Boston Scientific
Advancing science for life™

EKOS™ Endovascular System

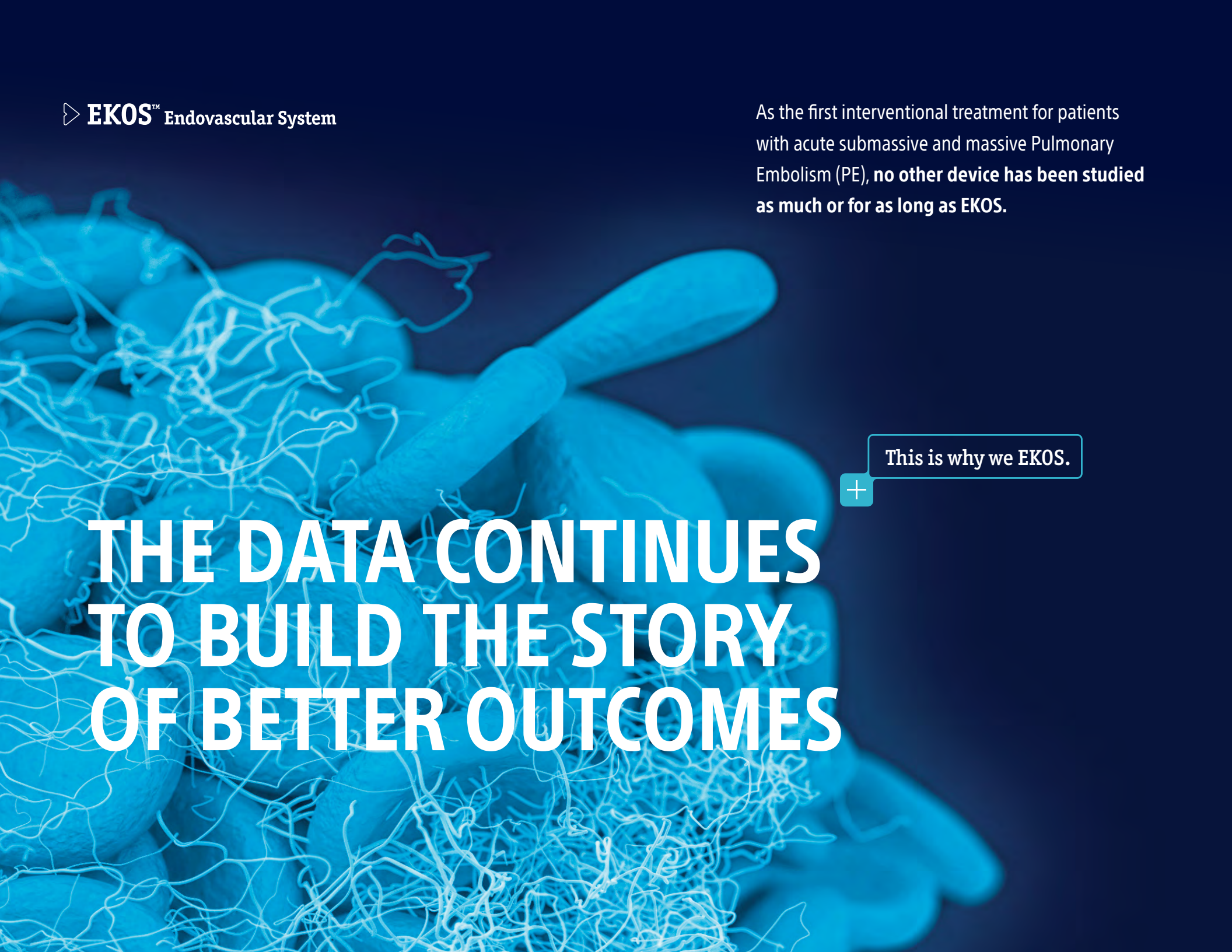
This is why we EKOS.

THE DATA STANDS BEHIND YOUR DECISION

EKOS™ ENDOVASCULAR SYSTEM CLINICAL TRIALS OVERVIEW

EKOS™ Endovascular System

As the first interventional treatment for patients with acute submassive and massive Pulmonary Embolism (PE), **no other device has been studied as much or for as long as EKOS.**



This is why we EKOS.

THE DATA CONTINUES TO BUILD THE STORY OF BETTER OUTCOMES

EKOS™ Endovascular System

THE DATA BACKS YOUR REASON TO INTERVENE IN MORE PE CASES

A safe, repeatable and reliable procedure that can treat a larger population of patients with acute submassive and massive PE.

THE FIRST CHOICE

INTERVENE IN MORE CASES

A proven safe treatment that allows a larger patient population of acute submassive and massive PE patients to be treated.

THE SMART CHOICE

LONG-TERM CLINICAL EVIDENCE

EKOS has a clinical legacy built on successful patient outcomes and long-term, clinical evidence.

THE RIGHT CHOICE

LARGEST RESEARCHED PATIENT POPULATION

A dedication and commitment to furthering clinical advancement that's setting the protocols for PE treatment to ensure successful outcomes.

PROVEN SAFE, REPEATABLE AND RELIABLE

EKOS safely dissolves thrombus with low lytic, low blood loss and low trauma for patients.

A DECADE COMMITTED TO CLINICAL ADVANCEMENT

2014

ULTIMA[1]

PROSPECTIVE, RANDOMIZED CONTROLLED STUDY VS. STANDARD OF CARE (ANTICOAGULATION)

PATIENTS:
59 patients with acute intermediate-risk PE

CONCLUSION:

EKOS was superior to anticoagulation alone without an increase in bleeding complications. ULTIMA was the first and remains the only level 1, head-to-head trial for the interventional treatment of PE.

2015

SEATTLE II[2]

PROSPECTIVE, MULTI-CENTER, SINGLE-ARMED TRIAL

PATIENTS:

150 patients with acute submassive and massive PE

CONCLUSION:

EKOS continued to show efficacy and safety in reducing RV dilation in patients with acute submassive and massive PE. SEATTLE II was the second pivotal trial that led to EKOS PE indication and remains the largest published prospective trial in the interventional treatment of PE.

2018

OPTALYSE[3]

PROSPECTIVE, MULTI-CENTER, PARALLEL-GROUP TRIAL

PATIENTS:
101 patients with acute intermediate-risk PE

CONCLUSION:

Low dose/short duration EKOS protocols showed the same efficacy as previous studies and long-term data showed sustained RV re-modeling out to one year. OPTALYSE provides the only long-term data for the interventional treatment of PE to date.

2021

KNOCOUT[4]

REGISTRY

PATIENTS:
991 retrospective, 489 prospective patients with acute intermediate-risk PE

CONCLUSION:

EKOS users have shifted their clinical practice toward lower-dose/shorter-duration OPTALYSE protocols. Also KNOCOUT PE confirmed, yet again, the safety and efficacy of EKOS therapy in PE with zero intracerebral hemorrhage observed and significant improvements in QOL scores.

2024

HI-PEITHO[5]

PROSPECTIVE, MULTI-CENTER, RANDOMIZED CONTROLLED TRIAL

PATIENTS:
406-544 patients with acute intermediate-high risk PE

OBJECTIVE:

To compare the outcomes of EKOS, plus anticoagulation versus anticoagulation alone for the treatment of acute intermediate-high risk PE.

PROVING LOWER LYTIC USE AND SHORTER DURATION TIME EMPOWER YOU TO SAFELY INTERVENE MORE OFTEN.

EKOS™ Endovascular System

THE DATA IS ADVANCING PROTOCOLS

KEY CLINICAL OUTCOMES

The following are key summaries that measure both short- and long-term efficacy in patients with acute submassive and massive PE.

- Proven to reduce RV/LV ratio by more than 23% in as little as 2 hours[3]
- Demonstrated a low risk of bleeding and minimized risk of ICH (0 ICH in the recent KNOCOUT Registry) [1-4]
- Shown to reduce PA pressure by 28% in 48 hours[2]
- Up to 88-92% less thrombolytic dose than standard systemic treatment[3,6]
- Only device with a prescribed protocol, allowing for predictable procedural workflow and proven patient outcomes[2,3]

ULTIMA TRIAL

First (and only) head-to-head prospective, randomized-controlled trial that showed EKOS is more effective than anticoagulation alone and just as safe.

CLINICAL SIGNIFICANCE

THE ONLY LEVEL 1 DATA
FOR INTERVENTIONAL TREATMENT OF PE

23% REDUCTION (P<0.001) IN RV/LV RATIO IN 24 HOURS

THE FIRST HEAD-TO-HEAD
PROSPECTIVE, RANDOMIZED-CONTROLLED TRIAL AGAINST STANDARD OF CARE

0% MAJOR BLEED

0 ICH

OVERVIEW

+ Prospective, Multi-Center, Randomized, Controlled Trial
+ 59 patients with acute intermediate-risk PE
+ 8 centers in Germany and Switzerland
+ Infusion time: 15 hours. Total dose: 20 mg
+ 23% reduction (p<0.001) in RV/LV ratio from baseline vs. 2.5% (p=.031) in Heparin group
+ No major bleeds, deaths or recurrent VTE at 90 days
+ 0 ICH

CONCLUSION:

ULTIMA showed that a fixed-dose EKOS regimen was superior to anticoagulation alone in improving right ventricular dysfunction at 24 hours without an increase in bleeding complications.

SEATTLE II TRIAL

Patients treated with EKOS showed significant RV/LV ratio, thrombus burden and systolic PA pressure reductions.

CLINICAL SIGNIFICANCE

25% REDUCTION (P<0.0001) IN RV/LV RATIO IN 48 HOURS

0 ICH
SEVERE BLEED = 0.67%
MODERATE BLEED = 9.3%

STILL THE LARGEST
PROSPECTIVE DEVICE TRIAL IN PE

OVERVIEW

+ Prospective, Multi-Center, Single-Armed Trial
+ 150 patients with acute submassive (n=119) and massive (n=31) PE
+ 22 centers in U.S.
+ Infusion time: 12 hours. Total dose: 24 mg
+ 25% reduction (p<0.0001) in RV/LV ratio 48 hrs. from baseline
+ 6.7 reduction (p<0.0001) in Thrombus Burden 48 hrs. from baseline
+ 13.9 mm Hg reduction (p<0.0001) in PA systolic pressure 48 hrs. from baseline
+ GUSTO Severe/Life-Threatening Bleed: 0.67%; GUSTO Moderate Bleed: 9.3%
+ 0 ICH
+ First EKOS protocol established

CONCLUSION:

SEATTLE II, the largest trial to-date, confirmed that EKOS continued to show safety and efficacy and provided a proven procedural protocol for the interventional treatment of PE.

OPTALYSE TRIAL

Patients treated with EKOS protocol (i.e. low dose and short duration), showed measured improvement in quality of life, exercise tolerance and physical functioning at one year.

CLINICAL SIGNIFICANCE

23%-26% ↓ REDUCTION (P<0.0001) IN RV/LV RATIO IN 48 HOURS

LOW DOSE AND SHORT DURATION
SHOWED THE SAME EFFICACY AS SEATTLE II

SUSTAINED RV-REMODELING
OUT TO ONE YEAR

THE ONLY
LONG-TERM DATA
IN THE PE DEVICE SPACE

OVERVIEW

+ Prospective, Randomized Parallel-Group
+ 101 patients with acute intermediate-risk PE
+ Patients randomly sorted into four separate low dose/short duration EKOS protocol cohorts
+ 17 centers in U.S. & Europe
+ 23-26% reduction (p<0.0001) in RV/LV ratio 48 hr. from baseline across all cohorts
+ Infusion time: 2, 4, 6 hrs. Total dose: 4/8 -12/24 mg
+ 4 major bleed (3%)
+ 1 ICH

CONCLUSION:

Confirmed that EKOS was safe and effective with a lower dose tPA and shorter duration. OPTALYSE provided a proven patient protocol for the interventional treatment of PE. It also supplied long-term RV remodeling and QOL data to the EKOS data set.

KNOCOUT REGISTRY

This prospective registry was designed to understand the adoption of low-dose, short-duration OPTALYSE protocols and add to the safety, efficacy, and quality of life evidence supporting EKOS.

CLINICAL SIGNIFICANCE

0 ICH **2.5%** BLEEDING RATE
489 PATIENTS, 83 CENTERS

23% ↓ REDUCTION (P<0.0001) IN RV/LV RATIO IN 48 HOURS

EQUIVALENT OUTCOMES
TO SEATTLE II & OPTALYSE PE

32.4% OF PATIENTS
WERE TREATED WITH A LOW-DOSE OPTALYSE PROTOCOL (<12MG r-tPA)

OVERVIEW

+ Patient Registry
+ 489 prospective patients
+ Patients with acute intermediate-high and high risk PE
+ 83 centers in the U.S. & Europe
+ 23% reduction (p<0.0001) in RV/LV ratio 48 hr from baseline
+ Mean infusion time: 10.4 hr Mean r-tPA dose: 17.9 mg
+ 0 ICH
+ 2.5% major bleeding rate
+ Significant improvement in QoL as measured by PEmb-QoL and EQ-5D-5L VAS

CONCLUSION:

EKOS users have shifted their clinical practice toward lower-dose/shorter-duration OPTALYSE protocols. Also KNOCOUT PE confirmed, yet again, the safety and efficacy of EKOS therapy in PE with zero intracerebral hemorrhage observed and significant improvements in QOL scores.

HI-PEITHO TRIAL

This study aims to address a critical gap in clinical evidence in PE by comparing the clinical benefit of intervention with EKOS versus the current standard of care – anticoagulation. It is designed to generate the most rigorous, highest level of data, contributing to the body of evidence for the treatment and outcomes in acute intermediate-high risk PE.

CLINICAL SIGNIFICANCE

PUTTING EKOS TECHNOLOGY HEAD-TO-HEAD WITH CURRENT STANDARD OF CARE

1ST AND LARGEST TRIAL OF ITS KIND IN PE

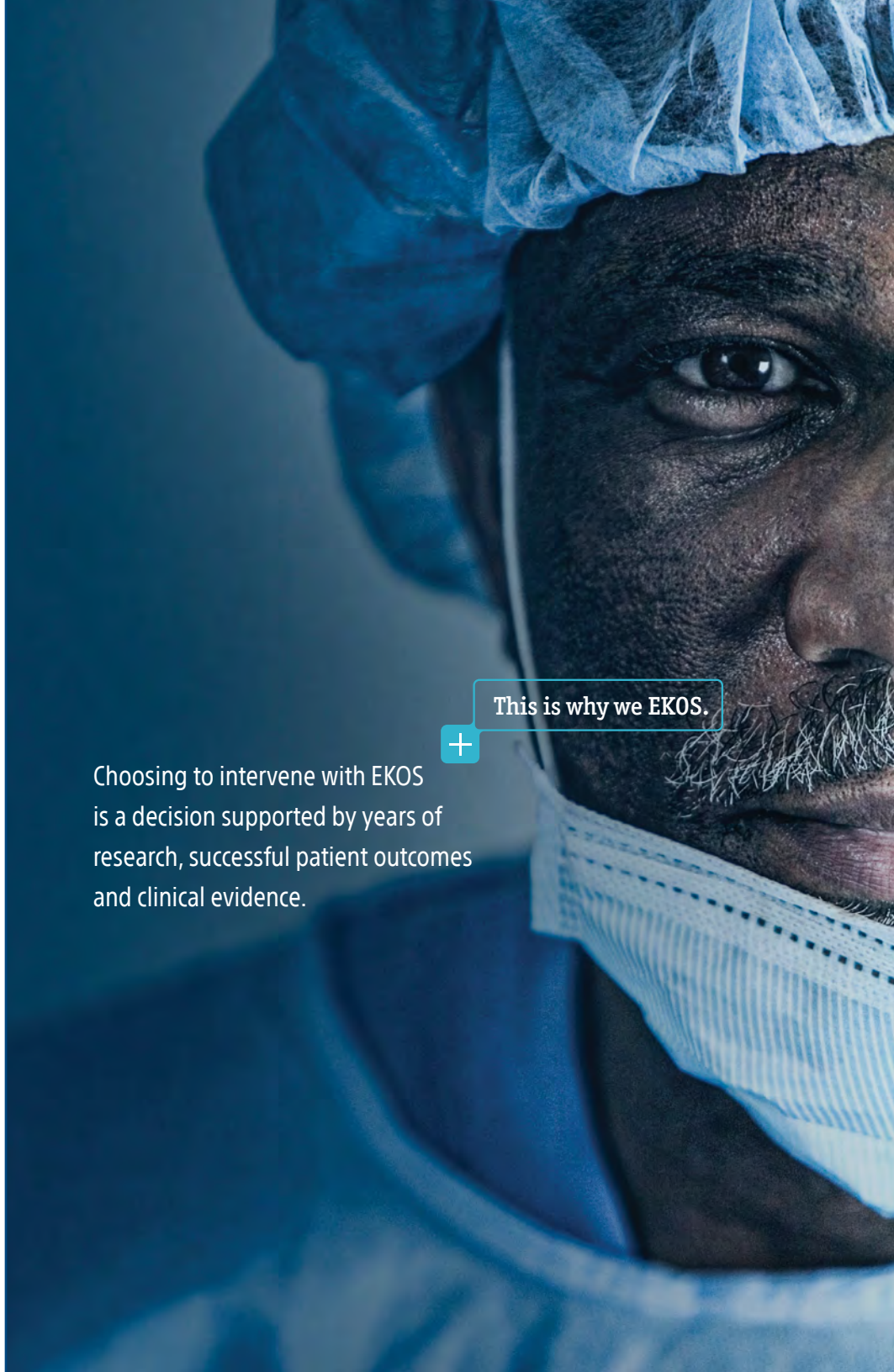
POTENTIAL TO CHANGE GUIDELINES

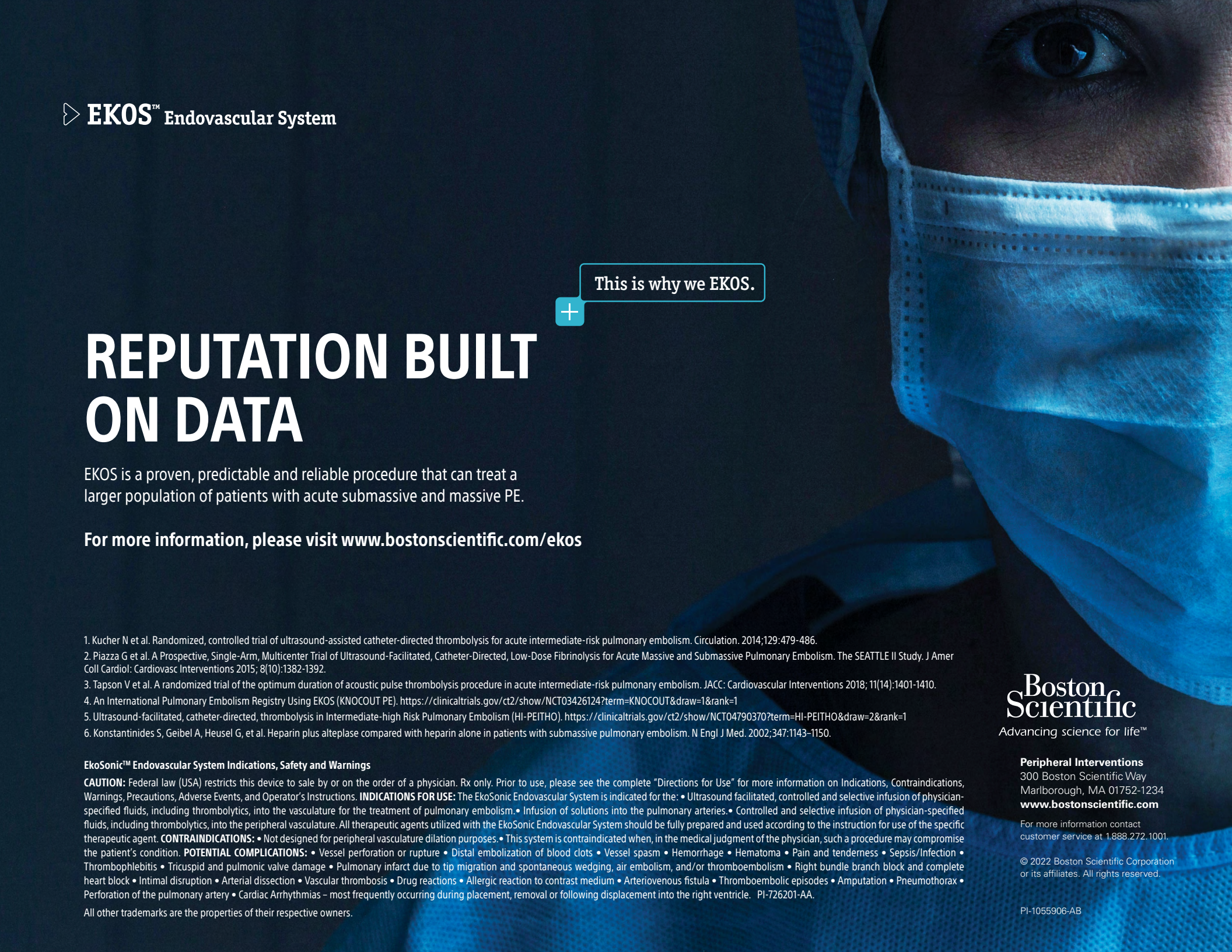
OVERVIEW

+ Large-Scale, Transatlantic, Multi-Center, Prospective, Randomized, Controlled Trial
+ 406-544 patients with acute intermediate-high risk PE
+ Up to 65 centers in U.S. & Europe
+ Primary outcome: composite of PE-related death, cardiorespiratory decompensation or collapse, and non-fatal symptomatic and objectively confirmed recurrence of PE
+ 18 additional secondary endpoints to be assessed

OBJECTIVE:

To compare the outcomes of EKOS, plus anticoagulation versus anticoagulation alone for the treatment of acute intermediate-high risk PE.





EKOS™ Endovascular System

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REPUTATION BUILT ON DATA

EKOS is a proven, predictable and reliable procedure that can treat a larger population of patients with acute submassive and massive PE.

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

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. Ultrasound-facilitated, catheter-directed, thrombolysis in Intermediate-high Risk Pulmonary Embolism (HI-PEITHO). https://clinicaltrials.gov/ct2/show/NCT04790370?term=HI-PEITHO&draw=2&rank=1
6. 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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