EKOS

Interventional Vascular
23 September 2014

BTG

Imagine where we can go.

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What is Thrombus & where is it a problem?

Thrombus is blood clot formed in vascular system impeding blood flow, as a result of occlusions, injury or damage to endothelial lining of the blood vessel, stasis or hypercoagulability

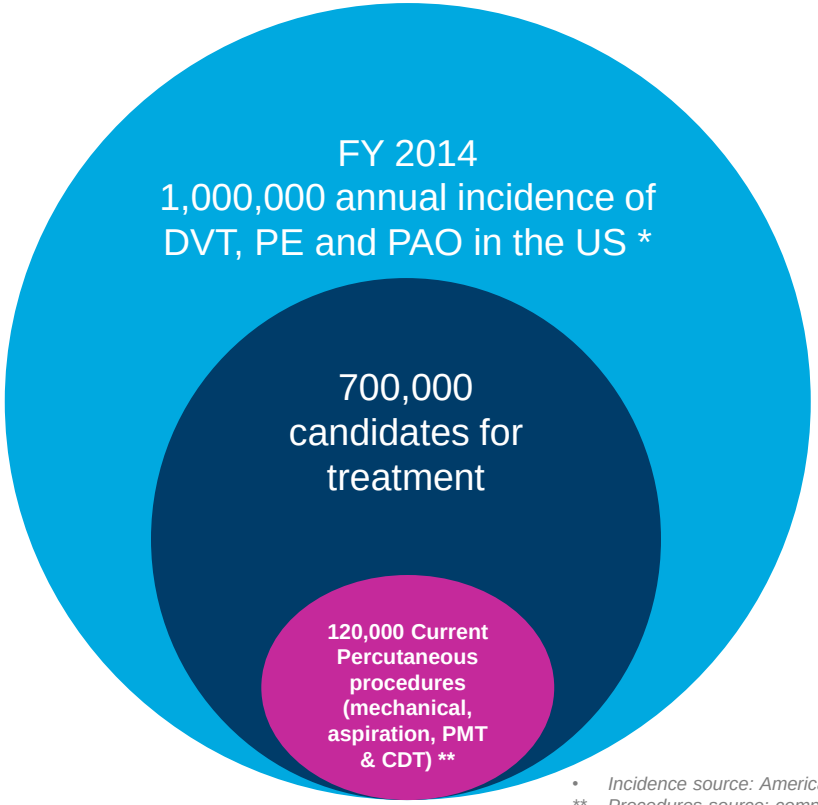
VTE is Venous Thromboembolism or DVT, which includes thrombus in the deep veins & upper extremity

Peripheral Arterial Occlusions, occlusions that often include thrombus in the major peripheral arteries

PE is Pulmonary Embolism and is where thrombus has lodged in the pulmonary artery

Large Underserved Population

Underpenetrated Market (US)



	Clot Management 2018 (Percutaneous Procedures)	
	US	ROW
Acute Deep Vein Thrombosis (DVT)	80K	1 to 2 X U.S.
Arterial (PAO)	70K	
Pulmonary (PE)	40K	
Total opportunity	300K-400K procedures ~ $1 Billion opportunity	

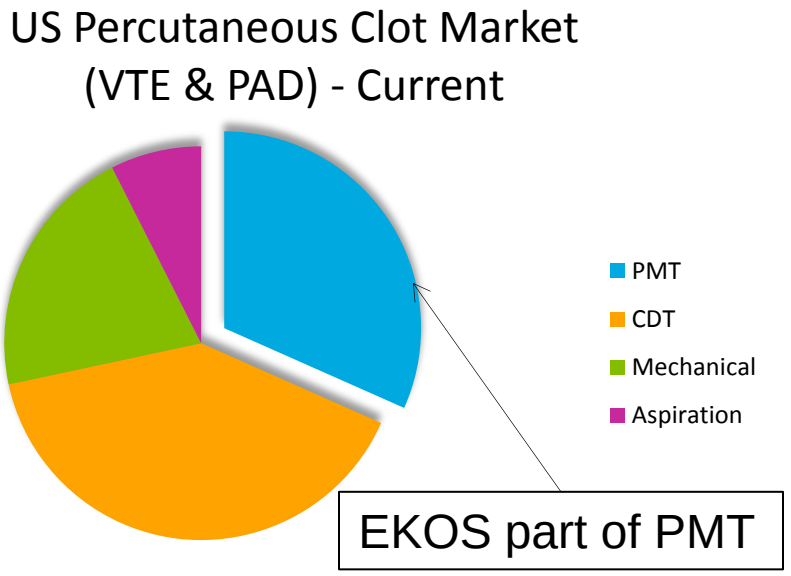
* *Incidence source: American Heart Assoc.*
** *Procedures source: compilation of 3rd Party & Company data*

Growth of interventional landscape

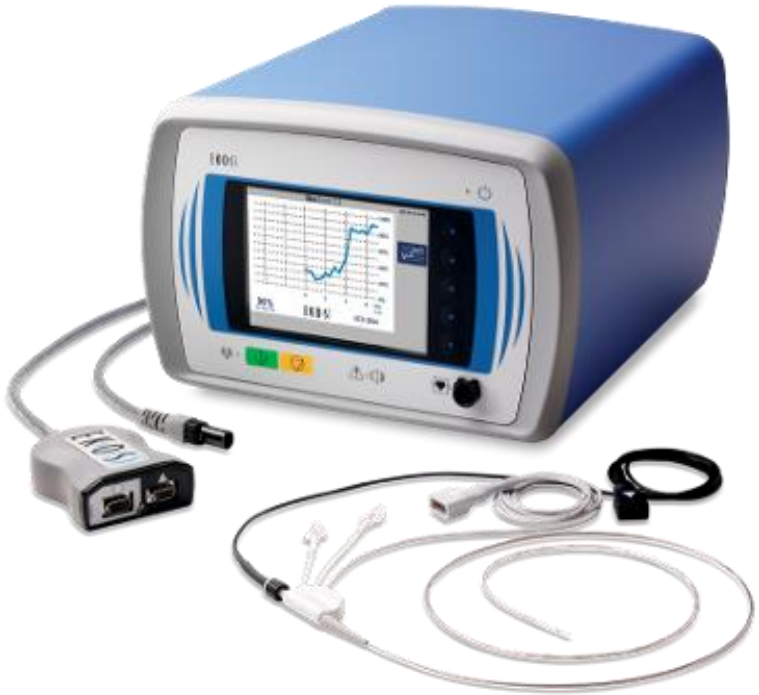
- Clinical Studies showing positive results of interventional treatment
- Better thrombus treatment options available vs. compression stockings and anticoagulation
- Minimally invasive technology reducing procedure and recovery times
- More awareness of thrombus disease through better imaging and diagnosis

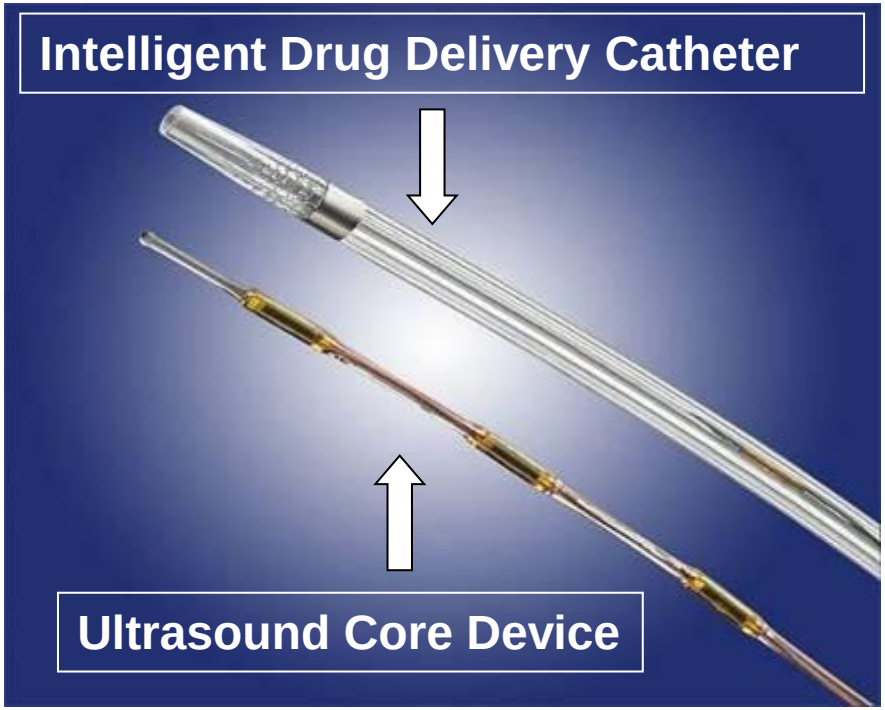
Current Treatments for Thrombus DVT, PAO & PE

- Pharmacomechanical thrombectomy (PMT)
  - **EKOS Ultrasound Assisted Thrombolytic** (USAT)
- Catheter Directed Thrombolysis (CDT)
- Mechanical devices
- Aspiration



EkoSonic® Endovascular System

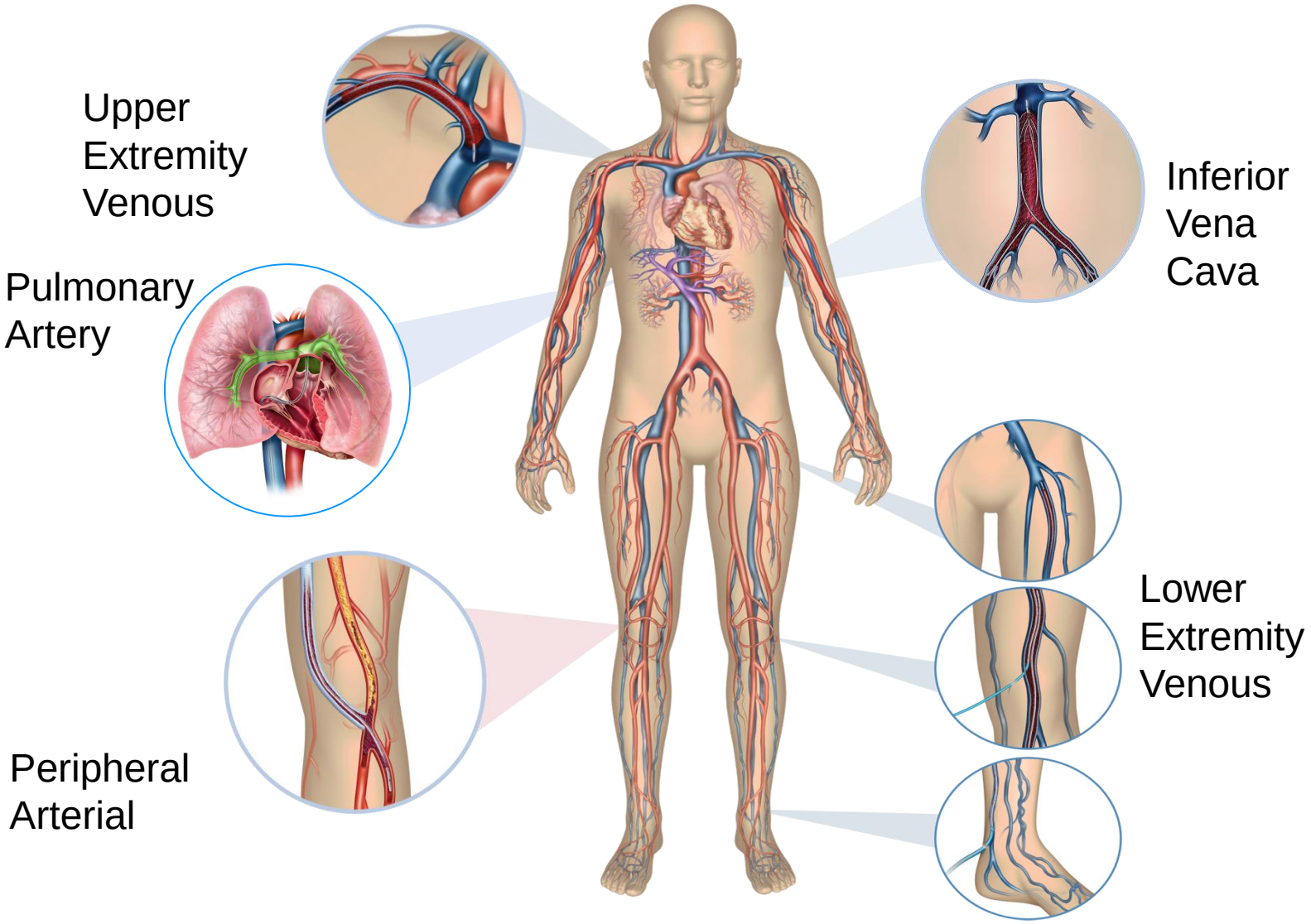




Features

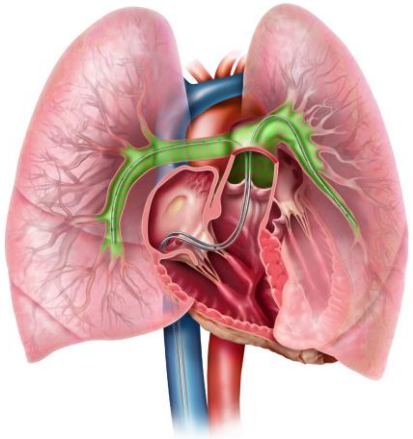
- *5.4 Fr catheter*
- *106 and 135 cm working length*
- *6, 12, 18, 24, 30, 40 and 50 cm treatment zones*

We treat thrombus in…



Differentiated from Competitors

- Less lytic & infusion time vs. CDT
- More complete resolution than other PMT, Mechanical or Aspiration devices
- Pulmonary FDA clearance, currently only medical device cleared for treatment of pulmonary embolism
- STEMI like PE protocols being developed across the nation
- Trained Peripheral & Pulmonary Sales organization
- Leveraging BTG European presence
- Backed by clinical evidence



Clinical benefits

EKOS® technology offers superior thrombus clearance[1]

- Increased drug uptake[2]
- 48% greater drug absorption within 1 hour
- 84% greater drug absorption within 2 hours

Overall reduction of lytic dose by 50-80%[1,4]

Shortens time-to-dissolution and dissolves thrombus more completely compared to standard catheter-based infusion[5]

Fast and simple placement reduces physician lab time[5]

1. Parikh, S., et al. Journal of Vascular and Interventional Radiology, Volume 19, Issue 4, April 2008, pp 521-528.
2. Francis, CW., et al. Ultrasound in Medicine and Biology 21.3 (1995): 419-424.
3. Kucher et al. Circulation. 2014;129:479-4863.
4. Lin et al. Vascular 2009;17(Suppl 3):S137 – S147
5. Compared to mechanical devices which must be operated solely in the lab.

Patient safety

Unlike other pharmacomechanical technologies available on the market, the EkoSonic® Endovascular System does not cause hemolysis or vessel and valve damage

- No hemolysis[1]
- No bradycardia/heart block
- No renal failure risk beyond that of angiography
- No mechanical disruption[2] resulting in distal embolization
- No vessel or valve damage[1]

Reduced risk of bleeding complications reported with use of EKOS® compared to CDT[3]

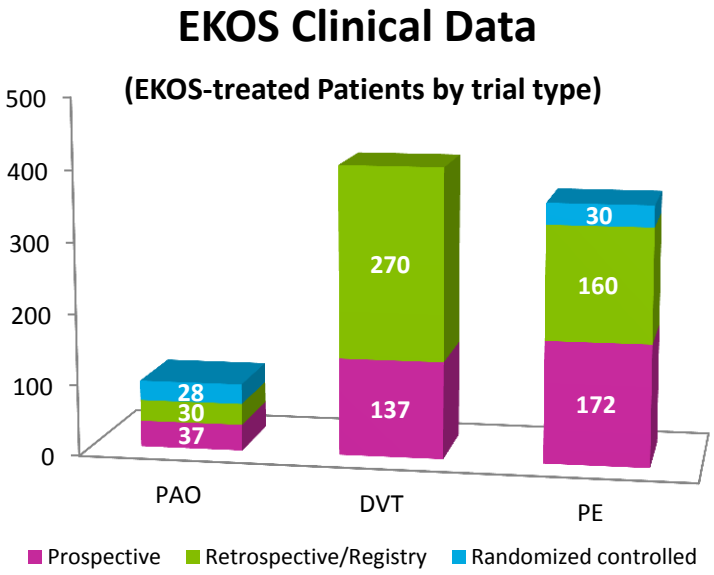
1 Soltani, A., et al. Ultrasonics 46 (2007) 60-67
2. Braaten, JV., et al. “Throm Haemost 1997; 78:1063-8..
3. Lin et al. Vascular. 2009 Nov-Dec;17 Suppl 3:S137-47

EKOS Clinical Data

– Prospective & retrospective data for all 3 disease states

– World device leader in prospective level 1 data for treatment of PE

"The EKOS clinical data established that patients stricken with a life-threatening pulmonary embolism can be successfully and safely treated with the EkoSonic system," said Samuel Z. Goldhaber, M.D., professor of Medicine at Harvard Medical School and director of the Thrombosis Research Group at Brigham and Woman's Hospital in Boston, Mass. ***"This is the first FDA cleared treatment option for PE since the approval of the drug, tPA, in 1990."***



ULTIMA Study
EKOS, +tPA & heparin randomized vs. heparin, 59 pts
- RV/LV ratio significantly improved at 24 hours in EKOS arm, P<.001
- No deaths or significant bleeding complications
- Systolic RV function significantly improved

SEATTLE II Study
22 centers, 150 pts.
- 25% reduction in RV/LV ration within 48 hrs.
- Minimized risk of intracranial hemorrhage (0%)
- Rapidly relieved pulmonary artery obstruction P<0001 vs. pre procedure

EkoSonic® Endovascular System
Current approvals

FDA clearance

The EkoSonic® Endovascular System is indicated for:

- controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature
- infusion of solutions into the pulmonary arteries
- the ultrasound facilitated, controlled and selective infusion of physician-specified fluids, including thrombolytics, into the vasculature for the treatment of pulmonary embolism

CE Mark

The EkoSonic® Endovascular System is intended for:

- controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature
- the treatment of pulmonary embolism patients with ≥ 50% clot burden in one or both main pulmonary arteries or lobar pulmonary arteries, and evidence of right heart dysfunction based on right heart pressures (mean pulmonary artery pressure ≥ 25 mmHg) or echocardiographic evaluation.

http://www.ekoscorp.com/6084-001_H_IFU,%20Control%20Unit,%20EkoSonic%20with%20MACH4e%20Software%20(English).pdf
http://www.ekoscorp.com/fall2013/MACH4,%205.4F%20Peripheral%20(English).pdf
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http://www.ekoscorp.com

Growth through expansion

US

- Expanding our label
  - EKOS received FDA 510K clearance for treatment of PE
- Expanding our footprint
  - EKOS installed in less than ½ of potential US Institutions
  - Sales force well positioned to capitalize on opportunity
- Expanding our product lines

International

- Expanding our footprint
  - Feet on the street in U.K., France coming shortly
  - # of Distributors in EU & LA, Asia to follow

Positioning for long term growth

- Clinical Studies
  - Clinical trial to investigate treatment of chronic PTS
  - Next Pulmonary Study
- Product Development Pipeline
  - New Hardware to address bilateral cases & ease of use
  - New Device technology to increase speed to resolution and reduce lytic doses
  - Investing in Manufacturability
- Geographic Expansion

$100m - $200m opportunity by 2021