



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





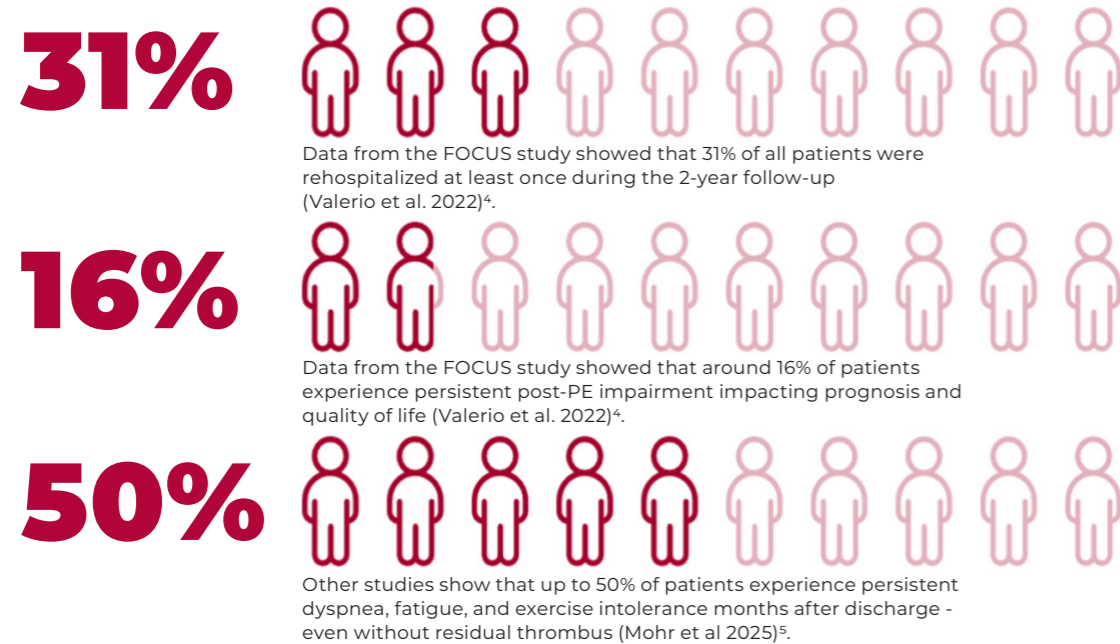
Discover the Angel® Catheter: Rethinking Early PE Protection

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 declines in mortality rates associated with PE, annual incidence of acute PE continues to rise across the globe, (Mohr et al. 2025; Brækkan & Hansen, 2023)².

PE is the third most common cardiovascular disease after myocardial infarction and stroke, and is a leading, preventable cause of in-hospital mortality (Bartholomew, 2024)³

Negative impacts of Pulmonary Embolism



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)⁶.

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;⁷ Tomaselli et al. 2020;⁸ Ortel et al. 2020⁹).

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.

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](https://doi.org/10.1016/S0140-6736(20)32658-1)

² Brækkan, S. K., & Hansen, J.-B. (2023). VTE epidemiology and challenges for VTE prevention at the population level. *Thrombosis Update*, 10, 100132. <https://doi.org/10.1016/j.tru.2023.100132>

³ Bartholomew, J. R. (2024). Epidemiology of pulmonary embolism. In *PERT Consortium Handbook of Pulmonary Embolism (Living reference work entry)*. Springer Nature. https://doi.org/10.1007/978-3-030-70904-4_2-2

⁴ Chronic thromboembolic pulmonary hypertension and impairment after pulmonary embolism: The FOCUS study. *European Heart Journal*, 43, 3387–3398. <https://doi.org/10.1093/eurheartj/ehac206>

⁵ Mohr, K., Barco, S., Neusius, T., & Konstantinides, S. (2025). Socioeconomic burden of pulmonary embolism in Europe: Shifting priorities and challenges for novel reperfusion strategies. *Thrombosis and Haemostasis*, 125(5), 933–943.

⁶ Brakenbridge, 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.

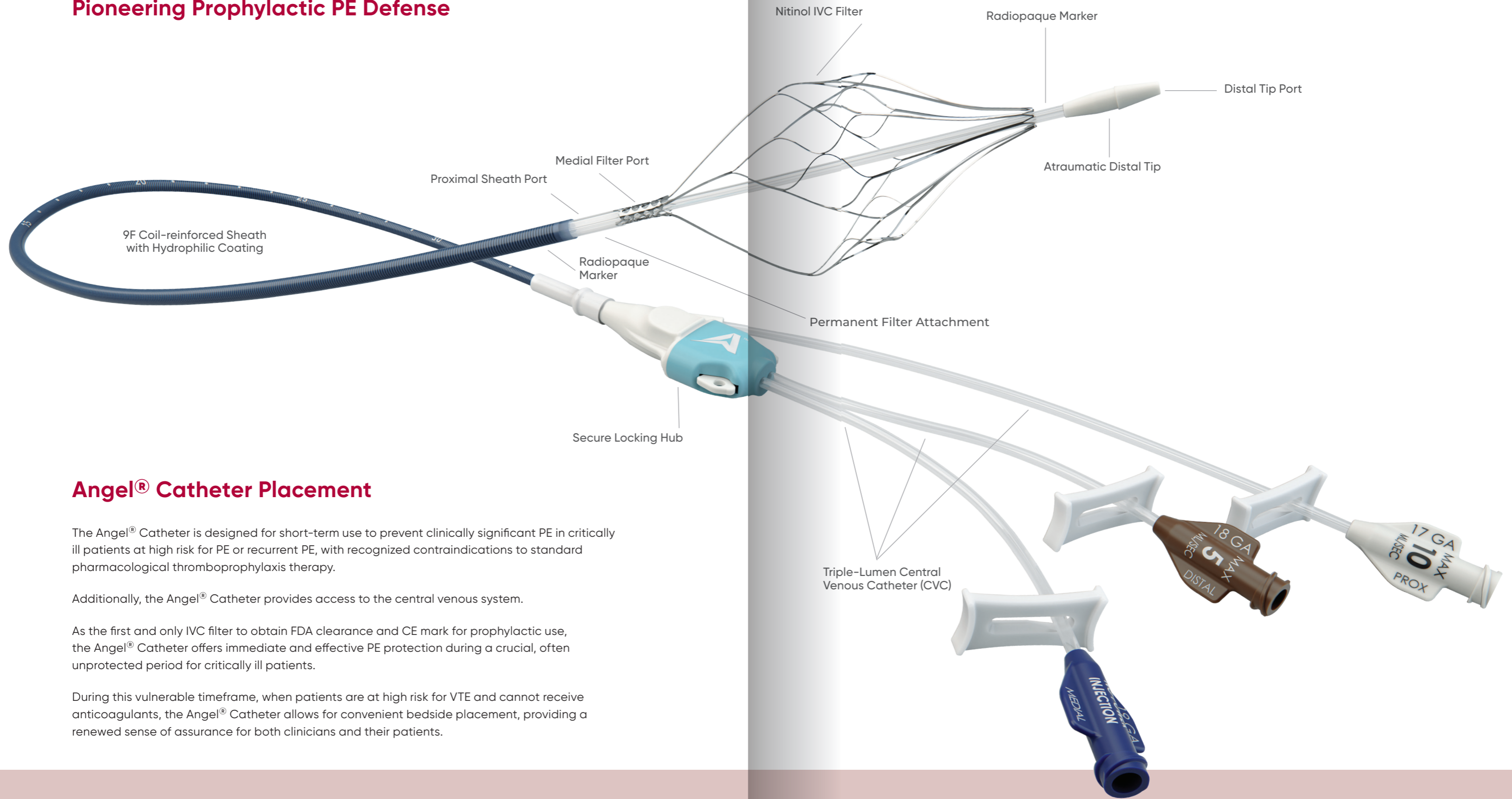
⁷ du Breuil, AL. Perioperative Management of Antithrombotic Medications: Guidelines From the American College of Chest Physicians. *Am Fam Physician*. 2023 Aug;108(2):208-211. PMID: 37590842.

⁸ 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.

⁹ 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., Schönemann, H. J., Wiercioch, W., Zhang, Y., & Zhang, Y. (2020). American Society of Hematology 2020 guidelines for management of venous thromboembolism: Treatment of deep vein thrombosis and pulmonary embolism. *Blood Advances*, 4(19), 4693–4738.



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.



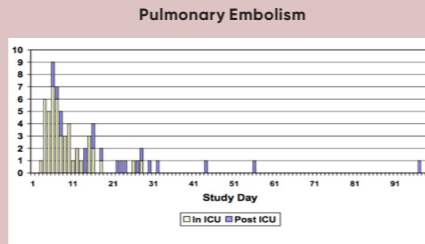


Clinical Need and Target Patient Population

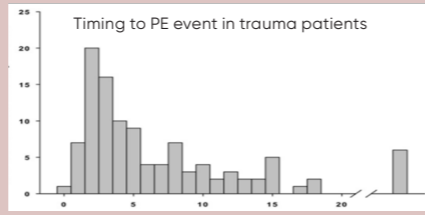
PE often occurs early in a patient's hospitalization. In trauma cases involving long bone fractures, the peak incidence occurs as soon as day 2, with the majority of cases emerging within the initial 4 days¹¹. Similarly, for patients with head injuries, the highest incidence falls within days 5 to 7. 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.

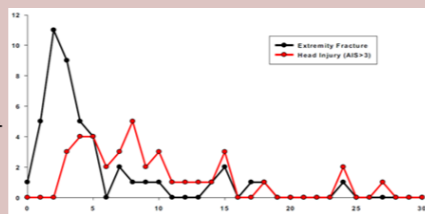
PE represents a preventable cause of death, highlighting the need for improved prevention strategies. It is imperative to adopt proactive measures to address this critical issue.



Peak incidence of PE was day 6 in non-trauma patients¹⁰



PE occurs earlier in trauma patients¹¹



Peak incidence is day 2 in ortho-trauma patients
Peak incidence is day 5 in neuro patients¹¹

Despite the current standards of care, annual incidence of acute PE continues to rise across the globe (Mohr et al 2025¹²; Brækkan & Hansen, 2023¹³)

	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.	Therapeutically 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.	<ul style="list-style-type: none"> 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.				



Angel[®] Catheter Prophylactic PE Defense, Delivered at the Bedside

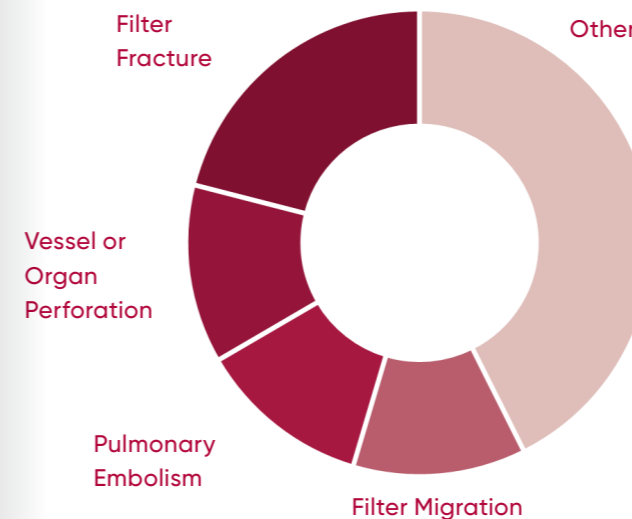
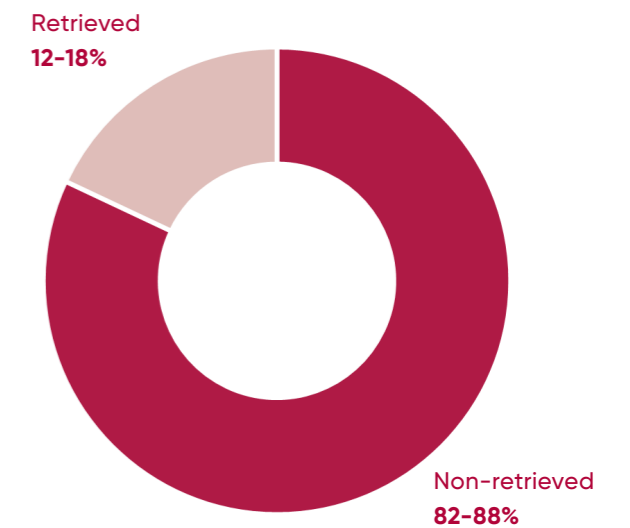
In the field of vascular health, the use of IVC filters has become routine, serving as a solution to minimize the risk of PE. Unfortunately, there is a troubling pattern associated with the retrieval of filters - a procedure that is frequently neglected despite its significance.

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%¹⁴.

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 consequences¹⁵.

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 filters¹⁴.

¹⁰ Brakenridge SC, Toomay SM, Sheng JL, Gentilello LM, Shafi S. Predictors of early versus late timing of pulmonary embolism 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.

¹¹ *The American Journal of Surgery* (2011) 201, 209-215

¹² Mohr, K., Barco, S., Neusius, T., & Konstantinides, S. (2025). Socioeconomic burden of pulmonary embolism in Europe: Shifting priorities and challenges for novel reperfusion strategies. *Thrombosis and Haemostasis*, 125(5), 933-943.

¹³ Brækkan, S. K., & Hansen, J.-B. (2023). VTE epidemiology and challenges for VTE prevention at the population level. *Thrombosis Update*, 10, 100132. <https://doi.org/10.1016/j.tru.2023.100132>

¹⁴ 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: PMC10020861.

¹⁵ *The J Vasc Interv Radiol.* 2011; 22:1522-1530.

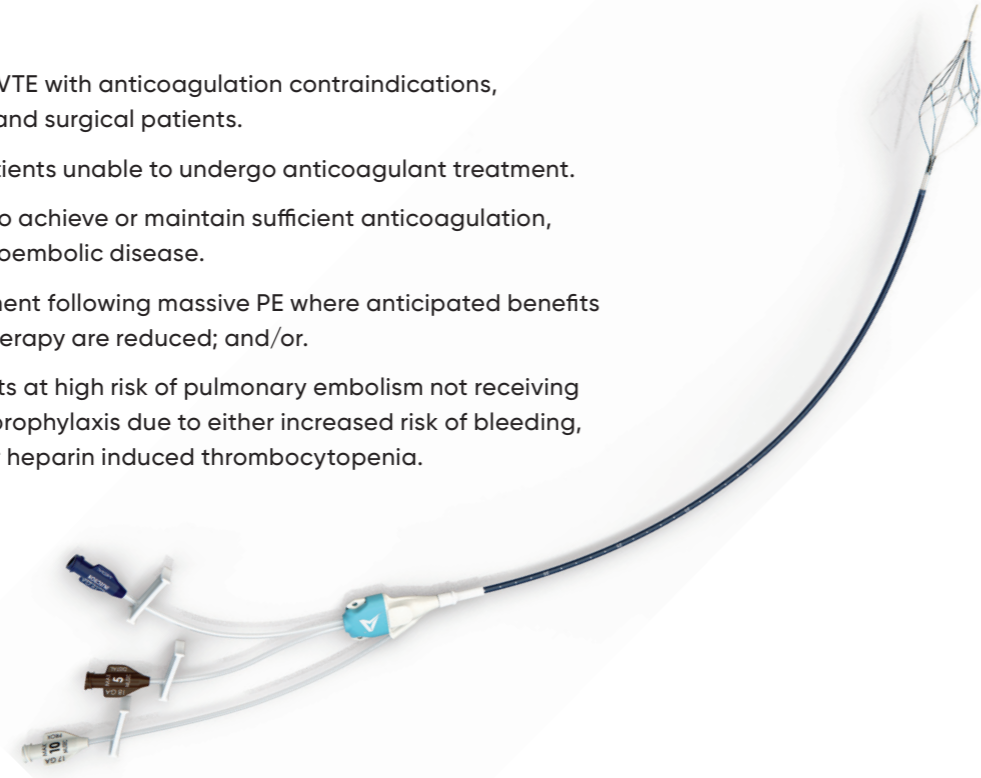




Previous Patient Applications Examples

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 \$31,000¹⁶. Angel® prophylaxis is cost-effective especially for trauma patients.



Clinical Evidence - European ANGEL-Registry

Real-world safety and efficacy of the Angel® Catheter in critically ill patients with contraindications to anticoagulation.

Study Snapshot		Patient Characteristics:	
Study Type:	Multicenter, observational registry.	Mean age:	44 years; 65% male.
Regions:	8 ICU sites across 5 European countries.	Primary diagnoses:	Major trauma: 55%, Intracerebral hemorrhage/stroke: 15%, Prior VTE (PE/DVT): 15%, Active bleeding: 10%.
Population:	60 critically ill adults at high risk for PE and with contraindications to anticoagulation.	Timing:	Device inserted median 4 days after ICU admission.
Period:	March 2013 – July 2014.	Approach:	90% placed safely at the bedside without fluoroscopy; 78% via right femoral vein.
		Indwelling time:	Mean 6 days (range 4–8).

Study Methodology:

The registry followed 60 ICU patients in whom the Angel® Catheter was placed due to:

- Contraindications to anticoagulation
- High risk of PE
- Or acute VTE requiring protection without pharmacologic therapy

Placement, retrieval, complications, PE events, and captured clots were tracked based on real world ICU practice. Imaging (primarily cavography) was performed before retrieval when possible.

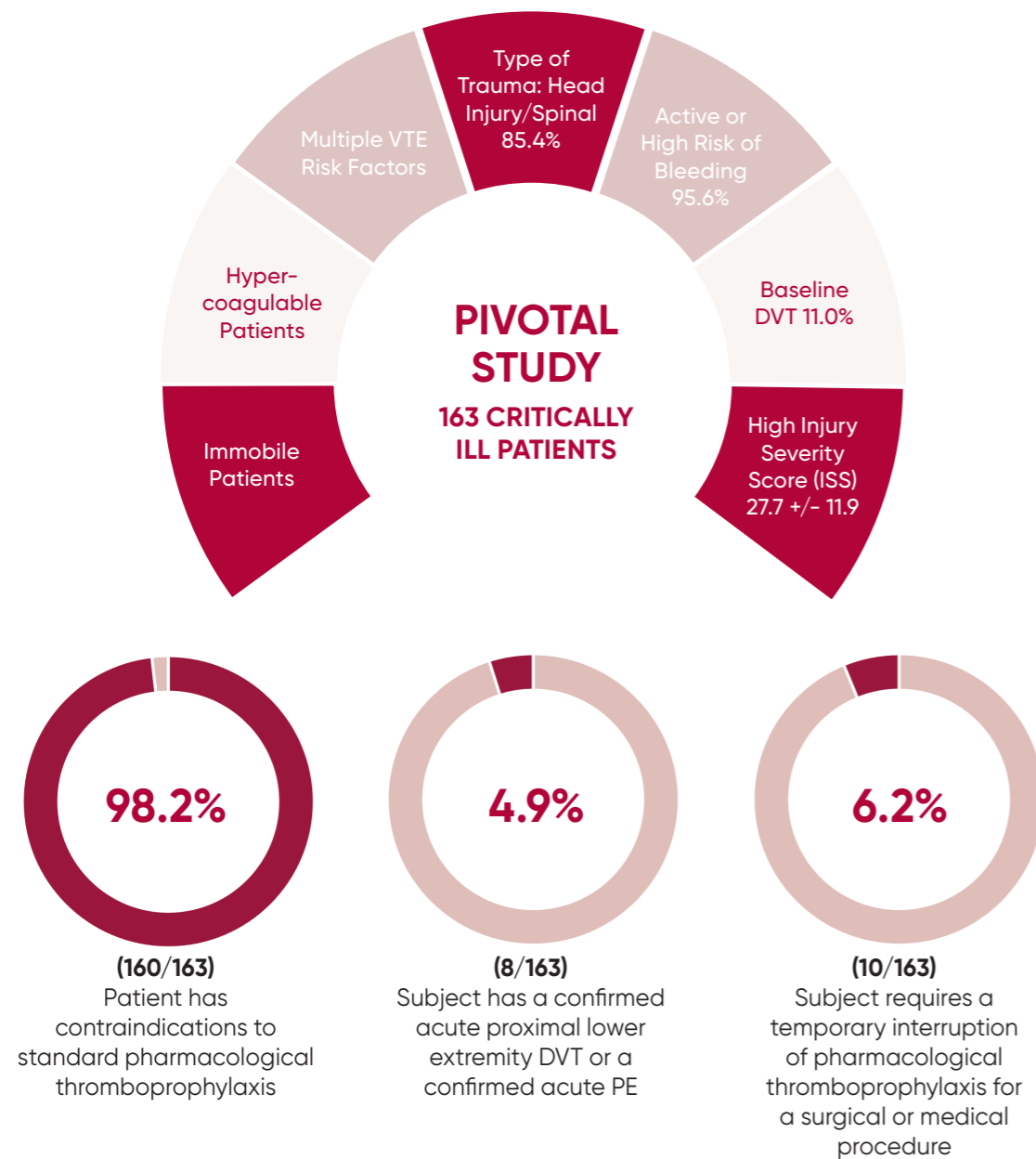
Primary Efficacy Endpoints:	Efficacy Outcomes:	Safety Endpoints:	Safety Outcomes across 381 catheter days:
<ul style="list-style-type: none"> • Number of clinically significant PEs • Number of averted PEs (large trapped clots ≥2 cm) 	<ul style="list-style-type: none"> • 22% of the imaged filters contained smaller clots (<2cm) • 5% of the imaged filters contained larger clots (>2cm) • 1 non-clinically relevant PE occurred in 1 patient (it was presumed that it occurred before device placement) 	<ul style="list-style-type: none"> • Catheter-related bloodstream infection (CRBSI) • IVC thrombosis, perforation, migration • Insertion-site thrombosis • Major bleeding • Device-related death 	<ul style="list-style-type: none"> • 0 CRBSI • 0 caval thrombosis • 0 perforations • 0 insertion-site DVTs • No device-related deaths • Migration >2 cm: 2 cases (3%), both resolved without complications • Guidewire kink: 1 case, resolved immediately • Successful device retrieval

The European Registry demonstrates that the Angel® Catheter provides safe, early, bedside PE protection for critically ill patients who cannot receive anticoagulation.

Taccone, F. S., Bunker, N., Waldmann, C., De Backer, D., Brohi, K., Jones, R. G., & Vincent, J.-L. (2015). A new device for the prevention of pulmonary embolism in critically ill patients: Results of the European Angel Catheter Registry. *Journal of Trauma and Acute Care Surgery*, 79(3), 456–462.

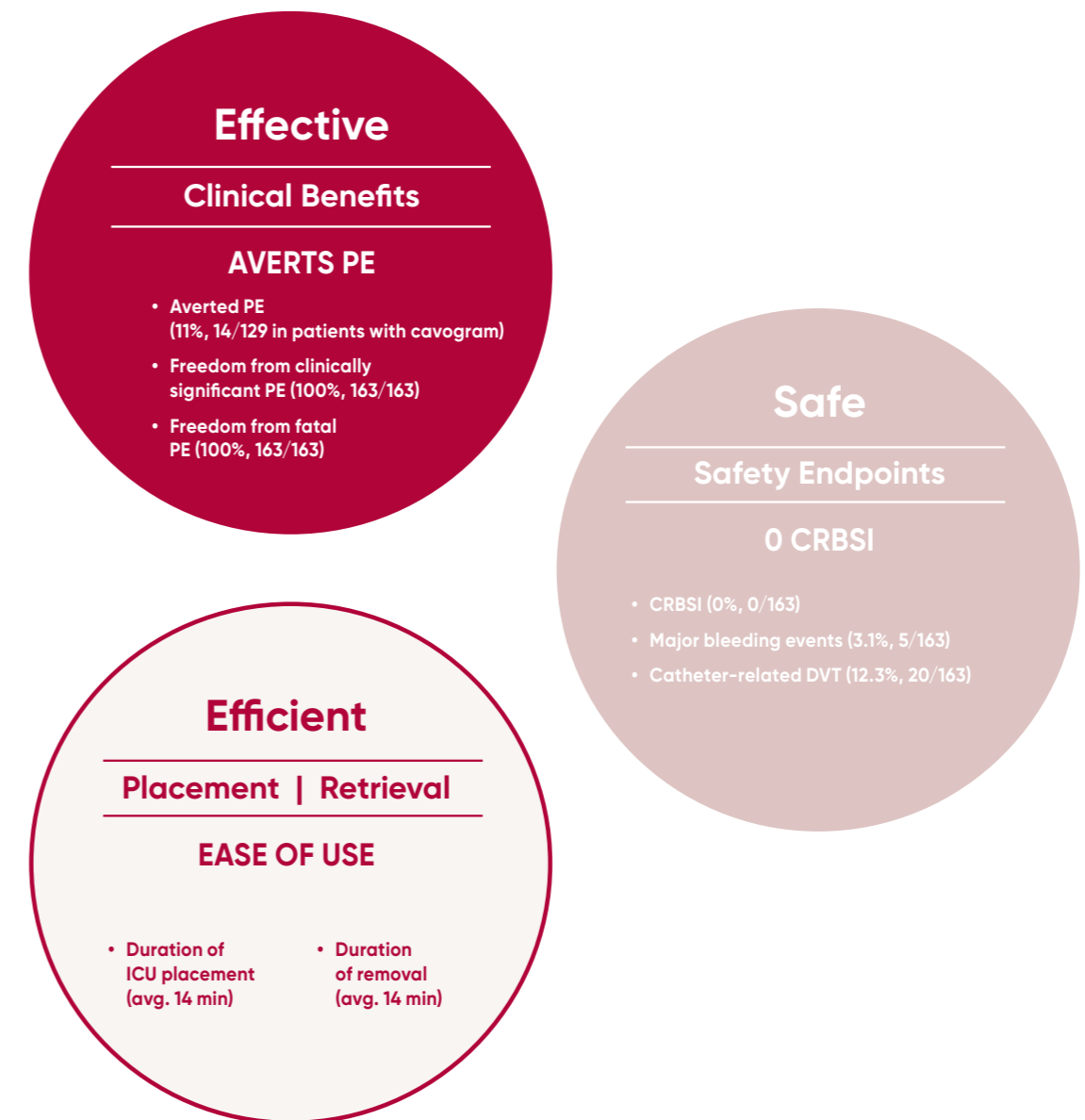


IDE Multi-Center Control Trial



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.





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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 ENG Rev. 02.