PHARMACOMECHANICAL THROMBOLYSIS WITH THE BASHIR™ CATHETER: UNIQUE AND DIFFERENTIATED APPROACH
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Disclosures

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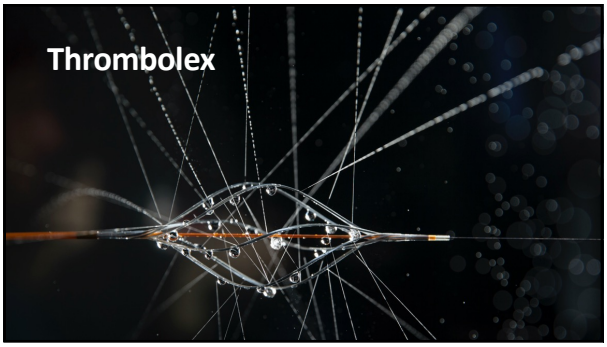
What Does the Optimal Device for PE Look Like?

What if there was a single session, single device therapy to treat acute PE that could:

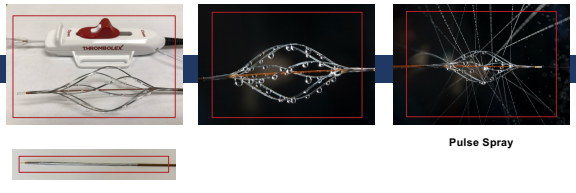
- Avoid high dose lytic infusion
- Avoid overnight lytic infusion
- Acutely lower RV/PA pressure
- Acutely improve RV function
- Rapidly and optimally resolve PA thrombus
- Improve safety dramatically without sacrificing clinical efficacy

The Novel BASHIR™ Endovascular Catheter is Poised to Disrupt the Treatment for PE

References:
1. Dr. Rob Lookstein – Mount Sinai Hospital; presented at SIR2024

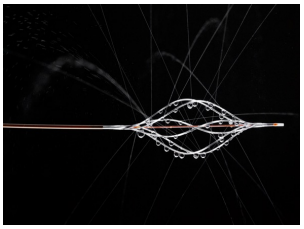


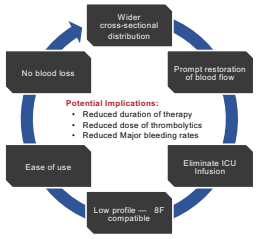
Pharmacomechanical Lysis with the BASHIR™ Endovascular Catheter



Pulse Spray

Advantage of the BASHIR™ Endovascular Catheter





Disruptive Platform Technology

Hybrid Pharmaco-mechanical Device

BASHIR® endovascular catheter

BASHIR S-B endovascular catheter

Portfolio for Long Lesion Treatments

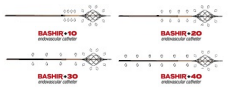
BASHIR+ endovascular catheter

BASHIR•10 endovascular catheter

BASHIR•20 endovascular catheter

BASHIR•30 endovascular catheter

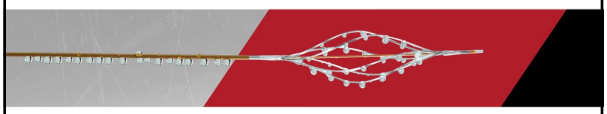
BASHIR•40 endovascular catheter



The BASHIR™ Endovascular Catheters and the BASHIR™ Plus Endovascular Catheters are intended for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with various thrombus.

THE RESCUE-II STUDY

Study of the Safety and Feasibility of the On-The-Table Pharmacomechanical Lysis for treating Acute Intermediate-Risk Pulmonary Embolism



Funding support: Commonwealth of Pennsylvania Department of Health and Thrombolex Inc.

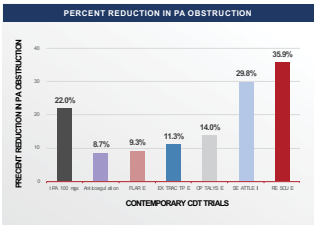
Is PML enough on the table without post-procedure infusion?

PM-CDT

- Markedly reduced PA obstruction

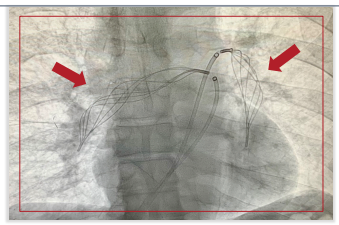
Bench Testing

- >50% of the r-tPA was adsorbed in the IV bag and tubing



1 Blinc et al. Thromb Haemost. 1994 Feb;71(2):230-5. 2 Comerota et al. Ann Surg. 1997;226(3):306-314. 3 Gurevitch. J Am Coll Cardiol. 2016 Nov 8;68(19):2089-2108.

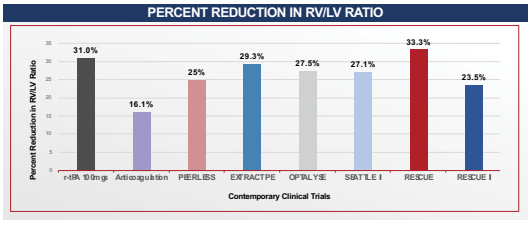
RESCUE-II Protocol



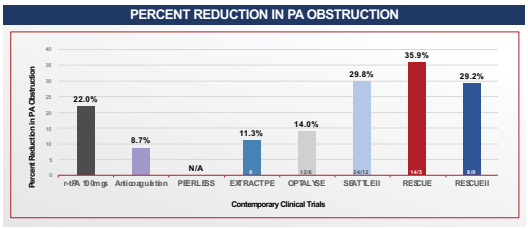
Unilateral PE – Total 4 mgs of r-tPA (Four pulse sprays 1 mg each)

Bilateral PE – Total 8 mgs of r-tPA (Eight pulse sprays 1 mg each — four mgs in each lung)

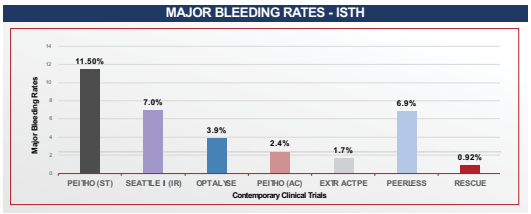
DISCUSSION – Reduction in RV/LV Ratio



DISCUSSION – Reduction in PA Obstruction



DISCUSSION – Major Bleeding Rates



SAFETY: Major Bleeding rates with PML parallels that seen with anticoagulation alone.

No Major Bleeding RESCUE II

*Meyer G., Fibrinolysis for patients with intermediate-risk pulmonary embolism. N Engl J Med 2014;370:1402-11.

Comparative PE Clinical Data

PE Clinical Studies	Total Lytic Dose	Device time	Post Procedure ICU Admission	Total Length of Stay	Safety: Adverse Events	Safety: Major Bleed Rate
Thrombolex - RESCUE-II	8mg	39 Min	0%	3.0 Days	0%	0%
Inari - PEERLESS	n/a	47.9 Min	41.6%	4.5 Days	13.3%	6.9% (2 ICH)
CDT - PEERLESS	16mg	915 Min	98.6%	5.3 Days	11.5%	6.9% (1 ICH)

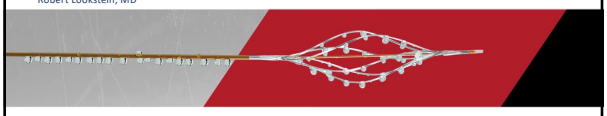
Comparative PE Clinical Data

PE Clinical Studies	Total Lytic Dose	RV/LV Ratio: Improvement	PA Obstruction: Improvement	Safety: Major Bleed Rate
Thrombolex - RESCUE-II	8mg	22.3%	29.2%	0%
Thrombolex - RESCUE	14 mg	33.3%	35.9%	0.92%
EKOS – SEATTLE II	24 mg	27.1%	29.8%	10.00%
EKOS – OPTALYSE / ARM 3	12 mg	26.3%	14.0%	3.60%
Penumbra – EXTRACT PE	n/a	29.3%	11.3%	1.70%
INARI - PEERLESS	n/a	25%	n/a	6.9% (2 ICH)
INARI - FLARE	n/a	24.4%	9.3%	0.96%
PEITHO - Anticoagulation	n/a	16.1%	8.7%	2.40%
PEITHO - Systemic Lytics	100 mg	31.0%	22.0%	11.50%

RAPID-PE Study

On-the-table registry of Pharmacomechanical Lysis with the BASHIR Endovascular Catheter for Acute Pulmonary Embolism

Principal Investigators
Wissam Jaber, MD
Robert Lookstein, MD



RAPID-PE Clinical Study

Treating 500 Patients at 50 Clinical Sites

- Single Arm, Multi-Site Post Market Study
- Shorter Treatment Time
- Eliminate Need for ICU Stay
- Reduce Lytic Dose
- No Capital Equipment
- Shorter Total Length of Stay

Driving a Paradigm Shift in The Treatment of Pulmonary Embolism

Drug Administration

r-tPA Administration
- Unilateral PE: 4mg r-tPA administered in 10cc/1mg increments x 4 pulse sprays
- Bilateral PE: 8mg r-tPA total administered in 10cc/1mg increments x 8 pulse sprays

Anticoagulant Dosage and Administration
- Pre and post procedure: Anticoagulation to be administered according to the investigator's standard of care

Thank you

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