

THROMBOLEX, INC. HAS RECEIVED FDA CLEARANCE FOR USE OF BASHIR™ ENDOVASCULAR CATHETERS FOR TREATMENT OF ACUTE PULMONARY EMBOLISM

By Thrombolex | April 20, 2023 | Press Release

NEW BRITAIN, PA – April 20, 2023 – Thrombolex, Inc. has received 510(k) clearance for use of the BASHIR™ and BASHIR™ S-B Endovascular Catheters for the treatment of acute pulmonary embolism (PE). This PE specific clearance was based upon the positive results from the pivotal RESCUE Study, which was funded by the National Heart, Lung and Blood Institute of the National Institutes of Health (*Grant # R44HL151032-03*) and the Commonwealth of Pennsylvania’s Department of Health.

Now physicians may offer this novel technology to customize and personalize treatment for their patients with PE, the third largest cause of cardiovascular death. The BASHIR™ catheters use a unique combination of mechanical and pharmacological mechanisms of action to safely resolve blood clots. Targeted thrombolytics are delivered from the expandable infusion basket directly into the clot enabling the immediate restoration of blood flow and optimal resolution of thrombus, thus helping patients to recover rapidly.

Dr. Kenneth Rosenfield, Co-Principal Investigator of the RESCUE Trial and Section Head, Vascular Medicine and Intervention at the Massachusetts General Hospital, said “This represents a significant advance in the treatment of acute PE, with a rapid reduction in right ventricular strain and less than 1% rate of major bleeding.”

Dr. Robert Lookstein, Executive Vice Chair, Diagnostic, Molecular and Interventional Radiology at the Icahn School of Medicine at Mt Sinai Hospital, New York, stated “This novel approach with the BASHIR™ catheter and low dose tPA demonstrated rapid resolution of obstruction in the central and the segmental pulmonary arteries. The striking reduction of blockages in the segmental arteries is a crucial step forward in the treatment of this deadly disease”.

The cleared BASHIR™ Catheters are available for immediate shipment to hospitals in the USA. Thrombolex is currently scheduling dates for installation and in-service training. For further information or to schedule a representative visit, please contact Customer Service at 844.792.6300.

About Thrombolex, Inc.

Founded in 2016, THROMBOLEX is a privately held company in Pennsylvania focused on the design, development and distribution of innovative endovascular catheters used in interventional procedures, particularly in pharmaco-mechanical catheter-directed thrombolysis (PMCDT) in patients who suffer from arterial and venous thromboembolic (VTE) conditions. For more information, please visit www.thrombolex.com.