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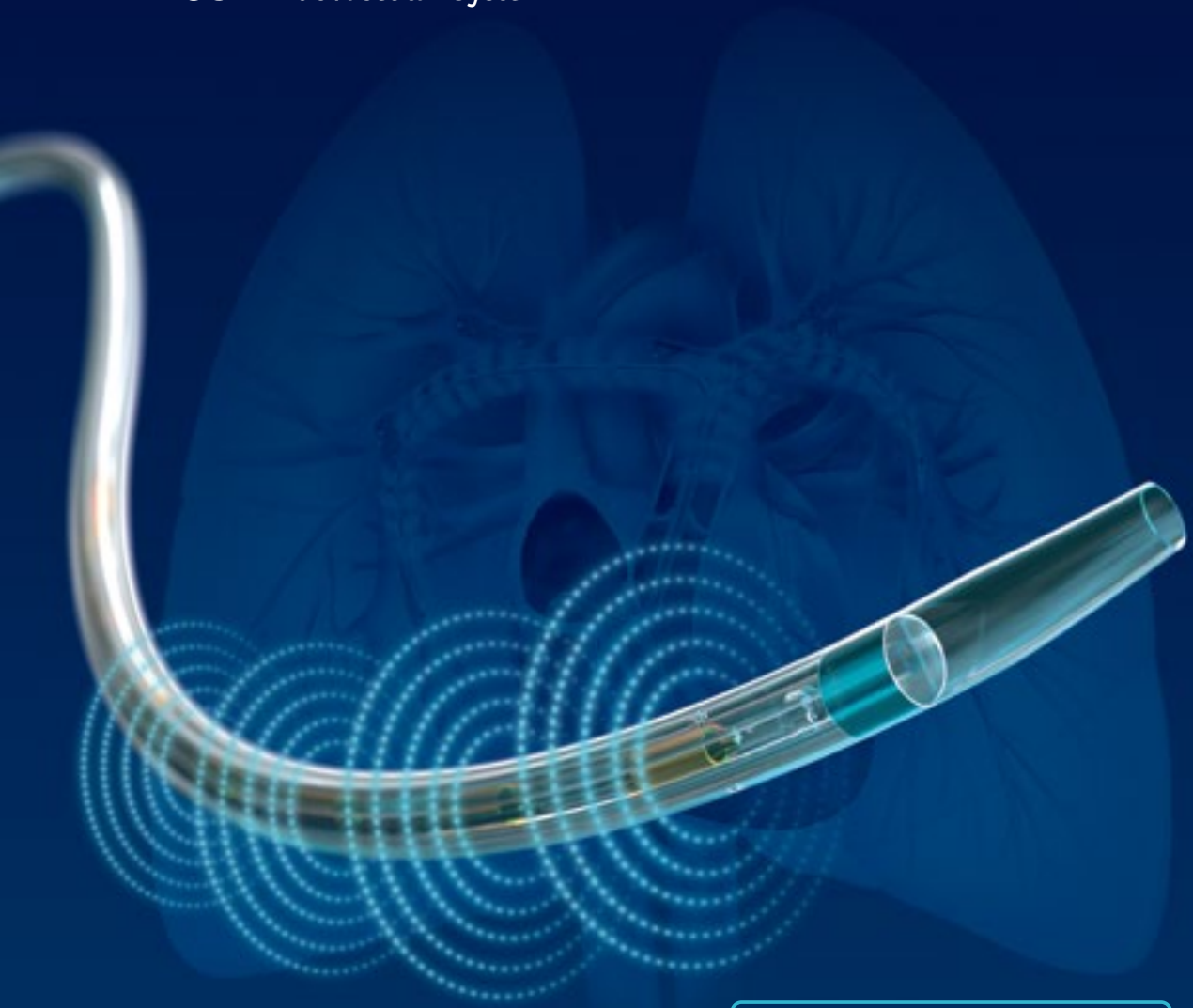
EKOS™ Endovascular System



This is why we EKOS.

TREAT THE PATIENT NOT JUST THE CLOT

A REASON TO INTERVENE IN MORE PE CASES

LOW LYTIC | LOW BLOOD LOSS | LOW TRAUMA

This safe, repeatable and reliable treatment dissolves thrombus quickly with low lytic, low blood loss and low trauma, resulting in proven long-term outcomes. EKOS leverages the power of targeted ultrasonic waves to thin and separate fibrin strands and to accelerate lytic dispersion deeper into the clot. Backed by long-term data, EKOS is the first choice, smart choice and right choice.

THE DECISION TO INTERVENE IS BACKED BY PATIENT OUTCOMES AND LONG-TERM, CLINICAL EVIDENCE

2014

ULTIMA[1]

Level 1
Prospective RCT
n=59 Showed that EKOS was more effective than anticoagulants alone in RV/LV reduction and was just as safe

2015

SEATTLE II[2]

Prospective
n=150 Confirmed EKOS improved RV function, pulmonary hypertension and clot burden without an increase in bleeding

2018

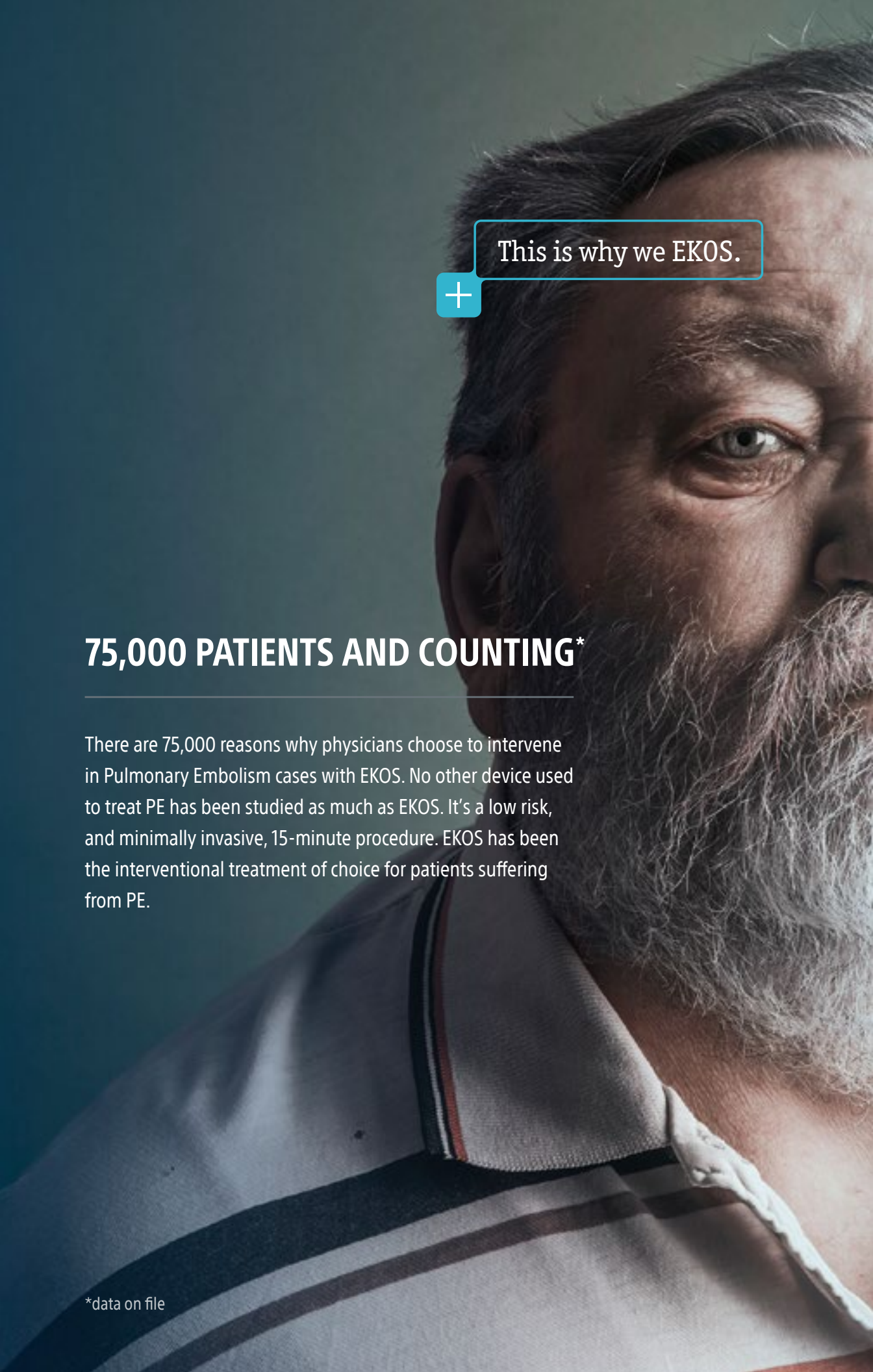
OPTALYSE[3]

Prospective n=101
Lower doses and shorter infusion times showed similar efficacy as previous studies
Long-term data showed RV re-modeling out to one year

2021

KNOCOUT[4]

Retrospective and Prospective n=1,500 Patient Registry to understand OPTALYSE protocol adoption and to provide additional safety, efficacy, and long-term data to the EKOS data set



75,000 PATIENTS AND COUNTING*

There are 75,000 reasons why physicians choose to intervene in Pulmonary Embolism cases with EKOS. No other device used to treat PE has been studied as much as EKOS. It's a low risk, and minimally invasive, 15-minute procedure. EKOS has been the interventional treatment of choice for patients suffering from PE.

*data on file

EKOS™ Endovascular System

THE FIRST CHOICE

+ Long legacy built on successful patient outcomes and long-term, clinical evidence
+ Up to 88-92% less thrombolytic dose than standard systemic treatment [3,5]

THE SMART CHOICE

+ Most studied device in the PE space
+ The only interventional device to treat PE with long-term data [3]
+ Proven to reduce RV/LV ratio by more than 23% on average in as little as 2 hours of therapy [1,2,3]

THE RIGHT CHOICE

+ Patient safety and efficacy
+ Minimized risk of bleeding
+ Avoid potential thrombectomy-related complications
+ Only device with a prescribed protocol that allows for predictable procedural workflow and proven patient outcomes

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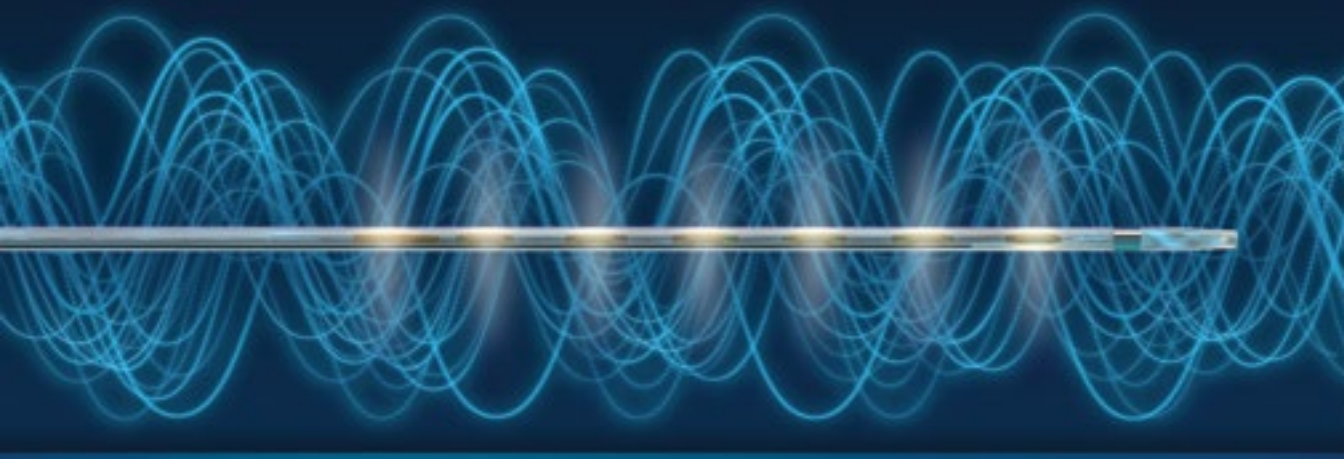
Ultrasonic Core Technology

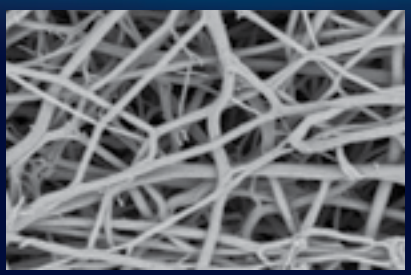
+ Minimally invasive, 15-minute procedure that is quick to perform
+ Lytic agent: as low as 8 mg tPA used[3]
+ Ultrasonic waves accelerate clot dissolution by unwinding and thinning fibrin strands to expose more drug receptor sites; acoustic streaming drives the drug deeper into the clot for safe dissolution

ONE 15-MINUTE PROCEDURE

Target Thrombus Safely | Acoustic Pulse Acceleration | Superior Clot Dissolution

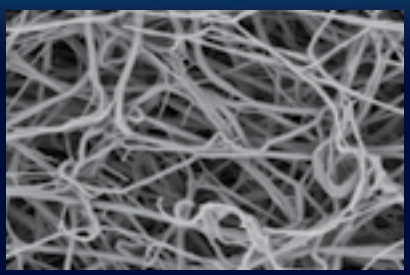


BEFORE EKOS ULTRASOUND



Fibrin protein strands collect in a mesh-like structure strengthening thrombus formation.

AFTER EKOS ULTRASOUND



EKOS Ultrasonic Core Technology unwinds and thins fibrin strands to expose more drug receptor sites.

EKOS™ Endovascular System

Product	Working Length	Treatment Zone
500-55106	106 cm	6 cm
500-55112	106 cm	12 cm
500-55118	106 cm	18 cm
500-55124	106 cm	24 cm
500-55130	106 cm	30 cm
500-55140	106 cm	40 cm
500-55150	106 cm	50 cm
500-56112	135 cm	12 cm
500-56130	135 cm	30 cm
500-56140	135 cm	40 cm
500-56150	135 cm	50 cm

5.4 F infusion catheter for all EKOS products

(106 cm long, 0.035 inch guidewire compatible) and one ultrasonic core matched to infusion length.

(135 cm long, 0.035 inch guidewire compatible) and one ultrasonic core matched to infusion length.

For more information, please visit www.bostonscientific.com/ekos #whyweEKOS

Sources

[1] Kucher N et al. Randomized, controlled trial of ultrasound-assisted catheter-directed thrombolysis for acute intermediate-risk pulmonary embolism. Circulation. 2014;129:479-486.

[2] Piazza G et al. A Prospective, Single-Arm, Multicenter Trial of Ultrasound-Facilitated, Catheter-Directed, Low-Dose Fibrinolysis for Acute Massive and Submassive Pulmonary Embolism. The SEATTLE II Study. J Amer Coll Cardiol: Cardiovasc Interventions 2015; 8(10):1382-1392.

[3] Tapson V et al. A randomized trial of the optimum duration of acoustic pulse thrombolysis procedure in acute intermediate-risk pulmonary embolism. JACC: Cardiovascular Interventions 2018; 11(14):1401-1410.

[4] An International Pulmonary Embolism Registry Using EKOS (KNOCOUT PE). https://clinicaltrials.gov/ct2/show/NCT03426124?term=KNOCOUT&draw=1&rank=1

[5] Konstantinides S, Geibel A, Heusel G, et al. Heparin plus alteplase compared with heparin alone in patients with submassive pulmonary embolism. N Engl J Med. 2002;347:1143–1150.

EkoSonic™ Endovascular System Indications, Safety and Warnings

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete "Directions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INDICATIONS FOR USE**: The EkoSonic Endovascular System is indicated for the: • Ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism.• Infusion of solutions into the pulmonary arteries.• Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature. All therapeutic agents utilized with the EkoSonic Endovascular System should be fully prepared and used according to the instruction for use of the specific therapeutic agent. **CONTRAINDICATIONS**: • Not designed for peripheral vasculature dilation purposes.• This system is contraindicated when, in the medical judgment of the physician, such a procedure may compromise the patient's condition. **POTENTIAL COMPLICATIONS**: • Vessel perforation or rupture • Distal embolization of blood clots • Vessel spasm • Hemorrhage • Hematoma • Pain and tenderness • Sepsis/Infection • Thrombophlebitis • Tricuspid and pulmonic valve damage • Pulmonary infarct due to tip migration and spontaneous wedging, air embolism, and/or thromboembolism • Right bundle branch block and complete heart block • Intimal disruption • Arterial dissection • Vascular thrombosis • Drug reactions • Allergic reaction to contrast medium • Arteriovenous fistula • Thromboembolic episodes • Amputation • Pneumothorax • Perforation of the pulmonary artery • Cardiac Arrhythmias – most frequently occurring during placement, removal or following displacement into the right ventricle. PI-726201-AA

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For more information contact customer service at 1.888.272.1001.

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