angel® catheter

Innovating ICU Care: Rethinking PE Prevention
IVC filter attached to a triple lumen CVC - reliable retrieval, instant protection against PE in the ICU

mermaid medical®

Discover the Angel® Catheter: Rethinking Early PE Protection

The Angel® Catheter is the first and only commercially available integrated triple lumen central venous catheter (CVC) and inferior vena cava (IVC) filter system that can provide prophylactic pulmonary embolism (PE) protection from the moment of hospital admission, without requiring patient transfer or traditional IVC filter removal.

Venous thromboembolism (VTE), for which PE represents the most severe clinical presentation, poses a substantial healthcare challenge on a global scale and affects approximately 10 million people every year worldwide (Kahn et al. 2021)[1]. Despite previous declines in mortality rates associated with PE, recent trends indicate a concerning resurgence in the USA (Martin et al. 2020)[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 (Morrone & Morrone, 2018)[3].

PE 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[4].

33%

A third of those affected experience post-PE syndrome, which can persist for three months or longer[4].

25%

One-quarter of individuals with acute massive PE die within the first few hours of symptom onset[4].

[1] *Khan, F., Tritschler, T., Kahn, S. R., & Rodger, M. A. (2021). Venous thromboembolism. The Lancet, 398(10294), 64–77. https://doi.org/10.1016/S0140-6736(20)32658-1*
[2] *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.*
[3] *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.*
[4] *Data and Statistics on Venous Thromboembolism Source: Centers for Disease Control and Prevention (CDC) URL: https://www.cdc.gov/ncbddd/dvt/data.html*

Angel® Catheter Prophylactic PE Defense, Delivered at the Bedside

The Angel®Catheter is an IVC filter permanently integrated with a triple-lumen CVC.

Its design provides critical care teams with the possibility for immediate prophylactic protection against PE during the early period when critically ill trauma patients face the highest risk of developing VTE yet often cannot receive anticoagulation, typically during the first 2-4 days after hospital admission (Brakenbridge et al. 2011)[5].

As the first and only IVC filter to receive FDA clearance and CE mark for a prophylactic use indication, the Angel® Catheter delivers effective PE protection exactly in this early critical window and when conventional therapy is contraindicated.

This could, for example, include patients with active bleeding, recent major surgery and/or trauma, severe coagulopathy, intracranial pathology, or those expected to undergo multiple surgical procedures (du Breuil, 2023;[6] Tomaselli et al. 2020;[7] Ortel et al. 2020[8]).

During this unstable phase, when anticoagulants are contraindicated, but PE risk is highest, the Angel® Catheter can be placed conveniently at the bedside, providing protection and predictable IVC filter retrieval once the patient stabilizes.

For a deeper look at the clinical evidence, patient profile, and how the Angel® Catheter can potentially fill the gaps in conventional therapies, see page 6 and onwards of this brochure.

First and only IVC filter to receive FDA clearance and CE Mark for a prophylactic use indication.

Provides immediate and effective PE protection during a critical and often unprotected time.

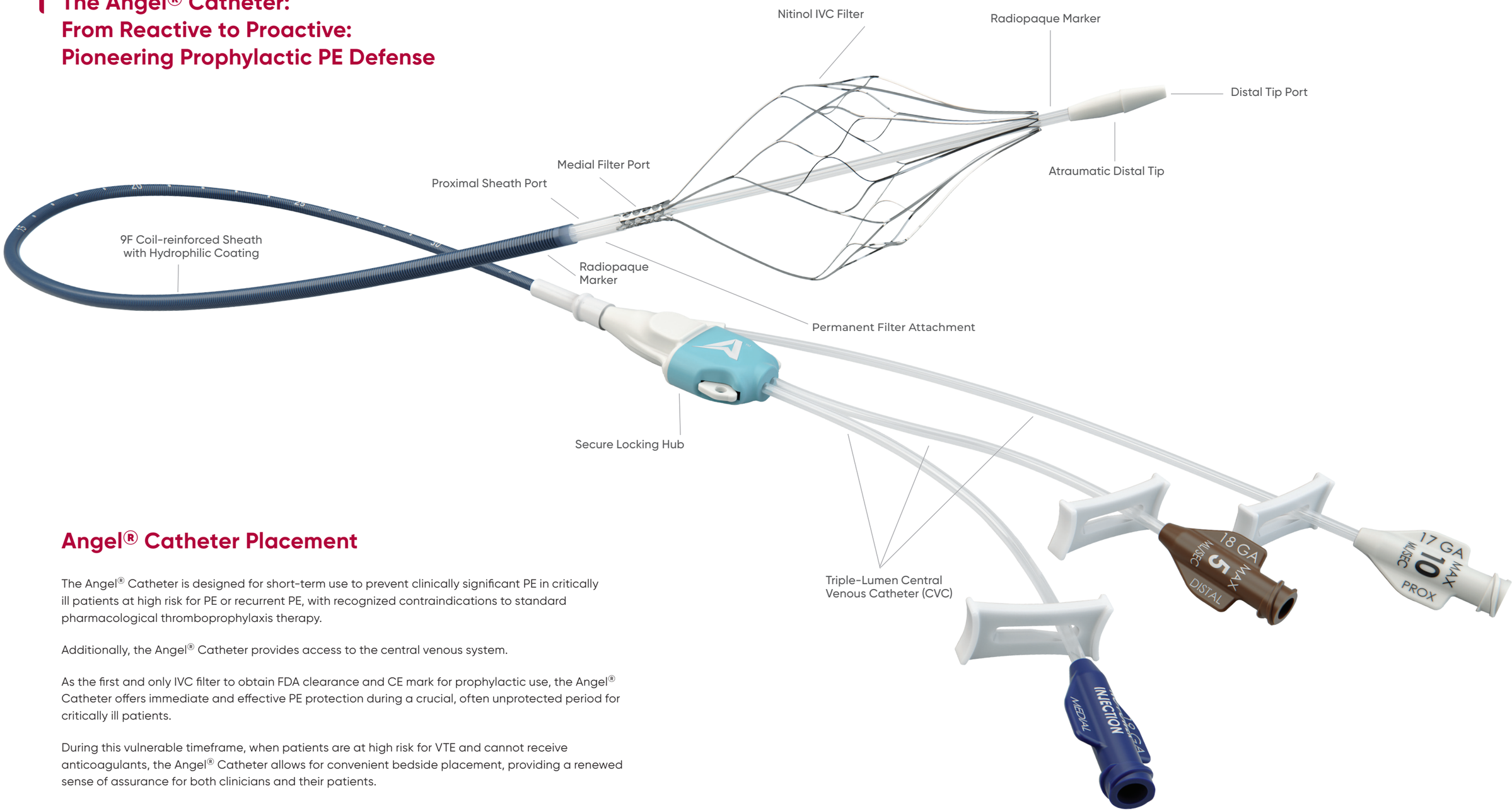
The innovative design allows for bedside placement using an x-ray KUB to confirm placement.

Provides access to the venous system with a fully functional triple lumen CVC.

Short term protection for up to 30 days.

[5] *Brakenridge, S. C., Toomay, S. M., Sheng, J. L., Gentilello, L. M., & Shafi, S. (2011). Predictors of early versus late timing of pulmonary embolus after traumatic injury. The American Journal of Surgery, 201(2), 209–215.*
[6] *du Breuil, AL. Perioperative Management of Antithrombotic Medications: Guidelines From the American College of Chest Physicians. Am Fam Physician. 2023 Aug;108(2):208-211. PMID: 37590842*
[7] *Tomaselli, G. F., Mahaffey, K. W., Cuker, A., et al. (2020). 2020 ACC expert consensus decision pathway on management of bleeding in patients on oral anticoagulants: A report of the American College of Cardiology Solution Set Oversight Committee. Journal of the American College of Cardiology, Published July 14, 2020.*
[8] *Ortel, T. L., Neumann, I., Ageno, W., Beyth, R., Clark, N. P., Cuker, A., Hutten, B. A., Jaff, M. R., Manja, V., Schulman, S., Thurston, C., Vedantham, S., Verhamme, P., Witt, D. M., Florez, I. D., Izcovich, A., Nieuwlaat, R., Ross, S., Schünemann, H. J., Wiercioch, W., Zhang, Y., & Zhang, Y. (2020). American Society of Hematology 2020 guidelines for management of*

The Angel® Catheter: From Reactive to Proactive: Pioneering Prophylactic PE Defense



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 and CE mark 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.

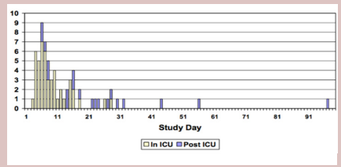
Clinical Need and Target Patient Population

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[10]. 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.

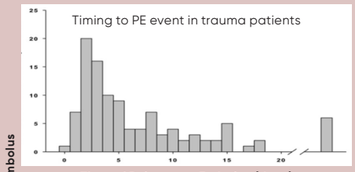
During this vulnerable period when patients are deemed high-risk for VTE and have contraindications for anticoagulants, the Angel® Catheter offers a solution with its bedside placement, providing a sense of assurance for physicians and their patients.

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.

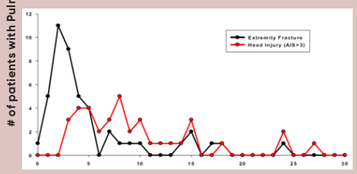
Pulmonary Embolism



Peak incidence of PE was day 6 in non-trauma patients[9]



Time of Pulmonary Embolus (days)
PE occurs earlier in trauma patients[10].



Time of Pulmonary Embolus (days)
Peak incidence is day 2 in ortho-trauma patients
Peak incidence is day 5 in neuro patients[10]

Despite the current standards of care, annual incidence of acute PE continues to rise across the globe (Mohr et al 2025[12]; Brækkan & Hansen, 2023[13])

	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 complications 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.**				

The Angel® Catheter: Optimizing PE Management Through Timely Retrieval

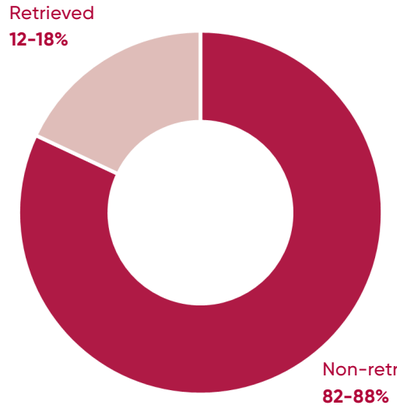
In the field of vascular health, the use of IVC filters has become routine, serving as a solution to minimize the risk of PE. Unfortunately, there is a troubling pattern associated with the retrieval of filters - a procedure that is frequently neglected despite its significance.

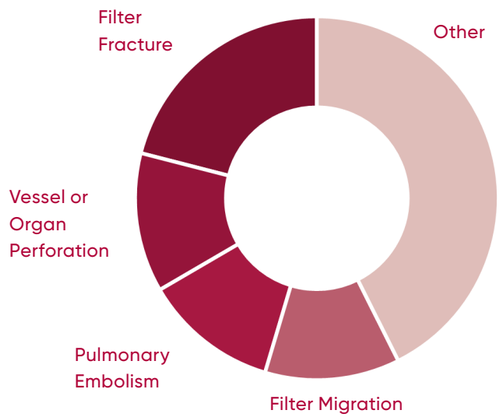
Annually, over 250,000 IVC filters are implanted in the United States. While a considerable number of these filters are intended to be retrieved, many are left in place permanently, even when they no longer serve a purpose.

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%[12].

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[13].

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[12].

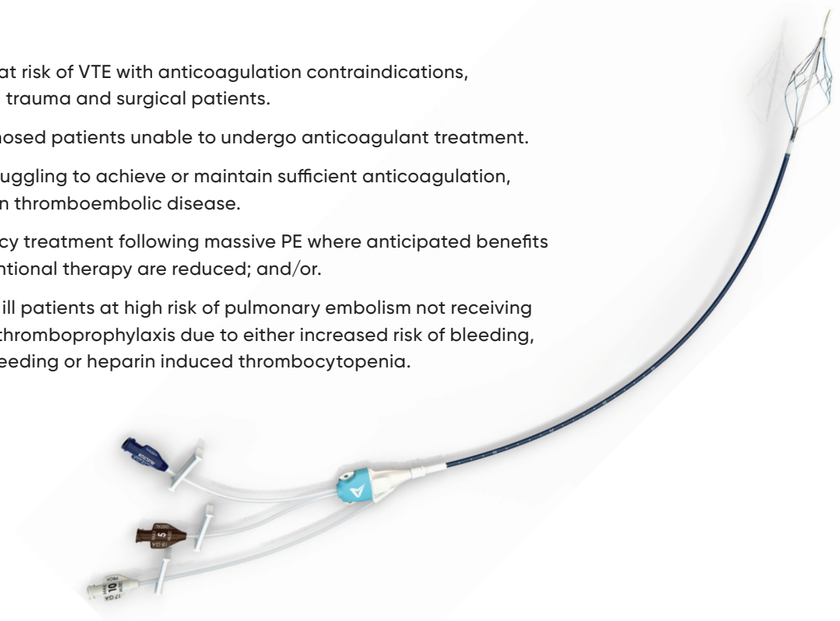
[9] *Brakenridge SC, Toomay SM, Sheng JL, Gentilello LM, Shafi S. Predictors of early versus late timing of pulmonary embolus after traumatic injury. Am J Surg.2011 Feb;201(2):209-15. doi: 10.1016/j.amjsurg.2009.12.005. Epub 2010 Apr 10. PMID: 20385370; PMCID: PMC5575912.*
[10] *The American Journal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

[12] *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.)*

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.
- PE-diagnosed patients unable to undergo anticoagulant treatment.
- Those struggling to achieve or maintain sufficient anticoagulation, 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.



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[14]. Angel® prophylaxis is cost-effective especially for trauma patients.

Clinical Evidence

Cedars-Sinai Caseseries

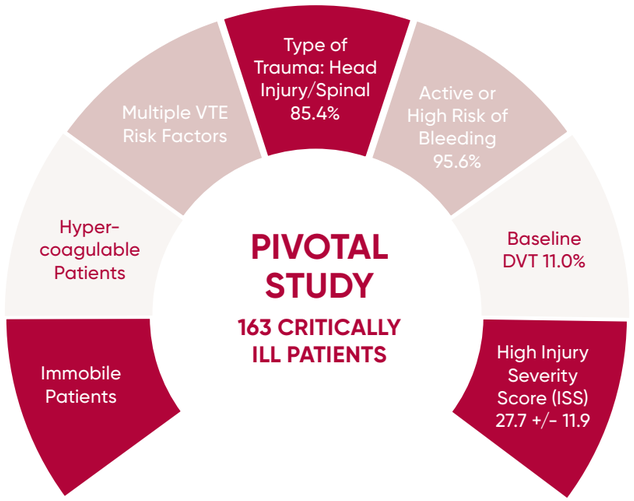
This retrospective case series involved all patients admitted to medical intensive care at a major tertiary referral hospital (Cedars-Sinai Medical Center) between 2017 and 2019 who had Angel® Catheters placed for PE management or prevention. Most were male (67%), aged 74, with diverse comorbidities.

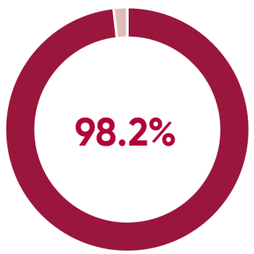
Endpoint	Results	Background info
Freedom from clinically significant or fatal PE	18/18 (100%)	Non-clinically significant PE rate not studied.
Averted Pulmonary Embolism (PE)	3/18 (16.6%)	In subjects with pre-removal imaging. Thrombus caught in 5/18. 3 out of 5 > 25 thrombus burden
Acute Proximal Lower 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

Matusov, Y., Weinberg, A. S., Liang, R., Meza, J., Friedman, O., & Tapson, V. F. (2019).

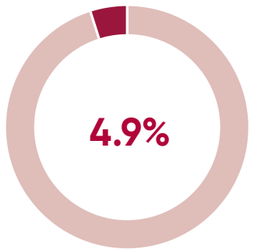
IDE Multi-Center Control Trial

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.

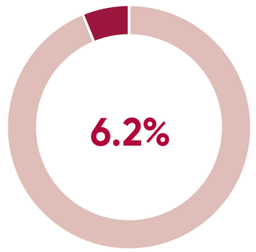




(160/163)
Patient has contraindications to standard pharmacological thromboprophylaxis



(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.

Effective

Clinical Benefits

AVERTS PE

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

Safe

Safety Endpoints

0 CRBSI

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

Efficient

Placement | Retrieval

EASE OF USE

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

Tapson, V. F., Hazelton, J. P., Myers, J., Robertson, C., Gilani, R., Dunn, J. A., Bukur, M., Croce, M. A., Peick, A., West, S., Lottenberg, L., Doucet, J., Miller, P. R., Crookes, B., Gandhi, R. R., Croft, C. A., Manasia, A., Hoey, B. A., Lieberman, H., Guillamondegui, O. D., Novack, V., Piazza, G., & Goldhaber, S. Z. (2017). Evaluation of a device combining an inferior vena cava filter and a central venous catheter for preventing pulmonary embolism among critically ill trauma patients. Journal of Vascular

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Item nr.	Description	Qty/box
AC3930A	Angel® Catheter	5
AK9035B	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 01-6000-05 USA Rev. 01

MM 01-6000-05 USA Rev. 01_Angel (DOC-7541) Ver. 0

Approved By:

(CO-760) New Angel Brochures for Europe and USA

Description

Two new Angel brochures for Europe and USA. Replaces the cancelled CO-699.

Justification

The brochures need to be updated after the Angel Catheter has received CE certification. The Us brochure needs to be visually updated to match the current branding, as well as having added that the product has both CE mark and FDA approval. The brochure for the EU has been created from new because of the CE certification.

Assigned To:	Initiated By:	Priority:	Impact:
Anne Juel Nielsen	Anne Juel Nielsen	Low	Minor

Version History:

Author	Effective Date	CO#	Ver.	Status
Anne Juel Nielsen	April 7, 2026 12:02 PM GMT	CO-760	0	Published