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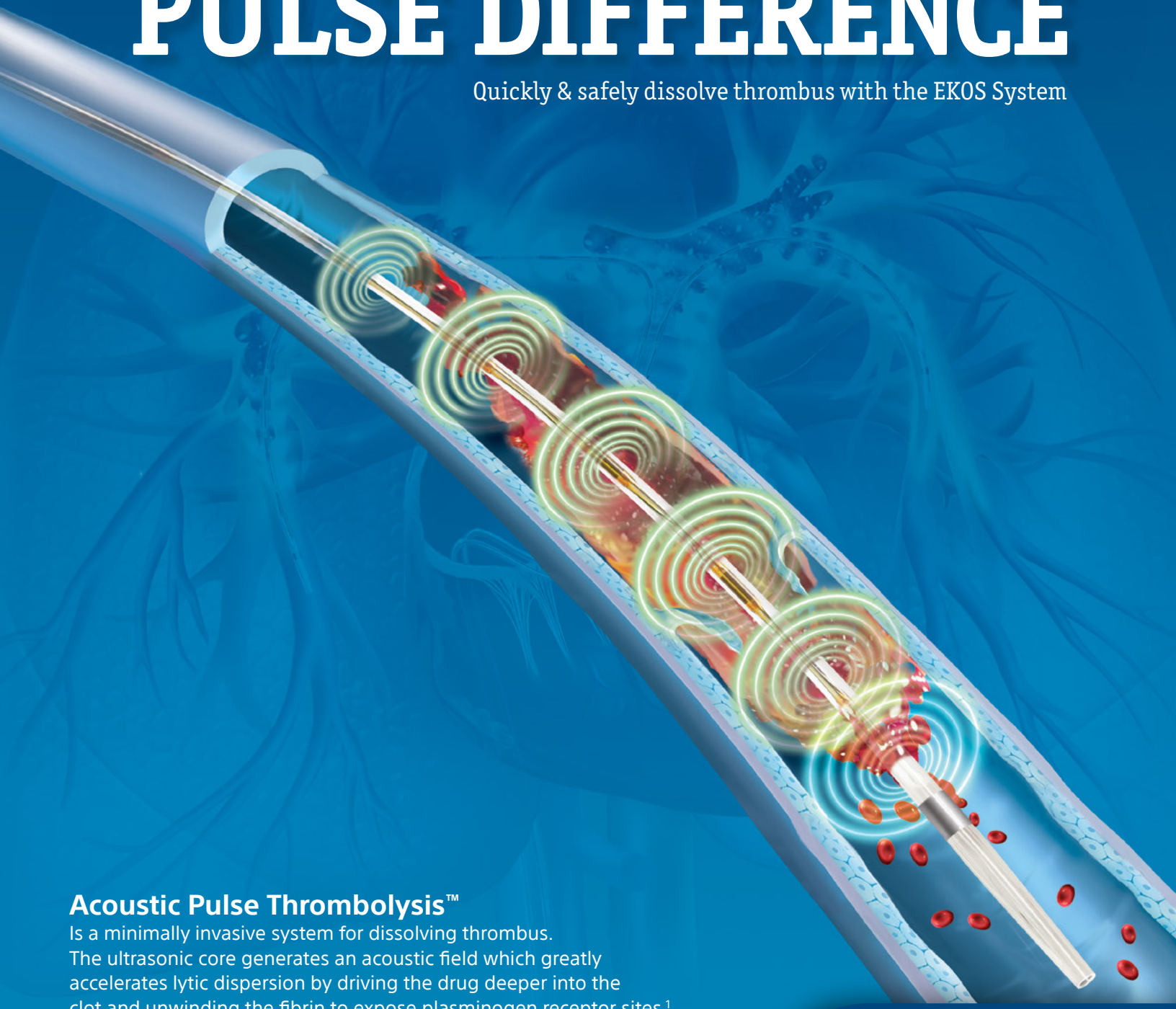
Advancing science for life™

EKOS™ Acoustic Pulse Thrombolysis Treatment

THE ACOUSTIC PULSE DIFFERENCE

Quickly & safely dissolve thrombus with the EKOS System



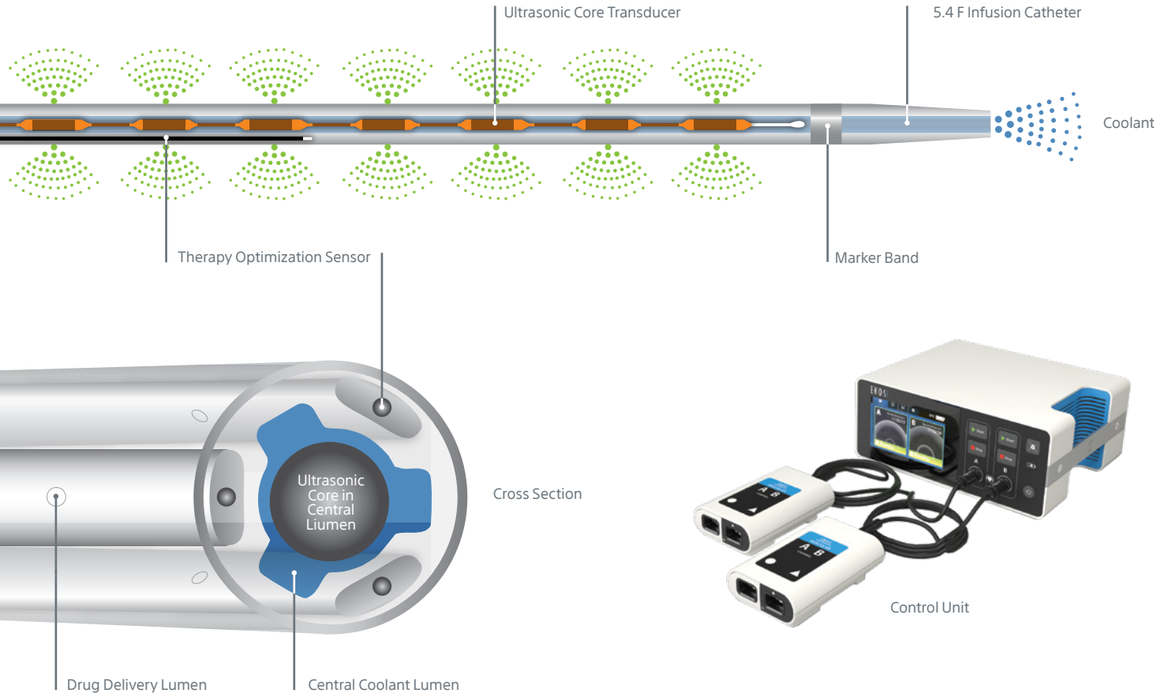
Acoustic Pulse Thrombolysis™

Is a minimally invasive system for dissolving thrombus. The ultrasonic core generates an acoustic field which greatly accelerates lytic dispersion by driving the drug deeper into the clot and unwinding the fibrin to expose plasminogen receptor sites.[1]

1. Francis CW et al. Ultrasound accelerates transport of recombinant tissue plasminogen activator into clots. Ultrasound in Medicine and Biology,1995;21(5):419-24

Accelerate Thrombus Dissolution with Targeted Ultrasound Waves

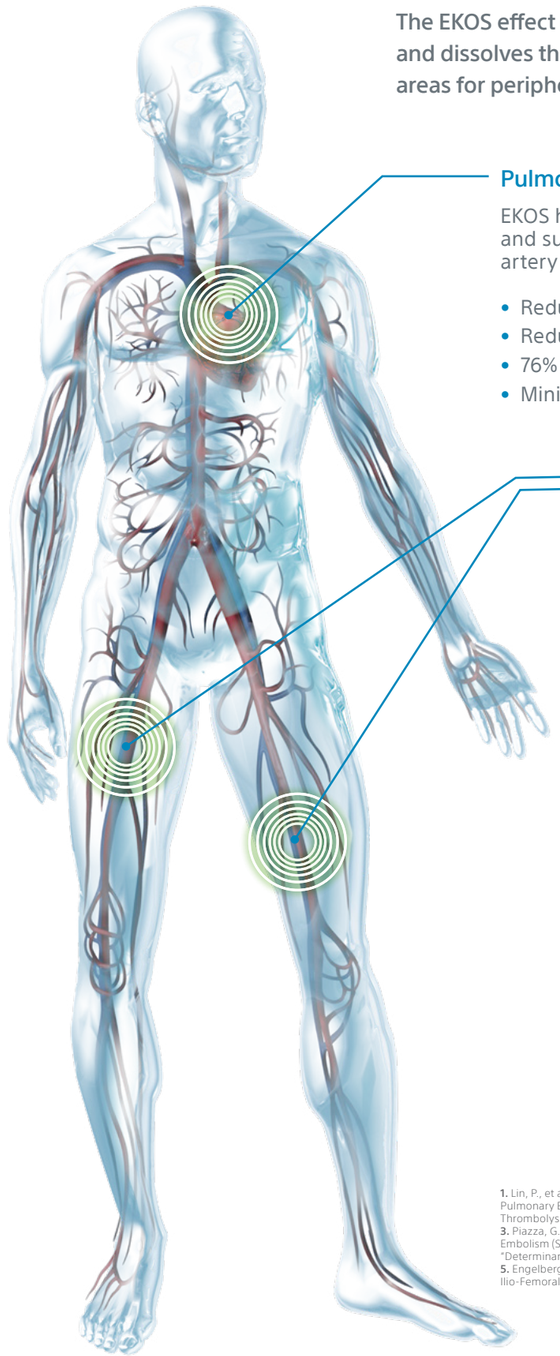
The EkoSonic™ Endovascular System includes an ultrasonic core within an infusion catheter, and control unit.



Acoustic Pulse Thrombolysis Treatment has clinically shown:

- More effective drug delivery
- More efficient thrombus clearance
- Reduced procedure time

The EKOS effect changes the standard of care for pulmonary embolism and dissolves the thrombus more completely, even in difficult-to-reach areas for peripheral arterial occlusion.



Pulmonary Embolism

EKOS has been shown to yield safe and effective results for acute, massive and submassive PE. It improves right ventricular function and pulmonary artery pressure while minimizing the risk of bleeding.[1]

- Reduces RV/LV ratio by more than 23% on average in as little as 2 hours[2]
- Reduces PA pressures by 28% (at 48 hours)[3]
- 76% less thrombolytic drug dosage than standard treatment[3]
- Minimized risk of bleeding[1]

Infusion of Thrombolytics

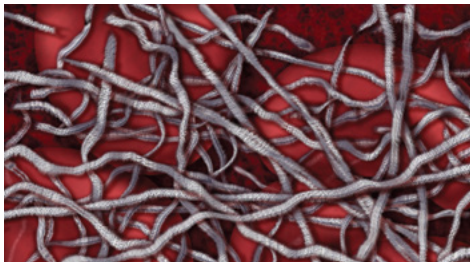
The EKOS catheter can be used for the infusion of physician selected therapeutics, including thrombolytics into the peripheral vasculature.

- Removes thrombus more completely compared to CDT[4]
- Reduces post-thrombotic syndrome[5]

1. Lin, P., et al., "Comparison of Percutaneous Ultrasound-Accelerated Thrombolysis versus Catheter-Directed Thrombolysis in Patients with Acute Massive Pulmonary Embolism." Vascular, Vol. 17, Suppl. 3, 2009, S137-S147. **2.** Tapson, Victor, et al., "A Randomized Trial of the Optimum Duration of Acoustic Pulse Thrombolysis Procedure in Acute Intermediate-Risk Pulmonary Embolism: The OPTALYSE PE Trial." JACC: Cardiovascular Interventions Jul 2018, 11 (14) 1401-1410. **3.** Piazza, G., et al., "A Prospective, Single-Arm, Multicenter Trial of Ultrasound-Facilitated, Low-Dose Fibrinolysis for Acute Massive and Submassive Pulmonary Embolism (Seattle II)." American College of Cardiology 63rd Annual Scientific Session, Washington, D.C., March 30, 2014. **4.** Kahn, Sr. Shrier I. Julien, J.A., et al., "Determinants and Time Course of the Post-thrombotic Syndrome After Acute Deep Venous Thrombosis." Annals of Internal Medicine, 149, 2008, 698–707. **5.** Engelberger, R., et al., "Fixed, Low-Dose Ultrasound-Assisted Catheter-Directed Thrombolysis Followed by Routine Stenting of Risidual Stenosis for Acute Ilio-Femoral Deep-Vein Thrombosis." Journal of Thrombosis and Haemostasis, 2014, 111.6.

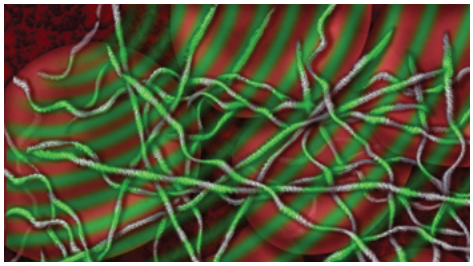
The EKOS System's targeted ultrasound waves accelerate thrombus dissolution by unwinding the fibrin matrix.[1]

The Thrombosis Barrier



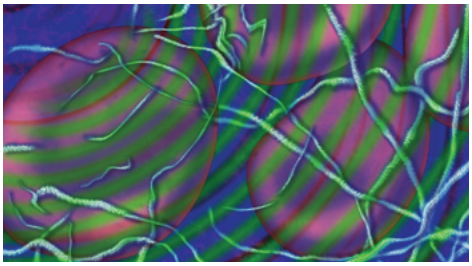
Tightly wound fibrin prevents lytic from reaching receptor sites.

With Acoustic Pulse



Ultrasonic energy thins fibrin and exposes receptor sites.

With Acoustic Pulse + Lytic



More drug reaches entire thrombus, accelerating absorption.

5.4 F infusion catheter for all EKOS products

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

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

500-56112	135 cm	12 cm
500-56130	135 cm	30 cm
500-56140	135 cm	40 cm
500-56150	135 cm	50 cm

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

1. Braaten JV et al. Ultrasound reversibly disaggregates fibrin fibers.Thromb Haemost 1997;78:1063-8

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EKOS Acoustic Pulse Thrombolysis Treatment
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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PI-718703-AB