

THROMBOLEX Announces Interim RAPID-PE Results Showing Favorable Safety and Reproducible Multicenter Results in Acute Pulmonary Embolism

Mechanically channeled thrombolysis procedure disrupts and dissolves thrombus in a single on-the-table session.



NEW BRITAIN, Pa., October 6, 2026 — THROMBOLEX, Inc., a leader in the development of innovative treatments for pulmonary embolism (PE), announced today the interim analysis of the first 150 patients in RAPID-PE, a prospective, multicenter, single-arm study of on-the-table (OTT) mechanically channeled thrombolysis (MCT) with the THROMBOLEX® device in acute intermediate-risk PE. Through 30 days, there were no device-related deaths, no ischemic or hemorrhagic strokes, and 90% of patients did not require a post-procedure ICU stay. Results were presented at The VEINS 2026 in Las Vegas by Wissam Jaber, MD, Emory University, RAPID-PE co-national principal investigator.

Interim findings in the first 150 participants include:

- 0.7% (1 of 150): all-cause mortality or hemodynamic decompensation through 7 days
- 0.7% (1 of 150): major bleeding within 72 hours
- 100% procedural success (150 of 150) across 45 operators at 20 U.S. sites

In the THROMBOLEX OTT procedure, the expanded device basket mechanically creates channels in the clot and delivers targeted lytic to dissolve it. The dose and spray sequence are fixed before the case begins, giving the physician a defined procedural stopping point and a repeatable, streamlined workflow. No post-procedural infusion is required, and the procedure uses no capital equipment.

“45 operators at 20 sites ran the same protocol and saw the same low early event rates, and 90% of these patients needed no ICU stay,” said Dr. Jaber. “A single-session treatment with this safety profile changes the calculus of when to intervene. Most catheter-based PE treatment today happens once a patient is deteriorating. The question this dataset raises is whether we should be intervening earlier, across a broader range of patients than we treat now.”

RAPID-PE extends the THROMBOLEX evidence base across a wider range of operators and sites. In RESCUE, a pivotal multicenter study of the THROMBOLEX device involving 109 patients with acute intermediate-risk PE at 18 U.S. sites, the physician-specified lytic dissolved main and downstream thrombus and restored patency in the distal segmental branches. The RESCUE data demonstrated that reduced pulmonary arterial obstruction significantly correlated with a reduction in right ventricle to left ventricle (RV/LV) ratio only at the segmental level ($P=0.0026$), highlighting the importance of reducing thrombus burden in the segmental arteries. Enrollment in RAPID-PE continues toward 350 participants; a CT angiography sub study of RV/LV ratio and subsegmental clearing completes in 2027.

“We are encouraged that the findings from this data set continue to reinforce the on-the-table approach: one session, a defined stopping point, and nothing infusing afterward,” said Michael D. Tuter, Chief Executive Officer of THROMBOLEX. “Reproducibility is what makes a therapy adoptable. A procedure that requires no capital equipment and no routine ICU bed fits into how a hospital already delivers care, and that is the barrier we set out to remove. We look forward to completing enrollment and reporting the full dataset.”

About THROMBOLEX, Inc. THROMBOLEX® is innovating mechanically channeled thrombolysis — an endovascular approach that disrupts and dissolves thrombus in a single, on-the-table treatment session. By creating flow channels within thrombus, the THROMBOLEX procedure facilitates thrombolytic delivery to promote clot dissolution and restore blood flow in the main and segmental pulmonary arteries. The THROMBOLEX procedure requires no routine ICU admission, and no capital equipment. THROMBOLEX 7Fr and 8Fr Endovascular Devices and their S-B configurations are FDA-cleared for the controlled and selective infusion of physician-specified fluids, including thrombolytics, into the pulmonary arteries for the treatment of pulmonary embolism, and for infusion of physician-specified fluids, including thrombolytics, into the peripheral vasculature, enabling the restoration of blood flow in patients with venous thrombus. For more information, visit www.thrombolex.com.

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