materials and plastic film construction - Requirements and test methods
- ASTM F3263:2018 Standard Guide for Packaging Test Method Validation
- ASTM D642:2020 Standard Test Method for Determining Compressive Resistance of Shipping Containers, Components, and Unit Loads
- ASTM D999:2023 Standard Test Methods for Vibration Testing of Shipping Containers
- ASTM D4169:2023 Standard Practice for Performance Testing of shipping Containers and systems
- ASTM D5276:2023 Standard Test Method for Drop Test of Loaded Containers by Free Fall
- ASTM F2096-11:2019 Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM D4332:2022 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM F88/F88M:2023 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F756:2017 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTM F2052:2021 Standard Test Method for Measurement of Magnetically Induced Displacement Force on Medical Devices in the Magnetic Resonance Environment
- ASTM F2213:2017 Standard Test Method for Measurement of Magnetically Induced Torque on Medical Devices in the Magnetic Resonance Environment
- ASTM F2503:2023 Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
- ASTM F2063:2018 Standard Specification for Wrought Nickel-Titanium Shape Memory Alloys for Medical Devices and Surgical Implants
- ASTM F2382:2024 Standard Test Method for Assessment of Circulating Blood-Contacting Medical Device Materials on Partial Thromboplastin Time (PTT)
- ASTM F1886/F1886M-16:2016 Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- AAMI TIR28:2024 Product adoption and process equivalence for ethylene oxide sterilization

- AAMI TIR16:2023 Microbiological aspects of ethylene oxide sterilization
- AAMI TIR17:2017 Compatibility of materials subject to sterilization
- AAMI TIR14:2016 Contract sterilization using ethylene oxide
- ANSI ST72:2019 Bacterial endotoxins - Test methods, routine monitoring, and alternatives to batch testing

9. References

[1] D. M. Caplin, B. Nikolic, S. P. Kalva, S. Ganguli, W. E. A. Saad, and D. A. Zuckerman, "Quality improvement guidelines for the performance of inferior vena cava filter placement for the prevention of pulmonary embolism," Journal of Vascular and Interventional Radiology, vol. 22, no. 11, pp. 1499–1506, Nov. 2011, doi: 10.1016/j.jvir.2011.07.012.

[3] M. Vera A De Palo, "Venous Thromboembolism (VTE): Practice Essentials, Background, Pathophysiology." Accessed: Jun. 15, 2023. [Online]. Available: https://emedicine.medscape.com/article/1267714-overview

[7] S. V. Konstantinides et al., "2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS)The Task Force for the diagnosis and management of acute pulmonary embolism of the European Society of Cardiology (ESC)," Eur Heart J, vol. 41, no. 4, pp. 543–603, Jan. 2020, doi: 10.1093/EURHEARTJ/EHZ405.

[8] P. L. Lutsey and N. A. Zakai, "Epidemiology and prevention of venous thromboembolism," Nature Reviews Cardiology 2022 20:4, vol. 20, no. 4, pp. 248–262, Oct. 2022, doi: 10.1038/s41569-022-00787-6.

[9] C. W. Tsao et al., "Heart Disease and Stroke Statistics-2023 Update: A Report From the American Heart Association," Circulation, vol. 147, no. 8, pp. E93–E621, Feb. 2023, doi: 10.1161/CIR.0000000000001123.

[15] Brian Covello, MD Martin Radvany, MD, "Back to the Basics: Inferior Vena Cava Filters", Semin Intervent Radiol 2022;39:226–233, DOI https://doi.org/10.1055/s-0042-1751294.ISSN 0739-9529.

[18] D. M. Dudzinski, J. Giri, and K. Rosenfield, "Interventional Treatment of Pulmonary Embolism," Circ Cardiovasc Interv, vol. 10, no. 2, Feb. 2017, doi: 10.1161/CIRCINTERVENTIONS.116.004345.

[19] P. M. Rali and G. J. Criner, "Submassive pulmonary embolism," Am J Respir Crit Care Med, vol. 198, no. 5, pp. 588–598, Sep. 2018, doi: 10.1164/RCCM.201711-2302CI/SUPPL_FILE/DISCLOSURES.PDF.

[20] M. U. Baig and J. Bodle, "Thrombolytic Therapy - StatPearls - NCBI Bookshelf." Accessed: Jun. 15, 2023. [Online]. Available: https://www.ncbi.nlm.nih.gov/books/NBK557411/

[21] D. M. Ruohoniemi and A. K. Sista, "Interventional Radiology Therapy: Inferior Vena Cava Filter and Catheter-based Therapies," Crit Care Clin, vol. 36, no. 3, pp. 481–495, Jul. 2020, doi: 10.1016/j.ccc.2020.02.005.

[24] Nicholson M, Chan N, Bhagirath V, Ginsberg J. Prevention of venous thromboembolism in 2020 and beyond. Journal of Clinical Medicine. 2020;9(8):2467.

[28] Alessandra Iaccarino, Giacomo Frati, Leonardo Schirone, Wael Saade, Elio Iovine, Mizar D'Abramo, Antonio De Bellis, Sebastiano Sciarretta, Ernesto Greco, "Surgical embolectomy for acute massive pulmonary embolism: state of the art", Journal of Thoracic Disease, doi: 10.21037/jtd.2018.07.87. View this article at: http://dx.doi.org/10.21037/jtd.2018.07.87.

[37] A. H. Kelkar and A. Rajasekhar, "Inferior vena cava filters: a framework for evidence-based use," Hematology, vol. 2020, no. 1, pp. 619–628, Dec. 2020, doi: 10.1182/HEMATOLOGY.2020000149.

[49] C. Kearon et al., "Antithrombotic therapy for VTE disease: CHEST guideline and expert panel report," Chest, vol. 149, no. 2, pp. 315–352, Feb. 2016, doi: 10.1016/J.CHEST.2015.11.026/ATTACHMENT/777A3BA6-466F-4B97-A4C8-24B29A22D6AB/MMC2.MP3.

[50] S. M. Stevens et al., "Antithrombotic Therapy for VTE Disease: Second Update of the CHEST Guideline and Expert Panel Report," Chest, vol. 160, no. 6, pp. e545–e608, Dec. 2021, doi: 10.1016/J.CHEST.2021.07.055/ATTACHMENT/60F8BB3C-A059-42FA-8B95-6DC6A6BEF07D/MMC1.MP3.

[53] Raffaella Benedetti, Simone Marino, Flavio Tangianu, and Davide Imberti, "Inferior Vena Cava Filters: A Clinical Review and Future Perspectives", J. Clin. Med. 2024, 13, 1761. https://doi.org/10.3390/jcm13061761.

[55] US Centers for Disease Control and Prevention (CDC), "Data and Statistics on Venous Thromboembolism", [Online] Available: https://www.cdc.gov/blood-clots/data-research/facts-stats/index.html.

[57] M. E. Cheung, L. T. Mellert, M. S. Firstenberg, M. E. Cheung, L. T. Mellert, and M. S. Firstenberg, "Bedside Procedure: Retained Central Venous Catheter," Vignettes in Patient Safety - Volume 2, Dec. 2017, doi: 10.5772/INTECHOPEN.69748.

[58] A. R. Patel et al., "Central Line Catheters and Associated Complications: A Review," Cureus, vol. 11, no. 5, May 2019, doi: 10.7759/CUREUS.4717.

[59] R. N. Smith and J. P. Nolan, "Central venous catheters," BMJ, vol. 347, Nov. 2013, doi: 10.1136/BMJ.F6570.

[61] X. Ge, R. Cavallazzi, C. Li, S. M. Pan, Y. W. Wang, and F. L. Wang, "Central venous access sites for the prevention of venous thrombosis, stenosis and infection," Cochrane Database Syst Rev, vol. 2012, no. 3, p. CD004084, Mar. 2012, doi: 10.1002/14651858.CD004084.pub3.

[62] "Central venous catheter - Wikipedia." Accessed: Jun. 16, 2023. [Online]. Available: https://en.wikipedia.org/wiki/Central_venous_catheter

[71] S. Kozek-Langenecker, C. Fenger-Eriksen, E. Thienpont, and G. Barauskas, "European guidelines on perioperative venous thromboembolism prophylaxis: Surgery in the elderly," Eur J Anaesthesiol, vol. 35, no. 2, pp. 116–122, Feb. 2018, doi: 10.1097/EJA.0000000000000705.

[82] A. Pillai, M. Kathuria, M. del P. Bayona Molano, P. Sutphin, and S. P. Kalva, "An expert spotlight on inferior vena cava filters," Expert Rev Hematol, vol. 14, no. 7, pp. 593–605, 2021, doi: 10.1080/17474086.2021.1943350.

[83] M. T. Ayad and D. L. Gillespie, "Long-term complications of inferior vena cava filters," J Vasc Surg Venous Lymphat Disord, vol. 7, no. 1, pp. 139–144, Jan. 2019, doi: 10.1016/j.jvsv.2018.01.022.

[84] D. M. Sella and W. A. Oldenburg, "Complications of inferior vena cava filters," Semin Vasc Surg, vol. 26, no. 1, pp. 23–28, Mar. 2013, doi: 10.1053/J.SEMVASCSURG.2013.04.005.

[85] "Medical Device Material Safety Summaries | FDA." Accessed: May 23, 2023. [Online]. Available: https://www.fda.gov/medical-devices/science-and-research-medical-devices/medical-device-material-safety-summaries.

[88] Kwok M. Ho, Ph.D. et, al., “A Multicenter Trial of Vena Cava Filters in Severely Injured Patients”, The New England Journal of Medicine, DOI: 10.1056/NEJMoa1806515.
[89] Irfan Shafi et, al., “Catheter-Directed Thrombolysis of Pulmonary Embolism”, StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2025 Jan-.
[90] Khadeejah Hussain Al Huraiz, “Evaluating Compliance Rates in Thromboprophylaxis: Key Insights and Implications for Patient Safety in ICU Care”, Sch. J. App. Med. Sci., 2014; 2(6H): 3484-3493, DOI: 10.36347/sjams.2014.v02i06.128.
[91] Patricia Chaney, “How to avoid pressure injury from IPC use”, [Online] CardinalHealth.
[92] Mohamed M. Harraz et, al., “Pharmacomechanical thrombectomy in management of pulmonary embolism”, Harraz et al. Egypt J Radiol Nucl Med (2024) 55:185, https://doi.org/10.1186/s43055-024-01359-z.
[93] NICE, “Ultrasound-enhanced, catheter-directed thrombolysis for PE”, ISBN 978-1-4731-1242-1, www.nice.org.uk/guidance/ipg524.
[94] David Green, MD et, al., “USE OF MECHANICAL PROPHYLAXIS IN THE CRITICALLY ILLNONSURGICAL PATIENT”, New York University, Electronic ISSN 1944-0030.
[95] Zied Ltaief et, al., “Venoarterial Extracorporeal Membrane Oxygenation in High-Risk Pulmonary Embolism: A Case Series and Literature Review”, Rev. Cardiovasc. Med. 2022; 23(6): 193, https://doi.org/10.31083/j.rcm2306193.
[96] Castiglione SA & Landry T. What evidence exists that describes the efficacy of mechanical prophylaxis for venous thromboembolism (VTE) in adult surgical patients? Rapid Review Evidence Summary. McGill University Health Centre; July 2015.
[97] Elliott J, Ng L, Meredith C, Mander G, Thompson M, Reynolds L. Interventions to manage occluded central venous access devices: An umbrella review. The Journal of Vascular Access. 2024;1–9. DOI: 10.1177/11297298241246092. Available at: https://journals.sagepub.com/home/jva.
[100] Long-term complications of inferior vena cava filters. Ayad MT, Gillespie DL., J Vasc Surg Venous Lymphat Disord. 2019 Jan;7(1):139-144. doi: 10.1016/j.jvsv.2018.01.022. Epub 2018 Aug 17. PMID: 30126794 Review.
[101] Long-term computed tomography follow-up results of strut penetration of inferior vena cava filters. Yang SS, Yun WS. J Vasc Surg Venous Lymphat Disord. 2019 Sep;7(5):646-652. doi: 10.1016/j.jvsv.2019.03.013. Epub 2019 Jun 21.PMID: 31231055