FlowTriever All-Comer Registry for Patient Safety and Hemodynamics (FLASH)

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- Clinical signs and symptoms consistent with acute PE
- Echo, CTPA or pulmonary angiographic evidence of proximal filling defect in at least one main or lobar pulmonary artery
- Scheduled for PE treatment with the FlowTriever System per the Investigator's discretion*
- US only: Patients enrolled in the Conservative Therapy Sub-study are not required to meet this inclusion criteria but must instead be scheduled for primary anticoagulation therapy as the primary treatment strategy.

Exclusion Criteria:

- Unable to be anticoagulated with heparin or alternative
- Diagnosis with a minor PE with a less than 0.9 RV/LV ratio
- Known sensitivity to radiographic contrast agents that, in the Investigator's opinion, cannot be adequately pre-treated*
- Imaging evidence or other evidence that suggests, in the Investigator's opinion, the subject is not appropriate for mechanical thrombectomy intervention*
- Life expectancy < 30 days, as determined by Investigator
- Current participation in another investigational drug or device treatment study that, in the Investigator's opinion, would interfere with participation in this study
- US Only Patients enrolled in the Conservative Therapy Sub-study are not required to meet these exclusion criteria

Conditions & Interventions

Interventions:
Device: FlowTriever System, Drug: Anticoagulation Agents
Conditions:
PE - Pulmonary Embolism, PE - Pulmonary Thromboembolism
Keywords:
PE, pulmonary embolism, thromboembolism, thrombectomy, FlowTriever, Anticoagulation Medication

More Information

Description: FLASH is a post-market, prospective data collection registry. The intention of this registry is to evaluate the safety and effectiveness of the FlowTriever System for use in the removal of emboli from the pulmonary arteries in the treatment of acute pulmonary embolism (PE). The use of the device will be assessed in a real-world population, with eligibility criteria that closely approximate its use in clinical practice. The study involves no intervention and all medical procedures are standard of care and not research. The device is FDA approved and being used according to the instructions for use and the physician's discretion.
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Phase: Phase IV
IRB Number: STUDY00008046
System ID: NCT03761173

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