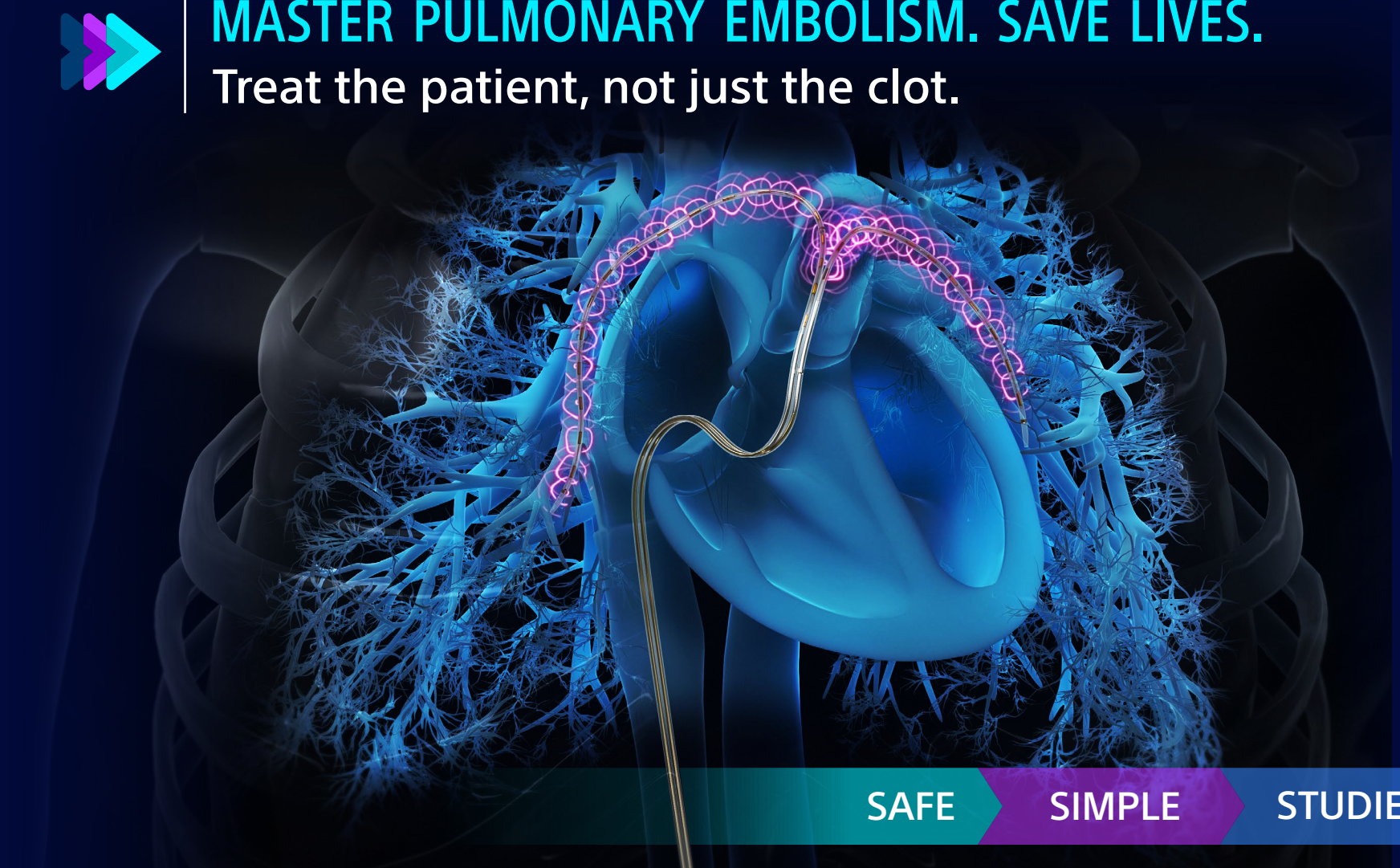
Boston Scientific
Advancing science for life™

EKOS™
Endovascular System

MASTER PULMONARY EMBOLISM. SAVE LIVES.

Treat the patient, not just the clot.

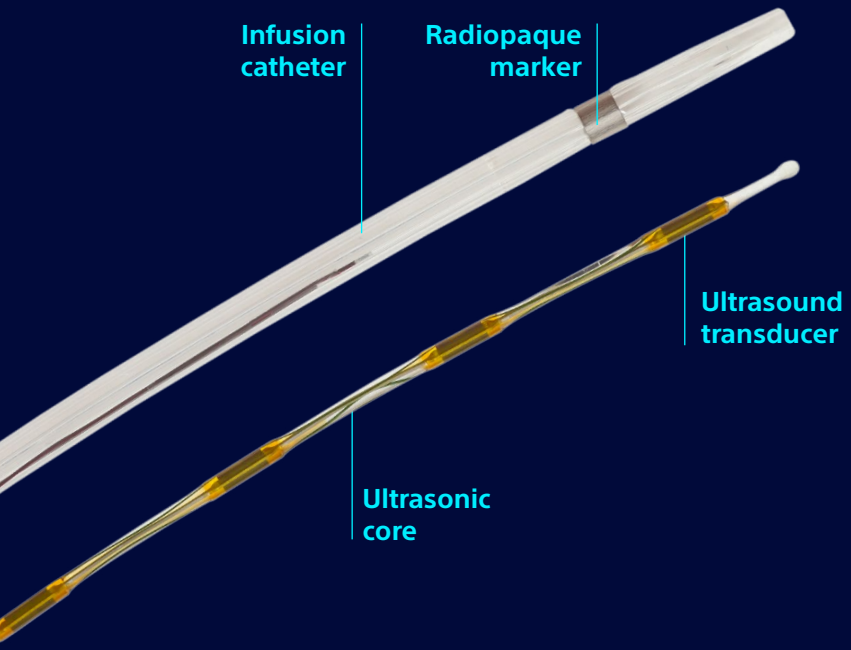


SAFE SIMPLE STUDIED

CHALLENGING THE STANDARD OF CARE IN PULMONARY EMBOLISM: EKOS™

The EKOS™ Endovascular System uses the power of ultrasound to redefine catheter-directed thrombolysis (CDT) for the treatment of pulmonary embolism (PE).

With EKOS™, you can achieve **effective clot dissolution in less time,** with **lower lytic dose** and **reduced risk of bleeding complications** than conventional CDT.[1-4,7]



EKOS™
Endovascular System

SAFE | SIMPLE | STUDIED

THIS IS WHY WE EKOS™

SAFE

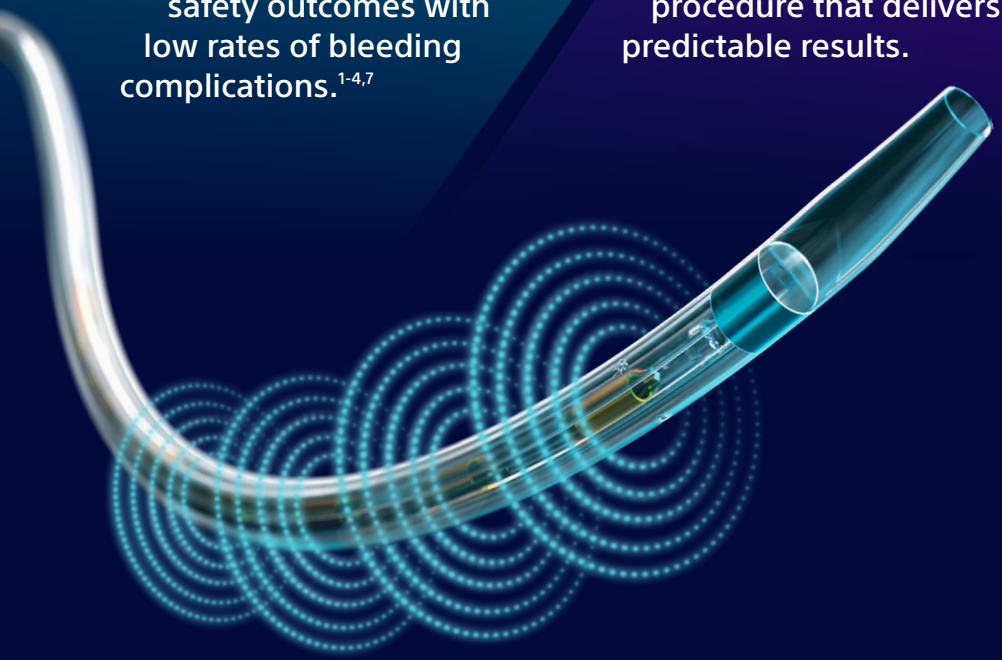
EKOS™ consistently demonstrates excellent safety outcomes with low rates of bleeding complications.[1-4,7]

SIMPLE

EKOS™ is designed for simplicity – a predictable procedure that delivers predictable results.

STUDIED

EKOS™ is backed by robust long-term evidence and ambitious ongoing studies. Together, we've been advancing PE interventional data for 10 years... and counting.[1-4,7,8]



EKOS™
Endovascular System

SAFE

EKOS™ offers a safe, repeatable and reliable treatment that dissolves thrombus quickly with low lytic dose and statistically significant lower rates of major bleeding and intracerebral haemorrhage (ICH).

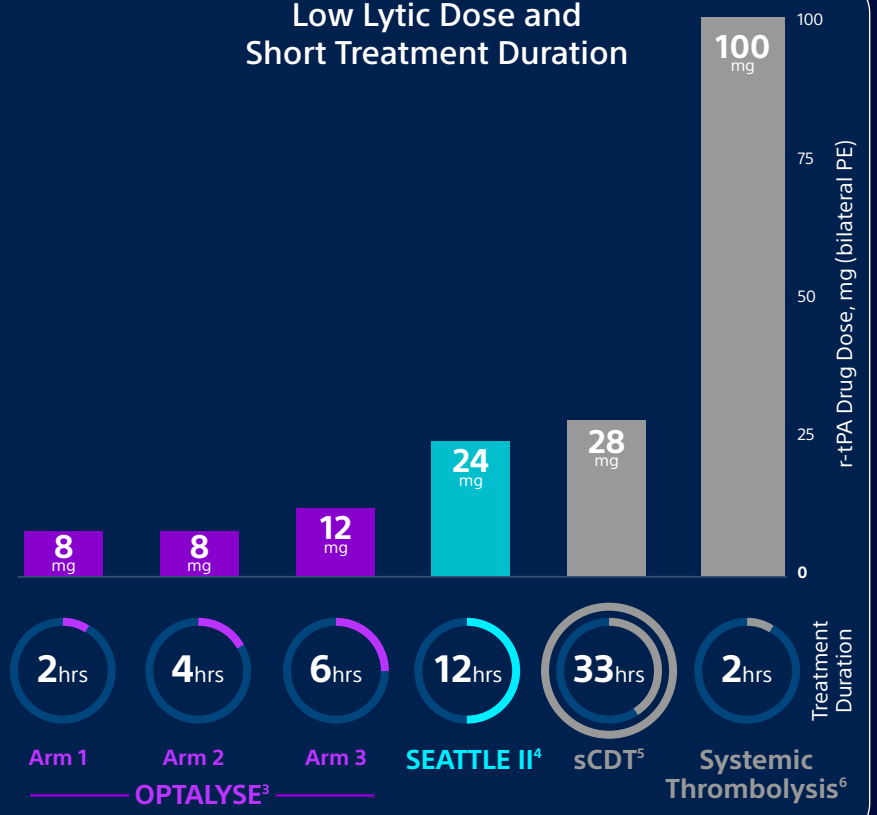
Low Rates of Bleeding and Mortality

	ULTIMA[1] N= 59	SEATTLE II[2] N=150	OPTALYSE[3] N= 101	KNOCOUT[4] N=489
MAJOR BLEEDING	0%	0.7%	3.6%	1.6%
	At 90 days (ISTH)	Within 30 days (GUSTO severe†)	Within 72 hours (ISTH)	At 30 days (ISTH)
INTRACEREBRAL HAEMORRHAGE (ICH)	0	0	1	0
MORTALITY RATE	0%	2.7%	2%	1%
	At 90 days†	At 30 days††	At 365 days	At 30 days

REAL-PE FINDINGS

† GUSTO moderate bleeding complication rate: 10%. †† All 4 deaths unrelated to device/procedure.

Low Lytic Dose and Short Treatment Duration



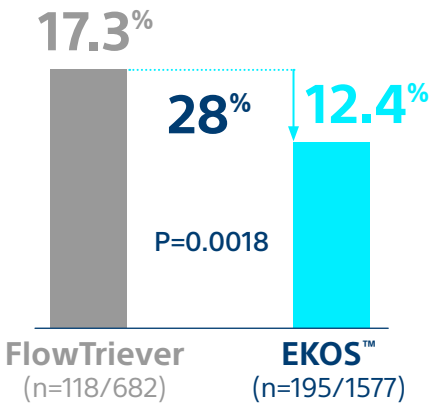
GUSTO: Global Utilization of Streptokinase & t-PA for Occluded Coronary Arteries (for bleeding complications); **ICH:** Intracerebral haemorrhage;
ISTH: International Society on Thrombosis and Haemostasis (bleeding scale); **r-tPA:** Recombinant tissue plasminogen activator; **sCDT:** Standard catheter-directed thrombolysis

SAFE

EKOS™ offers a safe, repeatable and reliable treatment that dissolves thrombus quickly with low lytic dose and statistically significant lower rates of major bleeding and intracerebral haemorrhage (ICH).

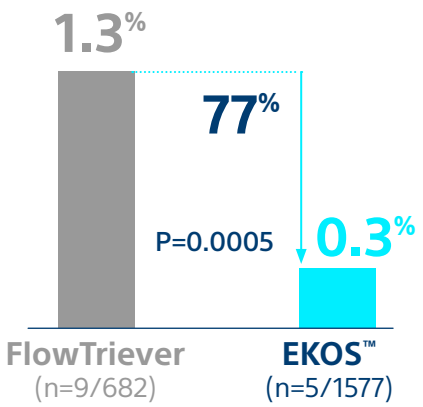
In the **REAL-PE** analysis[7], patients treated with EKOS™ had statistically significant lower rates of major bleeding and ICH than those treated with FlowTriever™.

Major Bleeding



ISTH Bleeding Definition

Intracerebral Haemorrhage



ICH events based on ICD-10-CM and SNOMED codes

ICD-10-CM: International Classification of Diseases, Tenth Revision, Clinical Modification; **ICH:** Intracranial haemorrhage; **ISTH:** International Society on Thrombosis and Haemostasis (bleeding scale); **SNOMED:** Systemized Nomenclature of Medicine

SIMPLE

With EKOS™, a minimally invasive endovascular procedure enables a treatment you can count on to achieve fast and effective clot burden relief.

Similar to a right-heart catheterisation, the EKOS™ procedure is **easy to incorporate into your practice with no new learning curve**.

Straightforward **15-minute procedure** leads to **rapid restoration of haemodynamic stability.**

MORE

Established, clinically-verified protocols with defined durations tell you when treatment is complete.

Predictability of procedure helps **increase case throughput and efficiencies**.

The EKOS™ System

Easy-To-Use Platform:

- **Intuitive touch-screen streamlines therapy management**
- Two ports **simplify bilateral PE**
- Built-in battery enables therapy during transit

Low-Profile Catheters:

- Easy access to small distal pulmonary vessels
- Choice of access site (jugular, femoral, popliteal, etc)
- Predictable access site management
- Minimal bleeding

SIMPLE

With EKOS™, a minimally invasive endovascular procedure enables a treatment you can count on to achieve fast and effective clot burden relief.

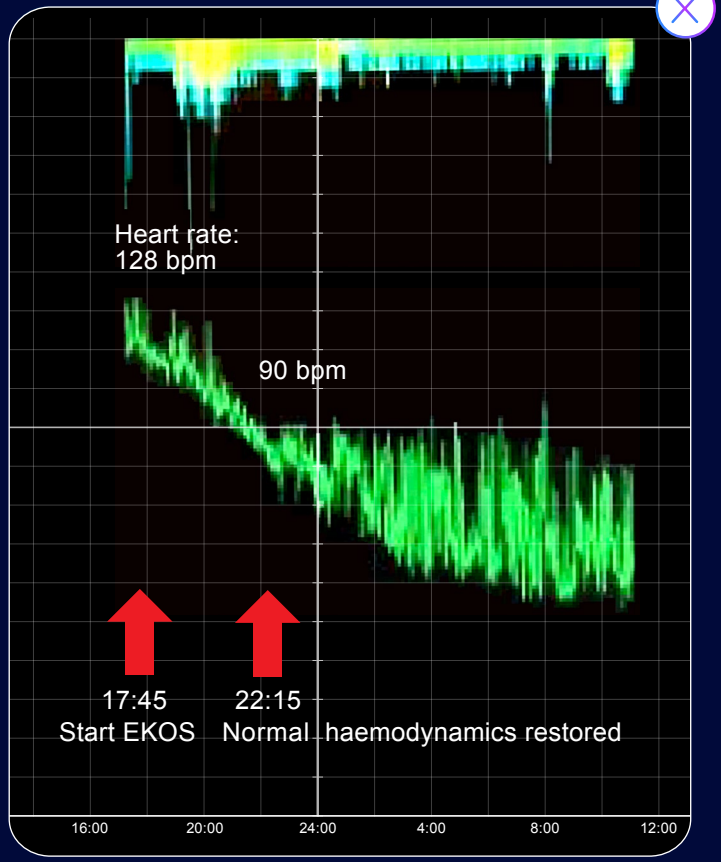
Similar to a right-heart catheterisation, the EKOS™ procedure is **easy to incorporate into your practice with no new learning curve**.

Straightforward **15-minute procedure** leads to **rapid restoration of haemodynamic stability.**

MORE

Established, clinically-verified protocols with defined durations tell you when treatment is complete.

Predictability of procedure helps **increase case throughput and efficiencies**.



Bpm: Beats per minute

EKOS™
Endovascular System

SAFE SIMPLE STUDIED

STUDIED

For over a decade, we have been partnering with physicians to deliver the evidence you need and establish protocols you can rely on for consistently successful outcomes. Our commitment to research continues as we work with you to build a legacy of quality PE data.

6 clinical studies

3400+ patients

Prospective trials validated by **real-world data**

EKOS™ is the only PE device with **long-term outcomes**

EHR: Electronic health record

STUDIED

HI-PEITHO

HI-PEITHO is the first and largest study of its kind in PE, designed to inform clinicians and guidelines by addressing a critical gap in the evidence surrounding the treatment and outcomes for acute intermediate-high risk PE.

544
patients

65
centres U.S. & Europe

Follow-up through
1 year

EKOS™ + Anticoagulation vs. **Anticoagulation Alone**

Inclusion Criteria:

- Intermediate high risk PE patients:
- RV/LV >1
- Troponines
- At least other 2 clinical parameters

Primary endpoint:

- 7-day composite of PE-related mortality
- PE recurrence
- Cardiorespiratory decompensation or collapse

To meet the primary endpoint, EKOS™ + anticoagulation (study arm) must show 3 x fewer events vs anticoagulation alone (control arm)

EHR: Electronic health record

EDUCARE

At Boston Scientific, we're committed to making medical education more relevant, more comprehensive and more accessible, helping you deliver the best patient care possible. Medical education is a key element of our mission and the programme we use to deliver it is called **EDUCARE**.

The EDUCARE pulmonary embolism (PE) curriculum uses a blended learning approach to **combine latest research and evidence-based practice with real-world clinical and practical insights from experts in the field**. This integrated approach allows you to develop your expertise, build your practice and **benefit from being part of a unique global community of experts and learners**.

EDUCARE
COMMUNITY

Scan or click to register on the EDUCARE online platform

PULMONARY EMBOLISM

Once registered, scan or click to access the PE curriculum

EKOS™
Endovascular System

EKOS™ Endovascular System UPN Codes:

EKOS™ Control Unit (CU 4.0)	H7493959340010
EKOS™ CU 4.0 Connector Interface Cable	H7493966540060

EKOS™ Infusion Catheters

Working Length	Treatment Zone	
106 cm	6 cm	H74939590106060
106 cm	12 cm	H74939590106120
106 cm	18 cm	H74939590106180
106 cm	24 cm	H74939590106240
106 cm	30 cm	H74939590106300
106 cm	40 cm	H74939590106400
106 cm	50 cm	H74939590106500
135 cm	12 cm	H74939590135120
135 cm	30 cm	H74939590135300
135 cm	40 cm	H74939590135400
135 cm	50 cm	H74939590135500

References:

1. Kucher N et al. Randomized, controlled trial of ultrasound-assisted catheter-directed thrombolysis for acute intermediate-risk pulmonary embolism (ULTIMA). Circulation 2014;129(4):479-486. doi: 10.1161/CIRCULATIONAHA.113.005544.
2. Piazza G et al. A prospective, single-arm, multicenter trial of ultrasound-facilitated catheter-directed low-dose fibrinolysis for acute massive and submassive PE (SEATTLE II). J Amer Coll Cardiol: Cardiovasc Interventions 2015;8(10):1382-1392.
3. Tapson VF et al. A randomized trial of the optimum duration of acoustic pulse thrombolysis procedure in acute intermediate-risk pulmonary embolism (OPTALYSE). JACC Cardiovasc Interv. 2018;11:1401-1410. doi: 10.1016/j.jcin.2018.04.008.
4. Sterling K. KNOCOUT PE: international EkoSonic registry of the treatment and clinical outcomes of patients with PE. Presented at: VIVA 2021.
5. Kuo W et al. PE response to fragmentation, embolectomy, and catheter thrombolysis (PERFECT). CHEST 2015;148(3):667 673. doi: 10.1378/chest.15-0119.
6. Konstantinides S et al. Heparin plus alteplase compared with heparin alone in patients with submassive pulmonary embolism. N Engl J Med. 2002;347:1143–1150. doi: 10.1056/NEJMoa021274.
7. Monteleone P et al. Modern Treatment of Pulmonary Embolism (USCDT versus MT): Results from Real-World, Big Data Analysis (REAL-PE). J Soc Cardiovasc Angiogr Interv. 2023;3(1):101192. doi: 10.1016/j.jscai.2023.101192.
8. Ultrasound-facilitated, Catheter-directed, Thrombolysis in Intermediate-high Risk Pulmonary Embolism (HI-PEITHO). ClinicalTrials.gov ID NCT04790370.

Boston Scientific
Advancing science for life™

www.bostonscientific.eu

CE 2797

PI-2176001-AA