mermaid medical®

Angel® Catheter

Innovating ICU Care: Redefining PE Prevention

IVC filter attached to a triple lumen CVC - reliable retrieval, instant protection against PE in the ICU

ANGEL® CATHETER

Angel® Catheter
IVC Filter Retrieval, Finally Reliable

The Angel® Catheter is an IVC filter permanently attached to a triple lumen central venous catheter. The smart, elegant design of the Angel® Catheter provides critical care physicians and their patients with prophylactic PE protection and reliable IVC filter retrieval, a game changing promise that no other IVC filter can make.

As the first and only IVC filter to receive FDA clearance for a prophylactic use indication, the Angel® Catheter provides immediate and effective PE protection during a critical and frequently untreated window for critically ill patients. During this vulnerable time when patients are deemed high risk for VTE and unable to receive anticoagulants, the Angel® Catheter offers the convenience of bedside placement.

- First and only IVC filter to receive FDA clearance for a prophylactic use indication.
- Provides immediate and effective PE protection during a critical and often unprotected time.
- The innovative design allows for bedside placement using an x-ray KUB to confirm placement.
- Provides access to the venous system with a fully functional triple lumen CVC.
- Short term protection for up to 30 days.
- Dedicated placement accessory kit for the ease of Angel® Catheter insertion.

Winner of Premier Breakthrough Innovation Award 2023.

The Premier Breakthrough Innovation Award honors companies for pioneering healthcare innovations.

The Angel® Catheter won for its unique approach to addressing a critical healthcare challenge by combining an IVC filter with a central venous catheter, offering superior pulmonary embolism (PE) protection and easy filter retrieval.

Discover the Angel® Catheter: Transforming VTE Care

VTE, including PE and DVT, poses a substantial healthcare challenge on a global scale. Despite previous declines in mortality rates associated with PE, recent trends indicate a concerning resurgence[1].

In the United States, around 500,000 to 600,000 individuals are affected by pulmonary embolism each year, resulting in 200,000 to 300,000 deaths annually[2].

Survivors often contend with lingering complications that significantly diminish their quality of life. If parties involved fail to come together in a unified effort, this issue is poised to escalate over time[2].

Pulmonary embolism ranks among the top preventable causes of hospital deaths in the USA

Negative impacts of pulmonary embolism

30%

10-30% of individuals die within one month of diagnosis[3].

33%

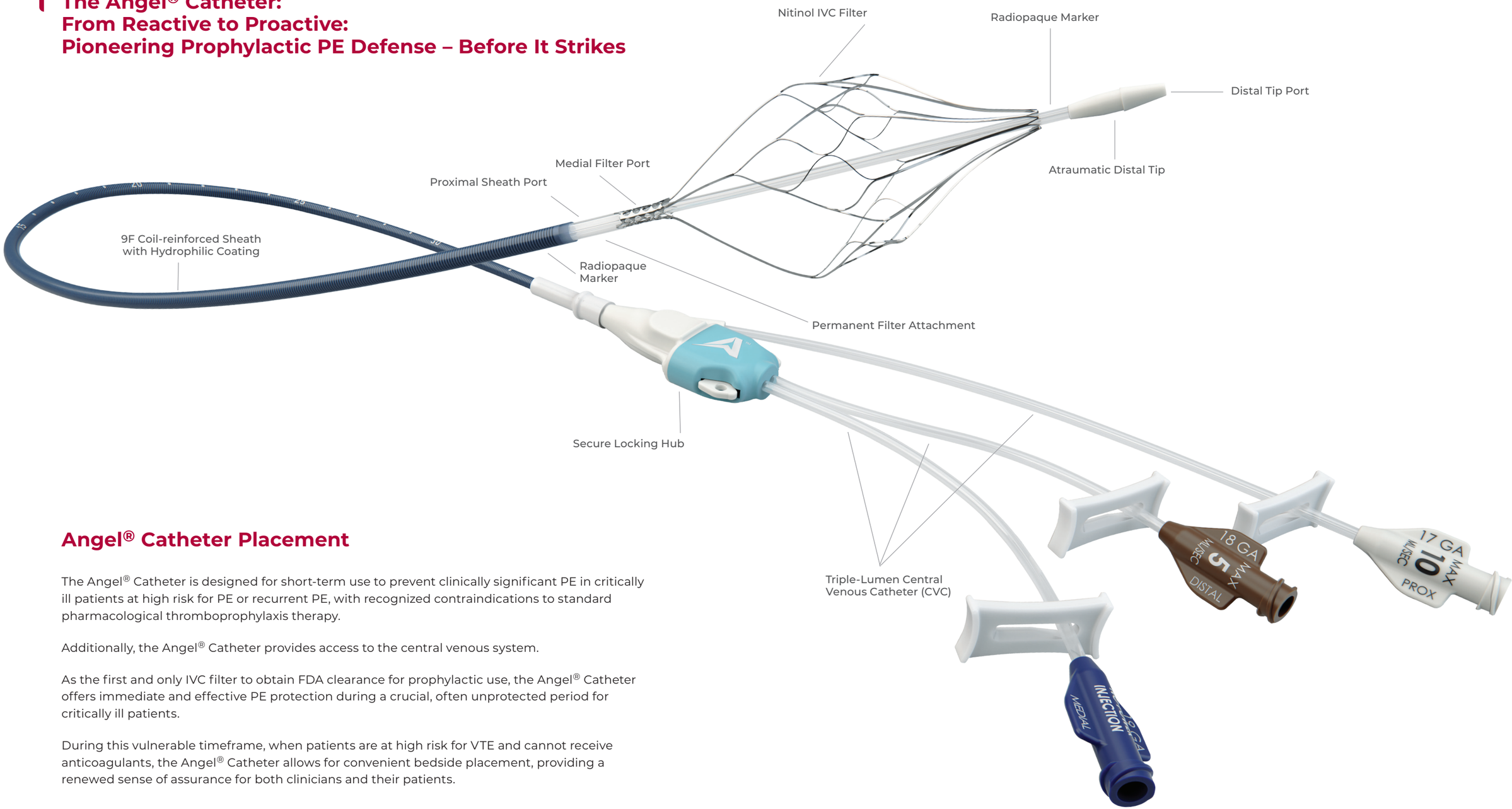
A third of those affected experience post-PE syndrome, which can persist for three months or longer[3].

25%

One-quarter of individuals with acute massive PE die within the first few hours of symptom onset[3].

[1] *Martin KA, Molsberry R, Cuttica MJ, Desai KR, Schimmel DR, Khan SS. Time Trends in Pulmonary Embolism Mortality Rates in the United States, 1999 to 2018. J Am Heart Assoc. 2020 Sep;9(17):e016784. doi: 10.1161/JAHA.120.016784. Epub 2020 Aug 17. PMID: 32809909; PMCID: PMC7660782.*
[2] *Morrone D, Morrone V. Acute Pulmonary Embolism: Focus on the Clinical Picture. Korean Circ J. 2018 May;48(5):365-381. doi: 10.4070/kcj.2017.0314. Erratum in: Korean Circ J. 2018 Jul;48(7):661-663. PMID: 29737640; PMCID: PMC5940642.*
[3] *Data and Statistics on Venous Thromboembolism Source: Centers for Disease Control and Prevention (CDC) URL: https://www.cdc.gov/ncbddd/dvt/data.html*

The Angel® Catheter:
From Reactive to Proactive:
Pioneering Prophylactic PE Defense – Before It Strikes



Angel® Catheter Placement

The Angel® Catheter is designed for short-term use to prevent clinically significant PE in critically ill patients at high risk for PE or recurrent PE, with recognized contraindications to standard pharmacological thromboprophylaxis therapy.

Additionally, the Angel® Catheter provides access to the central venous system.

As the first and only IVC filter to obtain FDA clearance for prophylactic use, the Angel® Catheter offers immediate and effective PE protection during a crucial, often unprotected period for critically ill patients.

During this vulnerable timeframe, when patients are at high risk for VTE and cannot receive anticoagulants, the Angel® Catheter allows for convenient bedside placement, providing a renewed sense of assurance for both clinicians and their patients.

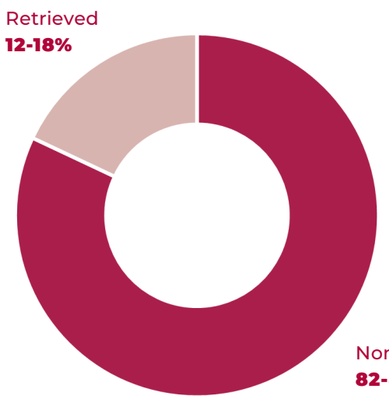
The Angel® Catheter: Optimizing PE Management Through Timely Retrieval

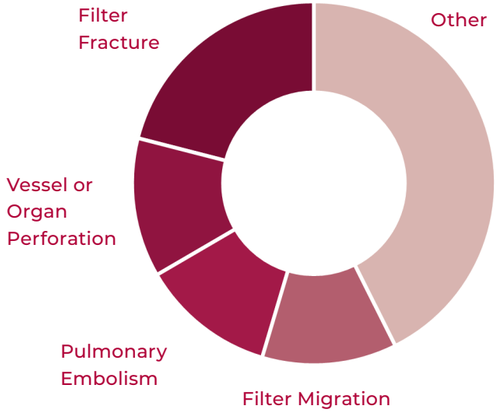
In the field of vascular health, the use of IVC filters has become routine, serving as a solution to minimize the risk of PE. Unfortunately, there is a troubling pattern associated with the retrieval of filters - a procedure that is frequently neglected despite its significance.
Annually, over 250,000 IVC filters are implanted in the United States. While a considerable number of these filters are intended to be retrieved, many are left in place permanently, even when they no longer serve a purpose.

Importance of filter retrieval

Research has shown the critical importance of retrieval. Studies have demonstrated that the optimal period for removing IVC filters falls within a 90-day timeframe. Statistics indicate that the average retrieval rate in the USA is around 18%[4].

Failure to retrieve filters or delaying their removal can result in preventable complications that have adverse effects on the patients' well-being.





Mitigates risks of extended IVC filter complications

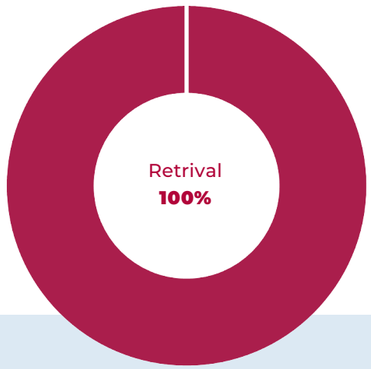
Leaving IVC filters in place for an extended duration comes with various risks, including filter migration, fracture, an elevated risk of pulmonary embolism, and the potential for vessel or organ perforation. These complications can result in severe consequences[5].

The Angel® Catheter presents a unique design specifically tailored to mitigate these common issues. This innovative approach aims to address and reduce the risks associated with prolonged use of IVC filters[4].

Removal rate of the Angel® Catheter

Ensuring reliable retrieval and removing most devices before the patient is discharged from the ICU, the Angel® Catheter achieves a 100% removal rate.

This contributes substantially to minimizing the risks typically associated with traditional filters.



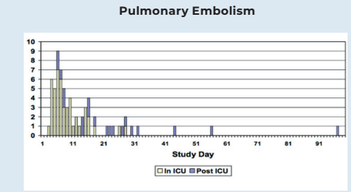
[4] *Sterbis E, Lindquist J, Jensen A, Hong M Jr, Gupta S, Ryu R, Ho PM, Trivedi P. Inferior Vena Cava Filter Retrieval Rates Associated With Passive and Active Surveillance Strategies Adopted by Implanting Physicians. JAMA Netw Open. 2023 Mar 1;6(3):e233211. doi: 10.1001/jamanetworkopen.2023.3211. PMID: 36929400; PMCID: PMC10020881.)*
[5] *J Vasc Interv Radiol. 2011; 22:1522–1530.*

Clinical Need and Target Patient Population

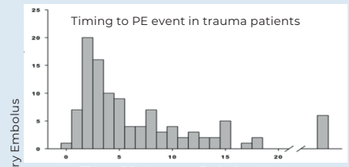
PE often occurs early in a patient's hospitalization. In trauma cases involving long bone fractures, the peak incidence occurs as soon as day 2, with the majority of cases emerging within the initial 4 days[7]. Similarly, for patients with head injuries, the highest incidence falls within days 5 to 7. These trends accentuate the critical necessity for promptly implementing effective prophylactic measures.

During this vulnerable period when patients are deemed high-risk for VTE and have contraindications for anticoagulants, the Angel® Catheter offers a solution with its bedside placement, providing a newfound sense of assurance for physicians and their patients.

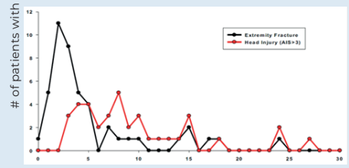
PE represents a preventable cause of death, highlighting the need for improved prevention strategies. It is imperative to adopt proactive measures to address this critical issue.



Peak incidence of PE was day 6 in non-trauma patients[6]



PE occurs earlier in trauma patients[7].



Peak incidence is day 2 in ortho-trauma patients
Peak incidence is day 5 in neuro patients[7]

Despite the current standards of care, PEs still occur in approximately 300,000-600,000 patients per year in the USA[8]

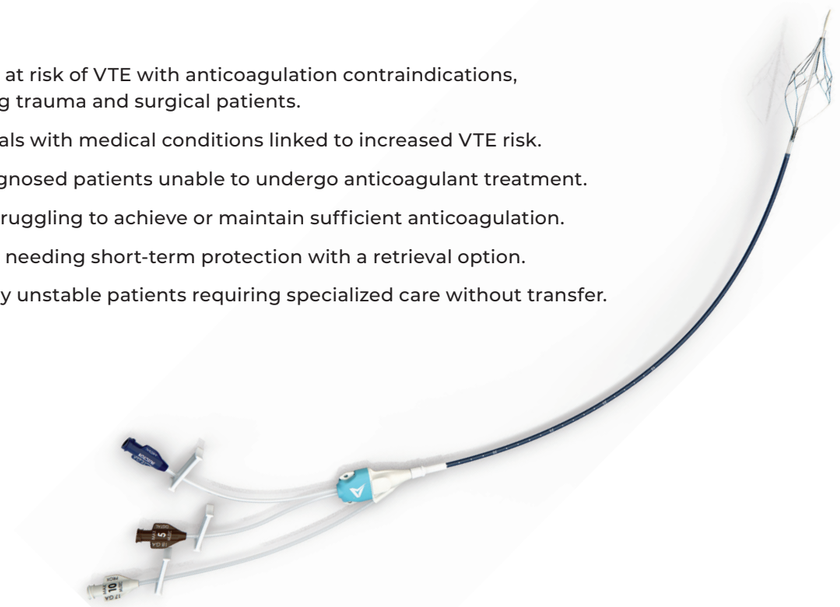
	1. THERAPY Anticoagulation	2. THERAPY Thrombolytic Agents	3. THERAPY Compression Stocking	4. THERAPY Thrombectomy Devices	5. THERAPY Traditional IVC Filters
Utilization/ Approach	Used to prevent thrombus formation. Preferred prophylactic method of prevention.	Therapeuticaly used to lyse (dissolve) existing thrombus.	Prevent stagnation of the blood in the lower extremities.	Surgical/mechanical extraction of thrombus.	Physically filter emboli traveling from the lower extremities to the lungs.
Complications	Due to the high risk of bleeding, there is a large population of trauma and ICU patients contraindicated for anticoagulation, at high risk for PE, and left unprotected from PE for their stay in the ICU.	Therapeutic treatment to lyse existing clots does not provide PE prophylaxis.	Minimizes occurrence of DVT/ PE, but does not catch or treat blood clots.	Therapeutic devices, do not provide PE prophylaxis.	• Effective, although there are significant compliations associated with current device designs and procedural indications. • Many retrievable devices are never removed as indicated, turning a temporarily indicated retrievable device into a permanently implanted one, leading to long-term complications. • Currently prophylactic use is common but an off-label indication.
Solution	The Angel® Catheter was designed to address the complications associated with the current standards of care.				

[6] *Brakenridge SC, Toomay SM, Sheng JL, Gentilello LM, Shafi S. Predictors of early versus late timing of pulmonary embolus after traumatic injury. Am J Surg.2011 Feb;201(2):209-15. doi: 10.1016/j.amjsurg.2009.12.005. Epub 2010 Apr 10. PMID: 20385370; PMCID: PMC5575912.*
[7] *The American Journal of Surgery (2011) 201, 209–215*
[8] *Martinson, M., and Martinson, N., "Pulmonary Embolism Study." Feb 2016*

Previous Patient Applications Examples

The Angel® Catheter is designed to address the unique requirements of a diverse patient population, including:

- Patients at risk of VTE with anticoagulation contraindications, including trauma and surgical patients.
- Individuals with medical conditions linked to increased VTE risk.
- VTE-diagnosed patients unable to undergo anticoagulant treatment.
- Those struggling to achieve or maintain sufficient anticoagulation.
- Patients needing short-term protection with a retrieval option.
- Medically unstable patients requiring specialized care without transfer.



Economic: Value Analysis

The Angel® Catheter delivers a economic advantage in critical care scenarios, backed by thorough research and economic expertise. Hospitals benefit in two key scenarios:

Preventing PE in critically ill patients

The Angel® Catheter provides cost advantages compared to current methods.

Avoiding additional procedural costs

An average PE event costs $31,000[9]. Angel® prophylaxis is cost-effective especially for trauma patients.

Clinical Evidence

Cedars-Sinai Case-Series

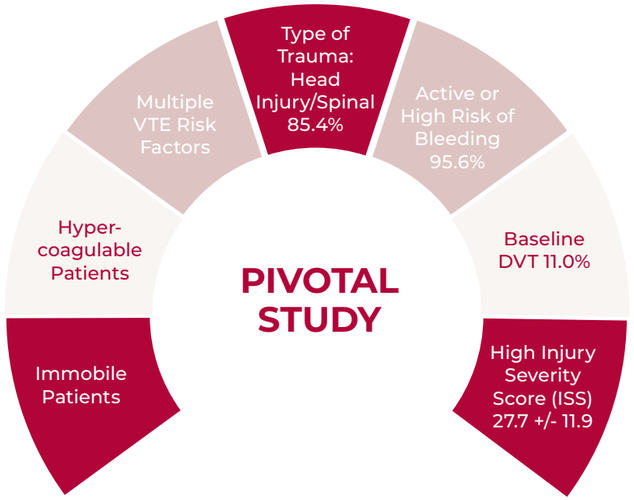
This retrospective case series involved all patients admitted to medical intensive care at a major tertiary referral hospital (Cedars-Sinai Medical Center) between 2017 and 2019 who had Angel® Catheters placed for deep vein thrombosis (DVT) or PE management or prevention. Most were male (67%), aged 74, with diverse comorbidities.

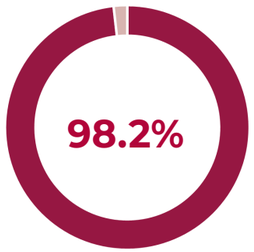
Endpoint	Results	Background info
Freedom from clinically significant or fatal PE	18/18 (100%)	Non-clinically significant PE rate not studied.
Averted Pulmonary Embolism (PE)	3/18 (16.6%)	In subjects with pre-removal imaging. Thrombus caught in 5/18. 3 out of 5 > 25 thrombus burden
Acute Proximal Lower Extremity (LE) Deep Vein Thrombosis (DVT)	13/18 (72,2%)	At the time of catheter insertion
Catheter Related DVT	0/18 (0%)	No new DVT detected
Catheter Related Blood Stream Infection (CRBSI)	0/18 (0%)	111 catheter days
Major Bleeding	0/18 (0%)	1 mild bleeding reported

[9] *Technomics analysis of MEDPAR data.*

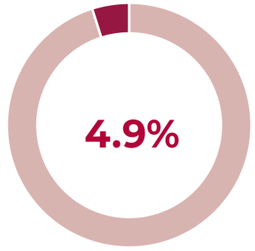
IDE Multi-Center Control Trial

The clinical study examined the safety and efficacy of the Angel® Catheter, a CV catheter and IVC filter combo. Focused on preventing clinically significant PE in critically ill patients, the single-arm, multicenter study enrolled 172 subjects across 26 U.S. sites. The device, successfully placed in 163 subjects, primarily addressed contraindications to anticoagulation (98.2%). This study offers key insights into the Angel® Catheter's practical application and efficacy in real-world clinical settings.

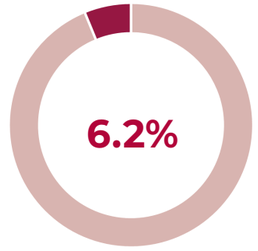




(160/163)
Patient has contraindications to standard pharmacological thromboprophylaxis



(8/163)
Subject has a confirmed acute proximal lower extremity DVT or a confirmed acute PE



(10/163)
Subject requires a temporary interruption of pharmacological thromboprophylaxis for a surgical or medical procedure

Patient Benefits (ITT)

All subjects achieved freedom from clinically significant and fatal PE, meeting the study's primary effectiveness endpoint. Secondary safety endpoints included 30 cases of acute proximal DVT (18.40% ITT, 19.87% PP), 20 catheter-related DVTs (12.27% ITT, 13.25% PP), no catheter-related bloodstream infections, and a 3.07% ITT (2.65% PP) rate of major bleeding events. The averted PE rate was 8.59% ITT (9.27% PP). Importantly, the study device had no reported events related to filter fracture, migration, or embolization.

Safe

Safety Endpoints

0 CRBSI

- CRBSI (0%, 0/163)
- Major bleeding events (3.1%, 5/163)
- Catheter-related DVT (12.3%, 20/163)

Effective

Clinical Benefits

AVERTS PULMONARY EMBOLISM

- Averted PE (11%, 14/129 in patients with cavogram)
- Freedom from clinically significant PE (100%, 163/163)
- Freedom from fatal PE (100%, 163/163)

Efficient

Placement | Retrieval

EASE OF USE

- Duration of ICU placement (avg. 14 min)
- Duration of removal (avg. 14 min)

mermaid medical®

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Item nr.	Description	Qty/box
AC3930A	Angel® Catheter	5
AK9035A	Percutaneous Access Kit	5

Technical information

Guidewire compatibility	0.035''
Filter size	30 x 50 mm
Catheter profile and useable length	9F, 30cm
Power injection	Distal and Proximal port
MR conditional	1.5 and 3 Tesla

MM 01-6000-04 USA Rev. 01

ANGEL® CATHETER