Acoustic Pulse Thrombolysis™ Treatment
Quickly & safely dissolve thrombus with the EKOS™ System.

The Acoustic Pulse Difference

Acoustic Pulse Thrombolysis™ treatment 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.

**Acoustic Pulse Thrombolysis™ Treatment:**
- Speeds time-to-dissolution\(^{15}\)
- Increases thrombus removal and clinical improvement compared to either standard Catheter Directed Therapy (CDT) or thrombectomy\(^ {2}\)
- Lowers the risk of bleeding and other complications\(^ {1,4}\)

**More Effective Drug Delivery:**
- Reduces dosage requirements by as much as 68% compared to standard CDT\(^ 4\)
- Requires up to 4x less drug dosage than systemic delivery\(^ {6,7}\)
- Reduces RV/LV ratio with as little as 8mg total tPA used in combination with EKOS™ therapy\(^ {16}\)

**Superior Thrombus Clearance\(^ {2,4}\):**
- 48% greater drug absorption within 1 hour\(^ 8\)
- 84% greater drug absorption within 2 hours\(^ 8\)

The EKOS™ System’s targeted ultrasound waves accelerate thrombus dissolution by unwinding the fibrin matrix.
Lower patient risk. Higher procedure predictability.

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

Targeting the Thrombus, Safely
With EKOS™ Acoustic Pulse Thrombolysis™ treatment most of the drug remains in the thrombus and you can typically use less lytic. It dissolves the thrombus without damaging vessels, valves or walls.4, 12 There is no mechanical disruption resulting in distal embolization.13

The EKOS™ System’s safety and efficacy is supported by Level 1 and Level 2 data.3, 7, 14, 15, 16

Reduced Procedure Time2,4
EKOS™ requires significantly shorter treatment times, typically only 33–50% of standard CDT. Unlike more complex surgical solutions,1, 5 EKOS™ is an efficient, three-step process:

1) Insert the EKOS™ 5.4 F infusion catheter through the thrombus.
2) Insert the ultrasonic core until it locks in place.
3) Activate the lytic infusion and acoustic pulse.

Treatment zones range from 6cm to 50cm with radiopaque marker bands at each end of the treatment zone to enhance visualization. At-a-glance operating status, alarms and treatment times are easy to read from a distance.
Deep Vein Thrombosis
The EkoSonictm Endovascular System dissolves thrombus more completely even behind valves and IVC filters. It quickly restores blood flow, potentially reducing the risk of pulmonary embolism and post-thrombotic syndrome (PTS). Approximately 50% of patients with acute ilio-femoral DVT develop PTS. A low-dose lytic and EKOS™ regimen has been associated with a low-bleeding rate and high venous patency with 90% of patients experiencing no DVT complications.

In the ACCESS PTS study, 73 patients with chronic DVT treated with a regimen of both balloon dilatation and EKOS™ therapy saw a significant reduction in Villalta Score of 49% and a 36% improvement in VEINES-QOL at one year.

Periferal Arterial Occlusion
The EkoSonictm Endovascular System improves on standard CDT by safely accelerating drug penetration, even in difficult-to-reach areas. Compared to traditional CDT the EkoSonictm Endovascular System offers:

• Shorter treatment times
• Higher dissolution rate of entire thrombus (95.3% vs. 66.7%, p=0.002)
• Lower bleeding rates (4.7% vs. 23.8%, p=0.026)
• Lower 30-day amputation rate (19.5% vs. 42.9%, p=0.04)
• Shorter hospital stays (5.7 vs. 8.3 days, p=0.027)

Pulmonary Embolism
The EkoSonictm Endovascular System is the first endovascular device cleared by the FDA for the treatment of pulmonary embolism. The current standard of care, anticoagulation, does not resolve existing thrombus. EKOS™ has been shown to yield safe and effective results for acute, massive (high risk) and submassive (intermediate risk) PE. It improves right ventricular function and pulmonary artery pressure while minimizing the risk of bleeding.

In the Seattle II study of 150 patients with massive or acute intermediate-risk PE using an EKOS™ and lytic combination, the mean RV/LV ratio decreased from 1.55 pre-procedure to 1.13 at 48 hours post-procedure (P<0.0001) while PA systolic pressure decreased from 51.4 mm Hg to 36.9 mm Hg (P<0.0001). In contrast to the 2.5–3% rate of intracranial hemorrhaging associated with historical systemic fibrinolysis and full-dose tPA, no patients in this study experienced intracranial bleeding or fatal bleeding events.

In the OPTALYSE PE study of 101 patients with submassive PE utilizing EKOS™ therapy, each of the OPTALYSE 2, 4 & 6 hr cohorts reduced RV/LV ratio by 23-26%. Total tPA doses in the study ranged from 8-24mgs bilaterally and the bleeding rate was a very low 3%. The one-year data demonstrated a 2% mortality rate - significantly below both anticoagulation and systemic therapy.
The fast, safe solution for vascular thrombosis.

The EkoSonic™ Endovascular System:
- Quality clinical outcomes
- Predictable results
- Minimized bleeding risk
- Efficient procedures

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

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

Deep Vein Thrombosis
- Up to 50% of DVT patients have PE
- Removes thrombus more completely compared to CDT
- Reduces post-thrombotic syndrome

Arterial Occlusion
- Lower 30-day amputation rate
- Lower bleeding rates when compared to CDT
- Higher complete dissolution rate of thrombus

The EkoSonic™ Endovascular System

106cm Working Length: Includes one 5.4 F infusion catheter (106cm long, 0.035 inch guidewire compatible) and one ultrasonic core matched to infusion length.

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135cm Working Length: Includes one 5.4 F infusion catheter (135cm long, 0.035 inch guidewire compatible) and one ultrasonic core matched to infusion length.

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References


Product availability varies by country. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Prior to use, please refer to the applicable Instructions for Use (IFU) for complete product indications, contraindications, warnings, and precautions.

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