



EKOS™ Endovascular System

**TREAT THE PATIENT
NOT JUST THE CLOT**



This is why we EKOS.





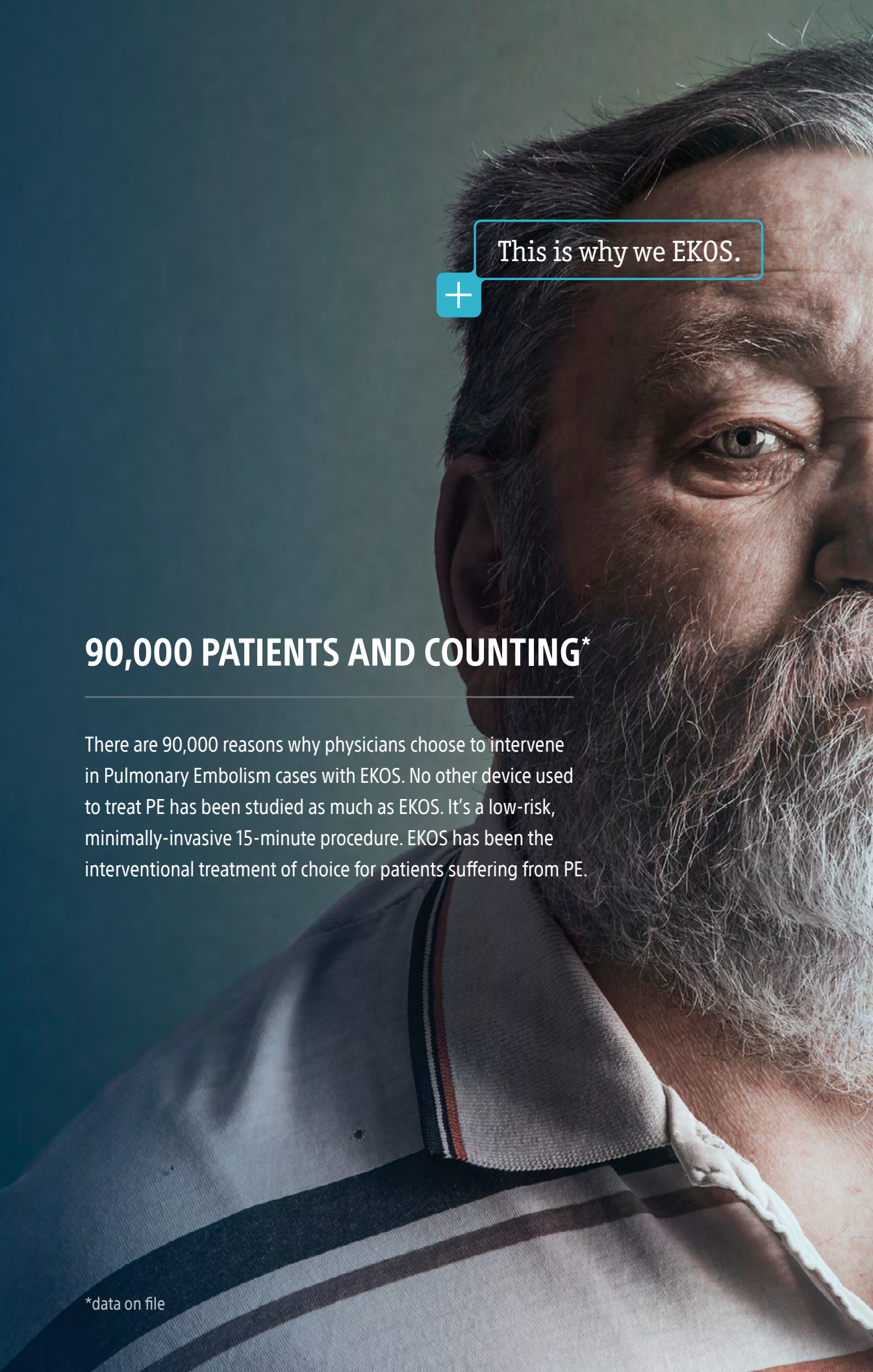
A REASON TO INTERVENE IN MORE PE CASES

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 accelerates lytic dispersion deeper into the clot. The new EKOS+ catheter delivers 50% more ultrasound power to resolve PE clot burden more quickly & completely. 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	2015	2018	2021
ULTIMA¹	SEATTLE II²	OPTALYSE³	KNOCOUT⁴
Level 1 Prospective RCT n=59 Showed that EKOS was more effective than anticoagulants alone in RV/LV reduction and was just as safe	Prospective n=150 Confirmed EKOS improved RV function, pulmonary hypertension and clot burden without an increase in bleeding	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	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



This is why we EKOS.



90,000 PATIENTS AND COUNTING*

There are 90,000 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, 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

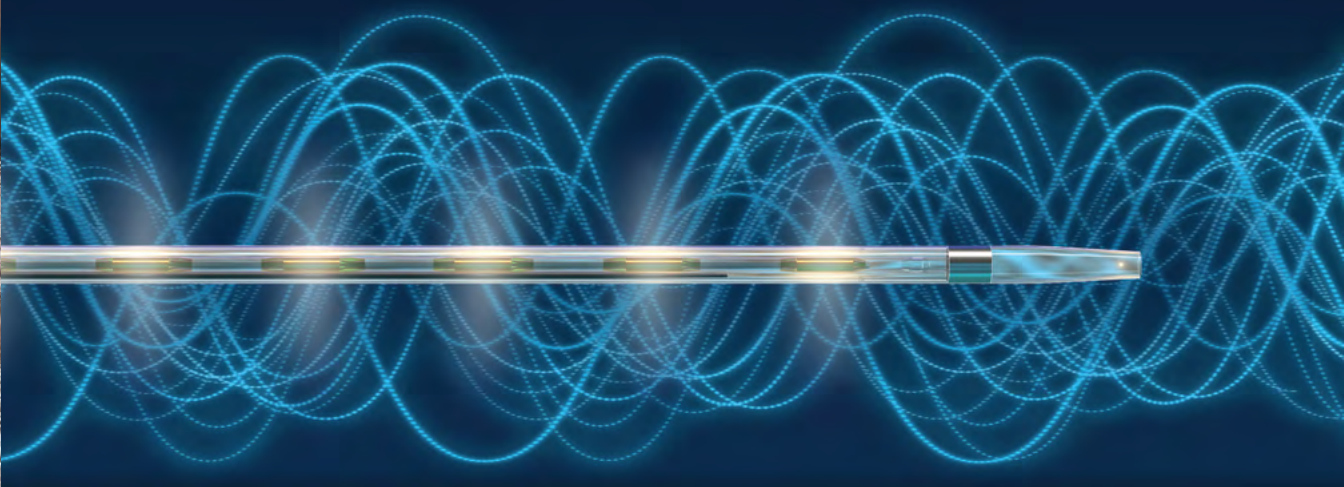
+ Long legacy built on successful patient outcomes and long-term, clinical evidence

THE SMART CHOICE

+ The most studied device in the PE space and the only device 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

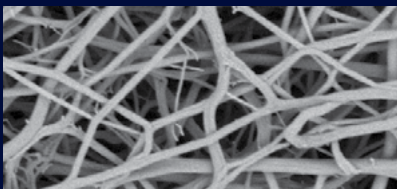
+ Low lytic, low blood loss, low trauma



ULTRASONIC CORE TECHNOLOGY

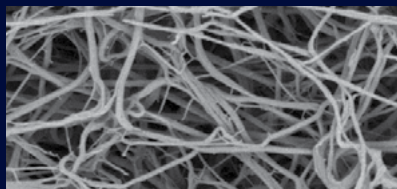
+ Ultrasonic waves accelerate clot dissolution by unwinding and thinning fibrin strands to expose more drug receptor sites; acoustic streaming drives the drug deeper into the clot for safe dissolution

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.

Introducing EKOS+ SAME PROCEDURE, NOW 50% MORE POWERFUL

ONE 15-MINUTE PROCEDURE

Tailor-made for treating PE, EKOS+ provides interventionalists with more ultrasound power to resolve clot burden more quickly and completely without any required changes to lytic dose, treatment duration, or current clinical practice.



Target Thrombus Safely



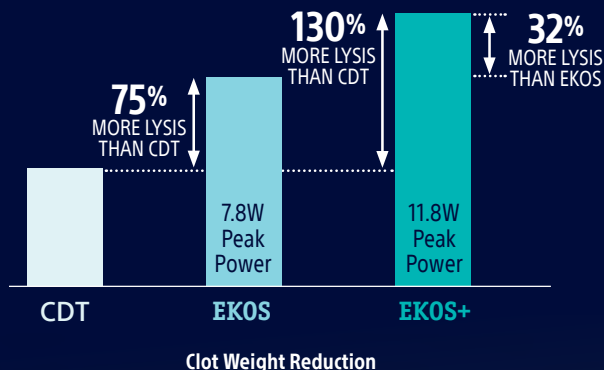
Acoustic Pulse Acceleration



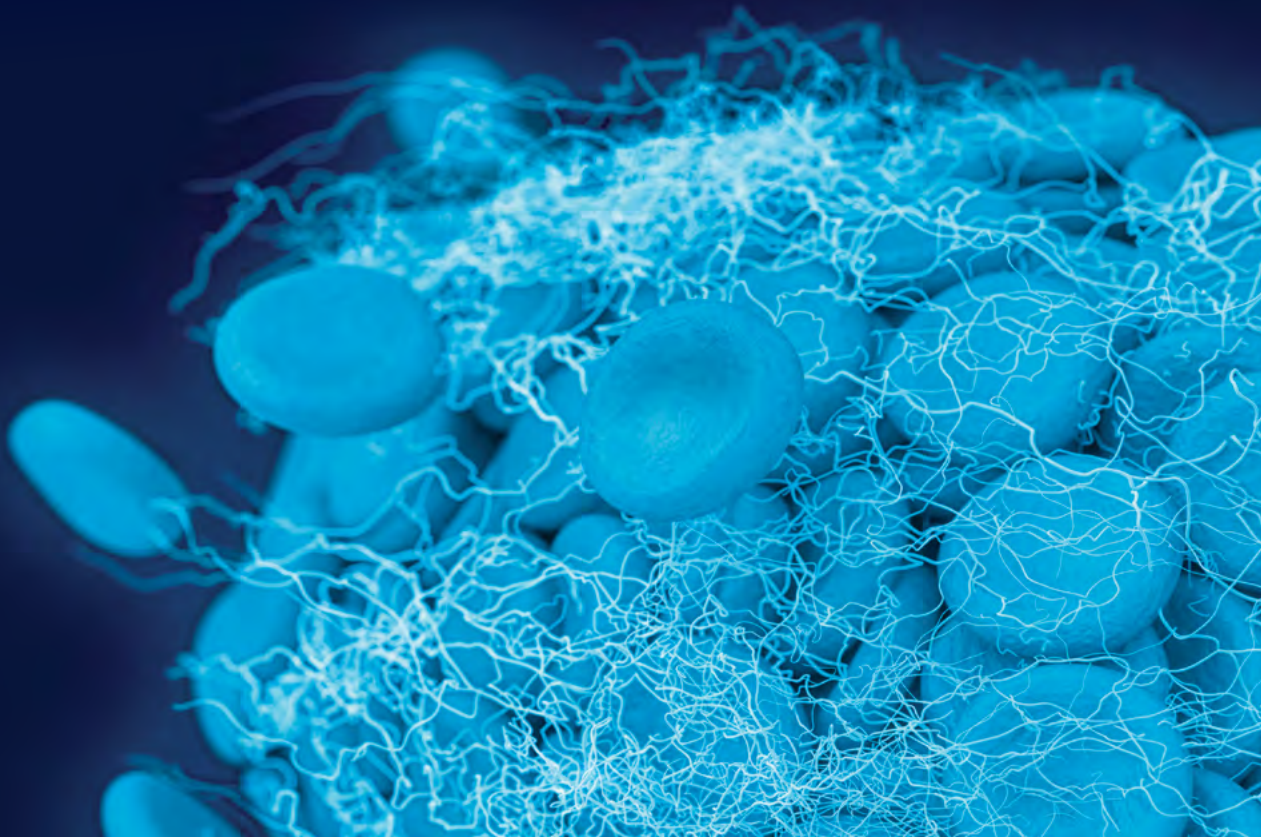
Superior Clot Dissolution

CLOT RESOLUTION COMPARISON

With 50% more ultrasound power, EKOS+ delivers 130% more clot lysis than standard CDT and 32% more lysis than conventional EKOS.*



*bench data on file



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 infusion catheter (0.035" guidewire compatible) with one ultrasonic core matched to corresponding length.

135 cm infusion catheter (0.035" guidewire compatible) with one ultrasonic core matched to corresponding length.

EKOS™+ Endovascular System

Product	Working Length	Treatment Zone
H74939605106080	106 cm	8 cm
H74939605106120	106 cm	12 cm
H74939605106160	106 cm	16 cm
H74939605106200	106 cm	20 cm
H74939605135080	135 cm	8 cm
H74939605135120	135 cm	12 cm
H74939605135160	135 cm	16 cm
H74939605135200	135 cm	20 cm

7.8 F infusion catheter for all EKOS+ products

106 cm infusion catheter (0.035" guidewire compatible) with one ultrasonic core matched to corresponding length.

135 cm infusion catheter (0.035" guidewire compatible) with one ultrasonic core matched to corresponding 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>

EKOS™ and EKOS™+ Endovascular Device

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 "Instructions for Use" for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator's Instructions. **INTENDED USE:** The EKOS™ Endovascular Device is intended to be used with EKOS-branded control systems to employ high frequency (1.5 MHz to 1.9 MHz), low-power ultrasound to facilitate the infusion of physician-specified fluids, including procedural fluids and thrombolytics, into the pulmonary and/or peripheral vasculature of adults. It is intended to be used by physicians experienced in endovascular interventional procedures. The EKOS™ Endovascular System is not intended for use in the neurovasculature. Refer to the product insert supplied with the physician-specified fluid for fluid-specific preparation, contraindications, side effects, warnings, and precautions. **INDICATIONS FOR USE:** The EKOS™ Endovascular System, consisting of the Infusion Catheter and the Ultrasonic Core, is indicated for the: • Ultrasound facilitated, controlled and selective intravascular infusion of physician-specified fluids, including thrombolytics, for the treatment of pulmonary embolism and/or deep vein thrombosis. • Controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries and/or peripheral vasculature. **Clinical Benefit Statement:** The EKOS™ Endovascular Device is intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature or the pulmonary arteries. The clinical benefit can be measured by overall clinical outcomes, including, but not limited to, improved right ventricular heart function and hemodynamic stability when treating PE or the ability to infuse physician-specified fluids into the peripheral vasculature, along with low rates of hemorrhage, recurrent PE, and all-cause mortality. **CONTRAINDICATIONS:** The EKOS™ Endovascular Device is contraindicated for use in: • Patients in whom thrombolytic and/or anticoagulation therapy is contraindicated. • Any situation in which the medical judgment of the physician determines such a procedure may compromise the patient's condition. **WARNINGS:** The following warning statements provide important information for safe operation of the EKOS™ Endovascular System. Observe all warnings provided in these Instructions for Use. Failure to do so may result in patient injury, operator injury, or product damage. • Always verify that BOTH electrical connectors from an Ultrasonic Core and Infusion Catheter pair are connected to the SAME Connector Interface Cable (CIC). Failure to properly connect both electrical connectors from an Ultrasonic Core-Infusion Catheter pair to the same CIC could result in over-temperature operation of the Ultrasonic Core, potentially causing damage to the patient. • Never aspirate blood into the drug lumens as perfusion ports and/or drug lumens may become occluded. • Do not connect the Infusion Catheter "Drug" or "Coolant" infusion luer to a power injector. • Do not exceed 200 psi applied to any infusion luer. • If flow through the Infusion Catheter becomes restricted, do not attempt to clear by high pressure infusion. Either remove the Infusion Catheter (and Ultrasonic Core, if in place) to determine and eliminate the cause of the obstruction or replace the Infusion Catheter with a new Infusion Catheter of the same model. • Never activate ultrasound energy with the Infusion Catheter or Ultrasonic Core's working length exposed to the air. The device should be placed within the patient anatomy, with physician-specified fluids running through the drug lumen and coolant flowing through the coolant lumen. Otherwise, overheating may occur, potentially causing burns, damage to the Ultrasonic Core, and/or interrupting therapy. • Always turn off the ultrasound before removing the Ultrasonic Core from the Infusion Catheter. Otherwise, overheating may occur, potentially causing burns, damage to the Ultrasonic Core, and/or interrupting therapy. Use of a damaged Ultrasonic Core may result in vascular trauma. • Do not deform or kink the Ultrasonic Core during delivery into the Infusion Catheter. If the Ultrasonic Core is kinked at any time, do not attempt to use the Ultrasonic Core, as kinking may lead to degraded performance or fracture during use. • Never attempt to use the Ultrasonic Core with any catheter except the compatible EKOS™ Infusion Catheter. • Do not attempt to use non-compatible working lengths (i.e., 135 cm Infusion Catheter and 106 cm Ultrasonic Core and vice-versa). Incorrect size matching may be harmful to the patient and require additional intervention or surgery. • Never place the Ultrasonic Core into the patient without previously placing the Infusion Catheter. • Never immerse the electrical connectors or the gray housing of the Infusion Catheter in fluid. • Do not use an introducer sheath with a rotating hemostasis valve to introduce the EKOS™ Endovascular Device. Insertion or removal through a rotating hemostasis valve may result in removal of the radiographic marker band, stretching, or other damage to the catheter. • The EKOS™ Endovascular System is not intended for use in the neurovasculature. **PRECAUTIONS:** Carefully read all Instructions for Use prior to use. Observe all precautions noted throughout these instructions. Failure to do so may result in complications. • Prior to introduction, and each time the Infusion Catheter is removed from the vascular system, the Infusion Catheter should be flushed. • If flow through the Infusion Catheter becomes restricted, do not attempt to clear by high pressure infusion. Either remove the Infusion Catheter (and Ultrasonic Core, if in place) to determine and eliminate the cause of the obstruction or replace the Infusion Catheter with a new Infusion Catheter of the same model. • The EKOS™ device is designed to provide optimum acoustic output during the first 24 hours of operation. • The EKOS™ device should only be used to infuse physician-specified fluids, including thrombolytics. Other types of fluids, outside of thrombolytics and procedural fluids (heparinized saline, saline, contrast media, etc.), have not been evaluated for use with the EKOS™ Endovascular Device. • This device is not designed for use as a peripheral vascular dilator. • During normal use, ultrasound energy may cause a temperature rise in the treatment zone. The catheter surface temperature is limited to a maximum of 43 °C. • Therapeutic agents, such as thrombolytics, should be administered through the drug port whereas the procedural fluids (such as saline and contrast agent) should be administered through the coolant port or central lumen. • EKOS™ Endovascular Devices will only run on EKOS Control Unit 4.0. They are not compatible with earlier generations of EKOS / Ekosonic Control Units. If EKOS™ device is connected to a control unit other than EKOS CU 4.0, the EKOS™ device will not be recognized by the control unit and will require exchange of device or control unit in order to proceed. **ADVERSE EVENTS:** Potential adverse events which may be associated with use of the EKOS™ Endovascular System when used as indicated include, but are not limited to: • Allergic reaction (contrast, device, or other) • Arrhythmia • Burn • Cardiac Tamponade • Cardiac Trauma • Death • Embolism (air, device, plaque, thrombus, tissue, or other) • Hematoma • Hemorrhage • Hypotension • Infection/Sepsis • Ischemia/Necrosis • Need for additional intervention or surgery • Pain • Pneumothorax • Renal Insufficiency/Failure • Respiratory Failure • Thrombosis/Thrombus • Vasospasm • Vessel Occlusion • Vessel Trauma (AV fistula, dissection, perforation, pseudoaneurysm, rupture or injury) **92882188 A.1**

All other trademarks are the properties of their respective owners.

Boston Scientific
Advancing science for life™

Peripheral Interventions
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

For more information contact customer service at 1.888.272.1001.

© 2022 Boston Scientific Corporation or its affiliates. All rights reserved.

PI-1322305-AA