

# EKOS™ Endovascular System

## The REAL-PE Analysis

Modern Treatment of Pulmonary Embolism (USCDT versus MT): Results from Real-World, Big Data Analysis (REAL-PE)

### Authors

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### Objective

Investigate the safety of ultrasound-assisted catheter-directed thrombolysis (USCDT; i.e. the EKOS System, Boston Scientific, Marlborough, MA) and mechanical thrombectomy (MT; i.e. the FlowTriever™ System, Inari Medical™, Irvine, CA) in real-world treatment of pulmonary embolism (PE).

### Data Source

Truveta™, Inc. (Bellevue, WA) is a growing collective of more than 30 health systems in the U.S., providing 17% of the daily clinical care across all 50 states from 800 hospitals and 20,000 clinics. Comprised of nearly 100 million de-identified patient records, linked across health systems, and augmented with social determinants of health (SDOH) and claims data, the Truveta Studio platform enables real-world analysis and powerful insights to inform healthcare decision making.

### Patients

Patients treated with ultrasound-assisted catheter-directed thrombolysis (USCDT; i.e. the EKOS System) or mechanical thrombectomy (MT; i.e. the FlowTriever System) for pulmonary embolism (PE) were identified through ICD10, SNOMED, UDI, and Truveta codes. Only patients diagnosed in the electronic health records with a PE within 30 days before the date of the USCDT or MT procedure or up to 1 day after the procedure were included in the analysis. The primary analysis was based on all data available in

the Truveta Studio (index procedures Jan 2009 through early May 2023). A contemporary analysis was also performed (index procedures Jan 2018 through early May 2023).

### Methods

Adverse events within 1 week of the procedure were investigated including: major bleeding (modeled after ISTH and BARC3b definitions), intracerebral hemorrhage (ICH), and in-hospital death. Events were identified utilizing LOINC, CPT, SNOMED, ICD-9 and ICD-10 codes and laboratory results.

### Key Results Summary

In comparison to patients treated with the Inari Medical FlowTriever System (N = 682), **patients treated with the EKOS System (N = 1577) had:**

- A statistically significant **28% lower rate** of major bleeding events
- A statistically significant **77% lower rate** of intracerebral hemorrhage (0.3% incidence of ICH in patients treated with EKOS).
- **Comparable** in-hospital mortality rates, 30-day all-cause readmission rates, and median lengths of hospital stay

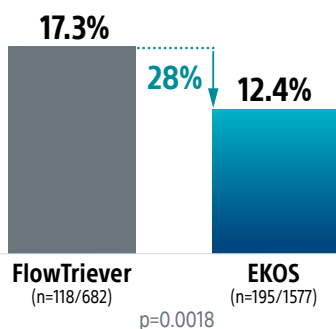
## Key Results\*

### Rates of Major Bleeding

#### 28% lower rate of major bleeding events

In the REAL-PE analysis, patients treated with the EKOS System had significantly lower rates of major bleeding than patients treated with the Inari Medical FlowTriever System.

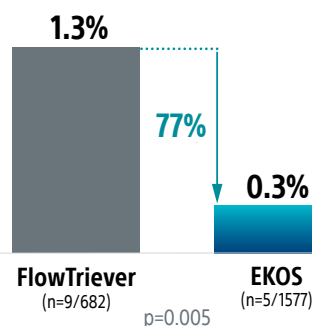
ISTH Definition



### Rates of Intracerebral Hemorrhage (ICH)

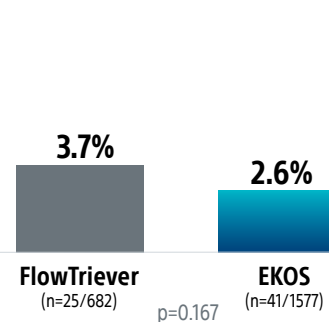
#### 77% lower rate of ICH

Rates of ICH were significantly lower for patients treated with the EKOS System than for those treated with the FlowTriever System.



### In-Hospital Mortality Rates

For the more than 2200 patients studied in the REAL-PE analysis, in-hospital mortality rates were comparable for patients treated with the EKOS System (2.6%) or with the FlowTriever System (3.7%).



\*Primary analysis, patients with index procedures Jan 2009 through early May 2023.

## Median Length of Hospital Stay

Patients who received intervention with the EKOS System had a median length of hospital stay equal to those treated with the FlowTriever™ System (3.6 days).

## 30-Day All-Cause Readmission Rates

There was no meaningful difference in 30-day all-cause readmission rates between patients treated with the EKOS System than those treated with the FlowTriever System (EKOS 5.1%, FlowTriever 5.4%,  $p=0.777$ ).

## Conclusions

In the REAL-PE analysis—a real-world, 2200-patient dataset evaluating advanced therapies for PE—**patients treated with the EKOS System (N=1577) had:**

- 28% lower rates of major bleeding
- 77% lower rates of ICH
- comparable in-hospital mortality rates, 30-day all-cause readmission rates, and median lengths of hospital stay when compared to patients treated with the FlowTriever System (N=682).

These findings from the primary analysis (2009–2023) were consistent in the contemporary analysis (2018–2023), which reflects more recent practice.



### Reference

Monteleone P, et al. Modern Treatment of Pulmonary Embolism (USCDT versus MT): Results from Real-World, Big Data Analysis (REAL-PE). Journal of the Society for Cardiovascular Angiography & Interventions; Oct 2023.

Boston Scientific provided funding to Truveta for data reporting.

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PI-1711606-AA